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INTELLECTUAL PROPERTY PRACTICES IN THE FIELD OF BIOTECHNOLOGY

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Acknowledgement

This document presents a synthesis of national submissions in answer to a questionnaire on intellectual property practices in the field of biotechnology, elaborated by the Trade Committee Working Party. It was prepared by Evdokia Moïsé of the Trade Directorate and Daniel Gervais, Consultant, under the supervision of Anthony Kleitz, on the basis of information provided by Patent Offices in OECD Member countries. The OECD Secretariat wishes to thank Patent Officers who actively contributed to this project by developing the questionnaire and providing data on their national practices.

This text is released as a general distribution document under the responsibility of the Secretary-General of the OECD, with the aim of bringing information on this subject to the attention of a wider audience.

This document can also be found on the world wide web at http://www.oecd.org/ech/tradedoc/htm/.

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Responses to the Questionnaire on intellectual property practices in the field of biotechnology have been received from twenty-two Member countries (Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Japan, Korea, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States of America), as well as from the European Commission, the European Patent Office (EPO) and South Africa. The full texts of most of the answers are available on the password-protected Internet site http://appli1.oecd.org/ech/BiotechIPR.nsf.

A summary of the answers received is presented following each question. Summaries below may vary in length and degree of detail depending on the type of information that was requested by the corresponding question as well as the amount of information provided by various respondents. Highlights are provided, whenever possible using the language employed in the answers received.

The response from the European Commission refers to Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. Laws, regulations and administrative provisions of EU Member States are to be brought into compliance with this Directive no later than 30 July 2000.

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 therefore:

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.

All answers received indicate that the product inventions mentioned in this question, i.e., 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, are eligible to be patented. No answer indicates a difference based on 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 living organisms. 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).

Product inventions mentioned in this question, i.e., chemical structures composed principally of a sequence of amino acids that corresponds, in part or in whole, to a sequence found in living organisms,

are eligible to be patented according to all answers received. No distinction is made on the basis of the source of the amino acid sequence, although Finland indicates that this is true only "as far as the source is not contrary to morality".

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.

The product inventions mentioned in this question, i.e., 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 are eligible to be patented according to all answers received.

iv) Living unicellular organisms, (e.g., bacteria, yeast).

Product inventions mentioned in this question, i.e., living unicellular organisms, are eligible to be patented according to all answers received.

v) Plants per se, parts of plants or plant varieties.

Product inventions mentioned in this question, i.e., plants *per se*, parts of plants and plant varieties are described as eligible to be patented in five answers (Australia, Hungary, Japan, New Zealand, United States). In 13 answers, plants and parts of plants appear as patentable, but not plant varieties, although in many cases a *sui generis* scheme exists (Austria, Belgium, Czech Republic, Denmark, EPO, Finland, France, Germany, Italy, Spain, Sweden, Switzerland, United Kingdom). In Germany, manipulated plants are eligible to be patented if the manipulation is not restricted to a variety, while Korea specifies that only asexually reproduced plants are eligible to be patented. In the Netherlands and in Norway, neither plants *per se* nor plant varieties are eligible to be patented. A *sui generis* system exists for the latter. In Norway parts of plants or cell-lines which can differentiate to whole plants are not eligible to be patented, while parts of plants which cannot differentiate to whole plants are eligible. The Canadian answer indicates that no patents have been granted for plants *per se*, parts of plants or plant varieties, and that plant varieties can be protected under the *Plant Breeders Rights Act*.

In the EC, following Article 4 of the Directive 98/44/EC, inventions which concern plants shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety.

vi) Animals per se, animal organs or animal varieties.

The product inventions mentioned in this question, i.e., animals *per se*, animal organs and animal varieties are eligible to be patented according to six answers received (Australia, Hungary, Japan, Korea, New Zealand, United States). Animal varieties are excluded from patentability according to 15 answers received (Austria, Belgium, Czech Republic, Denmark, EPO, Finland, France, Germany, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom). In the Netherlands, on the basis of an interpretation of the applicable Act by the Parliament, animals *per se* are also excluded. A similar interpretation excludes animals per se also in Norway, where, however, animal organs are eligible to be patented.

However, according to the Hungarian and Italian answers, the invention is excluded from patentability on the basis of moral considerations if pain or physical harm is caused to animals by the genetic identity manipulation process without ensuring a proportionate advantage or medical utility for humans or animals

The German answer also indicates that manipulated animals are patentable, provided "the manipulation according to the invention does not merely concern the breed of a certain animal species", and adds that "possible breaches of public order or morality must be considered." In the United Kingdom, "animal organs to be used in transplants would be objected to as not capable of industrial application unless there is some clearly technical treatment of the material." The Canadian answer states that no patents have been granted for any of these inventions.

In the EC, following Article 4 of the Directive 98/44/EC, inventions which concern animals shall be patentable if the technical feasibility of the invention is not confined to a particular animal variety. Following Article 6 of the Directive, inventions shall be considered unpatentable if they concern 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.

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

Humans are excluded from patentability according to all answers received. Human organs are not eligible to be patented, but human-derived products are according to 13 answers received (Canada, Denmark, EPO, Finland, Germany, Hungary, Italy, Japan, Korea, Spain, Sweden, Switzerland, United Kingdom). According to the French answer, based on ethical considerations, the human body, its parts and products as well as the knowledge of all or part of the structure of a human gene are not eligible to be patented. Similarly, on the basis of ethical considerations, humans and human germ-lines are excluded from patentability in Norway, although other elements isolated from the human body may constitute a patentable invention. The Dutch and Swiss answers do not categorically exclude human organs. In the answer from the United Kingdom, human organs used in transplants would be objected to as not capable of industrial application, unless there was some clearly technical treatment of the material. Human organs or human-derived products, including cell lines, genes and nucleic or amino acid sequences are not eligible to be patented according to three answers received (Austria, Belgium, Czech Republic).

In the EC following Article 5 of the Directive 98/44/EC, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. However, 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.

Please indicate whether the manner by which any of the products specified in question a (i) to (vii) above are produced, without more, can disqualify a product from eligibility to be patented.

No answer received indicates that the manner in which any of the products are produced affects its eligibility. Two answers (Hungary, New Zealand) add that this would change if the process was not morally acceptable.

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

i) Methods of treatment of humans or animals by surgery.

The process inventions referred in this question, namely methods of treatment of humans or animals by surgery, are eligible to be patented according to five answers received (Australia, except for essentially biological processes which produce human beings; Japan, for animals only; Korea, for animals only; New Zealand, with respect to cosmetic surgery; and the United States). Such process inventions are not eligible to be patented according to 21 answers received (Austria, Belgium, Canada, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, for humans, Korea, for humans, Netherlands, New Zealand, except with respect to cosmetic surgery, Norway, South Africa, Spain, Sweden, Switzerland, UK).

Reference is made in a number of answers to Article 52(4) of the European Patent Convention, which, according to the EPO answer, states that "methods of treatment of the human or animal body by therapy or surgery, and diagnostic methods practised on the human or animal body" are not "susceptible of industrial application and are hence excluded from patentability." The German answer adds that use claims in the form "use of substance X to treat illness Y" are eligible to be patented if the use of the substance is taught for a new therapeutic purpose susceptible of industrial application.

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 effect genetic modifications;*

The process inventions referred to in this question, namely, methods of treatment of humans or animals by therapy, are eligible to be patented according to five answers received (Australia, except for essentially biological processes which produce human beings; Japan, for animals only; Korea, for animals only; New Zealand, for animals only; United States). Such inventions are not eligible to be patented according to 21 answers received (Austria, Belgium, Canada, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, for humans; Korea, for humans, Netherlands, New Zealand for humans, Norway, South Africa, Spain, Sweden, Switzerland, UK). The German answer adds that use claims in the form "use of substance X to treat illness Y" are eligible to be patented if the use of the substance is taught for a new therapeutic purpose susceptible of industrial application. The French answer adds that the definition of "methods of treatment by therapy" includes gene therapy and the use of biological agents that indirectly cause genetic modifications. Some answers (Austria, Spain) add that products prepared for use in such methods are eligible to be patented. This would equally be the case for the *in vitro* method for preparing altered cells (for somatic cell gene therapy) according to the response from Spain. Reference is made here also to Article 52(4) of the EPC (see answers to the previous question).

iii) Methods of diagnosis practised on humans or animals.

The process inventions referred to in this question, namely methods of diagnosis practised on humans or animals, are eligible to be patented according to six answers received (Australia, except for essentially biological processes which produce human beings; Canada, except if they involve surgery or therapy; Japan, for animals only; Korea, for animals only; New Zealand, provided no surgery is involved; and United States). Such inventions are not eligible to be patented in 19 answers received (Austria, Belgium, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, for humans, Korea, for humans, Netherlands, Norway, South Africa, Spain, Sweden, Switzerland, UK). In the Czech Republic *sui generis* protection is provided by virtue of Decree 3312/1991 of the Ministry of Health, which certifies new ways of preventing, diagnosing and treating human diseases. The German answer adds that use claims in the form "use of substance X to treat illness Y" are eligible to be patented if the use of the substance is taught for a new therapeutic purpose susceptible of industrial application. Some answers (Austria, Spain) add that products prepared for use in such methods are eligible to be patented.

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).

The process inventions referred to in this question, namely methods involving genetic engineering of humans or animals for purposes other than surgery, therapy or diagnosis, are eligible to be patented according to 17 answers received (Australia, except for essentially biological processes which produce human beings; Austria; Belgium; Denmark, only for "processes for preparing or modifying animals or parts of animals… which do not cause suffering without substantial benefit"; EPO, although methods applicable to humans may be excluded, depending on the type of treatment, on grounds of "ordre public" and morality; France, provided they can be considered as "process inventions"; Germany; Hungary, for animal genes only; Italy; Japan; Korea, for animal genes only; New Zealand, unless the methods produce humans; Spain, for animals only, provided that the medical usefulness for humans or animals compensates the animal suffering; Sweden, for animals only; Switzerland, for animals only; UK; United States). Such inventions are not eligible to be patented according to twelve answers received (Canada, for experiments or tests; Czech Republic, with respect to methods *in vivo*; Finland, which indicates that such methods are "not likely" to be patentable; Hungary, with respect to human genes; Japan, for inventions applicable only for academic or experimental purposes; Korea, when a human is used as the "constituent of the invention"; Netherlands, on grounds of "ordre public" and morality; Norway, South Africa; Spain, with respect to humans; Sweden, with respect to humans; Switzerland, with respect to humans).

A number of answers (Denmark, Finland, Germany, Hungary, Netherlands, Spain, Sweden, Switzerland, UK) indicate that morality or animal suffering may be invoked to defeat patentability. The US answer adds that the eligibility of such methods to be patented does not affect the question of whether they may be practised which is governed by specific federal, state or local laws and regulations.

v) Essentially biological processes, such as natural cross breeding processes.

With respect to the above process inventions, if only one or other of humans or animals are eligible, please indicate which one.

The process inventions referred to in this question, namely essentially biological processes, are eligible to be patented according to five answers received (Australia, except if they produce human beings; Austria; Japan; New Zealand, except if they produce human beings; United States, provided that they are distinguishable from naturally occurring methods). Such inventions are not eligible to be patented according to 18 answers received (Belgium, Canada, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Korea – unless an "artificial step" is included in the process-, Netherlands, Norway, South Africa, Spain, Sweden, Switzerland, UK). Belgium, France and Korea point out that exclusion from patentability does not extend to microbiological processes. The answer from the Czech Republic makes the same comment concerning "industrial micro-organisms for purposes of production and biotechnological processes and products obtained with their help".

Reference is made to Article 53(b) of the EPC in a number of answers. No answer indicates that a distinction is made between humans and animals in this context

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 according to 19 answers received (Australia, Belgium, Canada, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan -- see answer to b(ii), Korea, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland). Two answers (Canada, New Zealand) specify that such therapies must treat pathological conditions in order to be considered as methods of medical treatment. In the response from Austria, this question is considered still open, while the US response specifies that this distinction does not affect in any way the eligibility of inventions to be patented. In the UK, the answer to the question whether any particular gene therapy falls within the definition of therapy (i.e., medical treatment of disease, both curative and prophylactic) would determine its eligibility to be patented. As a result such therapies would appear eligible to be patented in Australia, Japan, for animals; Korea, for animals; and the United States, while they would be excluded in Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Japan, for humans; Korea, for humans; Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland and the EPO.

Biopharmaceutical products produced by gene therapy techniques are eligible to be patented according to almost all answers received, except from the Danish response. Three answers refer to an exclusion from patentability if humans are used or produced (Korea, New Zealand) or where humans *per se* are claimed (Australia). The EPO furthermore indicates that products used in germ line gene therapy are not patentable pursuant Article 53(a) of the EPC.

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.*

All answers received indicate that a party could obtain patent 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. The French answer refers to an Appellate decision that refused a patent for a second therapeutic purpose. However, the court based its decision mostly on the employment situation of the inventor. The answer from the Netherlands states that its Patent Office "did not accept use claims, but did allow compound or composition claims provided the known compound was used in a form or composition which could be distinguished as such from known forms or compositions of that compound."

A number of answers indicate how the protection would be made available. The EPO and Spanish answers suggest using "compound X for use in the treatment of disease Y" or, where the medical use of the compound is already known, "use of compound X for the manufacture of a medicament for treating disease Y." The German answer adds that the requirement of industrial applicability is fulfilled because the "teaching is not directed to the patient or doctor only, but also to the manufacturer of the pharmaceuticals". The Japanese answer indicates that patentability is possible "by expressing it as a product category (e.g., pharmaceutical substance comprising…"). Three answers (Czech Republic, Denmark, New Zealand) refer to the acceptability of "Swiss-style" or "Swiss-defined" claims, i.e., claims concerning a novel use for a known compound.

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)?*

With respect to processes *in vivo*, the answers would remain the same for all respondents, that is, eligibility to be patented would be as indicated under questions A b) i) to iii).

With respect to processes *ex vivo*, the answer would not change in Australia and the United States (eligible), the Czech Republic, Italy and Denmark (not eligible), Korea (eligible for animals, but not for humans), and New Zealand (eligible, unless it involves surgery). For all the other respondents (Austria, Belgium, Canada, EPO, Finland, France, Germany, Hungary, Japan, Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom) the answers would change, thus admitting the eligibility of processes *ex vivo*. However, for several countries (Canada, Finland, Hungary, Japan, Spain, and the United Kingdom) *ex vivo* processes are understood to cover only processes carried out entirely outside a human or animal host, insofar as cells, tissues or fluids removed are not returned to the host.

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.*

Exclusions on the basis of ethical or moral concerns are mentioned in 18 answers received (Austria, Belgium, Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, Korea, Netherlands, New Zealand, Norway, Spain, Switzerland, UK). In most answers, reference is made to a general standard preventing the protection of inventions the exploitation or publication of which

would be contrary to "ordre public" or "morality", and corresponding in most cases to Art.53(a) of the European Patent Convention (other principles used to describe the applicable criterion include "humanity", "dignity" or "the sense of decency of anyone thinking just and fair"), rather than a criterion specific to biotechnology. The German answer refers to the Biotechnology Law of June 20, 1990 which protects the environment and human life and health "against the potential dangers of biotechnology."

Most answers indicate the absence of case-law on this issue. The EPO answer refers to decisions T 19/90 and T 356/93 of its Technical Board of Appeal, which considered as relevant factors the suffering of animals and environmental risks on the one hand, and benefits to humans, on the other. The answer from New Zealand refers to a case considered by the New Zealand Court of Appeal with respect to the medical treatment of humans.

In the EC, following Article 6 of the Directive 98/44/EC, the following shall be considered unpatentable on the basis of ethical or moral concerns ("ordre public" or morality): processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.

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.

No other exclusions from patentability are mentioned, except in the Japanese and Korean answers, which refer to inventions that "contravene" (Japan), or "injure" (Korea) public health. Australia has no other specific exclusions regarding biotechnological inventions but has a general provision to prohibit the patenting of inventions whose use would be contrary to law. In Norway, the exclusion from patentability of "essentially biological processes for the production of plants and animals" is interpreted as extending 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.

A number of answers (the Czech Republic, Denmark, Finland, Italy, Netherlands, Sweden, Switzerland, United States) indicate that the criterion used to determine industrial applicability for biotechnological inventions is the same as for inventions in any field of technology. The Danish answer adds that "the applicant has to provide evidence that a representative number of the claimed compounds have unexpected therapeutic effect, e.g. in form of experimental data. If closely related known compounds have the same therapeutic effect the new compounds must show an even better effect."

The French answer adds that a therapeutic purpose is a form of industrial applicability for a substance used to treat diseases. For some countries (Australia, New Zealand, and the United States) the inventor needs just to identify a specific area of usefulness. For others (Canada and the UK) the inventor should provide evidence of the effectiveness of the therapy; rudimentary evidence would be sufficient in

the UK. The answer from the EPO states that the standard used is applied fairly liberally, i.e. it usually suffices if the therapeutic application appears plausible from the demonstrated activity of the therapeutic compound.

Other answers (Austria, Germany, Hungary, Japan, Korea, Norway, Spain, Switzerland) indicate that, as pointed out in answers to questions A b) above, certain methods of treatment are not eligible to be patented because they are considered as lacking industrial applicability. The German answer indicates that an "invention in the field of pharmaceutical products will, as a rule, be considered as useful if the applicant furnishes *prima facie* evidence by means of secured statistical data that the subject matter of the application has valuable therapeutic properties."

More detailed information with respect to the guidelines available to patent applicants is contained in the answers from Japan and the United States.

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 answers to this question vary considerably in scope and form.

The answer from Australia indicates that only a small number of cases has occurred where the applicant has not provided a specific use for a gene sequence of unknown function. In these cases, the gene sequences would not be patentable. More common are the cases where the function of the actual gene sequence is unknown, but there is still a specific use for the gene sequence, and such applications are not considered deficient in Australia.

The Canadian answer states that occasionally, "claims directed to nucleic acid sequences which encode proteins having no known or no described function are rejected for lack of industrial applicability/utility." The Hungarian and Korean answers indicate that in the circumstances described in this question, the application would not meet patentability criteria, including industrial applicability. According to the Japanese answer, applications where the "characteristics or functions are not known or described by the applicant do not enter into substantive examination." The EPO answer indicates that no case law is available, but "the provisional view of the EPO is that it may be questionable whether such nucleic acid sequences have any industrial applicability other than their use as probes." Sweden made a similar comment. Norway indicated that to date no deficiencies related to industrial applicability/utility have been found in applications directed to nucleic acid sequences.

The French and German answers state that no particular problem has arisen, adding that nucleic acids do not qualify for patent protection if the making available of the substance is merely based on a discovery. The German answer adds that the "complete indication of the nucleotide sequence certainly is the best way for describing the subject matter of the application clearly and completely." However, a sufficient number of parameters may be enough to identify a polynucleotide.

The Italian answer adds that a complete indication of the nucleotide sequence and of its functions and specific use is necessary.

The answer from the United States indicates that no simple answer could be given and depends on the facts of each application, adding that the problems described in this question have not been frequently encountered. If no indications are made as to practical utility in the application, "the claims directed to the protein would likely be deficient under section 101" (utility).

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.

Most of the answers refer to the general standard contained in national patent laws with respect to all technical fields, i.e. disclosure of all the essential features enabling a person skilled in the art to carry out the invention. The Australian answer adds that "a citation must contain clear and unmistakable directions to the claimed invention but need not necessarily have physically produced the invention as long as the invention can be produced without further invention." According to the Canadian answer, "the whole subject matter defined by a claim [*must have been*] disclosed completely in a single prior art reference." The German answer states that novelty would be defeated if "a publication forming part of the state of the art discloses and anticipates everything the skilled person obviously or almost necessarily completes or what he or she realises without effort when reading the text attentively, or what is implicitly understood by the skilled person."

The Japanese answer provides four examples specific to biotechnology to illustrate when a claimed invention meets the novelty requirement. The Spanish answer states that "if a document discloses the purification and characterisation of the protein expressed by the claimed DNA, then the novelty of the protein expressed by the DNA claimed is defeated by that document."

The Dutch answer states that "novelty was only defeated if according to an earlier disclosure the invention had already been carried out […] However, where the 'whole content' approach was applicable, a disclosure of all the essential features enabling a person skilled in the art to carry out the invention would be sufficient to take away the novelty of a later application."

The UK answer describes the Patent Office's practice in this area (document annexed to the UK answer). Finally, the answer from the United States states that "there is a requirement that the printed publication or patent contain a sufficiently complete disclosure of the claimed invention so as to place the claimed invention in the possession of the public." A number of cases are cited in that answer.

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;

Most answers received indicate that the criteria applied to biotechnological inventions are the same as for any other field of technology, and can be summarised as follows: would an (unimaginative/ordinary) person skilled in the art have been directly (and without difficulty) led to the claimed invention at the priority date?

The Australian answer describes a four-step approach used by their Patent Office to apply this basic test. Germany and the Netherlands indicate taking into account not only the state-of-the-art closest to the claimed invention but also "the general knowledge and professional competence of the skilled person in the relevant field of technology".

The Japanese answer refers to a number of biotechnology-specific examples, concerning genes, recombinant vectors, transformants, fused cells and monoclonal antibodies . The Spanish answer states that "a document which describes a DNA sequence coding for the same activity claimed, but in a different organism" would affect that claim. The Norwegian answer indicates that "patents have not been granted for applications directed to a nucleic acid gensequence when the protein coded for by the gensequence is not new". The answer from the United States refers to a number of both general and biotechnology-specific court cases. To reject a claimed invention on the grounds of obviousness, the USPTO is required to establish a *prima facie* case, a procedure and guidance for which is provided to examiners. The United States also follows a practice consistent with other examining authorities whereby a process of making or using a novel and non-obvious biotechnological product is treated as being itself non-obvious.

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

Administrative or judicial decisions discussing directly or indirectly the application of inventive step in biotechnology are referred to only by Australia, the EPO, Germany, Italy, the UK and the United States. The Australian answer refers to a number of administrative decisions and gives a detailed summary of each one. The EPO answer states that the Technical Board of Appeal had ruled on inventive step in a number of cases, including the T 386/94 case "where it is held that inventive step may be acknowledged in the field of gene technology if there is no reasonable chance of success that the cloning and expression of a given gene can be carried out." The German answer briefly describes two decisions by the Federal Supreme Court ("Bundesgerichtshof") and to other decisions by lower courts and scholarly papers. The Italian answer refers to two decisions of the Board of Appeal ("camera dei ricorsi") concerning the onco-mouse patents. The UK answer refers to a number of court decisions presented in the annex to their answer. The answer from the United States gives a detailed summary of six Federal Circuit cases in the field of biotechnology rendered between 1986 and 1997.

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.

While most responses indicate not having encountered specific difficulties, several of them point out that predictions are hard to make in this rapidly evolving field.

Among the responses referring to specific difficulties, the most common seems precisely to be the rapid progress of the technology, which may make what is inventive at one time to be routine shortly after (Australia, Hungary, Sweden, and United Kingdom). The Australian answer further indicates that the usual problem/solution method may not be appropriate here, since, in the field of biotechnology, "not only are the original goals often known, but many of the techniques to achieve those goals are also standard. In these cases, the invention does not always reside in the implementation of an inventive approach to solve the problem as much as it resides in overcoming practical difficulties inherent in the application of a standard approach to solving the problem." The Hungarian answer also refers to the integrative nature of

biotechnology, encompassing several fields of science. The UK and United States answers comment on the difficulty of hiring, training and retaining experienced examiners, which is overcome through building up biotechnology specialisation and intense training of examiners.

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.*

A product or composition which already exists in nature would not be eligible to be patented, or its non-obviousness would be questioned (Netherlands), unless (Australia, Spain, Canada and Italy) there has been a technical intervention to change its form or to isolate, purify and characterise the product or composition, which had no previously recognised existence. In the same vein, such a product or composition would be eligible to be patented if isolated, purified or synthesised by a technical process (Denmark, EPO, France, Hungary, Japan, Norway, Sweden, Switzerland, UK). "Discoveries" are not patentable, as is stated in several answers received (Austria, Canada, Denmark, France, Germany, Hungary, Italy, Japan, Korea and the UK). The UK answer defines discovery as "the finding of a new substance or micro-organism occurring freely in nature." The answer from the United States indicates that under US patent law, an invention cannot be patented if it is defined in a claim so as not to differ in any manner from subject matter as it occurs 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.*

All answers indicate that a deposit is required only where such deposit is necessary in order to enable a claimed invention to be repeated. This means that a deposit is needed in the case of inventions consisting of, or using specific biological material, if that material cannot be reproduced or generated by a person skilled in the art on the basis of the written description included in the application, and is not publicly known and reasonably available to a person skilled in the art. With respect to micro-organisms, the answer from EPO indicates that "a specific micro-organism which cannot be reproduced from a written description alone must always be deposited"; while in the Czech Republic "if an industrial production micro-organism is the invention, it must be deposited in a public collection of growths by the day since which the applicant keeps the right of a priority." The answer from the United States provides detailed rules from the USPTO examination manual.

"Biological material" is defined in various ways among respondents, although self-replication is a key element of most definitions. The answers from EPO and Hungary refer to Rule 28(6)(a) of the EPC which defines such material as "meaning any material containing genetic information and capable of self-reproducing or of being reproduced in a biological system." A similar definition is given by Australia. A definition by enumeration is mentioned in the answers received from Canada, Finland, France, Germany, and Korea. The United States use both a generic definition "to encompass any form of material that is capable of self-replication, either directly or indirectly", and a representative list of materials that fall within this definition.

Most respondents (with the exception of New Zealand) require the deposit to be made with a depositary institution, recognised either under the Budapest Treaty (Australia, Denmark, France, Germany, Hungary, Italy, Japan, Norway, Spain, United States), or nationally (France, Germany, Japan, Netherlands, Switzerland, United States). Rules concerning the maintenance of the micro-organism during the patent term, and exceptions thereto, are also mentioned.

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

– *whether deposit after filing is allowed;*

The answers received from Australia, Austria, Belgium, Canada, Czech Republic, Denmark, EPO, Finland, France, Germany, Italy, Japan, Korea, Netherlands, Spain, Sweden, Switzerland and the UK state that deposit after the filing date is not allowed. The Finnish answer adds that this requirement applies if the deposit is essential for enablement purposes. The French and Danish answers add that the applicant has 16 months after filing to indicate where the deposit was made.

The answer received from Hungary states that "if the culture of a micro-organism is deposited after the filing of the patent application, the date of deposit shall be regarded as the date of filing." The Norwegian answer states that "deposit after filing, but within the priority year, can cause loss of priority rights". The answer received from New Zealand indicates that the issue has not arisen, but that "the deposit would have to be available to a skilled reader when they were aware of the micro-organism or cell."

The answer from the United States indicates that deposit after filing is permissible if (a) the material to be deposited is adequately identified in the application and (b) the introduction of information corresponding to the deposit does not add any substantive "new matter" to the application. The answer also refers to the detailed provisions of US regulations.

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

Amendment of accession numbers is allowed prior to the publication in Australia and in Austria, or within 16 months of the priority or filing date in Denmark, the EPO and in Switzerland. Furthermore, most answers indicate that amendments are possible in general when they do not introduce new matter into the application, i.e. in case of clerical errors (Canada, Germany, Hungary, Spain, Switzerland, United Kingdom, United States); on the occasion of the deposit of a new sample required by the International Depositary Authority where the original deposit has not remained viable(Canada, Korea, United States) or of the transfer from one IDA to another (Canada, Finland, United States).

– *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*

The answers received from Australia, Belgium, Denmark, EPO, France, Germany, Hungary, Japan, Korea, Sweden, Switzerland and the United States indicate that reference to material deposited by a third party is possible. In this case the consent of the third party would be required in Japan, Switzerland and the EPO, while in Hungary provisions on compulsory licensing shall apply if the material is under patent protection. In Denmark, "if the experiments result in a new invention a patent application can be filed on the basis of this invention". The United States indicates that an applicant can rely on a deposit made by a third party if that deposit makes the material "known and publicly available".

Reference to material deposited by a third party is not possible in Canada and the UK, nor, for the time-being, in Spain.

– *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;*

After publication of the application, unrestricted access to deposited material is provided for in Australia, Austria, Canada, Denmark, EPO, Finland, France, Germany, Hungary, Korea, Spain, Sweden and the UK. However, any person obtaining a sample undertakes not to make the material available to third persons and to use it only for experimental purposes. Several answers indicate the possibility for the applicant to request that access to deposited material while the application is pending be limited to a nominated expert (Australia, Canada, Denmark, Norway, UK). Once a patent is granted, lapsed, withdrawn or refused, no restriction can be imposed on access to the deposit in Australia, Austria, Canada, Norway. On the contrary, in the answers received from EPO and Finland, public availability can be limited upon request for 20 years from filing if the final decision on the application does not result in the grant of a patent.

The answers from Belgium, Switzerland and the United States indicate that applications are not published prior to issuance.

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

With the exception of the United States, no answer received indicates a specific number of seeds. The answer received from Hungary states that it is the depositary authority that would determine the number of seeds required. Finnish and Korean legislation do not provide for seed deposits, while seed deposits are not accepted by the IDA in Japan. The US answer refers to applicable regulations and especially PTO and DoA practice, according to which 2500 seeds is considered a minimum number in normal cases, with possible exceptions.

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

Deposits in other institutions than those listed by the Budapest Treaty are not accepted in Australia, Austria, Belgium, Canada, France, Spain and Sweden. Among the other respondents, the Czech Republic accepts any deposit made in a "publicly available collection"; Denmark, the EPO and Finland accept deposits to a number of other institutions recognised by the EPO; while Hungary would accept

deposits outside the Budapest Treaty "subject to reciprocity". Germany, Japan, Korea, Netherlands, Switzerland, the UK and the United States also accept deposits to institutions meeting national criteria. These criteria are described in detail in the answers from Switzerland, the UK and the United States.

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 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.

There are no provisions for electronic filing in Australia, Austria, Belgium, the Czech Republic, Denmark, France, Italy, New Zealand and the United Kingdom. Electronic filing is not compulsory but possible in Switzerland, as well as in the Netherlands when this is required by the EPO in its capacity as searching authority for the Netherlands, and recommended in Finland, Spain and Sweden. Special provisions concerning electronic filing requirements are described in the answers from Canada, the EPO, Germany, Japan and the United States. In Canada, Germany and Japan the requirements are based on WIPO/PCT norms. Preparations with a view to require electronic filing are underway in Hungary and Korea.

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

Several respondents only accept large numbers of sequences if they relate to a single inventive concept (Australia, Austria, the Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, Korea , Netherlands, New Zealand, Norway, Sweden, Switzerland and the UK). 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. In particular, the Swiss answer refers to similar use or similar properties, while the German answer indicates that "the effect establishing patentability must be plausible with regard to all the substances subsumed in the formula" and evidence provided "that the invention may be carried out in the full range claimed." The French answer adds that the examiner will consider (a) whether claims are independent from one another; (b) whether the application concerns one sequence of multiple small sequences; (c) the degree of similarity of sequences and (d) their respective function.

According to United States PTO policy, up to ten independent and distinct nucleotide sequences can be claimed in a single application. This number may be reduced if necessitated by the complex nature of the claimed material.

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.*

A number of search tools and notably specialised databases, such as STN databases, GENETYX, GenBank of NCBI, or CAS Registry file are mentioned in several answers (Australia, Austria, Denmark, EPO, Finland, Germany, Hungary, Japan, Korea, Spain, Sweden, UK and the United States). The Canadian answer refers to a "SUN workstation" used to carry out novelty searches by comparing the structure of a claimed sequence with known sequences. The French answer states that the search report is prepared by the EPO. The answer from the United States contains a detailed description of the system used by the USPTO (attachment E to that answer). Germany further refers to technical literature and documents arranged according to the IPC system, Sweden to the PCT minimum documentation, Norway to Dgene-database and Hungary to information available on Internet. Australia also uses sequence alignment results (GCG) to provide examiners with citations on novelty and inventive step.

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

Sources mentioned are electronic databases and journals (Australia, Austria, Canada, the Czech Republic, Denmark, EPO, Finland, France, Germany, Hungary, Korea, Netherlands, Spain, Sweden, UK, United States), the World Patent Index (Australia), international searching authorities, such as ISA/PCT (Norway), other national patent files (Australia, Austria, Canada, Denmark, Hungary, Norway, UK, United States), prior art disclosed by the applicant (Australia, EPO, Germany, Hungary, Spain, Sweden, UK), published search results by other authorities, including the EPO (Australia, Canada, Denmark, EPO, Finland, Hungary, Korea, Norway, Spain, Sweden, UK), reference texts (Australia, Finland, Germany, United States), systematically arranged collections of patent documents (Netherlands), and PCT material (Austria, Czech Republic, Hungary, Japan, Korea, Sweden, United States). The Japanese answer refers to Rule 34 of the Regulations under PCT (which defines "minimum documentation" for PCT purposes).

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

Most of the answers received generally indicate that a biotechnology patent may be granted in all three cases described "provided the claim as presented adequately defines the claimed invention" (Australia, Austria, Canada, EPO, Germany, Hungary, Italy, Japan, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, United Kingdom and United States). This implies that functional claims must "provide adequate directions to enable a skilled worker to produce all the products which have the claimed function", while structural claims must contain satisfactory indications of the industrial applicability. According to the French answer, describing the result would not be sufficient; a description of the function itself is required. Several other answers explain that while an application containing purely functional claims does not *a priori* exclude patentability, it may make it more difficult: in particular, the Canadian answer indicates that a purely functional claim could be objected as unduly broad, while the Finnish answer indicates that structural claims are "preferred". Purely functional claims are not accepted in the Czech Republic, Denmark and, in principle, in Korea. The answer from the United States specifies

that, in the area of biotechnology, functional claims are common "primarily because such characteristics often provide an effective means of defining physical characteristics or properties of biologically active substances."

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.*

The test described in several answers is that a skilled worker should understand the nature of the invention and how to put it into practice (carry it out) on reading the specification (Australia, Austria, Canada, EPO, Germany, Hungary, Japan, Korea and the UK). The claims should describe the invention "specifically" and indicate at least one way to carry it out (Denmark). The claims should be clear and concise (Canada, Spain, United States), and would be rejected if there is a doubt as to the invention's utility or operability (Canada). They should allow the invention to be carried out "over the whole area claimed using common general knowledge" (EPO, Italy). Germany, Japan and the United States indicate that an important question in determining compliance with the "enablement" requirement is whether the ordinary skilled worker could practice the invention without engaging in "undue experimentation". The answer from the United States provides citations to cases that explain the factors that are used to assess whether this standard is met. The US answer also points out that US law requires the inventor to disclose the "best mode" of practising the invention.

The information should allow the person skilled in the art to carry out the invention "easily" (Korea). The drawings are also taken into account (Austria, Hungary and Japan). The French answer states that failure to sufficiently describe an invention may not be a ground to reject an application, but may be used by courts to invalidate patent claims. However, the description must be sufficient to allow the prior art search. The Swiss answer indicates that the description and examples contained in the application should render the invention "plausible" and capable of being reproduced. .

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.*

Several answers indicate that in the situation described in this question, a more detailed specification would probably not be necessary (Australia, Austria, Czech Republic, Denmark, EPO, Finland, Hungary, Italy, Japan, New Zealand, Norway, Sweden, Switzerland, UK, United States). The Austrian answer adds that this depended "on the specific application, the technical field and the general technical knowledge in the technical field concerned." The French and German answers state that at least one working example is required. The Spanish answer is to the same effect. The answer from the United States indicates that, although nothing precludes an applicant from filing a purely "prophetic" application (*as these applications are termed in US practice*), such application will rarely satisfy the requirements for enablement and disclosure in technological fields where there is a substantial amount of unpredictability. The Canadian answer states that in such a situation specifications often make "unwarranted assumptions taking for granted what needs to be accomplished to practice the invention. Specifications of this type are rejected as being insufficient."

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

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;

Several answers point out that a claim wider than the specification may have sufficient support in the specification and this will be determined on a case-by-case basis (Australia, Austria, Canada, Denmark, EPO, Finland, France, Germany, Hungary, Italy, Japan, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland -provided the claims are entirely reproducible-, United States). The test mentioned in that connection is whether the claim is limited to the inventive concept or "whether there is sufficient likelihood that the effect is produced by all embodiments covered by the claims" (Netherlands). In the UK, a claim wider than the working examples may have sufficient support in the specification if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the specification. An invention that opens up a new field ("pioneer") will be entitled to broader protection (EPO, Hungary). Reasonable speculation is allowed (New Zealand). On the contrary, the Korean answer indicates that in principle in such a case the claim would be rejected as being unduly broad.

As regards the situation described in question (i), the Australian answer specifies that "if the inventive concept resides in recognising a beneficial property which is common to a class of compounds, a claim can define the class of compounds". The Canadian answer states that the claim to a class of products will be allowed if (a) the members of the generic class are structurally-related; (b) the class is defined in the description in terms of a generalised structure; and (c) the working examples demonstrated that the applicant was successful in obtaining one or more members of the class. In Denmark, "if a considerable probability exists that the class of products can be made according to the working examples, it is acceptable." In Germany the applicant may be asked to prove that the alleged result is achievable for parts of the subject-matter. The answer from the United States refers to a number of applicable judicial decisions on point.

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;

Functional claims can be accepted provided they meet applicable patentability criteria (Australia, Austria, EPO, Finland, France, Germany, Italy, Japan, New Zealand, Norway, Spain -if there is no other way of defining the product-, UK and the United States). The Dutch and German answers add that functional indications should not limit themselves "to the description of the problem underlying the invention". In the Netherlands, "there should be a clear link between the function claimed and the effect produced". The Danish answer states that a product "must be defined by its name, formular, parameter or as a result of a process." A "physical characteristic" (structure) is considered necessary in Canada, the Czech Republic, and Korea, while in Switzerland this requirement applies to new products only.

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

Several respondents apply the principle of "absolute product protection", i.e. consider one disclosed application to be sufficient to support a claim embracing any therapeutic use if it is the first time the product is used in therapy (Australia, Denmark, EPO, Finland, Germany, Hungary, Sweden and the UK). The answer from the United States similarly explains that it is possible to obtain patent claims that will enable the patent holder to prevent third parties from practising any therapeutic or diagnostic use of the patented product, but that claims of the form "the use of product X for therapeutic purposes" are not permitted under US practice, as such claims fail to properly define processes." The answers from Japan and New Zealand state that this type of application can be allowed provided it complies with the usual criteria of sufficient disclosure.

On the contrary, in the situation described in this question, in Canada, Italy, the Netherlands, Norway and Switzerland the claims would be limited to the application disclosed, while in Korea, in France and in Spain the claim would be refused as not sufficiently supported by the specification. In Australia, if the product was known and the invention resided in a new therapeutic application of the product, then the claims have to be limited to that therapeutic application and could not include all therapeutic applications.

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).

Judicial decisions are mentioned in the answers from France, Japan, New Zealand, the UK and the United States (with citations). The answer from Switzerland mentions two decisions from the Swiss Supreme Court (Federal tribunal) on related matters.

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;

A number of answers refer to the "doctrine of equivalents" or "purposive construction" of patent claims. The answers received from Australia and Austria mention cases dealing with other fields of technology. The answers from Japan and the United States contained references to and a summary of judicial decisions in the field of biotechnology.

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

Apart from the decisions referred to in the answers to the previous question, one answer received (New Zealand) refers to the case usually followed in such situations. The answer from the United States indicates that no US court has held that literal infringement can be avoided under the theory of the so-called "reverse doctrine of equivalents". The US answer notes that this theoretical defence has been mentioned in a number of judicial decisions, but has never been successfully applied to avoid literal infringement. The Hungarian answer refers to a provision of its Patent Law applicable to the situation described in this question.

iii) Whether claim language specifying physiological, biological or other functional characteristics of a product specified in question A.a) has been interpreted in the context of defining the scope of the claim or in finding infringement through equivalence;

The answer from Finland refers to a decision by the Board of Appeal of the National Board of Patents and Registration, of 1995. The answer from the United States summarises a 1991 decision by the Federal Circuit on this point.

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

The Swiss answer refers to the decision mentioned under question B (a) above. The Swedish answer refers to a Board of Appeal decision according to which plant and animal varieties are patentable if they are the result of a microbiological process. The answer from the United States refers to two Federal Circuit decisions.

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.

The Canadian response quotes an affirmative decision by the Commissioner of Patents. In the United States, no cases have addressed this point. However, under US law infringement would be found if the successive generations of the organism derived from a patented plant or animal possess characteristics that place them within the literal scope of the patent claim.

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.

A number of answers received state that biotechnological inventions would be treated as inventions in any other field of technology (Australia, Austria, Belgium, Canada, Czech Republic,

Denmark, France, Japan, Korea, Netherlands, New Zealand, Norway, Sweden, Switzerland, UK and the United States). The answers received from Australia and the UK refer to applicable judicial precedents.

The Hungarian answer states that according to the Patent Law "the exclusive right of exploitation does not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the registration of medicines." The Norwegian answer is to the same effect.

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.

No judicial decision is reported in any of the answers received. The Hungarian answer refers to an applicable provision of its Patent Law.

Use without Authorisation 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 right to use has been granted and whether any such right to use has been granted with respect to patented biotechnological inventions specified in questions A a) or b).

The answers received from Australia, Austria, Canada, Denmark, France, Hungary, Japan, Korea, Netherlands, New Zealand, Sweden, Switzerland and the UK refer to provisions of their patent legislation dealing with compulsory licensing / use without authorisation of the patent holder, which are applicable in all fields of technology. The Dutch answer refers to Article 92 of EC Regulation 2100/94. The French answer adds that the provisions have been harmonised with the provisions of the TRIPS Agreement. The Norwegian answer indicates that compulsory licences 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 interest.

According to the answer from the United States, no basis exists in US law to grant a compulsory license for a patent in this field.

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.

This question is answered positively by 21 countries (Australia, Austria, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Japan, Korea, Netherlands, New Zealand, Norway, South Africa, Spain, Sweden, Switzerland, UK and the United States).

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

1991 Act: Denmark, Italy, Netherlands, Sweden and the United States; South Africa is in the process of ratification; Spain has signed but not yet ratified;

1978 Act: Australia, Austria, Canada, Czech Republic, Finland, France, Germany, Hungary, Italy, Japan, Netherlands, New Zealand, Norway, South Africa, Spain (signed but not yet ratified), Sweden, Switzerland, UK and the United States;

1972: France, Germany, Netherlands, Spain;

1961: France, Germany, Italy, Netherlands, Spain.

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

This question is answered positively by Australia, Denmark, Germany, Korea, South Africa, Sweden, UK (in force May 1, 1998) and the United States. Plans to conform to the 1991 Act are in progress in the Czech Republic, Finland, France, Hungary, Italy, Japan, Spain and Switzerland.

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.

Patent protection is possible according to ten answers received (Australia, Hungary, Italy –for process inventions only-, Japan, Korea -only for asexually reproduced plants-, New Zealand -except for

algae and bacteria-, Spain, Sweden and UK -- for plants per se, although not for specific botanical genera and species of plants excluded from plant variety protection- and the United States). Patent protection is not possible according to eleven answers received (Austria, Canada, Czech Republic, Denmark, Finland, France, Germany, Netherlands, Norway, South Africa and Switzerland).

c) Indicate whether a part 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.

Concurrent protection is possible according to seven answers received (Australia, Japan, Korea, New Zealand, Sweden, UK and the United States). The question is answered in the negative in 14 answers received (Austria, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, South Africa, Spain and Switzerland).

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.

No judicial decision is mentioned in any of the answers received.

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.

The situation described in this question would be considered an infringement according to the answers received from Australia, Canada, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Japan, Korea, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, the UK and the United States. None of the answers received state that this use would be allowed.

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

The situation described in this question would be permitted according to the answers received from Australia, Austria, Canada, Czech Republic, Denmark -- for holdings below a specified acreage -- Finland, Hungary, Italy -- subject to an equitable remuneration or on licence --, Japan, Korea, Netherlands -- as far as they are not in conflict with the owner's right to produce, commercialise, offer for sale, export or stock propagating material --, New Zealand, Norway, Spain, Sweden, Switzerland, UK - subject to an equitable remuneration --, and the United States -- except if the seed is protected under a utility patent --. This situation would be considered an infringement in France.

iii) Other uses of the propagating material (e.g. barter or seed exchange).

The situation described in this question would be considered an infringement according to the answers received from Australia, Austria -except in the case of "mutual agricultural aid"-, Canada, the Czech Republic -non-commercial use is permitted-, Finland, France, Hungary, Japan - with respect to barter or seed exchange-, Korea, New Zealand, Sweden, UK and the United States - if the material is protected by a utility patent or a PVP certificate, but would be allowed if protected under a plant patent. The Danish answer states that "other uses of the propagating material are permitted. It is allowed freely to use plant varieties for research and breeding purposes." The answer from the Netherlands indicates that uses mentioned above are permitted "only as far as they are not in conflict with the sole right" (to produce, commercialise, offer for sale, export or stock for commercial purposes). The answer received from Switzerland indicates that using seeds with a view to growing new varieties is permitted. The Japanese answer states that, while acts concerning barter or seed exchange would be considered an infringement, other uses, such as the use of plant varieties for research and breeding purposes, are permitted.

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.

In the situation described in this question, the person would be eligible for plant variety protection according to the answers received from Australia, Austria, Canada, the Czech Republic, Denmark, France, Germany, Hungary, Japan, Korea, Netherlands, New Zealand, South Africa, Sweden, Switzerland, UK and the United States. However, several answers refer to the possibility that, in the situation described under (ii), consent of the patent holder may be required to exploit the new variety (under patent legislation).