

WORLD TRADE ORGANIZATION

RESTRICTED

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**Council for Trade-Related Aspects
of Intellectual Property Rights**

Original: English

REVIEW OF LEGISLATION

Questions posed by Japan

By means of a communication from the Permanent Mission of the Japan, dated 20 January 2001, the Secretariat has received a copy of the following questions that Japan has communicated to Bolivia, Brazil, Cameroon, Congo, Grenada, Guyana, Jordan, Namibia, Papua New Guinea, Saint Lucia, Surinam, Venezuela, respectively.

BOLIVIA

A. GENERAL

1. Please explain how Decisions 344, 345, 351, 391 and 486 of the Commission of the Cartagena Agreement are implemented in your country, indicating whether they are applied directly or through national legislation.

B. COPYRIGHT AND RELATED RIGHTS

2. Please explain exceptions or exemptions of the National Treatment and Most-Favoured-Nation Treatment under the Copyright and Neighbouring Rights Law, if any, as permitted in Articles 3 and 4 of the TRIPS Agreement.

C. PATENTS

3. (i) Please describe how Decision 486 of the Commission of the Cartagena Agreement and, if applicable, its national legislation define the notion of "invention", in the light of Article 27.1 of the TRIPS Agreement stipulating that patents shall be available for any "inventions" in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. What is the reasoning that the subject matters prescribed in Article 15(b) of Decision 486 are deemed non-inventions; is it because they exist in nature or because they are related to living thing or biological material?
- (ii) If a living thing, its part or biological material that has no previously recognized existence has been first isolated or purified artificially from its surroundings in nature (i.e., if it involves "human intervention"), is it deemed an invention under Article 15

of Decision 486? Otherwise, is it automatically deemed a non-invention regardless of the extent of human intervention involved?

- (iii) Where a particular type of chemical substance exists in nature but is neither a part or whole of living thing nor a biological material (such as carbon beads isolated from the oil residue which is produced through the oil refinement process when lamp oil and light oil are removed from crude oil), is it deemed an invention under Article 15 of Decision 486 if it is first isolated or purified artificially from its surroundings?

4. Please explain whether or not the below-listed subject matters are deemed an invention under Article 15 of Decision 486 and, if applicable, its national legislation. If any of those subject matters is deemed a non-invention, please specify the reason. Please suppose that (a), (h), (i), (l), (m), (n), and (o) have been no previously recognized existences and have been first isolated or purified artificially from their surroundings in nature, and that all of those listed meet other requirements for patenting, such as novelty (in the sense that they have not been known to the public), an inventive step, and industrial applicability.

- (a) Human insulin isolated or purified from beta cells of a human pancreas
- (b) A gene which encodes the said human insulin
- (c) An expression vector which carries the said gene
- (d) *Escherichia coli* transformed by the said expression vector
- (e) A process for producing human insulin by culturing the said *Escherichia coli*
- (f) Recombinant human insulin obtained by the said process
- (g) A mutant obtained by genetically modifying the said recombinant human insulin
- (h) Baker's yeast isolated or purified artificially from its surroundings in nature
- (i) A microorganism which is isolated or purified artificially from its surroundings in nature and produces an antibiotic mycin X
- (j) An antibiotic mycin X produced by the said microorganism
- (k) A mutant obtained by artificially mutating the said microorganism with UV ray
- (l) A hybridoma which produces an antibody recognizing antigen A
- (m) Human hepatocyte Y
- (n) Human liver tissue Z
- (o) Carbon beads isolated from the oil residue which is produced through the oil refinement process when lamp oil and light oil are removed from crude oil

5. Please explain the relationship between Article 29.1 of the TRIPS Agreement and Articles 26(h) and (i) of Decision 486 which oblige patent applicants to submit a copy of the contract for access to genetic resources and a copy of the documents certifying the authorization to use of traditional knowledge. Does your country consider the above-mentioned applicant's obligation as enablement requirement which is clearly stipulated in Article 29.1 of the TRIPS Agreement, or as an additional requirement which is not stipulated in that Article?

6. Please explain the rationale of Article 21 of Decision 486 stipulating that a product which has been already patented and included in the state of the art may not be the subject of a new patent solely because the product is put to a use different from that originally contemplated by the initial patent. Please also explain how Article 21 of Decision 486 complies with Article 27.1 of the TRIPS Agreement stipulating that patents shall be available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Is the rationale of Article 21 based on the lack of novelty? If so, can a patent claim directed to a new "use" (not a "product" as such) be deemed a new invention? What other types of patent claims for a new use can be patentable?

BRAZIL

A. COPYRIGHT AND RELATED RIGHTS

1. Please explain exceptions or exemptions of the National Treatment and Most-Favoured-Nation Treatment under Law No.9.610 of February 19, 1998, if any, as permitted in Articles 3 and 4 of the TRIPS Agreement.

B. PATENTS

2. (1) Please describe how Law No.9.279 of May 14, 1996 defines the notion of "invention," in the light of Article 27.1 of the TRIPS Agreement stipulating that patents shall be available for any "inventions" in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. What is the reasoning that the subject matters prescribed in Article 10(IX) are deemed non-inventions; is it because they exist in nature or because they are related to living thing or biological material?

(2) If a living thing, its part or biological material that has no previously recognized existence has been first isolated or purified artificially from its surroundings in nature (i.e., if it involves "human intervention"), is it deemed an invention under Article 10(IX) of Law No.9.279? Otherwise, is it automatically deemed a non-invention regardless of the extent of human intervention involved?

(3) Where a particular type of chemical substance exists in nature but is neither a part or whole of living thing nor a biological material (such as carbon beads isolated from the oil residue which is produced through the oil refinement process when lamp oil and light oil are removed from crude oil), is it deemed an invention under Article 10 of Law No.9.279 if it is first isolated or purified artificially from its surroundings?

3. Please explain whether or not the below-listed subject matters are deemed inventions under Article 10(IX) of Law No.9.279. If any of those subject matters is deemed a non-invention, please specify the reason. Please suppose that (a), (h), (i), (l), (m), (n), and (o) have been no previously recognized existences and have been first isolated or purified artificially from their surroundings in nature, and that all of those listed meet other requirements for patenting, such as novelty (in the sense that they have not been known to the public), an inventive step, and industrial applicability.

- (a) Human insulin isolated or purified from beta cells of a human pancreas
- (b) A gene which encodes the said human insulin
- (c) An expression vector which carries the said gene
- (d) *Escherichia coli* transformed by the said expression vector
- (e) A process for producing human insulin by culturing the said *Escherichia coli*
- (f) Recombinant human insulin obtained by the said process
- (g) A mutant obtained by genetically modifying the said recombinant human insulin
- (h) Baker's yeast isolated or purified artificially from its surroundings in nature
- (i) A microorganism which is isolated or purified artificially from its surroundings in nature and produces an antibiotic mycin X
- (j) An antibiotic mycin X produced by the said microorganism
- (k) A mutant obtained by artificially mutating the said microorganism with UV ray
- (l) A hybridoma which produces an antibody recognizing antigen A
- (m) Human hepatocyte Y
- (n) Human liver tissue Z
- (o) Carbon beads isolated from the oil residue which is produced through the oil refinement process when lamp oil and light oil are removed from crude oil

4. Articles 10(IX) and 18(III) of Law No.9.279 appear not to permit the grant of patents for "microorganisms" found in nature even if they are new, involve inventive step and are capable of industrial applications. Please explain how Articles 10(IX) and 18(III) of Law No.9.279 comply with Articles 27.1 and 27.3(b) of the TRIPS Agreement.

5. Please explain the additional conditions, if any in your legislation, other than the sufficient disclosure of the invention provided in Article 29.1 of the TRIPS Agreement (e.g. submission of a copy of the contract for access to biological material or a copy of the documents certifying the authorization to use traditional knowledge). If such an additional condition exists, please point out the relevant provisions and describe the additional condition.

6. Article 18(II) of Law No.9.279 stipulates that substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus, are not patentable. Please explain how Article 18(II) complies with Article 27 of the TRIPS Agreement.

CAMEROON

A. COPYRIGHT AND RELATED RIGHTS

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CONGO

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JORDAN

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GRENADA

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GUYANA

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NAMIBIA

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PAPUA NEW GUINEA

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SAINT LUCIA

A. COPYRIGHT AND RELATED RIGHTS

1. Please explain exceptions or exemptions of the National Treatment and Most-Favoured-Nation Treatment under the Copyright and Neighbouring Rights Law, if any, as permitted in Articles 3 and 4 of the TRIPS Agreement.

SURINAM

A. COPYRIGHT AND RELATED RIGHTS

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VENEZUELA

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