ANNEX

Response of the United States to the Questionnaire on Intellectual Property Practices in the Field of Biotechnology

Working Party on Trade
Organization for Economic Cooperation and Development

Response Compiled by the
United States Patent and Trademark Office

Intellectual Property Practices in the Field of Biotechnology
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A. PATENT EXAMINATION PRACTICES RELATED TO BIOTECHNOLOGY INVENTIONS

(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;

Yes, chemical structures composed of a sequence of nucleic acids as characterized above are eligible to be patented without restriction in the United States.[4] No distinctions are made as to the source of the chemical structure for purposes of determining if it is eligible to be patented. Information related to the source of the sequence may be used to conduct a search and examination of the application claiming the nucleotide sequence invention.

(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);

Yes, chemical structures composed of an amino acid sequences as characterized above are eligible to be patented without restriction in the United States. No distinctions are made as to the source of the chemical structure for purposes of determining if it is eligible to be patented. Information related to the source of the sequence may be used to conduct a search and examination of the application claiming the protein or peptide invention.

(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;

Yes, compounds or compositions isolated from living organisms are eligible to be patented without restriction in the United States. No distinctions are made as to the source of the isolated compound or composition for purposes of determining if it is eligible to be patented. Information related to the source of the isolated material may be used to conduct a search and examination of the application claiming the invention.

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

Yes, all product inventions involving uni-cellular organisms are patentable subject-matter in the United States. The US Supreme Court definitively settled this concept in its

[4] As used in answers to section A, the phrase "eligible to be patented without restriction" means that the compound or composition in question may be the subject of a patent grant, provided the claimed invention is useful, novel and non-obvious, and the application complies with all the requirements of 35 U.S.C. § 112.

decision *Diamond v. Chakrabarty*, 447 US 303, 206 USPQ 193 (1980). Parenthetically, it should be noted that the United States issued a patent to Louis Pasteur on purified yeast as an article of manufacture as early as 1873 (US Patent No. 141,072).

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

Yes, plants, per se, parts of plants and plant varieties (as defined in the questionnaire) are eligible to be patented without restriction in the United States. Plants can be protected through utility patents (under 35 U.S.C. § 101)[5] or plant patents (under 35 U.S.C. § 161).

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

Yes, animals, per se, animal organs and animal varieties (as defined in the questionnaire) are eligible to be patented without restriction in the United States.

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

Human beings, *per se*, are ineligible to be patented in the United States. See, 1077 OG 24 (April 21, 1987) (Annex B). See also, *Animal Legal Defense Fund, et al., v. Quigg*, 932 F.2d 920, 18 USPQ2d 1677 (Fed. Cir. 1991), rejecting challenge to PTO administrative notice announcing examination policy.

Compounds and compositions isolated from a human body, including organs, are not excluded from being eligible to be patented under US law. See also answers to questions (i) to (iii) above.

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

No, the process of production of any of the products identified above (with the exceptions of human beings per se) does not affect the eligibility of any of the described products to receive patent protection. The process of production may be a significant factor in determining whether the invention is useful, novel or non-obvious, or in defining claim scope, definition and enablement.

(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;

Yes, all methods of treatment of humans or animals by surgery are eligible to be patented in the United States.

[5] See, *Ex parte Hibbard*, 227 USPQ 443 (PTO Bd. Pat. App. & Int'f 1985) (holding novel non-obvious plant to be patentable subject matter under 35 U.S.C. §101).

(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;*

Yes, all methods of treatment of humans or animals by therapy are eligible to be patented in the United States.

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

Yes, all methods of diagnosis practiced on humans or animals are eligible to be patented in the United States.

(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*

Methods for genetic engineering of non-human animals face no restrictions in their eligibility to be patented. Whether such methods satisfy the requirement of utility, novelty or non-obviousness will be assessed in each case.

US patent law does not contain provisions that would deny patent eligibility for methods for genetic engineering of humans other than for surgery, therapy or diagnosis. However, it should be noted that the patentability of such procedures should not be construed as suggesting that such methods may be practiced in the United States without restriction. Instead, the question of whether an individual may practice a patented invention is governed by specific Federal, State or local government laws (e.g., regulation of the practice of medicine or sale or use of certain products). Furthermore, if certain procedures cannot be practiced due to their prohibition by law, inventions based on such procedures would not be likely to be encountered in a patent application filed in the PTO.

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

Methods that are indistinguishable from naturally occurring biological processes cannot be patented through application of the requirements of utility and novelty. Methods that are distinguishable from naturally occurring methods are eligible to be patented.

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

See response to part (iv).

(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 ?

No distinctions are made under U.S. law based on the nature of processes as to their eligibility to be patented, other than as described in question (b)(iv) above. As such, there is no significance that attaches to a process being designated a "therapeutic process" or "medical treatment" other than in terms of administering the examination process within the Patent and Trademark Office (e.g., an application claiming a method of therapy by genetic modification would be classified as such to ensure that an appropriately qualified examiner was assigned to conduct the examination of the application).

Biopharmaceutical products, including 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.

Yes, an entity can obtain patent protection for a process of using a known compound if the process is novel and non-obvious[6]. No unique restrictions exist as to the form of the process claim.

(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)?

No.

(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.

No, other than as indicated above in response to question A(a)(vii), no provisions in US law exclude the eligibility of biotechnological inventions to be patented on the basis of moral or ethical aspects of the characteristics, production or use of a biotechnological invention. As a result, the Patent and Trademark Office and the Federal courts in reviewing patent validity do not evaluate ethical or moral issues related to the character, production or use of a biotechnological invention. Such issues are addressed through legal or regulatory measures, as needed, that directly prohibit or regulate the activity in question (e.g., the production or use of a biotechnology invention).

(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.

[6] The process must also be useful in the context of 35 U.S.C. § 101 and the application must satisfy the requirements of 35 U.S.C. §112.