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BIOTECHNOLOGIES AND PLANT
VARIETY PROTECTION

COMMUNICATION BY THE SWISS FEDERAL
INTELLECTUAL PROPERTY OFFICE

Document prepared by the Office of the Union

The Annex to this document contains the text of a communication from the Swiss Federal Intellectual Property Office concerning the amendment of its guidelines for the examination of patent applications in the field of biotechnology. The communication was published in the Swiss Patents, Designs and Trademarks Gazette, Edition A, of March 27, 1986.

[Annex follows]

ANNEX

AMENDMENT OF THE GUIDELINES FOR EXAMINATION UNDER
ARTICLE 1a OF THE PATENT LAW

Developments in biotechnology in general and in related protection rights in various States has led the Patent Office to revise its guidelines for the examination under Article 1a of the Patent Law. The new version (of March 1986) is based on the following considerations:

1. The essential requirement to be examined remains the existence of sufficient disclosure:

1.1 If the claimed invention relates to a microorganism which is not available to the public, its production, its isolation, or its use, and if it is impossible to produce a sufficient disclosure, the applicant shall supplement its description by a reference to the deposit of a culture of the microorganism (see Article 27(1) of the Patent Regulations).

1.2 The deposit can only supplement the written description, never replace it. The applicant must therefore include in the description any useful information known to him on such matters as the outward appearance, distinctive characteristics, growing conditions and, where relevant, classification. Then, with reference to Article 26, number 3, of the Patent Law, he must decide whether the description is to be supplemented by a reference to a deposit. The Office, for its part, will only request a deposit when the description of the microorganism is manifestly insufficient.

1.3 The deposit of a microorganism is an auxiliary means available to applicants who could not obtain a (valid) patent without it. The practice of the Office in accepting deposits will therefore be as liberal as possible despite the narrow scientific meaning of the term "microorganism." The two decisive criteria for acceptance are:

- Acceptance of the culture in question by a depository recognized by the Office;

- Ability of the deposited culture to multiply (or to be replicated in a "host organism") so that samples may be produced.

Viruses, plasmids, hybridomas, cell lines, etc. may also be deposited already now for patent purposes.

2. The invention must also be examined in respect of reproducibility, i.e. of the possibility of repeating the technical teaching which is the basis of the claim; the type of claim therefore plays an essential role:

2.1 If the microorganism serves as starting material or as means for working the claimed invention, the repeatability of the technical teaching is ensured by the possibility of obtaining a sample of the deposited culture and by the information given in the description.

2.2 But if the claim is to the microorganism itself, or to its production by isolation, selection, genetic modification, etc., then the means used (and possibly claimed) must be repeatable. The production of the same result by other means, i.e. by culturing a microorganism, for example a sample obtained from a collection, is not a repetition of the teaching. For such claims the applicant must therefore specify at the time of the application how he obtained the microorganism; the reproducibility of its production must be at least plausible.

3. Article 1a of the Patent Law is an exception to the general rule contained in Article 1(1) of that Law; it must therefore be interpreted restrictively.

3.1 Contrary to the so far prevailing opinions, it cannot be admitted that microorganisms necessarily belong to either the plant kingdom or the animal kingdom. For the purposes of Article 1a of the Patent Law it is more appropriate to consider a division into plants, animals and microorganisms. The Office has therefore decided to accept from now on claims to microorganisms in so far as the general conditions specified in paragraphs 1 and 2 above are satisfied.

3.2 With respect to inventions relating to plants, only new varieties as such are not patentable since they are eligible for plant variety protection, a system specially designed for them and which may not be cumulated with patent protection on the same subject matter. The following claims will be admitted in future:

- Product claims relating to whole plants or their propagating material (seeds, tubers, cuttings, etc.) but in which no variety is specified, i.e. claims containing only characters that are valid for several varieties (for example a whole genus). In this context the variety notion must be interpreted as in the Plant Variety Protection Law (R.S. 232.16), i.e. by reference to the criteria of homogeneity, stability and distinctness from other plant varieties. Acceptance of such claims is in conformity with case law resulting from Article 2, number 2, of the Patent Law (see Patents, Designs and Trade-marks Gazette 1975 I 66-67).

- Product claims relating to other botanical material, in particular structural elements that may not be regenerated into whole plants such as cell lines, modified cells, genes, plasmids, etc.

3.3 With respect to inventions relating to animals, the applicable criteria will be the same as for plants.

3.4 Concerning "processes for the production of plants or animals," there is no reason to revise the present criteria for the interpretation of the notion "essentially biological" (number 23.3 of the guidelines for examination) for their application has not raised any problem so far.

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