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Union of Industrial and Employers' Confederations of Europe
Union des Confédérations de l'Industrie et des Employeurs d'Europe

5.1/4/1 19 March 1999

EPC implementation of the biotechnology directive

AMICUS CURIAE BRIEF

BY UNICE

I. INTRODUCTION

UNICE is seriously concerned at the direction matters have taken over implementation of the biotechnology directive. It is a situation for regret that Europe appears not to be able to arrive at a solution to the problems posed by new industries in less than ten or more years of debate and, in the case of biotechnology, risks potential legislative failure. The main new developments - computer software, information technology and biotechnology - share these difficulties, while Europe's main competitor, the United States appears to be able to find solutions relatively easily which have made a substantial contribution to that country's economic success.

Difficulties in Europe arise from the widely different views of the Member States. In the meantime industry is losing ground against its main competitors in the United States: research is not done here, and the economy and employment suffer.

The biotechnology directive represents the outcome of about 12 years of debate involving two sets of proceedings in the European Parliament. Now that the Parliament has passed the necessary legislation, UNICE finds it intolerable that this legislation is challenged in the Administrative Council of EPO by some of the member states which agreed to it. It is clear from discussions in the Administrative Council in December 1998 on implementation of the Directive and from Document CA/155/98, which the Council endorsed, that EU Member States are bound by the Directive and that it has to be implemented.

The Council has referred this question to the Committee on Patent Law. The directive was negotiated in good faith on the basis of EPC as interpreted by decisions up to 1995. It represents the will of Member States. If the interpretation up to 1995 is maintained little or nothing is needed in the Rules and it will not be necessary to amend EPC. None of the provisions of the directive goes against EPC and its implementing regulations.

While it will not be necessary to revise EPC if the decision in the present case G1/98 (Novartis) confirms its pre-1995 interpretation, if the Enlarged Board interprets EPC to be incompatible with the Directive something must be done, e.g. amendment of Rule 28 to make it clear that claims to plants and seeds are not excluded by Article 53(b) if the embodiment of the claimed invention is not restricted to a particular plant variety. UNICE submits that such a rule amendment will be sufficient following the analogous effect of Rule 30 which gives a binding interpretation of unity of invention in Article 82 and the effect of the Rule 28 disclosure provisions on Article 138(1)(b), even where deposit of biological material cannot be made in the Contracting state in question.

Amending the Rules would then make it possible not only to enshrine the principles of the Directive into the European patent law swiftly and effectively but also to clarify the conditions for patentability in an area which is particularly important for European industry.

II. UNICE WISHES TO EMPHASISE THE FOLLOWING PARTICULAR POINTS

1. It is an important general principle that discrimination against individuals or corporate bodies on any basis (eg. race, creed and colour) is unacceptable. In the case of patent law, Article 27.1 TRIPS explicitly outlaws discrimination as to the availability and enjoyment of patent rights based on field of technology, place of invention and whether products are imported or locally produced. However Article 27.3(b) does allow the option of discrimination against inventions relating to plants and animals per se, pending a review during 1999.

2. EPC itself was promulgated without any mention of such a discrimination. It excludes the patentability of plant and animal varieties but there is no mention of the exclusion of plants and animals as such. Furthermore, in case T 49/83 the Board of Appeal held that no general exclusion of inventions in the sphere of animate matter can be inferred from EPC. The Strasbourg Convention of 1963 confirms this interpretation. Case T 49/83 also held that the wording of Article 53(b) before the semicolon precludes the equating of plants to plant varieties. In case T 320/87 the Board confirmed the opinion of the Board in case T 49/83 that a plant variety must be homogeneous and stable and also held that the exceptions to patentability in Article 53(b) must be construed narrowly.

A claim involving plants embraces hybrids (which are not homogeneous and stable) and therefore cannot be for a plant variety. In case T 19/49, the five-member Board of Appeal held that Article 53(b) cannot be interpreted as excluding animals as such. Exceptions to patentability must be narrowly construed. Obviously the exclusions of plant and animal varieties must be interpreted in the same way. This was the jurisprudence on this subject up to 1995.

3. Article 29.3 TRIPS allows WTO members to exclude from patentability:

"(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof".

4. Article 27.3(b) TRIPS distinguishes the concept of "plants and animals other than micro-organisms" in its first sentence from "plant varieties" which must be protected by an effective *sui generis* system in its second sentence.

5. If the interpretation of a claim to a plant or animal per se by the Board of Appeal in case T 1054/96, that it necessarily includes plant or animal varieties, is correct, there would be no need for the first three words in the first sentence of Article 27.3(b), TRIPS. The exclusion option would have been directed to "plant and animal varieties other than micro-organisms". This alone shows that the Board's interpretation in T 1054/96 is incorrect.

6. EPC contacting states have not invoked the option of excluding "plants and animals other than micro-organisms" (see the first three words of Article 27.3(b), TRIPS). They have merely chosen to protect plant varieties by a *sui generis* system in accordance with its second sentence. It is improper to broaden the effect of that exclusion by judicial interpretation.

7. The European Patent Convention is based on a legislative background stretching back to the Strasbourg Convention of 1963 and UPOV I of 1961, when biotechnology involving gene technology was unknown. At that time only unpredictable breeding techniques were known involving the creation of special combinations of genes in a total complex genome, i.e. plant varieties. Gene-cloning techniques were unforeseen.

8. It was generally recognised when EPC was promulgated that Article 2 of the Strasbourg Convention and Article 53b EPC express a general intention to exclude patent protection for subject matter capable of protection within the UPOV Convention. However, plants per se are

not protectable under that Convention. Under the UPOV Convention, only plant varieties are protectable provided they are distinctive, homogeneous and stable.

9. Subsequently it became necessary to legislate in the European Union by way of a Directive to its member states with the objective of harmonising national laws - the Biotechnology Directive 98/44/EC of 6 July 1998 referred to herein as the "Directive".

10. The European Union is not an EPC contracting state and has no *locus standi* to ask for corresponding legislative provisions in the EPC and its Implementing Regulations. However it is incumbent on EPC contracting states which are member states of the EU to ensure conformity between their national patent laws, CPC, EPC and PCT (Declaration on the adjustment of national patent law in the Community Patent Convention). It follows that it is incumbent on the EU member states concerned to ensure that there is no divergence between the EPC and their national patent laws as required under the Directive.

11. For promulgation of the Directive, the legislative process in the European Union was conducted under Article 100a, Treaty of Rome (Maastricht) involving participation by the European Parliament. The latter rejected a first proposal by the Council of Ministers in 1995 but accepted a second proposal in July 1998.

This double consideration of the Directive by the EU legislative bodies was conducted in good faith with the overall objective of regulating the patent protection of biological material in full conformity with the patent conventions (Paris Convention, EPC, CPC, PCT and TRIPS).

12. Consequently, notwithstanding the challenge to the Directive in the European Court of Justice by the Netherlands, which has no suspensive effect, the EU member states are bound by the content of the Directive and must adopt that content in respect of and insofar as they are contracting states under other international agreements, i.e. CPC and EPC.

13. It follows that if the Enlarged Board of Appeal of the EPO or judicial bodies in an EPC contracting state or any other appeal body forming part of the European Patent Organisation, interpret EPC or its implementing regulations in a manner inconsistent with the Directive, EPC will be rendered inconsistent with the obligations under the treaties forming the European Union of most of its contracting states. Not only is this contrary to the above mentioned Declaration on the adjustment of national patent law in the Community Patent Convention, but EU Member States would then be placed in an intolerable position which can only be resolved by amendment of EPC and/or its Implementing Regulations to require an interpretation consistent with the Directive.

14. UNICE respectfully requests the Enlarged Board of Appeal to note these exigencies, to avoid this unfortunate and embarrassing eventuality, and to confirm the interpretation of EPC as it existed up to 1995.

15. It is unnecessary to amend EPC if the Enlarged Board of Appeal confirms its interpretation up to 1995 since none of the provisions of the Directive go against that interpretation. For example:

- article 2(1)(a) of the Directive is just an interpretation of "biological material" in Rule 28;
- article 2(1)(b) of the Directive is just an interpretation of "micro-biological process" in Article 53(b);
- article 2(2) of the Directive is just an interpretation of "essentially biological" in Article 53(b);
- article 2(3) of the Directive is just an interpretation of "plant varieties" in Article 53(b);
- article 3(1) and (2) of the Directive are just interpretations of "invention" in Article 52(1);
- article 4(1) of the Directive repeats part of Article 53(b) up to the semicolon;
- article 4(2) of the Directive is just an interpretation of Article 53(b);
- article 4(3) of the Directive repeats Article 53(b) after the semicolon together with a clarification of the position of technical processes as not essentially biological;

- article 5(1) of the Directive is an interpretation of Article 53(a) with respect to the human body and of Articles 52(1), 53(a), 56 and 57 with respect to the simple discovery of one of its elements including gene sequences;

- article 5(2) of the Directive is just an interpretation of Articles 52(1) and 54(2);

- article 5(3) of the Directive corresponds to Rule 27(1)(f);

- article 6(1) of the Directive corresponds to Article 53(a);

- article 6(2) of the Directive is just an interpretation of Article 53(a);

16. Consequently it is perfectly possible for the Enlarged Board to decide that in view of Article 31(3) of the Vienna Convention in the law of treaties, the EPC should be interpreted in alignment with the Directive, without any amendment of EPC being needed.

17. UNICE hopes that a discordant interpretation will not be made, but if it is, UNICE would like to point out the following consequences:

(a) applicants will be forced to obtain national patents where the invention is a plant characterised by a specified gene.

(b) there will be legal uncertainty and expensive litigation when such a patent, allowable under the directive, is litigated against in a member state of the European Union.

(c) this will render the litigation of such patents unnecessarily expensive, possibly involving proceedings before the European Court of Justice.

(d) in the forthcoming review of Article 27.3(b) TRIPS, EU Member States would be seen to be pointing both towards and away from amendment with respect to the patentability of plants and animals as such. This gives a bad signal to developing countries.

18. Regarding the substance of G1/98, UNICE is of the opinion that patent claims have to be interpreted in accordance with classical learning on the meaning of such definitions, as well understood in most Member States. A claimed invention can be shorthand for a list of embodiments falling under it. However, if the invention is a general invention defined by genus and species in which specified subject matter is characterised by one or more features which define a new combination, it is not shorthand for a list of species but instead defines a general inventive concept. Claims on plants characterised by one or more genes are claims of this type. They are not claims to an infinite number of possible plant varieties.

19. The general interpretation of broad claims is well understood in patent law. UNICE submits that such an interpretation is consistent with the Directive, the national patent laws as modified to be consistent with the Directive, and the patent conventions.

III. CONCLUSIONS

1. UNICE respectfully requests the Enlarged Board of Appeal to confirm the interpretation of EPC up to 1995.

2. No amendments to EPC are needed if that interpretation is confirmed.

3. If nevertheless, amendments to the EPC are contemplated, an amendment to the Implementing Regulations suffices, as has been suggested by EPO, since no provision in the Directive contravenes the EPC articles.

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