

Decision of Technical Board of Appeal 3.3.8 dated 6 July 2004

T 315/03 – 3.3.8*

(Language of the proceedings)

Composition of the board:

Chairman: F. L. Davison-Brunel
Members: C. Rennie-Smith
P. Julià
T. J. H. Mennessier
V. Di Cerbo

Patent proprietor/Respondent: THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Opponent/Appellant: British Union for the Abolition of Vivisection

Bundesverband der Tierversuchsgegner et al

Ökologisch – Demokratische Partei

Büchner Reinhard

Meinel A. et al; Fraktion Bündnis 90

Fuchs U. et al

Fraktion Bündnis 90/DIE GRÜNEN im Bayer. Landtag

Evangelischer Stadtkirchenverband Köln

Koehlin F., Schenkelaars P. et al. "No Patents on Life"

Voggenhuber J. et al

Keine Patente auf Leben

Hamberger Sylvia et al

Bundeszentrale der Tierversuchsgegner Österreichs

Wiener Tierschutzverein und Zentralverband der Tierschutzvereine Österreichs

Helleberger H.

Deutsche Tierhilfswerk e.V.

Headword: Transgenic animals/HARVARD

Article: Art. 52(1), 53(a), 53(b), 56, 57, 83, 112(1), 116(1), 125, 164(2), 177(1) EPC

Rule: 23b, 23c, 23d, 27, 67 EPC

RPBA Art. 10

Directive 86/609/EEC of 24 November 1986

Directive 98/44/EC of 6 July 1998

European Convention on Human Rights and Fundamental Freedoms Art. 6(1)

Keyword: "Method for producing transgenic rodents – whether contrary to Rule 23d(d) EPC (yes)" – "Method for producing transgenic mice – whether contrary to Rule 23d(d) EPC (no) or Article 53(a) EPC (no) or Article 53(b) EPC (no)"

Headnote

I. Rules 23b to 23e EPC apply to a case such as the present which was pending on the date when, as provided for by the legislator, those Rules took effect. (See Reasons, section 5)

II.1 A case falling within one of the four categories listed in Rule 23d(a) to (d) EPC must ipso facto be denied a patent under Article 53(a) EPC and there is no need to consider that Article further; but a case not falling within one of those categories must be considered further under Article 53(a) EPC. (See Reasons, section 6)

II.2 Thus, in cases falling within it, Rule 23d(d) EPC inserts an objection under Article 53(a) EPC (a "Rule 23(d) type" Article 53(a) EPC objection) which, depending on the facts and thus on the outcome of the test, may be either additional or alternative to an objection under Article 53(a) EPC itself (a "real" Article 53(a) EPC objection) as developed by the case law. (See Reasons, section 6 and paragraph 10.1)

III. Rule 23d(d) EPC is neither ultra vires nor inconsistent with the principle of narrow construction of exclusions or with the previous law. (See Reasons, section 7)

IV. Assessment of a "Rule 23(d) type" Article 53(a) EPC objection is to be made as of the filing or priority date of the patent or application in suit. Evidence arising thereafter may be taken into account provided it is directed to the position at that date. (See Reasons, paragraphs 8.2, 9.5 and 9.6)

V.1 The Rule 23d(d) EPC test requires only three matters to be considered: animal suffering, medical benefit and the necessary correspondence between the two in terms of the animals in question. (See Reasons, paragraph 9.1)

V.2 The level of proof is the same for both animal suffering and substantial medical benefit, namely a likelihood. (See Reasons, paragraphs 9.2 and 9.3)

VI.1 In the assessment of a "real" Article 53(a) EPC objection, no single definition of morality based on e.g. economic or religious principles represents an accepted standard in European culture. Opinion poll evidence is of very limited value for the reasons given in T 356/93. (See Reasons, paragraphs 10.1 to 10.4)

* Die Entscheidung in der gekürzten Fassung wird demnächst im ABI. EPA veröffentlicht. Der vollständige Text der Entscheidung in der Verfahrenssprache ist auf der Website des EPA abrufbar.

* An abridged version of the decision will be published in a later issue of the OJ EPO. The full text of the decision in the language of the proceedings is available on the EPO website.

* Un extrait de la décision sera publié prochainement dans le JO OEB. Le texte intégral de la décision dans la langue de la procédure est accessible sur le site web de l'OEB.

VI.2 In animal manipulation cases, the test in T 19/90 is appropriate. This differs in several respects from the test in Rule 23d(d) EPC, most importantly by allowing matters other than animal suffering and medical benefit to be taken into account. (See Reasons, paragraphs 10.5 and 10.6)

VI.3 Since the T 19/90 test is "mainly" the basis of assessment, other arguments as to the appropriate standard of morality or "ordre public" can additionally be considered but all arguments must be supported by evidence. (See Reasons, paragraphs 10.7 and 10.8)

VI.4 Assessment of a "real" Article 53(a) EPC objection is made as of the filing or priority date; evidence arising after that date may be taken into account provided it is directed to the position at such date. (See Reasons, section 10.9)

VII.1 In an assessment under Article 53(b) EPC, the principle enunciated in G 1/98 (OJ EPO 2000, 111) concerning plants and "plant varieties" should be followed in the case of animals: a patent should not be granted for a single animal variety (or

species or race, depending on which language text of the EPC is used) but can be granted if varieties may fall within the scope of its claims. (See Reasons, paragraph 11.4)

VII.2 The definition of animal variety (or species or race) by reference to taxonomical rank would be consistent with the position in relation to plant varieties and in the interest of legal certainty, allowing assessment under Article 53(b) EPC as interpreted by Rule 23c(b) EPC to be made by considering whether the technical feasibility of the invention is not confined to a particular animal variety (or species or race). (See Reasons, paragraphs 11.5 to 11.6)

VII.3 The different terms used in each official language are inconsistent and denote different taxonomic categories. Thus strict compliance with Article 177(1) EPC would lead to the absurd result that the outcome of an Article 53(b) EPC objection would depend on the language of a case, with German having the highest taxonomic order "species" ("Tierarten") and thereby offering the widest objection. (See Reasons, paragraphs 11.1, 11.2 and 11.7)