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D E C I S I O N
of 6 July 2004

Case Number: T 0315/03 - 3.3.8

Application Number: 85304490.7

Publication Number: 0169672

IPC: C12N 15/85

Language of the proceedings: EN

Title of invention:
Method for producing transgenic animals

Patentee:
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Opponents:
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
Koechlin 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
Helletberger H.
Deutsche Tierhilfswerk e.V.

Headword:
Transgenic animals/HARVARD

Relevant legal provisions:
EPC Art. 52(1), 53(a), 53(b), 56, 57, 83, 112(1), 116(1), 125, 164(2), 177(1)
EPC R. 23b, 23c, 23d, 27, 67
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)"

Decisions cited:
G 0005/88, G 0005/93, G 0009/93, G 0003/95, G 0004/95, G 0003/97, G 0004/97, G 0001/98, G 0003/99, J 0007/90, J 0016/90, T 0320/87, T 0019/90, T 0346/92, T 0356/93, T 0272/95, T 0194/96, T 1054/96, T 0862/98, T 0900/02

Headnote:
1. 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)

2.1 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)

2.2 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)

3. 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)

4. 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)

5.1 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)

5.2 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)

6.1 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)

6.2 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)

6.3 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)

6.4 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)

7.1 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)

7.2 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)

7.3 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)

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0315/03 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 6 July 2004

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Representative:
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Representative: -

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Representative: -

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 16 January 2003 concerning maintenance of European patent No. 0169672 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

History of the Previous Proceedings

I. These appeals are from the decision of the Opposition Division of 16 January 2003 to maintain European patent No. 0169672 ("the patent") in amended form. The patent is based on European patent application No. 85304490.7, entitled "Method for producing transgenic animals", which was filed on 24 June 1985 claiming a priority date of 22 June 1984. Although the title and early versions of the claims refer to animals, the only embodiments disclosed relate to mice and the subject-matter of the patent has come to be referred to as the "oncomouse". In this decision that word is used, as it was by the parties during the proceedings, as a convenient means of denoting the subject-matter.

II. The application as filed contained *inter alia* independent claims directed to:

"1. A method for producing a transgenic eucaryotic animal having an increased probability of developing neoplasms, said method comprising introducing into an animal embyro [*sic*] an activated oncogene sequence.

17. A transgenic non-human eucaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage, said oncogene optionally being further defined according to any one of claims 3 to 10, said animal preferably being a rodent."

III. The application was refused by the Examining Division on the grounds of Article 53(b) EPC, which prevents patenting of animal varieties, and of Article 83 EPC, since it could not be assumed that the only examples in the application, namely mice, could be extended to all other animals. The Examining Division also considered the application of Article 53(a) EPC, which excludes patents for inventions the publication or exploitation of which would be contrary to "ordre public" or morality, but concluded that patent law was not appropriate for resolving the potential problems thereby raised. The claims in the application as refused corresponding to those quoted above read as follows:

"1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.

17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent."

IV. The applicant appealed against that decision. In its decision of 3 October 1990 in those previous appeal proceedings (T 19/90 OJ EPO 1990, 476), the Board of Appeal held that Article 53(b) EPC applies to certain categories of animals but not to animals as such; and that, in the absence of serious doubts substantiated by verifiable facts, there was no reason to refuse the application under Article 83 EPC on the ground that it involved an extrapolation from mice in particular to mammals in general. As regards Article 53(a) EPC, the Board expressed the view that, particularly in cases such as the present of genetic manipulation of animals by the insertion of an activated oncogene, there were compelling reasons to consider this Article. The Board remitted the case to the Examining Division for further prosecution.

V. Following further proceedings before the Examining Division, the patent was granted on 13 May 1992 with independent claims as follows:

"1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22."

VI. Between 18 December 1992 and 13 February 1993 seventeen oppositions were filed against the patent alleging variously several grounds under Articles 100(a) and 52 to 57 EPC including lack of industrial application, lack of novelty and inventive step, the absence of an invention, a non-patentable method for treatment of the animal body, that exploitation of the invention would be contrary to morality or "ordre public", and that the patent was for animal varieties. There were also objections of insufficient disclosure under Articles 100(b) and 83 EPC (in the case of opponents 4, 6 and 8 to 15).

VII. (1) The representative of Opponent 4 - a group consisting of an individual (Mr R. Büchner), a registered association (the "Tierschutzverein Göppingen" - the Göppingen Animal Protection Society), and an unregistered association of fourteen individuals (the Initiative "Kein Patent auf Leben" - No Patent on Life) - informed the EPO in a letter of 12 May 1995 that the unregistered association no longer existed, that his professional fees were largely unpaid, and that he wished his clients' opposition to be considered withdrawn. Although subsequent notifications were

sent to this opponent, it played no further part in the proceedings.

(2) Opponent 5, a "Fraktion" (parliamentary party) in the Parliament of the German "Land" (province) of Sachsen (Saxony) ceased to exist, although this fact was only disclosed in a letter of 5 February 2003 sent on receipt of the Opposition Division's written decision. That letter explained that the "Fraktion" ceased activity after the provincial elections in 1994 and the subsequent liquidation was thereafter finalised at an unspecified date.

(3) Opponent 9, the "Bundesland Hessen" (the German province of Hesse), withdrew its opposition in a letter received on 19 April 2000.

VIII. The opposition proceedings continued until 16 January 2003. Oral proceedings were held by the Opposition Division from 21 to 24 November 1995 and again from 6 to 7 November 2001. In its decision the Opposition Division rejected the patent proprietor's objections to the admissibility of the oppositions and rejected all the opponents' objections to the patent except those under Article 53(a) EPC. It found that the claims directed to non-human mammalian animals were not allowable under that Article and accordingly maintained the patent in an amended form with independent claims directed to rodents in accordance with the proprietor's fourth auxiliary request filed on 24 April 1997. In the course of its decision, the Opposition Division also decided that Rules 23b to 23e EPC applied to the present case and rejected arguments to the contrary based on the principle of legitimate

expectations; rejected as an abuse of procedure a request made at the first oral proceedings that all its members should be disqualified for partiality; and rejected requests from the patent proprietor and opponents 1, 8 and 10 to 15 for an award of costs against the EPO in respect of the second oral proceedings.

IX. The independent claims of the patent as maintained by the decision of the Opposition Division read as follows:

"1. A method for producing a transgenic rodent having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a rodent.

19. A transgenic rodent whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

22. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A cell derived from a somatic cell obtained from a transgenic animal as defined in any one of claims 19 to 21."

The Appeal Proceedings

X. Appeals against the decision of 16 January 2003 were filed by one of the two legal persons forming opponent 1 which filed a notice of appeal on 25 March 2003, paid the appeal fee on 26 March 2003 and filed a statement of grounds of appeal on 23 May 2003; by opponent 2 which paid the appeal fee on 11 March 2003 and filed a combined notice and statement of grounds of appeal on 13 March 2003; and by opponents 8, 12, 13 and 15 which all filed notices of appeal and paid appeal fees on 26 March 2003 and filed statements of grounds of appeal on 26 May 2003. These opponents which filed appeals are referred to below as appellants 1 to 6 respectively. Opponents who did not file appeals were parties to the appeal proceedings as of right pursuant to Article 107 EPC but, with the exception of opponent 3 which attended the oral proceedings, none of those non-appealing parties played any part in the appeal proceedings.

XI. A communication of the Board dated 24 November 2003 dealt with the following matters.

(1) The Board expressed the provisional opinion that all the appeals were *prima facie* admissible but, if any appeal should be held inadmissible, the party in question would none the less be a party as of right and its grounds of appeal would stand as written submissions made by such a party.

(2) The Board directed the parties to file copies of any published material, including national laws and case-law, referred to in their written

submissions and on which they intended to rely. As regards the appellants, this was to be done within one month. None of the appellants complied with this direction although appellants 3 to 6, who - unlike appellants 1 and 2 - had filed with their grounds of appeal copies of new documents referred to therein, replied to the communication by filing (under cover of a letter of 29 December 2003) several new documents not referred to in their written submissions.

(3) The Board stated its intention to avoid unnecessary delay in the appeal proceedings and gave various directions, *inter alia* that replies (including requests) be filed by the respondent (patent proprietor) and the parties as of right (non-appealing opponents) within four months with no extensions of time to be permitted. The communication also indicated that oral proceedings would be held in the week of 5 to 9 July 2004. The respondent filed its reply to the statements of grounds of appeal, and a main and five auxiliary requests, by a fax of 2 April 2004. No other parties filed replies.

XII. In a second communication sent with the summons to oral proceedings dated 23 April 2004, the Board indicated the order in which it proposed matters be discussed at the oral proceedings, namely admissibility issues, objections to the patent other than under Article 53 EPC, Article 53(a) EPC objections, and Article 53(b) EPC objections. On 13 May 2004 the respondent filed by fax a request,

made on what was described as a precautionary basis, to refer ten questions to the Enlarged Board of Appeal.

XIII. In a third communication of 17 May 2004, the Board drew the parties' attention to the claims directed to a chromosome and a cell and stated that discussion of those claims would take place at the oral proceedings.

XIV. (1) In faxes dated 4 June 2004 and transmitted on 8 June 2004, appellants 3 to 6 asked (in reply to the communication of 23 April 2004) that Article 53 EPC issues be discussed first in the oral proceedings because their case was based on that Article, they were not commercial organisations and did not have the resources to be represented at a hearing lasting up to five days. The same faxes indicated that one or more persons, some identified by name and some not, would wish to speak at the oral proceedings on the subject of patenting animals.

(2) In a fourth communication of 15 June 2004, the Board replied that, first, it could not alter the order of the discussion at such a late stage but that in fact it expected the oral proceedings to last less than the five days which had been reserved; and second, by drawing attention to decision G 4/95 of the Enlarged Board of Appeal (OJ EPO 1996, 412) and related decisions mentioned in "Case Law of the Boards of Appeal of the European Patent Office", 4th edition 2001, section VI.K.7.1 at pages 371 to 373.

(3) Appellants 3 to 6 wrote again by fax of 24 June 2004 complaining of the Board's refusal to change the order of discussion and announcing that the same persons would speak on behalf of those appellants at the oral proceedings before the Board as had spoken at the oral proceedings before the Opposition Division.

XV. Oral proceedings took place on 5 and 6 July 2004 attended throughout by appellants 3 to 6, the respondent and opponent 3. Contrary to its previously expressed intention, appellant 1 did not attend the oral proceedings for reasons of cost but, in its fax of 2 July 2004 announcing its non-attendance, sent a further written submission in response to the respondent's reply which it asked to be admitted. The Board supplied copies of that submission to the parties attending the oral proceedings. Appellant 2 attended the oral proceedings on 5 July 2004 but, without any notice or explanation, absented itself during the afternoon of that day and did not appear again thereafter. Despite being duly summoned no other party gave any notice of or explanation for its non-attendance.

XVI. (1) At the opening of the oral proceedings on 5 July 2004, the respondent filed new main and first and third auxiliary requests, the new third auxiliary request being the previous fifth auxiliary request filed with its reply of 2 April 2004, and withdrew all its previous requests except for the second auxiliary request. The respondent's new main request contained the same claims as those of the request allowed by the Opposition Division (see

paragraph IX above) but without the claims to a chromosome and a cell. The new first auxiliary request was the same as the previous third auxiliary request filed with its reply except for the deletion of claims directed to a chromosome and a cell, such claims having been removed in response to the Board's communication of 17 May 2004 (see paragraph XIII above).

(2) In the course of the oral proceedings on 6 July 2004, the respondent filed a slightly amended version of the first auxiliary request in which references to "animal" were replaced by "transgenic mouse" and certain dependent claims were renumbered to allow for the fact that an independent claim to a plasmid appeared in the middle of the dependent method claims depending on claim 1; and it also filed an amended description.

(3) Independent claims 1 and 19 of the respondent's first auxiliary request as filed on 6 July 2004 read as follows:

"1. A method for producing a transgenic mouse having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a mouse.

19. A transgenic mouse whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally

being further defined according to any one of claims 3 to 10."

(4) The respondent's second and third auxiliary requests were restricted to claims directed to the use of a transgenic rodent (second auxiliary request) or transgenic mouse (third auxiliary request) for test purposes and methods of testing materials by exposing (respectively) a transgenic rodent or mouse to them.

XVII. The following documents are mentioned in the decision:

(1) Jaenisch, R. and Mintz, B., Proc. Natl. Acad. Sci. USA, Vol.71, No.4, 1974, pages 1250 to 1254;

(28) Proposed Resolution of the European Parliament, 8 February 1993 (in German);

(29) Proposed Resolution of the European Parliament, 10 February 1993 (in nine languages) and Resolution, 11 February 1993 (in German);

(47) Ekins, S. et al., Br. J. Clin. Pharmacol, Vol.36, 1993, pages 165 to 166;

(48) Long, B. et al., Br. J. Cancer, Vol.65, 1992, pages 865 to 869;

(49) Ming Liang Li et al., Proc. Natl. Acad. Sci. USA, Vol.84, 1987, pages 136 to 140;

(81) Declaration of Dr L. Hennighausen dated 6 September 2001;

(82) Declaration of Dr P. Leder dated 6 September 2001;

(83) Declaration of Dr. R. Pitman dated 6 September 2001;

and the following annexes to document (82):

(A1) Pupa, S.M. et al., Gene Ther., Vol.8, 2001, pages 75 to 79;

(A2) Gyorffy, S. et al., J. Immunol., Vol.166, 2001, pages 6212 to 6217;

(A3) Crane, P.D. et al., J. Nucl. Med., Vol.36, No.10, 1995, pages 1862 to 1868;

(A4) Chen G. et al., Int. J. Immunopharmacol., Vol.18, 1996, pages 251 to 258.

XVIII. *Arguments of the Parties: General*

(1) In the paragraphs XIX to XXXV below, the arguments of the various parties who took part in the appeal proceedings are summarised. In the case of those who both filed written submissions and attended the oral proceedings (appellants 2 to 6 and the respondent), the summary reflects both their written and oral submissions. In the case of appellant 1, which did not attend the oral proceedings, the summary is of the arguments in its statement of grounds of appeal and the written submissions filed by fax on 2 July 2004. In the

case of opponent 3 (a party as of right) which took no part in the written proceedings but attended the oral proceedings, the summary is of arguments presented at the oral proceedings. Save where otherwise indicated, all of a party's arguments applied to all the respondent's main and auxiliary requests. Appellants 3 to 6 were jointly represented and filed virtually identical grounds of appeal. However, although still jointly represented at the oral proceedings, appellants 3, 5 and 6 then made both joint and separate submissions. Accordingly, the arguments of these appellants are in part summarised together and in part set out separately.

(2) Appellants 1 and 2 limited their submissions to Article 53(a) EPC. No objections were raised by any appellants under Article 123(2)(3) EPC. Appellants 3 to 6 referred in their statements of grounds of appeal, by reference back to arguments filed with their grounds of opposition, to all the other Articles mentioned in paragraphs XX to XXIII below. Articles 53(a), 53(b), 56 and 83 EPC were also the subject of argument at the oral proceedings before the Board, but no comments were made in respect of the other Articles. The respondent made no submissions with regard to Articles 123(2)(3) EPC and Article 54 EPC.

XIX. *Arguments of the Parties: Admissibility of Oppositions*

(1) As regards the admissibility of the oppositions, the respondent disagreed with the Board's view in its communication of 24 November 2003 (see

paragraph XI(1) above) and argued that, if an opposition were to be found inadmissible (which was still possible in appeal proceedings), the opponent in question could be neither appellant nor party as of right. The respondent then quoted from headnote III of Decision G 3/99 (OJ EPO 2002, 347) the words "...it has to be clear throughout the procedure who belongs to the group of common opponents or common appellants" and submitted that the oppositions of appellants 2 to 6 did not fulfil that condition.

(2) In particular, the respondent argued that appellant 2 (opponent 2) originally included an organisation not shown to be a legal person; that it was unclear whether appellant 3 (opponent 8) was a legal person or not - the respondent had seen no documentation establishing its status; that appellant 4 (opponent 12) was an organisation described by its representative as "formed or supported by" a large number of listed organisations of uncertain legal status; that appellant 5 (opponent 13) was three named natural persons said to be supported by a "co-ordination" made up of another long list of entities - at the least this contrasted with the position of appellant 4; and that, as regards appellant 6 (opponent 15), it had again not been established that its two member organisations were legal persons, the situation being further confused by the long list of entities said to "belong" to those two organisations, and the respondent put the issue to proof.

(3) As regards non-appealing opponents, the respondent referred to the letter of 12 May 1995 from the representative of opponent 4 and submitted this amounted to a withdrawal of the opposition. The Opposition Division had held it did not, but the letter of 14 February 1995 from Mr Büchner, one of the persons comprising opponent 4, to the opponent's representative suggested otherwise. Opponent 6 was simply a long list of over 1,200 persons and it was inconceivable that, in the eleven and a half years since the opposition was filed, each and every one of those persons remained alive and retained both an interest in and a willingness to take part in the proceedings.

(4) None of the other parties made any submissions on the issues of admissibility. However, appellants 3 to 6 each commented in their grounds of appeal, under the heading "Admissibility", that they welcomed the rejection (presumably by the Opposition Division) of the respondent's "attempts to exclude the participation of the public in the present proceedings", which had been made not just because of the present case but because of the precedent it could set for the business behind the patentee and for other businesses active in the field of gene technology. The respondent denied it had made any such attempts.

XX. *Arguments of the Parties: Article 52 EPC (Invention)*

(1) Appellants 3 to 6 argued in their grounds of appeal that, whereas an invention was made in a technical context by reference to a technical

problem and its technical solution, an animal and its natural progeny or offspring could not be defined as a technical solution to any technical problem. Even if the introduction of a foreign gene into the genome of an animal could be seen as a technical method and thus as an invention, this was not the case for the resulting animals.

(2) The respondent referred to the established jurisprudence of the Boards of Appeal, wherein critical intervention steps of a technical nature in an otherwise biological process were acknowledged to change the overall nature of that process so that it was no longer regarded as essentially biological. The claimed transgenic rodents and their natural progeny could not be provided without the intervention of the hand of man in a technical manner to provide for the chromosomal incorporation in somatic and germ cells of oncogenic sequences.

XXI. *Arguments of the Parties: Article 56 EPC (Inventive Step)*

(1) Appellants 3 to 6 stated that, from a statistical point of view, it would have been unexpected - using a known method for introducing a known oncogene into the mouse genome - not to find at least a few animals with the oncogene integrated into their genomes. Similarly, the presence of only healthy transgenic animals would also have been surprising. Indeed, the skilled person would expect that, under certain conditions, the introduction of an oncogene into

an embryo would result in its integration into the genome of at least some animals, especially if the method was repeated thousands of times with different genes and animals. The teachings of the opposed patent were based on a known method with a very low success rate - less than 1% of animals surviving - and which only produced expected results. No inventive merit could be seen therein.

(2) The respondent referred to the declaration of Dr Philip Leder filed during the examination proceedings under cover of a letter dated 22 December 1988 (**not** document (82), a later declaration of Dr Leder). In particular, it was outlined that at the priority date the available bacterial test systems for studying suspected carcinogens were inappropriate. Similarly, studies with laboratory animals were expensive, requiring long monitoring time and administration of large doses of suspected carcinogens. Furthermore, continuous cell lines were not available for many tissues and studies on cell lines could not be compared to studies using a complete organism with all possible metabolic interrelations. At the priority date of the opposed patent, experimentation in mice was not so advanced that, given the possible reactions of the animal immune system to a human protein, physiological incompatibility, etc, it could be foreseen whether the introduction of an activated oncogene into the genome of an embryo would result in the animal's death, in the absence of expression of that oncogene, or in any effect at all. The claimed method was not obvious to try and, even if it had

been obvious, then there would have been no reasonable expectation of success.

XXII. *Arguments of the Parties: Article 57 EPC (Industrial application)*

(1) The appellants submitted no arguments under Articles 54 and 57 EPC in their grounds of appeal. However, in the context of Article 83 EPC, it was stated that whereas an oncomouse could be a suitable system for studying cancer, this was not the case for other rodents, such as beavers, squirrels, etc. which were not known as animal models for studying any human diseases. Thus, no industrial application could be seen for such rodents.

(2) The respondent argued that industrial application as a test had to be pitched very broadly, certainly broad enough to encompass industry devoted to medical treatments and the furtherance of such treatments.

XXIII. *Arguments of the Parties: Article 83 EPC (Sufficiency of Disclosure)*

(1) Appellants 3 to 6 asserted that, on the basis of the only examples in the patent which all related to mice, it was unacceptable to grant protection for an animal group (rodents) that included more than 2000 species. In the light of the low success rate achieved in mice, it was not credible that the same result could be obtained for each and every species of rodent including for example

squirrels and beavers. Whereas on the one hand the patentee argued that the opposed patent made an inventive contribution since, in the light of the technical difficulties referred to in the prior art, the production of transgenic mice was surprising, on the other hand it was said that no technical problems were to be expected when carrying out the teachings of the invention in other rodents. A gene had multiple functions depending a number of factors such as the animal in which it was expressed and its age and living conditions. The exemplified oncogene (myc) was a regulation gene, which only induced cancer under certain conditions. It could not be expected that the same gene would have the same effect in different rodents and that all onco-rodents would be useful models for studying human diseases. Indeed, whereas rats were used as a model for diseases of blood circulation, mice were not appropriate models for those diseases. Rodents were not a uniform group. At the oral proceedings before the Board, opponent 3 stated that in the opposed patent the only examples related to the production of transgenic mice and that there was no indication how to produce other rodents and to achieve the claimed effect in those rodents.

(2) The respondent argued that rodents were a reasonable extrapolation from the specific work described in the opposed patent and encompassed most laboratory animals in use over the years. The claimed rodents were a model for studying cancer, which was known to occur in both rats and mice - contrary to blood circulation diseases. As

a group of animals, rodents showed no important differences in their metabolic and immunologic systems. The oncogene used (myc) was involved in the regulation (interference) of cell division and this function was essentially the same in all rodents. A patent might be objected to for lack of sufficient disclosure only if there were serious doubts, substantiated by verifiable facts (T 19/90, OJ EPO 1990, 476, Reasons, paragraph 3.3). Indeed, there was no evidence on file to contradict the teachings of the opposed patent and to show that the invention could not be performed in rodents other than the exemplified mice.

Arguments of the Parties: Article 53(a) EPC ("ordre public" and morality)

XXIV. *Appellant 1*

(1) Appellant 1, after noting the test propounded in T 19/90 and the comment in that case on Article 53(a) EPC (OJ EPO 1990, 476, Reasons, paragraph 5), argued that the Board in T 19/90 had accepted that the present invention fell within the scope of the Article. Once so accepted, it was irrelevant whether the exclusion was interpreted narrowly or broadly and the Opposition Division must simply establish the European public's moral approach to the invention. The Opposition Division apparently approved the definition of "morality" in T 356/93 (OJ EPO 1995, 545, Reasons, paragraph 6) and its task was therefore to ascertain what were the beliefs as to right and

wrong behaviour and the accepted norms of European culture in relation to the invention.

(2) Animal patents aroused public unease such as that in the United States noted in T 19/90 (OJ EPO 1990, 476, Facts, paragraph II) and also reflected by the refusal to grant the invention a patent in Canada (*Harvard College v Canada (Commissioner of Patents)* 2002 SCC 76). The EU Treaty of Amsterdam and the proposed European Constitution recognised animals are sentient beings. Therefore the EPO must scrutinise animal biotechnological inventions more than others under Article 53(a) EPC, the more so since patentees might make broader claims than their research justified in order to overcome problems posed by Article 53(b) EPC.

(3) As with other patentability tests, morality was to be viewed as at the filing or priority date. (Hereafter in this decision those two dates as alternatives are referred to for convenience as "the effective date".) However, since the European public knew little or nothing of the invention at the effective date, it had neither opportunity nor reason to form a moral view then. The Opposition Division began by considering whether animal experiments were permitted in EPC Contracting States. This was too general - some might accept such experiments but oppose genetic manipulation of animals, or oppose manipulation which caused pain to animals. The public was sophisticated in its approach to moral issues. For these reasons laws, which lag behind scientific invention, were a poor guide to morality and there must be an

element of hindsight in the assessment of morality. The correct test was: in the light of what was now known about the public's moral approach to the invention, what could be deduced about what its approach would have been at the effective date, had it been in possession of the relevant facts?

(4) Article 53(a) EPC was concerned with the morality of patenting as well as of exploiting the invention. In its faxed submissions of 2 July 2004, appellant 1 argued that the application of Article 53(a) EPC in the present case was not, as the patentee asserted, a matter of ascertaining the public view at the effective date of the morality of animal experiments but of the morality of this particular invention. Similarly, arguments relating to animal testing of drugs and activities such as bullfighting were irrelevant.

(5) The Opposition Division suggested a two-stage approach to Article 53(a) EPC, first to consider what was right or wrong in European society and then to apply a cost-benefit test. Appellant 1 agreed a two-stage approach was needed but the first step should be to make a Rule 23d(d) EPC assessment and then consider more general matters if necessary. A two-stage approach did not, as the respondent argued, represent "double jeopardy" - it was two stages of one test, not two tests.

(6) As regards Rule 23d(d) EPC, the Opposition Division was right to apply the Rule but did so

incorrectly. After accepting, as had been common ground throughout, that the invention caused suffering to animals, it failed to balance that suffering against the alleged benefit but simply asserted that, because there was (as it found) a substantial medical benefit, there was no objection under Article 53(a) EPC. This approach was flawed for several reasons:

(a) Rule 23d(d) EPC provided an absolute bar to a patent if animal suffering was established and there was no medical benefit. If there was a benefit, it must then be considered whether morality dictated against a patent. Rule 23d(d) EPC could be decisive against an applicant but not against an opponent.

(b) The Opposition Division took no account of the degree of suffering involved. It did not in fact make a cost-benefit analysis but simply used suffering as a trigger to consider whether there was substantial medical benefit. Appellant 1 and other opponents had produced extensive evidence, not seriously disputed, that the technique of the invention caused substantial suffering. Moral acceptability by the public would be influenced by the level of suffering so to omit consideration of it made a nonsense of Article 53(a) EPC.

(c) The Opposition Division's approach made the question of the availability of non-animal alternatives irrelevant but this was also a

factor in public acceptability (cf. EC Directive 86/609, Articles 7.2 and 7.3). which provided, respectively, that an animal experiment must not be carried out if there was an adequate non-animal replacement and, where the use of an animal was scientifically justified, the suffering must be kept to the minimum). Appellant 1 had also provided evidence that cell lines would be equally suited to study cellular metabolism (e.g. documents (47) to (49)).

(d) Whether substantial medical benefit existed should be assessed objectively but the Opposition Division allowed a subjective test - whether at the effective date the inventor had *bona fide* reasons to believe his invention would lead to such a benefit. An inventor was only likely to assert his invention had a value. In fact in the present case after nearly two decades the benefits had been only modest.

(e) Although the test had to be made as at the effective date, it would be artificial to exclude evidence which became available between then and the date of decision. The respondent's own arguments supported this.

(7) Since no substantial medical benefit could have been foreseen at the effective date, that should have lead to revocation. However, even if the appellant was wrong in that respect, it was not, as the Opposition Division thought, the end of the

matter. It should have proceeded to consider whether other considerations of morality or "ordre public" dictated against a patent. It should have completed the cost-benefit assessment and considered alternative techniques but it did neither.

(8) The Opposition Division should also have considered all available evidence about the European public's view of the morality of the invention, something which it attempted but, again, its approach was flawed for several reasons. It considered laws and regulations and not other evidence such as opinion polls. Although legislation was an important indicator of public morality, it was not the only indicator (cf. T 356/93 OJ EPO 1995, 545, Reasons, paragraph 7). The Opposition Division did not identify any legislation dealing with exploitation of genetically modified animals. The EC Directive 86/609 neither prohibited nor allowed any particular animal experiments. In for example the United Kingdom, a licensing system required researchers to obtain permission to use animals for a particular purpose and a number of tests must be satisfied. There was no blanket authority to engage in genetic manipulation such as that of the patent. The EC Directive 98/44 addressed the patenting of biotechnological animal inventions by excluding patentability in certain circumstances, specifically leaving this to considerations of morality on a case-by-case basis. European legislation was therefore a poor guide to morality and the Opposition Division admitted that, apart

from the EC Directive 86/609, it did not know what legislation there was. As for other evidence, opinion polls however imprecise were used in the formulation of legislative policy by the EU so must be legitimate tools in assessing public morality.

(9) Two such polls were referred to by appellant 1. In 1998 a poll it commissioned in the United Kingdom found 82% of those questioned were opposed to animal patenting and therefore must have been opposed to the present invention. An EU poll on biotechnology in 1996 of 16,000 persons across Europe included the question "Do you think it is morally acceptable for society to develop genetically modified animals for laboratory research studies, such as a mouse that has genes which cause it to develop cancer?". 47.8% thought it unacceptable, 41.2% thought it acceptable. (Despite the Board's direction to file copies, no further details of these polls were supplied.)

XXV. *Appellant 2*

(1) Appellant 2 argued that, just because the four members of the Opposition Division were of the opinion that the medical advantages outweighed the suffering to animals, it was not established that the use of the invention was not contrary to morality. The Opposition Division had not shown why its own opinions were representative. There was nothing in Article 53(a) EPC to suggest it was limited to major infringements of morality or "ordre public".

(2) The EPO had tried to prevent the implementation of Article 53(a) EPC in a number of ways. First, by a too narrow interpretation. The same expression (in German "die guten Sitten") appeared in many German national laws and the correct approach to its interpretation was that found in German jurisprudence; the appellant quoted from two decisions of the "Bundesverwaltungsgericht" (Federal Administrative Court) and also cited seven decisions of the "Bundesverfassungsgericht" (Federal Constitutional Court). (Despite the Board's direction to file copies, no further details of these decisions were supplied.)

(3) Second, the expression had been given the wrong definition in T 356/93 (OJ EPO 1995, 545, Reasons, paragraph 6): "The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture". This definition suggested a dangerous path. At the 1995 oral proceedings the patentee's representative referred to activities which were accepted as part of a "non-culture" such as bullfighting and hunting and perhaps this was meant to suggest that a "cancer mouse" was not so bad.

(4) The simple question which had to be answered was: was there an infringement of morality or not? In this context "morality" meant the dominant moral feeling of society at large. This could not be

ascertained within a bureaucracy, nor could the members of the Board adopt their own views. Equally one could not ask the whole population of Europe for their views.

(5) There were a number of indications that the majority view precluded patenting the production of "cancer animals" under Article 53(a) EPC, including the multi-national opposition in the present case. One also had to consider opinion polls which were used by the European Union. The Boards of Appeal had said opinion polls did not necessarily represent what was deeply rooted in European culture. However, whether something was deeply rooted had nothing to do with culture. Something deeply rooted could be a "non-culture" such as slavery, torture or some medical experiments.

(6) Opinion polls about animal experiments generally and genetic manipulation of animals in particular showed that a majority considered the development of "cancer animals", for the sole purpose of giving them cancer, was contrary to morality. This further suggested that a majority considered the suffering of such animals to outweigh the marginal benefits to cancer research. For example, a poll in Germany in 1993 in which 70% of 500 persons questioned considered the patenting of genetically manipulated animals for cancer research was morally reprehensible. Reference was also made to polls and resolutions of national parliaments mentioned by other opponents.

(7) The volume of animal testing and the number of transgenic animals was increasing. Patenting such animals was an incentive to produce them and to cause animal suffering. It was contrary to the views of citizens generally. Animal protection was enshrined in the German and Swiss constitutions and included in the new European constitution.

(8) The claimed "cancer animals" were not free from associated risks for mankind and the environment, such as possible epidemics, contagion, or the accidental release of modified animals into natural ecosystems.

XXVI. *Appellants 3 to 6 (Joint Arguments)*

(1) Appellants 3 to 6 made clear that, in their view, the main issue in the present case was not the actual subject-matter of the patent in suit but the patenting of animals in general. This case would set a precedent; patenting of animals *per se* should be excluded. The patenting of animals was part of the systematic destruction of social values and the patent in suit took that process one step further. Patenting of animals threatened natural animals, denaturised mankind and was contrary to evolution. This case was therefore seen by the general public as a chance to deal with the problem of declining standards in general and patenting of animals in particular.

(2) These appellants considered the implementation of Rules 23b to 23e EPC to be unacceptable. In complete agreement with the Examining Division

which originally dealt with this case, these appellants were of the view that, before the introduction of those Rules, the EPC excluded the patenting of animals. Who wanted and who did not want the patenting of animals? It was only wanted by those interest groups for whom it had economic advantages - the international genetic engineering industry, patent attorneys and the EPO. Against a background of widespread revulsion at the patenting of animals and the extraordinarily high number of oppositions in this case, the introduction of Rules 23b to 23e EPC was not a mere clarification of a text but a fundamental amendment or addition with retrospective and prospective effect on the patenting of animals. Such changes should be made in the Convention itself not the Implementing Regulations. The EPC should be applied in this case as at the date of the patent application or, at the latest, the date of filing of the oppositions.

(3) As regards possible alternatives to the invention, appellants 3 to 6 said the oncomouse could not be compared with cancer in a human being. There was a range of non-animal models available for cancer research and cancer testing, for example cell cultures.

XXVII. *Appellant 3*

(1) Appellant 3 argued that the EPO was expressly required by Article 53(a) EPC to consider the ethical issue of patenting living animals. The appellant was convinced that the oncomouse was

contrary to morality and "ordre public". The Opposition Division based its decision on a concept of morality "related to the belief that some behaviour is right whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture which, in the case of the EPC, is the culture inherent in European society and civilisation" (see paragraph 9.2 of the decision under appeal). It was deeply rooted in European culture that a difference existed between animals and inanimate material and the removal of this distinction could lead to great barbarity. To treat a genetically manipulated mouse like a piece of technical equipment offended mankind's basic morality and could lead to a distortion of sensitivity in the earthly life of man. This was the reason for the Catholic Church's "Misereor" campaign of 2002-3 which, under the slogan "No patents on life", demanded that patents be ruled out for seeds, plants and animals and parts or genes thereof. The Evangelical Church had taken similar steps.

(2) Both the wording and the spirit of Article 53(a) EPC meant that patenting a genetically manipulated mouse was contrary to "ordre public" and morality. The Implementing Regulations had been changed to make this case different. Whether Article 53(a) EPC should be interpreted differently for living beings was a matter which should be referred to the Enlarged Board of Appeal. There should be different rules for animals than those for bottles and air pumps. The acts of the EPO in this case

departed from the European Judaeo-Christian tradition and the humanism of the Enlightenment and could lead to the barbarisation of society.

XXVIII. *Appellant 5*

(1) Appellant 5 argued that it was the wrong approach to consider a balance between animal suffering and medical use because no such balance was possible. Animals were sentient beings. They could not be equated with humans but lay between humans and things. It was typical of European culture that animals could be owned and used but patents on living matter were not so typical. One could not say he/she had invented animals. The Opposition Division decision did not reflect this distinction. This case was not about the medical use of mice but about the patenting of animals. Patents encouraged trade in animals and downgraded them to the status of things. It was accepted that patents on animals led to greater production of such animals. The German constitution and the new EU constitution both enshrined animal protection. The Board should acknowledge that animal protection had gained increasing acceptance in recent years. Many bodies, including a committee of the Bundestag (the lower house of the German parliament), the Council of Europe and the principal churches, had expressed views contrary to the patenting of animals.

(2) Although against a balancing test, appellant 5 had two points to make regarding Rule 23d(d) EPC. First, as regards the time at which the balancing

test must be made, it could not be when the application was filed. This would mean that under Rule 23d(d) EPC, only a theoretical assessment of substantial medical benefit would be possible whereas it was the actual medical use which ought to be taken into account. Thus, the balancing test should be made in the present case as of 2003.

(3) Second, as regards the actual medical use, the patent presently covered rodents and there were some 2,000 types of rodents. The Opposition Division had not considered each to see if a medical benefit existed - was there a medical benefit to be had from a genetically manipulated squirrel? It was necessary to go step by step through all rodents and see if inclusion of every one in the patent was justified.

(4) In its 1991 Annual Report, the EPO said of this case:

"The granting of patents no longer depends on purely technical considerations: from now on, applications will have to bear scrutiny in respect of their wider social implications".

This had not been fully considered in this case.

XXIX. *Appellant 6*

Appellant 6 argued that patenting was a feature of capitalism, an economic and social system which was organised in the sole interest of the owners of capital. This system had no moral basis and only had

one principle - the maximisation of profit. What was allowed was what was profitable. Patents for genetic manipulation, while they undermined nature, supplied profits to their owners. While such patents were ecologically unthinkable, they were economically beneficial only to a few. The patent in suit, which caused animal suffering, must be revoked.

XXX. *Opponent 3 (Party as of Right)*

(1) Opponent 3 argued that if Rule 23d(d) EPC applied in the present case, two questions must be considered. First, the Rule must be looked at in the light of the text of Article 53(a) EPC and particularly the proviso that exploitation was not deemed contrary to morality just because it was prohibited in one or more Contracting States. The words "in particular" in Rule 23d EPC must also be noted. If Rule 23d(d) EPC applied, then if there was suffering on the part of the patented animals and there was a medical benefit, did this lead automatically to the patentability of animals? The proviso in Article 53(a) EPC referring to "prohibited by...regulation" suggested that, when more than half the population of a democratic state were in favour of prohibiting it, there was no support in that state for patenting of animals. What happened then to "ordre public" or morality? Suppose that position applied in several Contracting States? Was some doubt sufficient?

(2) Second, did the fact that Rule 23d EPC said one could not go beyond the line (i.e. not have a patent when there was insufficient benefit) mean

one could patent all the way up to the line (i.e. have a patent whenever there was a benefit)? These were fundamental questions which, if Rule 23d EPC applied, must be answered and, given the importance for other cases, they must be referred to the Enlarged Board of Appeal.

(3) Whereas the English text of Rule 23d(d) EPC used the word "likely", the German text used the word "geeignet" ("suitable"). Thus the test might not be whether processes for modifying the genetic identity of animals were likely to cause them suffering without medical benefit but whether such processes were suitable for causing suffering without medical benefit.

(4) The question of whether an alternative to the invention was available should be assessed at the date of the decision in these proceedings since there were forms of diagnosis available today which would avoid the need for the oncomouse.

(5) The date of assessment was also important as regards animal suffering and the extent of such suffering - was it enough if only one animal suffered or must all the animals falling within the claim suffer?

XXXI. *Respondent*

(1) The Board must operate within a certain pre-set legal framework which resulted from the democratic process. Unfamiliar as the opponents might find that framework, the Board could not accede to

arguments which would require it to go outside that framework. The appellants were using the proceedings as a vehicle for a general objection to the patenting of life forms. They wanted to change the law - it was not appropriate to use one case to secure a basic change in the law. The correct way to change the law was the democratic legislative system. The patent system should not be used to achieve something not so far achieved through democracy.

(2) Article 52(1) EPC, which says "European patents shall be granted...", carried a presumption of grant and therefore a reason for not granting a patent must be established. Exclusions, such as in Article 53(a) EPC, must be interpreted narrowly and objectively. No one set of beliefs must dominate a balanced and reasonable finding. The existing case law gave balanced guidance. As with other patentability criteria, assessment should, in the interest of legal certainty, be made as of the effective date (in the present case, the European priority date), and not subject to review over time. Evidence not focused on the effective date was irrelevant. The appellants' evidence encompassed legitimately held beliefs but gave no evidence of current attitudes to animal testing at the effective date. In the absence of relevant evidence, the Board must have regard to the principles of legal fairness and not decide on mere surmise or the expression of beliefs.

(3) T 19/90 (OJ EPO 1990, 476, Reasons, paragraph 5) provided the only test for judgments under

Article 53(a) EPC and, if the Board should differ from T 19/90, a reference to the Enlarged Board was necessary. T 19/90 was decided with full knowledge of the *travaux préparatoires* and was the only authoritative pronouncement on Article 53(a) EPC prior to the introduction of Rule 23d(d) EPC. If the new Rules were more restrictive than T 19/90, either a referral to the Enlarged Board was necessary or the new Rules may, to the extent they were more restrictive, be *ultra vires*. Otherwise the exclusion in Article 53(a) EPC would have been broadened contrary to the principle of narrow construction of exclusions, and inventions which might have satisfied the test in T 19/90 might now fail the test in Rule 23d(d) EPC. The application of Rules 23b to 23d EPC to Article 53(a) EPC was considered in T 272/95 (of 23 October 2002, unpublished in OJ EPO, Reasons, paragraphs 4 and 5) but in that case the Board merely adopted the approach of the Enlarged Board in G 1/98 (OJ EPO 2000, 111) to the application of the new Rules to Article 53(b) EPC, namely that those Rules were only interpretative. There was thus no authoritative statement that Rule 23d(d) EPC was consistent with Article 53(a) EPC.

(4) The respondent agreed with appellants 3 to 6 that the introduction of the new Rules into the proceedings after a six year delay from the first oral proceedings in 1995 was wrong and the EPO did not behave properly in that respect. The case was ostensibly to be continued in writing after the first oral proceedings in 1995 but in effect there was no such written phase. The delay was truly

immense and was a cause for complaint. Circumstances had changed in the time since 1995, so it was wrong that Rule 23d EPC should apply retrospectively.

(5) The respondent considered Rule 23d EPC should not apply in the present case subject to a *caveat*. The *caveat* was that, if application of Rule 23d EPC did no more than explain Article 53(a) EPC, it seemed reasonable that the Administrative Council should explain how they wanted things done. Whether the Rule was simply interpretation or not was not easy to decide. In reality, it was an exclusion from patentability which went to the very nature of the subject-matter to which Article 53(a) EPC applied. "Substantial medical benefit" defined an area of requirement for patentability which could not have been predicted from previous interpretation of Article 53(a) EPC. The expression "likely to cause suffering" itself required interpretation; if Rule 23d EPC not only overlapped with T 19/90 but also went further, it was *ultra vires*.

(6) Following a question from the Board during oral proceedings, the respondent agreed that its use of the term *ultra vires* was imprecise. The respondent's argument was that, if Rule 23d EPC led to a different interpretation of Article 53(a) EPC than that given in T 19/90 and the Board proposed to depart from the T 19/90 interpretation, a referral must be made to the Enlarged Board of Appeal.

(7) The appellants' evidence ignored scientific attitudes and motives at the effective date, when in fact the invention was seen as a useful tool in the fight against cancer. Animal experiments for disease research and drug testing purposes had been performed and required for many years and using more categories of and more advanced animals than just rodents. The invention, by providing animals which could be used for more "sensitive" tests, could be seen as reducing both the extent and duration of animal experimentation.

(8) It could not be necessary for the respondent to produce evidence of actual medical benefit let alone substantial medical benefit at the effective date since this would require the invention to be reduced to practice and shown to have utility by that date. Reduction to practice at the filing date was not an absolute requirement, it was enough that there should be a perception or expectation of a benefit at that date. Rule 23d(d) EPC said "likely to cause suffering without substantial medical benefit"; the word "likely" indicated that it was a matter of perception and not actuality. What was required was the perception of the skilled person at the filing date of the likely suffering of animals compared with the advantages seen by the skilled person at the same date. If the test applied under Rule 23d(d) EPC were to include assessment of facts not known at the filing date, this would create an impossible situation for patentees who would have to test every possible cancer compound, in other words engage in a gross reduction to

practice. If that was required, then there must be a referral to the Enlarged Board of Appeal.

(9) The respondent did not deny that it was at the filing date predictable that some animals would get cancer and would suffer. But it was also predictable that some animals would be useful laboratory tools in future cancer research. The benefit was thus that cancer research could be done which could not have been done before. Evidence in support of this could be found in documents (82) and (83).

(10) The appellants' evidence ignored many widespread negative attitudes to animals in many Contracting States, such as the mass-organised killing of animals for food, hunting and bullfighting for entertainment, and the economic and social factors associated with such activities. The present invention must be judged against all such real cultural attitudes and not just a "wish list" of some. Many experiments were made in the 1980s to find cancer cures and mice were often used. This was and still is the case - acceptable experimentation is part of the culture. It was plain from the specification as filed that the claimed subject-matter had the highest of motives in relation to human care and protection of humans from cancer. To want to cure cancer was thoroughly moral.

(11) Despite having had many years in which to do so, none of the appellants, on whom the onus lies, had produced any evidence of moral attitudes at the

effective date which were detrimental to the invention. The respondent accepted that specific evidence at that date about the oncomouse was not possible, but there was not even any evidence as to the general attitude to animals and the use of animals in *inter alia* tests and experimental research for the treatment and cure of cancer in humans.

(12) The invention satisfied Article 53(a) EPC as regards publication because as a matter of fact publication did not result in a breach of "ordre public". It also met the requirement of exploitation since this was regulated by national laws and EU regulation in Contracting States. If only legitimate exploitation governed by democratically delegated authority could occur, that exploitation was consistent with accepted standards of European culture. It was also consistent with the Article 53(a) EPC proviso. The Board was not concerned with illegal or immoral exploitation of an invention regardless of its nature. A new form of chisel should not be refused a patent because it might be used for killing or housebreaking; both those activities would be contrary to "ordre public" and morality but were regulated by other areas of the law. A patentee should not be required to limit his use to the purely legal. The oncomouse was directed to a particular area of research and still was.

(13) The claims of the main request covering rodents represented a narrow and appropriate extrapolation from mice which had historically been most

commonly employed in animal testing for *bona fide* medical purposes. The auxiliary requests were limited to mouse subject matter which involved no such extrapolation. The requests with claims limited to uses made no attempt to protect a product *per se* so the only exploitation to consider under Article 53(a) EPC was such uses as were permitted by law in the Contracting States. Such uses must by definition be consistent with European culture.

(14) The case law of the Boards of Appeal showed clear acceptance of the principle that patents may be granted for inventions concerning animals or plants (see T 356/93, OJ EPO 1995, 545, Reasons, paragraph 10; T 19/90, OJ EPO 1990, 476, Reasons, paragraph 4.6). The appellants' argument that animal subject matter was non-technical and non-patentable was therefore incorrect. In this respect the Board must either follow the case law or refer an appropriate question to the Enlarged Board of Appeal.

(15) The respondent referred to the *travaux préparatoires* (document IV/2071/61 of March 1961 on a "First working draft of a Convention on a European Patent"). Regarding Article 12 of that draft, the forerunner of Article 53(a) EPC, the document said:

"(b) Even if protection of new plant varieties and processes for producing new plants are excluded under European patent law, European patents will still have to be granted for processes which,

whilst being applicable to plants, are of a technical nature, for example processes for producing new plants by irradiation of the plants themselves or the seeds with isotopes. It remains to be examined whether that possibility of patent protection must be expressly incorporated in European law or whether it is obvious from general principles.

(c) The comments in (b) also apply mutatis mutandis to the patentability of new animal species."

Thus it appeared the legislators considered that the possibility of irradiating animals to obtain new species was something technical which they could not necessarily exclude.

(16) The respondent answered specific arguments of appellant 1 as follows.

- Appellant 1's argument - that it was accepted in T 19/90 that the present invention fell within the scope of Article 53(a) EPC and, once so accepted, the breadth or narrowness of that Article became irrelevant - took the relevant passage in paragraph 5 of T 19/90 out of context. In this passage, the Board had indeed over-ruled the Examining Division by saying that Article 53(a) EPC had to be considered in cases such as this and provided a balancing-act test for doing so. Yet, it had also provided a further reminder that the narrowness of exceptions to patentability was a repeated finding by the Boards of Appeal which

flowed from the permissive rule established by Article 52(1) EPC.

- While the respondent agreed that the test must be applied as of the effective date, appellant 1's suggestion that subsequently produced evidence could be considered would mark a departure from normal practice with other patentability tests and should not be allowed in order to be consistent with those other tests and because attitudes to morality changed with time. To allow that evidence of later experience could be used to inform an assessment at the effective date would be to allow the use of hindsight. The test must be a "looking backwards" not a "looking forwards" test.

- Appellant 1 had asserted the public was sophisticated in its approach to moral issues but, in fact, care had to be exercised in relying on media views since the media could create controversy to gain circulation. Any judgment as to moral standards must be made with an understanding of the technology. The respondent accepted there may be unease over animal patent inventions and it was true that the corresponding Canadian case was decided for different reasons, but neither of these matters could be even persuasive in the present case.

- Appellant 1's proposed application of the test in Rule 23d EPC was not correct; whereas it was accepted that the categories listed in Rule 23d(a) to (d) EPC were excluded, other categories not

expressly mentioned in Rule 23d EPC could not also be excluded under Article 53(a) EPC.

(17) With regard to appellant 2's arguments, the respondent answered as follows:

- The views of German courts were only of one Contracting State and could only be even persuasive if the circumstances were equivalent - there was an absence of evidence in this respect.

- As to the criticism that the Opposition Division failed to show their view was representative, there was no such burden on the first instance. Opposition Divisions, and the Boards of Appeal, must work within established procedures which depended upon evidence being supplied by parties. This was also the answer to appellant 2's claim that the EPO had tried to inhibit democracy by a narrow interpretation of Article 53(a) EPC, by introducing a test when the question was simply "is it moral or not?". A narrow interpretation was always intended (cf. the *travaux préparatoires*). The Boards of Appeal had to work within a given framework and could not "make it up as they went along"; they had thus produced an essentially narrow interpretation (e.g. T 19/90, OJ EPO 1990, 476; T 356/93, OJ EPO 1995, 545) about which appellant 2 complained.

- The Opposition Division had also been criticised by appellant 2 for not establishing that the majority of citizens of Contracting States

considered the invention immoral. However, the Opposition Division could only have done that if evidence to that effect had been provided by the opponents. Appellant 2 alleged that the simple question "is it moral or not?" was answered by finding the dominant popular opinion and that this was done by opinion polls. The opinion polls referred to by appellant 2 suffered from the same disadvantages as those discussed in T 356/93. The problem with opinion polls was that they could not take account of enough knowledge - in this case, of genetic engineering, ethics and patent law - to be sure the answers were meaningful. Appellant 2 also argued that, in the case of new technology, it was not enough to establish what was deeply-rooted in European culture; to this the respondent observed that, if that was the case, it was still relevant to establish what the moral attitudes were to related issues such as animals in general and the use of animals in testing.

- Appellant 2 had argued animal testing was increasing and animal protection was enshrined in the new European constitution. However, national governments still permitted animal testing. That was one of the tasks governments were assigned in a democracy.

(18) As regards appellant 3's arguments, a decision as to what was right and normal should not be based on one set of religious beliefs. It was not the current European way to allow one religion to dictate. As to appellant 3's distinction between living material and other inventions and the

argument that patenting living material could lead to barbarity, there was very little evidence that patenting of life forms had contributed to barbarity. Article 53(a) EPC was not about the morality of patenting.

(19) As regards appellant 5's arguments, the Respondent replied as follows:

- The answer to the argument that suffering could not be balanced by benefit to mankind, as reflected in T 19/90, because it took no account of the fact animals were sentient and life could not be invented, was simply that the Boards had upheld life-form patents and there was nothing in the established case-law to suggest any limit beyond what was in the EPC. An early example was T 320/87 (OJ EPO 1990, 71) concerning hybrid plants obtained by non-essentially biological breeding process. It was not the case that patents encouraged trade in animals - a patent discouraged the activities of others. Some activities resulted in situations which may be found unacceptable under Article 53(a) EPC. Thus, keeping, growing and distributing animals for food often had undesirable results such as mass commodity use and battery farming of animals. The respondent agreed with appellant 5 that the statements of ethical bodies must be taken into account, but it was for the Board to weigh such statements as evidence and not for the parties to demand that such statements governed this case.

- As regards Rule 23d(d) EPC, appellant 5 was incorrect to say this was about actual medical benefit - the Rule only referred to a likelihood of causing suffering without substantial medical benefit. As for such benefit in the present case, this was shown by the declarations of Pittman and Leder (documents (83) and (82) respectively). Some of the abstracts annexed to the Pittman declaration specifically talked about the advantages of the approach taken. This showed the scientific community at least worked with this invention for research purposes so, even on a retrospective test, there was some medical benefit.

(20) As regards the argument of appellant 5 and opponent 3 concerning the extension of the balancing act to all animals embraced by the claimed subject matter (for example, a genetically manipulated squirrel), rodents were accepted as laboratory animals for use in experimental research and they provided different model systems for studying cancer.

(21) As regards appellant 6's arguments largely based on the allegation that genetic engineering was dictated by a profit motive and the EPO needs to promote economic growth, the present invention was remarkably unprofitable. Everyone was aware that some extraordinarily profitable cases had come before the EPO. In this case, the issue for the scientists was: could they do something about cancer? The answer to appellant 6's statement that human beings lost their humanity by distorting

nature was that it was simply human to fiddle with nature - to use a car or produce mass-produced food was to fiddle with nature. Comparing this invention with the practices of farmers and animals breeders showed that, apart from any profit motive, genetic engineering provided a quicker route to the desired end since it avoided the delays of traditional breeding.

(22) As regards the argument, made on behalf of all of appellants 3 to 6, that values were being systematically destroyed if animals could be patented, the issue whether animals in general may be patented was considered in T 19/90 and the Board came to the conclusion there was no general exclusion of the patentability of animals (OJ EPO 1990, 476, Reasons, paragraphs 4.4 to 4.8). If the present Board disagreed, it must refer the matter to the Enlarged Board of Appeal. The respondent agreed with these appellants that the first instance procedures were unsatisfactory. As for the alternatives to the invention mentioned by appellants 3 to 6 (cell cultures), they were dealt with in document (82) which showed these tests were of doubtful relevance. On the contrary, by using the present invention one could adjust the promoter in accordance with knowledge of the tissues to achieve varying effects between tissues. More importantly, the entire organism (including, for example, the immune system) was being considered.

(23) As regards opponent 3's argument that some doubt in the public mind was sufficient to prevent

patenting, this was too vague and nebulous a test and would involve a task too political to be consistent with the role of the Board. Furthermore, if as argued by opponent 3, there were inconsistencies between the English and German texts of Rule 23d EPC, this may be another reason why that Rule was *ultra vires*. Finally, opponent 3's suggestion that alternatives to the invention be considered at the date of the decision was clearly wrong. Like it or not, the system was that, once granted, a patent lasted to the end of its term provided renewal fees were paid. Subsequent developments did not affect its validity.

Arguments of the parties: Article 53(b) EPC

XXXII. *Appellants 3 to 6*

(1) Appellants 3 to 6 referred back to the arguments in their grounds of opposition and emphasized the following arguments at the oral proceedings before the Board.

(2) Plant or animal species were not products as such but only abstract concepts. An animal species existed in a material sense when a number of animals had a specific common feature. The exclusion from patentability of plant or animal species as immaterial concepts would be absurd if the very animals themselves falling within these abstract concepts were not excluded from patentability. If the legislator had wanted the plants or animals of a new species - in contrast

to "species" as such - to be patentable, it would have said so explicitly and with an appropriate form of words. The absence of such a form of words showed that plants or animals as material manifestations of abstract species were not patentable. Decision T 1054/96 (OJ EPO 1998, 511, paragraph 97 of the Reasons) referred to Article 4(2) of the EU Directive 98/44 as being satisfied by permitting process claims for these products.

(3) According to the decision G 1/98 (OJ EPO 2000, 111, Reasons, paragraph 3.3.3), a copying machine for use exclusively in forging banknotes was not patentable, whereas the same machine to be used for other purposes could be patentable. By analogy, the claims of the first auxiliary request, which were exclusively directed to mouse species, could not be allowed. If this argument should not be accepted by the Board, the question filed by appellants 3 to 6 should be referred to the Enlarged Board of Appeal.

(4) The claimed method for producing transgenic mice was a biological process in view of the many and essential steps required to produce these mice once the oncogene had been injected in a fertilized egg cell. This became even more evident for their natural progeny obtained only by essential biological processes.

XXXIII. *Opponent 3 (Party as of Right)*

At the oral proceedings before the Board, the party as of right referred to the fact that the claimed transgenic mouse inherited a specific technical characteristic and thus for that reason alone it represented a new animal species.

XXXIV. *Respondent*

(1) Article 53(b) EPC intentionally made a distinction between animals and animal species and it did not exclude the patenting of animals as such. The decision of the Enlarged Board of Appeal G 1/98 (OJ EPO 2000, 111) allowed generic claims to plants even though such claims might embrace plant varieties as such - a "generic approach" as opposed to a "specific approach". Equal linguistic treatment was found in the EPC for plants and animals. Thus, there was no reason for taking anything other than a parallel view in relation to animals and therefore a generic approach had to be applied to the claimed transgenic mice. According to T 19/90 (OJ EPO 1990, 476, Reasons, paragraph 4.8), it should first be ascertained whether the claimed subject matter constituted one of the expressly stated categories in the three language versions of Article 53(b) EPC. If not, then this Article was no bar to patentability. The broadest of the terms used in Article 53(b) EPC in any of the three languages was "species" (Tierarten) in the German and the transgenic mice of the patent were at least two taxonomic orders above that.

Thus, they represented a generically applicable invention patentable under Article 53(b) EPC.

(2) This interpretation was in agreement with Rule 23c(b) EPC, which stated that if an invention was not restricted to any particular species, i.e. it was a generic invention, then it was patentable. This Rule 23c(b) EPC applied to the opposed patent too.

(3) Paragraph 3.3.3 of decision G 1/98 (cited by appellants 3 to 6, see paragraph XXXII(3) above) concerned morality issues (Article 53(a) EPC) and not issues related to Article 53(b) EPC. For Article 53(b) EPC, the conclusions summarised in Headnote I of G 1/98 were the relevant ones.

(4) Chromosomal incorporation into mice of an oncogene did not without more create a species as such. One feature alone could not define a new race. The boundaries of a species were determined by other criteria, such as the ability of the animals to breed among themselves. A red rose was not a plant variety *per se* just because it was red, although red colour was an inheritable characteristic. There were in fact many specific varieties of red roses. The same was true of the oncogene in mice.

XXXV. *Arguments of the parties: Costs*

Appellants 3 to 6 and the respondent all repeated the requests they and appellant 1 made at first instance, namely that the European Patent Office be ordered to pay their costs of the oral proceedings of 6 to

7 November 2001 before the Opposition Division on the grounds that the costs of those second oral proceedings were unnecessarily incurred. They argued that the Opposition Division should have taken a decision after the first oral proceedings. Appellants 3 to 6 observed that the reason given by the Opposition Division for refusing the same request in its decision, namely that there was no basis in the EPC to make such an order, amounted to an assertion by the European Patent Office that it never made a mistake. The respondent observed that the delays in the first instance proceedings were exceptional (see paragraph XXXI(4) above). Appellant 1 also commented on the delays but did not renew its costs request.

Requests

XXXVI. All the appellants (in the case of appellants 1 and 2 in writing) requested that the decision under appeal be set aside and that the patent be revoked. Appellants 3 to 6 further requested that the following question be referred to the Enlarged Board of Appeal:

"With reference to G1/98: Is a claim allowable if it is directed exclusively to transgenic animal races?" (Translation made by the Board; the question as filed was in German and read "Unter Bezug auf G1/98: Ist ein Anspruch gewährbar, wenn er ausschliessend auf transgene Tierrassen gerichtet ist?").

Appellants 3 to 6 also requested that their costs of the oral proceedings of 6 to 7 November 2001 before the Opposition Division be paid by the European Patent Office.

XXXVII. The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of its main request or alternatively one of its auxiliary requests 1 to 3 all filed during the oral proceedings.

The respondent also requested that the Board refer to the Enlarged Board of Appeal the questions in its letter of 13 May 2004, namely:

"1. Does Article 53(a) or (b) exclude the patenting of animals in general?

2. At what date is the morality or "ordre public" test of Article 53(a) to be assessed?

3. If the answer to question (2) is other than at the European filing date or priority date, is it possible for the legal validity of claimed subject-matter under Article 53(a) to change with time?

4. If the answer to question (2) is at the European filing date or priority date, is it permissible for an invention to be excluded from patentability under Article 53(a) as a consequence of evidence or facts which is or were not current at the European filing date or priority date, as the case may be?

5. Does Rule 23d(d), when referring to "substantial medical benefit", set a test which goes beyond the

meaning of Article 53(a) as interpreted without knowledge of this Rule?

6. If the answer to question (5) is "no", are the requirements of Rule 23d(d) satisfied by a reasonable expectation or hope of "substantial medical benefit" at the date of assessment for Article 53(a) purposes?

7. Is it relevant to a consideration of whether claimed product subject-matter meets the requirements of Article 53(a) that such product subject-matter may have been generated outside the EPC jurisdiction by use of a process or method which would itself be unpatentable under Article 53(a)?

8. If the answer to question (1) is "no", what is the proper extent of the exclusion from patentability under Article 53(b)?

9. If the answer to question (8) is any one or more of "animal varieties", "races animales" or "Tierarten", how is/are such term or terms to be interpreted in actual practice?

10. If the answer to question (8) is anything other than one or more of the terms listed in question (9), how is the nature of such exclusion from patentability to be interpreted in actual practice?"

The respondent also requested that its costs of the oral proceedings of 6 to 7 November 2001 before the

Opposition Division be paid by the European Patent Office.

Reasons for the Decision

1. *Introduction*

1.1 The focus of this case is a very small animal, namely a mouse - to use a poet's description, a "Wee, sleekit, cowrin, tim'rous beastie" (R. Burns, "To a Mouse", 1785). In all other respects however, this case is not small. It has been conducted by a large number of parties who have deployed a multiplicity of arguments. Therefore, it may assist to begin the reasons for the decision with a short outline of the structure the Board has adopted. After dealing first with matters of admissibility of the oppositions and appeals (sections 2 and 3), the Board will then consider a number of matters concerning Articles 53(a) and 53(b) EPC generally (sections 4 to 11). As is evident from the summary of the parties' arguments (see paragraphs XXIV to XXXIV above), the bulk of this case relates to those Articles. Thereafter the Board will consider the application of the law - both Articles 53(a) and 53(b) EPC and others - to the patent proprietor's requests (sections 12 and 13). Lastly, the Board will consider the various requests for referral of questions to the Enlarged Board of Appeal and for costs to be paid by the European Patent Office (sections 14 and 15).

1.2 The issues arising under Articles 53(a) and (b) EPC generally will be dealt with in the following order. First, it is important to establish what this case is

not concerned with since this will allow the large volume of arguments purportedly directed to Article 53(a) EPC (see paragraphs XXIV to XXXI above) to be reduced to that which is actually relevant (see section 4 below).

1.3 Second, it is then necessary to consider several questions relating to Rules 23b to 23e EPC as follows.

(a) First, whether or not those Rules, and in particular Rule 23d EPC, apply to this case at all (see section 5 below). If those Rules do apply to this case, then the further matters in (b) to (e) below arise.

(b) The relationship between Rule 23d(d) and Article 53(a) EPC (see section 6).

(c) Whether, as the respondent has argued, Rule 23d is inconsistent with the previous case-law relating to Article 53(a) EPC (see section 7).

(d) The point in time at which the conditions imposed by Rule 23d EPC are to be assessed (see section 8).

(e) The evidence which can be taken into account in making that assessment (see section 9).

1.4 Third, it is necessary to consider the application of Article 53(a) EPC other than in conjunction with Rule 23d(d) EPC. As is evident from its wording and as explained in more detail below, that Rule creates a "special case" application of Article 53(a) EPC which

requires a quite distinct factual and legal analysis from that required by the application of Article 53(a) EPC *simpliciter* (see section 10 below).

1.5 The fourth and last area of general consideration is Article 53(b) EPC and, again, this will also be influenced by the decision whether or not Rules 23b to 23e EPC apply (see section 11).

2. *Admissibility of the Oppositions*

2.1 Admissibility of oppositions can be questioned at any point in proceedings, including appeal proceedings (G 4/97 OJ EPO 1999, 270, Order, paragraphs 1 and 2; and see generally "Case Law of the Boards of Appeal of the EPO", 4th edition 2001, pages 462 to 463). A case such as the present with "multiple opponents" appears to be a pre-eminent example of a situation in which admissibility should be kept under review, although parties cannot expect the Opposition Division or Board to do this alone. It is clear that the Board has neither the resources nor the knowledge of the relevant laws of all the Contracting States necessary to police the composition of, and the legal status of all the members of, multiple opponents. As the Enlarged Board observed, such opponents must inform the EPO of changes in their composition or representation. Equally, once *prima facie* admissibility is acknowledged, it must be up to the party or parties seeking to challenge admissibility to make a case of inadmissibility.

2.2 The respondent objected at first instance to the admissibility of a number of the oppositions commenced

by "multiple opponents". The Opposition Division dismissed those objections by observing that the Enlarged Board had said in G 3/99 (OJ EPO 2002, 347, Order, paragraph 1):

"An opposition filed in common by two or more persons, which otherwise meets the requirements of Article 99 EPC and Rules 1 and 55 EPC, is admissible on payment of only one opposition fee."

As regards a similar objection of the patentee to that made in the appeal proceedings, namely that the identity of all the multiple opponents was in doubt, the Opposition Division said of all opponents it was "satisfied that sufficient proof was available as to the status of legal person of Opponents" (see paragraph 1.3 of the decision under appeal). The Board sees no reason to question those findings, the respondent not having pointed to any evidence which suggests that the legal status of the various persons in question is other than the Opposition Division held. For example, the respondent said it had seen no documentation establishing whether opponent 8 (appellant 3) or the two members of opponent 15 (appellant 6) were legal persons or not. The Opposition Division said of opponent 8 that it is "a corporation under public law having the status of a legal person" and, of opponent 15, that it "consists of two associations having the status of legal person under Austrian law" (see paragraph 1.3 of the decision under appeal - clearly, "person" was intended to read "persons"). If the respondent wished to challenge those conclusions, it was incumbent on it to produce or point to some evidence to question such conclusions

- for example evidence from official registers or the results of inquiries showing that a legal person never existed or no longer exists, or evidence that under the relevant national law a legal person does not have the status found by the Opposition Division.

2.3 However, a distinction can be drawn between, on the one hand, the legal status of each member of a multiple opponent and, on the other hand, changes over time in the composition of a multiple opponent. As regards the latter, the Board agrees with the respondent (see paragraph XIX(1) above). As the Enlarged Board also said in G 3/99 (see Order, paragraph 3):

"In order to safeguard the rights of the patent proprietor and in the interests of procedural efficiency, **it has to be clear throughout who belongs to the group of common opponents or common appellants**. If either a common opponent or common appellant (including the common representative) intends to withdraw from the proceedings, the EPO shall be notified accordingly by the common representative or by the new common representative determined under Rule 100(1) EPC in order for the withdrawal to take effect." *(Emphasis added)*

2.4 In the case of some "multiple opponents" the position will remain clear throughout as the Enlarged Board required. For example, opponent 1 was comprised of two English law legal persons, both having general animal welfare activities, of which only one elected to appeal and the Board was informed of the change of both composition and representation. This can be

contrasted to opponent 6, a group of over 1,200 natural persons whose only common interest was that they had all signed what was in effect a petition against the patent in suit. The respondent observed with some force that it was inconceivable that, in the eleven and a half years since the opposition was filed, each and every one of those persons remained alive and interested in and willing to take part in the proceedings. The Board agrees and, if opponent 6 had appealed or sought to take any part in the appeal proceedings, it would have been appropriate to consider further whether the conditions stipulated by the Enlarged Board could have been met. Unlike opponent 1 and several other multiple opponents, opponent 6 was purely and simply an "opposition club" which existed only for the purpose of these proceedings. In the case of such an opponent of more than 1,200 members, the absence over eleven and a half years of any notification as envisaged by the Enlarged Board could in itself be considered an indication that the "clear throughout" condition had not been complied with.

2.5 A further objection to the admissibility of certain other multiple opponents was that they were said to be "formed and supported" by persons of uncertain legal status. As regards "formation", the fact that certain opponents only came into being for the purpose of filing opposition to one patent cannot in itself be an objection to admissibility whether, as already observed in the case of opponent 6, this was all the members of the multiple opponent had in common or whether, as in the case of appellant 6 (opponent 15), the two members already shared a more general common

interest (in that case, as animal welfare organisations). It is apparent from the opinion of the Enlarged Board in G 3/97 (OJ EPO 1999, 245, Order, paragraph 1(a)) that an opponent's motive or lack of motive is irrelevant: a "straw man", such as a company formed for the sole purpose of opposing a patent, could be acceptable. Since multiple opponents are permissible, it would be illogical to impose a stricter requirement on them.

2.6 As regards "support", it appears to the Board to be wholly irrelevant that an opponent, whether individual or multiple, may be supported by others. Such supporters clearly cannot take any part in the proceedings and cannot affect its outcome. In relation to any proceedings there are likely to be non-parties who want to see a particular party succeed (for example, employees or shareholders of a company which is a party). The only difference is that in the present case some opponents have made varying reference to their supporters - in the case of appellant 5 (opponent 13), three natural persons with a long list of supporters, by suggesting their opposition is on behalf of their supporters. If such references were made in the belief that this might influence the result, then that was of course incorrect. However, support for a party cannot *per se* be a reason to challenge admissibility. In fairness to the respondent, it did largely acknowledge the distinction between "support" and "formation" and it was the legal status of individual members of multiple opponents on which its attack was concentrated.

2.7 Lastly, the respondent presented specific arguments about the admissibility of the oppositions of opponents 4 and 6. As regards opponent 6, the Board has already observed (see paragraph 2.4 above) it considers the respondent's comments to have force. As regards opponent 4, this was another "opposition club" consisting of three members - an individual, a registered association and an unregistered association itself consisting of fourteen individuals (see paragraph VII(1) above). It was clearly formed for the purpose of this opposition. The EPO was informed by a letter of 12 May 1995 from the opponent's professional representative that the unregistered association no longer existed and, although not expressed in so many words, that the representative would no longer act as such. No new representative was determined and indeed it would have been unlikely that any such determination would have had any effect since the retiring representative made clear he had received no instructions. It appears to the Board that the only conclusion which could and should have been drawn was to treat the opposition of opponent 4 as withdrawn since the requirements indicated by the Enlarged Board as to clarity of composition and ongoing representation of multiple opponents ceased as of the receipt of that letter. However, as in the case of opponent 6, little purpose would be served in pursuing this matter further in the absence of any appeal by or participation in the appeal proceedings by opponent 4 or any of its members.

2.8 The comments of appellants 3 to 6, under the heading in their grounds of appeal of "Admissibility", that they welcomed the rejection of the respondent's

"attempts to exclude the participation of the public in the present proceedings" (see paragraph XIX(4) above) are rejected by the Board as meaningless. The respondent denied it had made any such attempt and the Board can find no evidence on the file of any such activity. All that appellants 3 to 6 can have meant was that (unsurprisingly) they agreed with the Opposition Division's rejection of the patentee's various objections to admissibility of oppositions. However, if that is what they meant, they should have said so and should not have mis-described quite legitimate objections to the admissibility of oppositions as attempted exclusion of "the public".

2.9 In summary, in a case with "multiple opponents" such as the present admissibility should be kept under review to ensure it remains clear throughout who belongs to the group of common opponents or common appellants as noted by the Enlarged Board of Appeal in G 3/99 (OJ EPO 2002, 347, Order, paragraph 3). The Board accepts there are serious grounds for questioning the admissibility of the oppositions of opponents 4 and 6 since it may not have been clear throughout the proceedings who belongs to each of those multiple opponents. However, in the absence of any appeal by either of those parties or of any participation by them in the appeal proceedings, no purpose would have been served by pursuing those matters. As regards the other oppositions, the respondent did not produce or refer to any evidence sufficient to disturb the findings of the Opposition Division.

3. *Admissibility of the Appeals*

3.1 Since the appeals of the parties who have appealed are from decisions in oppositions which were themselves admissible, and since the appeals all comply with Articles 107 and 108 EPC, the admissibility of the appeals is not in question.

3.2 In its communication of 24 November 2003 the Board stated the opinion that if any appeal in this case should be held inadmissible, the party in question would none the less be a party of right and its grounds of appeal would stand as the written submissions of such a party. The respondent subsequently expressed disagreement with this, observing that if a party's opposition should be found inadmissible, that party could not appeal. That is of course strictly-speaking correct. The Board's communication was intended, as it stated, to reflect the Board's intention to avoid delay in the appeal proceedings. Further, the Board's opinion was only provisional and said to be such. In the event, nothing turns on this since the oppositions of all the appellants are considered by the Board to be admissible.

4. *Irrelevant Issues*

4.1 A large number of the appellants' arguments made in relation to Article 53(a) EPC were directed to issues with which the present case is quite simply not concerned. First, there is a straightforward question of interpretation, or rather misinterpretation, of the EPC on the part of certain appellants. Appellant 1

argued in terms (see paragraph XXIV(4) above) that Article 53(a) EPC was concerned with the morality of patenting as well as of exploiting the invention. Appellant 2 argued (see paragraph XXV(4) above) that there is a simple question to be answered namely, "is there an infringement of morality or not?". This could only mean "is the patent in suit an infringement of morality or not?" and it was abundantly clear appellant 2 considered the answer to that question to be "yes". And, as already indicated, appellants 3 to 6 argued (see paragraphs XXVI to XXIX above) that the patenting of animals should not be allowed and thus they too clearly considered that Article 53(a) EPC was concerned with the morality of patenting. The Board disagrees. The wording of Article 53(a) EPC is clear:

> "European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality...".

4.2 It is, in the Board's opinion, only possible to read the words "contrary to "ordre public" or morality" as qualifying "publication or exploitation". The same is true of the text in the other official languages. Accordingly, the Article raises no question of the morality of patenting a particular invention or of the morality of that invention *per se*. This conclusion, of course, applies to the particular animal invention claimed in the patent in suit: this case is concerned neither with the morality of genetically manipulating a mouse nor with the morality of the oncomouse thereby produced nor with the morality of patenting either the oncomouse or the genetic manipulation method but only

with the morality of publication or exploitation of the oncomouse or that method. The same is of course true of "ordre public": it must be the publication or exploitation of the invention (in this case, the oncomouse or the method of producing it) which is contrary to "ordre public". Indeed, that Article 53(a) EPC is only concerned with the morality of publication or exploitation is confirmed by considering "ordre public". Neither the making of an invention (which by definition must occur in private if there is to be any chance of a patent) nor the process of patenting an invention (conducted within a patent office) can be seen as contrary to "ordre public". Since in Article 53(a) EPC the words "morality" and "ordre public" both stand in the same relationship to the rest of the Article, both must be treated in the same way; and both quite clearly qualify only "publication or exploitation".

4.3 Second, this case is not - contrary to the assertion of appellants 3 to 6 - concerned with "the patenting of animals" or "whether or not animals are patentable under the EPC" (see paragraphs XXVI(1)(2), XXVII(1) and XXVIII(1) above). Such a decision quite simply cannot, as the EPC is currently formulated, ever fall to any of its first instance departments or to the Boards of Appeal. The EPC has a clear set of basic rules as to patentability. First, the fundamental principle is that inventions shall be patentable if they fulfil three criteria - novelty, inventive step and industrial application (Articles 52(1), 54 to 57 EPC). As use of the word "shall" clearly indicates, there is a *prima facie* presumption in favour of patentability. Second, certain categories of

subject-matter (for example, aesthetic creations) are not regarded as inventions at all - these are sometimes called the exclusions (Article 52 (2)(3) EPC). Third, certain other categories of subject-matter, while being acknowledged as capable of being inventions, are denied the protection of patents - these are sometimes called the exceptions (Article 53 EPC).

4.4 The categories of exclusions and exceptions may, depending on one's moral, social or other point of view, appear acceptable or unacceptable, quixotic or outdated, liberal or conservative. There may certainly be scope within the express wording of certain of those categories for interpretation in order to establish the exact boundaries of the categories but, subject to such interpretative scope, the law is clear: there is no excluded or excepted category of "animals in general". The only provisions which relate to patents for or concerning animals are in Article 53 EPC. The second limb of this Article (Article 53(b) EPC) denies patents to "animal varieties" (a term which certainly requires interpretation and to which the Board returns below - see section 11) but which, on even the most rudimentary analysis, cannot mean animals in general. The first limb of the same Article (Article 53(a) EPC) denies patents to inventions the publication or exploitation of which would be contrary to "ordre public" or morality and, subject to interpretation which has largely been supplied already by existing case-law and supplementary legislation, this can be invoked to stop a patent being granted for an invention which causes suffering to animals without some counterbalancing benefit. Those two provisions

apart, animal patent cases are treated in the same way as other cases. This case is therefore not, as appellants 3 to 6 asserted, concerned with the patentability of animals. This case is concerned with whether or not the EPC allows the patentability of the particular animal invention in question and, if so, how broadly that invention may be claimed.

4.5 A third and related matter to make clear is that, again contrary to the assertion of appellants 3 to 6, the position as described in the two preceding paragraphs has prevailed since the EPC entered into force. The respondent cited as an example of a life form case T 320/87 (OJ EPO 1990, 71) and referred to the *travaux préparatoires* to show life form patents had been considered a possibility from the outset of the framing of the EPC. The assertion of appellants 3 to 6 that, until the introduction of Rules 23b to 23e EPC, patenting of animals was not possible is quite simply erroneous. The introduction of those Rules may have been upsetting and/or unhelpful to certain parties (and the Board notes parties on both sides of this dispute argued those Rules should not apply to this case - see section 5 below), but to suggest those Rules changed the EPC from a régime under which animals could not be patented to a régime under which animals might or could be patented is quite simply wrong and those who advance such an argument have misunderstood the relevant legal history.

4.6 A fourth and final point to be made in this section concerns appellant 2's argument that it was not established that the opinion of the four members of the Opposition Division was representative (of, the

Board assumes, European society - see paragraph 10.2 below). The Board agrees with the respondent that the Opposition Division was under no obligation to establish any such thing. The Opposition Division was not required to form its own opinion and then somehow establish that such opinion was representative of a wider group. Quite the contrary, the task of the Opposition Division was to assess whether or not the exploitation of the invention conformed with conventionally-accepted standards of conduct in European society (see T 356/93 OJ EPO 1995, 545, Reasons, paragraph 6). The Opposition Division had to make that decision, as with all decisions between opposing parties, only on the basis of the evidence placed before it by the parties in support of their arguments and with no consideration for personal opinions. Similarly it is the task of the Board to decide, in the light of the evidence before the first instance and any further evidence permitted on appeal, whether the first instance decision made that assessment correctly. The actual opinion or opinions of the members of the Opposition Division (or the Board) are irrelevant.

4.7 In view of the observations in this section the following arguments of the appellants need not be considered further: the argument that Article 53(a) EPC is concerned with the morality of patenting (see paragraph XXIV(4) above); that the Opposition Division decision was not shown to be representative and that Article 53a EPC poses the question, "is there an infringement of morality or not?" (see paragraph XXV(1)(4) above); the whole case made jointly by appellants 3 to 6 as recorded in paragraph XXVI(1) and

(2) above, save as it related to the applicability of Rules 23b to 23e EPC in this case; and the whole case presented individually by appellants 3 and 6 (see paragraphs XXVII and XXIX above). The Board has no doubt that the parties in question genuinely hold the views they expressed; however, as arguments they fall outside the issues in these proceedings.

5. *Applicability of Rules 23b to 23e EPC*

5.1 It is necessary to decide whether Rules 23b to 23e EPC (the "new Rules") apply in this case since if, as the Opposition Division decided, they do apply, they must have an effect on the interpretation of Articles 53(a) and 53(b) EPC. All the submissions on this issue were confined to Rule 23c and 23d EPC, but all of Rules 23b to 23e EPC must be regarded as a "package" since they were promulgated together (by decision of the Administrative Council of 16 June 1999), since they entered into force together (on 1 September 1999, see OJ EPO 1999, 437 *et seq*), since they have a common derivation in EU Directive 98/44, since they form a chapter within the Rules of the EPC, and since they have a common purpose expressed in Rule 23b(1) EPC:

> "For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter."

The Board notes that it is clear from that sentence that the only function of the new Rules is to supply provisions for the application and interpretation of

pre-existing provisions of the EPC. This reinforces views of the Board expressed both above (that the new Rules did not mark an entire change of régime as regards animal patents - see paragraph 4.5) and below (that the new Rules did not create retrospective bars to patentability - see paragraphs 5.9 and 5.10).

5.2 The content of the new Rules would appear to leave no doubt that they should apply to the present case. Rule 23b(1) EPC states the new Rules apply to "patent applications and patents concerning biotechnological inventions". Rule 23b(2) EPC defines "biotechnological inventions" as "inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used". "Biological material" is in turn defined in Rule 23b(3) EPC as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system". There can be no doubt that any animal consists of a material containing genetic information and is capable of reproduction. An animal is therefore a product consisting of biological material in accordance with Rule 23b(2) EPC. The present case thus concerns a biotechnological invention, a conclusion none of the parties challenged. Accordingly, the new Rules must *prima facie* apply to this case unless one of the arguments to the contrary can succeed.

5.3 Of the parties who took part in the appeal proceedings, only appellant 1 agreed that the Opposition Division was correct to apply Rule 23d(d) EPC (the only one of the new Rules to which that appellant referred), although it disagreed with the way it was applied.

Appellant 2 made no mention of the issue. Opponent 3 did not in terms dispute the applicability of the new Rules, however at the oral proceedings it several times used the expression "if Rule 23d applies..." and devoted much of its subsequent argument concerning Article 53(a) EPC to questioning the effect of that Rule. The Board concludes that, if anything, opponent 3 would prefer that the new Rules did not apply in this case.

5.4 Appellants 3 to 6 and the respondent formed an unholy alliance against applicability of the new Rules to this case, albeit their reasons were vastly different. Appellants 3 to 6 saw the new Rules as a fundamental amendment to the EPC to provide, with both retrospective and prospective effect, for the patenting of animals. Those appellants argued that changes of such significance should be made in the EPC itself and not in the Implementing Regulations. Like the respondent they also complained of the delays in the opposition proceedings and, since these appellants considered patenting of animals only became possible as a result of the new Rules and that patenting of animals was only wanted by a very few interest groups including the EPO, they at least inferred that the proceedings were deliberately delayed in order that the new Rules could apply to the present case.

5.5 The respondent's position was more complex, involving two arguments - one in three stages and a simpler alternative (which it called a "*caveat*"). The principal argument proceeded thus - first, the respondent said Rule 23d EPC, by introducing the concept of "substantial medical benefit", made a

previously unpredictable change to the interpretation of Article 53(a) EPC. Second, this change in the law was introduced during a six year delay in the opposition proceedings and thus at a point in time when the proceedings should have been finished. Third, the outcome of the opposition proceedings was as a result unfairly affected by the change - it was thus at least implicitly argued that the new Rules had a retrospective effect. However, the respondent's simpler alternative argument (the so-called *caveat*) was, if Rule 23d EPC merely explained Article 53(a) EPC, that seemed reasonable (from which the Board infers the respondent would accept the application of that Rule, and therefore of all the new Rules, to this case if treated as "explanatory", see point 5.7 below).

5.6 The question of the applicability of the new Rules must be distinguished from, and must be decided before, questions of their interpretation. Moreover, the question of the fairness of applying the new Rules cannot be assessed with regard to their effect, since judging applicability in the light of effect would mean putting interpretation before applicability. Above all, applicability cannot be decided by reference to the effect on a particular party's case: it must be decided objectively and not subjectively. It follows that arguments based on the effect the new Rules (or any one of them such as Rule 23d EPC) have on the case of any one party must be discounted.

5.7 The argument of appellants 3 to 6 that the new Rules changed the law so as to make patenting of animals possible for the first time (a claim which is both startling and startlingly inaccurate) has already been

rejected by the Board (see paragraph 4.5 above). Not only is the argument manifestly wrong as a matter of legal history but accepting it would mean disapplying the new Rules for the subjective reason that they are not in favour of certain parties. Similarly, the respondent's alternative argument (the so-called *caveat*), that Rule 23d EPC may be applicable if merely "explanatory" of Article 53(a) EPC, can only be seen as special pleading. Since the respondent argued strenuously that Rule 23d(d) EPC should be interpreted no more narrowly than the test in T 19/90 (OJ EPO 1990, 476; see paragraph 7.1 below), its alternative argument can only have been intended to mean that it accepted the applicability of Rule 23d if this Rule "explained" Article 53(a) EPC as meaning the same as the T 19/90 test. Put at its simplest, the respondent's alternative argument amounted to saying "I accept the change made by Rule 23d if it makes no change to the law as previously interpreted". Thus, here again, accepting that argument would mean accepting a subjective reason for the applicability of the new Rules based on the effect on a particular party. While the Board may, as regards the issue of applicability of the new Rules, consider pleas of "unfair", it must ignore pleas of "unfair if against me".

5.8 As regards the argument of appellants 3 to 6 that changes of such significance as those made by the new Rules should be made in the EPC itself and not in the Implementing Regulations, the Board can see no legal basis for the proposition, nor did the appellants cite any principle or legal provision to support it. Article 164(2) EPC provides that, in the case of

conflict between the EPC and the Implementing Regulations, the EPC shall prevail. Thus, Article 164(2) EPC might, in the event of such a conflict, affect the application of the new Rules but it does not and cannot affect how changes in the law may be made, namely by amending Articles of the EPC and/or by amending the Implementing Regulations. Further, in the absence of any such provision, the Boards of Appeal have no power within their existing jurisdiction to pronounce upon such matters. The Boards do have jurisdiction *inter alia* to interpret the EPC - whether Articles enacted by the Contracting States in conference or Rules enacted by the Administrative Council - and must have jurisdiction to refuse enforcement of, and to declare invalid, legislation which has been defectively enacted (for example, if passed by an insufficient number of States or Administrative Council delegations), since otherwise parties could be prejudiced by "laws" which in fact do not exist. The Boards also have jurisdiction to give effect to Article 164(2) EPC - to refuse enforcement of a Rule of the Convention which conflicts with an Article. But none of these powers mean that the Boards have any power, express or necessarily implied, to prevent the operation of correctly enacted legislation and, as regards the passage of legislation, the choice between Articles and Implementing Regulations is one exclusively for the legislator.

5.9 This leaves, as possible reasons not to apply the new Rules in this case, only the arguments based on delay. It is beyond doubt that there were quite appalling delays in the opposition proceedings and that all

parties were thereby severely inconvenienced. The Board returns to this below (see section 15). A delayed case is of course more vulnerable to the effects of new legislation, or new case law developments, which arise while it is pending and, since legal certainty is desirable and parties should be able to commence proceedings with the best possible estimation of the outcome, such changes in the law are understandably unwelcome to parties. However, legislators and courts cannot suspend their activities for the duration of even the shortest case, since necessary legislation would thereby be delayed and cases could only be prosecuted one at a time. Thus new legislation normally **does** apply to pending cases unless its non-application is expressly provided for. That principle has a corollary, namely that new legislation normally **does not** apply retrospectively and, in order to safeguard interests based on the former state of the law, an express provision for retrospective effect is necessary before it will be judicially acknowledged. Neither form of express provision was made in the case of the new Rules - there was no saving for pending cases and no provision for retrospective effect.

5.10 Accordingly, appellants 3 to 6 and the respondent were incorrect to describe the effect of the new Rules as retrospective - the new Rules had no effect whatsoever on any concluded proceedings. That they entered into force while this case was pending is beyond doubt true, but it would have been equally true if the opposition proceedings had only been commenced the year before, or even the week before, the new Rules took effect. Since one could not in such cases make an exception by

not applying the new Rules on the grounds of delay, at what point would delay become so great as to allow such an exception? From this it becomes clear, and the Board concludes relatively easily, that the true cause of the parties' complaint should not be the new Rules, which had to be applied without exception to each and every case which might happen to be pending at the time of their introduction, but the delay itself about which the parties were quite right to complain.

5.11 The Board also agrees with the Opposition Division that the principle of legitimate expectations does not apply. When, to safeguard such expectations, a number of cases are to be exempted from a change in the law, that is expressly provided for. For example, on three occasions the Enlarged Board of Appeal, having reversed the previous law or practice has, to avoid unfairness to parties with pending cases commenced in reliance on the old law or practice, made a saving for such cases (G 5/88 OJ EPO 1991, 137; G 5/93 OJ EPO 1994, 447; G 9/93 OJ EPO 1994, 891). The very fact such a step was taken on that limited number of occasions shows, first, that the norm is **not** to exempt pending cases and, second, that such rare exemptions should apply to **all** pending cases.

5.12 To summarise this section, the Board has no hesitation in finding that the new Rules apply to the present case since, as with all changes in the law, the application of the new Rules took effect on the date provided for by the legislator and the opposition proceedings were pending on that date. That they were then still pending after many years is in itself a

legitimate source of complaint but not a reason for exempting this case from the new Rules.

6. *Article 53(a) and Rule 23d(d) EPC*

6.1 Application of the new Rules to the present case means that, as regards Article 53(a)EPC, Rule 23d(d) EPC must be taken into account. The relevant text of that Rule reads:

> "Under Article 53(a) European patents shall not be granted in respect of biotechnological inventions which, **in particular**, concern the following:...
>
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes". *(Emphasis added)*

It follows from the preamble, i.e. from the use of the words "in particular", that the Rule is not intended to provide an exhaustive list of inventions excluded from patentability but that, on the contrary, it is limited to four categories - its effect is simply to ensure that inventions which fall within sub-paragraphs (a), (b), (c) or (d) of Rule 23d EPC must not be granted patents under Article 53(a) EPC. A case not falling within the Rule does not thereby "escape" Article 53(a) EPC: there might well be biotechnological inventions not falling within sub-paragraphs (a) to (d) which, nonetheless, must not be granted patents under Article 53(a) EPC. In short, a case falling within one of the four categories must

ipso facto be denied a patent under Article 53(a) EPC and there is no need to consider that Article further; but, on the contrary, a case not falling within one of those categories must be considered further under Article 53(a) EPC (see section 10 below).

6.2 It is immediately apparent that Rule 23d(d) EPC imposes a test for assessing whether or not processes for genetically modifying animals, or animals produced by such processes, are allowable. The nature of that test is also immediately clear - it is a "balancing test" in which the suffering to animals must be weighed against the medical benefit to man or animal. Moreover it is abundantly clear that this test can only apply in cases where suffering to animals is likely. In other words, a likelihood - but no more than a likelihood - of such suffering is necessary to "trigger" the operation of Rule 23d(d) EPC - it is a *conditio sine qua non*.

6.3 To the extent that there may be some biotechnological inventions which "fail" the Rule 23d(d) EPC test and are thus denied a patent at that point while other such inventions may "pass" that test and therefore have to proceed to an Article 53(a) EPC assessment, appellant 1's argument that there is a "two-stage test" (see paragraph XXIV(5) above) is correct. Whether it is seen as two stages of one test or two tests is relatively unimportant, although the Board tends to the latter view as shown by the distinction in section 10 below between "Rule 23d(d) type" Article 53(a) objections and "real" Article 53(a) objections.

7. *Rule 23d(d) EPC and the Case Law*

7.1 In the decision T 19/90 (OJ EPO 1990, 476, Reasons, paragraph 5), which concerned the present invention during the examination stage of the patent application, it was said:

> "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."

The Board in that appeal was making the important observation that, contrary to the opinion of the Examining Division whose decision was under appeal, Article 53(a) EPC had to be considered in cases such as the present. And, as is immediately apparent, the balancing test in that earlier decision is very similar to that now found in Rule 23d(d) EPC. There is little doubt that the T 19/90 test was adopted, although adapted, by those who framed the Rule 23d(d) test. However, despite the similarity of the two tests, that in T 19/90 balances suffering of animals not against substantial medical benefit to man or animal, but against usefulness to mankind. It is manifestly clear that "usefulness to mankind" may embrace a wider range of benefits than the "substantial medical benefit" found in the Rule 23d(d) EPC test and accordingly the T 19/90 test is broader; and it is also manifestly clear that the reverse is true, namely that if "substantial medical benefit" is

established so as to satisfy Rule 23d(d) EPC, then "usefulness to mankind" is necessarily established.

7.2 The respondent saw this difference between the test in Rule 23d(d) EPC and that put forward in T 19/90 as so inconsistent that it considered the Enlarged Board of Appeal should decide whether, in spite of this difference, the Rule could be considered as a *bona fide* interpretation of Article 53(a) EPC. In the words of the fifth question the respondent sought to refer to the Enlarged Board:

> "Does Rule 23d(d), when referring to "substantial medical benefit", set a test which goes beyond the meaning of Article 53(a) as interpreted without knowledge of this Rule?".

7.3 The respondent's arguments as to this difference (see paragraphs XXXI(3), (5) and (6) above) appear to the Board to be unnecessarily complicated. First, the respondent argued that, unless the matter is clarified by the Enlarged Board, Rule 23d(d) EPC may be *ultra vires.* As the Board observed during the oral proceedings, such use of the term *ultra vires* appears incorrect. An administrative action or rule of subsidiary legislation is *ultra vires* if it falls outside the scope of a law which precludes or limits the legal power of the person or body doing the act or making the rule which is consequently invalid - the term *ultra vires* denotes an *"excès de pouvoir"*. That is quite clearly not the case here. The law in question, Article 53(a) EPC, contains nothing which precludes or limits its own subsequent interpretation whether by case-law (as in T 19/90) or by legislation

(as in Rule 23d EPC). The respondent appears to have argued that the law in question is not simply Article 53(a) EPC but that Article as interpreted in T 19/90. Not only is this a legal impossibility - one cannot combine a legislative provision with case-law interpretation to construct an artificial *vires* by which to judge an action or rule as *ultra vires* - but even if possible it would make no difference since that notional "law" would still contain nothing to preclude or limit subsequent interpretation. *Ultra vires* requires an inconsistency but there is none - Article 53(a) EPC as previously interpreted by T 19/90 remains unaffected by Rule 23d(d) EPC save that, as already indicated (see paragraph 6.1 above), the Rule deems four limited categories of inventions to fall within Article 53(a) EPC. That has been achieved in a perfectly valid - i.e. *intra vires* - manner.

7.4 Second, the respondent said Rule 23d(d) EPC broadens the exclusion in Article 53(a) EPC contrary to the principle of narrow construction of exclusions and thus inventions which might have satisfied the T 19/90 test may now fail the Rule 23d(d) test. In the Board's opinion, it is only correct to say the Rule broadens the Article 53(a) EPC exclusion in as much as the Rule now specifies four limited categories of inventions which are deemed to fall within that Article. However, since it is unimaginable that cases within those four categories would not always have been considered under Article 53(a) EPC, it would be incorrect to say that the new Rule broadens the law as regards the exclusion of such cases. If a case falls within one of the four specific categories, then it must without more be refused a patent; if it does not fall within one of

those categories, it must be considered under the law as it stood prior to the new Rules. That position is no more contrary to any principle than it is *ultra vires*. While the Board agrees that exclusions are generally interpreted narrowly, that does not mean the legislator is prevented from increasing or reducing the number of exclusions or, as in this case, from amending existing exclusions by specifying a certain result if certain conditions are met. As with the manner of legislation (see paragraph 5.8 above), so the scope of legislation is entirely a matter for the legislator.

7.5 Third, and last, the respondent presented a four step argument which can be summarised as follows. First, T 19/90 was the only authoritative pronouncement on Article 53(a) EPC prior to the introduction of Rule 23d(d) EPC - which, if meaning T 19/90 provided the only test or manner of assessment for an Article 53(a) EPC objection, is correct. Second, in G 1/98 (OJ EPO 2000, 111) the new Rules were considered, as regards Article 53(b) EPC, only to offer interpretation - which is also correct. Third, in T 272/95 of 23 October 2002 Board 3.3.4 followed G 1/98 in applying the new Rules to Article 53(a) EPC but in doing so quite simply followed the Enlarged Board decision and, it is at least inferred, made no independent assessment for itself. Fourth, the argument thus concluded, there was no authoritative statement that Rule 23d(d) EPC was consistent with Article 53(a) EPC.

7.6 The Board disagrees both with the argument and the conclusion. While the respondent's first and second

submissions are, as indicated above, correct, the third is not. While it is correct that T 272/95 followed G 1/98 in finding that the new Rules only interpret Article 53 EPC, it is only to be expected that Board 3.3.4 should have followed the approach of the Enlarged Board of Appeal - the function and purpose of Enlarged Board decisions is to give guidance to the Boards and others in matters of law ("to ensure uniform application of the law" - see Article 112(1) EPC). Further, the inference that Board 3.3.4 made no independent assessment is incorrect - paragraph 5 of the Reasons in T 272/95 begins:

> "Having regard to Article 164(2) EPC, the Board has to examine whether or not the new rules insofar as they relate to Article 53(a) EPC are in conformity with this article."

As mentioned above (see paragraph 5.8), Article 164(2) EPC provides that, in the case of conflict between the EPC and the Implementing Regulations, the EPC shall prevail. Thus it is clear that, in T 272/95, Board 3.3.4 posed the question whether the new Rules were consistent with Article 53(a) EPC and, relying as one would only expect on available guidance from the Enlarged Board, found that the new Rules were so consistent. The respondent was therefore quite simply wrong to conclude that there is no authoritative statement in that respect.

7.7 The relationship between Rule 23d(d) EPC and the earlier case law can be summarised as follows. The introductory provision of the new Rules - Rule 23b(1) EPC - states those Rules are interpretative (see

paragraph 5.1 above). The established and authoritative statement of the case law is to the same effect (see the previous paragraph). None of the arguments presented to the contrary are accepted by the Board for the reasons in this section. As regards cases such as the present which fall within Rule 23d(d) EPC, the effect of this interpretation is to insert a test which, depending on the facts and thus on the outcome of the test, may be either additional or alternative to that previously established by the case law.

8. *The point in time for applying the Rule 23d(d) EPC test*

8.1 Both appellant 1 and the respondent agreed that the Rule 23d(d) test should, as with all criteria for the assessment of patentability, be applied as of the effective date (the filing or priority date, as the case may be) of the patent or patent application in question. However, while the respondent also wanted the evidence which could be taken into account to be limited to that available at the effective date, appellant 1 wanted evidence arising after that date to be admissible. Appellant 5 and opponent 3 both considered the appropriate date for such assessment should be the date of decision in these proceedings and made clear their reason was specifically because this would allow evidence arising after, but not directed to, the effective date to be taken into account.

8.2 The Board has no hesitation in concluding that the date of assessment should, as with all criteria for

the assessment of patentability, be the effective date (the filing or priority date, as the case may be) of the patent or patent application. Any later date, as argued for by appellant 5 and opponent 3, would be inconsistent with other areas of patent law and would lead to unjustified differences between otherwise similar cases. Indeed, all the reasons for assessment at the effective date can be summarised as the need for legal certainty - assessment at the filing or priority date means all cases are treated alike whereas assessment at the date of final decision in any proceedings would encourage parties to delay opposition or appeal proceedings in the hope of evidence for or against arising, would encourage late filing of evidence, and could make the outcome of cases dependent on the length of proceedings.

9. *Rule 23d(d) EPC and Evidence*

9.1 The Board makes the following further observations on questions of evidence in an assessment using the Rule 23d(d) EPC test. First, this test requires three matters to be evaluated namely, whether animal suffering is likely; whether likely substantial medical benefit has been established; and whether the suffering and the medical benefit both exist in relation to the use of the same animals. The first two matters follow axiomatically from the wording of Rule 23d(d) EPC and, in the view of the Board, the third matter must also follow since otherwise that Rule could be circumvented. Thus to take a hypothetical example, if likely suffering to both cats and lions was established it would none the less be contrary to Rule 23d(d) EPC to allow claims which

encompassed both cats and lions when the only established likely medical benefit arose in relation to the use of cats. In short, Rule 23d(d) EPC should be applied to ensure that any patent should only extend to those animals whose suffering is balanced by a medical benefit. For convenience, this is referred to below as the necessary correspondence between suffering and benefit.

9.2 Second, in applying the Rule 23d(d) EPC test it is important to resist seeing the two integers of the test as requiring different degrees of proof. The expression "likely to cause suffering without any substantial medical benefit" may appear at first sight to contrast the words "likely" and "substantial" with the result that one seeks to balance mere likelihood of suffering by a medical benefit which, since it must be "substantial", is therefore actual or real - with the result that one looks for proof of the existence of such a benefit at the relevant date. The Board considers this is not in fact the case.

9.3 Opponent 3 observed at the oral proceedings (see paragraph XXX(3) above) that the German text of Rule 23d(d) EPC uses the word "geeignet" which is not the exact equivalent of "likely", being more usually translated as "suitable" or "suited". The Board notes that the French text uses the expression "de nature à", which would usually be translated as "of such a kind as to". Thus the three texts have marginally different words but all three use such words to qualify "processes for modifying the genetic identity of animals" and, as is highlighted by the German text in which the word "cause" ("verursachen") appears after

the words "substantial medical benefit to man or animal" ("wesentlichen medizinischen Nutzen für den Menschen oder das Tier"), it is the entire suffering-without-benefit dialectic which is the object of "likely". Thus there is no difference in the **level** of proof required between animal suffering and substantial medical benefit - the difference is quite simply between, on the one hand, **any** likely suffering by animals however minor and, on the other hand, the likely medical benefit to man or animal which must be **substantial**.

9.4 Third, it follows from the conclusion that only a likelihood of animal suffering need be proved that, in a Rule 23d(d) EPC assessment, the degree of suffering experienced by animals (which appellant 1 and opponent 3 argued should be taken into account) and the availability of non-animal alternatives (which all the appellants, except appellant 2, and opponent 3 argued should be taken into account) do not need to be considered. (This does not mean such matters should be ignored when considering the case under Article 53(a) EPC generally.) As regards animal suffering, the likelihood of any suffering and nothing else is all that must be established to bring Rule 23d(d) EPC into play.

9.5 Fourth, as to the nature of the evidence which may be relied on, this must be confined to evidence as to the relevant matters - namely the likelihood of suffering, the likelihood of substantial medical benefit and the necessary correspondence between the two; and such evidence must be directed to those matters as at the effective date. The appellants, understandably from

their point of view, argued that the evidence should not be confined to that in the patent application since this would inevitably lead to patentees claiming benefits for their invention, appellant 1 observing (see paragraph XXIV(6)(d) above) that an inventor will quite naturally assert that his invention has a value. The respondent, equally understandably, argued that any greater requirement than relying on the evidence in the patent application would allow the use of hindsight and require patent applicants to reduce their inventions to practice before filing which would be a complete departure from previous practice. The Board agrees with the respondent that it cannot be necessary to set a standard which requires reduction to practice before filing, but also agrees with the appellants that evidence cannot be confined to that in existence at the effective date: additional evidence, both for and against the patentee, may be considered subsequently but this must be evidence which demonstrates the state of affairs at the effective date. Such evidence may be open to the objection of hindsight (which, if established, may tell against the party relying in it) but the alternative - to allow only evidence in existence at the effective date - is subject to the greater criticism that only a patentee is likely to have admissible evidence. It must be acknowledged that some information about certain inventions will only emerge after, and on occasions some considerable time after, patent applications have been filed; a good example of how this may happen is given in T 356/93 (OJ EPO 1995, 545, Reasons, paragraph 18.4).

9.6 The Board considers the position in this respect to be analogous to that regarding evidence of sufficiency of disclosure under Article 83 EPC. Just as it is considered necessary for an initial disclosure in a patent application (or priority document) to establish plausibly that the invention disclosed can be performed, so the Board considers a patent application must plausibly establish the likelihood of medical benefit to balance any animal suffering evident from the application. In practice, in Rule 23d(d) EPC cases it will of course be clear beyond doubt from a patent application that, in a case of genetic manipulation of animals, suffering is at least likely even if not expressly mentioned. Further, just as later, post-published evidence may, in relation to sufficiency, be taken into account as confirmation or support for evidence initially produced in the patent application, so the Board considers further evidence may be filed to confirm or support the likelihood of medical benefit. Equally, just as opponents may file evidence in which they attempt to demonstrate insufficiency (for example, by trying and failing to work examples in a patent), so opponents may file evidence seeking to demonstrate that such medical benefit was not likely. However, just as in the case of a sufficiency debate the later, post-published evidence must be focused on the question whether the skilled person would have been able to perform the invention without undue burden at the effective date, so in Rule 23d cases the later, post-published evidence must be directed to the question of the likelihood of medical benefit at the effective date.

9.7 To summarise, the Rule 23d(d) EPC test requires three matters to be established: likely animal suffering, likely substantial medical benefit, and the necessary correspondence between the two in terms of the animals in question. The level of proof is the same for both animal suffering and substantial medical benefit, namely a likelihood. Since only a likelihood of suffering need be shown, other matters such as the degree of suffering or the availability of non-animal alternatives need not be considered. Evidence need not be limited to that available at the filing or priority date but evidence becoming available thereafter must be directed to the position at that date.

10. *Article 53(a) EPC - morality and "ordre public"*

10.1 As stated above (see paragraph 6.1), if a case falls within one of the four categories of exceptions set out in Rule 23d EPC (i.e. if a case concerning the modification of the genetic identity of animals falls within Rule 23d(d) EPC), then it must *ipso facto* be denied a patent under Article 53(a) EPC. However, cases not falling within the limited exclusions of Rule 23d EPC (including cases such as the present if they "pass" the Rule 23d(d) test) must then be considered under Article 53(a) EPC. There are thus in effect two quite different Article 53(a) EPC objections - on the one hand, a "Rule 23d - type" Article 53(a) objection which requires only that the invention is assessed as to whether or not it falls in one of the four limited categories set out in the Rule and, on the other hand, a "real" Article 53(a) objection which requires an assessment as to whether or not exploitation of the invention in question would

be contrary to morality or "ordre public". When making the latter assessment, the case law offers some guidance.

10.2 T 356/93 (OJ EPO 1995, 545, Reasons, paragraphs 5 and 6) supplies working definitions of the concepts of morality and "ordre public" for the purposes of Article 53(a) EPC:

> "5. It is generally accepted that the concept of "ordre public" covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public".
>
> 6. The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality."

Those definitions confirm the view, which appears from the words of Article 53(a) EPC itself, that "ordre public" and morality may form the basis of two separate objections either or both of which can be raised in a particular case (and are both raised in the present case).

10.3 In the course of the present proceedings, objections based on the concept of morality were numerous, varied and also sometimes contrary. Some defined the morality of "animal patenting" (in itself an irrelevant issue - see section 4) on the basis of economic criteria (see paragraph XXIX above), others defined it on the basis of religious creeds (see paragraph XXVII above). It was argued that legislation was a poor guide to morality (see paragraph XXIV(8) above) but also that the Board should take into account that animal protection was enshrined in the constitutions of some European states (see paragraphs XXV(7) and XXVIII(1) above). In the same manner, one should refrain from taking into consideration norms deeply rooted in a particular culture (see paragraph XXV(5) above), yet the Board must not forget the deeply-rooted norm that animals were not akin to inanimate objects (see paragraphs XXVII(1)(2) and XXVIII(1) above).

10.4 If anything, these divergences in points of view pay tribute to the wealth and diversity of human minds. However, they give the Board no help whatsoever in deciding what is the prevailing moral attitude. In fact, it would seem that certain of the appellants themselves appreciated that the beliefs they hold may not enjoy general acceptance since they put forward

the suggestion that morality is what the majority thinks and therefore they relied heavily on opinion polls. The validity of opinion polls as "barometers" of the public perception of morality was discussed in great detail in T 356/93 (OJ EPO 1995, 545, Reasons, paragraph 15), a decision which identified many drawbacks ranging from the type and the number of questions posed within one poll, through the size and representative nature of the cross-section of the population polled, to the manner of interpretation of the results obtained. The Board is in full agreement with the views on opinion poll evidence expressed in that earlier decision.

10.5 The Board considers the only starting point for a "real" Article 53(a) EPC assessment is the test suggested in T 19/90 for the assessment of cases concerning the genetic manipulation of animals (OJ EPO 1990, 476, Reasons, paragraph 5):

> "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."

This test may be employed in different cases using evidence relating to particular times and conditions and thus appears sufficiently flexible to allow for the current (i.e. current at the effective date - see paragraph 10.9 below) views as to social order, environmental risk and accepted standards of behaviour in European culture. In contrast to the test in

Rule 23d(d) EPC, it balances suffering of animals not against likely substantial medical benefit to man or animal, but against usefulness to mankind. It also suggests balancing possible risks to the environment against usefulness to mankind. Thus, it offers a test for use in "ordre public" cases, morality cases and both.

10.6 Most significantly, whereas the Rule 23d(d) EPC test only requires a likelihood of animal suffering (that is, any suffering, however minor) and a likelihood of substantial medical benefit, the T 19/90 test requires a "careful weighing up" of the matters to be balanced. That clearly allows the scope or extent of, on the one hand, the animal suffering and/or environmental risk and, on the other hand, the usefulness to mankind to be considered. Accordingly factors such as the degree of suffering and the possible use of non-animal alternatives can be taken into account.

10.7 Lastly, it is said in T 19/90 that a decision under Article 53(a) EPC would depend "mainly" on the test. This allows for other considerations to be taken into account, either by way of adapting the test - if, for example, other issues than animal suffering or environmental risk were advanced as contrary to "ordre public" or morality - or by way of considering other matters outside the framework of the test. For example, in the present case the arguments under Article 53(a) EPC included an alleged threat to evolution, alleged increased trade in genetically manipulated animals and alleged moral unacceptability of such manipulation (see paragraphs 13.2.10 *et seq* below).

10.8 There is no apparent reason why other such arguments could not be deployed as part of the T 19/90 test. (In passing, the Board observes that in cases other than those concerning genetic manipulation of animals, in which neither the Rule 23d(d) EPC test nor the T 19/90 test would apply, such arguments would form the core of any Article 53(a) EPC objection). Yet, as already established in T 356/93, these arguments like all arguments must be substantiated.

10.9 For the same reasons of certainty as given in relation to Rule 23d objections, the time as of which a "real" Article 53(a) EPC assessment is to be made must be the effective date (filing or priority date) of the patent or application in suit although later evidence may also be taken into account provided it is directed to the position as at the effective date (see paragraphs 8.2 and 9.5 to 9.6 above). However, the Board adds for completeness that the nature and extent of the evidence required for a Rule 23d(d) EPC objection will probably be quite different from that required for a "real" Article 53(a) EPC objection. Whereas Rule 23d(d) EPC only requires evidence of the likelihood of animal suffering and the likelihood of substantial medical benefit, other factors may be taken into account under Article 53(a) EPC (see paragraphs 10.6 to 10.8 above), i.e. the relevant evidence may be both greater in volume and more varied in nature.

10.10 To summarise the assessment of a "real" Article 53(a) EPC objection, decision T 356/93 supplies working definitions of morality and "ordre public". The many bases (economic, religious, etc) for definitions of morality suggested by the appellants are of no

assistance since no single such basis represents an accepted standard in European culture. Opinion poll evidence is of very limited value for the reasons given in T 356/93. 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 for matters other than animal suffering and medical benefit to be taken into account. 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, like any other argument, must be supported by evidence. 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 the effective date.

11. *Article 53(b) EPC*

11.1 Article 53(b) EPC explicitly excludes from patentability "plant or animal varieties or essentially biological processes for the production of plants or animals" with the proviso that "this provision does not apply to microbiological processes or the products thereof" - a proviso which is not relevant here (see Rule 23b(6) EPC and T 356/93 OJ EPO 1995, 545, Reasons paragraphs 33 to 39). Unlike Article 53(a) EPC, the exclusion is simply a denial of patents to the specified subject-matter *per se*, and not to inventions covering such subject-matter whose publication or exploitation must be measured by a moral or other standard. Thus an Article 53(b) EPC objection appears initially straightforward - it

requires only a decision as to the meaning of the exclusion and an assessment whether or not the patent or application objected to contains plant or animal subject-matter within that meaning. However, in a case concerning animals, ascertaining the exact meaning of Article 53(b) EPC is not straightforward due in particular to differences of language.

11.2 In the German and French texts of Article 53(b) EPC, the words used in place of "plant or animal varieties" are respectively "Pflanzensorten oder Tier**arten**" (i.e. plant varieties or animal species) and "les variétés végétales et les races animales" (i.e. plant varieties and animal races). Thus, as regards animals, three different terms are used in the three official languages: "varieties", "species" and "races". Rule 23c EPC, which specifies that certain biotechnological inventions shall be patentable, includes in Rule 23c(b) EPC (in the English language text) "plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety". While this narrows the application of Article 53(b) EPC to inventions confined to one particular plant or animal variety, the language problem is perpetuated because, in the German and French texts of the Rule, the words used in place of "plant or animal variety" are respectively "Pflanzensorte oder Tier**rasse**" and "une variété végétale ou une race animale" (i.e. in both languages, plant variety and animal race). Thus there is not only an inconsistency between the terms used in the three languages in Article 53(b) EPC and a similar inconsistency in Rule 23c(b) EPC, but also the further complication that, by use of "Tier**arten**" (species) and

"Tier**rasse**" (race), the two inconsistencies are themselves inconsistent!

11.3 All the parties who pursued Article 53(b) EPC objections in the appeal proceedings (appellants 3 to 6 and opponent 3) took a robust approach to the question whether Article 53(b) EPC is limited to an animal "variety" or "species" or "race". They simply used the term "species", no doubt because of the three alternatives that is the term with the widest meaning (see paragraph 11.6 below), thus giving Article 53(b) EPC the widest possible exclusionary effect. The respondent argued that, just as the decision of the Enlarged Board of Appeal in relation to plants in G 1/98 (OJ EPO 2000, 111) would allow claims which encompass several plant varieties but not a claim to a specific variety, so the same "generic approach" should be allowed in the case of animals. However, the respondent made no attempt to select "variety" or "species" or "race" but simply observed that the oncomouse was at least two taxonomic categories above the broadest of those three terms, namely "species".

11.4 The Board agrees with the respondent that the principle enunciated in the decision of the Enlarged Board of Appeal G 1/98 concerning plants and "plant varieties" should be followed in the case of animals. In that decision, the Enlarged Board of Appeal stated, in paragraph 3.10 of the Reasons, that:

> "In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within

> the meaning of Article 53(b) EPC. This is why it is, contrary to the conclusions of the referring Board, in agreement with the rules of logic that a patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of its claims".

However as indicated above, the difficulty which exists in the case of animals, but which the Enlarged Board did not encounter in the case of plants, is that there is no single term relating to animals in the EPC such as the term "plant variety". Not only is the exactly equivalent term for "plant varieties" used in all three language texts of the EPC, but in G 1/98 the Enlarged Board also had the benefit of earlier case-law of the Boards of Appeal, Article 2(2) of the UPOV Convention 1961 and Rule 23b(4) EPC to provide a clear definition of that term (namely, "any plant grouping within a single botanical taxon of the lowest known rank" which fulfils certain conditions specified in Rule 23b(4)(a) to (c) EPC).

11.5 While neither the jurisprudence of the Boards nor Rule 23b EPC (which is concerned with interpretation of the EPC as regards biotechnological inventions) provides a corresponding definition for "animal varieties" (or "species" or "races"), the Board considers that a definition by reference to taxonomical rank would be both consistent with the position in relation to plant varieties and in the interest of legal certainty. With such a definition, an assessment could be made as to whether the claimed subject-matter is excluded from patentability under Article 53(b) EPC as interpreted by Rule 23c(b) EPC -

i.e. whether, in a case concerning animals, the technical feasibility of the invention is not confined to a particular animal variety (however "variety" or its alternative French and German terms might be defined).

11.6 Although as already indicated the parties offered no evidence in this respect, taxonomic definitions exist for all three terms. Thus a dictionary definition of "animal variety" is:

> "any of various groups of animals ranking below a *species (subspecies)*";

and "animal race" is defined as:

> "an actually or potentially interbreeding group within a *species*; also a taxonomic category (as a *subspecies*) representing such a group".

Therefore, in the taxonomic hierarchy, both "variety" and "race" clearly appear below the category of "species". That category is in turn defined as:

> "a category of biological classification ranking immediately below the *genus or subgenus*, comprising related organisms or populations potentially capable of interbreeding, and being designated by a binomial that consists of the name of a genus followed by a Latin or latinized uncapitalized noun or adjective agreeing grammatically with the genus name".

Thus, examples of species include *Mus musculus (M. musculus), M. abbottii,* and *M. caroli*; and *M. musculus*, for instance, is further subdivided into sub-species such as *M. musculus domesticus* and *M. musculus bractianus*. "Genus" itself is defined as:

> "a category of biological classification ranking between the family and the species, comprising structurally or phylogenetically related species or an isolated species exhibiting unusual differentiation, and being designated by a Latin or latinized capitalized singular noun"

An example of a genus would thus be *Mus* (Mice). (All the definitions in this paragraph are from the "Merriam-Webster OnLine Dictionary" with italics in those definitions added by the Board.)

11.7 According to Article 177(1) EPC, the three texts of the Convention, i.e. in the English, French and German languages, are equally authentic. However, as just demonstrated, the three different terms used in each of the three official languages 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 term "species" ("Tierarten"), being of the highest taxonomic order and thereby offering the widest objection. While this uncertainty is clearly undesirable, it is unnecessary for the reasons appearing below (see paragraphs 13.3.1 to 13.3.5) to pursue this matter further in the present case. As the respondent argued (in relation to the first auxiliary

request - the first request to bring Article 53(b) EPC into play - although the same would have been true of the main request if it had not been disposed of for other reasons), and as the Board agrees, the patent clearly concerns a taxonomic category of animals higher than "species" which represents the widest definition which could be given to the animal exclusion in Article 53(b) EPC.

11.8 To summarise the Board's views regarding Article 53(b) EPC, the principle adopted in G 1/98 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 even if varieties may fall within the scope of its claims. 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, in a case concerning animals, the technical feasibility of the invention is not confined to a particular animal variety (or species or race). However, the different terms used in each official language 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.

12. *Main Request*

The respondent's main request, filed during the oral proceedings, contained the same claims as those upheld by the Opposition Division but without the claims to chromosomes and cells. Thus the independent claims of this request read as follows:

> "1. A method for producing a transgenic rodent having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a rodent.
>
> 19. A transgenic rodent whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10."

12.1 *Article 52 EPC*

12.1.1 Article 52(1) EPC states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. The technical character of an invention is emphasized in Rule 27(1)(a) and (c) EPC. In accordance with the case law, a subject-matter is to be regarded as an invention if it has a technical character i.e. if it provides a technical contribution to the art (see "Case law of the Boards

of Appeal of the European Patent Office", 4th Edition 2001, page 1).

12.1.2 The claimed method pertains to the field of genetic engineering and the transgenic animals produced by that method may be used as appropriate models for studying different aspects of cancer, such as the development of tissue-specific tumours and the effect of suspected carcinogens (see paragraph 13.2.2 below). They represent technical tools just as other means - such as bacterial tests and culture cell lines - are also technical tools. Thus, both the claimed method and the transgenic animals directly derived therefrom have a technical character. Similarly, the technical feature characterising these transgenic animals - the presence of an activated oncogene which confers an increased probability of developing neoplasm - is also found in their offspring. Therefore, this progeny would also be used as an appropriate technical tool. Thus, the subject-matter of claims 1 and 19 is an invention within the meaning of Article 52 EPC.

12.2 *Article 53(a) EPC*

The Rule 23d(d) EPC test

12.2.1 It is beyond doubt that the subject-matter of the patent in suit concerns a process for modifying the genetic identity of animals and thus Rule 23d(d) EPC must be considered. Further, it was not in dispute - indeed it was agreed by the parties - that the process is likely to cause those animals suffering. As the request embraces all animals within the taxonomic order *Rodentia*, suffering will - and must - be present

in the case of every such animal - not just mice but also squirrels, beavers, porcupines and every other rodent. In any event, no other conclusion would be possible in respect of a request in which claim 1 causes the rodents of claim 19 to have "an increased probability of developing neoplasms": in other words causes an abnormal - benign or cancerous - tissue growth which results in the animals suffering and eventually in their death. Animal suffering is not just a likelihood but an inevitable consequence of the very purpose of the patent.

12.2.2 The two questions which thus arise are first, whether there is also a likelihood of a substantial medical benefit to man or animal and second, whether that benefit is obtained in the case of all the animals which are likely to suffer i.e. whether there is the necessary correspondence between likely suffering and likely benefit (see paragraph 9.1 above).

12.2.3 There is no evidence on file, either in the patent itself or elsewhere, that any such benefit, let alone a substantial medical benefit, is likely to be derived from applying the claimed process to all rodents, or indeed to any animals of the order *Rodentia* apart from mice. The necessary correspondence, in terms of the animals in question, between the likely suffering and the likely benefit is absent. The respondent has referred to the advantageous provision of several model systems for studying cancer without being restricted to the limited physiology, metabolism, etc. of mice. However, there is quite simply no evidence to show that all the various animals in the category of rodents are so different that each of them would

provide a contribution to cancer studies, such as being specifically suited as a model for studying a specific type of cancer. Thus the respondent's argument appears to be no more than argument - it is purely hypothetical and unsubstantiated by any evidence. Therefore, the Board concludes that the likelihood of substantial medical benefit required by Rule 23d(d) EPC has not been satisfied for rodents.

12.2.4 Accordingly, the main request discloses a likelihood of animal suffering but not a likelihood of medical benefit in the case of all animals embraced by the claims. Consequently, the main request fails the balancing test of Rule 23d(d) EPC and must therefore be refused under Article 53(a) EPC. The main request is accordingly not allowable.

The T 19/90 test

12.2.5 Before proceeding to the first auxiliary request, the Board would add a further observation. As announced during the oral proceedings, the Board considers the same conclusion as regards the main request would have been reached in the framework of a "real" Article 53(a) EPC assessment (see section 10 above). In that event, the test in T 19/90 (OJ EPO 1990, 476, Reasons, paragraph 5) would apply to the main request. As observed above (see paragraph 7.1), "usefulness to mankind" can include medical benefit so the matters to be weighed against each other would essentially be the same in both tests. That more than a likelihood of suffering or usefulness may be considered in applying the T 19/90 test would make no difference since the parties agreed animals would suffer. Taking into

account other matters, such as the degree of animal suffering and the availability of alternative non-animal methods, would (assuming such other matters were established on the evidence) merely tilt the balance further against acceptance of the request.

13. *First auxiliary request*

The respondent's first auxiliary request contained independent claims corresponding to those of the main request but in which references to "rodent" had been replaced by references to "mouse". The independent claims of this request thus read as follows:

> "1. A method for producing a transgenic mouse having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a mouse.
>
> 19. A transgenic mouse whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10."

13.1 *Article 52 EPC*

None of the appellants raised an objection against the specific subject-matter of this request under Article 52 EPC. In the Board's judgment, the conclusion reached for the subject-matter of the main

request that it is an invention within the meaning in Article 52 EPC also applies to this request for the same reasons as given in paragraph 12.1.2.

13.2 *Article 53(a) EPC.*

The Rule 23d(d) test

13.2.1 Under Article 53(a) EPC the first auxiliary request must first be assessed according to the "balancing test" in Rule 23d(d) EPC. As regards the likelihood of animal suffering, there is evidence in the patent itself showing that the specific oncomice produced by the method of the opposed patent develop specific neoplasms and that they have been used for testing compounds suspected of being carcinogens or else suspected of conferring protection against the development of these neoplasms (see page 10, lines 15 to 31). There is thus not just a likelihood but a certainty of animal suffering. Moreover, as already observed in respect of the main request, the parties agreed that any animals resulting from the method of the patent would suffer and this must include mice.

13.2.2 As regards the likelihood of substantial medical benefit, this can at the very least be inferred from the patent itself: the purpose of both the claimed method and the oncomice thereby produced and used for test purposes is to further cancer research. Additionally there is evidence on file, in the form of declarations and post-published documents, demonstrating actual medical benefits achieved using mice such as those obtained by the claimed process. For example, it is stated in document (81) that "the

oncomouse may be the closest we can get to a human situation" and that "key genetic pathways controlling mammary gland development (and as an extension cancer) are conserved between mouse and man, and thus the mouse serves as the best approximation." Document (82), a declaration commenting on how oncogenic non-human mammals are of utility and of benefit in scientific and medical research, cites a number of scientific papers (attached as exhibits) reporting such benefits obtained with oncomice. In 1995, the oncomouse was reported as a useful model for *in vivo* imaging and preclinical screening of breast tumour imaging agents (document (A3)). In 1996, oncomice were used to show how ethanol and cocaine have tumorigenic effect and implicate a specific oncogene product in the deregulation of the immune system (document (A4)). A short-term combination therapy of IL2 and Type 5 adenovirus vectors expressing murin angiostatin was evaluated in an oncomouse model in 2001 demonstrating for the first time a delay and regression in tumour growth (document (A2)). The successful vaccination of oncogenic mice against mammary tumour development by using a DNA vaccine was also described (document (A1)).

13.2.3 As regards the need for correspondence between suffering and benefit (see paragraph 9.1 above), all the animals within the genus "*Mus*" are closely related to each other in most relevant biological aspects and this makes it credible that any member of the genus could be used as a model system for cancer studies in a manner similar to that taught in the patent using particular mouse examples. There can be no doubt that the consequence of using the claimed method - incorporation of an activated oncogene into the animal

chromosome - or the use made of any such mice, would result in suffering while at the same time offering the prospect of a contribution to medical research.

13.2.4 Accordingly, the Board considers that the subject-matter of claims 1 and 19 of the first auxiliary request "passes" the test in Rule 23d(d) EPC and thus does not fall within the category of inventions for which patents shall not be granted under that Rule. The request must therefore be assessed under Article 53(a) EPC without reference to that Rule: in other words, a "real" Article 53(a) EPC objection arises (see paragraph 10.1 above).

The T 19/90 test

13.2.5 The limitation of the auxiliary request to "mouse" also produces a different result in the application of the test in T 19/90 test (OJ EPO 1990, 476, Reasons, paragraph 5). Applying this test, on one side of the balance it is again agreed between the parties that the patented method causes actual suffering to the mice used. On the other side of the balance, actual medical benefit has been demonstrated (see paragraph 13.2.2 above) and this benefit is clearly of use to mankind. Unlike the main request, no suffering is envisaged to any animals without a corresponding prospect of benefit. Thus far, assessment under the T 19/90 test leads to the same result as under the Rule 23d(d) EPC test. However, the T 19/90 test permits other considerations to be taken into account as mentioned above (see paragraphs 10.6 to 10.8). In the present case two such other considerations were raised in argument by the appellants and opponent 3 -

the degree of animal suffering and the possibility of using non-animal alternatives to achieve the same aims as the patent in suit.

13.2.6 No evidence of the degree (as opposed to the existence) of animal suffering, an argument advanced by appellant 1 and opponent 3, was produced, which the Board finds wholly unsurprising. To suggest that the degree of suffering could be material is to suggest the possibility of a distinction between "acceptable suffering" and "unacceptable suffering". In the Board's opinion this is not a distinction which the parties in question really wished to evoke and it is certainly not a distinction which would assist in deciding this or similar cases. Those observations are sufficient to show how it would be not only distasteful but effectively impossible for the Board (or any other decision-making instance) to make findings as to degrees of suffering. Both Rule 23d(d) EPC and T 19/90 refer to "suffering" and not "degree of suffering"; in the view of the Board, this reflects the only possible approach - **any** animal suffering is sufficient to bring Article 53(a) EPC into play and requires a balancing benefit. Accordingly, the degree of animal suffering argument is of no assistance in making the T 19/90 test and, if anything, the unhappy distinction it suggests detracts from the case of those making the argument.

13.2.7 As regards non-animal alternatives, appellants 1 and 3 to 6 and opponent 3 all argued that these should be taken into account. The most pertinent of the alternatives mentioned was cell cultures but no evidence was filed showing any advantage over, or even

equality of benefit with, the method of the patent. The respondent rebutted these arguments by observing that only an animal offers the opportunity to use an entire organism including for example the immune system. The respondent also filed a declaration explaining why oncomice provided advantages over cell cultures (document (81), paragraphs 3 and 4). Thus, if this alternative is added to the matters to be weighed up in the T 19/90 test, the result will be, on the available evidence, to tilt the balance away from the appellants and in favour of the respondent.

13.2.8 The same result is reached when applying the T 19/90 test to balance environmental risks against usefulness to mankind. In this case, the same factors are considered except that the agreed suffering to animals is replaced by possible threats to the environment if oncomice were to escape (or to be released, deliberately or accidentally) into the wild. As is only to be expected of a danger yet to materialise, there was no evidence to support such environmental arguments which played very little part in the appeal proceedings. The environmental arguments are thus if anything weaker in this case than in T 356/93 (OJ EPO 1995, 545, Reasons, paragraphs 18 to 19) in which, as regards similar arguments relating to the alleged risks of "escape" of genetically modified plants, Board 3.3.4 considered a threat to the environment could be grounds for an Article 53(a) EPC objection but that, on the evidence before it, such a threat had not been established. In paragraph 18.6 of the Reasons that Board said:

> "In the present case, no conclusive evidence has been presented by the appellants showing that the exploitation of the claimed subject-matter is likely to seriously prejudice the environment. In fact, most of the appellants' arguments are based on the possibility that some undesired, destructive events (e.g. the transformation of crops into weeds, spreading of the herbicide-resistance gene to other plants, damage to the ecosystem) might occur. Of course, such events may occur to some extent. This fact has even been admitted by the respondents. However, in the board's judgment, the documentary evidence submitted on this subject is not sufficient to substantiate the existence of a threat to the environment such as to represent a bar to patentability under Article 53(a) EPC."

By comparison, the environmental case of those opposed to the patent in suit is considerably weaker.

13.2.9 The Board considers the environmental issues are at the utmost of neutral effect on the case. While a risk of release or escape exists, just as there is such a risk with zoo or circus animals, the risk can only be regarded as minimally more than hypothetical when one considers the secure conditions under which laboratory mice are kept and the level of regulation of the use and keeping of animals for experimental purposes in most countries. Further, in the event of release or escape, it must be questionable whether oncomice would cause any damage, let alone any lasting damage, to the environment. The only perceivable threat is that, by mating with mice already in the wild, the oncogene

would be spread. Against that, there must be the possibility that, because of their manipulated state, oncomice would not survive as long in the wild as non-manipulated mice.

Article 53(a) EPC - Other considerations

13.2.10 Accordingly, for the reasons in the previous five paragraphs, the first auxiliary request "passes" the T 19/90 test. It remains to be considered, under Article 53(a) EPC, whether any other arguments advanced by the appellants or opponent 3 are sufficient to establish that publication or exploitation of the invention as claimed in that request would be contrary to "ordre public" or morality. Those remaining arguments are in summary:

(a) that oncomice pose a threat to evolution;

(b) that the patent will promote an increase in the number of transgenic mice used in cancer research and, more generally, encourage trade in animals;

(c) that the use of genetically manipulated animals (in this case, mice) in medical research is morally unacceptable to the public.

These arguments will be considered in the following paragraphs. The Board observes these all appear to be morality objections, as none of them suggest anything contrary to "ordre public".

13.2.11 As regards the alleged threat to evolution, there was again - and unsurprisingly - no evidence. It is

therefore purely a question of argument. There are some developments in the course of evolution which are generally regarded by mankind as regrettable, such as the extinction of certain animals; and others, such as the eradication of the causative agent of smallpox, which are considered as having been indisputably beneficial to mankind. The furtherance of medical research with a view to curing or reducing or eliminating illness and disease can, in general terms, only be regarded as morally correct. As the respondent rightly observed at the oral proceedings, to want to cure cancer is thoroughly moral. The only real question therefore within this evolution argument is whether it is moral to use mice to this end and that is addressed in paragraphs 13.2.13 to 13.2.21 below.

13.2.12 As mentioned above, other arguments ranged from a fear of increased use of transgenic mice in cancer research to increased trade in animals generally. Such arguments come close to if not in fact within the area of irrelevant issues (see section 4 above). It must be remembered that it is the morality of exploitation of the oncomouse invention, and not the morality of animal patents, which is in issue. Thus it appears to the Board that these arguments amount to no more than the suggestion that allowing a patent will increase the use of modified mice. The Board cannot agree with that proposition (a proposition being, in the absence of evidence, all that the argument amounts to). Since a patent grants a temporary monopoly, only a patentee and its licensees can work the patent during its life - in the case of a European and most other patents twenty years. Since unfettered competition is usually considered to lead to increased economic activity,

such a monopoly period may actually mean that the use of modified mice is for an initial period lower than it would otherwise be. For what it is worth, the respondent's statement in argument at the oral proceedings (almost amounting to an admission against interest) that the present invention had been "remarkably unprofitable" (see paragraph XXXI(21) above) must be considered as substantially negating the wholly unsupported arguments of the appellants: if the patent really had increased trade in transgenic animals, one would have expected the holder of a monopoly for certain such animals to have done better than the respondent says.

13.2.13 Finally, the Board will now consider the further material regarding public attitudes at the priority date. Strictly speaking only the evidence relating to the present invention should be reviewed yet, as the respondent correctly observed (paragraph XXXI(11) above), no such evidence was produced. Thus the best the Board can do is to consider the arguments presented as to the public's perception of the genetic manipulation of animals in general. In this connection the material either filed as evidence or brought to the Board's attention as part of various parties' arguments included, in the case of the appellants: public unease; the outcome of the corresponding Canadian proceedings; references to animals in European treaties, EU and national legislation on the experimental use of animals, and statements and resolutions of various bodies including churches and national and EU parliaments; and opinion polls; and, in the case of the respondent, the accepted use of animals in medical research.

13.2.14 However, before considering this material, the Board wants to emphasize once more (see paragraph 10.8) that, as with all arguments, public perception arguments under Article 53(a) EPC must be substantiated by evidence. While the Board does not for one moment consider that any party sought by not producing evidence to be misleading, it is not sufficient proof of a fact simply to allege that fact in written or oral argument. To take but one example, that the proposed European Constitution provides for animal protection may easily be proved by filing a copy of the proposed constitution. Similarly, it is the generally accepted procedure, in most European countries (cf. Article 125 EPC) and beyond, that laws of other jurisdictions than the one before which proceedings are pending must be proved as a matter of evidence, for example by filing as documents copies (in translation if necessary) of such laws and/or as appropriate by filing as expert evidence the opinions of lawyers in the relevant jurisdictions. While the Board could have ignored all unsupported allegations (not least because it expressly invited the parties to produce evidence - see paragraph XI(2) above), it has where possible given them such weight as it can - in part because, even in the absence of evidence, the matters alleged may be well-known and/or easily checked, and in part because the respondent, while commenting on the overall shortage of direct evidence from the appellants, answered all their arguments including those based on unsupported allegations.

13.2.15 Appellant 1 argued that animal patents arouse "public unease" such as that in the United States noted in

T 19/90 (OJ EPO 1990, 476, Facts, paragraph II) and reflected in the corresponding Canadian decision. The relevant passage in T 19/90 which the appellant refers to reads:

> "... (c) The Division also felt that it should consider Article 53(a) EPC, which excluded patents for inventions whose publication or exploitation would be contrary to "ordre public" or morality; **in the United States, for example, the patenting of higher organisms had encountered severe criticism for ethical reasons**." *(Emphasis added)*

It is in fact no more than a mention by the earlier Board of an observation made by the Examining Division in the decision then under appeal. As a statement, it appears to the Board to be nothing more than an extremely general truism with which even the respondent would agree (see its reply of 2 April 2004, paragraph 13) and which would have no more impact on the case even if it could be demonstrated as referring to European, and not United States, opinion as at the effective date of 22 June 1984, and not late 1990.

13.2.16 The Board has obtained and considered the decision of the Supreme Court of Canada in the corresponding case in that jurisdiction. As appellant 1 mentioned, and as the respondent observed, the decision turned on the meaning of terms present in the Canadian patent legislation but not in the EPC. After three previous appeals following the examiner's decision, the Supreme Court finally decided that the terms "manufacture" and "composition of matter" excluded higher life forms. In summary, not only did this decision arise in a non-

European country, not only did it concern legislative terms which do not exist in the patent law of the EPC, not only were the views of the Supreme Court expressed in 2002, but the decision quite clearly does **not** establish that animal patents arouse public unease.

13.2.17 Very little evidence was provided in support of the arguments based on treaties, legislation, political and religious beliefs, to the effect that animals should be protected and animal patenting should be forbidden. However, even in the absence of all but a small volume of evidence (most notably documents (28) and (29), proposed resolutions of the European Parliament of 8 and 10 February 1993), the Board can readily accept that care and concern for the well-being of animals is an accepted tenet of European culture and was also such a tenet at the priority date of the patent in suit.

13.2.18 Against this it must also be noted that appellant 1 also referred to EC Directives 86/609 and 98/44 and to the licensing system in the United Kingdom for the use of animals in research. In doing so appellant 1 was apparently seeking to show that, in keeping with the concern for animal well-being referred to in the previous paragraph, the use of animals for experimental medical research is strictly controlled. However, the existence of these Directives and national legislation also supports the respondent's observation that the use of animals in medical and scientific research, albeit under strict controls in the measures referred to by appellant 1, is also an established feature of European culture. The Board agrees and thus finds that not just animal welfare but

also the use of animals for research and testing is established in European culture and was so established at the priority date of the patent.

13.2.19 The remaining category of evidence put forward by the appellants (principally appellants 1 and 2) was opinion polls. In paragraph 10.4 above, the Board has already expressed the opinion that, like Board 3.3.4 in T 356/93 (OJ EPO 1995, 545), it does not consider opinion pol9ls as reliable tools for assessing public perception. The respondent's objection that in order to answer poll questions meaningfully those questioned would need a certain level of education in several fields (see paragraph XXXI(17) above) is to much the same effect. Appellant 1 refers to a UK poll, which it commissioned itself, conducted in 1998, and to a Europe-wide poll on biotechnology of 16,000 persons in 1996. Appellant 2 refers to one poll of 500 persons in Germany in 1993. No information was put forward about the methodology of such polls - for example, whether they were conducted by trained professional pollsters or by casual staff recruited for the particular poll in question; whether the respondents were stopped on street corners and answered questions in a hurry or were invited into comfortable premises and given time to think; whether they were volunteers or were paid for participating; what other questions they were asked as well as those specifically relied on in these proceedings - if a previous question might provoke moral outrage, that could carry over to the question relied on; whether the questions they were asked were "open" - such as, "What is your opinion about genetic manipulation of animals?", a question which allows a variety of responses - or "closed" - such as "Do you

consider genetic manipulation of animals acceptable?", a question which allows only one of two responses; and how the results were analysed, for example how "don't know" responses were treated.

13.2.20 With those reservations, the Board has considered what can be extracted from the information it has been given about the three polls relied on.

(a) Appellant 1's own poll conducted in the United Kingdom in 1998 (sample size and composition unknown, number of questions asked unspecified) found 82% of those questioned were opposed to animal patenting and concludes those persons "must, by definition, have been opposed to patenting the oncomouse" (see appellant 1' grounds of appeal, paragraph 36(f)). However, it is exploitation of the oncomouse invention, and not the patenting of animals in general which is the issue in the present case (see paragraphs 4.3 and 4.4 above). Thus, Appellant 1's conclusion cannot be correct inasmuch as those who were asked could not have known of the use envisaged for the oncomouse. At most, this poll shows there might at that date have been some public reluctance in one large European country to endorse the exploitation of the present invention.

(b) Appellant 1 also relied on a Europe-wide poll of 16,000 persons conducted by the European Union in 1996. This was apparently restricted to matters of biotechnology. In answer to the question "Do you think it is morally acceptable for society to develop genetically modified animals for

laboratory research studies, such as a mouse that has genes which cause it to develop cancer?", appellant 1 says 47.8% (i.e. 7,648 persons) thought it was unacceptable and 41.2% (i.e. 6,592 persons) thought it was acceptable. This question is manifestly directed to the present invention, so the answer must be carefully evaluated. The first observation is that the number of persons whose views are not known (11% or 1,760 persons) is greater than the difference between those who are reported as expressing a view for or against (6.6% or 1,056 persons). The second observation is that, apart from any other questions in the poll not mentioned by appellant 1, the value of the question was undermined by its nature: it is a "double question", incorporating both the general and the particular. If the poll had first asked "Do you think it is morally acceptable for society to develop genetically modified animals for laboratory research studies?" and then, as the next question, to have asked "Do you think it is morally acceptable for society to develop a mouse that has genes which cause it to develop cancer?", the value of the second question would have been extremely limited. However, to have combined the two questions in one makes the response of those polled to the specific issue of a genetically modified mouse so loaded as to be virtually meaningless.

(c) Appellant 2 refers to a poll of 500 persons conducted in Germany in 1993 in which 70% said they considered the patenting of genetically manipulated animals for cancer research to be

morally reprehensible. Thus, all that his poll establishes is that **350** persons in **the largest** European country disapproved of genetic manipulation of animals for cancer research in 1993 - that is sufficient to show it has no evidential value in the present case.

13.2.21 Having thus considered all the "public perception" arguments, with or without evidence to support them, the only conclusion the Board can make is that in current European culture, and thus (in the absence of evidence to the contrary) in such culture at the priority date of the patent in suit, animals are on the one hand respected as sentient beings which are not to be gratuitously abused or misused (see paragraph 13.2.17 above); and, on the other hand, animals are accepted as being important in the testing of medicaments and curative methods prior to human application (see paragraph 13.2.18 above). One result of this dichotomy is, to use appellant 1's expression, the "unease" which may arise in relation to patents involving animals as to which both appellant 1 and the respondent agreed (see paragraphs XXIV(2) and XXXI(16) above). However, there is nothing before the Board to suggest that such unease could be elevated to the status of moral disapproval in European culture of the use of animals for medical research, let alone moral disapproval of the use of mice in cancer research - i.e. moral disapproval of the exploitation of the present invention. Accordingly, Article 53(a) EPC does not constitute a bar to patentability of the subject-matter of the first auxiliary request.

13.3 *Article 53(b) EPC*

13.3.1 It follows from the Board's observations (see section 11 above) that an Article 53(b) EPC objection will only succeed in excluding the present auxiliary request from patentability if one or more claims of the request are to a taxonomic category at least as narrow as an "animal species" - the broadest of the three taxonomic categories excluded in the three language texts of the Article 53(b) EPC. Appellants 3 to 6 and opponent 3 all asserted that the transgenic mice of the patent were a new species. In the case of opponent 3, this was because the mice inherited one particular characteristic, namely an increased probability of developing tumours. In the Board's opinion, this cannot be enough to create a new species when the possible "starting material" in accordance with the claims may originate from a whole genus of animals, namely from all mice. If opponent 3 was correct, one could perform the claimed method of the patent upon, for example, three different species of mice which would as a result all become members of one new species. However opponent 3 produced no evidence that the alleged new species would be seen or accepted as such by anyone, let alone by any expert in fields which require classification of animals such as biology or zoology.

13.3.2 Appellants 3 to 6 also produced no evidence to support their use of the term "species". They argued that species were mere abstract concepts and the intention of the law was to exclude all animals falling within any species. The Board rejects this argument - however Article 53(b) EPC may be defined, it is clear it only

excludes a limited category of animals and not all animals (as already observed - see paragraph 4.4). The Board's view is supported by the decision of the Enlarged Board in G 1/98 (OJ EPO 2000, 111) in relation to plants with which Article 53(b) EPC is also concerned. The same appellants also argued that, if the legislator had wished to allow patents for new species of plants or animals it would have said so explicitly. Again, the Board disagrees. The legislator may frame the exclusions from patentability in such words or form as it wishes (again, as already observed - see paragraphs 5.8 and 7.4). While it is true that, as observed in section 11, the differences in the words used in the three official language texts of Article 53(b) EPC is unfortunate, it is at least clear beyond any doubt that the Article does not represent a general exclusion of all animal patents.

13.3.3 The case-law cited by appellants 3 to 6 in support of their arguments does not, in the Board's judgment, assist them. They argued first that paragraph 97 of the Reasons in T 1054/96 (OJ EPO 1998, 511) referred to Article 4(2) of EU Directive 98/44 as being satisfied by permitting process claims. Article 4(2) of EU Directive 98/44 is effectively identical to Rule 23c(b) EPC. In T 1054/96 Board 3.3.4 referred a number of questions concerning Article 53(b) EPC to the Enlarged Board of Appeal whose opinion on those questions forms G 1/98. Thus the Reasons in the referring decision put forward alternative views and, by definition, do not express a final view. Paragraph 97, on which the appellants rely, begins with the following sentence:

> "On the other hand, it could be considered that Article 4(2) of the directive is satisfied by permitting process claims."

The words "On the other hand" serve to demonstrate this is merely one of alternative views; and indeed the previous paragraph 96 not only contains a different view but, following several quotations from the Directive made in paragraph 95, states in its first sentence:

> "From these quotations the most natural deduction is that the drafters of the Directive intended and the EC Parliament approved that in all cases where the technical situation is such that a concept of genetic engineering is the invention which can be applied to more than one variety the resulting products shall be patentable, even if they are plant varieties."

It is thus apparent that paragraphs 96 and 97 of T 1054/96 put forward, respectively, the possibility of patenting plant products and patenting plant processes and, if anything, the referring Board thought patenting of plant products the "most natural" interpretation. This simply cannot assist parties seeking to exclude animal product claims under Article 53(b) EPC.

13.3.4 Appellants 3 to 6 also relied on paragraph 3.3.3 of the Reasons in G 1/98. They maintained that in that paragraph the Enlarged Board had said that a copying machine for use exclusively in forging banknotes was not patentable, whereas the same machine, if to be

used for other purposes, could be patentable. The appellants argued that, by analogy, the claims of the first auxiliary request exclusively directed to mouse species could not be allowed. The relevant passage in G 1/98 (Reasons, paragraph 3.3.3) reads as follows:

> "It may be helpful to look at the neighbouring exclusion in Article 53(a) EPC and ask what the situation would be if a claim were to cover something immoral or contrary to "ordre public". Suppose that a claimed invention defined a copying machine with features resulting in an improved precision of reproduction and suppose further that an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it should also allow reproduction of security strips in banknotes strikingly similar to those in genuine banknotes. In such a case, the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Article 53(a) EPC. There is, however, no reason to consider the copying machine as claimed to be excluded since its improved properties could be used for many acceptable purposes."

It is manifestly apparent not only that this passage refers to Article 53(a) EPC and not to Article 53(b) EPC but also that it does not say what the appellants argued that it said - it says that one possible unlawful embodiment does not render an invention unpatentable. This quite simply does not support the analogy claimed by the appellants. Furthermore, even

if the purported analogy was viable, to substitute "mouse species claims" for "money forging claims" assumes it has already been accepted that the claims in issue are directed to mouse species, which is manifestly not the case. As already observed, these appellants simply called the mice of the first auxiliary request a species without any evidential basis for doing so.

13.3.5 The remaining argument of appellants 3 to 6 regarding Article 53(b) EPC was that the claimed method for producing transgenic mice was an "essentially biological process for the production of animals" and thus excluded by the Article. However, Rule 23b(5) EPC states:

> "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

It is self-evident that a process which includes genetic manipulation does not consist entirely of natural phenomena.

13.3.6 Accordingly, Article 53(b) EPC does not exclude the patentability of the first auxiliary request.

13.4 *Articles 123(2)(3) EPC and 84 EPC*

No objections to the first auxiliary request have been raised by any party under these Articles. A formal basis for all the claims of the request is found in the application as originally filed. The claimed

subject matter concerns mice, whereas the claims as granted were concerned with non-human mammalian animals. There is no extension of the conferred protection. The claimed subject-matter is clear. Thus, the requirements of Articles 123(2)(3) EPC and 84 EPC are fulfilled.

13.5 *Article 54 EPC*

None of the parties submitted further arguments nor provided further evidence with regard to novelty in relation to the claimed transgenic mice or to the process for producing them. In the Board's judgment, there are no documents on file which would destroy the novelty of the claimed subject-matter.

13.6 *Article 56 EPC*

13.6.1 At the priority date of the opposed patent, methods for introducing genes into the germ line of an animal at an early (one-cell) development stage already existed and transgenic animals had already been produced by such methods (see page 3, lines 5 to 15 of the patent). However, the effect of introducing into the chromosome of an animal, at such an early stage of development, an activated oncogene known to interfere with the regulation of cell division was still under investigation.

13.6.2 The closest prior art is, as identified by the opposition division, document (1). This document refers to previous studies wherein the development of mouse two-cell embryos (but not that of morulae) to the blastocyst stage was blocked by the introduction

of tumorigenic SV40 viral DNA (cf. page 1250, right-hand column, first paragraph). It shows that the introduction by microinjection of tumorigenic SV40 viral DNA into pre-implantation mouse blastocysts results in the normal development of such embryos into mature and apparently healthy animals that are tumour-free at the age of one year (see page 1251, right-hand column, Results).

13.6.3 The expectations of the skilled person when incorporating an activated oncogene into the chromosome of an animal (a method which is performed at the embryonal stage) would have been either the death of the embryo due to the interference of the activated oncogene with the normal cell division at a very early stage of development, or the normal development of healthy mature animals due to the absence of any effect of the activated oncogene at later stages of development. There is no other prior art suggesting a different result, namely no interference with cell division in the early stages of development but interference at a later stage (maturity) resulting in increased probability of developing tumours. Therefore, there was no objective reason to expect that at least a few embryos would inevitably survive which would develop into adults having an increased probability to develop neoplasms. Thus, contrary to the opinion of appellants 3 to 6 (see paragraph XXI(1) above), there was no reason to expect success of any degree whatsoever. The claimed method (claim 1) and its observed result (claim 19) are non-obvious.

13.6.4 In the light of the above considerations, the Board concludes that the requirements of Article 56 EPC are fulfilled.

13.7 *Article 83 EPC*

Appellants 3 to 6 provided neither technical evidence nor experimental data nor any reference to any documents to support their argument of lack of sufficient disclosure. Instead, they simply pointed out that the respondent had emphasised the difficulties of obtaining oncomice when arguing in favour of inventive step. The Board agrees that, according to the established case law (see "Case law of the Boards of Appeal", 4th Edition 2001, page 114), the same level of skill has to be applied when considering inventive step and sufficiency of disclosure in the same invention. However, the case law also establishes (for example, T 19/90 OJ EPO 1990, 476, Reasons, paragraph 3.3) a patent may only be objected to for lack of sufficient disclosure if there are serious doubts, substantiated by verifiable facts, that the claimed subject-matter could be reproduced. Taking into account the complete absence of any such facts and that, moreover, the patent in suit describes a method which is successful (albeit at a modest level), the Board concludes that the requirements of Article 83 EPC are fulfilled.

13.8 *Article 57 EPC*

The industrial applicability of oncomice resides, in particular, in their use as animal models for testing materials suspected of being carcinogenic as well as

for testing materials for the ability to confer protection against the development of neoplasms.

13.9 *Allowability of the First Auxiliary Request*

For the reasons set out in paragraphs 13.1 to 13.8 above, the Board considers the First Auxiliary Request, with claims limited to "mice", to fulfil the requirements of the EPC and the request is accordingly allowable.

14. *Requests to refer questions to the Enlarged Board of Appeal*

14.1 Article 112 EPC sets out the circumstances in which a Board of Appeal shall refer a question to the Enlarged Board of Appeal as such:

> "(1) In order to ensure uniform application of the law, or if an important point of law arises:
>
> (a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes."

A consistent interpretation of this provision in the case law (*inter alia* J 7/90, OJ EPO 1993,133; J 16/90, OJ EPO 1992, 260) is that, although a question may involve an important point of law, it will only be referred to the Enlarged Board of Appeal if the answer to it is necessary to decide the case under

consideration. Accordingly, the Board is only required to refer questions to the Enlarged Board when no other course is open to it in order to arrive at a decision. The parties should therefore appreciate that, if the questions they asked to be referred to the Enlarged Board are not so referred, it does not necessarily mean that the Board considers those questions to be unimportant but just that referral is unnecessary to dispose of the present case. Subject to that general comment, the Board considers in turn each of the proposed questions to be referred. Where a proposed question has already been disposed of earlier in this decision, reference will be made back to the relevant earlier passage herein.

14.2 Appellants 3 to 6 requested that the following question be referred to the Enlarged Board of Appeal:

> "With reference to G1/98: Is a claim allowable if it is directed exclusively to transgenic animal races?"

As the Board has observed (see paragraph 13.3.1 above), the transgenic mice embraced by the claims of the first auxiliary request do not, as appellants 3 to 6 asserted, form a category as limited as an animal species. Such mice could not therefore form a yet narrower category such as an animal race; thus, while slightly confusing, the difference in terms used by those appellants, in their Article 53(b) EPC arguments and in their proposed question to be referred to the Enlarged Board, is of no effect. The reference in the question to G 1/98 is to those appellants' argument (using the term "species") based on paragraph 3.3.3 in

that Enlarged Board decision but that argument has been dealt with in paragraph 13.3.4 above from which it is apparent that the argument was based on false premises. Accordingly, not only has the issue been disposed of above but also the question is not one of importance and, for both those reasons, it is unnecessary to refer this question to the Enlarged Board of Appeal.

14.3 The respondent also requested that the Board refer to the Enlarged Board of Appeal the questions in its letter of 13 May 2004. Those questions were presented on what was termed "a precautionary basis" and, in the light of earlier findings in this decision, it may be unsurprising that none of these questions have been referred to the Enlarged Board of Appeal. However, to deal with those questions in order:

"1. Does Article 53(a) or (b) exclude the patenting of animals in general?"

The answer is clearly "No" for the reasons in paragraphs 4.3 to 4.4 above.

"2. At what date is the morality or "ordre public" test of Article 53(a) to be assessed?"

The answer is the filing or priority date of the patent, as the case may be - see section 8 and paragraph 10.9 above.

"3. If the answer to question (2) is other than at the European filing date or priority date, is it possible

for the legal validity of claimed subject-matter under Article 53(a) to change with time?"

In view of the answer to the question (2), this question does not arise.

"4. If the answer to question (2) is at the European filing date or priority date, is it permissible for an invention to be excluded from patentability under Article 53(a) as a consequence of evidence or facts which is or were not current at the European filing date or priority date, as the case may be?"

As the Board has held (see paragraphs 9.5 and 10.9 above), evidence arising after the filing date or priority date may be permitted in the assessment of patentability under Article 53(a) EPC but such evidence must be directed to the position at the filing date or priority date.

"5. Does Rule 23d(d), when referring to "substantial medical benefit", set a test which goes beyond the meaning of Article 53(a) as interpreted without knowledge of this Rule?"

This question has already been considered *in extenso* in section 7 above and, for the reasons in that section, the Board sees no need to refer this question to the Enlarged Board of Appeal.

"6. If the answer to question (5) is "no", are the requirements of Rule 23d(d) satisfied by a reasonable expectation or hope of "substantial medical benefit" at the date of assessment for Article 53(a) purposes?"

This question was answered in paragraphs 9.3 and 9.6 above.

"7. Is it relevant to a consideration of whether claimed product subject-matter meets the requirements of Article 53(a) that such product subject-matter may have been generated outside the EPC jurisdiction by use of a process or method which would itself be unpatentable under Article 53(a)?"

This question raises issues which were not the subject of argument in the appeal proceedings. This appears in particular to be a question raised by the respondent on a precautionary basis. It is in any event evident from this decision that it was unnecessary to answer this question.

"8. If the answer to question (1) is "no", what is the proper extent of the exclusion from patentability under Article 53(b)?

This has been considered in section 11 above from which it is clear that the proper extent of the exclusion from patentability under Article 53(b) EPC is one of the terms "animal varieties", "races animales" or "Tierarten".

"9. If the answer to question (8) is any one or more of "animal varieties", "races animales" or "Tierarten", how is/are such term or terms to be interpreted in actual practice?"

As is apparent from paragraph 11.7, to dispose of the present case no more need be decided as to the interpretation of those terms than is contained in section 11 above.

"10. If the answer to question (8) is anything other than one or more of the terms listed in question (9), how is the nature of such exclusion from patentability to be interpreted in actual practice?"

Since the answer to question (8) is not anything other than one of those terms, this question does not arise.

Accordingly the Board sees no reason to refer any of the questions filed by the respondent to the Enlarged Board of Appeal.

15. *Costs Requests*

15.1 The requests of both the respondent and appellants 3 to 6 for payment of costs to be met by the EPO are in respect of the second oral proceedings before the Opposition Division. Such requests are, to the best of the Board's knowledge, unprecedented; and, since they do not relate to any power possessed by the Board, there can be no question of such requests being allowed. However, since the only response to these requests which the Board could announce at the conclusion of the oral proceedings was that these requests must be refused only for the reason that the Board has no power to allow them, some explanation of the Board's views is appropriate.

15.2 The first oral proceedings before the Opposition Division were held on 21 to 24 November 1995 and the second on 6 to 7 November 2001. The Opposition Division's communication of 20 September 2000 mentioned, first, that there had been a change in the composition of the Opposition Division since the oral proceedings in November 1995 in that the legally qualified member had been replaced. It is not clear exactly when this happened but it is clear that it had occurred by the date of the communication. This was not given as a reason for offering new oral proceedings but in such circumstances such an offer was clearly correct at the time it was made (see T 862/98 of 17 August 1999, Reasons, paragraph 2.3). Second, the communication observed that the Administrative Council had enacted Rules 23b to 23e EPC with effect from 1 September 1999 and reference was also made to decision G 1/98 (OJ EPO 2000, 111) which had become available. The Opposition Division therefore considered the legal position was not the same as at the time of the previous oral proceedings and offered the opportunity for further oral proceedings. Again, that was a correct offer to make at the time it was made (see Article 116(1) EPC and T 194/96 of 10 October 1996, Reasons, paragraphs 2 to 3). Thus the question the costs requests raise is: could and/or should the opposition proceedings have been disposed of before either of these events (the change of composition or change in the law) arose? The date of the change of composition is not clear so, the change in the law having taken effect on 1 September 1999 (OJ EPO 1999, 437 *et seq*), that is the key date for this purpose.

15.3 The Board's review of the file leads to the following observations. First, the parties are in part responsible for the delays in the first instance proceedings - to take only one, and possibly the worst, example: after the proceedings were continued in writing after the first oral proceedings for the parties to comment on the requests filed during the oral proceedings, the patent proprietor made four requests for two month extensions of time such that it obtained a total of twelve months to respond to comments of other parties. As for the arguments of several opponents, these almost invited delay in that, from the beginning (i.e. from the grounds of opposition), they drew attention to, and in some cases relied solely on, the then pending debates in the European Parliament on transgenic animals and the proposals for legislation on biotechnological inventions. Second, although the file does not reveal this as such, the Opposition Division was without doubt aware in the period from late 1995 onwards that the European Parliament was contemplating legislation which might impinge on cases such as the present and which eventually led to European Directive 98/44/EC and to the new Rules. It was also no doubt aware of the referral of 28 July 1995 by the President of the EPO of a question regarding the interpretation of Article 53(b) EPC to the Enlarged Board of Appeal, a referral which led to decision G 3/95 (OJ EPO 1996, 169) rejecting the referral as inadmissible. And it is clear from the Opposition Division's communication that it was aware of the further referral by Board 3.3.4's decision of 13 October 1997 (T 1054/96 OJ EPO 1998, 511) of further such questions to the Enlarged Board which gave rise to G 1/98 (OJ EPO 2000, 111).

15.4 All the matters referred to in the previous paragraph may, in answer to the question why the first instance proceedings took so long, be viewed as mitigating circumstances. However, nothing appears from the file to suggest why those proceedings needed to take as long as nearly ten years. If the delay may have been in part attributable to the demands of some parties, the Opposition Division should not have acceded so liberally to such demands. If the Opposition Division expected developments in the law, whether by way of amendments to the EPC or Enlarged Board decisions, to affect the present case, it should (as is often the practice when referrals to the Enlarged Board are pending) have announced to the parties that it intended to adjourn the present case until such developments occurred, not least because the parties would then have had the chance to be heard about the proposed delay. In the absence of any such announcement, the allegation that the case had been delayed so as to allow the introduction of the new Rules to affect its outcome (see paragraphs XXVII(2) and XXXI(4) above) was, even if not in fact the case, bound to gain some credence as the apparent reason for the extreme delay. From there it is only a short step to the further allegation that the Opposition Division may have delayed the proceedings at the instigation of or under pressure from others within the EPO (see paragraphs XXVI(2) and 5.4 above). However well-intentioned the motives for delay may have been and however much the delay may be attributable to the parties as well as the Opposition Division, all these matters only explain the delay, they do not justify it.

15.5 That there was unjustified delay, as alleged by the parties, is clear - on any view, ten years to dispose of first instance proceedings is far too long. Measured by reference even to bad examples of delay to be found in the case law of the Boards of Appeal, the delays in the present case were extreme (see for example T 900/02 of 28 April 2004, Reasons, paragraph 3 and the other decisions referred to there). The parties and the public should have known far sooner whether the patent in suit was to be maintained and if so in what form. The priority date being 22 June 1984, the opposition proceedings only ended when the life of the patent had virtually expired. Ten years to dispose of proceedings at one instance is much longer than some periods which have been found not to be "within a reasonable time" contrary to Article 6(1) of the European Convention on Human Rights and Fundamental Freedoms. Accordingly, while it was correct to offer the parties further oral proceedings at the time that offer was made, the proceedings should never have been allowed to continue until the reasons for that offer arose. The question now facing the Board is, what can it do about this sorry state of affairs? Its powers in such circumstances are limited to two remedies.

15.6 First, if it allows an appeal and if it considers it equitable by reason of a substantial procedural violation to do so, it may reimburse the appeal fee (Rule 67 EPC). In the present case, the appeals have been allowed (in as much as the patent has been narrowed in scope from "rodents" to "mice"), so Rule 67 EPC could apply. The delay in the opposition proceedings amounted beyond question to a procedural

violation. Whether that violation was "substantial" depends on whether or not it had a substantive effect on the outcome of the proceedings (see "Case Law of the Boards of Appeal of the European Patent Office", 4th edition 2001, pages 555 to 556). If, as alleged, the delay was deliberately imposed in order to ensure the new Rules applied to this case, then a substantive effect on the outcome was at the very least intended. However, this point need not be examined further since, in the Board's opinion, it would not be equitable to reimburse the appeal fees of the appellants making the costs requests for several reasons - first, appellants 1 and 2 made no such request but have the same equitable claim to some relief for the delay all the parties suffered; second, the same consideration also applies to those parties who did not appeal; third, the appeal fee is a trivial sum compared with the gravity of the delay and the likely additional costs thereby incurred; fourth, the respondent is as deserving as the appellants but, having paid no appeal fee, cannot obtain any relief under Rule 67 EPC; and fifth and last, an order for reimbursement of the appeal fee is no more than an order to repay to a party money necessarily spent to appeal - in the present case the requests are for compensation for expenditure which should never have been incurred.

15.7 Second, if the Board finds the first instance proceedings contained fundamental deficiencies, it must remit the case to the first instance unless there are special reasons for doing otherwise (Article 10, Rules of Procedure of the Boards of Appeal). For similar reasons to those mentioned in the previous paragraph, the Board's powers under Article 10 RPBA

are inappropriate. There is no doubt whatsoever that a fundamental deficiency in the first instance proceedings occurred but, equally, there is no doubt that remittal would achieve nothing for any of the parties in the current circumstances. The special, indeed overwhelming, reason for not remitting the case under Article 10 RPBA is that the deficiency (i.e. the delay) was so extreme that the additional delay which remittal would cause would just add insult to injury (see T 346/92 of 29 July 1993, Reasons, paragraph 7; T 900/02 of 28 April 2004, Reasons, paragraph 18).

15.8 In the circumstances the only satisfactory step which could be taken would be to pay all the parties their costs incurred by the delay and the only appropriate party to make such payment would be the EPO, the authority responsible for the Opposition Division. However, as already indicated, the Board has no power to make an order against the EPO to pay any costs. For that and only that reason, the Board must find the requests of appellants 3 to 6 and the respondent inadmissible.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of:

the first auxiliary request filed during the oral proceedings,

the description pages 3, 6 and 10 as amended during the oral proceedings,

pages 4, 5, 7 to 9 as granted, and Figures 1 to 8 as in the patent as granted.

3. The requests to refer questions to the Enlarged Board of Appeal are refused.

4. The requests for payment of costs by the European Patent Office are dismissed as inadmissible.

The Registrar: The Chairman:

A. Wolinski F. Davison-Brunel