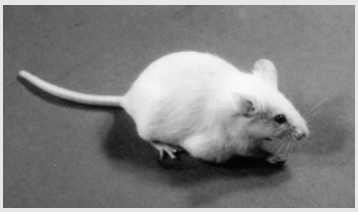
Techncial Board of Appeal EPO, 3 October 1990, Onco-mouse



PATENT LAW

Sufficiency of disclosure – article 83 EPC

- **There is thus no reason why the application should be refused on the ground that it involves an extrapolation from mice - as particularly featured in the application - to mammals in general.**

The invention clearly indicates how the skilled person can achieve chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammal, disclosing as it does an activated mouse myc gene introduced into a suitable plasmid and then micro-injected into mouse eggs at a given stage of cellular development. Firstly, this ensures that the invention can be reproduced on mice. Secondly, it may be assumed that the skilled person is aware - in the same way as in case T 292/85 - of other suitable mammals on which the invention can likewise be successfully performed. There is thus no reason why the application should be refused on the ground that it involves an extrapolation from mice - as particularly featured in the application - to mammals in general.

To sum up, the invention has in the Board's view been sufficiently disclosed within the meaning of Article 83 EPC.

Exclusion of animal varieties – article 53(b) EPC

- **first consider whether the subject-matter of the present application constitutes an "animal variety", "race animale" or "Tierart" within the meaning of that provision. If it comes to the conclusion that the subject-matter is not covered by any of these three terms, then Article 53(b) EPC constitutes no bar to patentability.**

In contrast to the exclusion of "plant varieties "from patentability under Article 53(b) EPC (cf. T 320/87 - see above), the preparatory documents to this provision are completely silent as to the purpose of excluding "animal varieties" from patentability. […]. In this context it should, inter alia, be borne in mind that for animals - unlike plant varieties - no other industrial property right is available for the time being.

4.8 To sum up, the Board concludes that the Examining Division was wrong in refusing the present application on the ground that Article 53(b) EPC excludes the patenting of animals as such. The proper issue to be considered is, therefore, whether or not the subject-matter of the application is an "animal variety" ("race animale", "Tierart") within the meaning of Article 53(b) EPC. On this point the contested decision is for obvious reasons entirely silent. In view of the importance of this matter and the desirability of having it considered by at least two instances, the Board will exercise its powers under Article 111(1) EPC to remit the case to the department of first instance for further prosecution. It should also be noted that a number of questions outlined below and not yet dealt with by the Examining Division now need to be considered.

In its resumed examination with regard to Article 53(b) EPC, the Examining Division must, as indicated above, first consider whether the subject-matter of the present application constitutes an "animal variety", "race animale" or "Tierart" within the meaning of that provision. If it comes to the conclusion that the subject-matter is not covered by any of these three terms, then Article 53(b) EPC constitutes no bar to patentability. If, however, it considers that any of these terms applies, then refusal of the application would only be justified if that specific term represents the proper interpretation of Article 53(b) (see point 4.3 above). This would also presuppose that Article 53(b) EPC can be applied at all in respect of animals which are genetically manipulated, given that neither the drafters of the Strasbourg Convention nor those of the EPC could envisage this possibility.

Microbiological processes – article 53(b) EPC

- **Not an essentially biological process: The oncogene is inserted by technical means into a vector (e.g. a plasmid), which is then micro-injected at an early embryonic stage.**
- **Article 53(b) EPC excludes only processes for the production of animals, with which Claim 19 is not concerned, this provision per se is no bar to patenting the product.**

As the Examining Division has noted, Claim 19 is a product claim. In the absence of any other definition, the product claimed is defined in terms of the process by which it is produced. Claim 19 is thus a "product-by-process" claim. But a product-by-process claim remains a product claim irrespective of the process it refers to. So a successful Claim 19 would result in a product patent, not a process patent. Since, however, Article 53(b) EPC excludes only processes for the production of animals, with which Claim 19 is not concerned, this provision per se is no bar to patenting the product. It may also be added that a reproductive process could conceivably be other than sexual, i.e. other than essentially biological, for example if an animal which has received the oncogene sequence by the first process were then to be cloned by asexual, technical means.

- **patents are grantable for animals produced by a microbiological process: general principle of patentability under Article 52(1) EPC is restored for inventions involving microbiological processes and the products of such processes.**

Article 53(b), second half-sentence, EPC provides that Article 53(b), first half-sentence, EPC does not apply to microbiological processes or the products thereof. The Examining Division did not decide whether the present

invention involves a microbiological process, taking the view that Article 53(b), second half-sentence, EPC does not apply if the product (in this case the animal) is excluded under the first half-sentence on the grounds that the second part of the provision cannot be interpreted in a manner which would set aside the first part. The Board does not share this view. As indicated above, Article 53(b), first half-sentence, EPC is an exception to the general principle of patentability contained in Article 52(1) EPC. The second half-sentence is an exception to this exception, ensuring that the patentability bar does not cover microbiological processes or the products thereof.
In other words, the general principle of patentability under Article 52(1) EPC is restored for inventions involving microbiological processes and the products of such processes. Consequently, patents are grantable for animals produced by a microbiological process. The Examining Division must therefore consider, should the case arise, whether the claimed processes constitute microbiologicial processes within the meaning of Article 53(b) EPC.

Source: epo.org; O.J. 1990, 476

Technical Board of Appeal EPO, 3 October 1990
(…)
Casenumber: T 0019/90
Applicant: Harvard University
Summary of Facts and Submissions
I. European patent application No. 85 304 490.7, published as No. 0 169 672, was refused by the Examining Division in its decision of 14 July 1989 (OJ EPO 1989, 451). The application as refused had 19 claims, Claims 1, 17 and 18 reading 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."
II. The grounds given for refusal were that the application did not meet the requirements of Articles 53(b) and 83 EPC. The relevance of Article 53(a) EPC was also discussed. The main arguments were as follows: (a) The question of reproducibility (compliance with Article 83 EPC) was ruled on in Decision T 226/85 (OJ EPO 1988, 336) to the effect that Article 83 EPC was satisfied only if, in essence, any embodiment of the invention, as defined in the broadest claim, could be carried out on the basis of the specific disclosure. The claims reproduced above related in the description to non-human mammalian animals - not only mice but also anthropoid apes and elephants, for example - whose genetic make-up was manipulated through the introduction of a single specified oncogene, the myc gene. These, however, had widely varying numbers of genes and differently developed immune systems; it could not therefore be assumed that the sole example described in the application - that of mice - could be extended to all other mammals. This view was supported by the inventor's declaration before the United States Patent and Trademark Office to the effect that it had actually been quite surprising that the experiment described in the application had produced the desired result. The declaration also gave the inventor's reasons for thinking he would fail. It was thus unlikely that the same genetic manipulation could be successfully performed on other mammals without inventive skill. (b) In interpreting Article 53(b) EPC it had to be borne in mind that its text was drawn virtually word for word from the Strasbourg Convention. This dated from 1963, when the question of patenting transgenic animals was scarcely conceivable. In interpreting the article, however, it was necessary to consider what the legislators' intentions had been at that time. The Strasbourg Convention enables the Contracting States to exclude animal varieties from patent protection. According to the Examining Division, the idea behind this exclusion was that animal varieties were not appropriate subject-matter for patent protection. This view was supported by the fact that the animal exclusion under Article 53(b) EPC used different taxonomic terms in the three languages: "animal varieties", "races animales" and "Tierarten". The Examining Division concluded that the intention of the legislator had been to exclude animals in general from patentability.
The Division then considered the applicability of the Article 53(b) EPC exclusion of "essentially biological processes" from patentability, concluding that in the light of decision T 320/87 (OJ EPO 1990, 71) it was to be construed narrowly and judged on the basis of the essence of the invention. The essence of the present process invention was the introduction of an oncogene into an animal by technical means such as micro- injection. As this was clearly not "essentially biological", no objection to the process claims was raised under Article 53(b), first half-sentence, EPC. With product Claims 17 and 18, however, the question arose as to whether they came under the exclusion provision of Article 53(b), second half-sentence, EPC. The answer was that they contained two different process steps, namely the non-biological step already mentioned and a purely breeding step. The two steps resulted in two different products. Animals which had been genetically manipulated themselves were products of an essentially non-biological process, whereas further generations were the product of sexual and thus exclusively biological reproduction. The latter were therefore non-patentable under Article 53(b), first half-sentence, EPC. Even accepting the appellants' argument that the process as a whole was essentially non-biological, this would not make the product claims allowable; only products of

microbiological processes within the meaning of Article 53(b), second half-sentence, EPC were patentable. However, the second half-sentence had to be seen in conjunction with the first; if the product of a process was manifestly excluded under the first part of the article, the second part could not be interpreted in such a way as to set aside the first. (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. In this connection it sought to address the following specific issues:

- Might it not be better to perform cancer tests of this kind on non-animal models?
- The purpose of the present invention was not to improve particular features but to produce tumours in the test animals.
- Animals were regarded as objects.
- Descendants of the transgenic animals might escape into the environment and spread malignant foreign genes through mating.
- Was evolution not being drastically interfered with?

The Division concluded that patent law was not the right legislative tool for resolving the potential problems.

III. The appellants appealed against the decision to refuse their application.

IV. With the statement of grounds the appellants filed four sets of claims: a main request and three auxiliary requests. Claims 1 and 19 of the main and first auxiliary requests read as follows:

Main request:

"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".

First auxiliary request:

"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 an embryonic stage.

19. 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 an embryonic stage, said oncogene optionally being further defined according to any one of claims 3 to 10." The sets of claims under the third and fourth auxiliary requests correspond to those in the main and auxiliary requests refused by the Examining Division. The appellants' arguments may be summarised as follows:

(a) Regarding Article 83 EPC:

The independent claims at issue in all the newly filed requests concerned the introduction of oncogene sequences into non-human mammalian animals, or mammalian animals thus genetically manipulated. The scope of the terms used was a reasonable extrapolation from the experiments actually performed, and set out in detail in the description. The Examining Division was quite wrong to take the inventor's declaration before the United States Patent and Trademark Office as indicating that the claimed process's surprising success on mice meant that it would not work with other mammals. On the contrary, it meant the process claimed was now potentially usable with any other mammal. Mammals' genetic systems were broadly similar and although there were of course differences they were not decisive. In support of this view, other scientists were cited as proposing to follow up the present inventor's work by studying other species to increase understanding of oncogenesis. The EPC did not require the description of every possible embodiment which might be covered by a general, broad claim. The techniques were relatively straightforward and employed at a level where from that point of view little distinction could be drawn between different species of mammals.

The appellants then analysed the interpretation given to Article 83 EPC in Board of Appeal case law, notably T 226/85 (see above), T 281/86 (OJ EPO 1989, 202), T 292/85 (OJ EPO 1989, 275) and T 301/87 (OJ EPO 1990, 335). Here they discerned a consistent approach insofar as not every embodiment covered by a broad claim is required to be set out in detail in the description, provided the latter makes it clear to the skilled person how to achieve the result given in the claim. This held good even if some variants were unsuitable or not particularly suitable or if certain possibilities covered by the claim did not yet even exist, as long as the skilled person was in a position to recognise this. In the absence of evidence such as comparative tests or literature to show that certain embodiments covered by a general claim could not be carried out - or not in the way described in the application - the Examining Division had no reason to query it, even if only one example was given in the description.

During proceedings before the Examining Division the appellants had submitted a number of references showing that transgenic animals other than mice could be and had been made, that genes from one species of mammal were used to produce transgenic animals of another, and that an oncogene reacted in one species of mammal in essentially the same way as in another, which showed that the nature of the oncogene was not the crucial factor. What was important was whether the skilled person could apply to other mammals the teaching set out in the description to the application. This was the case. Following the above case law would mean setting the Examining Division's decision aside. Should the Board find themselves unable to do so, the appellants requested that the Board of Appeal refer the

matter to the Enlarged Board of Appeal under Article 112(1)(a) EPC, submitting the question:
"What is the meaning of Article 83 EPC in terms of the required extent of evidence of performability of embodiments of the invention covered by a claim by the person skilled in the art?" (b) Turning to the Examining Division's basis for refusing the application - Article 53(b) EPC - the appellants argued that Board of Appeal case law had consistently been that patents should be granted for any invention meeting the general requirements of the EPC; wherever the law was not clear and admitted interpretation the Boards had taken the line that exceptions to patentability should be construed narrowly. The relevant decisions were G 5/83 (OJ EPO 1985, 64), T 49/83 (OJ EPO 1984, 112), T 385/86 (OJ EPO 1988, 308) and T 320/87 (see above). The present application provided an opportunity to develop this case law, as the meaning of Article 53(b) EPC was uncertain. The contested decision departed from this principle by placing a wide construction on the exclusion under Article 53(b) EPC. This ran counter in particular to Decision T 49/83 (see above), which held that no general exclusion of inventions in the sphere of animate nature could be inferred from the European Patent Convention. Above all, the Division erred in concluding that the different terms used in the three official languages to refer to the non- patentable subject-matter clearly showed that the legislators' intention had been to exclude animals generally. Had this been the case, they could clearly have said so in unambiguous terms. The entire process defined in the newly filed claims was essentially non-biological. The Examining Division had already accepted this for that part of the process involving micro- injection of oncogene sequences into the embryo at various stages of development. However, this technical operation was so central to the invention itself, and to its effect in descendants of the first genetically manipulated animals, that the entire process concealed in the product claims was not to be regarded as "essentially biological" within the meaning of Article 53(b) EPC.
The invention was in any case clearly a "microbiological process". The dominant feature of both process and product was genetic manipulation, which was unquestionably of a microbiological and technical nature. Lastly, the Examining Division's view that one exclusion provision could not be countermanded by another was wrong in law. It could not be right for subject-matter expressly declared patentable under Article 53(b) EPC - microbiological processes and their products - to be refused protection nonetheless on the basis that the products in question were excluded elsewhere in that provision.
The appellants requested that the following question be referred to the Enlarged Board of Appeal: "Insofar as the exclusion of Article 53(b) first part EPC relates to 'animal', to what extent is animal protection possible under Article 53(b) EPC (if at all)?"
V. A large number of observations by third parties, most of them expressing serious concern about genetic manipulation of animals, have been filed under Article 115(1) EPC, showing considerable interest by the public in the present case.
VI. The appellants request that the application be remitted to the Examining Division for further prosecution on the basis of any of the sets of claims submitted in the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. New claims in appeal proceedings (Article 123(2) EPC)
With the statement of grounds of appeal the appellants filed four sets of claims, Set A being the main request and Sets B, C and D auxiliary requests 1 to 3 respectively. Whilst Sets C and D contain the claims refused in the contested decision, in Set A the appellants claim the chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammalian animal, and in Set B the introduction of an activated oncogene sequence into a non-human mammalian animal at an embryonic stage. These amendments are supported by lines 4 to 14 on page 2 of the description as originally filed. Although this part of the description does not actually contain the word "genome" now used in the main claim of the main request, that concept is implicit in the reference to the oncogene sequence being incorporated "chromosomally" or "into the chromosome", the genome of higher organisms being the totality of their chromosomes.
The amendments are thus admissible under Article 123(2) EPC.

3. Sufficiency of disclosure (Article 83 EPC)

3.1 Claim 1 of the main request concerns the incorporation of an activated oncogene sequence into the genome of non-human mammalian animals in general. Independent Claim 19 relates to non-human mammalian animals in general, which have been genetically altered in this way. The description of the patent application describes as a preferred embodiment an activated oncogene sequence - the mouse myc gene - and its insertion into a plasmid suited to the desired process, followed by micro- injection into mouse eggs at the one-cell stage; the animals are then raised and the inserted gene, which may be active, is analysed.
3.2 As the Examining Division pointed out in the contested decision, the claimed invention refers to all non-human mammalian animals, whereas the invention described in the examples has been performed only on mice. In these circumstances the Division was not convinced that a skilled person would be able to carry out successfully on all other kinds of non-human mammals the invention as performed on mice. The Examining Division, therefore, refused the application, inter alia, on the ground that the claims were unrealistically broad.
3.3 However, the mere fact that a claim is broad is not in itself a ground for considering the application as not complying with the requirement for sufficient disclosure under Article 83 EPC. Only if there are serious doubts, substantiated by verifiable facts, may an application be objected to for lack of sufficient disclosure.
Although the Examining Division was right in saying

that certain non-human mammals other than mice have very different numbers of genes and different immune systems, it does not necessarily follow that the invention cannot be carried out on such animals. On the contrary, at least one source (Palmiter & Brinster, Ann. Rev. Genet. 1986, 20; 465-499) suggests that those skilled in the art might very well be able to carry out the invention on non- human mammals other than mice. Nor is the Board itself aware of any verifiable facts which could cast serious doubt on the possibility for a skilled person to carry out the invention as claimed.

3.4 The Examining Division's objection to the sufficiency of the disclosure was hardly supported by its reference in the contested decision to the declaration of co-inventor Philip Leder dated 29 December 1988 in the proceedings relating to the parallel US application. In this declaration, he indicated that the positive results with the mouse had been surprising, failure having looked likely for a number of reasons. The co-inventor's surprise at the success achieved is in the Board's view to be considered as relating rather to the fact that the invention could be carried out at all than to the fact that it had succeeded with a mouse.

3.5 The Examining Division's view that, if limited to rodents instead of mammals in general, the claims would be acceptable, would not seem to be fully in line with the reasoning of the Division referred to in paragraph 3.2 above. Furthermore, this idea would seem to be based on the arbitrary assumption that all rodents would behave in the same way as mice for the purpose of the invention. However, unless the EPO has convincing arguments against the scope of the invention as claimed, it may not require any particular limitation of the claims. In this context it should also be borne in mind that an applicant who seeks and obtains a patent which does not comply with Article 83 EPC runs an increased risk if involved in opposition proceedings and/or national revocation proceedings.

3.6 The decision in case T 226/85 (see above) is not relevant in the Board's view. There, the Board found that the disclosure was insufficient because the application did not give enough information. Only with luck, if at all, could the invention be reproduced. But in the present case it is not disputed that the information in the application is sufficient for performing the invention at least on mice.

3.7 The Examining Division also took the view that the decision in case T 292/85 (see above) - referred to by the appellants - was irrelevant to the present case. That decision concerned a genetic engineering invention involving polypeptide expression. Objections of insufficient disclosure had been raised to the broad term "bacteria" which, it was felt, could include unsuitable species or variants. There, the Board took the view that the unsuitability of unspecified variants was immaterial as long as suitable variants were known to the skilled person through the disclosure or on the basis of his common general knowledge. A biological invention was thus considered sufficiently disclosed if it clearly indicated at least one way in which the skilled person could carry it out.

3.8 The Board, in contrast to the Examining Division, considers that the above ruling can also be applied to the present case. The invention clearly indicates how the skilled person can achieve chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammal, disclosing as it does an activated mouse myc gene introduced into a suitable plasmid and then micro-injected into mouse eggs at a given stage of cellular development. Firstly, this ensures that the invention can be reproduced on mice. Secondly, it may be assumed that the skilled person is aware - in the same way as in case T 292/85 - of other suitable mammals on which the invention can likewise be successfully performed. There is thus no reason why the application should be refused on the ground that it involves an extrapolation from mice - as particularly featured in the application - to mammals in general.

3.9 To sum up, the invention has in the Board's view been sufficiently disclosed within the meaning of Article 83 EPC.

4. Exceptions to patentability under Article 53(b) EPC

4.1 The present patent application concerns, inter alia, genetically manipulated non-human mammals. The first half- sentence of Article 53(b) EPC reads as follows in English, French and German:

"European patents shall not be granted in respect of: (a) ... (b) plant or animal varieties or essentially biological processes for the production of plants or animals";

"Les brevets européens ne sont pas délivrés pour : a) ... b) les variétés végétales ou les races animales ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux" ;

"Europäische Patente werden nicht erteilt für: a) ... b) Pflanzensorten oder Tierarten sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren".

4.2 As pointed out by the Examining Division, the three texts of Article 53(b) EPC differ in terminology as to the non-patentable area. In particular, the German term "Tierarten" is broader than the English "animal varieties" and the French "races animales".

4.3 Article 177(1) EPC lays down that the English, French and German texts of the EPC are all equally authentic. In the present case, there is obviously a need to establish their common meaning through interpretation of the Convention in order to determine to what extent animals are excluded from patentability under Article 53(b), first half-sentence, EPC.

4.4 In the decision under appeal the Examining Division interpreted Article 53(b) EPC as excluding not only certain groups of animals from patentability but, in fact, animals as such. The Board is unable to accept this interpretation.

4.5 Firstly, the Examining Division did not take duly into account that Article 53(b) EPC is an exception, for certain kinds of inventions, to the general rule under Article 52(1) EPC that European patents "shall be" granted for all inventions which are susceptible of industrial application, which are new and which involve

an inventive step. Any such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly construed (cf. in particular T 320/87, point 6, OJ EPO 1990, 76). The Examining Division has given no convincing reasons for deviating in this particular case from this principle of interpretation, nor are any such reasons apparent to the Board.

4.6 The possibility that the reference to certain categories of animals rather than to animals as such was simply a mistake by the legislators can be ruled out. Nothing in the legislative history of either the EPC or the Strasbourg Convention of 27 November 1963 on the Unification of Certain Points of Substantive Law on Patents for Invention, whose Article 2(b) was taken over and incorporated into Article 53(b) EPC, supports such an assumption. On the contrary, a clear indication that the terms "animal varieties", "races animales" and "Tierarten" were not intended to cover animals as such is the wording of Article 53(b) EPC itself. The very same provision also contains, as appears from paragraph 4.1 above, a reference to "animals" (in general). In using the different terms "animal varieties" ("races animales", "Tierarten") and "animals" ("animaux", "Tiere") in this way, the legislators cannot have meant "animals" in both cases.

4.7 In contrast to the exclusion of "plant varieties "from patentability under Article 53(b) EPC (cf. T 320/87 - see above), the preparatory documents to this provision are completely silent as to the purpose of excluding "animal varieties" from patentability. However, the purpose of a law (ratio legis) is not merely a matter of the actual intention of the legislators at the time when the law was adopted, but also of their presumed intention in the light of changes in circumstances which have taken place since then. It is now the task of the European Patent Office to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept of "animal varieties", providing a proper balance between the interest of inventors in this field in obtaining reasonable protection for their efforts and society's interest in excluding certain categories of animals from patent protection. In this context it should, inter alia, be borne in mind that for animals - unlike plant varieties - no other industrial property right is available for the time being.

4.8 To sum up, the Board concludes that the Examining Division was wrong in refusing the present application on the ground that Article 53(b) EPC excludes the patenting of animals as such. The proper issue to be considered is, therefore, whether or not the subject-matter of the application is an "animal variety" ("race animale", "Tierart") within the meaning of Article 53(b) EPC. On this point the contested decision is for obvious reasons entirely silent. In view of the importance of this matter and the desirability of having it considered by at least two instances, the Board will exercise its powers under Article 111(1) EPC to remit the case to the department of first instance for further prosecution. It should also be noted that a number of questions outlined below and not yet dealt with by the Examining Division now need to be considered.

In its resumed examination with regard to Article 53(b) EPC, the Examining Division must, as indicated above, first consider whether the subject-matter of the present application constitutes an "animal variety", "race animale" or "Tierart" within the meaning of that provision. If it comes to the conclusion that the subject-matter is not covered by any of these three terms, then Article 53(b) EPC constitutes no bar to patentability. If, however, it considers that any of these terms applies, then refusal of the application would only be justified if that specific term represents the proper interpretation of Article 53(b) (see point 4.3 above). This would also presuppose that Article 53(b) EPC can be applied at all in respect of animals which are genetically manipulated, given that neither the drafters of the Strasbourg Convention nor those of the EPC could envisage this possibility.

4.9 Essentially biological processes (Article 53(b), first half- sentence, second alternative, EPC)

4.9.1 Process claims

Under Article 53(b), first half-sentence, EPC, European patents are not granted for essentially biological processes for the production of animals. The present invention contains process claims for the production of transgenic, non-human mammals with an increased propensity to develop neoplasms through chromosomal incorporation of an activated oncogene sequence into the genome of the non-human mammal. The oncogene is inserted by technical means into a vector (e.g. a plasmid), which is then micro- injected at an early embryonic stage. In the Board's view, the Examining Division correctly concluded that this is not an "essentially biological process" within the meaning of Article 53(b) EPC.

4.9.2 Product claims

Claim 19 under the main request relates to 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 genome of the animal itself or into the genome of one of its ancestors. It thus covers both transgenic animals produced according to the process claims, making use of micro-injection, and the descendants of such animals. While the former are the result of a non-biological process, their descendants can be the outcome of a biological process based on sexual reproduction.

The Examining Division took the view that by artificially combining a non-biological and a breeding process the applicant was seeking to circumvent the exclusion under Article 53(b), first half-sentence, EPC, particularly since the two processes would give rise to two different products. The Board doubts whether the latter point is legally correct as the products of the two processes, at least from the point of view of patent law, cannot be distinguished from each other in respect of the transferred gene. However, this question may be left open for the time being since the basic assertion in the contested decision - that Claim 19 circumvents Article 53(b) EPC, and thus precludes the grant of a patent - is wrong in any case. As the Examining Divi-

sion has noted, Claim 19 is a product claim. In the absence of any other definition, the product claimed is defined in terms of the process by which it is produced. Claim 19 is thus a "product-by-process" claim. But a product-by-process claim remains a product claim irrespective of the process it refers to. So a successful Claim 19 would result in a product patent, not a process patent. Since, however, Article 53(b) EPC excludes only processes for the production of animals, with which Claim 19 is not concerned, this provision per se is no bar to patenting the product. It may also be added that a reproductive process could conceivably be other than sexual, i.e. other than essentially biological, for example if an animal which has received the oncogene sequence by the first process were then to be cloned by asexual, technical means.

4.10 Microbiological processes and the products thereof (Article 53(b), second half-sentence, EPC)

Article 53(b), second half-sentence, EPC provides that Article 53(b), first half-sentence, EPC does not apply to microbiological processes or the products thereof. The Examining Division did not decide whether the present invention involves a microbiological process, taking the view that Article 53(b), second half-sentence, EPC does not apply if the product (in this case the animal) is excluded under the first half-sentence on the grounds that the second part of the provision cannot be interpreted in a manner which would set aside the first part. The Board does not share this view. As indicated above, Article 53(b), first half-sentence, EPC is an exception to the general principle of patentability contained in Article 52(1) EPC. The second half-sentence is an exception to this exception, ensuring that the patentability bar does not cover microbiological processes or the products thereof. In other words, the general principle of patentability under Article 52(1) EPC is restored for inventions involving microbiological processes and the products of such processes. Consequently, patents are grantable for animals produced by a microbiological process. The Examining Division must therefore consider, should the case arise, whether the claimed processes constitute microbiological processes within the meaning of Article 53(b) EPC.

5. Exception to patentability under Article 53(a) EPC

Under the heading "Considerations under Article 53(a) EPC" in the contested decision, the Examining Division argued that patent law is not the right legislative tool for regulating problems arising in connection with genetic manipulation of animals. The Board considers, however, that precisely in a case of this kind there are compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability. The genetic manipulation of mammalian animals is undeniably problematical in various respects, particularly where activated oncogenes are inserted to make an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, which necessarily cause suffering. There is also a danger that genetically manipulated animals, if released into the environment, might entail unforeseeable and irreversible adverse effects. Misgivings and fears of this kind have been expressed by a number of persons who have filed observations with the Board under Article 115 EPC. Considerations of precisely this kind have also led a number of Contracting States to impose legislative control on genetic engineering. 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. It is the task of the department of first instance to consider these matters in the context of its resumed examination of the case.

6. Requests under Article 122 EPC

The appellants have requested that two questions be referred to the Enlarged Board of Appeal: the extent to which patent protection for animals is possible under Article 53(b) EPC and the extent of the disclosure required within the meaning of Article 83 EPC in a case of the present kind. However, the Board considers that it would be premature to refer any of these questions to the Enlarged Board of Appeal before the department of first instance has reconsidered the basic problem of interpreting Article 53(a) and (b) EPC in the light of the Board's present decision. This request has therefore to be rejected.

ORDER

For these reasons, it is decided that:

1. The request that certain questions be referred to the Enlarged Board of Appeal is rejected.
2. The decision of the Examining Division is set aside.
3. The case is remitted to the Examining Division for further prosecution.