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Appeal number: **T0682/16-3.3.08**

Communication of the Board of Appeal pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal

The Rapporteur Pere Julià

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Annex(es):

Communication text

1. This communication is sent pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) (OJ EPO Supplement to Official Journal 1/2019, 29). Any opinions expressed herein are provisional and not binding on the board in arriving at its decision. The purpose of this communication is mainly to set out some of the issues to be discussed at the oral proceedings before the board, it is not an invitation to make further submissions generally. In this respect, the parties' attention is also drawn to Article 114(2) EPC and to Articles 13(1) and 13(3) RPBA.

2. European patent no. 1 456 346 is based on European patent application no. 02 714 955.8 (published under the PCT with the international application number WO 02/066613; hereinafter "the patent application") and was granted with 57 claims. Several oppositions were

filed on the grounds as set forth in Articles 100(a) and 100(b) EPC. The opposition division held that the grounds of opposition did not prejudice the maintenance of the patent as granted and, accordingly, rejected the oppositions.

3. An appeal was lodged by one of the opponents (appellant). In the statement setting out its grounds of appeal, the appellant filed new documentary evidence and maintained the objections raised at first instance under Article 53(a) EPC in combination with Rule 28(d) EPC (Article 100(a) EPC) and Article 83 EPC (Article 100(b) EPC). In reply thereto, the patent proprietor (respondent) filed an auxiliary request 1 and new documentary evidence (documents (7) to (10)). As an auxiliary measure, oral proceedings were requested by both parties.

Admissibility of the joint opposition and of the appeal

4. In reply to the appellant's statement of grounds of appeal, the respondent contested the decision of the opposition division on the admissibility of the joint opposition. According to the respondent, it was not clear at the end of the opposition period, who the opponents actually were, and who the common representative should have been and whether he acted under authorization from all opponents. The respondent argued that the opposition division "construed the ambiguous notice of opposition, as well as Mr. Then's submission of February 7, 2003 in favour of the alleged OP (namely the joint opponents comprising Testbiotech e.V. as Opponent), although it was left ambiguous in the notice of opposition whether Mr. Then as a natural person would be opponent". Since the appointed common representative can only be one of the opponents themselves (Rule 151 EPC) and Mr. Then was neither an opponent (as a natural person) nor duly

appointed and authorised in accordance with Article 133(3) EPC and Rule 151(1) EPC to be the common representative of the joint opposition, the opposition was deficient and without remedy within the opposition period.

5. There are no submissions from the appellant as regards this issue in appeal proceedings.

6. The facts and submissions on which the respondent argued against the admissibility of the opposition were summarised, first, in the Summons to attend oral proceedings issued by the opposition division on 13 February 2015, and then in the decision under appeal (cf. pages 3 to 6 of the decision under appeal; pages 2 to 4 of the Summons to attend oral proceedings). They are not contested in appeal proceedings; indeed, the arguments put forward by the respondent in appeal proceedings appear to be identical to those addressed at first instance and based on the same facts and submissions as summarised at first instance.

6.1 At the first page of a notice of opposition filed on 13 November 2012 together with the "Reasons for the opposition", there was a list of 11 opponents. At the bottom of this first page, there was a "Postal address for communication with the opponents" with the name "Christopher Then, Testbiotech e.V."; wherein Testbiotech e.V. was cited as one of the opponents in the opponents list. The date of the opposition was indicated as 14 November 2012.

6.2 On 13 November 2012, several notices of a joint opposition were filed; all of them indicated the date of the opposition as 14 November 2012 and none of them contained reasons for the opposition. One of these notices indicated as opponent's name "Christopher Then"

with the organisation's name "Testbiotech e. V.", and the date given with the signature was 13 November 2012.

6.3 On 14 November 2012, several notices of a joint opposition were further filed. All of them indicated the date of the opposition as 14 November 2012, contained "Reasons for the opposition", and a list of opponents with "Testbiotech" being one of them. A "Postal address for communication with the opponents" with the name "Christopher Then, Testbiotech e.V." was also given.

6.4 In a communication pursuant to Article 113(1) EPC dated 24 February 2014, the EPO formalities section informed the parties that the opposition appeared to be admissible. Although the issue was left open by the opposition division in the Summons to attend the oral proceedings issued on 13 February 2015, the opposition division stated that "Testbiotech e. V. continues to be regarded as opponent, and Mr. Then is only common representative for the joint opposition and legal representative of Testbiotech e.V. as legal person, but he is not opponent as natural person" (cf. bottom of page 6 in the Summons to attend oral proceedings).

6.5 In reply to the Summons to attend the oral proceedings, none of the parties filed further submissions as regards this issue. At the oral proceedings at first instance, the parties referred to their written submissions and, only at the chairman's request, referred to the role of Mr. Then in the opposition (cf. page 1, points 4 to 10 of the Minutes of the oral proceedings before the opposition division issued on 21 February 2016). In the decision under appeal, the opposition division followed its preliminary opinion and decided in line therewith (cf. pages 6 to 8 of the decision under appeal).

7. In view of the respondent's arguments and the evidence on file, the board sees no reason to deviate from the findings of the opposition division as regards the admissibility of the opposition.

Admission of new documentary evidence

8. According to the established case law, the function of an appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by an examining or opposition division. Appeal proceedings are not an opportunity to re-run or re-open proceedings before any of these divisions. It is within the board's discretion to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings (Article 114(2) EPC and Articles 12(4) and 13(1) RPBA; see "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, V.A.1, 1133 and V.A.4, 1206).

9. With its statement of grounds of appeal, the appellant filed a new document to support its argument on the likelihood of animal suffering. In reply thereto, the respondent filed documents (7) to (10) to support its argument on the likelihood of substantial medical benefits and it further requested the board to use its discretion and not to admit the appellant's new document into the proceedings.

10. In the Summons to attend oral proceedings, the opposition division stated that opponent's arguments and documents then on file were not concerned with the (claimed) genetic modification *per se* but with the genetic modification of animals in general. It was further stated that, whilst the likelihood of substantial medical benefit could be inferred from the patent itself, it remained to be determined whether this likelihood was present for all animals claimed

(cf. page 10, last full paragraph to page 11, third paragraph of the Summons to attend oral proceedings). In reply to the Summons and in preparation of the oral proceedings at first instance, the patent proprietor did not consider it necessary to file any new documentary evidence while the opponent filed several documents.

11. No reasons appear to have been provided by the parties to explain why the new documents - filed in appeal proceedings - could not have been filed at first instance. In the board's view, none of these documents addresses issues or arguments that were not addressed at first instance. They are not concerned with an issue or an argument arising - for the first time in the proceedings - from the decision of the opposition division.

12. Therefore, the board, in the exercise of its discretion, is minded not to admit any of these new documents into the appeal proceedings.

Main request (claims as granted)
The cited case law and the claimed subject-matter

13. The decision under appeal concerns the subject-matter of claims 48 to 53 as granted. These claims are directed to a **non-human organism** comprising the host cell of claim 45, i.e. a cell which is characterised by comprising the gene expression modulation system according to claim 12.

13.1 The subject-matter of the claims underlying the decision T 315/03 (OJ EPO 2006, 15) concerned a **transgenic** rodent whose germ and somatic cells contained an activated oncogene sequence. Likewise, the subject-matter of the claims underlying the decision T 606/03 of 12 January 2005 concerned a **transgenic**

mouse. In the patents underlying both decisions, reference was explicitly made to the production of transgenic animals by using embryonic stem cells (ESC) or cells at an embryonic stage. In the present appeal, the definition of a transgenic, recombinant or transformed organism is provided in paragraph [0078] of the patent, wherein such organism is characterised by having a **genetically stable inheritance** of a transgene or nucleic acid fragment transferred into the genome of the host organism. Transgenic organisms are mentioned in paragraphs [0035] and [0224] of the patent.

13.2 Whilst in the set of claims underlying decision T 606/03 (*supra*), there was a claim directed to a transgenic **mouse**, the corresponding claim in the patent application (published under the PCT as WO 01/29208) was directed to a transgenic organism in general. In the cases underlying decisions T 315/03 (*supra*) and T 19/90 (OJ EPO 1990, 476), the claims were directed to a transgenic non-human eukaryotic animal in general in the patent application and they were limited, after a first opposition and appeal proceedings and as a result of objections raised under Articles 53(a) and 83 EPC, to a transgenic non-human mammalian animal. After second opposition proceedings, the claims were further limited to a transgenic rodent and to a transgenic **mouse**, the claims of the main request and first auxiliary request, respectively, underlying decision T 315/03 (*supra*). In the present appeal, a non-exhaustive list of preferred non-human organisms is provided for in paragraph [0209] of the patent. According thereto, the preferred organism may be selected from a bacterium, a fungus, a yeast, an animal, and a mammal; more preferably a yeast, a mouse, a rat, a rabbit, a cat, a dog, a bovine, a goat, a pig, a horse, a sheep, a monkey, or a chimpanzee; i.e. the subject-matter of claims 49-50 and 52-53 which is

dependent on claims 48 and 51 of the main request, respectively.

13.3 It follows therefrom that the scope of claims 48 to 53 is substantially broader than that of the claims underlying decisions T 315/03 and T 606/03 (*supra*). In the present appeal, the claimed subject-matter is not limited to non-human **transgenic** organisms but comprises non-human organisms which do not have a genetically stable inheritance of the gene expression modulation system according to claim 12. Moreover, claims 48 to 53 are not limited to a transgenic **mouse**, not even to a non-human animal or mammal, but include, as shown by the subject-matter of the dependent claims, all sorts of non-human organisms such as bacteria, fungi and yeasts.

14. It is nevertheless common ground between the parties that claims 48 to 53 comprise non-human transgenic animals, including non-human transgenic mammals. The objections and arguments put forward by the parties as well as the case law cited in opposition and appeal proceedings, are all concerned with, and based on, non-human transgenic animals, in particular, non-human transgenic mammals. It is not disputed that non-human transgenic animals result from processes that modify the genetic identity of these animals and therefore, the subject-matter of claims 48 to 53 falls within the scope of Article 53(a) EPC and Rule 28(d) EPC.

Article 100(a) EPC; Article 53(a) EPC and Rule 28(d) EPC
General considerations

15. The board agrees with the parties on the relevance of the case law cited in the proceedings, in particular decision T 315/03 (*supra*). The parties' attention is drawn to the introduction to the Reasons for that decision, in particular, to the considerations made

therein under the heading "Irrelevant issues". According thereto, the morality and "ordre public" referred to in Article 53(a) EPC concerns only the publication or exploitation of the invention, not the making of the invention or the process of patenting the invention (cf. T 315/03, *supra*, point 4.2 of the Reasons; see also, in this context, the decisions cited in the decision under appeal T 866/01 of 11 May 2005, points 5.5 to 5.7 of the Reasons, and T 1213/05 of 27 September 2007, point 53 of the Reasons). In line with these considerations, the board considers that the present appeal is not concerned with the patenting of transgenic animals or whether or not transgenic animals are patentable (cf. T 315/03, *supra*, points 4.3 to 4.5 of the Reasons).

16. In the present appeal, the applicability of Rule 28(d) EPC and the relevance of the "balancing test" required by this rule (cf. T 315/03, *supra*, point 6.2 of the Reasons) is not disputed by the parties. The board considers the assessment of the two tests, namely the "Rule 28(d) EPC test" and the "real Article 53(a) EPC test" (cf. T 315/03, *supra*, point 6.3 of the Reasons), as carried out by the opposition division in the decision under appeal and by the parties in their submissions, to be necessary for examining claims 48 to 53 and, in particular, the subject-matter of these claims related to non-human transgenic animals.

The first test - Rule 28(d) EPC, the balancing test
The likelihood of animal suffering

17. According to decision T 315/03, a *sine qua non* condition for triggering this test is a likelihood - and no more than a likelihood - of animal suffering (cf. T 315/03, *supra*, point 6.2 of the Reasons). In line also with decision T 315/03, the relevant date for

the assessment of this test is the effective date (the filing or priority date) of the patent (cf. T 315/03, *supra*, point 8.2 of the Reasons).

18. Contrary to the case underlying decision T 315/03 wherein animal suffering, due to the specific nature of the transgene (oncogene), was "not just a likelihood but the inevitable consequence of the very purpose of the patent" (cf. T 315/03, *supra*, last sentence of point 12.2.1 of the Reasons), in the present appeal, as stated by the opposition division, "the specific harm for the process at issue could not be established because the gene operated by the genetic switch was not specified and the invention could be applied in many ways" (cf. page 11, last paragraph of the decision under appeal). There is no limitation in the isolated host cell of claim 45 as regards the gene whose expression is to be modulated by the gene expression modulation system according to claim 12. Therefore, the subject-matter of claims 48 to 53 comprises non-human transgenic animals wherein this gene (transgene) is **any** possible gene of interest.

18.1 According to the established case law, for the assessment of novelty and inventive step, there is no reason to use the description of the patent to interpret an excessively broad claim more narrowly, if it is not a question of understanding a concept but rather of examining an excessively broad request in relation to the state of the art (cf. "Case Law", *supra*, I.C.4.8, 122, and II.A.3.3, 295). Likewise, it is not possible to read restrictive features and limitations into the claims if they are neither explicit nor suggested by the explicit wording of the claim (cf. "Case Law", *supra*, II.A.3.2, 292 and II.A. 6.3.4, 312). In the board's view, the same criteria apply when assessing the subject-matter of claims 48 to 53 under Rule 28(d) EPC. In the present appeal, even if

the description is taken into account, it refers only to "genes of interest" in general and provides nothing more than what appears to be a "wish list" of possible genes (cf. paragraphs [0193] and [0194] of the patent).

18.2 In line with the so-called "whole content approach" (cf. G 2/06, OJ EPO 2009, 306), reference could also be made to the technical teaching of the patent as a whole and the claims be interpreted in the light thereof. However, in the board's view, not even this approach would allow to read the scope of claims 48 to 53 more narrowly, since the description of the patent contemplates the use of genes that may be "targets for drug discovery, functional genomics, and proteomics analysis and applications" (cf. paragraphs [0035], [0162] and [0194] of the patent). Therefore, as in the cases underlying decisions T 315/03 and T 606/03 (*supra*), the claimed subject-matter comprises non-human transgenic animals and mammals for purposes other than therapeutic, such as research models for the development of pharmaceutical drugs, etc.

18.3 In the light thereof, the board is of the opinion that the scope of claims 48 to 53 cannot be interpreted as being limited to non-human organisms that comprise host cells having a gene expression modulation system wherein the gene to be modulated is limited only to genes which neither result in nor cause any suffering. In the board's view, "any gene of interest" comprises also genes of a nature such as the transgene (oncogene) used in the transgenic mouse of the claims underlying decision T 315/03 (*supra*). Therefore, for this reason alone and contrary to the decision of the opposition division, the board is of the opinion that, in analogy with decision T 315/03 (*supra*), the likelihood of

animal suffering is established in the present appeal.

19. Indeed, in the present case, as acknowledged by the parties and the opposition division, the nature of the "gene of interest" is similar to that of the gene in the gene trapping construct of the transgenic mouse of the claims underlying decision T 606/03 (*supra*). In that case, the board considered that, since the gene trapping construct was inserted in the genome in a mutagenic manner, the modification of the genetic identity of the animal - "in instances where the mutated gene is an essential one" - was likely to result in suffering of the mutated mouse (cf. T 606/03, *supra*, point 2 of the Reasons). It was only by introducing into the claims of a second auxiliary request "a key technical feature of the claimed invention" - so that "the claimed mice did not suffer from the presence of the gene trap construct in their genome" - that the balancing test of Rule 28(d) EPC did not apply anymore (cf. T 606/03, *supra*, point 12 of the Reasons). In the present appeal, claim 45 requires the host cell to "comprise the gene expression modulation system according to claim 12", there is no limitation regarding the method for "introducing" the gene expression modulation system according to claim 12 into the host cell (see claims 36 and 39), let alone on its genomic location. Therefore, in the board's view, the scope of these claims allows for **any** possible method for introducing the gene expression modulation system into the genome of the animal as well as the introduction of this gene expression modulation system at **any** possible genomic location, including into an essential gene.

19.1 In the board's view, the considerations made in points 18.1 to 18.3 above as regards the case law and the generic nature of the gene of interest, apply also

to the method for introducing the gene modulation expression system into the host cell and to the genomic location of the gene modulation expression system introduced into the non-human transgenic organism.

19.2 In the light thereof, the board is of the opinion that the scope of claims 48 to 53 cannot be interpreted as being limited to those non-human organisms that comprise a gene expression modulation system introduced into a genomic location which does not result or cause any suffering. In the board's view, "any method of introduction" and "any genomic location" comprise methods and locations such as those referred to for the gene trapping construct used in the transgenic mouse of the claims underlying decision T 606/03 (*supra*). Therefore, contrary to the decision of the opposition division, the board is of the opinion that, in analogy with decision T 606/03 (*supra*), the likelihood of animal suffering is also established in the present appeal for this reason alone.

20. Although, as argued by the respondent, "the gene expression modulation system according to claim 12" may avoid some side effects compared to other gene switch systems known in the art (cf. paragraph [0125] of the patent) and this gene expression modulation system may also be introduced into targeted genomic regions by (unidirectional, irreversible) recombination technology, the scope of claims 48 to 53 is broader and not limited thereto. The subject-matter of these claims is limited neither to a particular technology nor to specific applications but to "a non-human organism" in general. In view of all these considerations, it is not necessary for the board to assess in detail the contents of documents (1), (5) and (6) concerned with the likelihood of transgenic animal suffering in general.

The likelihood of substantial medical benefit

21. As regards the likelihood of a substantial medical benefit, the opposition division referred to the broad definition of the substantial medical benefit on recital 45 of Directive 98/44/EC of the European Parliament and Council of 6 July 1998 on the legal protection of biotechnology inventions (cf. page 14, first paragraph of the decision under appeal). However, reference was also made to the narrower criteria established in decisions T 315/03 (*supra*, point 12.2.3 of the Reasons) and T 606/03 (*supra*, point 3 of the Reasons) and, accordingly thereto, the opposition division stated that (i) it must be established that "the likely substantial medical benefit is indeed directly related to the claimed invention rather than depending on other previous research" and that (ii) "any such benefit could be derived from all animals claimed" (cf. two last full paragraphs on page 14 of the decision under appeal). The opposition division did not further perform this assessment or analysis because it considered that, in the absence of a likelihood of animal suffering, the "balancing test" required by Rule 28(d) EPC was not pertinent.

22. Since the board, contrary to the opposition division, is of the opinion that there is a likelihood of animal suffering and that, accordingly, the "balancing test" required by Rule 28(d) EPC is pertinent, the consequences of applying the narrower criteria established in the case law are certainly relevant to the present appeal. Whilst, in the board's view, the first criterion referred to by the opposition division applies to, and is an essential part for, assessing the likelihood of a substantial medical benefit of the claimed invention, the second criterion is dealt with under the correspondence principle (*infra*).

23. It is not contested that the likelihood of a substantial medical benefit in general can at the very least be inferred from the patent itself, the applications referred to in paragraphs [0035], [0162] and [0194] of the patent, such as gene therapy and "the regulation of traits in transgenic organisms, where control of gene expression levels is desirable". The relevance of transgenic animals as advantageous models for, *inter alia*, drug discovery, functional genomics and proteomic analysis, is well-known in the art and not in dispute in the present appeal. In the board's view, the situation is somewhat similar to that for establishing a likelihood of animal suffering. If such a likelihood cannot be based on an alleged suffering of a generic transgenic animal or transgenic animals in general, the likelihood of a substantial medical benefit can likewise not be based on a medical benefit derived from animal models in general.

24. It is also not contested that, at the very least for some exemplary applications, a non-human transgenic animal comprising (host) cells with a gene expression modulation system according to claim 12 may provide a substantial medical benefit. This is not the relevant question in the present appeal. The key question appears to be whether, based on the contents of the patent, it can be unambiguously and directly derived that, in case of suffering of the claimed non-human transgenic animals, there is always a substantial medical benefit either as a result of the specific gene to be modulated, the particular mode of introduction of the gene expression modulation system and/or the genomic location(s) of such an introduction.

25. In the present appeal, in view of the evidence on file, the broad scope of claims 48 to 53, in particular, the generic nature of the gene to be modulated (cf. paragraphs [0161] and [0193] of the patent) and the

purpose of non-human transgenic animal models in general (cf. T 606/03, *supra*, last sentence of point 3 of the Reasons), the board is of the provisional opinion that the key question set out in paragraph 24 above is to be answered negatively.

The correspondence principle

26. According to the criteria established in decision T 315/03 for assessing the evidence in the Rule 28(d) EPC test, a **correspondence** is required between suffering and medical benefit, i.e. Rule 28(d) EPC "should be applied to ensure that any patent should only extend to those animals whose suffering is balanced by a medical benefit" (cf. T 315/03, *supra*, point 9.2 of the Reasons). As regards the nature of the evidence, the board stated in that decision that the evidence as to the relevant matters, i.e. the likelihood of both, suffering and substantial medical benefit, and the necessary correspondence between the two, must be directed to those matters **at the effective date** (cf. T 315/03, *supra*, points 9.5 and 9.6 of the Reasons).

27. The claims of the main request underlying decision T 315/03 were directed to a transgenic rodent (cf. T 315/03, *supra*, point 12 of the Reasons). The request embraced all animals within the taxonomic order *Rodentia* and the suffering was considered to be present in the case of every such animal, not just mice but also squirrels, beavers, porcupines and every other rodent (T 315/03, *supra*, point 12.2.1 of the Reasons). In that case, the board considered that there was "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".

Therefore, the board considered the main request to fail the balancing test of Rule 28(d) EPC and refused it under Article 53(a) EPC (cf. T 315/03, *supra*, points 12.2.2 to 12.2.4 of the Reasons).

28. In the present appeal, claims 48 to 53 are not limited to any taxonomic order but embrace any (non-human, transgenic) organism and thus, include all possible animal taxonomic orders, domains, kingdoms, phyla, classes, genera and species. In view of the broad scope of these claims, the board is of the opinion that the evidence on file does not support, and is not enough to demonstrate, that for each of all possible (non-human, transgenic) animals, when suffering occurs, a substantial medical benefit is necessarily provided for the purpose of the balancing test of Rule 28(d) EPC.

29. It is worth noting the opposition division's reference to decision G 1/98 (OJ EPO 2000, 111, point 3.3.3 of the Reasons). Based on considerations in relation to Article 83 EPC made in that decision, the opposition division considered that, for the purpose of Article 53(a) EPC, if a claim covers both allowable and non-allowable embodiments, the claim is not excluded under Article 53(a) EPC, unless the non-allowable embodiments are explicitly claimed (cf. page 13, second paragraph of the decision under appeal). The board does not agree with the opposition division on this issue. Whilst, under certain conditions, occasional failures may not impair the reproducibility of a claimed subject-matter (cf. "Case Law", *supra*, II.C.6.6.1, 364), sufficiency of disclosure presupposes that the skilled person is able to obtain **substantially all** embodiments falling within the scope of the claims (cf. "Case Law", *supra*, II.C.5.4, 357). Likewise, for the purpose of Article 56 EPC, if inventive step of a claimed invention is based on a given technical effect, the latter should, in principle, be achievable over the

whole area claimed (cf. "Case Law", *supra*, I.D.9.8.3, 250). In the board's view, the same criterion applies to the correspondence principle that must be evaluated under the balancing test of Rule 28(d) EPC.

Conclusion

30. It follows from the above considerations that the subject-matter of claims 48 to 53 fails the balancing test of Rule 28(d) EPC.

The second test - the "real" Article 53(a) EPC test

31. Although, in view of the above conclusion on the Rule 28(d) EPC test, there is no further need for the board to carry out the "real" Article 53(a) EPC test, the attention of the parties is nevertheless drawn to the following points:

31.1 It appears to be common ground between the parties that, in line with decision T 315/03 (cf. *supra*, points 10.5 to 10.10 of the Reasons), the starting point for carrying out the "real" test is the test suggested in decision T 19/90 (*supra*). It is however worth noting that, in decision T 315/03, the board referred to the introduction of other considerations in the starting test, either by way of adapting it or by broadening its framework (cf. point 10.7 of the Reasons), and, accordingly, the board further referred to the evidence required and to the effective date for carrying out this test (cf. point 10.9 of the Reasons).

31.2 Although the considerations laid out in decisions T 315/03 and T 606/03 were made at a latter date (6 July 2004 and 12 January 2005, respectively) than the effective date of the present case (date of the first priority: 20 February 2001), the subject-matter to be tested in the present case is the morality and

"ordre public" of the publication or exploitation of non-human transgenic animals in general and not of a particular transgenic mouse, as it was the case for the subject-matter underlying the decisions T 315/03 and T 606/03 (cf. T 315/03, *supra*, point 13.2.2 of the Reasons; T 606/03, *supra*, points 14 and 15 of the Reasons). The different scope of the claimed subject-matter must certainly be taken into account when assessing the relevance of all issues that must be considered when carrying out the "real" test, such as, for instance, environmental risks, threat to evolution, and public attitudes and public's perception of genetic manipulation of animals in general (cf. T 315/03,*supra*, points 13.2.8 to 13.2.13 *et seq*. of the Reasons).

31.3 In the board's view, the scope and subject-matter of claims 48 to 53 may be allowed only by disregarding or ignoring the facts and events of the (examination and opposition) proceedings underlying decisions T 19/90, T 315/03 and T 606/03 which resulted, in all of them, in a limitation of the claimed subject-matter to particular transgenic mice (cf. point 13.2 *supra*).

32. If, contrary to the provisional opinion expressed above, the board comes to a different conclusion on the Rule 28(d) EPC test, it will be then necessary to assess whether the subject-matter of claims 48 to 53 fails the "real" Article 53(a) EPC test. In the light of the actual scope of these claims, the board is of the provisional opinion that these claims cannot pass this test.

Article 100(b) EPC; Article 83 EPC

33. In view of the board's conclusions on Article 53(a) EPC and Rule 28(d) EPC, there is no need to assess, at this stage of the proceedings, appellant's objection raised under this article, nor to examine the reasons given by

the respondent for acknowledging claims 48 to 53 to fulfil the requirements of this article. Should the board come to a different conclusion on Article 53(a) EPC and Rule 28(d) EPC, it will be then necessary to assess whether these claims fulfil the requirements of Article 83 EPC.

Auxiliary request 1

Admission into the appeal proceedings

34. Auxiliary request 1, filed by the respondent in reply to the appellant's statement of grounds of appeal, is identical to the auxiliary request 1 originally filed in a letter dated 26 August 2013. According to the respondent, auxiliary request 1 is identical to the main request except for the amendments introduced into claims 48-49 and 51-52. Since the opposition division decided in the respondent's favour on the main request, there was no need for the opposition division to decide on the admissibility and patentability of auxiliary request 1. Accordingly, there is no reference to this request in the decision under appeal.

35. According to the case law, the mere fact of filing an auxiliary request at the first instance cannot serve as a justification for automatically admitting it into the appeal proceedings, especially when its admission has not even been examined at first instance (cf. T 217/15 of 14 March 2019, point 39.2 of the Reasons; T 105/14 of 12 April 2019, points 3 to 12 of the Reasons). There are no submissions on file from the appellant as regards the admission and patentability of this request. Should the board maintain its provisional opinion on the main request, the admission of auxiliary request 1 into the proceedings will be discussed.

36. For the sake of efficiency and without prejudice to any decision on the admission of this auxiliary request

into the appeal proceedings, the parties' attention is drawn to the following issues:

Article 123(3) EPC

37. Whilst claims 48-50 and claims 51-53 as granted require the claimed organism to comprise the host cell of granted claim 45 which is characterised by comprising the gene expression modulation system according to granted claim 12, claims 48 to 50 of auxiliary request 1 require the claimed organism to comprise the host cell of claim 42 which is characterised by comprising the gene expression modulation system of claim 1. The first and second gene expression cassettes characterising the gene expression modulation systems of claims 1 and 12 are different and thus, the subject-matter of claims 48-50 of auxiliary request 1 extends beyond the subject-matter of the granted claims. Therefore, auxiliary request 1 appears to contravene Article 123(3) EPC.

Article 123(2) and 84 EPC

38. Basis for the amendments has been indicated on page 34, lines 1-6 and page 38, lines 15-17 of the patent application. The disclosure on these pages is of "the gene whose expression is to be modulated" which is the amendment introduced into claims 49 and 52 of auxiliary request 1; the subject-matter of these claims being further limited to a non-human animal or mammal.

39. Claims 49 and 52 refer to a gene whose expression is to be modulated as being "a gene encoding a therapeutically desirable polypeptide or a product that may be used to treat a condition ...". There is no definition or characterisation in these claims of said "product" and "condition" nor does such a definition appear to have been given in the description of the

patent. It appears thus to be open to interpretation whether this product might be a (short) peptide, mRNA, non-coding RNA, etc. and likewise, whether the conditions might be a condition which does not cause disease, harm or death to the claimed non-human animal or mammal. Indeed, the condition might even be understood as a beneficial condition and, accordingly, a treatment for increasing, enhancing and/or improving such a condition. Thus, both terms and their combination are open to interpretation and ambiguous (Article 84 EPC). Moreover, it is questionable whether these embodiments are supported by the technical teaching of the patent application (Article 83 EPC in combination with Article 84 EPC; cf. "Case Law", *supra*, II.C.8, 385).

Article 53(a) EPC, Rule 28(d) EPC

40. The scope of claims 48 and 51 has been limited to "non-human organisms ... selected from the group consisting of a bacterium, a fungus, and yeast". These claims overcome the objections raised against the main request under Article 53(a) EPC and Rule 28(d) EPC. This does not appear to be the case for claims 49 and 52 which are directed to non-human (transgenic) animals and non-human (transgenic) mammals in general. The broad subject-matter of these claims appears to fail both, the balancing test under Rule 28(d) EPC and the "real" Article 53(a) EPC test. It is questionable whether this is also the case for claims 50 and 53.

Summary and conclusions

41. For convenience, the board summarises the main points of this communication as follows:

i) the opposition and the appeal appear to be admissible;

ii) the board is minded not to admit any of the new documentary evidence filed in appeal proceedings (Article 114(2) EPC and Article 12(4) RPBA);

iii) the main request (claims as granted) appears to contravene Article 53(a) EPC in combination with Rule 28(d) EPC (Article 100(a) EPC);

iv) if necessary, the admission of auxiliary request 1 into the appeal proceedings will be discussed at the oral proceedings;

v) auxiliary request 1 appears to contravene Articles 123(3) and 84 EPC as well as Article 83 EPC in combination with Article 84 EPC; auxiliary request 1 also appears to contravene Article 53(a) EPC in combination with Rule 28(d) EPC.

42. Since both parties have requested oral proceedings, the board issues a summons thereto.

43. The parties are asked to inform the board, and also the other party, as early as possible and in unambiguous way, if they intend not to attend the scheduled oral proceedings.