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Datasheet for the decision of 5 July 2018

T 2435/13 - 3.3.04 Case Number:

Application Number: 03766293.9

Publication Number: 1525317

IPC: C12N15/82, A01H1/00, C12N15/11

Language of the proceedings: ΕN

Title of invention:

Clubroot resistant Brassica oleracea plants

Applicant:

Syngenta Participations AG

Headword:

Clubroot resistant plants/SYNTGENTA

Relevant legal provisions:

EPC Art. 53(b), 84, 111

Keyword:

Main request and auxiliary requests 1 and 2 - essentially biological process for the production of plants (yes) Auxiliary requests 3 to 5 - clarity (no) Remittal to the department of first instance (yes)

Decisions cited:

G 0002/07, G 0001/08

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 2435/13 - 3.3.04

DECISION
of Technical Board of Appeal 3.3.04
of 5 July 2018

Appellant: Syngenta Participations AG

(Applicant) Schwarzwaldallee 215

4058 Basel (CH)

Representative: Syngenta International AG

CHBS-B4.8

Schwarzwaldallee 215 4058 Basel (CH)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 9 July 2013 refusing European patent application No. 03766293.9 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairwoman G. Alt Members: B. Claes

P. de Heij

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Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division to refuse European patent application No. 03 766 293.9. The application was published as international application No. WO2004/013334 with the title "Clubroot resistant Brassica oleracea plants".
- II. The examining division held that the subject-matter of claim 1 of the main request and auxiliary requests 1 and 3 to 5 was excluded from patentability pursuant to Article 53(b) EPC as it constituted an essentially biological process for the production of plants.

 Claim 1 of auxiliary request 2 lacked clarity (Article 84 EPC).
- III. With the statement of the grounds of appeal the appellant re-submitted the main request, filed new auxiliary requests 1 to 6 and submitted arguments to the effect that the subject-matter of claim 1 of all the requests was not excluded from patentability pursuant to Article 53(b) EPC.

Claim 1 of the main request read:

- "1. A method for producing a *B. oleracea* plant comprising a monogenic and dominant resistance to clubroot comprising the steps of:
 - a) obtaining a *B. rapa* plant resistant to clubroot comprising a monogenic and dominant resistance to clubroot;
 - b) crossing said B. rapa plant with a B. oleracea plant,
 - c) rescuing embryos resulting from the cross of step b);
 - d) regenerating a plant from a embryo of step c);

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- e) selecting a plant of step d) that is resistant to clubroot comprising a monogenic and dominant resistance to clubroot;
- f) back-crossing a plant resulting from step e)
 with a B. oleracea plant;
- g) rescuing embryos resulting from the back-cross of step f); and
- h) selecting a plant of step g) that is resistant to clubroot comprising a monogenic and dominant resistance to clubroot."

Claim 1 of auxiliary request 1 was identical to claim 1 of the main request except for the addition of the wording "wherein parent plants used in the cross are sexually incompatible" at the end of the claim.

Claim 1 of auxiliary request 2 read:

- "1. A method for producing a *Brassica oleracea* plant comprising a monogenic and dominant resistance to clubroot comprising the steps of:
 - a) transferring pollen of a *B. rapa* plant comprising a monogenic and dominant clubroot resistant phenotype by interspecific hybridization to a *B. oleracea* plant and fertilizing that plant,
 - b) isolating and rescuing embryos resulting from the fertilized B. oleracea plant of step a);
 - c) regenerating a plant from the embryo of step b);
 - d) selecting a B. oleracea plant resistant to clubroot;
 - e) back-crossing a plant resulting from step d)
 with a B. oleracea plant;
 - f) rescuing embryos resulting from the back-cross of step e); and

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g) selecting a *B. oleracea* plant of step f) that is resistant to clubroot comprising a monogenic and dominant resistance to clubroot."

Claim 1 of auxiliary request 3 read:

"1. A method of using embryo rescue of an embryo comprising the genetic background of a B. rapa plant comprising a monogenic and dominant resistance to clubroot and a B. oleracea to complete transfer of the monogenic and dominant resistance to clubroot from B. rapa to B. oleracea to obtain a clubroot resistant F1 hybrid of a B. rapa plant and of a B. oleracea plant and transfer of the monogenic and dominant resistance to clubroot from a F1 hybrid of a B. rapa plant and of a B. oleracea plant and of a B. oleracea plant to a B. oleracea plant to obtain a BC1 plant, and testing the resulting F1 hybrid and BC1 plant, respectively, for resistance to clubroot."

Claim 1 of auxiliary request 4 read:

"1. Use of embryo rescue of an embryo comprising genetic background of a *B. rapa* plant and a *B. oleracea* plant to complete transfer of the monogenic and dominant resistance to clubroot from *B. rapa* to *B. oleracea* to obtain a clubroot resistant *B. oleracea* plant comprising a monogenic and dominant resistance to clubroot."

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Claim 1 of auxiliary request 5 read:

"1. Use of embryo rescue to enable the expression of a monogenic and dominant resistance to clubroot in a B. oleracea plant comprising a monogenic and dominant resistance to clubroot from a clubroot resistant B. rapa plant."

Claim 1 of the five claims of auxiliary request 6 read:

- "1. A method for identifying a F1 hybrid plant comprising a monogenic and dominant resistance to clubroot resulting from a cross of a *B. rapa* plant resistant to clubroot comprising a monogenic and dominant resistance to clubroot with a *B. oleracea* plant, comprising the steps of:
 - a) rescuing embryos comprising a monogenic and dominant resistance to clubroot;
 - b) regenerating a plant from the embryo of step a) to obtain the F1 hybrid plant;
 - c) testing the plant obtained in step b) for resistance to clubroot."

Claims 2 to 5 of this request were dependent on claim 1.

IV. In a communication pursuant to Article 15(1) RPBA the board set out its preliminary opinion that the subject-matter of claim 1 of the main request and new auxiliary requests 1 and 2 was excluded from patentability by virtue of Article 53(b) EPC as it constituted an essentially biological process for the production of plants and that claim 1 of new auxiliary requests 3 to 5 lacked clarity (Article 84 EPC).

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The board furthermore stated its preliminary opinion that claim 1 of new auxiliary request 6 complied with the requirements of Articles 84 and 123(2) EPC and its subject-matter was not excluded from patentability by virtue of Article 53(b) EPC. The board envisaged remitting the case to the examining division for further prosecution on the basis of the latter request.

- V. In preparation for the oral proceedings the appellant submitted further arguments to the effect that the subject-matter of claim 1 of all requests was not excluded from patentability pursuant to Article 53(b) EPC, and an explanatory scheme of the claimed method as an annex.
- VI. At the oral proceedings the appellant was heard on the pertinent issues. At the end of the oral proceedings the chair announced the decision of the board.
- VII. The appellant's arguments may be summarised as follows:

Main request - claim 1 - essentially biological process for the production of plants (Article 53(b) EPC)

The decisions in consolidated cases G 2/07 and G 1/08 of the Enlarged Board of Appeal (EBA) dealt with the question of whether conventional methods for the breeding of plant varieties should be excluded from patentability under Article 53(b) EPC. The decisions specified in the third paragraph of point "6.4.2.3 Conclusions" that "These conventional methods included in particular those (relevant for the present referrals) based on the sexual crossing of plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired traits", and the sexual crossing of

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whole genomes was subsequently said to be "characterized by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis".

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Throughout point "6.4.2.3 Conclusions" and in answers 1 and 2 formulated by the EBA in the order of its decisions G 2/07 and G 1/08 (hereinafter referred to further as "answer 1 and answer 2 of decisions G 2/07 and G 1/08"), the decisions consistently referred to "sexually crossing the whole genomes of plants" as being the key criteria for determining whether a process for the production of plants was "essentially biological" and thus excluded from patentability or not.

The expression "sexually crossing the whole genomes of plants" emphasised that the conventional breeding processes referred to in the two decisions of the EBA were construed as being those involving meiotic recombination events throughout the whole genome during the pairing of homologous chromosomes.

The F1 embryo obtained by step b) of the claimed method comprised a juxtaposition of the ten A-chromosomes of Brassica rapa and the nine C-chromosomes of Brassica oleracea, which were not homologous to each other. This embryo was not viable and required embryo rescue and regeneration.

The meiosis in the regenerated F1 plant (grown from the rescued embryo) which preceded the back-crossing step f) of the claimed method was distorted. Indeed, since the A- and C-chromosomes were not homologous and did not pair with each other, only very few homologous recombination events took place over only very limited

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parts of their respective genomes (one being the required transfer of the clubroot resistance trait from A-genome to C-genome).

Furthermore, the genomes of the first generation of back-crossed plants (BC1 plants) produced in steps f) to h) of the claimed method could range from a CC-genome (2n=18, i.e. no Brassica rapa A-chromosome derived from the F1 plant present in the BC1 progeny) to an ACC-genome (2n=28, i.e. all Brassica rapa A-chromosomes derived from the F1 plant present in the progeny). In the former case, it was literally impossible to state that the whole genomes had been sexually crossed since no A-chromosomes were retained in the produced plant.

Accordingly, since only partial homologous recombination on limited portions of the respective genomes took place, the claimed method was not directed to a process for the production of plants involving sexually crossing the whole genomes of plants as referred to in answer 1 of the decisions G 2/07 and G 1/08. Consequently, decisions G 2/07 and G 1/08 did not apply and the claimed subject-matter did not fall within the exceptions of Article 53(b) EPC.

Even if the decisions were applicable, the claimed method fell into the category of methods referred to in answer 3 of decisions G 2/07 and G 1/08, and was therefore not excluded from patentability under Article 53(b) EPC.

In fact, the embryo rescue steps in the claimed method were carried out after the crossing steps, i.e. after the zygote had been produced, and before the selection was conducted. Consequently, the embryo rescue steps

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per se enabled or assisted neither the crossing step - as e.g. a new pollination technique would - nor the selection step - as e.g. molecular markers would. The embryo rescue steps of the claimed method could therefore not be characterised as steps of a technical nature which served to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants. The claimed method therefore did not fall under the ruling formulated in answer 2 of decisions G 2/07 and G 1/08.

The embryo rescue steps were rather contained within the steps of sexually crossing and selecting plants and were mandatory prerequisite steps for the clubroot resistance trait to be introduced from *Brassica rapa* into the genome of the plant produced. Consequently, answer 3 of decisions G 2/07 and G 1/08 applied to the present case and the claimed process was not excluded from patentability under Article 53(b) EPC.

Auxiliary requests 1 and 2 - claim 1 - essentially biological process for the production of plants (Article 53(b) EPC)

If the board were to conclude that the subject-matter of claim 1 of the main request was excluded from patentability by virtue of Article 53(b) EPC, then auxiliary requests 1 and 2 could not overcome the obstacle with regard to the patentability of the claimed method.

Auxiliary requests 3 to 5 - claim 1 - clarity (Article 84 EPC)

No submissions were made with regard to these requests.

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Auxiliary request 6 - claim 1

The claim did not relate to a method excluded from patentability by virtue of Article 53(b) EPC.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, on the basis of the set of claims of one of the auxiliary requests 1 to 6, all filed with the statement of the grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

Introduction - The invention described in the application

- 2. Disclosed in the application (see e.g. page 2, lines 6 to 15, page 10, line 5 to page 11, line 2, example 1) is the transfer of a monogenic dominant resistance to clubroot from Chinese cabbage (Brassica rapa) to initially broccoli (B. oleracea) and then further to other B. oleracea cole-crop forms such as white cabbage, cauliflower and Brussels sprouts.
- 3. The resistance to clubroot was transferred from *B. rapa* to *B. oleracea* by means of an interspecific cross (hybridisation) followed by embryo rescue of the hybrid F1 progeny. Clubroot-resistant F1 progeny plants were then used for repeated backcrossing to *B. oleracea* and disease tests in all backcross generations. Plants resulting from the first backcross (BC1 progeny) were also recovered by embryo rescuing.

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- 4. Embryo rescue which techniques as such were known in the art to obtain the F1 (and BC1) progeny after the interspecific cross is necessary in order to overcome the sexual incompatibility between B. rapa and B. oleracea due to the different number of chromosomes (n=10 or 9, respectively) in the two species. Embryo rescue in fact allows the problems of the non-viability of the embryo due to degradation of the endosperm in the seeds comprising the F1 embryos (10 + 9 chromosomes) to be overcome.
- 5. The method of the invention allows *B. oleracea* plants with a high level of resistance to clubroot to be produced whereby the resistance is stable and can be transmitted to further generations and transferred to susceptible or less resistant *B. oleracea* plants.

Main request - claim 1 - essentially biological process for the production of plants (Article 53(b) EPC)

- 6. Article 53(b) EPC states that "European patents shall not be granted in respect of (b) ... essentially biological processes for the production of plants ...; this provision shall not apply to microbiological processes ...".
- 7. In the decisions of consolidated cases G 2/07 and G 1/08 (OJ EPO 2012, 130 and 206) the Enlarged Board of Appeal (EBA), after having extensively revised the legislative history of the provision, held that "It must be concluded that the legislator's intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those (relevant for the present referrals) based on the

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sexual crossing of plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). The application of technical means or other forms of human intervention in such processes which helped to perform them was already common. Nevertheless, the said processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder's selection of plants having the desired trait(s). That these were processes to be excluded also follows from the fact that processes changing the genome of plants by technical means such as irradiation are cited as examples of patentable technical processes" (see third paragraph of point "6.4.2.3 Conclusions"; emphasis added by the board).

- 8. In accordance with this conclusion the EBA formulated answer 1 of the decisions G 2/07 and G 1/08 as follows:

 "A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC" (emphasis added by the board).
- 9. The appellant argued in a <u>first line of argument</u> that the claimed method was not a process for the production of plants which the EBA considered to be in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, as it did not involve sexually crossing the whole genomes

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of plants. By emphasising that conventional breeding processes involved sexual crossing of whole genomes, the EBA construed such processes as being those involving meiotic recombination events throughout the whole genome during the pairing of homologous chromosomes. However, the claimed process did not fall into this category since only partial homologous recombination on limited portions of the respective genomes could take place in the circumstances of the claimed method.

- 10. The board cannot concur with the appellant's first line of argument. It cannot see any reason to infer from the conclusion of the EBA referred to above (see point 7), or from the further content of the two decisions, that the EBA construed the methods based on "sexually crossing the whole genomes of plants" to be limited to merely those methods involving meiotic recombination events throughout the whole genome during perfect pairing of homologous chromosomes in the process of meiosis.
- 11. Indeed, the board considers that, in fact, it can rather be inferred from the conclusion quoted in point 7 above that the EBA considered all methods containing or consisting of steps of sexually crossing the whole genome of plants and the subsequent selection of plants, regardless of those plants being sexually incompatible or not, to be excluded from patentability. In the board's view this is so since it was decisive for the EBA that in such processes, in contrast to other processes to change the genome of plants, such as e.g. irradiation (see the end of the quote in point 7), the genetic make-up of the plants resulting from the cross is determined by the result of the meiosis in the parent plants.

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- 12. The board considers that it is in this context that the qualification of the term "sexual crossing of plants" by the wording "(i.e. of their whole genomes)" is to be understood, i.e. the natural phenomena of meiosis determine the genetic make-up of the respective gametes, based on the whole genome of the parent plants, which in turn determines the genetic make-up of the plants resulting from the cross.
- 13. The board considers that it is in this context also that the term "sexually crossing the whole genomes of plants" in answer 1 of decisions G 2/07 and G 1/08 is to be read and understood.
- 14. As the claimed method explicitly involves sexually crossing plants (steps (b) and (f)), involving gamete formation by meiosis based on the whole genome of the parent plants, and subsequent selection of plants (steps (e) and (h)), the board judges that it constitutes a process which the EBA considered excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, as formulated in answer 1 of decisions G 2/07 and G 1/08.
- In a <u>second line of argument</u> the appellant held that, if the board were to decide as above that the claimed method constituted a method as defined in answer 1 of decisions G 2/07 and G 1/08, then the claimed method constituted such a process as defined in answer 3 of decisions G 2/07 and G 1/08 and was accordingly not excluded from patentability under Article 53(b) EPC. In fact, the embryo rescue steps were contained within the steps of sexually crossing and selecting of plants defined in the claim and were mandatory prerequisite steps for the clubroot

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resistance trait to be introduced from *Brassica rapa* into the genome of the plant produced. Consequently, answer 3 in decision G 2/07 applied to the present case and the claimed subject-matter did not fall within the exceptions of Article 53(b) EPC.

- 16. In answer 3 of decisions G 2/07 and G 1/08 the EBA held that "[i]f, however, such a process [note: in this case the process defined in answer 1; see point 8 above] contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC" (emphasis added by the board).
- The board concurs with the appellant that the embryo rescue steps in the claimed method, which are as such of a technical nature, are contained within the steps of sexually crossing and selecting. However, the embryo rescue steps by themselves do not introduce the clubroot resistance trait into the genome of the plants produced and the appellant has not argued so. Rather, the introduction of the clubroot trait into the genome of the plants produced is the result of the mixing of the genomes of the plants chosen for the sexual crossing upon the production of the respective gametes by meiosis (see point 12 above).
- 18. Hence, the claimed method is not a process as referred to in answer 3 of decisions G 2/07 and G 1/08.

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19. Accordingly, in view of the above considerations the claimed subject-matter is excluded from patentability for being an essentially biological process within the meaning of Article 53(b) EPC.

Auxiliary requests 1 and 2 - claim 1 - essentially biological process for the production of plants (Article 53(b) EPC)

- 20. Neither the specification in claim 1 of auxiliary request 1 that the "parent plants used in the cross are sexually incompatible" nor the specification in claim 1 of auxiliary request 2 that the cross constitutes "interspecific hybridization" are considered by the board to result in claimed methods to which the reasons applying to claim 1 of the main request do not apply mutatis mutandis and which could thus potentially escape the exclusion of Article 53(b) EPC.
- 21. Also the appellant has submitted that the methods claimed in auxiliary requests 1 and 2 could not overcome the obstacle with regard to patentability of the claimed method in the main request.
- 22. The methods of claim 1 of auxiliary requests 1 and 2 are accordingly held to be excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.

Auxiliary requests 3 to 5 - claim 1 - clarity (Article 84 EPC)

23. Claim 1 of auxiliary request 3 (see section III) is for "A method of using embryo rescue of an embryo" to complete transfer of the resistance to clubroot from one plant to another to obtain a clubroot resistant F1 hybrid plant and transfer the resistance to clubroot from the F1 hybrid plant to another plant to obtain a

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BC1 plant and testing the F1 and BC1 plant for resistance to clubroot.

- 24. The board considers it unclear whether the subjectmatter of a claim for "A method of using embryo rescue
 of an embryo" is a method (or a process) and results in
 a product or whether it is a use and does not result in
 a product. Hence, the category of the claim is
 ambiguous and therefore the claim lacks clarity.
- The board considers further that the combination of the feature "a method of using embryo rescue of an embryo" with the feature "to complete transfer of the monogenic and dominant resistance to clubroot from B. rapa to B. oleracea and transfer of the monogenic and dominant resistance from a F1 hybrid (...) to a B. oleracea plant to obtain a BC1 plant" is not understood by the skilled person in view of their technical knowledge that an embryo rescue step itself has no direct technical causative relation with the introgression of the clubroot resistance from B. rapa to B. oleracea (see point 16, above).
- 26. In view of these considerations the board considers that claim 1 of auxiliary request 3 does not comply with the requirements of Article 84 EPC.
- 27. Similar considerations as in point 25 above apply to a "use of embryo rescue of an embryo"-claim in relation to the feature "to complete transfer of the monogenic and dominant resistance to clubroot from B. rapa to B. oleracea to obtain a clubroot resistant B. oleracea plant comprising a monogenic and dominant resistance to clubroot" (auxiliary request 4) and the feature "use of embryo rescue" in relation to the feature "to enable the expression of a monogenic and dominant resistance

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to clubroot in a *B. oleracea* plant" (auxiliary request 5) as a direct causative relationship of embryo rescuing and the other technical feature referred to is not given and not understood by the skilled person.

- 28. The board holds therefore that claim 1 of auxiliary request 4 and 5 accordingly does not comply with the requirements of Article 84 EPC.
- 29. The above considerations and findings had been communicated to the appellant in the communication of the board (see section IV). The appellant had refrained from commenting on them.

Auxiliary request 6 - claim 1

- 30. Claimed is a method for identifying F1 hybrid plants resulting from a cross of a clubroot-resistant *B. rapa* plant with a *B. oleracea* plant which comprise resistance to clubroot, by testing F1 hybrid plants obtained by rescuing embryos resulting from the cross and regenerating plants therefrom for resistance to clubroot.
- 31. The board is satisfied that a method for identifying progeny plants obtained by a cross of parent plants of which one comprises a resistance to clubroot by testing the progeny plants for the clubroot resistance does not read on a process for the production of plants, let alone on such a process which is essentially biological within the meaning of Article 53(b) EPC.
- 32. Hence, in view of the above considerations the board holds that this method is not excluded from patentability by virtue of Article 53(b) EPC.

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Remittal of the case to the examining division for further prosecution

- 33. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.
- 34. The board considers that a case like the present one, in which amendments have been proposed by the appellant in auxiliary request 6 which limit the requests to subject-matter on which the examining division has not expressed an opinion or issued a decision, gives rise to fresh issues which require further examination in relation to both the formal and substantive requirements of the EPC. The board considers it appropriate in these circumstances that the further examination should be carried out by the examining division.
- 35. The board foreshadowed this procedural step in the communication annexed to the summons to oral proceedings and the appellant consented to it in the oral proceedings.
- 36. Under the circumstances the board therefore considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the examining division for further prosecution.

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Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- The case is remitted to the examining division for further prosecution on the basis of auxiliary request 6, filed with the statement of the grounds of appeal.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated