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URGENT

CONFIDENTIAL

WILL NOT BE CONFIRMED

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APPEAL n° T0083/05-3304
APPEAL AGAINST MAINTENANCE OF EP-B-1 069 819 (99915886.8)

URGENT : ORAL PROCEEDINGS SCHEDULED FOR 4TH MAY 2006

Enclosures:	Pages:
Letter	1
Observations	11
Form 1037	1
Cover page.....	1
Total.....	14

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For the attention of Board of Appeal 3.3.04.

Your ref.: T0083/05-3304
Our ref.: LB220 - CA – Opponent OII
Lyon, 4th April 2006

ORAL PROCEEDINGS SCHEDULED FOR 4TH MAY 2006

RE: **APPEAL N° T0083/05-3304**
EP-B-1 069 819 IN THE NAME OF PLANT BIOSCIENCE LTD
APPEAL FILED BY OPPONENT OII, GROUPE LIMAGRAIN HOLDING,

Dear Sirs,

Further to the Summons to Oral Proceedings dated 15th February 2006, we hereby file final observations on behalf of Opponent OII, Groupe Limagrain Holding.

We would also like to inform the Board that we intend to use the English language during the Oral Proceedings of 4th May 2006 and will require simultaneous interpretation if any of the parties intend to use German.

Copy of our submissions is being sent directly to Patentee and Opponent OI.

Yours faithfully,

Carol ALMOND-MARTIN
Professional representative
Before the European Patent office

Enc. Observations
Form 1037

BREVETS

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T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OI)

4.04.06

T0083 / 05 - 3.3.4.
European Patent EP 1 069 819
granted in the name of Plant Bioscience Limited.

Submissions in response to communication under Rule 71(1) EPC
of Groupe Limagrain Holding (Opponent OII)

Further to the Summons to Oral Proceedings dated 15th February 2006 summoning the parties to Oral Proceedings on 4th May 2006, GROUPE LIMAGRAIN HOLDING (Opponent OII) hereby makes the following submissions :

1. Requests

GROUPE LIMAGRAIN HOLDING maintains the request that the decision of the Opposition Division dated 23rd November 2004 be set aside and that the patent be revoked in its entirety under Articles 100(a) 100(b) and 100(c) EPC.

2. Procedural Matters :

The Board will be aware that Patentee did not file an Appeal in the present case and is therefore Respondent in these proceedings. However, with his submissions of 24th October 2005, Patentee has filed a new Main Request and two new Auxiliary Requests. All of the new claim requests contain claims which are broader, or which involve a shift in scope, compared to those upheld by the Opposition Division, either as a result of deletion of claim features, or as a result of the replacement of a term by a broader term.

Such amendments therefore put the Opponents, and sole appellants, in a worse situation than if they had not appealed.

Enlarged Board of Appeal decision G1/99 has clearly defined the circumstances in which a non-appealing Patentee may make amendments of this type. Opponent submits that none of the Claim Requests filed by Patentee on 24th October 2005 correspond to the requirements laid down in G1/99. Moreover, many of the amendments are inadmissible for additional reasons.



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OI)

4.04.06

For the reasons set out below, Opponent submits that all claim requests are inadmissible.

2.1 Main Request :

a) Claims 5, 6 and 7 of the Main Request have been amended, with respect to the claims upheld by the Opposition Division, by the replacement of the word '*produced*' by the word '*producible*'.

This amendment is inadmissible for the following reasons:

- i) G1/99 : this amendment has been made spontaneously by Patentee. It is entirely independent of any issues raised during the appeal proceedings. This modification has therefore not been made in the conditions required by G1/99, i.e. in response to an objection raised by the Opponents or the Board during the Appeal proceedings, with a view to correcting an inadmissible amendment mistakenly held admissible by the Opposition Division. The change is merely an attempt by Patentee to broaden the scope of the product claims as interpreted by national courts. G1/99 prohibits this type of amendment.
- ii) Rule 57a EPC : Moreover, the amendment to Claims 5, 6 and 7 is also inadmissible under Rule 57a EPC, since it is not occasioned by grounds for opposition specified in Article 100 EPC.
- iii) Article 123(2) EPC : the application as filed contains no basis for the word '*producible*' in the context of new claims 5, 6 and 7. The amendment therefore contravenes Article 123(2) EPC.
- iv) Article 123(3) EPC : the replacement of the word '*produced*' by the word '*producible*' has the effect of broadening the claim scope with respect to the scope of the granted claims, at least in some of the contracting states (see for example '*The construction of product-by-process claims - A study in enlightened compromise*'. R.J.Young, 11th Patent Judges Symposium Copenhagen, 2002, Special Edition of Official Journal EPO, pp.20 to 43, in particular pages 34 to 35).

b) Claims 8, 9 and 10 of the Main Request have been amended, with respect to the claims upheld by the Opposition Division, by the deletion of the terms "*of said plant*", "*of the inflorescence*" and "*of the cell*". These amendments have apparently been made in response to Opponent OII's objections under Article 123(2) to these terms.



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OI)

4.04.06

However, these changes do not comply with the requirements of G1/99, which stipulates that, in such circumstances, Patentee may be allowed to file requests as follows :

- *in the first place, for an amendment introducing one or more originally disclosed features which limit the scope of the patent as maintained ;*
- *if such a limitation is not possible, for an amendment introducing one or more originally disclosed features which extend the scope of the patent as maintained but within the limits of Article 123(3) EPC ;*
- *finally if such amendments are not possible, for deletion of the inadmissible amendment, but within the limits of Article 123(3) EPC"*

[G1/99 Order]

In the present case, Patentee has made no attempt to file amendments corresponding to the first and second approaches required by G1/99 (listed above), but has simply deleted the offending amendment. This way of proceeding is not in line with the requirements of G1/99. Claims 8, 9 and 10 of the Main Request are therefore also not admissible.

In conclusion, the Main Request is inadmissible.

2.2 First Auxiliary Request :

The first Auxiliary Request contains all the amendments already made to the Main Request and is therefore inadmissible for the same reasons as those detailed above for the Main Request.

In addition, Claim 1 of the First Auxiliary Request has been amended by deletion of the feature that molecular markers are used in steps (b) and (c) to select hybrids with the desired genetic combination. The claim thus amended is consequently broader than the claims maintained by the Opposition Division and puts Opponents in a worse position than if they had not appealed.

The amended feature was originally added to the claim by Patentee during Opposition Proceedings in an attempt to take the claim out of the Article 53(b) prohibition on essentially biological processes. No formal objections have been raised to the introduction of this feature by the Opponents, i.e. this amendment is not an inadmissible feature mistakenly held as admissible by the Opposition Division. Consequently, the circumstances required by G1/99 for a non-appealing Patentee to amend his claims by broadening are not present, and again the amendment is not admissible in the light of G1/99.



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

In any event, even if the addition of the feature relating to molecular markers became an issue in the appeal proceedings Patentee would still have to follow the sequence of proposals for amendments defined in G1/99 before simply deleting the feature.

The First Auxiliary Request is therefore also inadmissible.

2.3 Second Auxiliary Request :

The Second Auxiliary Request contains all the amendments made to the First Auxiliary Request and is therefore inadmissible for the same reasons as those detailed above for the First Auxiliary.

3. Essentially Biological Processes (Article 53(b) EPC) :

Claims 1 to 4 of the Main Request contravene Article 53(b) EPC.

In his submissions of 24th October 2005, Patentee contests the submissions of Opponent OII with respect to Article 53(b) EPC, arguing that :

- Rule 23b(5) EPC provides an exhaustive definition of what is meant by "essentially biological process" in Article 53(b) EPC

- consequently, since the claimed process does not '*consist entirely of natural phenomena such as crossing or selection*' as recited in Rule 23b(5), the claimed process is not excluded from patentability by Article 53(b) EPC. In particular, Patentee argues that the method of claim 1 of the Main Request has three levels of human intervention which take the claim out of the Article 53(b) exclusion. These three levels of 'human intervention', according to Patentee are :
 - the use of molecular markers for the selection steps ;
 - the use of a non-natural double haploid strain of broccoli as starting material ;
 - the crossing of a wild strain of *B.villosa* or *B.drepansis* with a broccoli breeding line, unlikely to occur in nature.

Opponent submits that Patentee's arguments are not valid, and maintains the objection under Article 53(b), for the following reasons:



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

3.1. Rule 23b(5) is not an exhaustive definition of “essentially biological processes” :

Opponent OII maintains the opinion that Rule 23b(5) EPC provides an initial guideline for the interpretation of Article 53(b) but does not provide an exhaustive definition of essentially biological processes.

In Opponent's opinion, this can be seen from the stark contrast in wording between those parts of Rule 23 which indeed provide definitions, and paragraph (5) with which we are presently concerned. Compare for example Rule 23b(5) and Rule 23b(6) EPC :

Rule 23b(5) EPC: *A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.*

Rule 23b(6) EPC: *“Microbiological process” means any process involving or performed upon or resulting in microbiological material.*

Rule 23b(6) EPC indeed defines a microbiological process. This is apparent from the fact that the terms “*microbiological process*” are presented in inverted commas, and are followed by the word “means ...”. Thus is a clear and unambiguous definition. Exactly the same wording is used for Rule 23b(3), and Rule 23b(4), defining “biological material” and “plant variety” :

Rule 23b(3) EPC: *“Biological material” means*

Rule 23b(4) EPC: *“Plant variety” means... .*

The difference between the wording of Rules 23b(3), (4) and (6) compared to Rule 23b(5) is striking : **Rule 23b(5), relating to processes for the production of plants and animals, does NOT begin with the words “Essentially biological processes” means...”. It does not even contain the expression “essentially biological processes” as such.** If Rule 23b(5) had been intended to provide an exhaustive definition of “essentially biological processes”, as contended by Patentee, the legislator would have adopted the SAME wording as that found in the other definitions of Rule 23. In this respect, note that the definitions provided in Rule 23b(4)



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Lmagrain Holding (OII)

4.04.06

and 23b(6) concern terms which occur in Article 53(b) EPC, just like the terms "essentially biological processes". The contention of Patentee could only be correct if Rule 23b(5) had been formulated as follows :

Hypothetical Rule 23b(5) : ***"Essentially biological processes for the production of plants or animals" means*** any process which consists entirely of natural phenomena such as crossing or selection."

This is clearly NOT the case. Opponent thus maintains its position that Rule 23b(5) serves to provide a first indication that when a process consists entirely of natural phenomena it is "essentially biological". However, when a process contains steps which are arguably not natural phenomena, then the claim must be further examined under Article 53(b) EPC, applying the approaches already outlined in the case-law, particularly in T320/87.

Article 53(b) interpreted according to the T320/87 approach :

T320/97 ruled that in order to escape the Article 53(b) prohibition, a process must have at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result.

Opponent submits that this is NOT the case here. According to Patentee, claim 1 requires 'three levels of human intervention', concerning either the selection steps or the crossing steps, namely

- molecular markers are used for the **selection steps** (b) and (c);
- double haploid strains of broccoli are used as starting material for the first **crossing step** (a);
- the crossing of a wild strain of *B.villosa* or *B.drepansis* with a broccoli breeding line is "unlikely to occur in nature".

In Opponent's submissions, none of these steps meet the T320/87 criteria, as will be shown below :

The first level of human intervention concerns the use of double haploid strains as starting material for the first crossing step (a). However, the Board's attention is drawn to the fact that the creation of double haploid lines is a technique resulting in the artificial doubling of the existing genetic material in a cell. This characteristic is not transmitted to the progeny. The



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

technique of double haploids is used to reduce the length of the crop improvement cycle. It does not however have a decisive impact on the final result, it merely reduces the time necessary to obtain that result. According to Patentee, the essence of the present invention resides in the crossing of specific Brassica species to obtain hybrid plants with elevated levels of glucosinolates. Whether or not this result is obtained quickly, or less quickly, is immaterial to the invention. The step of using double haploids for the initial crossing step is therefore not an essential step, and has no decisive impact on the final result. This step therefore cannot save the claim from the Article 53(b) prohibition.

The second step of 'human intervention', according to Patentee, involves the use of molecular markers for the selection steps (b) and (c). Again, this step is not essential and is irrelevant to the final result. This point has been admitted by Patentee : it is stated in point 6.2 of the Opposition Division's decision that the use of molecular markers "*as admitted by Patentee, is in fact not essential to the invention, and the selection steps could equally well be carried out without using such markers ...*". There is therefore no doubt in the present case that the involvement of molecular markers does NOT meet the requirements laid down in T320/87 and this step of the claim can play no role in allowing the claim to escape the prohibition of Article 53(b) EPC.

Finally, the third aspect of the claimed process which, according to Patentee, requires human intervention, is the crossing of wild strains of *B.villosa* or *B.drepanensis* with broccoli breeding lines as required by step (a) of the claim. Patentee argues that this step is 'unlikely to occur in nature' because the different species '*do not look anything like each other*' and '*grow in remote geographical locations*', needing to be brought into contact with each other by human intervention. This argument is entirely invalid. The patent confirms that these species are related (see for example paragraph 0015 on page 4). No technical steps need to be taken to cross them, the crossing is entirely natural. The fact that they perhaps naturally grow in locations which are far from each other does not make this crossing 'non-natural'. Patentee's argument is analogous to saying that crossing between two members of the human species is non-natural if the members in question have to take an aeroplane to meet each other. According to the claimed process, the phenomenon of crossing is completely and necessarily natural. Consequently, this step of the claimed process does not correspond to a step of 'human intervention' as required by the T320/87 approach.

In conclusion, none of the three steps put forward by Patentee as being susceptible of saving the claimed process from the prohibition of Article 53(b) actually meet to the triple requirement of T320/87 i.e.



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

- the step must be an essential technical step,
- it cannot be carried out without human intervention and
- it must have a decisive impact on the final result

Consequently, if the 'traditional' T320/87 approach is applied, the process claims of the Main Request, are 'essentially biological processes' and are excluded from patentability under Article 53(b) EPC.

3.2. The claimed process is excluded from patentability by Article 53(b) even if Rule 23b(5) is an exhaustive definition of "essentially biological processes" :

Opponent also submits that, even if Rule 23b(5) does provide an exhaustive definition of "essentially biological processes", and Article 53(b) is assessed solely on the basis of this Rule, then the claimed process is still is an "essentially biological process" and as such is excluded from patentability under Article 53b EPC.

As discussed above, Patentee contends that the process of Claim 1 of the Main Request is NOT a process corresponding to the terms of Rule 23b(5) because it involves "three levels of human intervention".

However, the nature of the human intervention in the claimed process is decisive. In particular, with regard to the first two "levels of human intervention" i.e. :

- the use of molecular markers the **selection steps** (b) and (c);
- the use of double haploid strain of broccoli as starting material for the first **crossing step** (a);

it is immediately apparent that the human intervention is made **within the crossing and selection steps**, and the claimed process thus STILL consists entirely of crossing and selecting steps. The use of a molecular marker in the **selection steps** does not transform those steps into some other type of process step : they are still selection steps. Similarly, the use of a double haploid breeding line in the crossing step does not alter the fact that the step is still a crossing step. No other process steps are present in the claim. The process of claim 1 thus consists entirely of the "natural phenomena" of crossing and selecting.



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OI)

4.04.06

Importantly, the operations of 'crossing' and 'selecting' are explicitly listed in Rule 23b(5) as examples of natural phenomena. In Opponent's opinion, the inclusion of these examples in the Rule is clearly intended to remove any doubt that there might otherwise have been as to whether crossing and selection might be natural phenomena or not. Significantly, "selection" often involves human intervention to facilitate or accelerate identification of individuals having the desired combination of characteristics which has arisen by a natural process ; it is nevertheless explicitly listed as a natural phenomenon in Rule 23b(5). This demonstrates that the "natural phenomena" referred to in the Rule, include natural phenomena in which there is human intervention, but which nevertheless continue to exploit the underlying natural process without substantial change. Note that this interpretation would also appear to coincide with the opinion expressed by the President of the EPO in the context of the referral to the Enlarged Board of Appeal in case G1/98, in which it is stated :

"A process for the production of plants was essentially biological if it consisted entirely of natural phenomena, these being understood as including the methods used by conventional plant breeders, such as crossing or selection."

[G1/98 Facts and Submissions VII]

Note in this respect that the methods used by conventional plant breeders certainly involve human intervention, for example the use of markers for selection steps. This opinion thus reinforces the view that the natural phenomena recited in Rule 23b(5) include natural phenomena in which there is human intervention.

Consequently, the use of double haploid strains in the crossing step, and the use of markers in the selection step do not, in Opponent's opinion, prevent these steps from being 'natural phenomena' in the sense of Rule 23b(5).

Turning now to the alleged 'third level of human intervention' i.e. the crossing of a wild strain of *B. villosa* or *B. drepansis* with a broccoli breeding line, as discussed above, this step does not in fact involve human intervention, it is a completely natural phenomenon.

In conclusion, the claimed process consists entirely of crossing and selection steps, i.e. natural phenomena. Consequently, even if Rule 23b(5) is used solely to interpret Article 53(b) EPC, the claim is excluded from patentability as an "essentially biological process".



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

3.3 Auxiliary Requests I and II in the light of Article 53(b) EPC :

Auxiliary Requests I and II as filed on 24th October 2005 differ from the Main Request in that :

- i) Claim 1 of Auxiliary Request I no longer recites the use of molecular markers for the selection steps (b) and (c). The deletion of this step merely serves to confirm the non-essential nature of this step and reinforces Opponent OII's arguments under article 53(b) EPC.

- ii) Auxiliary Request II differs from the Claim 1 of the Main Request in that the use of molecular markers for the selection steps has been deleted, and a step of 'deriving' broccoli double haploid breeding lines has been incorporated. However, as pointed out above, the use of double haploid breeding lines is irrelevant to the present invention and cannot save the claimed process from the Article 53(b) prohibition.

Consequently, the First and Second Auxiliary Request also contravene Article 53(b) EPC.

3.4 Request for Referral to the Enlarged Board of Appeal

Should the present Board be inclined to consider that claims 1 to 4 of the present Claim Requests do not contravene Article 53(b) EPC, Opponent OII requests that the matter be referred to the Enlarged Board of Appeal under Article 112 EPC as an important point of law. In particular, Opponent OII would request referral of the following questions :

- Does Rule 23b(5) EPC provide an exhaustive definition of "essentially biological processes". If so, can the requirements of Article 53(b) be judged solely on the basis of Rule 23b(5) EPC ?

- If the response to the first question is 'yes', what extent of human intervention, if any, in a natural phenomenon such as crossing or selection is required for a process consisting solely of crossing and selection steps, to be outside the Rule 23b(5) provisions ?



T0083/05-3304
EP-B-1 069 819
Final submissions in response to Rule 71(1) communication
Groupe Limagrain Holding (OII)

4.04.06

4. Novelty (Article 54 EPC), Inventive step (Article 56 EPC) and Sufficiency of disclosure (Article 83 EPC) :

Opponent OII maintains all objections raised under Article 54, 56 and 83 EPC, and set out in Opponent's Statement of Appeal.

5. Arrangements for Oral Proceedings :

The Board and the Parties are informed that Opponent OII will use the English language during the Oral Proceedings scheduled for 4th May 2006. **Interpreters are requested if any of the parties intend to make submissions in German.**

6. Conclusions :

The invention as claimed in the Main Request and Auxiliary Requests does not meet the requirements of the EPC. The patent should be revoked in its entirety.

C. Admoud





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[Acknowledgement of receipt at the European Patent Office of] subsequently filed items relating to patent applications / patents.

Items filed

No.	Application (and Directorate) No. / Patent No.	Your reference	Nature and date of items (optional)
1	1069819	LB220-CA	Final submissions in view of Oral Proceedings of 4th May 2006. 04-04-2006