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Datasheet for the decision of 20 August 2020

Case Number: T 2456/17 - 3.3.04

Application Number: 07104762.5

Publication Number: 1818405

IPC: C12N15/82

Language of the proceedings: EN

Title of invention:
Compositions and methods for control of insect infestations in plants

Patent Proprietor:
Monsanto Technology, LLC

Opponent:
Syngenta Crop Protection AG

Headword:
Combination for control of plant insect infestations/MONSANTO

Relevant legal provisions:
EPC Art. 54, 56, 83, 114(1), 123(2)
RPBA Art. 12(4)
RPBA 2020 Art. 13(1)

Keyword:
Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Inventive step - (yes)

Decisions cited:
T 0134/11

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 2456/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 August 2020

Appellant: (Patent Proprietor)	Monsanto Technology, LLC 800 North Lindbergh Boulevard St. Louis, MO 63167 (US)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Appellant: (Opponent)	Syngenta Crop Protection AG Rosentalstrasse 67 4058 Basel (CH)
Representative:	SYNGENTA IP WRO B8-Z1-30 Rosentalstrasse 67 4058 Basel (CH)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 September 2017 concerning maintenance of the European Patent No. 1818405 in amended form.**

Composition of the Board:

Chairwoman	G. Alt
Members:	O. Lechner
	A. Bacchin

Summary of Facts and Submissions

I. Appeals against the interlocutory decision of the opposition division to maintain European patent No. 1 818 405 ("patent") in amended form, were filed both by the patent proprietor (appellant I; "patent proprietor" or "proprietor") and the opponent (appellant II; "opponent"). The patent has the title "*Composition and methods for control of insect infestations in plants*".

II. The patent is based on European patent application No. 07 104 762.5, a divisional application of European patent application No. 05 777 174.3, which had been filed as an international application and was published as WO 2005/110068.

III. The notice of opposition invoked lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) under Article 100(a) EPC, as well as the grounds under Article 100(b) and (c) EPC as grounds of opposition.

IV. In the decision under appeal, the opposition division dealt with a set of claims of a main request, the claims as granted and sets of claims of seven auxiliary requests. The opposition division decided that the main request failed to comply with the requirements of Article 76(1) and 123(2) EPC and that auxiliary requests 1 to 6 added subject-matter (Article 123(2) EPC). Auxiliary request 7 was found to comply with Articles 54, 56, 83 and 123(2) EPC.

V. The only claim of this auxiliary request 7 reads:

"1. A transgenic plant having more than one transgene for reducing or eliminating plant insect pest infestation, or a plant cell thereof, wherein said plant or said plant cell comprises a dsRNA for suppression of an essential gene in a target insect pest and a gene encoding a *Bacillus thuringiensis* insecticidal protein toxic against said target insect pest, wherein the plant produces the dsRNA and the *Bacillus thuringiensis* insecticidal protein and wherein the insect pest is a Western corn rootworm (WCR, Diabrotica virgifera virgifera Leconte)."

VI. With the statement of grounds of appeal, the proprietor filed sets of claims of a main request (the claims as granted) and four auxiliary requests.

VII. In their reply to the proprietor's statement of grounds of appeal, the opponent submitted arguments to the effect that, *inter alia*, claim 1 of the main request and claim 1 of auxiliary requests 1 to 4 added subject-matter (Articles 123(2) and 76 EPC). Auxiliary request 4 additionally lacked an inventive step (Article 56 EPC) because it was not shown in a credible way that the claimed invention indeed solved the problem over the entire claimed scope, which "*covers all Coleopteran species*".

It was stated that "*[w]hile all novelty, inventive step and sufficiency of disclosure objections currently on file apply mutatis mutandis to all 4ARs*", *at least AR4 generates additional issues [...]*".

VIII. With their statement of grounds of appeal, the opponent explained why the opposition division's decision to

find the claims of auxiliary request 7 to comply with the requirements of the EPC was wrong and filed to this effect arguments in relation to Articles 54 (in relation to document D9), 56 (concerning the combination of documents D12 and D13), 83 and 123(2) EPC. They further argued that the decision not to admit document D13a was wrong. A document was filed (denoted as D38, see below).

IX. In reply, the patent proprietor filed sets of claims of auxiliary requests 5 and 6 in which the only claim of auxiliary request 5 was identical to that of auxiliary request 7 held allowable by the opposition division. The proprietor submitted, *inter alia*, arguments in reply to the opponent's submissions regarding auxiliary request 7.

X. The board issued summons for oral proceedings and provided in an accompanying communication a preliminary opinion on some of the issues.

XI. In reply, the proprietor submitted arguments endorsing the presence of an inventive step for the subject-matter of all requests.

XII. By letter dated 10 August 2020, the proprietor requested that the oral proceedings be conducted by video conference.

The board ordered that the oral proceedings be held by video conference.

Subsequently, the opponent informed that they would not attend the oral proceedings.

XIII. Oral proceedings took place as scheduled in the presence of the proprietor.

During the oral proceedings, the proprietor withdrew the main request and auxiliary requests 1 and 2 and made auxiliary request 3 the main claim request (the denomination "Auxiliary Request 3" was kept).

At the end of the oral proceedings, the Chair announced the board's decision.

XIV. Claim 1 of the main request (labelled "Auxiliary Request 3") reads as follows:

"1. A transgenic plant having more than one transgene for reducing or eliminating plant insect pest infestation, or a plant cell thereof, wherein said plant or said plant cell encodes and comprises a dsRNA for suppression of an essential gene in a target insect pest and a gene encoding a Bacillus thuringiensis insecticidal protein exhibiting biological activity against said target insect pest."

XV. The following documents are referred to in this decision:

D3: Bolognesi R. et al., "*Characterizing the Mechanism* of Action of Double-Stranded RNA Activity against Western Corn Rootworm (Diabrotica virgifera *virgifera LeConte)*"; PLOS ONE, October 2012, 7(10), e47534

D12: WO 03/018810 A2

D13: WO 03/004644 A1

D13a: Set of claims filed for EP 10 184 533.7 on 9 March 2017

D24: Baum J. A. et al., "*Control of coleopteran insect pests through RNA interference*"; Nature Biotechnology, November 2007, 25(11), 1322-1326.

D38: van Frankenhuyzen K; "*Insecticidal activity of Bacillus thuringiensis crystal proteins*"; Journal of Invertebrate Pathology (2009), volume 101, pages 1–16

XVI. The arguments of appellant II (opponent), submitted in writing, relevant for the present decision and as far as substantiated, may be summarised as follows.

Admittance of documents D13a and D38

Documents D13a and D38 should be admitted into the proceedings as they were *prima facie* relevant for the case.

Main request - labelled "Auxiliary Request 3" ("auxiliary request 3" in the following)

Amendments (Article 123(2) EPC)

The subject-matter of claim 1 extended beyond the content of the application as filed for the following four reasons.

(a) Combination in claim 1 of the feature "encodes and comprises a dsRNA" with the absence of specific

nucleotide sequences from which the dsRNA molecule was derived

The passages indicated by the proprietor as a basis for claim 1 of auxiliary request 3 on page 6, lines 8 to 14, and page 7, lines 26 to 29, of the application as filed disclosed that both (i) a DNA construct encoding a dsRNA molecule and (ii) specific nucleotide sequences from which the dsRNA molecule was derived were required. Both features were absent from claim 1.

(b) The feature in claim 1: "transgenic plant having more than one transgene for reducing or eliminating plant insect pest infestation, or a plant cell thereof"

Page 7, lines 27 to 29, of the application as filed disclosed that the invention provided "*a transformed plant cell having in its genome at least one of the aforementioned recombinant DNA sequences*". The paragraph referred to in this passage disclosed plant cells with two different dsRNA sequences but not that one of the transgenes was a *Bacillus thuringiensis* insecticidal protein. Therefore, this passage failed to provide a proper basis for this feature.

(c) The feature in claim 1: "wherein said plant [...] encodes and comprises a dsRNA [...] and a gene encoding a Bacillus thuringiensis insecticidal protein exhibiting biological activity against said target insect pest"

The definition underlined above meant any undefined biological activity that the *Bacillus thuringiensis* insecticidal protein displayed against the target insect pest, i.e. not necessarily insecticidal or toxic

activity. However, the sentence bridging pages 8 and 9 of the application as filed specified that the *Bacillus thuringiensis* insecticidal protein must be "*toxic to the target pest*", thus limiting the biological activity of the *Bacillus thuringiensis* protein as being toxic against the target pest.

(d) Synergistic effect as an essential claim feature

The sentence bridging pages 8 and 9 of the application as filed clearly disclosed that the transgenic plants producing the dsRNA and the *Bacillus thuringiensis* protein together "*provide surprising synergies*". The next paragraph on page 9 explained the synergy element of the invention, namely "*it is believed that the Bt insecticidal proteins create pores through which the dsRNA [...] molecules are able to penetrate more effectively*". This meant that a direct interaction - synergy - between the modes of action of the two compounds was necessary for achieving the claimed technical effect.

Synergy between the dsRNA and the *Bacillus thuringiensis* protein was disclosed also in numerous other locations in the application as filed, such as on page 90, lines 17 to 19.

Consequently, "synergy" was an essential technical feature of the subject-matter of the invention which was, however, missing in claim 1.

Sufficiency of disclosure (Article 83 EPC)

For the following reasons, carrying out the claimed invention involved an undue burden for the skilled person.

(a) Reasons relating to the feature in claim 1 "a dsRNA for suppression of an essential gene in a target insect pest"

- Identification of the correct size of the dsRNA to be active

The patent taught the skilled person, on page 9, lines 36 to 37, that dsRNA within a wide range of lengths could be used: "*the ribonucleic sequence is transcribed from a contiguous DNA sequence that is at least from about 19 to about 5000 nucleotides in length*".

However, this was in contradiction to the teaching in document D3 that the length of the dsRNA had to be at least about 60 base pairs for exhibiting successful biological activity (see "Abstract").

The fact that Table 1 of Example 2 of the patent highlighted four working dsRNAs in the size range of 291 to 933 nucleotides did not remedy the situation that information was lacking from the patent that the minimum length of the dsRNA should be 60 base pairs.

- Identification of appropriate target genes and specific dsRNAs

The dsRNA was defined in claim 1 in an entirely functional manner: "for suppression of an essential gene in a target insect pest".

On page 85, lines 9 to 11, the application implied that far fewer than all the identified gene sequences would actually provide this technical effect.

Document D24 confirmed that not all sequences worked in relation to Western corn rootworm as the target pest. This document disclosed that 8 out of 26 tested Western corn rootworm dsRNA sequences targeted to different genes did not work. A further experiment revealed that only 125 out of the tested 290 dsRNAs directed to different genes achieved significant larval mortality and/or stunting.

Accordingly, nearly 57% of the tested Western corn rootworm genes failed to provide any insect pest control, and the skilled person would have therefore had a less than 50% chance of identifying an appropriate gene target.

The patent failed to give any indication or criteria on how to identify appropriate target genes or target gene sequences. The skilled person would have been left with randomly screening the target insect pest's genome to find the appropriate sequences. This would have equated to performing a research programme.

Inventive step (Article 56 EPC)

Document D12 was the closest prior art document. It disclosed, on page 37, line 18, "*co-expression of more than one insecticidal principle in the same transgenic plant*". As to the "*insecticidal principle*", it was disclosed on page 37, lines 11 to 12, that modified *Bacillus thuringiensis* "*Cry3A toxins of the invention*"

could be used together with "*other pesticidal principles of a distinct nature*".

However, the second pesticidal principle was not restricted by its nature, it just needed to be of a "*distinct*" nature. The fact that the examples of the other insecticidal principles listed on page 37, lines 14 to 17, were toxic proteins did not limit the identity of the second principle.

As to the effect of the claimed invention, in view of Example 3 in the patent, which disclosed *in planta* expression of dsRNA alone, it could not be said that the *Bacillus thuringiensis* insecticidal protein provided any additional technical effect. Thus, the technical teaching to be considered for inventive step was limited to a transgenic plant comprising a dsRNA for the suppression of an essential gene in a target insect pest.

Examples 5 and 6 described some efficacy of a dsRNA if targeted to the V-ATPase gene in the coleopteran pests corn rootworm and Colorado potato beetle, while Example 8 disclosed that a dsRNA targeted to the same gene failed to show any kind of efficiency against the coleopteran pest Cotton boll weevil (as stated on page 96, lines 6 to 7, of the application as filed). Thus, the efficacy, even for orthologues of the same gene target, varied depending on the pest. Hence, the technical effect of the claimed subject-matter recited in the claim - "for reducing or eliminating plant insect pest infestation" - was not present over the entire claimed scope.

The skilled person would have turned to document D13, which disclosed the delivery of dsRNA to an arthropod

by contacting the arthropod with the dsRNA in a composition comprising a transfection promoting agent.

However, the teaching of document D13 was not limited to this means of delivery. Claim 13 of document D13 specifically disclosed feeding the arthropod a transgenic plant expressing the dsRNA targeting an essential gene in that arthropod.

The fact that document D13 clearly conveyed the technical teaching of feeding arthropods transgenic plants expressing the dsRNA was confirmed by the patent granted for this patent application, document D13a. Granted claim 1 was directed to this subject-matter: "*A stacked transgenic event for reducing or eliminating plant pest infestation, comprising a dsRNA for suppression of an essential gene in a target pest and a pesticide exhibiting biological activity against said target pest.*"

The skilled person looking at document D12 would have had a strong incentive to combine its teaching with the teaching of document D13 and therefore would inevitably have arrived at the claimed invention.

XVII. The arguments of appellant I (proprietor), relevant to this decision, may be summarised as follows.

Main request - labelled "Auxiliary Request 3" ("auxiliary request 3" in the following)

Admittance of documents D13a and D38

Document D13a should not be admitted into the appeal proceedings. The admittance of document D38 was not objected to.

Amendments (Article 123(2) EPC)

(a) Combination in claim 1 of the feature "encodes and comprises a dsRNA" with the absence of specific nucleotide sequences from which the dsRNA molecule was derived

The amendment in claim 1 of auxiliary request 3 *vis-à-vis* claim 1 as granted was the addition of the term "encodes" to arrive at the feature "encodes and comprises a dsRNA". This amendment complied with Article 123(2) EPC in view of page 6, line 8 onwards, and page 7, lines 26 to 29.

In view of the application as filed as a whole, it was clear that the dsRNA molecules were not limited to the specific sequences described on page 4, lines 26 to 36, or page 5, lines 6 to 12.

(b) The feature in claim 1: "transgenic plant having more than one transgene for reducing or eliminating plant insect pest infestation, or a plant cell thereof"

The basis for this feature was found on page 7, lines 26 to 31; page 8, line 28, to page 9, line 1, of the application as filed.

(c) The feature in claim 1: "and a gene encoding a Bacillus thuringiensis insecticidal protein

exhibiting biological activity against said target insect pest"

It was clear from the wording of claim 1 that the biological activity of the *Bacillus thuringiensis* insecticidal protein was a toxic activity against the target insect pest. This meaning was also derivable from the summary of the invention on page 7, lines 26 to 31, and the paragraph bridging pages 10 and 11 of the application as filed.

(d) Synergistic effect as an essential claim feature

The application disclosed in the sentence bridging pages 8 and 9 that the transgenic plants according to the invention "*provide surprising synergies*". In the next paragraph, one of these synergies was disclosed, namely "*the reduction in the level of expression required for either the dsRNA(s) or the Bt protein(s)*". The assumed reason for this effect was that the *Bacillus thuringiensis* insecticidal proteins created pores through which the dsRNA was able to penetrate more efficiently. This passage implied neither that

direct interaction - which the opponent refers to as "synergy" - of the compounds was required nor that synergy represented an essential technical feature that had to be included in the claim.

Sufficiency of disclosure (Article 83 EPC)

The invention as claimed could have been carried out without undue burden.

(a) Reasons relating to the feature in claim 1 "a dsRNA for suppression of an essential gene in a target insect pest"

- Identification of the correct size of the dsRNA to be active

Document D3 demonstrated that the dsRNA targeting the Snf7 orthologue was active against Western corn rootworm and induced mortality in its larvae. Thus, this publication supported the teaching of the patent in suit.

Document D3 did not state that the dsRNA should have a length of about 60 base pairs to be effective against Western corn rootworm.

While document D3 acknowledged that the length of the dsRNA contributed to the effect of the suppression, this result could not be extrapolated beyond the specific sequence tested.

- Identification of appropriate target genes and specific dsRNAs

None of the experiments referred to in document D24 supported that it was not possible to identify suitable target genes in individual insect pests. On the contrary, the document disclosed that 18, i.e. more than half of the 26 tested Western corn rootworm dsRNA sequences targeted to different genes, actually worked.

Target genes could be identified by routine testing procedures. Example 1 of the patent illustrated the identification of nucleotide sequences that, when provided in the form of dsRNA molecules in the diet of

a corn rootworm, were useful for controlling the plant pest.

Amendment of the opponent's case in view of Article 13 RPBA

No inventive step attack had been formally raised by the opponent with respect to auxiliary request 3. Therefore, considering this ground of opposition by the board in relation to this request amounted to an unallowable amendment of the opponent's case.

Inventive step (Article 56 EPC)

Document D12, a patent application, represented the closest prior art. It disclosed *Bacillus thuringiensis* Cry3A toxins modified to comprise a non-naturally occurring protease recognition site. These modified proteins were highly active against insects (see page 7, top half).

Document D12 disclosed on page 11, lines 20 to 27, page 28, line 23 onwards, and on page 37, line 8 onwards, the embodiments in which the plant encoded, in addition to the modified *Bacillus thuringiensis* protein, a second pesticidal principle. However, all specifically identified second principles were toxic proteins. Document D12 did not disclose methods for controlling insects feeding on plants using dsRNA as a second principle.

The invention provided plants which could reduce plant insect pest infestations more specifically.

This effect being achieved was shown not only by the disclosure of the patent (see reply to appellant II's statement of grounds of appeal, page 13, point 3.4) but also by contemporaneous art such as documents D15, D16, D23 to D27 or D31 to D36.

The technical problem was the provision of improved plants and methods for insect control during plant production, with the improvement being caused by the highly specific activity of dsRNA against the respective pest species. The improvement was not better insecticidal activity but rather higher pest specificity.

Document D13 related to methods for determining the biological function of a target RNA in an arthropod. These methods could, for example, be used to screen RNAs for the identification of novel pesticide targets. Thus, document D13 did not disclose transgenic plants producing dsRNA suitable for reducing or eliminating plant insect pest infestation. Hence, in light of the problem to be solved, the skilled person would not have combined document D12 with document D13.

With regard to the administration of the dsRNA, document D13 taught in particular on pages 27 to 28 that "*oral administration*", i.e. immersing the larvae in a composition containing the dsRNA, was only effective, i.e. had an effect on gene expression, if it included a transfection promoting agent. In the absence of such a transfection promoting agent, the dsRNA was ineffective and did not have a gene suppressive effect as discussed on page 37, paragraph 1, of document D13.

Thus, the skilled person would not have derived from the disclosure in document D12 that dsRNA was envisaged as a second insecticidal principle.

With regard to the argument that the skilled person would have derived the administration of the dsRNA by feeding transgenic plants producing the dsRNA from document D13, the respective disclosure was not enabled.

Requests of the parties

XVIII. Appellant I's (the patent proprietor's) requests at the end of the oral proceedings were that:

- the decision under appeal be set aside and that a patent be granted on the basis of the set of clams of the main request ("auxiliary request 3") or, alternatively, on the basis of the set of claims of one of auxiliary requests 4 to 6, all filed with the reply to opponent's statement of grounds of appeal

- document D13a not be admitted into the proceedings.

XIX. Appellant II's (the opponent's) requests submitted in writing and relevant to the present decision were that:

- the decision under appeal be set aside and that the patent be revoked

- documents D13a, filed with the letter of 31 May 2017, and document D38, filed with its statement of grounds of appeal, be admitted into the proceedings.

Reasons for the Decision

Admissibility of the appeals

1. Both appeals comply with the requirements of Articles 106 to 108 and Rule 99 EPC and are admissible.

Admittance of auxiliary request 3, i.e. the main request (Article 12(4) RPBA 2007)

2. Auxiliary request 3 was filed with the statement of grounds of appeal. No objections were raised by the opponent as to its admittance.

3. Pursuant to Article 12(4) RPBA 2007 (which applies to the current case under Article 25(2) RPBA 2020), a board has the discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings. Otherwise, everything presented by the parties under Article 12(1) RPBA 2007 must be taken into account if and to the extent that it relates to the case under appeal and meets the requirements in Article 12(2) RPBA 2007.

4. The board acknowledges that auxiliary request 3 could have been presented at the proceedings before the opposition division. However, this does not lead automatically to the non-admittance of this request. Otherwise, a board could never take the specific circumstances of a case into account for deciding on how to exercise its discretion (see also decision T 134/11, point 3.3 of the Reasons).

5. In the board's view, auxiliary request 3 addressed in a straightforward and self-evident manner one of the reasons in the decision under appeal for holding claim 1 not allowable, namely those under Article 123(2) EPC. In addition, the amendment neither entailed complicated issues nor raised further objections. Admittance of this request would therefore not run counter to the principle of procedural economy.

6. This conclusion was confirmed by the fact that the admittance of auxiliary request 3 was not objected to by the opponent, which rather submitted arguments on the merits (see reply to the statement of grounds of appeal, point 2.4).

7. Thus, the board decided to exercise its discretion to take auxiliary request 3 into account in the appeal proceedings.

Admittance of documents D13a and D38

8. Document D13a was filed during opposition proceedings but was not admitted by the opposition division. Document D38 was filed with the opponent's statement of grounds of appeal. Admission of both documents into the appeal proceedings is thus subject to Article 12(4) RPBA 2007.

9. With regard to document D13a, the opposition division had the discretion not to admit it into the proceedings as it was filed after expiry of the time limit under Article 99 EPC. The opposition division decided not to admit D13a because it considered the document not relevant to the decision on inventive step (see point 28.2 of the Reasons of the decision).

10. A board overrules the way in which the responsible department has exercised its discretion if it concludes that the department has done so according to the wrong principles, without taking into account the right principles or in an unreasonable way.

11. In the case at issue, the board finds that the opposition division exercised its discretion in accordance with the proper criteria and in a reasonable manner. The board shares the opposition division's view that the text of a granted patent, published after the date of the current patent, cannot *per se* be considered an authority for establishing the technical teaching disclosed in the relevant application. Thus, document D13a is not taken into account in the appeal proceedings.

12. With regard to document D38, the board decided to admit it into the proceedings as it constituted a legitimate reaction to the decision under appeal concerning the limitation of insect pest species to Western corn rootworm, added by auxiliary request 7. Since this request, on the basis of which the patent was maintained, was filed at the opposition oral proceedings, the submission of document D38 at the very beginning of the appeal proceedings constituted a timely reaction. The board also accepted the opponent's submission that document D38 was filed to further support its line of argument regarding the lack of sufficiency of disclosure. The patent proprietor did not object to the admittance of this document.

Main request - labelled "Auxiliary Request 3"
("auxiliary request 3" in the following)

Amendments (Article 123(2) EPC)

13. The subject-matter of claim 1 differs from that of the claims as granted by the addition of the terms "encodes and" so that the claim reads:

"A transgenic plant having more than one transgene for reducing or eliminating plant insect pest infestation, or a plant cell thereof, wherein said plant or said plant cell encodes and comprises

[(a)] a dsRNA for suppression of an essential gene in a target insect pest and

[(b)] a gene encoding a *Bacillus thuringiensis* insecticidal protein exhibiting biological activity against said target pest."

14. The opponent submits that the feature "wherein said plant or said plant cell encodes and comprises a dsRNA for suppression of an essential gene in a target insect pest" had no basis in the passages referred to by the proprietor. Page 7, lines 27 to 29, disclosed plant cells with two different dsRNA sequences but not that one of the transgenes was a *Bacillus thuringiensis* insecticidal protein. Page 7, lines 26 to 29, of the application disclosed that both (i) a DNA construct encoding a dsRNA molecule and (ii) specific nucleotide sequences from which the dsRNA molecule was derived were required.

15. However, a disclosure of the definition that the plant comprises two different transgenes, one being a dsRNA

and the other a *Bacillus thuringiensis* insecticidal protein is found on page 8, line 28, to page 9, line 1 of the application as filed:

"*[...] or one derived using a transgenic approach that combines dsRNA methods and compositions with Bt methods [...]. Transgenic plants that produce one or more dsRNA [...] along with one or more B.t. insecticidal proteins [...].*"

16. Disclosures are furthermore found in claims 1, 2 and 4 of the application as filed.

Claim 1 reads:"*1. A stacked transgenic event for reducing or eliminating plant pest infestation, comprising a dsRNA for suppression of an essential gene in a target pest and a pesticide exhibiting biological activity against said target pest.*"

Claim 2 further defines that the "*stacked transgenic event*" is "*a plant*", and claim 4 lists 6 examples of "*pesticides*", one of them being a "*Bacillus thuringiensis insecticidal protein*".

17. These passages in the application as filed are also the reason it is not persuasive that the application as filed disclosed only dsRNA with specific sequences when encoded by a plant.

18. The opponent's objection to the feature "and a gene encoding a *Bacillus thuringiensis* insecticidal protein exhibiting biological activity against said target insect pest" rests on the opponent's interpretation of the claim to mean that the *Bacillus thuringiensis* protein could have any biological activity, i.e. one which was not necessarily insecticidal or toxic.

19. However, the skilled person would not have interpreted the expression in this way.

The first part of the feature defines the *Bacillus thuringiensis* protein as being "insecticidal". Generally, and certainly in the context of this application, the skilled person would have understood the term "insecticidal" as having the meaning of damaging the insect to the extent that the insect is killed or at least that its activity is severely inhibited, i.e. as having in fact the meaning "toxic". This meaning is, in the context of the claim, underlined by the word "against", which has a negative connotation here.

The second part of the expression defines the target of the protein, i.e. the insect pest. Recognising that the target of the protein is an object to be eliminated, a "pest", the skilled person would not have implied that the biological activity could be any activity but must be the very insecticidal activity of the *Bacillus thuringiensis* protein.

20. The opponent further argued that the subject-matter of claim 1 extended beyond the content of the application as filed because the claim did not comprise a feature expressly stating that there is "synergy" between the dsRNA and the *Bacillus thuringiensis* insecticidal protein. The opponent used the term "synergy" as meaning that there is a direct interaction between the two compounds.

21. Page 9, lines 1 to 9, of the application explains how the synergy between the dsRNA and the *Bacillus thuringiensis* insecticidal protein is generated,

namely: "*It is believed that the Bt insecticidal proteins create entry pores through which the dsRNA or siRNA molecules are able to penetrate more efficiently into spaces remote from the gut [...].*"

Thus, this passage discloses that "synergy" is the result of the simultaneous presence of dsRNA and a *Bacillus thuringiensis* insecticidal protein. It cannot be derived from the passage that a direct interaction between the two compounds is necessary.

22. The subject-matter of claim 1 relates to the simultaneous presence of dsRNA and *Bacillus thuringiensis* insecticidal protein.

Consequently, the subject-matter does not extend beyond the content of the application as filed because a "synergy", as understood by the opponent, is not a feature of claim 1.

Sufficiency of disclosure (Article 83 EPC)

23. The opponent argued that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person with regard to the feature "a dsRNA for suppression of an essential gene in a target insect pest" because both (a) the identification of the correct size of the dsRNA to be active and (b) the identification of appropriate dsRNA target genes would have involved an undue burden.

24. As to (a) above, the opponent argued that essential information from document D3, namely that the minimum length for a dsRNA to be active was 60 base pairs, was missing from the disclosure in the patent. In contrast,

the patent disclosed that the dsRNA could be between 19 and 5000 nucleotides in length.

25. The patent discloses on page 9, lines 12 to 17, that the nucleotide sequence complementary to the target sequence "*is at least from 19 to about 5000 nucleotides in length*". Page 20, lines 29 to 31, provides further information: "*A less than full length sequence exhibiting a greater homology compensates for a longer less 30 homologous sequence. The length of the identical nucleotide sequences may be at least about 25, 50, 100, 200, 300, 400, 500 or at least about 1000 bases. Normally, a sequence of greater than 20-100 nucleotides should be used,...*" Finally, Table 1 on page 48 in the patent shows effects for four dsRNAs having a length between 291 to 933 nucleotides.

26. The skilled person would have known that one of the steps necessary for the dsRNA to be functional within the meaning of the claim, i.e. "suppresses the expression of an essential gene", is that it hybridises to the target gene. The skilled person would also have known that proper hybridisation is, *inter alia,* an interplay between the extent of homology between the two sequences and the size of the hybridising molecule. In light of this common general knowledge, the board finds that the disclosure in the patent would have provided the skilled person with sufficient guidance to design dsRNA of a size that allows it to exert its function.

27. Document D3, published after the publication date of the application of the patent, is referred to by the opponent as evidence that identifying dsRNA of the correct size would have entailed undue burden. However, this document is not appropriate for casting doubt on

the knowledge set out above, nor can it be interpreted to disclose that a minimum size of 60 nucleotides is necessary for each and every dsRNA to be functional in suppressing an essential gene.

Document D3 acknowledges that the length of the dsRNA contributes to the effect of the suppression. However, the authors relate their results to the specific situation tested: "*We have selected the Snf7 ortholog[...]*" (see abstract).

28. As to (b) above in point 23., namely that it would have been an undue burden to identify "essential genes", i.e. genes that when suppressed resulted in growth inhibition or mortality of the pest, the application discloses on pages 29, line 25, to page 30, line 32, categories of genes which may be considered as essential, for example, genes that code for proteins involved in growth or reproduction. Furthermore, the application discloses on pages 59 to 85 specific examples of such essential genes with reference to sequences. Example 1 on pages 54 to 59 discloses methods for identifying such target genes and sequences.

29. Document D24, published shortly after the publication date of the application, is cited by the opponent as evidence that it would have been an undue burden to identify target genes and sequences. However, this document shows that 18 out of 26 tested Western corn rootworm gene sequences, i.e. the majority, were able to have an effect on the growth of the pest (see supplemental Figure 1 and Table 1). Of 290 dsRNAs targeting western corn rootworm tested, 125 showed significant larval mortality and/or stunting

(see page 1322, right-hand column, first full paragraph).

30. Hence, none of the opponent's arguments relating to sufficiency of disclosure is persuasive.

31. Therefore, the disclosure with regard to claim 1 of auxiliary request 3 is considered to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

Novelty (Article 54 EPC)

32. In the opponent's reply to the proprietor's statement of grounds of appeal, it was stated that, as far as the main request is concerned, "*O maintains the novelty, [...] objections filed with its opposition notice dated March 2nd, 2016 and its further letter dated June 01st, 2017*". It was furthermore stated that "*all novelty,* [...] *objections currently on file apply mutatis mutandis to all 4 ARs*" (see points 2.3 and 2.4 of the reply).

33. An unspecified reference to all submissions in opposition proceedings does not meet the substantiation requirements of Article 12(3) RPBA 2020. Such a general reference, not addressing the reasons for the opposition division's decision, does not enable the board and the parties to assess whether the appealed decision is incorrect. For this reason, the board decided not to take the argument under Article 54 EPC into account.

Admittance of the argument of lack of inventive step

34. During the oral proceedings, the proprietor had argued that there was "*no need*" to discuss inventive step for auxiliary request 3 because the opponent had not specifically objected to this request under Article 56 EPC. The board understands this as a request by the proprietor not to discuss inventive step for auxiliary request 3 as this would constitute an amendment to the opponent's appeal case under Article 13 RPBA.

35. However, the board disagrees. The line of argument of lack of inventive step made by the opponent in relation to auxiliary request 7 (the patent as maintained by the opposition division) was not only formally raised against all four auxiliary requests filed in appeal (see point 2.4 of the reply), in the board's view, it is immediately apparent that it applies *mutatis mutandis* also to the current request. Consequently, since the framework of the discussion under Article 56 EPC remained unchanged, there was no amendment of the party's appeal case, and the board decided to consider the argument.

Inventive step (Article 56 EPC)

Closest prior art

36. The board concurs with both parties that document D12 can be considered the closest prior art.

Document D12 discloses modified *Bacillus thuringiensis* Cry3A toxins comprising a non-naturally occurring protease recognition site for controlling plant pests.

The proteins may be delivered to the insects orally by feeding them a transgenic plant expressing the toxin (see page 7, lines 1; page 11, lines 6 to 8). On page 11, D12 discloses a method for controlling insects "*wherein the transgenic plant further comprises a second nucleic acid or groups of nucleic acid sequences that encode a second pesticidal principle*". According to page 37, line 8 onwards, the second insecticidal principles "*include, for example, lectins...*" and other pesticidal proteins (page 37, lines 14 to 17), δ-endotoxin and "*a Vegetative Insecticidal Protein toxin, as disclosed in two US patents*".

37. Contrary to the opponent's interpretation, the board understands the cited passage on page 37 of document D12 as providing a clear indication as to the nature of the second insecticidal principle to be used. All second principles identified on page 37, lines 8 onwards, are toxic proteins. There is no mentioning of dsRNA at all.

The difference, its technical effect and the problem to be solved

38. Hence, the subject-matter of claim 1 of auxiliary request 3 differs from the disclosure in document D12 in that the transgenic plant expresses, as the "*second insecticidal principle*", a "dsRNA for suppression of an essential gene in a target insect pest".

39. According to the proprietor's submission at the oral proceedings, the effect of this difference is that insect pests can be targeted more specifically (see, for example, page 1, lines 18 to 21 of the application).

40. Thus, the objective technical problem to be solved can be formulated as the provision of transgenic plants for specific insect control during plant production.

Obviousness

41. The question to be answered in assessing the obviousness of the claimed subject-matter is whether the skilled person, when faced with the problem above, would have modified the transgenic plant disclosed in the closest prior art document D12 to provide dsRNA as the second insecticidal principle.

42. The opponent argues that while document D13 disclosed the delivery of dsRNA to an arthropod by contacting the arthropod with the dsRNA in a composition comprising a transfection promoting agent, the disclosure in document D13 was not limited to this means of delivering dsRNA to an insect. The skilled person would have found in claim 13 of document D13 the unambiguous disclosure of feeding an insect a transgenic plant expressing the dsRNA to suppress the expression of a gene.

43. Document D13, a patent application, is concerned with using dsRNA for determining the biological function of an RNA in an arthropod (see the first sentence under the heading of "*Summary of the Invention*").

44. Document D13 discloses the different ways of delivery it envisages in the context of this method: "*the dsRNA is delivered by [...] contacting the arthropod with the dsRNA. Preferably, the contacting comprises wholly or partially soaking the arthropod in a composition comprising the dsRNA. In a further preferred embodiment, the dsRNA is delivered by a process*

comprising feeding the dsRNA to the arthropod. [...]. In an alternate embodiment, the dsRNA is delivered by a process comprising feeding a transgenic organism expressing the dsRNA to the arthropod. In yet another embodiment embodiment, the dsRNA is delivered by a process comprising contacting the arthropod with a virus expressing the dsRNA. [...]" (see page 4, lines 1 to 32).

Delivery by feeding is recapitulated in claims 12 (feeding a transgenic organism expressing the dsRNA to the arthropod) and 13 (the transgenic organism being a plant).

Thus, document D13 discloses a transgenic plant expressing dsRNA for delivery to an arthropod.

45. However, the skilled person would have derived from document D13 that the disclosure of this plant is only in the context of methods of determining the biological function of an RNA in an arthropod.

46. In fact, document D13 discloses on page 6 that one aspect of the invention is pest control. In this context, feeding with a transgenic plant expressing the dsRNA is not disclosed.

47. Consequently, the subject-matter of claim 1 of auxiliary request 3 is not considered to be obvious in light of a combination of the teachings of documents D12 and D13.

48. Hence, claim 1 of auxiliary request 3 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the set of claims of auxiliary request 3, filed on 18 January 2018 with appellant I's statement setting out the grounds of appeal, and a description to be adapted thereto.

The Registrar: The Chair:

D. Magliano G. Alt

Decision electronically authenticated