(2021) 01 IPAB CK 0007

In the Intellectual Property Appellate Board

Case No : Original Application No. 18 Of 2020/PT/CHN

Dow Agrosciences Llc — APPELLANT

Vs

Controller Of Patents And Designs — RESPONDENT

Date of Decision : 25-01-2021

Acts Referred:
Indian Patents Act, 1970 — Section 15, 117A

Citation : (2021) 01 IPAB CK 0007

Hon'ble Judges : Dr. B.P. Singh, Technical Member;Manmohan Singh, J

Bench : Division Bench

Advocate : Dr. Meera Venugopal

Final Decision : Allowed

Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 17/01/2020, passed by the Respondent,

being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellantâ??s Indian

patent application no. 5103/CHENP/2012.

2. The invention, as explained the appellant is as under:

This application is a divisional application of IPA 3542/CHENP/2006 granted as Patent number 253525 in the parent. This invention includes novel

transformation events of cotton plants comprising one or more polynucleotide sequences, inserted into specific site(s) within the genome of a cotton

cell, to protect plants from insects. Particularly said polynucleotide sequences as per the PCT specification encode â??stackedâ? Cry1F and Cry1Ac

lepidopteran insect inhibitory proteins. Owing to a lack of unity objection in the first examination report (FER) of the parent application, the application

was divided; The Cry1F event was pursued in the parent application which was granted.

Â The invention includes novel transformation event of cotton plants which is Cry1Ac event comprising a polynucleotide sequence inserted into

specific site(s) within the genome of a cotton cell. Particularly said polynucleotide sequences encode â??stackedâ? Cry1Ac lepidopteran insect

inhibitory proteins. Related assays for detecting the presence of the insect-resistance Cry1Ac event in cotton are also claimed.

Â The refused claims of the impugned application are two in number. Claim 1 relates to a polynucleotide consisting of a nucleotide sequence having

SEQIDNO: 2 which is the DNA sequence for the CrylAc cotton event 3006-210-23 as shown in figure 2 (see para 0015 & 0042). Claim 2 relates to

a method of detecting the presence of a cotton event in a sample having cotton DNA wherein said method is diagnostic for SEQ ID NO:2.

Â The claims of the impugned application as refused are as follows:

1. A polynucleotide consisting of a nucleotide sequence having SEQ ID NO: 2.

2. A method of detecting the presence of a cotton event in a sample having cotton DNA wherein said method is diagnostic for SEQ ID NO:2, wherein

said method consists of contacting said sample with

a. a first primer that binds to a flanking sequence consisting of residues 1-527 of SEQ ID NO:2 or residues 8,901-9,382 of SEQ ID NO:2 wherein said

first primer consists of SEQ ID NO:9 or SEQ ID NO:13; and

b. a second primer that binds to an insert sequence consisting of residues 528-8,900 of SEQ ID NO:2; and subjecting said sample to a polymerase

chain reaction; and assaying for an amplicon generated between said primers wherein said second primer consists of SEQ ID NO: 10 or SEQ ID NO:

12.

3. The Appellant submits that the present invention is inventive at least for the following reasons.

Â The prior art D1 [US 20040045054 A1] and D2 [WO 2002100163 A2] were cited by the Respondent.

Â Appellant submits that D1 and D2 are patent publications of MONSANTO TECHNOLOGY LLC. D1 does not describe any sequences at all, and

does not even contain a sequence listing. D2 describes only the sequence of the Cry1F event in the MON15985 event. Both D1 and D2 refer to the

Cry1Ac gene coding sequence, but the Cry1Ac gene coding sequence is not shown in D1 or D2. Furthermore, the Cry1Ac gene coding sequence is

about 1104 nucleotides long while the sequence of the construct of the present invention shown in Fig. 2 (SEQ ID NO:2) is 9382 nucleotides long.

Document D1 teaches cotton comprising crylAc in a specific elite event albeit a different elite event than the one being the subject-matter of claim.

D2 is directed to a transformation event of cotton plants, comprising a polynucleotide sequence encoding a Cry2Ab protein inserted into a specific site

within the genome of a cotton cell. D2 also refers back to the cotton event 531 of D1. The cotton event MON531, was transformed a second time

with a genetic construct named PV-GHBK11 comprising the coding sequence for Cry2Ab. It is denominated as MON15985. D2 has been identified

as background art along with its distinguishing features, in the applicantâ??s impugned specification page 3; para [0006]- page 55 of the appeal. D2

deals with the event involving Cry2Ab gene. Since D1 teaches cotton comprising crylAc in a specific elite event albeit a different elite event than the

one being the subject- matter of claim, D1 may be considered the closest prior art.

The present claims are directed to SEQ ID NO: 2 (Cry 1Ac event) and method of detecting the same in the plant. SEQ ID NO: 2 is 9382 nucleotides

long artificial DNA sequence for the crylAc event 3006-210-23 as shown in figure 2 (see para 0015 & 0042-page 56 and 61 of the appeal respectively

â?" Figure 2 on page 87 of the appeal). (Sequence listing on page 96 of the appeal.)

Â FIGURE 2 of the present invention is given below for quick reference.

The Cry1 Ac cotton event 531 described in D1 is depicted as below (reproduced from D1 abstract).

Â The difference in the construction of the events disclosed in the present invention and the closest prior art D1 has been clearly drawn out in the

Affidavit which the appellant has filed at the Indian patent office; in Table 1 and Table 2 of the Affidavit of Dr. terry white as filed is shown below for

quick reference.

It is to be noted that only common feature between the present invention and D1 is the Cry1Ac gene sequence described in D1 and D2 is only a

portion of the â??open arrowâ?? shown in Fig. 2. And the portion marked as

Cry1Ac in the above figure of D1. The Cry1Ac sequence is only 1104

nucleotides long. See Fig. 2 reproduced above; which shows the organization of the entire claimed SEQ ID NO: 2 which is 9382 nucleotides long.

Accordingly, the claimed polynucleotide sequence (SEQ ID NO: 2) is inventive because it contains at least 8278 nucleotides that are not described at

all in D1 or D2. Consequently, at most, only 12% of the nucleotides in the sequence of the construct shown in Fig. 2 (SEQ ID NO: 2) are described in

D1 and D2. About 88% of the nucleotides in SEQ ID NO: 2 were unknown at the time the patent application was filed relative to the sequences

described in D1 and D2.

Para [0012] of the Terry White Affidavit states that the usage of different genetic elements is significant, different promoters drive expressions of

transgenes in different tissues at varying levels of expression. The usage of Zea mays Ubiquitin 1 promoter surprisingly results in higher yields of

protein expression of the Cry1Ac transgene in whole mature plants of the Cry1Ac cotton event 3006-210-23 as compared to protein expression levels

of the Cry1Ac transgene when driven by the enhance 35 S Cauliflower mosaic Virus promoter in the Cry 1Ac cotton event 531. The different gene

elements used has profound influence upon the expression of the Cry1Ac gene, which therefore varies to a great extent in the present invention and

D1.

Â The events described in D1 or D2 is different from the claimed event and non-obvious in that 88% of the nucleotides in SEQ ID NO: 2 was

unpredictable from the teachings of D1 or D2.

Â Accordingly, the claimed CrylAc event is representative of an improvement that surpasses the CrylAC event disclosed in D1. The technical effect

obtained by the specific elite event being the subject-matter of claim 1 over D1 is an improved agronomic performance and an increased insect

resistance.

Â The Respondent has completely ignored the above evidence on record showing the surprising effects and went ahead and refusing the application

on the ground of non-obviousness.

Â The Respondentâ??s statement - â??The use of the entire sequence Id 2 with additional genetic elements which improvise or improves

insecticidal resistance, helps insertion, increases insert expression, etc (fig 1-2) would be straight forward path a skilled man would normally go in with

an expectation of successâ??- is nothing but oversimplification of the impugned invention.

Â Further the order states that â??The results obtained in the instant application cannot be termed surprising with the knowledge of prior art as this is

the outcome which is expectedâ?. This is followed by Respondentâ??s statement â??Applicant agentâ??s argument and the Notarized Affidavits

have been considered but not found persuasive for the reasoning aboveâ??.

Â The above statements are in complete contradiction to each other, as the Controller ignored the 5-6 fold increased protein expression and other

superior effects of the present invention as compared to D1, as demonstrated in the evidence on record. There is no discussion on the data about the

affidavit anywhere in the impugned order.

Â The Honâ??ble IPAB in OA/33/2015/PT/KOL emphasized the importance of considering additional data as. In para 26 of the said order the

Honâ??ble Board observed as follows:

25â?¦â?¦â?¦â?¦â?¦â?¦..However, there is not even a whisper of such affidavits and the data, or the details provided therein in the order of the Controller

dated 27th February, 2015.

26. â??In complete disregard of the evidence on record filed by the appellants, the Controller rejected the present application. This is clearly an error

by Respondent No. 1 and it is a complete violation of the principles of natural Justice.â??

Â Non- obviousness

The reason for rejection is not justified, since it address the question of inventive step regarding a claim directed at any event insertion of CrylAc into

the cotton genome, but not regarding a claim directed at a very specific insertion which is inventive over the cited prior art as will be outlined below.

Â The expression of foreign genes in plants is influenced by where the foreign gene is inserted in the chromosome. For example, the same gene in the

same type of transgenic plant (or other organism) can exhibit a wide variation in expression levels amongst different events. Thus, it is necessary to

create and screen a large number of events in order to identify an event that optimally expresses an introduced gene of interest.

Â To produce the subject invention, hundreds of events were screened in the initial screening for the subject event(s). It is quite difficult to identify

and predict which events will yield the best-performing products. The size of the cotton genome should also be considered. The insertions or

â??eventsâ? could occur anywhere in the genome. Its genome has proven difficult to sequence and assemble because of its large size as well as the

large quantity of repetitive DNA. The cotton genome, at about 2.7 billion nucleotides, is roughly comparable to the human genome at 3.2 billion.

Additionally, most organisms â?" including humans â?" have two sets of chromosomes. However, domesticated cotton has four sets.

This should illustrate the complexity of the task that was at hand. For example, the subject event was essentially one of over about 2 billion possible

options / genomic locations. In addition, for example, the subject event was found to be able to be stably propagated along many breeding lines.

Â Starting from D1, the skilled person would not have arrived at the subject-matter of claim 1 without inventive activity. In particular, the skilled

person had no reasonable expectation that the specific integration site named in present claim 1 would solve the problem of providing a cotton

plant/seed with an improved agronomic performance and an increased insect resistance.

Â Even if the skilled person starting from D1 would have endeavoured to identify better suitable elite events, he had no reasonable expectation of

identifying the particular elite event being the subject-matter of claim 1 due to the umpteen number of possibilities as stated above. Even if the skilled

person starting from D1 would have further considered the disclosure made in D1, he would not have arrived at the claimed subject-matter but merely

at a cotton variety comprising SEQ ID NO: 12 of D1 at a genomic integration site that provides inferior results, as compared to the present invention.

D2 does not in any way cure the deficiencies of D2. Thus, the subject-matter of claim 1 is also inventive over the disclosure in document D1 and

considering the disclosure of D2.

Â Thus, the above should show: (a) producing and selecting elite events is a complicated process that involves many possible options and approaches,

and empirical judgment calls and data interpretation along the way, and (b) the subject cry1Ac event was selected from a pool of many possible

options, thus showing its superior features over the other events. The Appellant believes that various factors were considered in selecting this single

event from amongst many. These factors would include agronomics (yield, plant appearance, growth, etc.) as well as insect resistance. The initial use

of multiple possible constructs should also show that the exact components and order of them in the construct is another consideration that should

illustrate the inventiveness of what is now claimed.

Â Although in the impugned decision, the Controller discusses many known methods for identifying a new event from the cited documents, the

knowledge of those methods does not mean that expression levels for any particular event produced by using those methods would be at all expected.

In fact, D1 cited by the Controller, says that â??there may be a wide variation in levels of expression of one or more exogenously introduced genes

among events.â? Consequently, a high level of expression of a protein as a result of production of any particular event is unexpected. The claimed

invention expresses 5-6 times greater amounts of the Cry1Ac protein, a toxin for insects, than the constructs described in D1 and D2 resulting in

insect resistance across a broader range of insect pests and providing more robust prevention of resistance development to the toxins by insects. This

property of the Cry1Ac event (SEQ ID NO:2) is completely unexpected and provides technical benefits for the claimed invention. Therefore, the

claimed invention has inventive step over D1 and D2.

4. Further the learned counsel of the appellant submitted about the grant of the parent application by the IPO and grant of corresponding patents in

other jurisdictions:

It may be noted that the parent patent has been granted for a similar invention for the Cry1F event (SEQ ID NO. 1). That the impugned order is not

maintainable as the Respondent has failed to consider that the inventive step of the SEQ ID NO: 1 (Cry1F event) was acknowledged by the Indian

Patent Office by the grant of INP No. 253525 in the parent application no. 3542/ CHENP/2006. So there is no reason that inventive step should be

denied for SEQ ID NO: 2 â?" the Cry 1Ac event.

Â In view of the above arguments, the Appellant humbly submits that the present invention involves inventive step and the impugned order refusing

this application is erroneous.

Â GRANT OF CORRESPONDING APPLICATIONS:

Â The present invention has been granted in most of the corresponding applications. The latest status of the corresponding applications is given in the

below table.

The presently refused subject matter has been granted in EP â?" please see claim 7 of EP 2333082 B1 (page 232 of the appeal) and claim 5 of EP

2892934 B1 (page 269 of the appeal) over D1 and D2. D1 equivalent WO 02/40667 was cited as D7 in EP application in the office action dated

30.01.2012. Reference was drawn on page 2 of the EP 2333082 B1 (page 201 of the appeal) where D1 equivalent WO 02/40667 and D2 has been

identified in the background section (para [0006]. In Europe, the same inventive step arguments discussed above, based on the comparative data, was

made and the same Declarations as in the presently filed Affidavits were filed in support of these arguments.

Â In the corresponding patent US 7179965B2, claim 4 covering cotton seed comprising Cry1Ac cotton event 3006-210-23 (SEQ ID NO:2) is granted

(page 303 of the appeal) and a method for detecting Cry1Ac cotton event 3006-210-23 (SEQ ID NO:2) were allowed in claim 2 of U.S. Patent No.

US7883850 B2 (page 336 of appeal). We also refer to Brazilian patent PI0418683-4 and BR122015009611-1 where claims of similar scope were

granted.

The Respondent has refused the patent completely disregarding the fact that the matter has been granted in other major jurisdictions.

5. Letâ??s have a look on the operating portion of the order of the respondent:

Â The prior art (D1 and D2) used 1104 nucleotides of the Cry1Ac sequence for successful generation of plants displaying insecticidal resistance. The

use of the entire sequence Id 2 with additional genetic elements which improvise or improves insecticidal resistance, helps insertion, increases insert

expression, etc (fig 1-2) would be straight forward path a skilled man would normally go in with an expectation of success. The use of additional

genetic elements to improve insecticidal resistance from a multitude of standard molecular biology tools is what a skilled person is aware of in view of

disclosures in the prior art D1 and D2. Similarly methods to prepare probes and use of probes for diagnostics is also very clearly denoted in prior art.

Thereby in view of prior art the instant application falls within common general

knowledge of the skilled person such as usage of full length Cry1Ac

gene sequence for developing transgenic plants showing insecticidal proteins, additional genetic elements in the construct, making transgenic plants,

preparation of primers/ probe and use of same as diagnostic?s to detect the gene insert. The results obtained in the instant application cannot be

termed surprising with the knowledge of prior art as this is the outcome which is expected. The skilled person with the ample disclosures of prior art

could generate transgenic cotton plants or their seeds containing cry1Ac genes by applying standard cloning and plant-transformation technologies and

would have applied a standard screening programmes to identify those plants exhibiting a desired expression level and pattern of the inserted

transgenes by applying standard DNA sequencing technologies. Starting from prior art D1-D2 there is ample amount of teaching or motivation to one

of ordinary skill in the art to arrive at the presently disclosed subject matter.

Â The instant application is merely one of several straightforward possibilities which the skilled person would select, depending on the circumstances,

without exercising inventive skill in view of the prior art. Applicant agent?s argument and the Notarized Affidavits have been considered but not found

persuasive for the reasoning above.

Â In view of this, inventive step u/s 2(1)(j)(a) of the Act is not acknowledged for the claimed subject matter.

Â Order: In view of the above, the requirements of objections 7 of hearing notice are not met. The instant patent application 5103/CHENP/2012 is

refused u/s 15 of Patents Act.

6. We have noted that a patent no. 253525 was granted in pursuance of the first mentioned application no. 3542/CHENP/2006 restricting itself to SEQ

ID No. 1. At the stage of FER, there was an objection taken on the ground of plurality of invention and accordingly, the instant application was filed,

as divisional application, restricting itself to SEQ ID No.2.

7. It is further noted that at the examination of first mentioned application two prior arts namely D1: WO002001013731A1 and D2:

WO001998022595A1 were cited for lack of novelty. There was no objection in respect of lack of inventive step in the parent application. The main

objection of FER in the parent application were as under:

8. The prosecution history of the parent application reveals that on submissions of the response of the Examination Report by the applicant, the subject

matter was found novel and hence the patent was granted to the appellant with patent no. 253525 which covered only features of SEQ ID No. 1,

which related to Cry1F insect inhibitory proteins.

9. The instant application was filed as divisional to the first mentioned application no. 3542/CHENP/2006 and covered only the features of and

Cry1Ac insect inhibitory proteins. The application was examined and two prior arts were relied upon for lack of novelty and inventive step as D1: US

20040045054 A1 & D2: WO 2002100163 A2.

10. On consideration of the relevant documents, we are convinced that the claimed polynucleotide sequence (SEQ ID NO: 2) is novel because it

contains at least 8278 nucleotides that are not described at all in D1 or D2. Only a partial cry1Ac gene coding sequence is described in D1 and D2,

and SEQ ID NO:2 contains many genetic elements not described in D1 or D2, including chimeric promoters and junction sequences. Also, the intricate

design of SEQ ID NO:2 and all of the various genetic elements in the SEQ ID NO:2 construct, have not been described in either D1 or D2.

11. In respect of objetion of lack of inventiove step, we are inclined to accept the arguments of the appellant. The claims have technical benefits

(unexpected results) over D1 and D2 when the claimed invention (containing SEQ ID NO:2) is compared directly (using comparative data) to the

Cry1Ac cotton event 531 (or the MON15985 event) described in D1 and D2. Importantly, the expression of Cry1Ac is increased 5-6 fold with SEQ

ID NO:2 in comparison to the Cry1Ac 531 event (or the MON15985 event) described in D1 and D2. Thus, SEQ ID NO:2 (the claimed Cry1Ac

event) more robustly expresses the Cry1Ac protein, a toxin for insects, which is critical for effective and consistent insect control as well as being an

important factor in robust prevention of resistance development to the Cry1Ac insect toxin proteins.

12. It is further noted that not only the patent was granted in India on the parent application but all the four prior arts quoted above have been relied

during the examination of the corresponding applications in various other jurisdictions, as informed by the appellant, and were verified to be true. The

patents in all other jurisdictions have been granted on considering these prior

arts.

13. We, however, find that though claim 1 is defined well, the method claim defined in claim 2 is not fully supported by the description. We do not find

any support of the terms â??first primersâ? anywhere in the description. No doubt the SEQ ID No. 9 and 13 are respectively defined as forward and

reverse set of primers but their application with SEQ ID NO.2 and the step defined in the claim do not find support in the description. The phrase

wherein said first primer consists of SEQ ID NO: 9 or SEQ ID NO: 13 have no support in the description. However, finding it as a drafting error, we

are inclined to give benefit of doubt and allow the amended claim 2 as it is on record now and no objection in this regard exist.

14. Considering the above facts, we set aside the order of the Respondent dated 17/01/2020 and direct the respondent to grant the patent on the

amended set of claims within 3 weeks from the date of issuance of this order.

15. Keeping in view the above, the instant appeal is allowed. No cost.

