Intellectual Property Appellate Board
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OA/18/2020/PT/CHN

MONDAY, THIS THE 25TH DAY OF JANUARY, 2021

HON'BLE SHRI JUSTICE MANMOHAN SINGH — **CHAIRMAN**
HON'BLE DR. B.P. SINGH — **TECHNICAL MEMBER (PATENTS)**

DOW AGROSCIENCES LLC
9330 ZIONSVILLE ROAD
INDIANAPOLIS, IN 46268-1054
USA **… APPELLANT**

(Represented by: Dr. Meera Venugopal)

Versus

CONTROLLER OF PATENTS AND DESIGNS
GOVERNMENT OF INDIA, PATENT OFFICE
INTELLECTUAL PROPERTY RIGHTS BUILDING
GST ROAD, GUINDY
CHENNAI – 600 032 **… RESPONDENT**

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

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 Appellant's Indian patent application no. 5103/CHENP/2012.
2. The invention, as explained the appellant is as under:

2.1 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 "stacked" 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.

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

2.3 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.

2.4 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.

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

3.2 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.

3.3 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 applicant'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.

3.4 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 – Figure 2 on page 87 of the appeal). (Sequence listing on page 96 of the appeal.)

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

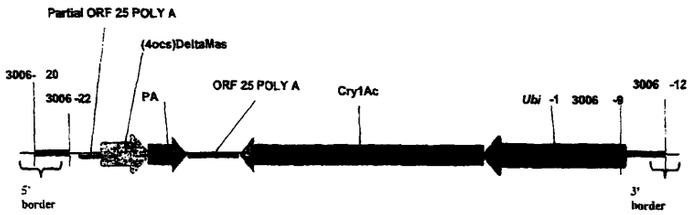
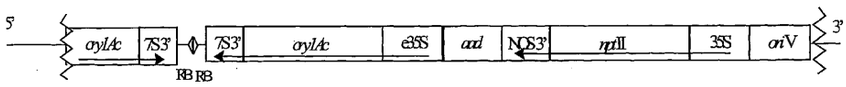


FIG. 2

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



3.7 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.

Table 1 . Gene elements used in the Cry1Ac event of the claimed invention.

Name	Description	Functions
P-UbiZm1	Constitutive promoter of ubiquitin 1 gene from *Zea mays*	Constitutive promoter.
I-UbiZm1	Intron 1 of ubiquitin 1 gene from *Zea mays*	Intron.
proCrySyn	Sequence encoding part of a *B. thuringiensis* CRYlCa3 protoxin and part of the CRY1Ab1 protoxin	Insect resistance.
cryIAc	Sequence encoding Bt endotoxin of *Bacillus thuringiensis* var. *kurstaki*	Insect resistance lepidoptera resistance.
Orf25polyA	3' Bidirectional termination sequence from Agrobacterium tumefaciens pTi 15955	Polyadenylation site.
pat	Sequence encoding the PAT (phosphinothricin acetyl	Glufosinate tolerance.
	transferase) enzyme from *Streptomyces viridochromogenes*	
E-OC	Enhancer sequence of octopine synthase transcription gene of *Agrobacterium tumefaciens* pTiAchS	Transcription increase.
P-mas2'	Constitutive promoter of the mannopine synthase gene of *Agrobacterium tumefaciens*	Constitutive promoter.

Table 2. Gene elements used in the Cry1Ac event 531 of D1.

Name	Description	Functions
5' FRund	Undesired sequence at the 5' flanking region	Not known.
3' 7S	Termination sequence of 7S soybean (*Glycine max*) gene	Polyadenylation site.
cry1Ac	Sequence encoding Bt endotoxin of Bacillus thuringiensis var. kurstaki	Insect resistance lepidoptera resistance.
P-e35S	Constitutive promoter of CaMV 35S gene	Constitutive promoter.
aad	Sequence encoding the 3'(9)-O-aminoglycoside adenylyltransferase enzyme with bacterial promoter	Antibiotic resistance.
3' nos	3' termination sequence of the nopaline synthase gene from Agrobacterium tumefaciens T-DNA	Polyadenylation site.
nptII	Sequence encoding the NPTII enzyme (neomycin phosphotransferase) from Tn5 transposon of *E. coli*	Antibiotic resistance.
P-e35S	Constitutive promoter of CaMV 35S gene	Constitutive promoter.
ori-V	Origin of bacterial replication	Plasmid replication.
3' Frund	Undesired sequence at the 3' flanking region	Not known.

3.8 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 'open arrow' 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.

3.9 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.

3.10 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.

3.11 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.

3.12 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.

3.13 The Respondent's statement - *"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"*- is nothing but oversimplification of the impugned invention.

3.14 Further the order states that *"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"*. This is followed by Respondent's statement *"Applicant agent's argument and the Notarized Affidavits have*

been considered but not found persuasive for the reasoning above".

3.15 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.

3.16 The Hon'ble IPAB in OA/33/2015/PT/KOL emphasized the importance of considering additional data as. In para 26 of the said order the Hon'ble Board observed as follows:

> *25……..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. "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."*

3.17 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.

3.18 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.

3.19 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 "events" 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 – including humans – have two sets of chromosomes. However, domesticated cotton has four sets.

3.20 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.

3.21 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.

3.22 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.

3.23 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.

3.24 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 "there may be a wide variation in levels of expression of one or more exogenously

introduced genes among events." 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:

4.1 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 – the Cry 1Ac event.

4.2 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.

4.3 GRANT OF CORRESPONDING APPLICATIONS:

4.4 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.

Country	Case Type	Status	App. Number	Filing Date	Publication Number	Publication Date	Patent Number	Issue Date
United States of America	DIV	Lapsed	13/021410	04-Feb-2011	US-2011-0191900-A1	04-Aug-2011		
European Patent Convention	PCT	Pending	04809955.0	29-Aug-2006	1737964	03-Jan-2007		
India	DIV	Pending	5103/CHENP/2012	11-Jun-2012		28-Feb-2014		
Argentina	DIV	Pending	P150100331	27-Oct-2006				
Argentina	ORD	Pending	P040103858	22-Oct-2004	AR046599	14-Dec-2005		
Australia	DIV	Issued	2012201287	02-Mar-2012		22-Mar-2012	2012201287	20-Nov-2014
Brazil	DIV	Pending	BR122015009617-0	29-Apr-2015		02-Jun-2015		
Brazil	DIV	Issued	BR122015009611-1	29-Apr-2015		02-Jun-2015	BR122015009611-1 B1	06-Sep-2016
Brazil	ORD	Issued	PI0418683-4	07-Nov-2012		12-Jun-2007	PI0418683-4	17-May-2016
European Patent Convention	DIV	Issued	14198791.7	18-Dec-2014	2862934	22-Apr-2015	2862934	29-May-2019
United States of America	ORD	Lapsed	13/729543	28-Dec-2012	US-2014-0189907-A1	03-Jul-2014		
China (People's Republic)	DIV	Lapsed	201110249211.5	13-Oct-2004				
Australia	PCT	Issued	2004318788	27-Sep-2006		19-Oct-2006	2004318788	05-Apr-2012
India	PCT	Issued	3542/CHNEP/2006	26-Sep-2006		03-Aug-2012	253525	26-Jul-2012
European Patent Convention	DIV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Belgium	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Switzerland	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Cyprus, Republic of	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Germany	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Spain	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
France	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
United Kingdom	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Greece	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	3085566	07-Jan-2015
Hungary	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Italy	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Ireland	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Luxembourg	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Netherlands	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Portugal	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	2333082	07-Jan-2015
Turkey	EDV	Issued	10015576.1	13-Dec-2010	2333082	15-Jun-2011	TR 2015 02518 T4	07-Jan-2015

United States of America	PRO	Expired	60/556586	26-Mar-2004				
United States of America	PRO	Expired	60/613851	27-Sep-2004				
Patent Cooperation Treaty	ORD	Expired	PCT/US2004/033844	13-Oct-2004	WO2005/103266	03-Nov-2005		
Mexico	PCT	Issued	PA/a/2006/011082	13-Oct-2004			279329	24-Sep-2010
China (People's Republic)	PCT	Issued	200480042571.6	26-Sep-2006	1010273968	29-Aug-2007	ZL200480042571.6	03-Aug-2011
United States of America	ORD	Issued	10/964838	13-Oct-2004	US-2005-0216969-A1	29-Sep-2005	7179965	20-Feb-2007
United States of America	DIV	Issued	11/704418	09-Feb-2007	US-2007-0143876-A1	21-Jun-2007	7883820	08-Feb-2011

4.5 The presently refused subject matter has been granted in EP – 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.

4.6 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.

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

5. Let's have a look on the operating portion of the order of the respondent:

5.1 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.

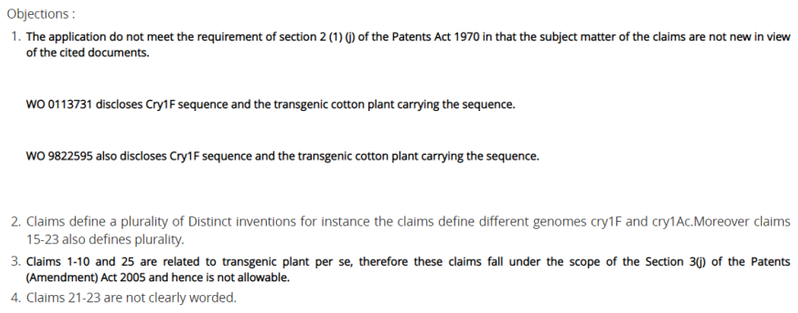
5.2 The instant application is merely one of several straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill in view of the prior art. Applicant agent''s argument and the Notarized Affidavits have been considered but not found persuasive for the reasoning above.

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

5.4 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:



Objections :

1. The application do not meet the requirement of section 2 (1) (j) of the Patents Act 1970 in that the subject matter of the claims are not new in view of the cited documents.

   WO 0113731 discloses Cry1F sequence and the transgenic cotton plant carrying the sequence.

   WO 9822595 also discloses Cry1F sequence and the transgenic cotton plant carrying the sequence.

2. Claims define a plurality of Distinct inventions for instance the claims define different genomes cry1F and cry1Ac.Moreover claims 15-23 also defines plurality.
3. Claims 1-10 and 25 are related to transgenic plant per se, therefore these claims fall under the scope of the Section 3(j) of the Patents (Amendment) Act 2005 and hence is not allowable.
4. Claims 21-23 are not clearly worded.

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 "first primers" 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.

-Sd/- -Sd/-

(Dr. B.P. Singh)
Technical Member (Patents)

(Justice Manmohan Singh)
Chairman