

MANU/DE/1388/2018

Equivalent Citation: MIPR2018(2)179, 2018(74)PTC12(Del)



IN THE HIGH COURT OF DELHI

FAO (OS) (Comm.) 86/2017, C.M. Appl. 14331, 14335, 15669, 17064/2017, FAO (OS) (Comm.) 76/2017, CAV. 328/2017 and C.M. Appl. 13348-13352/2017

Decided On: 11.04.2018

Appellants: **Nuziveedu Seeds Ltd. and Ors.**
Vs.

Respondent: **Monsanto Technology LLC and Ors.**

Hon'ble Judges/Coram:

S. Ravindra Bhat and Yogesh Khanna, JJ.

Counsel:

For Appellant/Petitioner/Plaintiff: Jayant Bhushan, Sr. Advocate, C.A. Sundaram, Diya Kapur, Swathi Sukumar, Swati Setia, Essence Obhan, Himanie Katoch, Nikhil Ratti Kapoor, Aakanksha Kaul, Pooja Katara, Charul Yadav, Abhishek Saket, Vijaya Singh, Jatin and Rohini Musa, Advocates

For Respondents/Defendant: Sandeep Sethi, Prathiba M. Singh, C.M. Lal, Sr. Advocates, Bitika Sharma, Kapil Midha, Namrita Kochhar, Deepshika Malhotra, Adarsh Ramanujam, Anil Dutt, Shantanu Agarwal, Rishi Agarwala, Anusuya Nigam, Lakshay Kaushik and Ruchika Wadhawan, Advocates

Case Note:

Patents - Sub-license agreements - Termination - Infringement - Section 3(j) of Patents Act, 1970 (Act) - Whether subject patent fell within exclusion spelt out by Section 3(j) of Act and subject patent and claims covered by it were consequently held to be unpatentable? Held, transgenic plants with integrated Bt. Trait, produced by hybridization (that qualified as an "essentially biological process") were excluded from patentability within purview of Section 3(j), and Monsanto could not assert patent rights over gene that had thus, been integrated into generations of transgenic plants. Bt. trait induced varieties were parts of "seed". Trait, by itself had no intrinsic worth; it was meant to be implanted or introgressed and later hybridized into a variety to be further hybridized through backcrossing and cross breeding with other existing varieties to produce seeds that were ultimately used. Without introgression, they were inert and inanimate. Process of hybridization undertaken by Nuziveedu group and Bt. Cotton hybrid plants as well as seeds produced thereafter, were squarely exempt under Section 3(j) of Act; these seeds were sold to farmers and other retailers. Moment DNA containing nucleotide sequence (subject patent) was hybridized to produce transgenic seeds/plants; seeds/plants fall within purview of Protection of Plant Varieties and Farmers' Rights Act, 2001 and, above, process of creation of such seeds/plants were also excluded from patentability as they squarely fall within meaning of an "essentially biological process" that was exempted from patentability within meaning of Section 3(j), as well. Subject matter, concerned nucleotide sequence over which Monsanto had patent rights and process was unpatentable by reason

of Section 3(j) of Patents Act. Patents - Injunction - Section 42 of Specific Relief Act, 1963 (Act) - Whether injunction be refused, to Monsanto, or rather, whether it be compelled to supply varieties containing trait, for any price other than price it sought? Held, agreements between parties were for a defined time; Monsanto sought to terminate it and also sued for infringement; it sought interim injunction as well. Nuziveedu counter-claimed, justifying its refusal to pay anything more than trait value fixed by state legislation, in first instance, as well as order issued by Central Government in 2015. That agreements were determinable could not be prima facie denied. Section 42 of Act, clarified that where a contract comprises an affirmative agreement to do a certain act, coupled with a negative agreement, express or implead, not to do a certain act, circumstances that, Court is unable to compel specific performance of affirmative agreement shall not preclude it from granting an injunction to perform negative agreement. If obligation of a seed developer or supplier was not to charge more than what law prescribed, it could not legally collect it, till law was overborne in a manner known to Constitution-either by judicial declaration or by repeal. In such context, insistence of Monsanto that, it was free to nevertheless withhold supplies of seeds or varieties of seeds, containing the Bt. Trait, to Nuziveedu, could not be countenanced. A negative obligation, implied to honour existing law, binds parties. Furthermore, as an essential commodity, supply of which was regulated by law (including control of trait value), Monsanto was obliged to maintain supplies, to facilitate production of Nuziveedu's varieties for onward sale to farmers, sowing and harvesting of crop. Balance of convenience element was an important element that, every Court was compelled to weigh, apart from question of prima facie likelihood of success in a suit or counter claim. Absence of a patent resulted in lack of property in use of CryAb2 and consequent lack of control by Monsanto about its use by others, like Nuziveedu, who might have acquired it under agreement, lawfully, developed their varieties or breeds and sold it to farming community. Grant of injunction was rendered untenable. Equally, denial of a positive order, resulted in violation of provisions of Essential Commodities Act, as it would deprive thousands, possibly a million or so farmers, right to access to seeds that were hitherto available to them. In ultimate event of Nuziveedu failing in its counter claim, harm that might befall Monsanto during pendent lite period was compensable, monetarily. In these circumstances, pending trial of suit, directions of Single Judge did not call for interference. Single Judge's directions to Monsanto to continue with its obligations under sub-license agreements, including consequential orders with respect to payment and receipt of trait value, were upheld. Monsanto's appeal was consequently dismissed. Nuziveedu's appeal, is partly allowed.

JUDGMENT

S. Ravindra Bhat, J.

Facts

1. This common judgment disposes of two appeals (FAO (OS) 86/2017 and FAO (OS) (COMM) 76/2017). Monsanto Technology LLC (referred to as "Monsanto") prefers FAO (Comm) 76/2017; Nuziveedu, the appellant in FAO (OS) 86/2017, would be referred to as such in this judgment. The facts in Monsanto's appeal are referred to, for convenience.

2. The second and third appellants in Monsanto's appeals are subsidiaries/affiliates of Monsanto Technology LLC ("Monsanto"). Monsanto set up the third appellant as a joint venture with Maharashtra Hybrid Seed Company ("Mahyco") to undertake Bt. Trait¹ licensing business in India. These entities (Monsanto, Mahyco et al) are referred to collectively as "Monsanto". Nuziveedu is a private sector seeds company in India. The other respondents (in Monsanto's appeals) are Nuziveedu's subsidiaries; all are engaged in the same business of, inter alia, developing new hybrids and varieties of cotton. Nuziveedu and its subsidiaries currently possess approvals for over 29% of all cotton hybrids approved by the Genetic Engineering Appraisal Committee ("GEAC"), one of the regulatory bodies constituted under the Environment (Protection) Act, 1986 and rules thereunder, by the Ministry of Environment, Forest and Climate Change, to accord approval on proposals relating to the release of genetically modified organisms and products into the environment.

3 . Monsanto appeals the judgment of a learned single judge (the "impugned judgment") which directed it to continue supplying Bt. Cotton transgenic variety (Donor Seeds) under the 2015 Sub-License Agreements except as to the rate of trait fee payable, thereunder. The learned single judge also held that Nuziveedu would be liable

"to tender, and pay, the trait fee to Monsanto, for the use of the suit patent and trademarks, at such rates as are in accord with the prevalent local laws, as in force or revised from time to time; and (iii) upon being suitably notified, be obliged to execute necessary documents so as to render the contract(s) in accord with the "GM Technology (GM Trait) Licensing Agreement" as prescribed under the "Licensing and Formats for GM Technology Agreement Guidelines, 2016", notified by the Government of India."

4 . Nuziveedu appeals the rejection of its application, which urged rejection of Monsanto's patent (Indian Patent No. 214436, covering an invention titled "METHODS FOR TRANSFORMING PLANTS TO EXPRESS BACILLUS THURINGIEN DELTAENDOTOXINS"- hereafter called "the subject patent") cannot be sustained as it is an excluded subject matter, by Section 3 (j) the Patents Act, 1970 (hereafter, the "Patents Act"). Section 3(j) excludes from patentability

"plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."

Brief Facts

5. Monsanto applied to the Indian Patent Office on May 1, 2001 in the National Phase PCT Application No. PCT/US99/26086, claiming a patent with a priority date of November 4, 1998. It was eventually granted to it (i.e. Patent No. 214436, the subject patent). The patent included the 'nucleic acid sequence' and the consequent process to insert the 'nucleic acid sequence' in plant cells. 27 claims were granted in the said patent. In this regard, Claims Nos. 25 to 27 related to a particular chemical product i.e. the nucleic acid sequence, Claims 1 to 24 were process claims which dealt with genetic engineering process or biotechnology methods to insert the nucleic acid sequence (claimed under claim Nos. 25 to 27) into a plant cell. Monsanto claimed that its invention comprised of:

- identification of desired gene (Cry2Ab) from the DNA of BT (Bacillus Thuringiensis) bacteria, which is found naturally in the soil;

- making (synthesizing) nucleic acid sequence by copying the Cry2Ab for insertion into a plant cell; and
- the method of inserting the said nucleic acid sequence into a plant cell.

6. Monsanto is the owner of the Indian Patent No. 214436, which is directed to an invention titled "Methods For Transforming Plants To Express Bacillus Thuringiensis Deltaendotoxins" with the following details:

PCT International Application No.	PCT/US99/26086
Date of National Phase Entry:	May 01, 2001
Date of Publication under Section 11A of the Patents Act	March 16, 2007
Grant of Patent	February 12, 2008
Post-grant journal data	March 31, 2008

7. The relevant grounds of the subject patent in India are in respect of the following claims:

"25. A nucleic acid sequence comprising a promoter operably linked to a first polynucleotide sequence encoding a plastid transit peptide, which is linked in frame to a second polynucleotide sequence encoding a Cry2Ab Bacillus thuringiensis 8-endotoxin protein, wherein expression of said nucleic acid sequence by a plant cell produces a fusion protein comprising an amino-terminal plastid transit peptide covalently linked to said 5-endotoxin protein, and wherein said fusion protein functions to localize said 5-endotoxin protein to a subcellular organelle or compartment.

26. The nucleic acid sequence of claim 25, wherein said second polynucleotide sequence encodes a Cry2Ab Bacillus thuringiensis 8-endotoxin protein selected from the group of sequences consisting of SEQ ID NO:2 and SEQ ID NO: 18.

27. The nucleic acid sequence of claim 26, wherein said second polynucleotide sequence is selected from the group of sequences consisting of SEQ ID NO: 1 and SEQ ID NO: 17."

8. Monsanto claims that the patent is a biotech invention containing the infusion of Bt gene into the cotton genome. The Bt. bacterium eradicates pests afflicting the cotton plant. Monsanto states that the patent does not cover plants per se, but does cover components that can be termed microbiological processes and microorganisms, thus patentable under the Patents Act. It claims that using the patented technology, it created a large number of donor Bt. cotton seeds and distributed them to seed companies, (including Nuziveedu and its subsidiaries under different agreements). The licensees agreed to payment of royalties for the use of such donor seeds to introgress² the desirable genetic trait into their own specific hybrid varieties by backcrossing.

9. Monsanto sold 50 seeds of a Bt. Cotton transgenic variety (Donor Seeds) for' 50 lakhs to Nuziveedu and its subsidiaries under licensing agreements signed in 2004. This was renewed through the signing of a new agreement in 2015. Nuziveedu and

its subsidiaries used those Donor Seeds in their breeding program to inherit the Bt. cotton trait to their proprietary cotton plant varieties. According to Nuziveedu, the Bt. Cotton plant Varieties (hereafter "Bt. Varieties") developed by it and its subsidiaries have their own distinct characteristics, apart from the Bt. Trait and are distinct from the Donor Seeds variety initially provided by Monsanto. Nuziveedu and its subsidiaries state that they have applied for IP protection for all their Bt. Cotton Plant Varieties under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (hereafter called the "PV Act").

10. Cotton was initially included in the list of essential commodities under the Essential Commodities Act, 1955 by the Central Government (Department of Agriculture, Cooperation and Farmers Welfare under the Ministry of Agriculture and Farmers Welfare), in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955. It was, however, later removed from the list of essential commodities. Again, it was reintroduced, with the issue and promulgation of the Cotton Seeds Price (Control) Order, 2015 on December 7, 2015 to provide for an effective system for fixing the sale price of cotton seeds to ensure their availability to the farmers at fair, reasonable and affordable prices and for uniform regulation across India of the sale price of cotton seeds with the existing and future Genetic Modification (GM) technologies.

11. The Central Government estimated that from 2010 to 2015, the domestic seed companies paid Monsanto's subsidiary, approximately ' 1,600 crore in excess of the actual trait value fixed by various State Governments. Since the State Governments considered a trait value lower than the contractually imposed trait value by the said third appellant, in fixing the maximum sale price, Nuziveedu and other domestic seed companies represented through letters dated July 19, 2015, July 23, 2015 and August 10, 2015 to Monsanto requesting them to consider charging the trait value at the rates determined by State Governments. Monsanto, which thereafter filed arbitration petitions under Section 9 of the Arbitration and Conciliation Act, 1996, rejected this, against the seed companies before the Bombay High Court, for securing the amount, which it claimed, was due and payable during the kharif 2015-16 season. The Bombay High Court did not grant any interim reliefs in favour of the Monsanto group in those petitions. They then issued notices dated November 14, 2015 to the Nuziveedu group, in effect terminating the license arrangements.

12. Cases under Section 19(1)(a) of the Competition Act, 2002 against Monsanto and its subsidiaries, were apparently filed before the Competition Commission of India (CCI) filed by the (i) All India Kishan Sabha, (ii) Department of Agriculture and Cooperation, (iii) State of Telangana, and (iv) National Seed Association of India and various other seed companies. The CCI eventually passed an order on 13.04.2016 directing the Monsanto group of companies not to enforce the post-termination clauses on the Nuziveedu group.

13. The issues in the present suit are confined to the infringement of patent, trademark and passing off which Monsanto filed against the Nuziveedu group, after disputes arose between them with respect to payment of fee. The Nuziveedu group refused to pay license fee in terms of the agreements with Monsanto, claiming that legally they were obliged to pay no more and Monsanto could not claim anymore than, the "trait value" fixed by the State governments. The suit also concerns the alleged continuing infringement by Nuziveedu and its subsidiaries, inter alia, of the Indian Patent Number IN 214436, as described above, which Monsanto claims are in violation of Monsanto's proprietary rights in the said patent.

14. Monsanto claimed to be the lawful owner and the patentee of the said patent and

claims entitlement to rights granted under section 48 of the Patents Act, 1970. Nuziveedu, on the other hand, refutes that the suit claim, for enforcement of patents is liable to be rejected as the subject patent is solely concerning an unpatentable matter (by reason of Section 3 (j)). It also counter-claims, stating that the patent granted is liable to be cancelled. As against Monsanto's application for interim relief (of injunction to restrain Nuziveedu and its subsidiaries from using the Bt. Variety and the traits in question without licensing or without payment on agreed terms), Nuziveedu sought rejection of the suit.

15. Nuziveedu submitted that the crops with the Bt. Trait³ are referred to as genetically modified crops ("GM crops"), because they acquire an insect resistant trait through genetic modification. In a laboratory Bt. Trait genes can be inserted only into a variety (which is amenable for regeneration in lab conditions) through a biotechnology process, which after transformation is called as a transgenic variety. However, this by itself is not a variety which can be grown by farmers. Nuziveedu submits that the Bt Trait can be transferred from this variety into other varieties by traditional plant breeding methods and by farmers, to get a successful yield can grow only such new transgenic varieties.

16. Nuziveedu contended that they used the Donor Seeds transferred by Monsanto in their breeding process for improving their varieties with the Bt. Trait. They argued that the gene or the method of transformation was not transferred to them and only seeds of the transgenic variety were given. Nuziveedu also reiterated that the donor seeds of the transgenic variety supplied by the Monsanto group could not be used by farmers unless they were used as a donor variety by them (i.e. the Nuziveedu companies) to breed new varieties with more or additional traits, produce their seeds and supply them to farmers. Nuziveedu invested in extensive R&D to integrate the Bt. Trait from the transgenic variety Bt. Cotton Seed procured from the Monsanto group.

17. It is argued by Nuziveedu, that Monsanto is solely responsible under law to ensure the quality of Bt. Cotton seeds that are produced and sold to the farmers. They (Nuziveedu) have no responsibility under law to maintain the quality of Bt. Cotton seeds. The quality standards for Bt. Cotton seeds have been prescribed and regulated under the provisions of the Seeds Act, 1966 (Sections 4, 5, 6 and 7) and the rules made thereunder. It is also relevant to mention that now the Seeds Act, 1966, governs all approvals for new hybrid varieties and there is no longer a requirement to obtain a No objection certificate (NOC) from the Review Committee on Genetic Modification (RCGM) or GEAC.

18. Monsanto, in its suit, sought for an ad interim injunction against Nuziveedu, claiming that cause of action arose on account of the Nuziveedu companies continuing to "market and sell" Genetically Modified Hybrid Cotton Planting Seeds despite termination of the sub-license agreements. These agreements included trademark sub-license arrangements. Monsanto alleged violation of their intellectual property rights vis-à-vis the registered patent (described above), and the trademarks BOLLGARD and BOLLGARD II, the acts of commission or omission indulged in by the Nuziveedu group companies being such as amounting to infringement or passing off of their "illegally" manufactured products sold or offered to be sold in such packing or under such labels (BOLLGARD) bearing such marks as are identical or deceptively or confusingly similar to that of Monsanto's.

19. The learned single judge, by the impugned judgment held that the Nuziveedu companies cannot be enjoined against the use of the suit patent or the trademarks, such right of the respondents to continued use of suit patent or trademarks not being unconditional. The learned single judge negated Nuziveedu's argument regarding

patentability and held that the patent in respect of the subject matter, i.e. the two traits in the varieties, which resulted in Bollworm resistant seeds, could be protected under the Patents Act. The learned single judge thereafter, gave the following directions:

"(1). The parties shall remain bound by their respective obligations under the terms and conditions of the 2015 Sub-License Agreements (except as indicated hereinafter) for the period(s) stipulated therein, or till the same are lawfully terminated, the post contractual obligations continuing to be effective even beyond, as mutually agreed;

(2). Monsanto shall :-

(i). be entitled to all the rights under the 2015 Sub-License Agreements except as to the rate of trait value payable thereunder;

(ii). suitably inform the defendants within four weeks of this order :-

(a). modification of terms as to the rate of the trait fee payable by the defendants (sub-licensees) bringing it in accord with the prevalent local laws, as in force or revised from time to time; and

(b). the proposal for modification of the contract(s) so as to render the same to be in accord with "GM Technology (GM Trait) Licensing Agreement", as prescribed under the "Licensing and Formats for GM Technology Agreement Guidelines, 2016", notified by the Government of India.

(3). The defendants shall :- (i). be entitled to all the rights under the 2015 Sub-License Agreements except as to the rate of trait fee payable thereunder; (ii). be liable to tender, and pay, the trait fee to Monsanto, for the use of the suit patent and trademarks, at such rates as are in accord with the prevalent local laws, as in force or revised from time to time; and (iii). upon being suitably notified, be obliged to execute necessary documents so as to render the contract(s) in accord with the "GM Technology (GM Trait) Licensing Agreement" as prescribed under the "Licensing and Formats for GM Technology Agreement Guidelines, 2016", notified by the Government of India;

(4). In the event of Monsanto not accepting the tender of the trait fee in terms of the above directions, the defendants will have the liberty to deposit the same, in the court, from time to time, in terms of the periodicity stipulated in the Sub-License Agreements, and notify Monsanto simultaneously;

(5). In the event of the trait fee being deposited in the court, as per the liberty granted above to the defendants, Monsanto will have the liberty to withdraw the amount(s) thus deposited in the court, from time to time;

(6). In the event of default on the part of Monsanto, to withdraw the amount(s) as above, within one month of such deposit(s), the Registrar General shall keep each such deposit in interest bearing fixed deposit receipt in a nationalized bank, initially for a period of six months with provision for auto-renewal;

(7). The defendants shall be obliged to maintain and render accounts - including of month-wise sales, for each quarter of every financial year for which this order ordains, with further liability to place on record of the court duly-audited accounts within two months of the close of each financial year, making available copies thereof to Monsanto;

(8). The directions about payment, or deposit, of trait fee or rendition of accounts shall presently pertain to the period beginning with financial year 2016-2017;

(9). The defendants shall make due compliance with directions concerning payment or deposit, and rendition of accounts for the period ending with March 2017 by 31st May, 2017 and would be entitled to adjust amounts, if any, already paid on such account in terms of earlier interim orders in this case, or in terms of orders of arbitral tribunals, or otherwise;

(10). All acts undertaken in terms of these directions, including in the nature of payment(s) or deposit(s) of the trait fee shall be without prejudice to the rights or contentions of all parties in the main suit; and

(11). The default, if any, by the defendants in strict compliance with the above directions would render them disentitled to the continued use of the suit patent or trademarks of Monsanto, consequent whereupon, in such event they would stand enjoined against continued use of suit patent and registered trademarks of Monsanto for the pendency of the suit."

20. Monsanto is aggrieved by the findings and directions given by the learned single judge in the impugned order, which directs it to compulsorily license its intellectual property in terms of the 2015 Sub-License Agreements, (that stood terminated in November, 2015) on the allegedly erroneous finding that such termination is invalid. Nuziveedu's argument in its appeals is with regard to the alleged erroneous conclusions with regard to the scope of the patent claims, the scope of Section 3 (j) of the Patent Act, the use of the suit patent and the applicability of the PV Act.

Procedure in appeal

21. After the initial hearing of the appeal, the counsel for parties indicated to this court that since the main issue to be addressed is the sustainability of Monsanto's patent, in view of the pointed challenge to it, by Nuziveedu, parties should consider and argue, finally this aspect. This meant that in case Monsanto's contentions prevailed, the question to be decided would be the extent of damages and also the direction impugned by it, contained in the learned single judge's decision. On the other hand, if Nuziveedu succeeded in its appeal, Monsanto's suit would stand rejected and the surviving issue would be the correctness of the learned single judge's direction to supply Bt. Cotton seeds. The court also notices that the impugned judgment had pertinently observed as follows:

"A perusal of the pleadings in the main suit and those concerning various applications (including counter claims) reveals that factual matrix forming the core of the cause of action alleged here is substantially undisputed, even to the event of facts forming the core of the circumstances leading the parties on both sides of the divide having run afoul of each other, the arguments raised on the prime application (under Order XXXIX Rules 1 and 2 CPC) essentially raising questions of law rather than questions of fact. In that view of the matter, the court had asked the parties, mid-way the hearing on the interlocutory applications, to explain as to why the questions of law

should be addressed twice in the same proceedings once in the context of the interim reliefs - where they would be based on prima facie assessment and consequently tentatively - and then again at the final adjudication, which may not be in sync with the letter and spirit of the Commercial Courts, Commercial Division And Commercial Appellate Division of High Courts Act, 2015 (hereinafter to as "the Commercial Courts Act"), jurisdiction whereunder has been invoked. Both sides, however, were lukewarm to the suggestion for expeditious disposal of the main suit, upon questions of law being addressed and adjudicated by recourse to the process of special procedure of "summary judgment" under Order XIII A CPC, as legislated by the Commercial Courts Act. Monsanto referred, in such context, to the counter claim (CC 51/2016) which has been pressed by the defendants as justification for such disinclination."

22. During the hearing, the parties agreed that the main issue, concerning legality of the patent, on a construction of Section 3 (j) of the Patents Act, could be decided finally and if the answer (as indicated earlier) was in favour of Monsanto, the facts pertaining to damages and injunctive relief may have to be gone into in the civil trial. Parties also agreed that the issue of patentability can be urged on the basis of the material on record, in the form of records before the learned single judge (spanning approximately 28 volumes of documents).

Nuziveedu's contentions

23. Mr. C.A Sundaram, learned senior counsel on behalf of Nuziveedu (which has appealed against the decision rejecting its argument against patentability of Monsanto's subject varieties) highlighted that the patent eventually granted to Monsanto only included the 'nucleic acid sequence' and the consequent process to insert the 'nucleic acid sequence' in plant cells. It is emphasized that under the Indian regulatory regime, a plant or seed, which has such a nucleic acid sequence containing the Cry2Ab gene, cannot be granted a patent in India and is an excluded matter, notwithstanding that it may be an 'invention' in view of the provisions of Section 3(j) of the Patents Act. Section 3(j) of the Patents Act, it is argued, categorically prohibits the grant of patent in regard to plants, including seeds (whole or part) and varieties. Accordingly, unlike the position in the USA, the patent granted to Monsanto in India does not include a plant or seed with the Bt. Trait. Nuziveedu thereby, submitted that the patent granted to Monsanto in India does not cover any claims for plants, seeds, breeding methods with respect to the Bt. Trait.

24. The above mentioned sub-license agreements also included clauses on payment of trait value, use of the Nuziveedu's trademarks on seed packets, restrictions on developing or entering into arrangements in relation to competing technologies and onerous provisions on termination of the sub-license agreements, including destruction of germplasm and parental lines. Nuziveedu pertinently mentioned that at no point of time did Monsanto in effect license any 'technology'. Nuziveedu merely sold cotton-seeds of a transgenic variety containing the Bt. Trait to seed companies and consequently demanded trait value on sale of all seeds of new varieties evolved by Nuziveedu thereafter.

25. It was further highlighted by Mr. Sundaram that the Bt. Trait by itself is neither useful nor can it be sold to the farmers directly. It needs to be transferred into superior cotton hybrids to be used by farmers. The Bt. Trait needs to be integrated with cotton hybrids through traditional plant breeding methods so that the cotton seeds have the agronomic traits required for the production of cotton. It was submitted that the Bt. Trait is only a loss prevention mechanism of the genetic

potential of the Cotton Hybrid and the same has no contribution to the enhancement of yield. The primary submission of Nuziveedu on the point of not violating the impugned patent of Monsanto lies within the shelter of Section 3 of the Patents Act. Nuziveedu cited Sections 3(c), (h) and (j) of the Patents Act, 1970 which are as follows:

- a. Section 3(c) of the Patents Act excludes from patentability "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature."
- b. Section 3(h) of the Patents Act excludes from patentability "a method of agriculture or horticulture."
- c. Section 3(j) of the Patents Act excludes from patentability "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."

26. Nuziveedu urged that the plant breeding and introduction of traits in a variety is a natural biological process. Upon integration or embedment of the Bt. trait into Nuziveedu's hybrid varieties, it cannot be detached and, in fact, there is no available technology either with Nuziveedu or in the public domain to remove or segregate the Bt. trait from its own proprietary varieties or restore them to their original status without the Bt. trait. The moment any nucleic acid sequence is introduced into any plant cell, the plant cell becomes unpatentable under Indian law; however, this does not extinguish all intellectual property rights in the inventions, improvements and innovations related to plants, seeds and varieties.

27. It was argued on behalf of Nuziveedu that Monsanto's claims under the suit patent are bad in law since Claim Nos. 1 to 24 -which were granted- are "process claims" which deal with genetic engineering or biotechnology method to insert the "nucleic acid sequence" (as in claims Nos. 25 to 27) into a plant cell; which steps are practiced only in laboratory conditions unlike Nuziveedu's procedure or of other seed companies, breeders and farmers, which are entirely biological processes. It is argued that Monsanto's claims are founded on other claims that were initially submitted with the application under the PCT (Patent Corporation Treaty), and withdrawn, as they were unacceptable to Indian authorities. It is submitted that of 59 original claims, only 26 survived and were granted. Monsanto's claim in the suit seeks enforcement of patent rights on claims that were disallowed and, therefore, withdrawn.

28. Nuziveedu in its counter claim (CC No. 51/2016) sought revocation of the suit patent under Section 64 of the Patents Act. Reliance on grounds such as absence of novelty [Section 64 (1) (e)], absence of obviousness [Section 64 (1) (f), complete specification not revealing any "invention" [Section 64(1)(d)], deficiency in complete specifications [Section 64 (1) (h)], deficiency of claims [Section 64 (1) (i)], false suggestions or representations [Section 64 (1) (j)], non-compliance of the requirements of Section 8 [Section 64 (1) (m)], non-disclosure of source or geographical origin [Section 64 (1) (b)] and the invention claimed in the complete specification being not useful [Section 64 (1) (g)]. It was argued that the learned single judge failed to notice that a specific challenge to the subject patent on the ground of Section 3 (j) of the Patents Act had been made. The relevant part of the counter claim, relied on by Nuziveedu, is as follows:

"Section 3(j) of the Act does not allow patenting of plants and animals in whole, or any part, thereof, other than microorganisms, but including seeds,

varieties and species and essentially biological processes for production or propagation of plants and animals.

82. It is submitted that claim 25 of the impugned patent relates to a nucleic acid sequence. It can be observed that the industrial application of the nucleic acid sequence as supported by the specification are only in terms of "a plant cell, a seed, a transgenic plant "or a plant variety", all of which are falling wholly within the exclusion prescribed in section 3 (j). Thus, the specification does not provide any industrial application which is outside the scope of section 3(j) of the Indian Patents Act. Therefore, regardless of the wordings, claim 25 falls squarely within Section 3{j) of the Act and is not patentable."

29. It was submitted that "nucleic acid sequence"(Claims 25-27) is not a microorganism, which is a living thing which can reproduce itself. A "nucleic acid sequence" is a chemical composition incapable of reproduction. The "nucleic acid sequence" when incorporated (into a living organism), imparts the Bt. trait (insect resistance) into such organism. The nucleic acid sequence is by itself, inert. Nuziveedu therefore, contests the interpretation given to Section 3 (j) by Monsanto, (whose position is that a nucleic acid sequence or part of a genome, is not a "part" of plant) as untenable. It was submitted that the exclusion in Section 3(j), of "microorganisms" is significant: it clarifies that a microbe or virus, bacteria, or a whole microscopic living entity, is excluded from the bar of unpatentability, whereas every other part of a plant, variety or seed, cannot receive patent protection under the Patents Act.

30. Mr. Sundaram cited the decision of the Canadian Supreme Court in *Harvard College v Canada (Commissioner of Patents)* MANU/SCCN/0074/2002 : [2002] 4 SCF 45. It was held that:

"...Higher life forms cannot be conceptualized as mere "compositions of matter" within the context of the Patent Act. Just because all inventions are unanticipated and unforeseeable, it does not necessarily follow that they are all patentable. It is possible that Parliament did not intend to include higher life forms in the definition of "invention". It is also possible that Parliament did not regard cross-bred plants and animals as patentable because they are better regarded as "discoveries". Since patenting higher life forms would involve a radical departure from the traditional patent regime, and since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues, clear and unequivocal legislation is required for higher life forms to be patentable. The current Act does not clearly indicate that higher life forms are patentable."

31. The majority judgment also noted:

"Of significance to the interpretation of the Patent Act and the issue of its applicability to higher life forms is the Plant Breeders' Rights Act, passed in 1990 subsequent to this Court's decision in *Pioneer Hi-Bred*, supra, in which it was determined that a crossbred soybean variety did not meet the disclosure requirements of the Patent Act. As noted by one commentator, the Act "is much better tailored than the Patent Act to the particular characteristics of plants" (N.M. Derzko, "Plant Breeders' Rights in Canada and Abroad: What are These Rights and How Much Must Society Pay for Them?" (1994), 39 McGill L.J. 144, at p. 159). In return for specifically tailored and less onerous requirements a narrower monopoly right is granted than that

available under the Patent Act.

The existence of the Plant Breeders' Rights Act is relevant to the issue of whether Parliament intended higher life forms to be patentable under the Patent Act for several reasons. First, it is argued that had plants been patentable under the Patent Act, it would have been unnecessary for Canada to pass a Plant Breeders' Rights Act to begin with. A related argument was put forward by the appellant, who submits that although Parliament passed "special legislation" to provide protection for plant breeders, it made no move to amend the Patent Act or to adopt other special legislation to provide for the protection of forms of animal life. In addition, in the face of Marceau J.A.'s opinion in *Pioneer Hi-Bred* (speaking for a majority of the Federal Court of Appeal) that the Patent Act had never been intended or understood to include crossbred plants - one form of higher life - in patentable subject matter, Parliament did nothing to alter that intention or understanding. A final point is that the Plant Breeders' Rights Act was passed in recognition that the Patent Act was not tailored to plants due to their unique characteristics. Since other higher life forms share many of these characteristics, it is reasonable to assume that Parliament would choose to protect these life forms through legislation other than the Patent Act or through an amended Patent Act that is better suited to the subject matter.

.....

The majority of the court in *Chakrabarty* rejected the above argument, asserting that factors other than congressional intent to exclude higher life forms from the definition of "invention" were responsible for the passage of the Acts. In particular, the majority notes that, prior to 1930, the belief existed that plants, even those artificially bred, were products of nature for the purposes of the patent law. The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description" requirement of the patent law. In enacting the Plant Patent Act, Congress addressed both of these concerns. The majority also addressed the passage of the 1970 Plant Variety Protection Act which, in its view, was passed to provide protection for sexually reproduced plants not covered by the 1930 Act.

Given that the Plant Breeders' Rights Act was passed following this Court's decision in *Pioneer Hi-Bred* that the soybean variety in question was unable to meet the written description requirement of the Patent Act, the point of view of the majority in *Chakrabarty* may have merit in the Canadian context. In other words, it may well be that the Plant Breeders' Rights Act was passed not out of recognition that higher life forms are not a patentable subject matter under the Patent Act, but rather out of recognition that plant varieties deserve some form of intellectual property protection despite the fact that they often do not meet the technical criteria of the Patent Act.

Nonetheless, this does not diminish the weight of the appellant's argument that although Parliament responded to *Pioneer Hi-Bred* by enacting special legislation for the protection of plant breeders, it did not address other higher life forms. This is particularly significant given the majority of the Federal Court of Appeal's conclusion in that case that crossbred plants did not fall within the definition of "invention" in the Patent Act, and the fact that this Court did not broach the subject, effectively leaving open the issue of whether or not such plants and other higher life forms are patentable subject matter. Given that the status quo position of the Patent Commissioner is that

higher life forms are not patentable, had Parliament intended to extend patentability to higher life forms other than crossbred plants, it would likely have done so at that time.

Though the arguments above are not absolutely indicative of parliamentary intent, they are of some significance. Far more significant, in my view, is that the passage of the Plant Breeders' Rights Act demonstrates that mechanisms other than the Patent Act may be used to encourage inventors to undertake innovative activity in the field of biotechnology. As discussed above, the Plant Breeders' Rights Act is better tailored than the Patent Act to the particular characteristics of plants, a factor which makes it easier to obtain protection. The quid pro quo is that a narrower monopoly right is granted. For example, the monopoly right relates only to the propagating material (the seed and the cuttings) and not to the actual plant. As explained by Derzko, supra, at p. 161, "[t]his is done because, unlike inert objects that are patentable, and unlike unicellular organisms that replicate into exact copies of each other, higher organisms such as plants start off from a cell and then grow and differentiate into a complete plant". The following statement of the Honourable Donald Mazankowski (then Minister of Agriculture) demonstrates that the Plant Breeders' Rights Act was passed to accommodate the special characteristics of crossbred plants as self-reproducing higher life forms while at the same time striking an appropriate balance between the holder of the monopoly right and others."

32. Learned counsel also relied on *Pioneer Hi-Bred Ltd. v. Canada* (Commissioner of Patents), MANU/SCCN/0052/1989 : [1989] 1 SCR 1623. He distinguished the decision cited by Monsanto in *Percy Schmeiser v Monsanto* 2004 1 SCR 902, before the learned single judge, highlighting that in that decision, involuntary "use" was held to be patent infringement, unlike in India, where Section 39 of the PV Act, which affords protection to "downstream" breeders and retail users.

33. Nuziveedu next highlighted that "plants" are excluded by Article 27(3)(b) of the TRIPS Agreement ("TRIPS") from patentability. India, to effectuate its obligation under TRIPS, for an effective sui generis system for protection of plant varieties, and taking care of the concerns for equitable sharing of benefits, introduced the PV Act. Nuziveedu cited the provisions of registration of a plant variety or a transgenic variety under Section 28 of that Act, which confers certain exclusive rights to the breeder. Next, Section 30 of the PV Act, which provides for "Researcher's rights" allowing use of any registered variety for developing new varieties, was relied upon to say that Nuziveedu could lawfully develop its own varieties, after purchasing the donor seeds from Monsanto. Mr. Sundaram also relied on Section 39, under which, the farmers have the right to save, sow, re-sow, exchange, share and sell the farm saved seeds of any protected variety including a transgenic variety. Furthermore, Nuziveedu also cited Section 26 of the PPVFR Act that provides for "benefit sharing". Accordingly, Nuziveedu averred that Monsanto had the choice of entering into "benefit sharing" arrangements with the seed companies who developed new Bt. Cotton plant varieties expressing Bt trait.

34. It was argued that Section 2(z) of PV Act defines "variety" to include a transgenic variety such as a plant variety developed by Nuziveedu containing the nucleic acid sequence, which can be registrable like a non-transgenic variety under the PPVFR Act. Nuziveedu stated that by demanding license fees for the Bt. Trait, Monsanto, are in effect going beyond the scope of the Patents Act, thus, Nuziveedu contended that, Monsanto by demanding license fees for the Bt. Trait, in effect went beyond the scope of the Patents Act and are attempting to extinguish the breeders'

rights, researchers' rights and farmers' rights available under the provisions of the PV Act.

35. Mr. Jayant Bhushan, learned senior counsel appearing for other Nuziveedu companies, argued that if any variety with a unique trait (like Bt. trait) is used to create a new variety, "benefit sharing" can be claimed from the creator of the new variety under Section 26, of the Plant Varieties Act read with rules 41 to 44 of the Plant Varieties Rules. Section 92 of the PV Act is relied upon; it provides that the provisions of said enactment shall have overriding effect notwithstanding anything inconsistent contained in any other law including the Patents Act. According to Mr. Bhushan, a joint reading of Section 3 (j) of the Patents Act, the National Seed Policy, 2002 (Para 6), the scheme of the PV Act and the views of the Ministry of Agriculture in the Government of India addressed to the Secretary, Department of Industrial Development in Ministry of Industry, New Delhi, clarifies that there can be no patent on any gene, the moment it becomes part of a plant or a seed.

36. It was furthermore argued that allowing patent claims such as Monsanto's to stand, would spell doom to the agricultural and farming sector, because, as in Percy Schmeiser's case, entirely unconcerned farmers, who might develop new varieties and use them, would be nevertheless prey to potential patent action, merely because they purchased and later developed their own varieties. Unlike Percy Schmeiser's case, such farmers in India, have independent rights under Section 39 of the PV Act; yet they would be subject to patent infringement claims. This poses a grave threat to age-old farming practices developed and refined over millennia, in the country. It is submitted that allowing such claims to stand, despite presence of another kind of intellectual property protection under the PV Act, despite statutory injunction under the Patents Act, poses a real threat to food security of the country. It was argued that allowing a wide patent monopoly (over and above the protection of benefit sharing, under Section 26 of the PV Act) would result in multinational agribusiness corporates like Monsanto eliminating agriculture from small farmers in a developing country like India; it also eliminates autonomy and independence in the matter of agricultural practice, promoting monocultures and dependence on such companies' products. Reliance was also placed on Chapter VI of the National Seeds Policy, 2002- Clause 6.8 of the said Policy provides that:

"transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation."

37. Nuziveedu submitted that a combined reading of Section 3 (j) of the Patents Act, 1970, the National Seed Policy, 2002 (Para 6 of the policy), the scheme of the PV Act and the comments of the Ministry of Agriculture and the Department of Industrial Policy and Promotion (DIPP), it is clear that there can be no patent on any gene the moment it is part of a plant or a seed. Further, under the scheme of the Patents Act, once transformation of a gene sequence takes place into a plant, the resultant transgenic plant variety cannot receive patent protection in India and the IP protection to such transgenic plant variety is provided under the PV Act. It is reiterated by Nuziveedu that the integration of the Bt. Trait in Cotton Hybrid varietal plants is an essential biological process, which falls outside the scope of the claims of Patent No. 214436.

38. Regarding the trademark used on the seed packaging, Nuziveedu submitted that by virtue of the sub- license agreements, up to 2011, Nuziveedu were using Bt. and Bt.2 as part of the name of their Bt. cotton varieties e.g. "NCS 9015 Bt2" to denote that the seeds have specific genetically modified gene(s) of *Bacillus Thurengiensis*

(Bt.) bacterium, and in accordance with paragraph 6.10 of the National Seeds Policy, Nuziveedu were complying with carrying a label on their seed packets, indicating that the seeds are transgenic, as well as indicating the name of the transgenes.

39. Nuziveedu also submitted that they used Bt. and Bt.2, which are approved as safe to the environment by Government of India and that the plants grown from those seeds are resistant to bollworms. In 2011, Mahyco, however, replaced the word "Bt." with "BG" and the word "Bt2" with "BGII" while issuing NOC to Nuziveedu, which was required to apply to the regulatory authorities using "BG" and "BGII" for approval of their Bt. Cotton varieties. After those regulatory approvals, Nuziveedu used the name of their seed variety on the seed packets as per the approval such as "NCS 245 BGII" or "NCS 207 BGII" or "PCH 9605 BGII" etc. Nuziveedu also claim that they use their own registered trademarks namely "Nuziveedu Seeds", "Bhakti" etc., which are prominently displayed on the packaging with distinctive color combination, get up and design. They aver that the descriptive use of a word is excluded from the infringement of a trademark by virtue of Section 35 of the Trade Marks Act, 1999.

40. Nuziveedu submits that Section 29 of the Trade Marks Act, 1999 provides that infringement of a trademark can occur only if a registered mark is used "as a trademark" and not otherwise. Nuziveedu argues that the expression "BG II" or "BG" at end of a variety name does not distinguish the seeds of Nuziveedu from the seeds of other traders in the market, and as such they do not use the word BG II "as a trademark". In a similar vein, they aver that there is no "passing off" by the use of the marks "BG" and "BG II", because the "added matters" used on Nuziveedu's packaging leaves no scope for any kind of confusion in the minds of the consumers or purchasers.

Monsanto's arguments

41. Monsanto argued that as the sub-license agreements were terminated, the use of the patented invention i.e., nucleotide sequence by the defendants constitutes infringement within the meaning of the expression under Section 48 of the Patents Act. Monsanto submits that whether Nuziveedu's ultimate product comprises of components or genetic material conferring other traits in addition to the DNA construct or nucleotide sequences of the suit patent is immaterial, as long as its invention is contained within the infringing product. Monsanto argues that infringement by "use" of the patented invention in claims 25 to 27 is established because Nuziveedu admits that their cotton varieties and hybrid exhibit Bt. trait which is triggered solely because of the DNA construct or nucleotide sequence on Claim Nos. 25 to 27.

42. Ms. Prathiba Singh, learned senior counsel for Monsanto argued that Claim Nos. 25 to 27 are products of permissible patentable biotechnology processes. She traced to the legislative history of amendments made to the Patents Act in 2002 and 2005 and also contrasted them with enactment of the PV Act. She submitted that Section 3(j) of the Patents Act only excludes naturally occurring substances and that by contrast, man-made or artificially created (in laboratory or under controlled environments) nucleotide sequences are biotechnological inventions not covered by the PV Act.

43. It is urged that the Section 3 (j) exclusion would apply to biological entities, per se and not to inventions, which properly fit the description of "micro-organisms" that are excluded specifically from the mischief of the provision. Learned senior counsel emphasized that the genome of the bacteria, *Bacillus thuringiensis*, codes for a protein which eliminates the bollworm, an insect that causes havoc upon cotton

plants. Significantly, argued counsel, the subject patent does not cover the plant (plants and animals are ineligible for patent protection in India, as are ordinary biological processes for creating them) but covers microbiological processes. Such processes include methods of creating transgenic varieties and microorganisms which are new and inventive transgenes and their constructs. These are patentable under the Patents Act. Monsanto's patents cover these constituents. Bt cotton technology is not constant but rather has been refined to address the needs of pest resistance. The technology pertaining to Bollgard-I was not patented in India (as it was invented prior to India's undertaking of Trade-Related Aspects of Intellectual Property Rights or TRIPS commitments). However, Bollgard-II was patented.

44. It is emphasized that a "plant" as understood in Section 3(j) is a "living organism"⁴. Similarly "DNA" is the "substance responsible for all the processes within a living organism"⁵ and a gene is inanimate, not a living thing but merely codes for the production of a protein in a living organism. Thus, the subject matter of the patent (Claim Nos. 25-27) are man made DNA sequences comprising the CryAb gene which confers insect resistance to plants, when introgressed or incorporated into the plant's genome. No part of the DNA sequence is a living organism. It is submitted, therefore, that the patented DNA sequence is neither plant, nor part of a plant. Ms. Singh argues that DNA cannot be called as "part" of a plant too, because it is not like an organ of an animal or the physical attribute of a plant, like flower, fruit, etc. It is further argued that in patent law, under the Patents Act, subject matter of an invention is different from its use or industrial application: this distinction is underlined by contrasting the provisions in Section 10(4) (c) with Section 10 (4) (a). It is claimed, therefore, that Section 3 (j) applies only when the subject matter of the invention is a plant or part thereof and cannot apply when the use of the invention is in a plant, seed or variety, each of which are separately defined.

45. Ms. Singh disputed that the subject patent was wrongly granted because of a potential overlap of protection under the PV Act. It is argued that in the Patent Amendment Act of 2005 the pre-existing Section 5 of the Patents Act, vis-à-vis "inventions where only methods or processes of manufacture patentable" stood repealed; the expression "invention" in Section 2(1)(j) was substituted. Now an invention means "a new product or process involving an inventive step and capable of industrial application". Section 5 before the 2002 amendment stood thus:-

"5. Inventions where only methods or processes of manufacture patentable -
In the case of inventions -

(a). claiming substances intended for the use, or capable of being used, as food or as medicine or drug, or

(b). relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods of processes of manufacture shall be patentable."

The 2002 amendment, added the following explanation:

"Explanation - For the purposes of this section, "chemical processes" includes biochemical, biotechnological and microbiological processes."

46. The 2005 amendment repealed altogether, Section 5. Thus, Ms. Singh urged that these legislative changes removed the prohibition on grant of patents to "products" of

biological or microbiological processes thereby stood removed.

47. No doubt, Section 3 of the Patents Act lists what are "not inventions". After the 2002 amendment, the list, in clause (j) states "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". Yet the legislative resolve behind the amendment is to be understood from the statement of objects and reasons. Para 4 is cited; the relevant part is as follows:-

"4. some of the salient features of the Bill are as under :

(a)....

(b). to modify section 3 of the present Act to include exclusions permitted by TRIPS Agreement and also subject matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention."

48. Thus, submits Ms. Prathiba Singh, that Section 3(j), cannot be interpreted without taking into account the changes to Section 2(1)(j) and repeal of Section 5. The patentee is entitled to protection for the invention resulting from innovations and skill. It is stressed that Nuziveedu concedes that claim Nos. 25 to 27 under the suit patent involve laboratory processes and do not lead to substances occurring in nature only which can be excluded from the plain terms of Section 3 (j). The subject claims being products or processes of biotechnology, were correctly protected by the Patent Act.

49. Ms. Singh argues that the suit patent is independent of, and un-affected (or un-curtailed) by, the provisions of the PV Act principally because that enactment only applies to a "variety", as defined in Section 2 (za). Here, the patented trait is beyond the scope of the expression "plant variety" defined under the PV Act. To receive coverage under the PV Act, a variety has to be a "plant grouping" that satisfies three conditions i.e. it has to be first, defined by the expression of the characteristics resulting from a given genotype of that plant grouping; second, distinguished from any other plant grouping by expression of at least one of the said characteristics; and lastly, considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation.

50. It is submitted that the expression "plant grouping" does not mean a single plant. Learned senior counsel cites the explanatory notes under the 1991 Act of International Convention for the Protection of New Varieties of Plants (UPOV Convention 1991), as adopted by the UPOV Council, which defines the expression "variety". That definition under the UPOV Convention is pari materia to what is provided in Section 2 (za) of the PV Act. Para 5 of the explanatory notes reads as follows:

"5. The definition that a variety means a "plant grouping" clarifies that the following, for example, do not correspond to the definition of a variety :

- a single plant; (however, an existing variety may be represented by a single plant or part(s) of a plant, provided that such a plant or part(s) of the plant could be used to propagate the variety)
- a trait (e.g. disease resistance, flower color)

- a chemical or other substance (e.g. oil, DNA)
- a plant breeding technology (e.g. tissue culture)"

51. It is urged that this definition by way of explanation, underlines that the insect or disease resistant trait or a chemical or other substance like DNA are not meant to be covered within the meaning of the expression "variety", the development of which is protected by the PV Act. Learned counsel argues, therefore, that the invention, which is the subject matter of suit patent is not same as development of a variety, under the PV Act. It is argued that Monsanto's patent for the Bt. Gene sequence in a cotton genome is used for insertion of the gene in the seeds provided by other companies, licensed for the purpose, such as Nuziveedu, who provide their seeds to it. Nuziveedu's seeds may be called a new variety, and can possibly be registered under the PV Act. Nuziveedu in such case might claim protection over such a variety. Therefore, when Nuziveedu sells the seed to the farmer, the seed may be protected by two forms of IP - one under the Patents Act, which belongs to Monsanto and the other under the PV Act, which belongs to companies like Nuziveedu. This ipso facto, does not preclude application of Patents Act and the soundness of the patent granted to Monsanto, which invented and developed the CryAb gene that imparts insect resistance characteristics. The Patents Act only can protect this unique function, introduced into the genome. Ms. Singh highlighted that the other interpretation, by Nuziveedu, would mean that until the licensee, who purchases donor seeds, satisfies the authority under the PV Act, about the protectibility of varieties bred from the Donor seeds, containing the Cry Ab gene, there would be no manner of protection to the intellectual labour of Monsanto.

52. Learned senior counsel also argued that Nuziveedu's claims, based on researchers' rights under Section 30 of the Plant Varieties Act has no merit. It is submitted that arguendo, if seed companies fall in the category of "researchers", they may have a legitimate claim to the use of any variety for the purpose of conducting experiment or research or for creating other varieties. It is contended that Section 30 of the Plant Varieties Act is a provision meant only for "researchers" and not for entities such as Nuziveedu group companies to commercially exploit and further that it gives, at the most, right to use a "variety" to develop other varieties but not so as to confer the right to use DNA or genetic material.

53. It was also argued by Monsanto that reference to the history of the suit patent, or the proceedings before the patent office, wherein the other claims under the international application were not pressed for grant of Patent in India is irrelevant. But this does not extend to the right to use the genetic material that is the subject matter of a patent granted and protected by the Patents Act, especially Section 48 of that Act. It is submitted that similarly, the protection under Section 26 of the PV Act cannot be taken for granted, without proof that the activity undertaken by Nuziveedu, may be by biological processes whereby the traits of the patented technology are transmitted from one hybrid variety to the other and the benefits accruing therefrom.

54. Monsanto contends that the foundational element of the insect tolerance exhibited by Nuziveedu's varieties lies, indisputably, in the DNA sequence. By developing, producing and selling plants/seeds containing the DNA sequence, Monsanto urges that Nuziveedu is infringing the patent on the DNA sequence because it is "using" the DNA sequence. To highlight this argument, reliance is placed on F. Hoffmann-La Roche Ltd. and Ors. v. Cipla Ltd. MANU/DE/3672/2015 : 225 (2015) DLT 391 and Merck Sharp and Dohme Corporation & Anr. v. Glenmark Pharmaceuticals Ltd. MANU/DE/0793/2013 : 201 (2013) DLT 126; in both cases the infringer was making and selling products that were rejected/withdrawn as not

patentable under Section 3. However, the patentee had another patent, the use of which was required to make and sell the infringing product and the Court found infringement of that granted patent since it was used in the making of the infringing product; it did not matter that the product produced by the infringer was not patentable. It was argued that enforcing claims 25-27 would not lead to circumvention of section 3 (j) since Monsanto is not enforcing the DNA sequence as against the entire plant, but only to the extent of use of the patented DNA sequence.

55. Monsanto also cited the Canadian Supreme Court judgment in Percy Schmeiser (*supra*), where 'purposive construction' was applied in similar facts and it was held that Monsanto's gene patent was infringed by "use" when an unauthorized person developed and commercialized seeds containing the patented gene, since the gene was present throughout the seed, conferring the advantageous trait to the plant and this amounted to taking advantage of the technical contribution of the patentee. Similarly a case of infringement by "use" (Section 48(a) of the Patents Act, 1970) of the invention in claims 26-27 is automatically made out since Nuziveedu admitted that their cotton varieties and hybrids contain the DNA sequences of claims 25-27 of the suit patent and that they are taking full advantage of the functionality of insect tolerance arising solely from the use of the patented DNA sequences in their cotton hybrids.

56. Monsanto urged that the "exhaustion" doctrine does not apply here because there was no unconditional sale of patented articles. The exhaustion doctrine does not permit a third party without license to use the sold articles to reproduce and make more copies of the same; reference in this regard was made to CS(OS) No. 1692/2006 Warner Brother Entertainment v. V.G. Santosh. Thus, it was averred by Monsanto that the impugned patent does not fall within the exception covered under section 3(j) of the Patents Act, 1970. It was also argued that once the sub-licenses were terminated on account of material breach of the agreement in the form of non-payment of contractual dues", the dispute is not arbitrable, because the right to use the patent or the trademarks under the sub-license agreements did not subsist in terms of the safeguards particularly in the form of Article 9.04. Monsanto argues that the arbitration claims presently pending against Nuziveedu concern only with issues arising from acts of commission or omission "during the currency" of the sub-license agreements (i.e. the non- payment of contractual dues) and not the conduct of Nuziveedu, post-termination.

57. Monsanto argues that the 2015 sub-license agreements contain a termination clause in Article 9.2 and thus, the 2015 sub-license agreements are determinable contracts; hence once they were terminated, they could not be restored and parties cannot be directed to perform the obligations contained therein in view of Section 14(1) of the Specific Relief Act, 1963. Reliance was placed on Indian Oil Corporation Ltd. v. Amritsar Gas Services and Ors., MANU/SC/0513/1991 : (1991) 1 SCC 533 in this regard.

58. It was argued by Mr. Sandeep Sethi learned senior counsel that the learned single judge, while upholding Monsanto's rights in its patented technology and trademarks, erred in effectively directing it to compulsorily license the same to the Nuziveedu, in direct conflict with the entire scheme of the Patents Act, 1970 and the Trade Marks Act, 1999, which it is submitted, are in circumvention of the due process of law contained in Chapter IV of the Patents Act, 1970, and beyond the jurisdiction of the learned single judge.

Analysis and Conclusions

59. The most important issue that needs resolution by this judgment is whether the

process described in Monsanto's nucleotide sequence in its Claims 25-27 -which were granted patent, resulting in isolation of the Cry2Ab gene, its synthesization and insertion into the plant cell, resulting in donor transgenic seeds and plants fall within the exceptions covered under Section 3(j) of the Patents Act. The related issues are whether any other patent exclusion provision of the Patents Act, is attracted; whether Monsanto's patent rights are unaffected by provisions of the Protection of Plant Varieties and Farmers Rights Act, 2001. The second issue is whether the injunction, though temporary, could have been granted, enjoining Monsanto to not charge any amount beyond what is prescribed by law, regardless of contractual conditions. In claim 25 of their patent, Monsanto specifically claimed a man-made DNA construct that does not exist in nature and does not otherwise form a part of a plant as existing in nature. Monsanto elaborates how this DNA construct, which when inserted into a plant confers the trait of insect tolerance to the plant and how plants without this DNA construct do not exhibit the trait of insect tolerance. At the outset, this court proposes to examine only the threshold challenge to the patent and not carrying out an analysis of whether prima facie the patent granted (or the claims under it) lacked inventiveness, or novelty or industrial application, in view of the statement of parties' counsel.

60. As member of the World Trade Organisation (WTO), in compliance with the instruments and annexes of the General Agreement on Tariffs and Trade (GATT), including the Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement, India, inter alia, introduced the Patents (Amendment) Act, 2002, in June 25, 2002. This amendment altered the definition of "an invention" under Section 2(1) (j) to include the term "new product", thereby, removing the embargo on the grant of patent to "products" of biotechnological and microbiological processes. During the course of these amendments, Section 3 (j) was also added in 2002 to the Patents Act, 1970. These amended sections are as follows:

"Section 2: Definitions and interpretation

(1) In this Act, unless the context otherwise requires,-

(j) 'invention' means a new product or process involving an inventive step and capable of industrial application

...

Section 3: What are not inventions

The following are not inventions within the meaning of this Act,-(j) plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals"

61. Monsanto argues that products of biotechnology are not excluded from patenting under Section 3(j) of the Patents Act. Although section 3(j) also excludes a 'part' of a plant, in its ordinary sense, this exclusion applies to what is ordinarily or naturally a part of a plant; therefore, the DNA construct or nucleotide sequence of claims 25-27 not being ordinarily part(s) of a plant, (as they are a result of invention)are inserted into plants, are patentable. Nuziveedu's refrain is on the text of Section 3 (j); it emphasizes that the Bt. Trait has not been and cannot be utilised in isolation. It sows seeds of its proprietary cotton variety alongside the Transgenic Bt. Cotton seed. The Transgenic Bt. Cotton seed and Nuziveedu's seeds yield different plants, which are cross-pollinated at the flower stage. Those Bt. Cotton Varieties are used for developing the proprietary hybrid ("Bt. Cotton Hybrids"). The Bt. Trait is only a loss

prevention mechanism of the genetic potential of the Cotton Hybrid and has no contribution to the enhancement of the yield. Nuziveedu introgresses the trait provided to them in the form of seed of the transgenic plant by Monsanto, as per their sub-license agreement. Such trait introgression was carried out by Nuziveedu using conventional plant breeding methods. The integration of the Bt. Trait from the Transgenic Variety Bt. Cotton Seed procured from Mayhco took place in the following manner:

- a) Nuziveedu sowed seeds of their proprietary cotton varieties alongside the Transgenic Bt. Cotton seed.
- b) The Transgenic Bt. Cotton seed and the Nuziveedu's varieties seed yielded different plants, which were cross-pollinated at the flowering stage.
- c) The cotton fruits from the Nuziveedu's cotton varieties had cotton seeds, which were carrying the Bt. Trait ("Bt. Cotton Varieties"). Those Bt. Cotton Varieties were used for developing the proprietary hybrid ("Bt. Cotton Hybrids").
- d) Nuziveedu conducted extensive agronomic evaluation trials of newly developed Bt. Cotton Hybrids to ascertain their utility to the farmers.
- e) Nuziveedu obtained the approval of the GEAC under the Environment (Protection) Act, 1986 for the commercial release of each new Bt. Cotton Hybrid which were considered satisfactory after internal evaluation, and thereafter produced in mass scale and distributed to the farmers.

62. Nuziveedu outline show the steps of plant breeding and introduction of traits in a variety is a natural biological process. On insertion of a trait, it cannot be removed from that variety; the Bt. Trait is integrated or embedded into Nuziveedu's hybrid varieties. There is no technology available to remove or segregate the Bt. Trait from its proprietary varieties or restore them to their original status without the Bt. Trait.

63. The record shows that Monsanto's patent comprises of a DNA construct or nucleotide sequence of claim 25 comprises three different components, i.e. (i) a promoter, (ii) a gene for the production of Cry2Ab 5-endotoxin and (iii) a third component for the production of a transit peptide⁶. The combination of these three components into a single DNA construct is itself new, inventive and does not exist in nature. Next, the second component of claim 25, is the gene for producing Cry2Ab 5-endotoxin, and - it argues, is a man-made gene. The sequence ID No: 1 is a naturally occurring gene which produces Cry2Ab 5-endotoxin in Bt. Bacteria; sequence ID 17 is the modified sequence by Monsanto and this modification is necessary for the gene to be more compatible with plants. This factor differentiates the man-made DNA construct of claim 25 from the naturally existing one. The DNA construct, upon insertion into a plant confers the insect tolerance trait to it. Plants without this DNA construct do not have such insect tolerance trait. A plant is next produced as a "fusion protein" which comprises the Cry2Ab S-endotoxin⁷ bonded with the transit peptide. This production of a fusion protein is critical in this respect for the technology to be effective in plants. The Bt. bacteria do not produce such a fusion protein. The only approved technology that allows a cotton plant to produce the Cry2Ab 8-endotoxin is Monsanto's technology, protected, inter alia, by claims 25-27 of the patented invention.

64. The subject patent claims the use of Bacillus thuringiensis strain and development of two genes designated cry2Aa and cry2Ab. Each gene sequence is

known for its ability to synthesize proteins with pesticidal properties. Preparations of natural isolates of *B. thuringiensis* were first used as a commercial insecticide long ago and *B. thuringiensis* subspecies was registered in 1961.

65. Since its discovery, Cry2Ab has been given various names. Collectively, "Cry2Ab" refers to two separate, virtually identical genes, cry2Ab1 and cry2Ab2. The gene sequences differ at nucleotide 1035; where there is a cytosine in cry2Ab1 and a thymine in cry2Ab2. The nucleotide difference is translationally silent (i.e., DNA mutations which do not alter the amino acid sequence of the protein), so that the genes each encode a protein with the same amino acid sequence. Each sequence corresponds to a peptide of 633 amino acids, and the two peptides share 87% amino acid identity. Since its initial discovery, genes encoding Cry2Ab proteins have been identified in Bt strains found throughout the world; yet the peptide corresponding to cry2Ab is not produced in such strains. The peptide encoded by cry2Aa is toxic to certain bollworms, i.e. cotton crop pests. The peptide encoded by cry2Ab was thought to be toxic only to one pest species, (*Manducasexta*), as in case of the Cry1 group of proteins. It was later found that the sequences of Cry2Aa and Cry2Ab differ in terms of amino acids present with different levels of toxicity.

66. The Cry2Ab sequence, used to create cotton event 15985 was modified from that of the wild-type cry2Ab gene to use plant-preferred codons, for better expression in cotton (Perlaket al., 1991). In addition, aNcoI restriction site was introduced at the N'-terminal end of the gene to facilitate cloning, resulting in an additional aspartic acid residue at position 2 of the peptide. Lastly, the N-terminal chloroplast transit peptide, from the *Arabidopsis thaliana* epsps gene, comprising 79 amino acids, was inserted immediately preceding the cry2Ab gene. Once the peptide is targeted to the chloroplast, the transit peptide is cleaved, leaving three amino acids at the N'-terminal end of the peptide. The final protein product contains 633 amino acids, plus four other additional amino acids. Monsanto's application- originally made in India was for claims titled "Methods for Transforming Plants to Express *Bacillus Thuringiensis* Delta Endotoxins". The patent descriptions highlighted, methods of inserting DNA construct/nucleic acid sequence into a plant genome its effect in the plant transformed by that method. The claims were:

- * Claims 1 to 36,39,40: A plant comprising a nucleic acid sequence comprising a plant functional promoter sequence operably linked to polynucleotide sequence encoding Cry2A Bt endotoxin protein...wherein expression of said nucleic acid sequence in said plant yields protein localized to a sub-cellular organelle or compartment.. (and other dependant claims)
- * Claims 37 to 38: A progeny plant wherein said plant has inherited said nucleic acid sequence.
- * Claims 41 to 43: A method of producing a transgenic progeny plant comprising of obtaining the first plant, obtaining a second plant and crossing the first and second plants to obtain a crossed transgenic progeny plant, said progeny plant having inherited the said nucleic acid sequence from the said first plant (and other dependant claims).
- * Claims 44 to 47: A nucleic acid sequence "comprising..." and other dependant claims.
- * Claims 48 to 52, 54, 55, 56: A plant cell comprising a nucleic acid sequence comprising...(and other dependant claims)
- * Claims 53: A plant tissue derived from the progeny of the plant cell where

the plant tissue comprises a plant, plant seed, plant cells or progeny tissues thereof containing said polynucleotide sequence.

67. By objections of the Indian Patent office, on 30.03.2006 of Monsanto's 58 claims -claims 1-40, 48-56, 57, 58 were rejected as not allowable under Section 3(j). Claim Nos. 41-43, 59 were rejected under Section 3(b) and other grounds. Only claims 45, 46, 47 were not objected to. These were a sub-set of claims on nucleic acid sequence. Subsequent correspondence between the Patent office and Monsanto resulted in exclusion of plants, plant cells, tissues and progeny plant containing the nucleic acid sequence as well as plants created through an essentially biological process (excluded on account of Section 3(j)). This narrowing of the patent claims, in the opinion of the court, is relevant, because ultimately what was granted was not a patent over the product, or even the method, but of identification of the "event" i.e. the place in the genetic sequence of the DNA where the CryAB2 protein, in the plant cell. These are important facts, which the court would deal with later in the judgment.

Prior Legislative history

68. Section 2 (q) and Section 5 of the Patents Act, 1970, before amendment to the Act permitted only process patents and did not allow products of chemical processes to be patented. Section 3 (i) which existed under the original Patents Act excluded from patent protection:

"the following are not inventions within the meaning of this Act....i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products."

69. Section 5 of the Patents Act was amended by the Patents (Amendments) Act, 2002, inserted an explanation, stating that "chemical processes" include biochemical, biotechnical and micro-biological processes" to Section 5(2)(b). After amendment, the provision read as follows:

"Section 5 Inventions where only methods or processes of manufacture patentable- In the case of inventions-

(a).....

(b) relating to substances prepared or produced by chemical process (including alloys, optical glass, semi-conductors and inter-metallic compounds.

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Explanation - For the purposes of this section, "chemical processes" include biochemical, biotechnical and micro-biological processes"

70. The 2005 Amendment repealed Section 5 altogether. In isolation, this would have meant that the extended definition of "chemical process"- covering "biochemical, biotechnical and micro-biological processes" could be patented. However, the insertion of Section 3 (j) which excluded "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and

species and essentially biological processes for production or propagation of plants and animals" and the simultaneous enactment of the PV Act meant that facially, the Parliament intended not to afford intellectual property protection in the form of patents, to processes and products that would otherwise be called inventions and be entitled to patents.

Application of principles of statutory interpretation

71. It is evident that Parliamentary intent was to exclude from patenting plants, seeds or part thereof excluding micro-organisms "but including...essential biological processes". This meant that process or products, that otherwise meet the test of patentability (i.e. novelty, inventive step and industrial application, are nevertheless as a matter of public policy, ineligible for patent protection. The mechanism adopted by Parliament was to spell out what was not patentable i.e., plants, seeds, plant varieties, - whole or part and then exclude micro-organisms, but clarify that the exclusion would not apply to "seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". Therefore, the principal provision (Section 3) provides for non-patentability of matters spelt out - i.e.

- i. plants, animals in whole or part thereof;
- ii. excluding micro-organisms
- iii. but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals

72. In this context, this court recollects that the expression "includes" is used as a legislative device to enlarge the meaning of words or phrases "occurring in the body of the statute; and, when it is so used, these words or phrases must be construed as comprehending, not only such things as they signify according to their natural import, but also those things which the interpretation clause declares that they shall include."(Ref. Dilworth v. Stamps Commissioners (1899) A.C. 99) which the Supreme Court of India consistently followed.⁸

73. It would also be useful to notice the judgment of the Supreme Court in Sardar Gurmej Singh v. Sardar Pratap Singh Kairon MANU/SC/0107/1959 : AIR 1960 S.C 122 where the question involved was the true interpretation of Section 123 (7) of the Representation of Peoples Act, 1951 which read as follows:

"Section 123. Corrupt practices. - The following shall be deemed to be corrupt practices for the purposes of this Act :-

(7) The obtaining or procuring or abetting to obtain or procure by a candidate or his agent or, by any other person, any assistance (other than the giving of vote) for the furtherance of the prospects of the candidate's election, from any person in the service of the Government and belonging to any of the following classes, namely :

(f) revenue officers including village accountants, such as, patwaris, lekhpals, talatis, karnams and the like but excluding other village officers."

74. The court held in the judgment that:

"...It is an elementary rule that construction of a section is to be made of all the parts together and not of one part only by itself, and that phrases are to be construed according to the rules of grammar. So construed the meaning of the clause is fairly clear. The genus is the "revenue officer," and the "including" and "excluding" clauses connected by the conjunction "but" show that the village accountants are included in the group of revenue officers, but the other village officers are excluded therefrom. If X includes A but excludes B, it may simply mean that X takes in A but ejects B. It is not necessary in this case to consider whether the inclusive definition enlarges the meaning of the words "revenue officers", or makes them explicit and clear, viz., that the enumerated officers are within the fold of "revenue officers"; for in either construction the village accountants would be revenue officers. But we cannot accept the argument that what is excluded was not part of that from which it is excluded, and that lambardars were not revenue officers and yet had to be excluded by way of abundant caution. If so, it follows that the village officers, who included lambardars, were excluded from the group of revenue officers, with the result that they are freed from the disqualification imposed by the provisions of the said clause. But it is said that this construction would make the words "revenue officers" and the words "excluding other village officers" unnecessary, for, the same result could be achieved by enacting simply "village accountants, such as, patwaris, lekhpals, talatis, karnams and the like"

This argument, if we may say so, overlooks the difference between the terms "revenue officers" and "village officers". "Revenue officers", as we have pointed out, is a more comprehensive term and takes in all officers who are employed in the revenue business, whereas the jurisdiction of the village officers is confined to their respective villages. Village officers do not exhaust the content of revenue officers, and even after their exclusion there will be many revenue officers at higher levels who would be governed by cl. (f). If this be the construction, every word used in the clause is given a meaning and no words become a surplusage."

75. In *Narpatchand A. Bhandari v Shantilal Moolshankar Jani* MANU/SC/0279/1993 : 1993 (3) SCC 351 the issue was whether expression 'landlord' under Section 13 (1) includes usufructuary mortgagee where tenanted premises were subject of usufructuary mortgage. The extended definition of "landlord" according to Explanation (b) to Section 13 (2) was that it "shall not include a rent-farmer or rent-collector or estate-manager". Section 5 (3), on the other hand, gave an inclusive extended definition: "'landlord' means any person who is for the time being, receiving, or entitled to receive, rent in respect of any premises whether on his own account or on account, or on behalf, or for the benefit of any other person or as a trustee, guardian, or receiver for any other person or who would so receive the rent or be entitled to receive the rent if the premises were let to a tenant, and includes any person not being a tenant who from time to time derives title..". The court held that a usufructuary mortgagee is a landlord, entitled to maintain eviction proceedings.

76. A plain textual interpretation of Section 3 (j) of the Patents Act therefore, is that plants, animals "whole or parts thereof" are excluded from patentability, as are "seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". However, microorganisms are not excluded; whole or parts thereof can be patented, provided other conditions of the Patent Act are fulfilled. Significantly, the expression "variety"(undefined under the Patents Act)

is defined under the PV Act by Section 2 (za) to exclude microorganisms ("variety means a plant grouping except a microorganism..."). The exclusion of microorganisms from the PV Act meant that they are not capable of registration as any "variety" under that Act; their exclusion from Section 3 (j) means that the Patents Act enables patent protection to them.

77. "Micro-organism" has not been defined either under the Patents Act, or under the PV Act. The Cambridge Dictionary (online) defines a micro-organism as "A living thing that on its own is too small to be seen without a microscope", examples: bacteria, germs Viruses⁹.

78. The Oxford dictionaries (online) defines it as

"A microscopic organism, especially a bacterium, virus, or fungus."¹⁰

The Law Dictionary (Featuring Black's Law Dictionary Free Online Legal Dictionary 2nd Ed.) defines micro-organism as

"Visible under a microscope, this type of living organism is too small to be seen with naked eye. Also known as microbe."¹¹

79. As the precise definition of a microorganism has not been enacted by Parliament, the ordinary meaning of that expression, gleaned from dictionaries would apply. The discussion about the subject patent discloses that the nucleic acid sequence which is the invention in question (the Cry2AB gene) has no existence of its own; it is of use, after introgression at a particular place, none else. Even thereafter, the seed material has to undergo further steps of hybridization to suit local conditions. Therefore, these products are not "microorganisms" and consequently excluded from the exclusion clause in Section 3 (j).

80. There is another obstacle in Monsanto's submissions regarding patentability of its subject invention as a micro-organism. Arguendo the subject matter of the patent in question is a micro-organism, patenting micro-organisms in India is contingent upon regulations for the deposit of micro-organisms, in recognized International Depository Authorities (IDA) in terms of Article-7 of the Budapest Treaty¹² as well as the accessibility of the concerned microorganism from the depositories. In terms of Section 10(4) (d) (ii) of the Patents Act, if the micro-organism is not fully described and is unavailable to the public it has to be deposited before the IDA under the Budapest Treaty as a pre-condition for filing of application in India. All the characteristics of the microorganisms and details of depository institutions along with accession number are to be stated in description for its correct identification.

81. Section 10 (4) of the Patents Act reads as follows:

"Section 10(4)..

(4) Every complete specification shall-

(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) end with a claim or claims defining the scope of the invention for

which protection is claimed;

(d) be accompanied by an abstract to provide technical information on the invention:

Provided that-

(i) the Controller may amend the abstract for providing better information to third parties; and

(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing [the material to an international depository authority under the Budapest Treaty] and by fulfilling the following conditions, namely:-

(A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;]

(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;

(C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority;

(D) disclose the source and geographical origin of the biological material in the specification, when used in an invention."

82. Therefore, by Section 10 (4) of the Patents Act, if the patent applicant describes a biological material, it is to be deposited in terms of the Budapest Treaty (Article 7) with an IDA before the application is made. This procedure is mandatory even in other systems. Commenting on the obligatory nature of this condition, the US Federal Circuit Court of Appeals stated, in *Ajinomoto Co. Inc. v. Archer Daniels Midland Co.* 228 (2000) F.3d 1330, that when an invention relates to a new biological material, which may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification, then,

"It is then a condition of the patent grant that physical samples of such materials be deposited and made available to the public..."

83. Monsanto nowhere states that in terms of Section 10(4), the biological material was deposited with an IDA, as a pre-condition for its application under the Patents Act. Monsanto has allegedly failed to:

"(a) disclose the source and, origin as well as accession details, of *B. thuringensis* from which Cry2A gene was isolated; (b) disclose source and origin as well as accession details of *Agrobacterium tumefaciens* from which nopalinesynthase gene, octopine synthase gene were isolated and used; (c)

disclose source and origin as well accession details of potato and tomato from which 3' end of the protease inhibitor I or II genes were isolated; disclose source and origin as well as accession details of a plant, particularly maize plant from which the, PTPs have been isolated; disclose source and geographical origin as well as accession details, of Arabidopsis thaliana from which PTPs has been isolated; disclose source and geographical origin along with, the accession/variety details of maize, cotton, tobacco plants being used in the examples; disclose source, geographical origin as well as the accession/variety details-from; which the FMV35S promoter has been isolated; (e), disclose details of petunia heat shock protein (HSP70), maize heat shock protein (HSP70) is absent; and disclose the source, geographical origin and accession details of... (ineligible) phosphatransferase gene (NPTII)."

84. Section 3(j) of the Patents Act, excludes, inter alia, "essentially biological processes" from patentability in pursuance of Article 27(3)(b) of the TRIPS Agreement, however the phrase has not been defined in the Patents Act, neither in any other statute. Article 27(3)(b) of the TRIPS Agreement reads as follows:

"3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

85. The International Convention for the Protection of New Varieties of Plants (UPOV 1991) was preceded by conventions of 1961 and 1978, which had created international frameworks for signatory nations to afford intellectual property rights to innovations in plant varieties. India is not a signatory to UPOV and has, instead, chosen to exclude from patentability certain subject matter in relation to plants, or parts thereof, seeds and essential biological processes but not including microorganisms. This, instead, in accord with its TRIPS commitment to "provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof" has enacted the PV Act. The relevant provisions from other international covenants/instruments are Articles 2(2), 4(1) and 4(3) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions (hereinafter, the "Biotech Directive") and Article 53(b) of the European Patent Convention ("EPC"). Relevant provisions of the Biotech Directive are as follows:

- "Art. 2(2): A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

- Art. 4(1): The following shall not be patentable: (...)

(b) essentially biological processes for the production of plants or animals.

- Art. 4(3): Paragraph 1(b) shall be without prejudice to the patentability of

inventions which concern a microbiological or other technical process or a product obtained by means of such a process. "

86. The Article 53 (b) of the European Patent Convention pertinently states that:

"European patents shall not be granted in respect of:

(a) [...];

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof [...]"

Rule 26(5) EPC: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

Rule 26(5) EPC is identical to Article 2(2) of the Biotech Directive.

87. To expand on the definition of "essentially biological process", the Enlarged Board of Appeals, in its decision of *Plant Bioscience Limited v. Syngenta Participations AG Groupe Limagrain Holding* [G2/07] held in its ruling that:

"...the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability." ¹³

(emphasis added)

88. The decisions of the European Patent Office in *State of Israel- Ministry of Agriculture v. Unilever N.V.* [G 0001/08] (the "Tomato case") and *Plant Bioscience Limited v. Syngenta Participations AG Groupe Limagrain Holding* [G 0002/07] (the "Broccoli case") are also relevant in this context. In both the decisions the Enlarged Board of Appeal the following was held:

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b)EPC.

2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

In determining the meaning of Rule 26(5) of the EPC, the Enlarged Board held as follows:

"...On the other hand, it is hardly conceivable that the terms "crossing" and "selection" in Rule 26(5) EPC are intended not to refer to plant breeding at all but only to purely natural events taking place without human control. The expression "processes for the production of plants" (German version: "Verfahren zur Zucht von Pflanzen", French version: "procédes... d'obtention de végétaux") in Article 53(b) EPC implies at least some kind of human intervention. Furthermore, it would have the awkward consequence of restricting the scope of the exclusion to subject-matter which, owing to its complete lack of technical character, does not qualify as an invention anyway, so that there would be no need to exclude it from patentability by an explicit provision. The referring Board therefore takes the view that the mere fact that a claimed process requires some kind of human intervention is not, even in the light of Rule 26(5) EPC, sufficient to take the process outside the patentability exclusion. The crucial issue, according to the referring Board, is rather to determine what kind of human intervention is required."

"The standard definition of the term "essentially biological process" within the meaning of Article 53(b) EPC 1973 was developed in decision T 320/87 (supra, Headnote 1 and points 6 to 9 of the Reasons) and was confirmed in later decisions cited in the referring decision T 83/05, in particular decision T 356/93 (supra).

In decision T 320/87 the Board held:

"6. ... whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character.

7. ...

8. In analysing the claimed processes, it appears that their essence lies in the particular manner of the combination of specific steps... The totality and the sequence of the specified operations do neither occur in nature nor correspond to the classical breeders' processes...

9. In decision T 356/93, cited by the referring Board in the present context, that Board undertook to explore more comprehensively the legislator's considerations when drafting the provision. After furthermore considering the findings in T 320/87 cited above, the Board then concluded that:

.....

"28. ... a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result (see points 25 to 27 supra), does not fall under the exceptions to patentability under Article 53(b), first half-sentence, EPC."

89. In *Plant Genetic Systems v Greenpeace* (T0356/93, decided on 21.02.1995) the European Enlarged Board of Appeals held that:

"if the expression "microbiological process" was broadly interpreted to cover any product of a process conducted in the laboratory at microscopic level and the first plant directly obtained thereby was considered to be the product of a microbiological process, it could not be said that subsequent generations of plants (e.g. the 10th generation of a herbicide-resistant plant) were something that with any reason could be regarded as the product of a microbiological process. In fact, the latter were the product of an essentially biological process, because they were spontaneously generated, and no intervening human process was required for their generation. Accordingly, such processes of generation and the resulting plants were not patentable under Article 53(b) EPC."

90. Earlier, in *Lubrizol/Hybrid Plants* [1990] EPOR 173, the Technical Board of Appeal considered the meaning of "essentially biological" and stated:

"Fundamental alteration of the character of a known process for the production of plants is required before the applicant can avoid the rigors of being termed "essentially biological". The claimed processes must represent an essential modification of known biological and classical breeders processes."

91. The above rulings instruct that "essentially biological processes" has to be interpreted in a manner such that, human intervention, does not take it out of the exclusionary sweep of Section 3(j), unless such intervention ipso facto, plays an intrinsic role in the insertion of the DNA, i.e. that it results in fundamental alteration of the character of a known process of production of plants or seeds.

92. The Indian Guidelines for Examination of Biotechnology Applications for Patents¹⁴ published by the Office of the Controller General of Patents, Designs and Trade Marks does broadly indicate what is "essentially biological process"; it may not be conclusive; yet throws light on the same through the following illustrative example:

"ILLUSTRATIVE EXAMPLE 2: Claim: A method of producing at least one of

substantially pure hybrid seeds, plants and crops, comprising the steps of (i) producing a male parent which is male fertile, (ii) breeding the male parent with a female parent which is substantially male sterile, and (iii) harvesting seeds from the female parent which contain pure hybrid seeds.

Analysis: The claimed method involves the step of cross breeding for producing pure hybrid seeds, plants and crops. Thus, it is an essentially biological process and not allowable under Section 3 (j) of the Act."

93. From the varied judicial interpretation of what constitutes an "essentially biological process", the primary criteria that emerge for qualifying as an essentially biological process and thereby, to be excluded from patentability, are as follows:

- The process for the production of the plants/variety should be based on the sexual crossing of whole genomes.
- Further, in the subsequent selection of the plants/variety, the degree of human intervention (even when it is of a technical nature) should be enabling and in the nature of assistance to the performance of the process steps. Merely because a step of human technical intervention exists does not rule out the disqualification as an "essentially biological process", such intervention needs to amount to a significant alteration/introduction in the genetic composition.

94. As far as the cases cited by Monsanto are concerned, in *Pioneer Hi-Bred*, (supra) the Supreme Court of Canada held that the Commissioner correctly rejected a patent application claiming a new variety of soybean resulting from artificial cross-breeding and selection, because it could not be sufficiently disclosed by depositing a seed in the reproduction cycle but not intervention which alters the actual rules of reproduction, which continues to obey the laws of nature. In *Percy Schmeiser* (supra) Monsanto learned that Schmeiser was growing a worm resistant crop for which it held a patent. It asked him to pay license fee and sign a license to its patents. He declined, saying that the contamination was accidental and that he owned the seed he harvested, and he could use the harvested seed as he wished because it was his physical property. Monsanto then filed an infringement action. Canadian law does not mention grant of "farmer's rights". The Canadian Supreme Court held that the farmer's right to save and replant seeds is simply the right to use his or her property as he or she wishes. The right to use the seeds is subject to the same legal restrictions on use as rights that apply in any case of ownership of property, including restrictions arising from patents in particular. It was held that:

"Thus a farmer whose field contains seed or plants originating from seed spilled into them, or blown as seed, in swaths from a neighbour's land or even growing from germination by pollen carried into his field from elsewhere by insects, birds, or by the wind, may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene, or of the seed or plant containing the patented gene or cell."

95. The dissenting four judges (out of the five judges who constituted the majority) followed the majority in *Harvard College v Canada (Oncomouse)* case and held that though a proprietor can patent products and processes, patent of higher forms of life such as the whole plant itself is impermissible. It was held that "the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant tissues, at which point the claim would be for every cell in the plant".

96. A crucial difference between Canadian law and Indian law is that there is no "farmer's right" carving out an exception of the kind, available in the PV Act in India.

97. A recent significant development was, the decision of the European Patent Office, to amend the relevant regulations in order to exclude from patentability plants and animals exclusively obtained by an essentially biological breeding process¹⁵; this proposal took into account a notice¹⁶ of the European Commission from November 2016, where the Commission clarified its position that it was the intention of the European legislator to exclude not only processes but also products obtained by these processes. These new processes came into effect on 1 July 2017. The decision is in the wake of the two rulings in Broccoli (G2/13) and Tomato II (G2/12) of the Enlarged Board of Appeal at the European Patent Office (EPO) in March 2015, where the Board decided that, claims to products derived from an essentially biological process can be allowed as long as the other criteria for patentability are fulfilled, even if the process used to obtain the products is essentially biological and thus not patentable. Rules 27 and 28 of the European Patent Convention (EPC) have since been amended to that effect to state that, "under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of essentially biological process". Most notably, Rule 28 has been amended to add an additional paragraph (2):

"(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process."

98. Thus, the exclusion of transgenic plants and seeds propagated after hybridization from patentability under section 3(j) of the Patents Act, 1970, is congruent with the amendment of Article 53(b) of the EPC, wherein, patents cannot be granted in respect of plants or animals exclusively obtained by means of essentially biological process. The conclusion that the court draws therefore, is that transgenic plants with the integrated Bt. Trait, produced by hybridization (that qualifies as an "essentially biological process" as concluded above) are excluded from patentability within the purview of section 3(j), and Monsanto cannot assert patent rights over the gene that has thus been integrated into the generations of transgenic plants.

99. The other reason why this court concludes that Section 3 (j) prohibits grant of patents to Bt. trait induced varieties is that they are parts of "seed". The trait, by itself has no intrinsic worth; it is meant to be implanted or introgressed and later hybridized into a variety to be further hybridized through backcrossing¹⁷ and cross breeding with other existing varieties to produce seeds that are ultimately used. Without introgression, they are inert and inanimate. Their utility is when they are introduced at a place (in the DNA sequence of the seed)- the event which Monsanto claims proprietary rights over. Their function is to be part of a seed. Furthermore, the process of hybridization undertaken by the Nuziveedu group and the Bt. Cotton hybrid plants as well as seeds produced thereafter are squarely exempt under Section 3(j) of the Patents Act; these seeds are sold to the farmers and other retailers.

100. The future propagation of the transgenic plants (after introgression and hybridization) and the subsequent transfer of the Bt. Trait in such plants and consequently, the transgenic seeds, will be a process of nature, and no step of human intervention can impede such transfer of the sequence. Therefore, it would be contrary to law and Parliamentary intent to enable Monsanto to have patent rights over the nucleic sequence once it is been duly introgressed and hybridized into the transgenic plants. Unlike other products, the process of integration and further hybridization sets into motion a chain of events, which is part of nature; the seeds

and propagating material, including future generation of seeds would contain the DNA sequence with the particular strand or trait. In other words, the moment the DNA containing the nucleotide sequence (subject patent) is hybridized to produce the transgenic seeds/plants; the seeds/plants fall within the purview of the PV Act, and, above, the process of creation of such seeds/plants are also excluded from patentability as they squarely fall within the meaning of an "essentially biological process" that is exempted from patentability within the meaning of section 3(j), as well. For these reasons, it is held that the subject matter, the concerned nucleotide sequence over which Monsanto has patent rights and the process is unpatentable by reason of Section 3 (j) of the Patents Act.

Scheme under the PV Act- is Monsanto entitled to intellectual property protection under the enactment

101. The PV Act was passed by Parliament in August, 2001; it received Presidential Assent on 30th October 2001. This is a pioneering legislation that recognizes farmers' contribution in conserving biodiversity and developing new plant varieties. India has consciously opted for a sui generis system of protection of plant varieties to recognize farmers' age-old contribution in agriculture and agro-biodiversity. The four major underlying objectives of the Act are:

- (i) To recognize and protect the rights of farmers for their contribution made in conserving, improving and making plant genetic resources available for development of new varieties.
- (ii) To protect plant breeders' rights, to stimulate investment for research and development, both in public and private sector, for the development of new plant varieties.
- (iii) To facilitate the growth of seed industry in the country, to ensure the availability of high quality seeds and planting material to farmers.
- (iv) To give effect to Article 27.3(b) in Part II of the TRIPs Agreement.

102. Nuziveedu applied for PV protection for all its Bt. Cotton Plant Varieties under the PV Act. As it urged "plants" were specifically excluded from patentability under Article 27(3)(b) of the TRIPs Agreement. Pursuant to India's obligation to provide an effective sui generis system for protection of plant varieties, IPR rights in respect of plant varieties was developed by integrating the rights of breeders, farmers and village communities by way of the PV Act. Intellectual property rights in relation to plant varieties, including transgenic varieties, are the subject matter of protection under the provisions of the PPVFR Act. Under the PV Act, a new variety created is registrable under Section 15 of the PPVFR Act. Section 2(za) of the PPVFR Act defines 'variety' as follows:

- "(za) "variety", means a plant grouping except micro-organism within a single botanical taxon of the lowest known rank, which can be-
- (i) defined by the expression of the characteristics resulting from a given genotype of that plant grouping;
 - (ii) distinguished from any other plant grouping by expression of at least one of the said characteristics; and
 - (iii) considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation,

and includes propagating material of such variety, extant variety, transgenic variety, farmers' variety and essentially derived variety"

Section 2(z) includes a transgenic variety, such as the one developed by the Respondents containing the nucleic acid sequence, which can be registrable like a non-transgenic variety under the PPVFR Act.

103. Section 14 of the Act entitles the registration "by (a) any person claiming to be the breeder of the variety; or (b) any successor of the breeder of the variety; or (c) any person being the assignee of the breeder of the variety in respect of the right to make such application; or (d) any farmer or group of farmers or community of farmers claiming to be the breeder of the variety" (Section 16). The subject matter of the application should be that the seed or variety should be "a. of such genera and species as specified under sub-section (2) of section 29; or which is an extant variety; or c. which is a farmers' variety." (by Section 14). Section 15 (1) enacts what are registrable varieties and states a "new variety shall" be registered if it "conforms to the criteria of novelty, distinctiveness, uniformity and stability." The requirement that an extant variety too shall be registered if it confirms to the same criteria is stipulated in Section 15 (2); Section 15 (3) enacts by explaining the criteria of novelty, distinctiveness, uniformity and stability. Section 15 (4) states that

"4. A new variety shall not be registered under this Act if the denomination given to such variety-

- i. is not capable of identifying such variety; or
- ii. consists solely of figures; or..."

104. A transgenic variety can be a "new variety" and, therefore, registrable under Section 15 (1) provided it satisfies the conditions of "novelty, distinctiveness, uniformity and stability"; a "breeder" under Section 14(1) includes the breeder of such transgenic variety. Therefore, there is no merit in Monsanto's argument that its products cannot ipso facto be registered and secure protection under the PV Act. Under Section 24, varieties, other than essentially derived varieties can be given registration. The facility of benefit sharing then is conferred upon all interested to seek the advantages, upon fee determined in this regard. What is crucial in this enactment is benefit sharing under Section 26. If someone's variety with a unique trait (like the Bt. Trait) is used to create a new variety, benefit sharing can be claimed from the creator of the new variety under Section 26 of the PPVFR Act read with Rules 41 to 44 of the PPVFR Rules. The registration of a plant variety or a transgenic variety under Section 28 of the PPVFR Act confers certain exclusive rights enshrined therein on the breeder. Section 30 of the PPVFR Act provides for "Researcher's rights" allowing use of any registered variety for developing new varieties. Under section 39, the farmers have the right to save, sow, re-sow, exchange, share and sell the farm saved seeds of any protected variety including a transgenic variety. Section 39(iv) gives farmers the right to save, use, sow, resow, share or sell his farm produce including seed of a variety registered under the Act. This kind of wide collection of rights is not available in any other farmers' rights legislation. Section 39(2) gives farmers certain protections and guarantees of performance of the variety or peculiar feature which a registered variety's owner represents. This is relevant in the context of the failure of crop including of registered varieties; farmers can sue the company or breeder who claims the particular feature, which does not materialise, or underperforms. These are invaluable rights, which no other farming community or individual farmer apparently possesses anywhere else; herein lies the uniqueness of Indian legislation which sets it apart from the US and

Canada; it is a clear rationale to distinguish the ruling in Percy Schmeiser(supra).The court also notices that under the PV Act, if a variety (including a transgenic variety) is used without permission or authority of the registered proprietor, it is open to the latter to claim injunctive remedy under Section 64 in a suit for infringement. Such right to infringement includes a right to sue for a "right relating to a variety" (Section 65 (1) (a)). Thus, if a trait (like a DNA strand, or the nucleic acid sequence as in the present case) is used without the registered proprietor's permission, in any manner (with or without registering a further variety) it could amount to infringement and thereby, invite a suit for injunction and damages, under Section 64 (a) or (b).

105. As regards benefit sharing, in addition to the provisions under the PV Act, relevant sections of the Biological Diversity Act, 2002 (the "Biodiversity Act"), that were enacted in compliance with the requirements of the Convention on Biological Diversity to which India is a signatory; are also be applicable. The purpose of the Biodiversity Act is to, inter alia, realize equitable sharing of benefits arising out of the use of biological resources and associated knowledge. The main objectives of the Act are conservation, sustainable use and equitable benefit sharing out of the utilization of bioresources.¹⁸ Section 21 of this Act provides for benefit sharing when given effect to, by the National Biodiversity Authority; clause (2) of which specifically provides as follows:

"(2) The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:-

(a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;

(b) transfer of technology;

(c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;

(d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilisation;

(e) setting up of venture capital fund for aiding the cause of benefit claimers;

(f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit."

105. Section 92 of the PV Act enacts a non-obstante clause, which overrides all provisions to the contrary, contained in any other law. The cumulative effect of these is that when Section 3 (j) was enacted as a patent exclusion, the Parliament had knowledge of the PV Act, which was enacted almost contemporaneously. A known principle of statutory construction is that the Parliament or the concerned legislature is deemed to be aware of existing laws when it enacts new law [Syndicate Bank v Prabha D. Naik MANU/SC/0197/2001 : (2001) 4 SCC 713]. Likewise, as observed in Royal College of Nursing of the UK v Depat. of Health and Social Security MANU/UKHL/0009/1980 : 1981 (1) All ER 545, the Parliament or a legislative body is presumed to be aware of existing state of affairs and the laws particularly of the facts

relevant "fall within the same genus of facts as those to which the expressed policy has been formulated". So viewed, India's commitment to TRIPs, especially its commitment to enact a sui generis law, the enactment of the PV Act and its conscious exclusion of patent protection to matters falling within Section 3 (j) are to be construed as an expressed intention to deny patents to "plants.. including seeds, varieties" or any part thereof. The construction advocated by Monsanto, i.e that the trait value created otherwise than by a natural biological process, does not fall within the exclusion is, therefore, without force; in fact, the "trait" it developed and for which patent was granted, is subsumed by the "variety" culminating in a "seed" and later a "plant". Undoubtedly, the trait is part of both the variety or the seed, or both and, therefore, excluded. It is, therefore, held that Section 26 of the PV Act read with Rules 41 to 44 of the PPVFR Rules, should be read concurrently with section 21(2) of the Biodiversity Act, in order for Monsanto to claim benefit sharing for Nuziveedu's use of the Bt. Trait contrary to its submission.

106. Monsanto had urged that Nuziveedu had enjoyed the benefit of its patent, and paid license fee all these years; it also sought its no objection - to apply for registration under the PV Act. This estopped Nuziveedu from urging that Monsanto could not patent the CryAb2 trait. This court is of opinion that the payment of license fee, under the arrangement by Nuziveedu was on an assumption that Monsanto's patent was valid in law. This could not have precluded Nuziveedu from challenging the validity of the patent in the suit. It is well established that there can be no estoppel or waiver of statutory rights; in the field of taxation it is, for instance recognized that mere payment of amounts extracted under pretence of lawful levy do not preclude challenge to the collection at a later stage: State of Punjab & Anr v Devans Modern Breweries Ltd. MANU/SC/0961/2003 : 2004 (11) SCC 26; Suraj Mal Mehto v AV Viswanath Sastri MANU/SC/0026/1954 : AIR 1954 SC 545 Bashesharnath v. I.T Commissioner MANU/SC/0064/1958 : AIR 1959 SC 149; and Olga Tellis v Bombay Municipal Corporation MANU/SC/0039/1985 : AIR 1986 SC 180.

107. For the above reasons, it is held that the learned single judge's conclusion that the PV Act and the protective mechanism was an option, or alternative, which Monsanto could possibly have resorted to, in addition to patent protection, under the Patents Act, is incorrect. These two systems are not complimentary, but exclusive, in the case of all processes and products falling under Section 3 (j) of the Patents Act. Nuziveedu's contention with respect to patent exclusion, therefore, succeeds. The court at the same time realizes that the patent granted to Monsanto has stood all this while. Given these factors, it is held that Monsanto is at liberty to claim registration under the PV Act, with the benefit of its filing the patent application, as far as the date of filing and for purposes of Section 15 of the PV Act. In case Monsanto wishes to avail its right, the application or applications (for registration) under the PV Act shall be preferred within three months and decided in accordance with its provisions; such claims shall be decided in accordance with law. Subject to these liberties, Nuziveedu's counter claim succeeds and is allowed.

Trademark Aspect and the Termination of the sub-license agreements

108. In light of the intent expressed in the Cotton Seeds Price (Control) Order, 2015, the learned single judge held that the termination of the sub-license agreements by Monsanto without considering Nuziveedu's request was unwarranted, and stated as follows:

"128. The State government legislations or notifications issued on the subject in exercise of powers conferred upon them by such law, as indeed the Cotton Seeds Price (Control) Order, 2015 promulgated by the Central

Government, again in exercise of its statutory powers conferred by Essential Commodities Act, 1955 provide not only the "law" but also reflect the "public policy" of the State and, thus, the "consideration" of the agreement between the parties in order to be lawful, within the meaning of Section 23 of the Contract Act must be in accord with such law and public policy and not be opposed or in derogation thereof.

129. Thus, in the opinion of this court, Monsanto were duty bound to consider the request of the defendants as made by the communications beginning July 2015, for modification of the terms as to the rate of trait fee payable under the 2015 sub-license agreements for which the mechanism had earlier been agreed upon in the form of Article 11.03. Since Monsanto did not adhere to their obligation under the contract, the demand of payment under the contract terms being not lawful, it apparently being higher than the trait fee permitted by the law in force, the defendants could not have been found to be in default or to have breached their obligations within the meaning of Article 9.02. As a sequitur, the termination of the sub-license agreements by communications dated 14.11.2015 appears prima facie to be illegal and arbitrary.

130. One is conscious that the defendants seem to have reconciled to the position wherein the sub-license agreements are to be treated as all but dead. It appears that they having at one stage sought restoration of the contract, including by counter claim (CC 50/2016) presented before this court (which was withdrawn on 15.02.2017), do not seem to be interested in renewed arrangement with the plaintiffs, now taking the position that the grant of patent itself is bad in law and thus, asserting their right to continued use of the technology with impunity. Having taken the plea in the case that the termination of the 2015 sub-license agreements was illegal and arbitrary, and having demonstrated this contention to be prima facie correct, the unilateral termination of the contract by the plaintiffs being unauthorised, the defendants cannot wish away the natural corollary of the sub-license agreements coming back to life. Their stand in this litigation that the suit patent was wrongly granted by the Indian patent office has been found prima facie to be devoid of merit. Having been the beneficiary of the patented technology ever since entering upon the sub-license agreements with the plaintiffs in 2004, and taking advantage of the same all these years, apparently for commercial exploitation, it does not lie in the mouth of the defendants to turn around and say that they cannot be bound by such obligations under the sublicense agreements as protect the statutory rights of the plaintiffs vis-à-vis the suit patent or the registered trademarks.

131. As this court is of the opinion that the sub-license agreements were illegally and arbitrarily sought to be terminated by the plaintiffs, the communications to such effect issued on 14.11.2015, followed by subsequent communications reiterating the same, are bound to be treated as of no consequence. In these circumstances, the parties are bound to be treated as continued to be locked with each other in the arrangement under the 2015 sub-license agreements, as the same stood prior to the purported termination communications dated 14.11.2015 (such communications being non-est) though, of course, with obligation for the consideration (trait value/fee) to be charged not more than what is permitted by the law in India. For removal of doubts, if any, it must be added that such obligations vis-à-vis the trait fee chargeable would have to abide by the prescription in terms of the Cotton Seeds Price (Control) Order, 2015 as indeed of the Licensing

and Formats for GM Technology Agreement Guidelines, 2016, both promulgated by the Government of India."

109. It is evident, therefore, that the learned single judge held that for as long as the sub-license agreements were in force, or do not come to an end, by efflux of time, or upon being lawfully terminated, Nuziveedu cannot be enjoined against the use of the patented traits or the trademarks, and such rights to continued use of the suit patent or trademarks not being unconditional. With this subsisting position, the learned single judge held that no comment was necessary at that stage of the proceedings on the contentions of the parties as to the permissibility or otherwise of the use of the abbreviations "BG" and "BG-II" by the defendants as trademarks.

110. Monsanto's grievance with respect to the learned single judge's directions, in its appeal, is regarding the prima facie conclusion that the termination of the sub-licenses was illegal. It is urged that as proprietor of the technology and sole owner of the knowledge, which results in the development of the concerned trait, it cannot be compelled to part with its information, nor be prevented from recovering from those using it in an unauthorized manner. It urges that with the service of notice and expiry of the period of notice, the sub-licenses ended. As agreements that are terminable, the remedy of injunction - at the behest of the counter claimant- was impermissible. Monsanto cites Sections 14 and 41 of the Specific Relief Act and states that no specific relief is permissible in respect of agreements for which adequate monetary compensation is available. Nuziveedu, on the other hand, urges that the prima facie conclusions as to illegality of the termination of the sub-licenses is justified and further that being an essential commodity, under law, Monsanto cannot stop supply of the seeds or varieties that contain the traits in question. It further urges that the proper remedy for Monsanto is to claim registration under the PV Act, and if its registered variety is infringed, seek appropriate relief. In the meanwhile, it is under an obligation to supply the seeds and varieties it has for the "trait value" fixed by the Central Government.

111. For a considerable time, seeds were listed as an "essential commodity" in terms of the Essential Commodities Act, 1955 ("ECA"). On 12 July 2007, the Essential Commodities Amendment Act, 2006 was notified by which 'cotton seed' was deleted from the ECA. The amendment also introduced under Section 2A to the ECA, empowering the Central Government to add or remove any commodity to/from the Act in consultation with the State. On 22.12.2009, the Central Government by notification brought cottonseeds back in the list of essential commodities for six months; later by another notification, it was extended to one year and on 22.12.2010 the Central Government issued a Notification including cotton seeds under the schedule to the ECA. By a Central Government order dated 07.12.2015, in exercise of the powers under Section 3, ECA [Clauses 5(1), (2) and (5)] the power to fix maximum price was conferred upon that government. Consequently, by a notification (dated 8 March, 2016) the maximum price for Bt. Cotton seed packets (450 grams of Bt. Cotton seed plus 120 grams refugia) was fixed for both BGI version and BG II version. The maximum price for Bt. Cotton seeds of the quantity notified for BG I is ' 635 (with no trait value) and the maximum price for Bt. Cotton seeds of the BG II variety was fixed at ' 800/- (including ' 40 fixed for the trait value).

112. This court notices, at the outset that under Section 14 (1) (a) of the Specific Relief Act, there can be no specific performance of contracts for personal services. The supply of varieties or seeds, containing the Bt. trait, in this case, clearly does not fall within the exception under Section 14 (1) (a). Section 14 (b) and (d) fall into a category, or type, i.e where contractual obligations encompass minute details and continuous duty, which renders court's supervision impracticable, or for the oversight

of which the court cannot enforce material terms. In terms of Section 14 (1) (c) specific relief cannot be granted in respect of a contract which is in its nature determinable. Under Section 41 (e) injunctive remedy is not available "to prevent the breach of a contract the performance of which would not be specifically enforced". Monsanto relies on Section 14 (1) (c), the termination notices it issued to Nuziveedu and Section 41 (1) (e) to say that it cannot be enjoined to continue to supply the seeds or mandated to supply materials containing Bt. Trait, at any value, other than what it wishes to collect, from a customer chosen by it. Nuziveedu cites the trait value, fixed in state legislation, inclusion of seeds under the ECA and Section 42 of the Specific Relief Act.

113. The facts of this case show that the agreements between the parties were for a defined time; Monsanto sought to terminate it and also sued for infringement; it sought interim injunction as well. Nuziveedu counter-claimed, justifying its refusal to pay anything more than the trait value fixed by state legislation, in the first instance, as well as the order issued by the Central Government in 2015. That the agreements are determinable cannot be prima facie denied. However, the question is: can injunction be refused, to Monsanto, or rather, can it be compelled to supply varieties containing the trait, for any price other than the price it seeks? It is here that Section 42 of the Specific Relief Act, requires a closer look. That provision clarifies that where a contract comprises an affirmative agreement to do a certain act, coupled with a negative agreement, express or implied, not to do a certain act, the circumstances that the Court is unable to compel specific performance of the affirmative agreement shall not preclude it from granting an injunction to perform the negative agreement. If the obligation of a seed developer or supplier is not to charge more than what the law prescribes, it cannot legally collect it, till the law is overborne in a manner known to the Constitution- either by judicial declaration or by repeal. In such context, the insistence of Monsanto that it is free to nevertheless withhold supplies of seeds or varieties of seeds, containing the Bt. Trait, to Nuziveedu, cannot be countenanced. In the facts of this case, prima facie, the Court holds that a negative obligation, implied to honour the existing law, binds the parties. Furthermore, as an essential commodity, the supply of which is regulated by law (including the control of trait value), Monsanto is obliged to maintain the supplies, to facilitate production of Nuziveedu's varieties for onward sale to farmers, sowing and harvesting of the crop.

114. The court notes that the balance of convenience element is an important element that every court is compelled to weigh, apart from the question of prima facie likelihood of success in a suit or counter claim. The absence of a patent results in the lack of property in the use of CryAb2 and the consequent lack of control by Monsanto about its use by others, like Nuziveedu, who might have acquired it under agreement, lawfully, developed their varieties or breeds and sold it to the farming community. The grant of injunction is rendered untenable in these circumstances. Equally, the denial of a positive order, in the opinion of the court, results in the violation of provisions of the Essential Commodities Act, as it would deprive thousands, possibly a million or so farmers, the right to access to seeds that were hitherto available to them. This is a public interest element that the court cannot be blind to. In the ultimate event of Nuziveedu failing in its counter claim, the harm that might befall Monsanto during the pendent lite period is compensable, monetarily. In these circumstances, the Court is of opinion that pending trial of the suit, the directions of the learned single judge do not call for interference.

115. As far as the challenge to the injunction with regard to trademark infringement is concerned, the learned single judge had recorded as follows:

"84. Though at the hearing, the defendants made it clear that they do not intend to use the registered trademarks "BOLLGARD" or "BOLLGARD-II" of the plaintiffs, the plaintiffs argued that insistence on the use of abbreviations "BG" "BG-I" or "BG-II" or any variation thereof is specious and ex facie unsustainable, referring in this context, inter alia, to Section 2(o) of the Trademarks Act wherein "name" includes any abbreviation thereof, as is relevant for purposes of the definition of the expression "mark" given in Section 2(m) of the Trademarks Act."

116. In view of the above reasons, this Court records its conclusions and directs as follows:

(1) The subject patent falls within the exclusion spelt out by Section 3 (j) of the Patents Act; the subject patent and the claims covered by it are consequently held to be unpatentable. Nuziveedu's counter claim is, therefore, entitled to succeed and is consequently allowed.

(2) Monsanto's Suit CS(OS)(Comm) 132/2016, to the extent it seeks enforcement of the subject patent, is dismissed. However, the suit can proceed with respect to the claim for damages and other reliefs, in the light of the sub-license termination notices issued.

(3) The learned single judge's directions to Monsanto to continue with its obligations under the sub-license agreements, including consequential orders with respect to payment and receipt of trait value, are upheld.

(4) Monsanto can apply for registration under the PV Act (within three months of this judgment); if it does so in terms of this judgment, the benefit of its previous patent can be granted to it, for the purposes of the said Act, in respect of determination of prior publication provisions and requirements.

117. Monsanto's appeal, FAO(OS)(Comm) 76/17 is consequently dismissed. Nuziveedu's appeal, [FAO(OS)(Comm) 86/2017] is partly allowed; its counter claim is allowed to the above limited extent. There shall be no order on costs.

¹"Bt." refers to the bacteria bacillus thuringiensis which is toxic to the bollworm, a pest that commonly attack certain crops (i.e. cotton). ²"introgression" is the process of the introduction of genes from the gene pool of one species into that of another during hybridization, Collins Dictionary (available at: <https://www.collinsdictionary.com/dictionary/english/introgression>)(last accessed on 09.04.2018) ³A "trait" signifies a "characteristic, quality or tendency" possessed of by anything. (Ref Collins Dictionary (supra)). In technical parlance, therefore, a genetic trait is typically those characteristics or attributes of an organism that are expressed by genes. ⁴Oxford Reference Dictionary (2013) ⁵Supra 4 at p. 414. Likewise, a gene is a "functional unit of DNA, responsible for the production of a protein" (ref. supra at p. 578) ⁶Proteins and peptides are fundamental components of cells that carry out important biological functions. Proteins give cells their shape, for example, and they respond to signals transmitted from the extracellular environment. Certain types of peptides play key roles in regulating the activities of other molecules. Structurally, proteins and peptides are very similar, being made up of chains of amino acids, which are held together by peptide bonds (also called amide bonds). Peptides are smaller than proteins: the former are small molecules containing between 2 and 50 amino acids; proteins contain more than 50.- (Encyclopedia Britannica, available at: <https://www.britannica.com/story/what-is-the-difference-between-a-peptide-and-a->

protein) (last accessed on 11.02.2018) ⁷Pesticidal crystal protein; the toxic segment of the protein is located in the N-terminus (available at: <http://www.uniprot.org/uniprot/P21254>) (last accessed on 11.02.2018).

An endotoxin is a toxic substance present inside a bacterial cell and is released when the cell disintegrates. It is sometimes responsible for the characteristic symptoms of a disease. (available at: <https://en.oxforddictionaries.com/definition/us/endotoxin>)

(last accessed on 11.02.2018) ⁸Commissioner of Income Tax Andhra Pradesh v M/s. Taj Mahal Hotel Secunderabad MANU/SC/0239/1971 : (1971) 3 SCC 550; State of Bombay v The Hospital Mazdoor Sabha MANU/SC/0200/1960 : AIR 1960 SC 610 Forest Range Officer & Ors v P. Mohammed Ali & Ors MANU/SC/0037/1994 : AIR 1994

SC 120 ⁹Meaning of microorganism (Cambridge Dictionary, available at: <http://dictionary.cambridge.org/dictionary/english/microorganism>) (last accessed on 05.10.2017)

¹⁰Meaning of microorganism (Cambridge Dictionary, available at: <https://en.oxforddictionaries.com/definition/microorganism>) (last accessed on 05.10.2017)

¹¹Meaning of microorganism (The Law Dictionary, Featuring Black's Law Dictionary Free Online Legal Dictionary 2nd Ed., available at: <http://thelawdictionary.org/microorganism/>) (last accessed on 05.10.2017)

¹²Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (adopted in 1977, amended in 1980), available at: <http://www.wipo.int/treaties/en/registration/budapest/> (last accessed on 03.03.2018)

¹³Plant Bioscience Limited v. Syngenta Participations AG, Groupe Limagrain Holding G 0002/07, (available at: <http://www.epo.org/law-practice/case-law-appeals/pdf/g070002ex1.pdf>) (last accessed on 14.02.2018)

¹⁴Guidelines for Examination of Biotechnology Applications for Patent, Office of the Controller General of Patents, Designs and Trade Marks, March 2013, available at:

http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf (last accessed on 03.03.2017)

¹⁵WPO clarifies practice in the area of plant and animal patents, 29 June 2017, available at: <https://www.epo.org/news-issues/news/2017/20170629.html> (last accessed on 03.03.2017)

¹⁶Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1108\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1108(01)&from=EN)) (last accessed on 03.03.2017)

¹⁷"Backcrossing" is the process of cross-breeding a hybrid plant or seed with one of its parents or with an individual genetically identical to such parents (Ref. The Free Dictionary, available at: <https://www.thefreedictionary.com/backcross>) (last accessed on 03.03.2017)

¹⁸National Biodiversity Authority, FAQs (available at: <http://nbaindia.org/content/19/16/1/faq.html>) (last accessed on: 05.03.2018)

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