REPORTABLE

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NOS.4616-4617 OF 2018

MONSANTO TECHNOLOGY LLC THRU
THE AUTHORISED REPRESENTATIVE
MS. NATALIA VORUZ & OTHERS ....APPELLANT(S)

VERSUS

NUZIVEEDU SEEDS LTD. THRU
THE DIRECTOR & OTHERS ...RESPONDENT(S)

with

CIVIL APPEAL NO(s). 188 OF 2019
(arising out of SLP(C) No.19411 of 2018
FEDERATION OF SEED INDUSTRY
OF INDIA (FSII) ....APPELLANT(S)

VERSUS

NUZIVEEDU SEEDS LTD. AND OTHERS....RESPONDENT(S)

CIVIL APPEAL NO(s). 189-190 OF 2019
(arising out of SLP(C) Nos.16479-16480 of 2018
NUZIVEEDU SEEDS LTD. AND ORS. ..APPELLANT(S)

VERSUS

MONSANTO TECHNOLOGY LLC
AND OTHERS ...RESPONDENT(S)

CIVIL APPEAL NO(s). 191-192 OF 2019
(arising out of SLP(C) Nos.19409-19410 of 2018
ALL INDIA KISAN SABHA ..APPELLANT(S)

VERSUS

MONSANTO TECHNOLOGY LLC
AND OTHERS ...RESPONDENT(S)

Signature Not Verified
Digitally signed by R NATARAJAN
Date: 2019.01.08 16:49:55 IST
Reason:

JUDGMENT

NAVIN SINHA, J.

Leave granted.

2. The appellants/plaintiffs in Civil Appeal Nos.4616-4617 of 2018 instituted Civil Suit (Comm) No. 132 of 2016 seeking permanent injunction against the defendants from using the trademark "BOLGARD" and "BOLGARD II" brand cotton technology, violating the registered patent no. 214436 of the plaintiffs, and also to further restrain the defendants from selling and or using seeds/hybrid seeds bearing the patented technology, infringing the registered patent of the plaintiffs, along with rendition of accounts. The parties shall, for convenience, be referred to by their position in the original suit.

3. The plaintiffs pursuant to their patent rights had entered into a sub-licence agreement dated 21.02.2004 with the defendants for an initial period of ten years. The agreement entitled the defendants to develop "Genetically Modified Hybrid Cotton Planting Seeds" with help of the

plaintiffs' technology and to commercially exploit the same subject to the limitations prescribed in the agreement. The agreement also provided for payment of licence fee/trait value by the defendants, for use of the plaintiffs' patented technology. The agreement after extension was ultimately terminated by the plaintiffs on 14.11.2015 due to disputes regarding payment of licence fee/trait value in view of subsequent price control regime introduced by the State, and to which the defendants required adherence by the plaintiffs. The plaintiffs filed an application for injunction under Order 39, Rule 1 and 2 of the Code of Civil Procedure (hereinafter referred to as 'the Code"), to restrain the defendants from using their registered trade mark in violation of the registered patent during the pendency of the suit in view of the termination of the agreement.

4. The defendants in their written statement *inter alia* contended that their rights were protected under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (hereinafter referred to as 'the PPVFR Act'). The suit patent was bad because claims 1-24 were "process claims"

concerning genetic engineering or biotechnology method to insert "Nucleic Acid Sequence" (NAS) into a plant cell as in claim 25-27 practiced in laboratory conditions, unlike the complete biological process adopted by the defendants. The NAS was a chemical composition incapable of reproducing itself and was thus not a micro-organism. Only on insertion into a plant, a living organism, it imparts Bt.trait (insect resistance) to the living organism. The defendants also filed a counter claim no.51 of 2016 seeking revocation of the patent under Section 64 of the Act, as being in violation of Section 3(j) of the Patents Act (hereinafter referred to as "the Act") in respect of plants and seeds that contained DNA sequences, denying any infringement.

5. The learned Single Judge on 28.03.2017, while deciding the plaintiffs' application for injunction, observed that the issues arising in the suit necessarily required formal proof, particularly expert opinion, which in complicated matters like that of patent were crucial for ascertaining the breadth of the monopoly granted by the specifications of a patent claim. The nature and extent of the patent claim was more properly

a matter to be examined after pleadings were complete and evidence adduced on the issues arising, which did not merit comments at the stage of interim injunction. Considering the existing patent registered under Section 48 of the Act, it was ordered that during the pendency of the suit, the parties shall remain bound by their respective obligations under the sub-licence agreement and that the licence fee/trait value payable by the defendant shall be governed by the laws in force. The learned Single Judge simultaneously only issued notice on the counter claim no.51 of 2016. The order of injunction dated 28.03.2017, therefore did not deal with or consider the counter claim. It was *prima facie* observed that the defendants having had the advantage of a sub-licence ever since 2004, appeared unjustified in contending that they were not bound by the obligations under the agreement in view of the claimed statutory protections vis-à-vis the suit patent or the registered trademarks. Prima facie opining that the termination of the sub-licence agreement by the plaintiffs on 14.11.2015 appeared unjustified in view of the statutory

price restrictions, the termination was held not to be of any consequence.

6. Aggrieved, both the Plaintiffs and the defendants preferred appeals. The Division Bench dismissed the plaintiffs' appeal upholding the defendants' contention with respect to patent exclusion under Section 3(j) of the Act and that the plaintiffs were at liberty to claim registration under the PPVFR Act, as the two Acts were not complementary, but exclusive in the case of all processes and products falling under Section 3(j) of the Act. Consequentially, the defendants' counter claim succeeded. The suit was, however, permitted to continue with regard to the claim for damages and other reliefs. The plaintiffs were required to continue with their obligations under the sub-licence agreement including payment of licence fee/trait value by the defendants in accordance with law.

7. We have heard learned senior counsel Dr. Abhishek Manu Singhvi, Sri Kapil Sibal, Sri Neeraj Kaul, Sri K.V. Vishwanathan, Sri Arvind P. Datar, Sri Jayant Bhushan, Sri

Krishnan Venugopal, Sri Shyam Divan and Sri Sanjiv Sen, and learned counsel Sri Prasahant Bhushan and Ms. Anandita Mitra on behalf of the parties.

8. Dr. Abhishek Manu Singhvi contended that the plaintiffs' suit was for injunction restraining infringement of an existing and valid patent. The lack of patentability was never an issue in the suit. The defendants argued lack of patentability to invalidate the primary issue relating to infringement only. The counter claim for revocation of the patent as unpatentable, was neither argued nor adjudicated by the learned Single Judge. Only notice was issued on the counter claim bearing no.51 of 2016 while counter claim bearing no.50 of 2016 challenging the termination of sub-licence agreement was withdrawn. The issue for existence of the patent, patent exclusion under Section 3(j) of the Act was a heavily mixed question of law and facts requiring formal proof and expert evidence, to be considered at the hearing of the suit, as rightly observed by the Single Judge. The defendants in their memo of appeal themselves contended that the issue regarding existence of the patent

and/or its revocation could not have been decided summarily by the learned Single Judge as these were matters which required evidence and could be adjudicated only at the final trial of the suit. The plaintiffs' claims were under 25-27 only. The process claims 1-24 was never an issue in consideration before the Single Judge and yet the Division Bench delved into the same and held the process claims to be bad also.

9. The plaintiffs had never consented to a summary adjudication regarding the validity of its patent. The consent referred to by the Division Bench, had been given only to decide whether the plaintiffs' patent had been infringed or not, as also the scope of the patent, so as to allow or disallow the relief of injunction. It is incomprehensible that the plaintiffs holding a valid registered patent under the Act nonetheless would have agreed to a summary consideration and validation/invalidation of the patent. The patent comprises of a DNA construct or nucleotide sequence in claim 25-27 comprising of three different components, i.e. (i) a promoter (ii) a man-made gene for the production of Cry2Ab

5-endotoxin and, (iii) a third component for the production of a transit peptide 6. The DNA construct so created did not exist in nature and upon insertion into a plant confers insect tolerant trait. A plant is next produced as a "fusion protein" which comprises the Cry2Ab S-endotoxin 7 bonded with the transit peptide. The subject patent claims use of *bacillus thuringiensis strain* and the development of two genes designated Cry2Aa and Cry2Ab. Each gene sequence is known for its ability to synthesize proteins with pesticidal properties. The NAS is not a living organism but a chemical created in a laboratory. The "event" which is the positioning of the NAS at a unique location in the genome of a plant cell is a separate, subsequent and entirely different invention for which the plaintiffs have obtained a different patent no. 232681 and which is not the subject matter of the present suit. In this case, the invention is the NAS and the target of the invention is its use in a plant cell. The property of the NAS is what makes the plant produce and localize the toxin protein in a specific location in the plant cell so as to make the toxin protein present throughout the plant, in pesticidal

effective levels and still produce agronomically stable plants. Relying on **"Marker -Assisted Recurrent Backcrossing in Cultivar Development" by Guoyou et.al,** it was submitted a NAS gene once inserted into a plant, was removable and did not become part of the plant genome, to lose its patentable characteristics. These were matters to be considered in the suit on basis of expert evidence.

10. Shri Vishwanathan and Shri Datar for the defendant have adopted directly and mutually contradictory stands by contending that claims 25-27 are product claims, namely parts of a plant, and subsequently that the said claims are essentially biological process claims. Claims 1-24 are not excluded under Section 3(j) being essentially biological processes as there exists significant human intervention. Dr. Singhvi very fairly admitted that he was not in a position to support the termination of the sub-licence agreement and that the plaintiffs' claims for licence fee/trait value had to be in accordance with the statutory price regime. The seeds from the plaintiffs' patented technology were the highest selling compared to similar other seeds. The plaintiffs have

no intention to sue any Indian farmer for violation of patent. It was lastly submitted that either this Court may remand the entire matter for adjudication of the patent issue and infringement or decide the patent issue and then remand the suit for other issues.

11. Shri Kapil Sibbal contended that a chemical/gene/DNA construct is not a plant variety, and is not eligible for protection under the PPVFR Act. A gene cannot be a plant variety and it would be denied such registration on account of lack of fulfillment of the conditions precedent in Section 2(za) read with Sections 14 and 15. A gene cannot be a "plant grouping", "within a single botanical taxon of the lowest rank", which in simple terms means that it cannot belong to the lowest rank of a plant, namely a species. The PPVFR Act came into effect from 2007 and in the last 11 years, no infringement action has been filed under the same or injunction obtained. The department of bio-technology on their official website has acknowledged the role agro-biotechnology has to play in feeding billion plus mouths in this country and the role that "novel genes" can play to deal

with biotic and abiotic stresses, enhance productivity and nutritional quality.

12. Sri Neeraj Kaul submitted that the patented NAS is not the creation of any biological process. The correct admixture of the promoter, the man made gene for the production of Cry2Ab endotoxin and the 3rd component for the production of the transit peptide leading to the DNA construct, is entirely the creation of the human intervention. The Division Bench wrongly holds the invention to be a plant variety. It is only plant varieties and seeds which are covered by the PPVFR Act. The Patent Act and the PPVFR Act are mutually exclusively.

13. Shri Vishwanathan leading the arguments on behalf of the defendants submitted that no patent rights can be exercised with respect to genetically modified cotton planting seeds being developed by the defendants through conventional breeding methods and sold to the farmers. If the patent rights of the plaintiffs be accepted, then the regime provided under the PPVFR Act for plant intellectual property

with respect to genetically modified plants would be entirely defeated. The plaintiffs' claim was essentially of a "breeder" for developing a variety and therefore its donor seed containing the NAS was registerable under the PPVFR Act and they were entitled to benefit sharing under Section 26 after such registration. No patent could be granted in a plant, or part of a plant, under Section 3(j) of the Act. Patent infringement analysis involves two steps: the proper construction of asserted claims and the determination as to whether the product infringes the asserted claim as properly construed. The plaintiffs claim to patent was never for a chemical sequence in a vial. The plaintiffs' claimed invention was only an improvement on prior art where it claimed that it had found a way to have a plant produce a higher level of expression of the endotoxin protein by localizing it to the plastid thereby reducing insect tolerance and at the same time producing morphologically normal plants. The plaintiffs were also precluded from claiming rights on the genetically modified Bt. cotton seeds on basis of prosecution history estoppel. The order of the Division bench being based on

consent; it is not open for the plaintiffs to contend to the contrary now.

14. Shri Datar submitted that the "product" in claim 25-27 for NAS is a chemical is false, because any chemical that is inserted into a plant is not capable of being passed on to the seeds of that plant and to the future progeny as the chemical will be metabolized by the plant itself and will never be transmitted to its seeds. Further, the NAS, by the wording of claims 25-27 itself, is a plant gene which is meant to be an inherent, intrinsic and integral part of the plant as it exists at the sub cellular level. The cell after transformation with the gene through the biological process of tissue culture results in a transgenic plant that produces seeds having the essential characteristic of these transgenic plants. Therefore, claims 25 to 27 even if it represents merely a "gene" will manifest as an inseparable and inheritable part of a plant and cannot be patented. The NAS gene inserted into the plant becomes an inseparable part of the plant at the sub-cellular level by an irreversible biological process. It exists in every cell of the transformed plant. It not only expresses in

the plant to produce endotoxin but also inherits into progeny plants in perpetuity. It does not result in a "product" which can be put into a vial and sold as such. The claims must be construed so as to give an effective meaning to each of them but the specifications and the claims must be looked at and construed together.

15. Shri Jayant Bhushan submitted that the plaintiffs did not bring the NAS in a vial and but imported plants seeds containing NAS. These seeds were not protected by Patent. Indian seed companies were given donor seeds which already had the NAS/Bt. Trait integrated in them and was capable of germination. What the Indian Seed companies do is to cross one of the plaintiffs' plants with the plants of their proprietary Indian varieties suitable for cultivation in India, to develop a third/new cross-bred cotton variety which would have the Bt. trait from plaintiffs' variety so as to resist Bollworm and other traits from their own developed varieties. Since the Indian Seed Companies do not use the NAS in isolation nor do they use the method of introducing the NAS into the plant through the method described in the patent,

there is no infringement of the patent. NAS is an essentially biological process in which the patented product is neither separately used nor the patented process of insertion into a plant is used, the NAS is not being made or used by the Indian Seed Companies. The patent on a gene sequence in a test tube cannot negate/undo the important researchers' and farmers' rights under Sections 30 and 39 of the PPVFR Act. Section 39 relates to Farmer's Rights entitling him to save, use, sow and re-sow his farmed produce including a registered variety protected under the Act. It was lastly submitted that if the Court is not inclined to uphold the order of the Division Bench, the matter may be remanded to the Division Bench for fresh hearing on the injunction matter because the correctness of the injunction order dated 28.03.2017 never came to be tested or considered by the Division Bench.

16. Shri Divan submitted that that there is no inventive step in the plaintiffs' patent claim, until the artificial NAS is inserted into a plant so that the plant starts producing the delta endotoxin which is toxic to the Bollworms. There is no

capability of industrial application of the NAS except to become part of a plant and to develop a transgenic plant. The threshold requirements of an invention in terms of the patents Act are missing until the implant stage. The inventive qualities begin when the NAS is inserted in a plant cell and not before that stage. Once, the NAS is inserted in a plant cell, the exclusion under Section 3(j) applies and the PPVFR Act becomes operative.

17. Shri Venugopal submitted that a conjoint reading of Section 2(j) and Section 3(c) of the Act makes it clear that it excludes patentability both of transgenic plants (invented through recombinant gene technology in the laboratory) and those invented through conventional breeding techniques even where a new plant, variety or species is initially created through genetic manipulation, to the extent that the subsequent production or propagation of the plant, variety or species is done through "an essentially biological process", the biological process would not be patentable under Section 3(j) of the Act. Even if patent exclusion under Section 3(j) was not applicable, still the patent claim could never permit

plaintiffs to claim the right to prevent farmers from making, using, offering for sale or selling plants or seeds of the cotton plant that contain Bt. gene. The patent of an artificial gene and the process for inserting it into the genome of a plant, will not entitle the exercise of rights under Section 48 of the Act in respect of a plant that contains the artificial gene on which it has a patent. The protection under Section 48 of the Act is capable of being exercised against other biotechnology companies that seek to replicate the Bt. gene product or the process of insertion of that gene in the genome of the cotton plant. Both the Patents Act and PPVFR Act have a link that is to protect the interests of the farmers so that they are not burdened by exorbitant rates of seeds.

18. Shri Prashant Bhusan, Shri Sanjiv Sen, and Smt. Anandita Mitra on behalf of the interveners submitted that the NAS is not "capable of industrial application" unless it becomes a part of the plant cell where it is expressed by the plant cell through essentially biological processes of transcription, translation, and replication, to produce the desired protein. The Biodiversity Act which prohibits the

"use" of any biological resources occurring in India for commercial utilisation and which includes genes used for improving crops and livestock through genetic intervention necessitates prior permission from the National Bio Diversity Authority which has not been taken by the plaintiffs. The NAS only adds a trait to a plant leading to development of a transgenic variety creating donor seeds. The seeds are not patentable under Section 3(j) of the Act though the plaintiffs may be entitled for benefit sharing under the provision of the PPVFR Act as defined under Section 2(h) of the PPVFR Act. The claim of the plaintiffs has ramifications beyond the immediate parties.

19. We have considered the respective submissions made on behalf of the parties. Though very elaborate submissions have been made with regard to facts and the technical processes involved in the patent in question, the provisions of the Act, the PPVFR Act and a large volume of case laws for construction of patents, the obligations under the World Trade Organisation (WTO), General Agreement on Tariffs and

Trade (GATT), Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, leading to the Patents Amendment Act, 2002 on 25.06.2002, in view of nature of the order proposed to be passed, we do not consider it necessary to deal with the same at this stage, and leave open all questions of facts and law to be urged for consideration in appropriate proceedings.

20. The patent claims 1-24 are with regard to the processes while claims 25-27 are with regard to the chemical product called NAS. According to the plaintiffs, the latter was a man-made DNA construct that did not exist in nature and did not otherwise form part of a plant existing in nature. The DNA construct was inserted into a plant which confers the trait of insect tolerance to the plant. It comprises of 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 peptide. Of these three, Cry2Ab 5-endotoxin is stated to be a man-made gene. This nucleic acid sequence is then inserted into the cell of the plant at a particular location resulting in the production of "a fusion

protein" which comprises the Cry2Ab 5-endotoxin 7 bonded with transit peptide. The production of a fusion protein is critical in this respect for the technology to be effected in plants. The *bacillus thuringiensis strain* does not produce such a fusion protein. It is the plaintiffs' claim that it is only its technology that allows a cotton plant to produce the Cry2Ab 8-endotoxin protected inter-alia by claims 25-27 of the patented inventions. 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.

21. It is the contention of the defendants apart from the unpatentability of the plaintiff's claim, they have not violated patented rights, if any, as:

> "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 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."

22. Manifestly, the counter claim of the defendants was never considered by the learned Single Judge as only notice had been issued on the same. The plaintiffs had preferred an appeal against the nature of the injunctive relief with regard to the issue of licence fee/trait value, now conceded by the plaintiffs. We see no reason to reject the submission of Dr. Singhvi that it stands to reason why the plaintiffs would have consented to a summary adjudication of an existing patent and risk losing the same without any merit adjudication. The defendants themselves had contended in their appeal that the issues were complicated requiring expert evidence to be considered in a full-fledged trial. The Division Bench therefore ought to have confined its adjudication to the question whether grant of injunction was justified or unjustified in the facts and circumstances of the case. The

Division Bench ought not to have examined the counter claim itself usurping the jurisdiction of the Single Judge to decide unpatentability of the process claims 1-24 also in the summary manner done. Summary adjudication of a technically complex suit requiring expert evidence also, at the stage of injunction in the manner done, was certainly neither desirable or permissible in the law. The suit involved complicated mixed questions of law and facts with regard to patentability and exclusion of patent which could be examined in the suit on basis of evidence.

23. Section 64 of the Act provides for revocation of patent based on a counter claim in a suit. It necessarily presupposes a valid consideration of the claims in the suit and the counter claim in accordance with law and not summary adjudication sans evidence by abstract consideration based on text books only. The Civil Procedure Code provides a detailed procedure with regard to the manner in which a suit instituted under Section 9, including a counter claim has to be considered and adjudicated. The Code mandates a procedure by settlement of issues,

examination and cross examination of witnesses by the parties, including discovery/inspection of documents, culminating in the hearing of the suit and decree. A suit can be disposed of at the initial stage only on an admission inter alia under Order 12 Rule 6 or when the parties are not in issue under Order 16 Rule 1 and the other grounds mentioned therein, none of which are applicable herein. We are therefore satisfied that the Division Bench ought not to have disposed of the suit in a summary manner by relying on documents only, extracted from the public domain, and not even filed as exhibits in the suit, much less examination of expert witnesses, in the facts of the present case. There is no gain saying that the issues raised were complicated requiring technological and expert evidence with regard to issues of chemical process, biochemical, biotechnical and micro-biological processes and more importantly whether the nucleic acid sequence trait once inserted could be removed from that variety or not and whether the patented DNA sequence was a plant or a part of a plant etc. are again all matters which were required to be considered at the final hearing of the suit.

24. The manner in which a suit instituted under Section 9 of the Code is required to be dealt with and decided, fell for consideration in ***Alka Gupta vs. Narender Kumar Gupta***, (2010) 10 SCC 141, observing as follows:-

> "27. The Code of Civil Procedure is nothing but an exhaustive compilation-cum-enumeration of the principles of natural justice with reference to a proceeding in a court of law. The entire object of the Code is to ensure that an adjudication is conducted by a court of law with appropriate opportunities at appropriate stages. A civil proceeding governed by the Code will have to be proceeded with and decided in accordance with law and the provisions of the Code, and not on the whims of the court. There are no short-cuts in the trial of suits, unless they are provided by law. A civil suit has to be decided after framing issues and trial permitting the parties to lead evidence on the issues, except in cases where the Code or any other law makes an exception or provides any exemption.
>
> .....
>
> 30. But where the summons have been issued for settlement of issues, and a suit is listed for consideration of a preliminary issue, the court cannot make a roving enquiry into the alleged conduct of the plaintiff, tenability of the claim, the strength and validity and contents of documents, without a trial and on that basis dismiss a suit. A suit cannot be short-circuited by deciding issues of fact merely on pleadings and documents produced without a trial.
>
> 31. In this case, the learned Single Judge has adjudicated and decided questions of fact and

> rendered a judgment, without evidence tested by cross-examination.…"

25. The Division Bench ought to have confined itself to examination of the validity of the order of injunction granted by the learned Single Judge only. But we are not inclined to remand the matter for that purpose to the Division Bench as we are satisfied in the facts and circumstances of the case that the nature of the injunctive relief granted by the Single Judge was in order and merits no interference during the pendency of the suit.

26. The order of the Division Bench is set aside. The order of the Single Judge dated 28.03.2017 is restored and the suit is remanded to the learned Single Judge for disposal in accordance with law. In view of the importance of the question involved, we expect the parties to cooperate and facilitate the learned Single Judge in early disposal of the suit.

27. The appeals and the intervention applications stand disposed of.

.....J.
[ROHINTON FALI NARIMAN]

.....J.
[NAVIN SINHA]

NEW DELHI
JANUARY 08, 2019.