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Genetically Modified Organisms and Intellectual Property Rights in India: The Patent-Plant Variety Divide

Arisha Aamir

I. Introduction

Plant varieties' exclusion from patentability under the Patents Act,¹ and their relocation to the sui generis regime of the Protection of Plant Varieties and Farmers' Rights Act², (PPVFR Act) is now, a settled theorem amongst Indian IP scholars. Analysis on genetically modified (GM) crops time and again restates this divide and concludes with *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.*³ as its illustrative precedent. What this proposition has not asked is a narrower but more consequential query: if the Patents Act will not grant a product legal right over a GM seed, how exactly does a technology developer actually get paid for it; and what happens when that payment procedure runs into a statute which was never created to regulate it? The Patent-PPVFR divide has not resolved the question of profit extraction from GM technology; it has relocated that question onto private licensing contracts, which the government has then had to regulate through executive price-control orders that are outside the ambit of both the statutes. The *Nuziveedu* precedent is best read not as a case about patent eligibility, but as a case about what happens to the lacuna that the eligibility rule creates.

II. The Settled Doctrine

Section 3(j)⁴ classifies "plants and animals in whole or any part thereof other than micro-organisms," as non-patentable, with express inclusion of seeds and varieties, and essentially biological processes for their production. This gives effect to the flexibility India retained

¹ The Patent's Act, 1970, S 3(j), No. 39, Acts of Parliament, 1970 (India).

² The Protection of Plant Varieties and Farmers' Rights Act, No. 53, Acts of Parliament, 2001 (India).

³ *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.*, (2019) 3 SCC 381.

⁴ The Patent's Act, 1970, S 3(j), No. 39, Acts of Parliament, 1970 (India).

under Article 27(3)(b) of the WTO TRIPS Agreement⁵, which allows signatory states to protect plant varieties through patents, a sui generis system, or a combination of both. India preferred the sui generis route via the PPVFR Act which grants breeders, farmers, and communities a variety-level right, not a right over any single gene or trait, subject to novelty, distinctiveness, uniformity, and stability, and safeguard the farmers' privilege to save, use, and replant the seed⁶. The consequence can be configured: a GM plant is deprived of patent protection the moment it becomes a plant, but a trait or gene construct inserted into it (via either a nucleotide sequence, a process, a nucleic acid) can, and mostly does, receive a patent, since Section 3(j)⁷ includes micro-organisms or non-biological processes. Monsanto's Indian patent followed precisely this course: it protected the gene sequence *Bacillus thuringiensis*-derived Cry2Ab and the process of introducing it, not the cotton plant itself.⁸ This is where most literature stops: at the observation that the trait comes under the ambit of patent and the PPVFR Act covers the variety. The question is what legal instrument governs the potential profits gained when the two are integrated into a single commercial seed.

III. The Stopgap: Trait Licensing as Substitute for a Product Right

Due to the unavailability of product patent over the GM seed itself, Indian technology developers have counted on a private ordering process entirely outside patent law: sub-licensing the patented gene construct to seed companies or agtech firms under contractual obligations imposing a recurring "trait value" or "trait fee" in addition to the price of the seed, separate from the cost of the seed.⁹ Indian joint venture of Monsanto, Mahyco Monsanto Biotech Ltd, licensed its Bollgard and Bollgard II Bt cotton technology on this model beginning in 2002 to around fifty domestic seed companies, signing a decade's sub-license with Nuziveedu Seeds and its subsidiaries in 2004. The licensed trait was introgressed into their own local hybrid lines by those seed companies, a breeding practice the PPVFR Act would ordinarily not regulate as part of a breeder's exemption, and paid for the privilege under the private contractual trait-fee schedule.¹⁰ This is the process by which the patent-

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(3)(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁶ The Protection of Plant Varieties and Farmers' Rights Act, 2001, SS. 15, 39, No. 53, Acts of Parliament, 2001 (India).

⁷ The Patent's Act, 1970, S 3(j), No. 39, Acts of Parliament, 1970 (India).

⁸ *Monsanto Tech. LLC v. Nuziveedu Seeds Ltd.*, (2019) 3 SCC 381.

⁹ *Id.*

¹⁰ The Protection of Plant Varieties and Farmers' Rights Act, 2001, S 39(1)(iv), No. 53, Acts of Parliament, 2001 (India).

PPVFR lacuna is usually bridged in commercial practice: the PPVFR Act (or ordinary breeding practice) governs the downstream variety, the patent secures the upstream gene, and a bilateral licence, extracts value across the gap which is adrift from either statute. This arrangement stands fragile because contract law doesn't offer any of the standard checks a legislature provides into a property right, i.e., no compulsory licensing threshold, no statutory royalty cap, no public interest overrule; unless a dispute forces the authorities to intervene ad hoc, which is precisely what happened in the *Nuziveedu* dispute.

IV. *Nuziveedu* Re-Read: A Contract Dispute Disguised as Patent

In November 2015, the sub-license of 2004 was terminated by Monsanto, not because of the use of a technology Monsanto objected to, but the trigger was a disagreement over the rate of the trait fee, after the Indian Government introduced a price control regime for Bt cotton seed that effectively capped what Nuziveedu was liable to pay.¹¹ Monsanto then sought an injunction restricting Nuziveedu from utilizing the technology, trademarks and framing the conflict as patent infringement.¹² However, Nuziveedu's defence was two-pronged: that the 2004 agreement survived termination on its original terms and that the underlying technology was unpatentable subject matter under Section 3(j). The Division Bench of Delhi High Court decided the case on the second ground alone, peremptorily revoking the patent and opined that Monsanto's product was properly protected under the PPVFR Act, the result most of the literature reads as decision of the case. In an appeal, the Supreme Court did not affirm this. It instead highlighted that the Division Bench of Delhi High Court had erred in promptly deciding a complex question in an interim application of patent validity without a full trial considering the technical evidence, and it remanded the validity question to the lower court while reinstating the interim arrangement that the parties had applied for before the Division Bench's order. That arrangement required Nuziveedu to continue the technology usage and to recurrently pay a trait fee, but at a rate which is aligned with the Licensing and Formats for GM Technology Agreement Guidelines, 2016¹³, a subordinate, short lived, executive instrument, rather than the original contractual rate or any rate derivable from the Patents Act or the PPVFR Act. In the light of this, the Supreme Court's order did not resolve the patent-PPVFR question at all; it left the boundary ambiguous at the apex level and permitted a price-

¹¹ *Monsanto Tech. LLC v. Nuziveedu Seeds Ltd.*, (2019) 3 SCC 381.

¹² *Id.*

¹³ Licensing and Formats for GM Technology Agreement Guidelines, S.O. 1813(E) (May 18, 2016) (Ministry of Agriculture & Farmers Welfare).

regulation instrument to function as the de facto governing precept for the underlying commercial ties. The doctrinal question that writing on this topic treats as resolved was, in the actual record, deferred, and what filled the gap was not Intellectual Property law but agricultural price control.

V. The Regulation Patch: Price Control Substituting Statutory Royalty Rules

The instrument the courts leaned on did not originate in IP policy. The Cotton Seed Price (Control) Order, 2015,¹⁴ issued under the Essential Commodities Act, 1955,¹⁵ fixed the price ceiling maximum retail price of Bt cotton seed packets and capped the trait value component payable to the technology provider within that price, reportedly cutting the per-packet cost by a sizable margin from the existing contractual rate. The Ministry of Agriculture followed suit in May 2016 with the Licensing and Formats for GM Technology Agreement Guidelines,¹⁶ which went further: it required technology holders to grant licences to any eligible seed company or agtech upon request within thirty days, capped royalties at 10% of the MSP for an initial five-year period with compulsory annual step-downs thereafter, and prohibited any royalty claim once a trait lost potency. The guidelines were withdrawn within a week of notification and reissued in draft form for public consultation after opposition from the biotechnology industry. What is not in doubt is the sequence itself: a technology excluded from product patentability was, within the same decade, made subject to a compulsory-licensing-style policy imposed neither by the Patents Act's own obligatory licensing provisions, nor by anything in the PPVFR Act, rather by an essential commodities price order calibrated for a food security emergency statute never drafted with biotechnology royalties in mind or consideration. The instrument doing the actual regulatory work in this space is neither of the two statutes the existing literature treats as the field's complete map.

VI. Why This Will Recur

Bt cotton remains India's only commercially cultivated GM crop, but the same structural gap awaits the next one. Bt brinjal cleared regulatory trials over a decade ago and remains under

¹⁴ The Cotton Seeds Price (Control) Order, 2015, Ministry of Agriculture and Farmers Welfare, Notification No. G.S.R. 936(E), Gazette of India, pt. II, sec. 3(i) (Dec. 7, 2015).

¹⁵ The Essential Commodities Act, 1955, No. 10, Acts of Parliament, 1955 (India).

¹⁶ Ministry of Agriculture, Gov't of India, *Draft Licensing Guidelines and Formats for GM Technology Agreements* (May 18, 2016).

an vague respite for reasons unrelated to IP law, while GM mustard's commercial release has proceeded in stages after July 2024, when a two-judge Supreme Court bench comprising B.V. Nagarathna and Sanjay Karol JJ, opined a split verdict on challenges regarding the conditional environmental clearance granted to the transgenic hybrid GM mustard (DMH-11). Justice Nagarathna voted to quash the endorsement over procedural and biosafety flaws, while Justice Karol voted to uphold it. Should either be commercialised, the similar anomaly will recur: a trait patent upstream, a PPVFR eligible variety downstream, and a licensing relationship in between which neither statute governs. The PPVFR Act's authority to order mandatory licensing after three years acknowledges availability of variety, not trait royalty rates, and contains no mechanism akin to a FRAND (Fair, Reasonable and Non Discriminatory) obligation under Section 47.¹⁷ The Patents Act's Sections 84 and 92¹⁸ own compulsory licensing provisions were not invoked in *Nuziveedu*, and the Essential Commodities Act price control rests as a dull, crop-specific, politically contingent tool rather than answer to an actual problem. The lack of a deliberate legislative choice, whether an amendment to the PPVFR Act addressing trait-level royalty disputes, or a dedicated biotechnology-licensing statute, most future GM crop disputes in India are likely to be resolved similar to the way of Bt cotton precedent: through emergency price orders improvised after the fact.

VII. Conclusion

The patent-PPVFR divide is tangible and mentioned in the existing literature rightfully so, but it only outlines where ownership resides, not how compensation is regulated once ownership splits across two separate statutes. Upon proper reading, the *Nuziveedu* litigation shows that India's apex court has never actually settled the Section 3(j) issue the divide is supposed to answer, and that the practical administration of GM-seed value has instead defaulted to executive improvisation for price control under emergency legislation. The more urgent reform question for Indian IP policy, therefore, is not which GM plant comes under the ambit of which statute, but who has the authority to set the price of the trait inside it, a question the Patents Act, the PPVFR Act, and the courts have each, in turn, skipped to answer.

¹⁷ The Protection of Plant Varieties and Farmers' Rights Act, 2001, S 47, No. 53, Acts of Parliament, 2001 (India).

¹⁸ The Patents Act, 1970, SS 84, 92, No. 39, Acts of Parliament, 1970 (India).