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## Monsanto's Patent On Bt Gene Invalidated

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The world's largest seed company, Monsanto, has lost an appeal to secure patent rights over its Bt gene technology for bollworm resistance in India.

In an order that may have widespread ramifications for biotech jurisprudence in the country, on April 11, 2018 a Division Bench (two judge bench) of the Delhi High Court held that Monsanto – the world's largest seed company – cannot own a patent over its Bt gene technology for bollworm resistance in India. The verdict (*Monsanto Technology LLC and Ors. v. Nuziveedu Seeds Ltd. and Ors*) was the outcome of cross appeals filed by Monsanto and Nuziveedu against the order of a single judge.

The dispute arose out of sub-licensing agreements that Monsanto had entered into with Nuziveedu involving a patent for a 'nucleic acid sequence' containing the Bt gene and the consequent process to insert the Bt gene in plant cells. Surprisingly, both parties had agreed that the issue of patentability under Section 3(j) of the Indian Patents Act (which prohibits, amongst other things, 'plants', 'seeds', and 'essentially biological processes' for production or propagation of plants and animals from patentability) could be decided by the court on the basis of the material on record without any trial. Accordingly, the Bench proceeded without any expert evidence which is otherwise quite crucial in deciding the merits of such claims.

Understanding how Bt cotton hybrid seeds are produced is helpful whilst analysing the dispute in question. The first step involves Monsanto modifying a specific gene into a form which does not occur in nature and thereafter, inserting this modified 'Bt gene' into plant cells to obtain 'modified cotton seeds' – such seeds, called 'donor seeds', are then sold to seed companies. In the second stage, seed companies introgress the Bt trait into their own specific hybrid varieties by backcrossing to produce 'Bt varieties' which have their own characteristics, apart from the Bt trait of the patented technology. In the current instance, the court concluded that Monsanto's patent encompassing its Bt technology for bollworm resistance was invalid for it fell within the exclusion spelt out by Section 3(j). But experts challenging the decision reference the two stages and argue that the first stage, which involves human intervention in fundamentally altering the genetic makeup of a seed, is not a natural phenomenon or 'essentially biological process' and therefore, does not fall within the exclusion of Section 3(j). They further argue that the court's reasoning on the application of Section 3(j) is also faulty in regarding a 'recombinant nucleic acid sequence' – a modified synthetic molecule that renders a specific trait to a transgenic seeds/plants – as a 'part' of the plant.

On its part, observing that seed companies subsequently cross a Bt gene containing plant (obtained from Monsanto's donor seeds) with their proprietary cotton varieties, the court opined that in its view, this crossing of plants, was a process of nature and therefore, it would be contrary to law to allow Monsanto to have patent rights over its nucleic acid sequence once it has been duly introgressed and hybridised into generations of transgenic plants. In so doing, the Court has raised questions on not just patentability, but also the enforceability of such 'recombinant nucleic acid molecules' under Indian law. Moreover, as per the Court, the protection of 'Bt trait induced seed/plant varieties' came within the purview of a *sui generis* legislation – the 'Protection of Plant Varieties and Farmers' Rights Act, 2001'. Accordingly, it granted Monsanto a three month window to apply for registration under the Plant Varieties Act.

Challenging the ruling of the Division Bench, Monsanto has filed an appeal before the Indian Supreme Court and hearings in the matter were expected to commence in early July.