

6. MONSANTO'S BT COTTON PATENT, INDIAN COURTS AND PUBLIC POLICY

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ABSTRACT

This Paper primarily deals with an unanswered substantial question of patent law that has arisen in India. The question is whether an invented Nucleic Acid Sequence after being inserted into a seed or plant becomes part of the seed or the plant. If answer is in the affirmative, said invention is not patentable under Section 3 of the (Indian) Patents Act 1970, which excludes from patentability, inter alia plants, seeds, or any part thereof. If answer is in the negative, said invention is patentable. Answer will determine the fate of patenting of such inventions in the field of agrotechnology. Problem is that the question has moved forth and back like pendulum from one court to another but in vain. This paper seeks to address this question in light of the decisions of Indian courts. Further, this paper seeks to address a policy question: whether statutory exclusion of plants, seeds or any part thereof and essentially Prof. Dr. Ghayur Alam, IAS (Retd.) is the author of this paper. He is currently Professor of Law and Director of the Centre for Intellectual Property Rights at the National Law Institute University, Bhopal, India (NLIU). At NLIU, he is the

The problem is that the question of patentability of the claimed invention has moved like a pendulum from one court to another but in vain. Prima facie judicial answer by the court of first instance was that an invented NAS is a result of human intervention and ingenuity and is not a product of nature; hence, it is patentable. Whereas, the answer given by the appellate court was that by virtue of the provisions of Section 3 (j), an invented NAS after being inserted into a seed becomes part of the seed; hence, it is not patentable. The Supreme Court of India (hereinafter, 'Supreme Court'), set aside the answer of appellate court. The Supreme Court also remanded the case for expeditious trial and disposal to the court of first instance. As a result, answer of the court of first instance is the only judicial answer to the question, prima facie though.

The question of patentability of claimed invention has arisen in a case for infringement of patent filed by Monsanto against Indian seed companies (hereinafter, 'Indian companies'). The case was filed before the Single Judge of Delhi High Court court of first instance. On 30 March 2016

seeds, or any part thereof is explicitly excluded by s 3 (j) of the Patents Act, hence are not patentable.

⁴ There is a three-tier judicial hierarchy in India. At the lowest level there are subordinate courts including District Courts with defined territorial, subject matter and pecuniary jurisdiction. At the middle level there are high courts with defined jurisdiction. Thereof

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already expired on 4 November 2019. Hope for an answer,

- v. Indian companies obtained approval of Genetic Engineering Approval Committee (GEAC) ~~dated~~ under Rule²⁸ for commercial release of new Bt. Cotton hybrid seeds.
- vi. Indian companies produced Bt. cotton hybrid seeds in mass scale and sold the same to Indian farmers.
- vii. Sublicense agreement can be terminated, inter alia, for non-payment of trait value. Parties continued adhering to the terms and conditions of agreement including payment of trait value as per the stipulations of agreement.
- viii. In the meantime, the Government of India and several State Governments issued notification~~s~~ on the price control of cotton seeds, fixing maximum sale price, trait value and seed value. Compliance to notifications was made obligatory on the licensor and licensee.
- ix. Indian companies wrote to Monsanto to abide by the notifications and accept payment of trait value~~s~~ notified by Governments. Monsanto refused and terminated the agreement.
- x. Trait value fixed by the Governments was substantially lesser than the trait value stipulated in the agreement.
- xi. The Government of India estimated that Indian companies paid Monsanto approximately INR 1,600/ Crore (INR 16 Billion) more in excess of actual trait value fixed by various State Governments.

Dispute~~s~~ between Monsanto and~~the~~ Indian companies would not have arisen had Monsanto acceded to the requests of the Indian companies to abide by notifications issued by Governments. Monsanto not only terminated the agreement unilaterally but also filed applications before the court of first instance seeking injunction and suit for infringement of patent, trademarks and passing off~~to~~ against Indian companies. In response, Indian companies contested the

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validity or otherwise of claims 227 without trial. Single Judge decided the application for grant of ad interim injunction.

The first reasoning of the Single Judge appeals to sense of justice. In his opinion validity of the patent can only be decided after hearing on merits and formal proposition, particularly expert opinion which in complicated matters like patents may be crucial.³² This reasoning is clearly right. The validity of a patent, be it related to patentable subject matter, novelty, non-obviousness, or utility, raises mixed questions of law and fact. In other words, a patent infringement suit cannot be decided without trial and in the absence of expert opinion, examination and cross-examination.

Second reasoning of Single Judge was as under:

Prima facie the amendment of 2005 repealed Section 5³³ from the statute book altogether, the conclusion to be drawn from such legislative changes naturally being that the embargo on grant of patents to 'products of biological or microbiological processes thereby stood removed.

The above reasoning hangs in the air and suffers from logical hiatus for the following related reasons. First, it is an established principle of statutory construction that a statute must be read as a whole, section by section and clause by clause. The Single Judge read the provisions of the repealed section without giving due weight to the provisions of Section 3(j). Second, it was imperative on the part of Single Judge to ask what was the field covered by the repealed section. But he did not do so. The field covered by the repealed section was only limited to the grant of process patents and not product patents to certain chemical substances of inanimate

nature. On the other hand, the field covered by Section 3(j) of the Patents Act belongs to the world of animate objects excluding only microorganisms. Third, the Judge invoked explanation to Section 5. Explanation at best is an internal aid to interpretation and does not control the meaning and scope of section. Moreover, explanation to Section 5 did not employ the word 'product' it merely explained the meaning of chemical process to include biochemical, biotechnological and microbiological processes. Furthermore, explanation to Section 5 did not employ the term 'biological processes' but the Judge read it. Fourth, embargo of Section 5 was specifically on grant of product patents in the field of pharmaceuticals. Foreign pharmaceuticals were lobbying for product patents on pharmaceuticals. Indian pharmaceuticals were lobbying against product patent on pharmaceuticals. Foreign pharmaceuticals won. As an interim measure, India introduced a mailbox system of exclusive marketing rights in the year 1999 by amending the Patents Act. 31 December 2004 was the last date of introducing the product patent regime in all fields of technology including pharmaceuticals. India did so by repealing Section 5. The purpose of repealing Section 5 was by no means to make every product and process eligible for grant of patent. The purpose was to introduce a product patent regime for all fields of technology without any discrimination whatsoever. Fifth, a well known principle of patent law is that the product or process to be eligible for grant of patent must satisfy all the requirements of patent law. The first and foremost requirement of patentability is that the product or process must be eligible for grant of a patent. In other words, the product or process must not fall in the prohibited category of non-patentable

³² Monsanto v Nuziveedu (Del HC) 5) 185186, para 97. The Supreme Court affirmed the first reasoning of the Single Judge; Monsanto v Nuziveedu (SC) (n 15) 385, para 7.

³³ Patents Act (n 2), s 5 read:

Inventions where only methods or processes of manufacture patentable

(1) In the case of inventions—

(a) claiming substances intended for 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, semiconductors 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.

(2) [...]

Explanation— For purposes of this section, 'chemical processes' includes biochemical, biotechnological and microbiological processes.'

s 5 was repealed by the Patents (Amendment) Act 15 of 2005, s 4 with effect from 1 January 2005.

³⁴ Monsanto v Nuziveedu (Del HC) 5) 187, para 103.

³⁵ The Patents (Amendment) Act 17 of 1999 (India).

subject matter. Even if a product or process meets all the requirements of patentability but one, non-fulfillment of one requirement is enough to kill a

grouping' cannot be equated with a single plant.

answer in affirmative and declared Monsanto's patent invalid.

The first reasoning of the Division Bench was that [r]epeal of Section 5⁴⁸ meant that process or products, that otherwise meet the test of patentability are nevertheless as a matter of public policy, ineligible for patent protection by virtue of Section 3(j).⁴⁹ This reasoning of the Division Bench and the second reasoning of the

The third reasoning of the Division Bench was that 'Monsanto has not deposited the microorganism with the International Depository Authority in terms of Article 7 of the Budapest Treaty⁵¹ and Section 10(4)⁵² of the Patents Act.⁵³ Depositing of microorganism is a condition precedent for grant of patent on inventions involving biological material under Section 10(4)⁵⁴ of the (Indian) Patents Act.

The fourth reasoning of the Division Bench was as under:

[T]ransgenic plants with the integrated Bt. trait, produced by hybridization (that qualifies as 'essentially biological process'..) 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.

Hybridization by cross-pollination of transgenic plants with the integrated Bt. trait with the Indian varieties of cotton plants is an essentially biological process as it does not involve an inventive step. Cross-pollination is a natural phenomenon. Natural phenomena are not patentable. Essentially biological processes are expressly excluded from patentability by Section 3(j).

The fifth reasoning of the Division Bench was, 'NAS once inserted in the seed becomes part of the seed through the process of nature, and no step of human intervention can impede such transfer of the sequence.⁵⁵ Since seeds, whole or in part, are excluded from patentability by Section 3(j), this observation of the Division Bench is in tune with the statutory

law,

In the light of the analysis of the judgments of Single Judge and Division Bench, the arguments of Indian companies seem to outweigh the arguments of Monsanto. However, the Supreme Court decided not to decide the rival contentions of parties and remanded the case to the Single Judge for trial observing, '[T]he counterclaim for revocation of the patent as unpatentable, was neither argued nor adjudicated by the learned Single Judge.' The Supreme Court did not agree with the approach of the Division Bench. Jurisdiction of Division Bench was confined to hear the appeal against orders passed by the Single Judge on the interim applications. The Division Bench has exceeded its jurisdiction and the decision without jurisdiction was a nullity in law. The Supreme Court set aside the decision of Division Bench observing, esse

otherwise there would have been at least an opinion of the Supreme Court on prima facie validity or otherwise of patent. The Supreme Court further observed as under:

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, 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.

As noted above, the Supreme Court did not express any opinion on the substantial question of law. On the one hand, the Single Judge prima facie answered the question in the negative, i.e. an invented NAS after being inserted into a seed or plant does not become part of seed or plant. On the other hand, the Division Bench answered in affirmative. The approach of the Single Judge on application of substantive patent law seems to be very weak but on application of procedural patent law the Single Judge was clearly right. On the application of substantive patent law, the approach of the Division Bench is clinching but on application of procedural patent law it is clearly erroneous and also against the basic principles of justice and fairness. Mixed questions of law and facts cannot be decided without a trial and hearing.

We are at sea for following two reasons. One, the answer to the substantial question of law, given by the Division Bench, is no more an answer after the decision of the Supreme Court. Two, there is a strong possibility that the prima facie answer given by the Single Judge on application of substantive patent law may be reversed after trial. A question is: if plant or any part of the plant is not eligible for patent but still the Patent Office has granted patent, can the patentee of such

an invention prevent third persons from reproducing the plant containing the patented NAS? If so, will it not amount to indirect patenting of statutorily excluded subject matter?

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⁷³ Monsanto v Nuziveed (SC)(n 15) 389, para 18.

⁷⁴ TRIPS Agreement (n 41) art 27.3(b). Members may also exclude from patentability...plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes. However, Members shall provide for the protection of plant

The Supreme Court knew that patent is going to expire within a few months, on 4 November 2019. Instead of remanding the

