1. Introduction

Arguably, the most notorious requirement of the Trade Related Intellectual Property Rights Agreement (TRIPS)⁶⁶² is that Article 27.3(b), requires that members 'shall provide for the protection of plant varieties either by a patent or by an effective sui generis system or by any combination thereof. Article 8 of the Agreement⁶⁶³, in enunciating the principles which are to animate it, provides that 'consistent with the provisions of the Agreement', signatories may, 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'.664 Thus it is a logical corollary that the obligation to protect plant varieties might be inconsistent with a given nations' need for food security. Developing countries argue that because the needs and interests of their countries are different than those of developed countries, they should have flexibility in enacting intellectual property regimes that offer the proper balance for their individual situations. The debate about balancing strong IPRs and farmers rights is especially important to India given its dependence on agriculture sector.

Thus, the patentability of plants and plant varieties is one area of interface between intellectual property rights and national interest, that evokes passionate responses from both sides of the divide and renders judicial pronouncements on this point highly crucial. The recent decision of the Appellate Tribunal in, Monsanto Technology LLC. v The Controller of Patents and Designs and The Deputy Controller of Patents and Designs (IPAB)⁶⁶⁵,

⁶⁶² The Trade Related Intellectual Property Rights Agreement (adopted 15 April 1994, entered into force 1 January 1996) 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

⁶⁶³ Ibid

⁶⁶⁴ Id. Article 8.

⁶⁶⁵ Monsanto Technology LLC. v The Controller of Patents and Designs and The Deputy Controller of Patents and Designs (IPAB) Order No. 146 of 2013 [hereinafter Monsato Case]

being a first on this issue, is a welcome step in India's patent law jurisprudence. Generating widespread interest, it is hailed by the legal fraternity and social activists as a landmark judgment, finally defining the correct position of law with respect to the patentability of plants.

This case note seeks to examine the issues that arose in the *Monsato Case*, and how they were dealt with by the Appellate Tribunal. For this purpose, the note first traces the history of the case which includes a scrutiny of the facts and then proceeds to analyse the manner in which it was dealt with by the Appellate Tribunal. Subsequently, the author would strive to acquaint the reader with the ensuing impact of this decision by way of a careful perusal of the decision.

1.1. THE BACKGROUND OF THE CASE

For centuries, Indian farmers have used ingenious methods, handed down from generations to create salt-resistant seeds for seasons when the oceans flood the country's farmland and cold-resistant seeds for years when it's too cold to grow regular crops.

Though lately at the behest of multi-national corporations like Monsanto, the global government have passed laws that has taken away the rights of naturally altered seeds from the public domain and handed them over to corporations. Furthermore in 2003, the WTO forced India to revise its patent laws to consent to corporate ownership of entire plant and animal species. 666

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⁶⁶⁶Paromita Pain, 'Battling India's Monsanto Protection Act, Farmers Demand End to GMO' (2013) Occupy.com, *available at* <a href="http://www.truth-out.org/news/item/18337-battling-pain-defeat-bat

India refused to allow patents on animals, but agreed for corporate ownership of plants. The omission of 'plants' from section 3(i) implied that a modification of a plant could now be counted as an invention and hence be patented. Consequently, Monsanto could have Bt cotton patents in India. The Amendment of 3(i) of Indian Patents Act, 1970 was termed as 'Monsanto Amendment.'667 Thus began India's long and contentious history with Monsanto, the multinational Ag-biotech Corporation.

Since then almost 270,000 farmers have committed suicide. Most of these suicides are from the cotton belt, and Monsanto controls 95% of cotton seed supply through its GMO Bt cotton. Monsanto has taken over 1000 patents on Climate Resilient crops already.⁶⁶⁸

Recently⁶⁶⁹ Monsanto sought to patent its 'Methods of Enhancing Stress Tolerance in plants and methods thereof,' and 'A method of producing a transgenic plant, with increasing heat tolerance, salt tolerance or drought tolerance.' Monsanto filed patent application No.2407/DEL/NP/2006 on 01/05/2006.⁶⁷⁰ However the patent application was rejected by the Patent Office. The company subsequently preferred an appeal in the

indias-monsanto-protection-act-farmers-demand-end-to-gmo (last accessed 13 April 2014).

⁶⁶⁷Vandana Shiva, 'The Real Reasons for the Second Amendment of the Indian Patent Act' (2011) greens.org, *available at* http://www.greens.org/s-r/30/30-19.html (last accessed 12 April 2014).

⁶⁶⁸P.K Vishwanathan, N. Lalitha, 'India's Experience with Bt. Cotton' (2012) isid.ac.in, *available at* http://www.isid.ac.in/~bharat/Research/tripp.pdf (last accessed 10 April 2010).

669 May 1, 2006 (priority date of Sept. 29, 2003)

670 <u>http://www.ijlt.in/pdffiles/Patents-Act-1970.pdf</u> (last accessed on 10th April 2014)

Appellate Tribunal praying for reversal of the Patent Office's decision and grant of patent.

1.2. SUBJECT MATTER OF PATENT APPLICATION

At the outset the application claimed (a) recombinant DNA (rDNA) molecule encoding a specific cold shock protein (CSP) (b) steps for inserting the rDNA into plant cells and (c) transgenic plants expressing CSP.

This invention relates to technique of increasing the biotic and abiotic stress tolerance of plants, which is of use for farmers as it reduces their losses. The method disclosed in the patent accomplishes the objective by expressing a cold shock protein(s) within the cells of said plant, or in elementary terms, by altering the cellular structure of plants.

Later, Monsanto restricted the scope of the application to 'A method of producing a transgenic plant with increased Heat Tolerance, Salt Tolerance, or Drought Tolerance'. The claims on proteins of the 'cold shock domain' responsible for the cold tolerant properties and the resultant stress resistant plants were excluded.

1.3. CONTENTIONS RAISED BY THE APPELLANT

I. In its attempt to persuade the IPAB (Intellectual Property Appellate Board) to reverse the controller general's decision Monsanto had made 20 claims in its original application. Monsanto claimed that the prior art had been wrongly assessed and submitted various test results to refute the obviousness claim.

During the proceeding, Monsanto admitted that as of the priority date of its application, quite a number of eukaryotic and plant stress related genes were already known and had been identified in the art. However, Monsanto argued that a person trained in the art would have used eukaryotic genes to produce stress tolerant plants rather than bacterial genes as the expression of bacterial genes in plants is unforeseeable.

Consequently, on the priority date of the application, the prior art taught away from methods of producing stress tolerant plants by incorporating bacterial genes (whose function, even in the bacterial system, was unclear). And so, according to Monsanto, one skilled in the art had no reason to resort to a bacterial system for such genes. 671

II. Monsanto claimed the method was not a 'new use' of a known process but instead it involved a 'new product' (a transgenic plant) that altered with the prokaryotic cold stress gene that exhibited heat, salt and drought tolerance. Therefore they argued that their invention did not fall under the ambit of Section 3(d) of the Act.⁶⁷² Monsanto further argued that it had submitted ample data signifying the superiority of the new plants when compared to wild type exposed to the similar conditions of heat, salt or drought tolerance.⁶⁷³

^{671&}lt;u>Latha Jishnu</u>, 'Saying no to Monsanto'(2013) downtoearth.org.in, available at http://www.downtoearth.org.in/content/saying-no-monsanto.html (last accessed 13 April 2014)

⁶⁷²The Patents Act, 1970 s. 3(d) (the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product employs at least one Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy) [hereinafter Patents Act

⁶⁷³ Sai Vinod, '3(d)-ed by IPAB, Monsanto denied patent on method of producing climate-resistant plants' (2013) spicyip.com, available at http://spicyip.com/2013/07/3d-ed-

III. The counsel for appellant submitted that the claims of the subject application do not fall within the scope of section 3(j) of the Patents Act as they do not constitute an essentially biological process. Monsanto tried to create an extraneous and false opposition of natural production of plants v. production based on human intervention. Monsanto argued that the production of transgenic variety involves 'substantial human intervention' in inserting the rDNA molecule into the plant cell and transforming the cell into climate resistant plant

They argued it is not possible to obtain the transgenic plants mentioned in subject application through processes which occur in nature and which do not involve human intervention. Even the selection step of the instant application does not involve 'natural selection'. Rather it is a step that entirely involves human intervention. ⁶⁷⁴

1.4. ISSUES EXAMINED BY THE COURT

It can be broadly studied under three heads.

1.5. LACK OF INVENTIVE STEP

The Controller General had held that the structure and function of cold shock protein responsible for climate resistant is a 'known' and hence rejected the claim as obvious. The IPAB, rejected Monsanto's claims relying on prior art which demonstrated reasonable degree of predictability in employing CSPs in developing stress-resistant varieties. The Board agreed with the Controller findings that:

The claimed invention is related to production of transgenic plant by transformation with admittedly known cold shock protein. Claims do not define any invention under section

<u>by-ipab-monsanto-denied-patent-on.html</u> (last accessed 13 April 2014)

674 Ibid.

2(1)(ja) of the Patents Act, 1970 as structure and function of cold shock protein was already known in cited prior art and it is obvious to person skilled in plant to make transgenic plant.⁶⁷⁵

1.6. SECTION 3(D): NEW USE OF KNOWN SUBSTANCE

The Board yet again rejected the Monsanto's arguments reiterating that the cold tolerant properties of CSPs were previously known. The Board held that the application in essence claims 'new use' of specific proteins from 'cold shock domain' for producing desired traits and therefore disqualified under Section 3(d)⁶⁷⁶.

The selection of particular proteins from 'cold shock domain' to attain better result in plants contributes merely to a new use of such substance. Mere application of an admittedly known substance is not allowed under section 3(d). The claim of 'surprising result' will not alter the position as it will be still be a new use of known substance even if it produces superior results. They agreed with the respondents observations i.e. "It is mere application of already known cold shock protein in producing cold stress tolerant plant and tolerant to heat, salt and drought conditions, claims fall within the scope of Section 3(d) of The Patents Act, 1970." Section 3(d) 678 provides that a mere discovery of a new property of known substance is not considered patentable. A case in point can be

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⁶⁷⁵Monsato case, Supra note 4.

⁶⁷⁶Vandana Shiva, 'Monsanto's Climate resilient plant patent rejected by India's Patent Office, Rejection upheld by the Intellectual Property Appellate Board' (2013) navdanya.org, available at http://www.navdanya.org/news/360-monsantos-climate-resilient-plant-patent-rejected-by-indias-patent-office-rejection-upheld-by-the-intellectual-property-appellate-board

⁽last accessed 12 April 2014) 677 Monsato case, Supra note 4.

⁶⁷⁸Patents Act, Supra note 11.

that of the *paracetamol*. It has antipyretic property. An additional discovery of new property of *paracetamol* as an analgesic cannot be patented. ⁶⁷⁹

For instance use of *Aspirin*, originally an analgesic, for treatment of the cardio-vascular disease is not patentable. However, a new and different process for preparing Aspirin is patentable.⁶⁸⁰

The main objective of this section is to prevent pharmaceutical companies from obtaining patents on old medicines which are just a mere augmentation or trivial improvement of the known substances and also a refusal to the patent on discovery of new form or new use of old drugs. It is for the first time in this case, that section 3(d) has been applied to plant patents.

1.7. SECTION 3(J) - AN ESSENTIAL BIOLOGICAL PROCESS

Monsanto argued that the production of transgenic variety involves 'substantial human intervention'. The Controller, however, rejected the claim on the ground that the invention relates to essential biological process of regeneration and selection and hence ineligible as per Section 3(j)⁶⁸¹, and stressed Monsanto's application was not an invention but

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⁶⁷⁹Suchi Rai, 'Innovation Going Turn Down' (2013) lexology.com, available at http://www.lexology.com/library/detail.aspx?g=abf4f391-4e93-4489-9f74-d63ba4a73510 (last accessed 13 April 2014) 680Ibid.

⁶⁸¹Patents Act, Supra note 11, Article 3(j) (excludes from patentability 'plants and animals in whole or in any part thereof other than micro-organisns but including seeds, varieties, and species, and essentially biological processes for production or propagation of plants and animals')

based on many generic steps that are essentially biological , taken in sequence, still essentially biological.

The IPAB agreed with Monsanto's submission that the plant cell is altered as a result human intervention in the manner claimed in the application. To this degree, the Controller's findings were set aside. This is the first judgement citing section 3(j) that says plants and animals are not patentable. 682

2. THE DECISION OF THE APPELLATE TRIBUNAL

The IPAB (Intellectual Property Appellate Board) upheld the decision of the Controller against grant of patent to Monsanto Inc. for a technique of producing plants which can endure harsh environmental conditions. They concurred with the Controller's findings on all counts except Section 3(j). The tribunal upholding the decision of the patent office refused to grant patent as it was found subject matter of claims lack inventive step in view of

- (i) Willimsky Gerald Journal of bacteriology .Vol174,No 20 ,1992,6326-6335, and WO 90/09447and US 5470971.
- (ii) Claims don't describe any invention under section 2(1)(ja) of the Patents Act, 1970 as composition and purpose of cold shock protein was identified in cited prior art and it is obvious to person skilled in plant to make transgenic plant.
- (iii) It makes use of previously known cold shock protein in producing cold stress tolerant plant and tolerance to heat, salt and drought conditions. The claims fall within the scope of Section 3(d) of The Patents Act, 1970. ⁶⁸³

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⁶⁸²Sanjay Vijayakumar, "Monsanto's Climate-Resilient Crop Patent Claims Rejected" *The Economic Times*, 10 July 2024 at p.

⁶⁸³Monsato case, Supra note 4

2.1. IMPACT: A MILESTONE IN THE SAGA OF FOOD SECURITY AND SEED SOVEREIGNTY

The decision in the *Monsato case* is a defining moment for India's patent regime and has far reaching implications towards strengthening India's food sovereignty and protecting it from the monopoly of profit motivated multinationals. Article 27.3 of TRIPS that mandates the protection of plant varieties is the genesis of the conflict between IPRs and food security. This was the most contested article during panel discussions⁶⁸⁴ where developing countries had strongly voiced their concern over the implications of this section. India has however been a frontrunner in fulfilling its obligations under TRIPS by enacting the Plant Varieties and Farmers' Rights Act 2001⁶⁸⁵ providing patent protection to plant varieties. However the present decision of the tribunal evinces that India's compliance with TRIPS was not at the cost of the welfare of its people.

2.2. AN EXHIBITION OF COMMITMENT TOWARDS FOOD SOVEREIGNTY

According to Jeremy Bentham's principle of Utilitarianism, 'pain' and 'pleasure' are the sovereign masters under which every human being is bound.⁶⁸⁶ Every legislation should be capable of maximizing the pleasure and minimizing the pain of the subjects. The Benthamite perspective, instead of focusing on 'whose rights' or 'who deserves', thinks of the welfare of the largest number of people. This ideology of preferring national interest has been recognised in the

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⁶⁸⁴Ashish Kothari, "Biodiversity and Intellectual Property Rights: Can the Two Coexist?", *Linkages Journal*, Vol. 4, No. 2, May 1999, pp. 142-4.

⁶⁸⁵ The *Plant Varieties and Farmers'* Rights Act, 2001 (hereinafter Plant Varieties Act)

⁶⁸⁶Jeremy Bentham, An Introduction to the Principles of Morals and Legislations, Dover Publications, London, 2007.

Convention on Biological Diversity⁶⁸⁷ and the International Treaty on Plant Genetic Resources for Food and Agriculture⁶⁸⁸, both of which have been ratified by India. This decision cements India's position as a welfare state which has in the past been displayed through India's unique legislation, Plant Varieties and Farmers' Rights Act 2001, ⁶⁸⁹enacted to ensure India's compliance to TRIPS agreement.

Seed is the basis of the food chain, making seed sovereignty the foundation of food sovereignty. Seed sovereignty includes the farmer's rights to reserve, breed and trade seed, to have access to assorted open source seeds which can be saved and are not patented, genetically modified, owned and governed by emerging seed giants. Denial of this right means the denial of seed sovereignty and consequently of food sovereignty of the entire nation. Monsanto's patent application for climate resilient plant variety covers a extensive range of seeds, which includes soybean, barley, canola, oats, corn, rice, cotton, turf grasses, cotton and wheat making this patent very crucial for Monsanto as it could have enjoyed exclusive patent rights for all the seeds sold in India that used this technology. 690 It is understood that climate resilient traits will become increasingly important in times of climate instability, thus

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⁶⁸⁷Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 79 (affirming a country's sovereignty over its biological resources and recognizing the need to conserve these resources).

⁶⁸⁸International Treaty on Plant Genetic Resources for Food and Agriculture (adopted 3 November 2001, entered into force 29 June 2004) AGP I0510, Article 1 (overall aim of the treaty is the promotion of sustainable agriculture and food security). ⁶⁸⁹The Plant Varieties Act, Supra note 17.

⁶⁹⁰ Arjun Walia, 'Indian Government Rejects Monsanto's Climate Resilient Plant Patent' (2013) Collective Evolution.org, at http://www.collective-evolution.com/2013/07/11/indian-government-rejects-monsantos-climate-resilient-plant-patent/ (last accessed 14 April 2014).

giving monopoly of such seeds to a multinational corporation would hamper India's food security prospects beyond repairable measures. With patents of such broad nature, corporations like Monsanto can prevent access to climate resilient seeds after climate disasters, because a patent would award them an exclusive right to manufacture, distribute and sell the patented product.

Thus, the decision of the patent office and appellate board must be applauded for its boldness and reaffirmation of India's stand to protect its' farmers rights and food sovereignty as it will have a positive impact on India's biodiversity, farmers' rights and food security.

2.3. THE CONSERVATION OF THE COMMON HERITAGE PRINCIPLE

In spite of the large formal agricultural system in India,⁶⁹¹ the majority of farmers depend on informal seed systems. The principle of 'Common heritage' or the principle of free exchange based on the view that the major food plants of the world are not owned by anyone and are a part of our human heritage governed genetic resources is the ageless belief in Indian agricultural practice. Consequently, formal sources (public and private sector) account for a minor proportion of the seed used by farmers. It is estimated that only about 1/10th of the total seed requirement of farmers in all crops is met by formal institutions. Traditional seed supply

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⁶⁹¹World Bank Study 'The Growth of the Private Agricultural Sector in Developing Countries' (2001) Worldbank.org, available at http://lnweb18.worldbank.org/oed/oeddoclib.nsf/DocUNIDViewForJavaSearch/EAA847661F5C30D1852567F5005D8C3D (last accesses 10 April 2014) (there are more than 500 private seed companies, 24 of them with links to multinational seed companies, and many with their own hybrid development programs operating in India).

systems, on the other hand, are relied upon by 80 per cent of the farmers.692

The decision of the appellate tribunal in the present case is a sigh of relief to the farmers for a variety of reasons. Firstly, such a patent would reduce access to seeds and genetic resources to farmers and breeders in turn restricting their right of free exchange and saving of seeds. Secondly, it would also make seeds more expensive for the small farmers due to royalty payments and increased commercialisation. Once the seed is planted companies can compel the farmers to purchase new seed every year, and penalise them for saving seeds.⁶⁹³ Another danger to seed and seed sovereignty is genetic contamination of seed. India has lost its cotton seeds owing to contamination from Bt. Cotton.694 contamination, Seed Corporations sue farmers with patent infringement cases, as happened in the infamous Canadian case of Monsato Canada Inc and Monsato Company v Percy Schmeiser and Schmeiser Enterprises⁶⁹⁵. Also, the penalties

indiabudget.nic.in,

⁶⁹²Ministry of Finance, 'Economic Survey, 2005-06' (2006)

available at http://indiabudget.nic.in/es2005-06/esmain.htm (last

accessed 10 April 2014).

⁶⁹³Monsanto Co. v. McFarling 302 F. 3d 1291 (Fed. Cir.2002.) (the case illustrates how (under US law) a farmer that saves a patented genetic sequence faces infringement with severe fine impositions)

⁶⁹⁴Vandana Shiva, 'The Seed Emergency: Threat to Food and democracy' (2013)aljazeera.com, available http://www.aljazeera.com/indepth/opinion/2012/02/20122 4152439941847.html (last accessed 12 April 2014) (Also, Canada has lost its canola seed because of contamination from Roundup Ready canola. Mexico has lost its cotton because of contamination from Bt. Cotton).

⁶⁹⁵²⁰⁰¹ FCT 256 (a Canadian Farmer Percy Schmeiser whose field was contaminated by genetically engineered canola has been asked to pay Monsanto around \$10,000 for licensing fees and up to \$75,000 in profits from his 1998 crop).

provided for patent infringement by the farmers, largely uneducated and unaware in the case of India, are very severe and harsh.⁶⁹⁶ The already indebted farmer could be forced to pay lakhs of rupees for infringement and face imprisonment.

Thus, if these laws and practices are transposed to India it will be a disaster for the poor farmers who primarily rely on farm saved seed and enter the market to purchase seeds once in five years and rely on the traditional age old practices of farming.

2.4. THE ENCOURAGEMENT OF CLARITY IN INDIAN PATENT LAW

India's patent law needs to be clear and reliable in order to effectuate the purpose of advancing innovation. The 2005 Amendment and Section 3(d)⁶⁹⁷ introduced considerable uncertainty into Indian patent law. Although Section 3(d)'s limitation on patenting derivatives of known substances is not without parallels in other patent regimes, the problem stems from uncertainty about how the India patent office and judiciary will interpret 'enhanced efficacy', as the 2005 Amendment⁶⁹⁸ does not define 'efficacy'.

Some clarity was obtained on this issue in the case of Novartis, this however is the first time Section 3(d) has been used on plant patents, and its implications are far reaching.

⁶⁹⁶D.S Wright, 'Monsato loses case on Climate Resilient Crop' (2013) firedoglake.com, available at http://news.firedoglake.com/2013/07/10/monsanto-loses-patent-case-on-climate-resilent-crops/ (last accessed 12 April 2014) (according to a report by the Washington based Center for Food Safety, Monsanto had received over \$23.5 million from patent infringement lawsuits against farmers and farm business by end of 2012.).

⁶⁹⁷Patents Act, Supra note 11

⁶⁹⁸The Patents (Amendment) Act, 2005

Specifically, the Board stated that the 'Mere use of [an] admittedly known substance is not permitted under Section 3(d).'699 The Board also stated that Monsanto's evidence of 'surprising' results did not change the outcome because the invention would 'still be a new use of [a] known [substance] even if it produces better results.'700'The judgement may set precedent for debates relating to GM crops, and the Biotechnology Regulatory Authority of India Bill'701 which is supposed to set rules for regulating such corps.

3. CONCLUSION

A successful intellectual property regime must strike a balance between creating incentives for innovation and protecting the national interest. The *Monsato case* is just a piece in a much larger puzzle. A patent system is meant to provide incentives for technical progress, and India may benefit from stronger patent protection. More and more domestic companies and multinationals are engaging in original research and such unfavourable decisions might discourage Research and Development and hamper innovation in the long run. India has demonstrated great commitment to the welfare of its people by maintaining an ardent stand on matters of Intellectual Property Rights by not succumbing to the pressures of mammoth multinationals and powerful foreign governments. The *Monsato Case* is to food security what the Novartis Case⁷⁰² was to public health.

In totality, in light of the above discussion, the observations made by the Appellate Tribunal in the instant case should be lauded. The decision is an attempt to prevent the practice of

⁶⁹⁹Monsato Case, Supra note 4.

⁷⁰⁰Ibid.

⁷⁰¹The Biotechnology Regulatory Authority Of India (BRAI) Bill, 2013

⁷⁰² Novartis A.G. v. Union of India (2007) 4 MLJ 1153

abuse of patents through biopiracy⁷⁰³, thus preventing monopolistic practices in the market. The tribunal has also laid down a very strict and high standard for the qualification of a product as an "invention", thereby emphatically upholding the principle of social welfare.

⁷⁰³Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge*, UBC Press, Chicago,2005 (Biopiracy is defined as The practice of commercially exploiting naturally occurring biochemical or genetic material, especially by obtaining patents that restrict its future use, while failing to pay fair compensation to the community from which it originates).