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

Ghayur Alam\*

### **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(j) 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 agro-biotechnology. 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 biological processes from patent eligible subject matter promotes public policy and farmers' interests.

**Keywords:** Bt. cotton, patent eligible subject matter, nucleic acid sequence, plant, public policy, revocation of patent, seed, TRIPS.

### 1. INTRODUCTION

A substantial question of patent law (hereinafter, 'question') of great significance has arisen in India and is awaiting an answer from Indian courts. The question is whether an invented Nucleic Acid Sequence (NAS) after being inserted into a seed or plant becomes part of the seed or the plant? Specifically, the question is whether the patent granted¹ by the Indian Patent Office to Monsanto Technology LLC (Monsanto) on transgenic variety of cottonseeds, containing invented Bt. trait is valid or not? If the answer is in affirmative, claimed invention is not patentable under the (Indian) Patents Act 1970² (Patents Act) which excludes from patentability, *inter alia*, plants, seeds, or any part thereof. If the answer is in negative, claimed invention is patentable since Sections 3 and 4 of the Patents Act do not expressly exclude an invented NAS from patentability.³

\* Ghayur Alam (India). He is Professor in Business Laws and IPR Chair at the National Law Institute University, Bhopal, India (NLIU). At NLIU, he is the Dean, Under-Graduate Studies, Chairperson of Centre for Business and Commercial Laws and Chairperson of Centre of Science, Technology and Law. He received his primary education in Bombay (India). Completed his secondary and higher secondary education in Azamgarh (India). He earned his Degrees of B Com (Hons), LLB and LLM from the Aligarh Muslim University, Aligarh (India). He earned his doctoral degree in law from NLIU. He has been designing and teaching several UG and PG courses including Common Law Method, Intellectual Property Law, Patent Law, Copyright Law, Law of Industrial Designs, and Traditional Knowledge and IP Law. Three candidates have successfully completed, two candidates have submitted their doctoral dissertations on different topics of IP Law. Forty students (35 on various topics of IP Law and 5 on other topics of law) have done their LLM Dissertations under his guidance. Ten students of BALLB (Hons) have completed their Dissertations under his guidance. He has a number of publications to his credit in the form of articles, books handbooks. Email: ghayuralam@nliu.ac.in; website: <www.nliu.ac.in>

<sup>&</sup>lt;sup>1</sup> Patent Number: 214436. Title of Invention: Methods for Transforming Plants to Express Bacillus Thuringiensis Delta-Endotoxins. PCT International Filing Date and Date of Patent: 4 November 1999. Life of patent has begun on 4 November 1999, because PCT International Filing Date as per the provisions of *Explanation* to s. 53 (1) the Patents Act, 1970 (India) is the date of filing in India. Patent has expired on 4 November 2019; <a href="http://ipindiaservices.gov.in/PatentSearch/PatentSearch//eRegist-rationReport">http://ipindiaservices.gov.in/PatentSearch/PatentSearch//eRegist-rationReport</a> accessed 11 December 2019.

<sup>&</sup>lt;sup>2</sup> The Patents Act 39 of 1970 (India) [hereinafter Patents Act], s 3 (j) inserted by Act 38 of 2002, s 4 (with effect from 20 May 2003 provides, '[P]lants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.'

<sup>&</sup>lt;sup>3</sup> Patents Act (n 2) s 3 provides a long list of non-patentable subject matter and s. 4 of the Patents Act excludes inventions relating to atomic energy from patentability. As per the scheme of the Patents Act, whatever is not excluded by the provisions of s 3 and s 4 of the Act is included in the category of patentable subject matter. Plants,

The problem is that the question of patentability of the claimed invention has moved like a pendulum<sup>4</sup> from one court to another but in vain. *Prima facie* judicial answer by the court of first instance<sup>5</sup> 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<sup>6</sup> 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<sup>7</sup> for infringement of patent<sup>8</sup> 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,<sup>9</sup>

Indian companies filed written statement and on 2 May 2016<sup>10</sup> they also filed counterclaim for revocation of Monsanto's patent. In counterclaim it was asserted that said invention is not patentable under Section3 (j) of the Patents Act. On 15 February 2017<sup>11</sup> a Single Judge issued notice to Monsanto to file appropriate reply. Monsanto's reply was awaited. 12 In absence of a reply, the court of first instance could not decide the question without trial. However, the Single Judge held the patent prima facie valid and adjudicated the application for grant of interim reliefs and issued ad interim orders, inter alia, directing Indian companies not to use the patented invention of Monsanto without payment of fees and trait value. Both Monsanto and Indian companies aggrieved by the decision of Single Judge filed appeals before Division Bench of Delhi High Court in Nuziveedu Seeds Ltd v Monsanto Technology LLC.13 The Division Bench of the Delhi High Court dismissed the appeal of Monsanto and admitted the appeal of Indian companies in part. Division Bench, inter alia, declared the patent invalid. Monsanto, aggrieved by the decision of Division Bench filed an appeal by way of Special Leave Petition 14 in the Supreme Court. On 8 January 2019 in

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

<sup>4</sup> 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. The apex court is the Supreme Court of India. A patent case is filed under s 104 of the Patents Act in the District Court or High Court. If a counter-claim is filed under s. 104 of the Patents Act for revocation of patent, the case is transferred to the High Court. In the High Court, Single Judge is the court of first instance. Decision of the Single Judge is appealable as a matter of right before a Division Bench comprising of two judges of the same High Court. Decision of the Division Bench is not appealable as a matter of right to any court including the Supreme Court of India. However, an appeal by leave of the Division Bench of the High Court may be filed before the Supreme Court but if the High Court refuses to grant leave to appeal then in the alternative an appeal by way of Special Leave Petition (SLP) may be filed before the Supreme Court under art 136 of the Constitution of India. The Supreme Court is not bound to admit the SLP. If the Supreme Court admits the SLP, the same is treated as appeal before the Supreme Court. The instant case commenced before the Single

Judge, went in appeal to the Division Bench, reached the Supreme Court by way of SLP, Supreme Court remanded the case to the Single Judge – back to square one.

- <sup>5</sup> Monsanto Technology LLC v Nuziveedu Seeds Ltd, 2017 (70) PTC 145 [Del] [hereinafter Monsanto v Nuziveedu (Del HC)].
- Nuziveedu Seeds Ltd v. Monsanto Technology LLC 2018 (74) PTC
   [Del] [hereinafter Nuziveedu v Monsantov (Del HC)].
- <sup>7</sup> Monsanto v Nuziveedu (Del HC) (n 5).
- <sup>8</sup> After a patent infringement case is filed, the defendant is required to file written statement and she may also file, at her option, counter-claim for revocation of the patent under s. 104 read with s. 64 of the Patents Act. Trial in the case cannot commence until the written statement has been filed. If written statement has also been filed, trial cannot commence until reply to the written statement has been filed. In India the terms 'written statement' and 'reply' have different connotations in civil proceedings.
- <sup>9</sup> Monsanto v Nuziveedu (Del HC) (n 5) 147, para 4.
- <sup>10</sup> ibid 148.
- 11 ibid.
- 12 ibid.
- <sup>13</sup> Nuziveedu v Monsantov (Del HC) (n 6).

<sup>&</sup>lt;sup>14</sup> See n 4.

Monsanto Technology LLC v Nuziveedu Seeds Ltd, 15 the Supreme Court did four things. One, it set aside the order of Division Bench. Two, it restored the ad interim injunction order of Single Judge. Three, it did not decide substantial question of patent law on technical grounds. Four, it remanded the suit for trial to a Single Judge and not a Division Bench without expressing any opinion as to the validity or otherwise of the patent. In a hurry, however, some leading newspapers 16 reported that the Supreme Court upheld the validity of Monsanto's patent on Bt. Cotton seeds. Legally speaking, Monsanto's patent was valid and lived its whole life until 4 November 2019 not because of the decision of the Supreme Court but because of the absence thereof. While remanding the case, the Supreme Court observed that, '[...] 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 suit.'17 Since 8 January 2019, the

date on which the case was remanded to the Single Judge, no visible progress has been made in the case. The website of the Delhi High Court 18 shows that some notices have been issued to parties and replies have been filed but hearing has not commenced. Hence, there is no judicial answer on the patentability of the claimed invention. Therefore, in the absence of judicial answer, different high courts may render inconsistent and conflicting decisions in cases involving invented NAS. High courts in some States of India may follow the approach of Single Judge or that of Division Bench, though not strictly bound by either. 19 Only outcome of three aforesaid judicial decisions has been that there is no authoritative and final answer, though there is prima facie answer to substantial question of law. More than three years have elapsed since the birth of question and a lot of ink has been spilled over it, i.e., 183 pages have been written by the courts in aggregate. 20 Interestingly enough, the patent has

<sup>&</sup>lt;sup>15</sup> Monsanto Technology LLC v Nuziveedu Seeds Ltd [2019] 3 SCC 381 [hereinafter *Monsanto v Nuziveedu (SC)*].

 $<sup>^{\</sup>rm 16}$  Aashish Aryan, 'SC overturns Delhi HC Ruling, Grants Bt Cotton Patent to Monsanto' Business Standard (India, 8 January 2019) <a href="https://www.business-standard.com/article/markets/sc-">https://www.business-standard.com/article/markets/sc-</a> overturns-delhi-hc-ruling-grants-bt-cotton-patent-to-monsanto-119010801126\_1.html> accessed 8 January 2019; Madhvi Sally, 'Delhi High Court dismisses Monsanto Plea to Enforce BT Cotton Seed Patent' Economic Times (India, 8 January 2019) <a href="https://economictimes.indiatimes.com/news/economy/agricultur">https://economictimes.indiatimes.com/news/economy/agricultur</a> e/delhi-high-court-dismisses-monsanto-plea-to-enforce-bt-cottonseed-patent/articleshow/63713854.cms?from=mdr> accessed 8 January 2019; Upmanyu Trivedi, 'GM Cotton: Monsanto Wins Patent War in India as SC Rules in its Favour' Business Standard (India, 8 January 2019) <a href="https://www.business-">https://www.business-</a> standard.com/article/companies/gm-cotton-monsanto-winspatent-war-in-india-as-sc-rules-in-its-favour-119010800376\_1.html>accessed 8 January 2019; Krishnadas Rajagopal, 'Supreme Court backs Monsanto on GM Cotton Patents' The Hindu (India, 8 January 2019) <a href="https://www.thehindu.com/news/national/supreme-court-backs-">https://www.thehindu.com/news/national/supreme-court-backs-</a>

<sup>&</sup>lt;https://www.thehindu.com/news/national/supreme-court-backs-monsanto-on-gm-cotton-payments/article25940071.ece>
accessed 8 January 2019; 'Monsanto patent victory on GM cotton seeds can aggravate agrarian crisis' Hindustan Times (India, 8 January 2019) <a href="https://www.hindustantimes.com/india-news/monsanto-patent-victory-on-gm-cotton-seeds-can-aggravate-agrarian-crisis/story-045Xf1MejmdHBBjNJMpSzJ.html">https://www.hindustantimes.com/india-news/monsanto-patent-victory-on-gm-cotton-seeds-can-aggravate-agrarian-crisis/story-045Xf1MejmdHBBjNJMpSzJ.html</a>

accessed 8 January 2019; Kaunain Sheriff, 'The Bt. cotton dispute in Delhi HC and SC: What the latest order means' *The Indian Express* (India, 8 January 2019)

<sup>&</sup>lt;a href="https://indianexpress.com/article/explained/the-bt-cotton-dispute-in-delhi-hc-and-sc-what-the-latest-order-means-5547531/">https://indianexpress.com/article/explained/the-bt-cotton-dispute-in-delhi-hc-and-sc-what-the-latest-order-means-5547531/</a> accessed 8 January 2019; 'India's top court allows Monsanto to claim patents on GM cotton-company source'

\*\*Reuters\*\* (New Delhi, 8 January 2019)

<sup>&</sup>lt;https://www.reuters.com/article/india-monsanto/indias-top-court-allows-monsanto-to-claim-patents-on-gm-cotton-company-source-idUSD8N1SS00K> accessed 8 January 2019.

<sup>&</sup>lt;sup>17</sup> Monsanto v Nuziveedu (SC) (n 15).

<sup>&</sup>lt;sup>18</sup> Last notice has been issued on 1 November and case is listed on 16 December 2019

<sup>&</sup>lt;a href="http://delhihighcourt.nic.in/dhcqrydisp\_o.asp?pn=268563&yr=20">http://delhihighcourt.nic.in/dhcqrydisp\_o.asp.pn=268563&yr=20">http://delhihighcourt.nic.in/dhcqrydisp\_o.asp.pn=268563&yr=20">http://delhihighcourt

<sup>&</sup>lt;sup>19</sup> The decisions of the Supreme Court of India are binding on all the courts within the territory of India by virtue of art 141 of the Constitution of India. However, the decisions of the High Courts are binding only on smaller benches of the same of the High Court and subordinate courts within the territorial jurisdiction of the respective High Court by virtue of the arts 226 and 227 of the Constitution of India. Decision of one high court is not binding on any other High Court, though a high court may follow the decision of another High Court at its discretion.

<sup>&</sup>lt;sup>20</sup> Single Judge wrote the Order in 96 pages, Division Bench wrote 60 pages and the Supreme Court wrote 27 pages.

already expired on 4 November 2019.<sup>21</sup> Hope for an answer, however, is not lost. Adjournment sought by Monsanto has been refused by court and case is listed on 16 December 2019.<sup>22</sup> Commencement of hearing, completion of trial and pronouncement of judgment are going to take time. In all probability, decision of Single Judge will go in appeal to Division Bench, which may either affirm or reverse the Single Judge's decision. In all likelihood, the decision of the Division Bench will go in appeal to the Supreme Court, which may either affirm or reverse the Division Bench. As of now we are at sea! Hence, there is a need to evaluate the strength and weakness of the *prima facie* answer given by the Single Judge and the answer of the Division Bench. It is also imperative to evaluate the approach of the Supreme Court.

This paper, therefore, seeks to address the said question in light of decisions of the Single Judge, <sup>23</sup> Division Bench, <sup>24</sup> and the Supreme Court <sup>25</sup> and tries to answer a related policy question. This paper proceeds in three stages. It begins by summarizing the facts of the case. Then it moves on to analyze and evaluate the responses of the three Indian courts to substantial question of patent law. In next stage, an attempt has been made to answer the question: whether the statutory exclusion, of plant, seeds or any part thereof and essentially biological processes, from patent eligible subject matter is in furtherance of public policy and farmers' interest. Finally, the paper concludes.

Monsanto obtained a patent on 24 process claims and 3 products claims on transgenic variety of cotton exhibiting Bt. trait<sup>26</sup> and entered into sub-license agreement with Indian companies.<sup>27</sup> Under the agreement, Indian companies received 50 grams (50 seeds), at Indian Rupees (INR) 1,00,000/- per seed of transgenic Bt. cottonseeds containing patented NAS (invented Bacillus thuringiensis or Bt. cotton seeds) from Monsanto, in consideration for an upfront payment of INR 50,00,000/- subject to payment of trait value and other terms and conditions of the agreement. Indian companies were entitled to develop genetically modified (GM) hybrid cotton seeds, subject to terms and conditions of license, to commercially exploit the same as under:

- i. Indian companies sowed seeds of their proprietary cotton varieties alongside the transgenic Bt. cotton seed. Transgenic Bt. cotton seeds and the seeds of Indian companies yielded different plants, which were crosspollinated at the flowering stage.
- ii. Cotton fruits from Indian companies' cotton varieties had cotton seeds which were carrying the Bt. trait.
- Indian companies used Bt. cotton varieties for developing the proprietary hybrid (Bt. cotton hybrids).
- iv. Indian companies conducted extensive agronomic evaluation trials of newly developed Bt. Cotton hybrids to ascertain their utility to farmers.

<sup>23</sup> Monsanto v Nuziveedu (Del HC) (n 5).

applicant deleted claims 1-40 and 57-59. Claims 41-43 were amended and replaced with claims 1-28, claims 44-47 were amended and replaced with claims 29-31, claims 48-56 were amended and replaced with claims 32-36. In other words, out of 59 original claims 43 claims were deleted and 16 claims were modified as 36 claims. As to the amended 36 claims, Second Examination Report (SER) dated 16 October 2006 declared claims 4, 26-28 and 32-36 as not allowable under Section 3(j). Accordingly, the applicant deleted these claims. In other words, out of 36 amended claims 9 claims were rejected under Section 3(j) and 27 claims were allowed; <a href="http://ipindiaservices.gov.in/PatentSearch/PatentSearch/ViewDocuments">http://ipindiaservices.gov.in/PatentSearch/PatentSearch/ViewDocuments</a> accessed 11 December 2019.

<sup>2.</sup> SUBSTANTIAL QUESTION OF PATENT LAW: RESPONSES OF INDIAN COURTS

<sup>&</sup>lt;sup>21</sup> Patent Number: 214436 (n 1) Date of Expiry: 4 November 2019 <a href="http://ipindiaservices.gov.in/PatentSearch/PatentSearch//eRegist">http://ipindiaservices.gov.in/PatentSearch//eRegist</a> rationReport> accessed 11 December 2019.

<sup>&</sup>lt;sup>22</sup> ibid.

<sup>&</sup>lt;sup>24</sup> Nuziveedu v Monsanto (Del HC) (n 6).

<sup>&</sup>lt;sup>25</sup> Monsanto v Nuziveedu (SC) (n 15).

<sup>&</sup>lt;sup>26</sup> Originally there were 59 claims. The First Examination Report (FER) dated 30 March 2006 *inter-alia* raised the following objections: 'Claims 1-40, 48-56, 57, 58 not allowable under Section 3(j); Claims 41-43, 59 not allowable under Section 3(b); Claim 44 is defined with respect to end effect, cannot be allowed, needs to be reworded; Claim 57, 58, 59 does not sufficiently definitive in the absence of explicit statement of invention.' In response to FER, the

<sup>&</sup>lt;sup>27</sup> See n 21.

- v. Indian companies obtained approval of Genetic Engineering Approval Committee (GEAC) constituted under Rules<sup>28</sup> 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. Sub-license 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 notifications<sup>29</sup> 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 as 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.

Disputes 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 action against Indian companies. In response, Indian companies contested the application and suit and filed counterclaims for revocation of patent, challenging the validity of three product claims.

- 25. A nucleic acid sequence comprising a promoter operably linked to a first polynucleotide sequence encoding a plastid transit peptide, which is linked in frame to a second polynucleotide sequence encoding a Cry2Ab Bacillus thuringiensis 8-endotoxin protein, wherein expression of said nucleic acid sequence by a plant cell produces a fusion protein comprising an amino-terminal plastid transit peptide covalently linked to said 5-endotoxin protein, and wherein said fusion protein functions to localize said 5-endotoxin protein to a subcellular organelle or compartment.
- 26. The nucleic acid sequence of claim 25, wherein said second polynucleotide sequence encodes a Cry2Ab Bacillus thuringiensis 5-endotoxin protein selected from the group of sequences consisting of SEQ ID NO: 2 and SEQ ID NO: 18.
- 27. The nucleic acid sequence of claim 26, wherein said second polynucleotide sequence is selected from the group of sequences consisting of SEQ ID NO: 1 and SEQ ID NO:  $17^{-31}$

Claim 25 is an independent claim. Claim 26 is dependent on claim 25. Claim 27 is dependent on claim 26. Since reply to counterclaim was awaited, the Single Judge could not decide

Title of patent specification is 'Methods for Transforming Plants to Express Bacillus Thuringiensis Delta-Endotoxins.' <sup>30</sup> It is noticeable that title of specification is limited to Methods and does not mention nucleic acid sequence (NAS). It is noticeable that the title of specification does not expressly cover products or NAS as such, it only mentions methods or means for transforming plants. However, claims 25-27 are about invented NAS. If Monsanto was coming with clean hands, why it did not mention NAS as such in the title of specification and why the Indian Patent Office did not ask Monsanto to amend the title of specification in view of claims 25-27. These are some open questions. We hope that the court of first instance will ask these questions to the counsels of Monsanto. Controversy primarily relates to these three product claims. Product claims 25 to 27, read as under:

<sup>&</sup>lt;sup>28</sup> The Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells Rules 1989 (India) framed under the Environment (Protection) Act 29 of 1986 (India), ss 6, 8, and 25.

<sup>&</sup>lt;sup>29</sup> Monsanto v Nuziveedu (Del HC) (n 5) 195-197, paras 128-132.

<sup>&</sup>lt;sup>30</sup> See n 21.

<sup>&</sup>lt;sup>31</sup> See n 21.

validity or otherwise of claims 25–27 without trial. Single Judge decided the application for grant of *ad interim* injunction.

The first reasoning of the Single Judge appeals to a sense of justice. In his opinion, validity of the patent can only be decided after hearing on merits and formal proof, particularly expert opinion which in complicated matters like patents may be crucial.<sup>32</sup> 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 5<sup>33</sup> 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.<sup>34</sup>

The above reasoning hangs in the air and suffers from a 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 the 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. 35 31 December 2004 was the last date for 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

<sup>32</sup> Monsanto v Nuziveedu (Del HC) (n 5) 185-186, para 97. The Supreme Court affirmed the first reasoning of the Single Judge; Monsanto v Nuziveedu (SC) (n 15) 385, para 7.

<sup>33</sup> Patents Act (n 2), s 5 reads:

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, semi-conductors 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.

<sup>&</sup>lt;sup>34</sup> Monsanto v Nuziveedu (Del HC) (n 5) 187, para 103.

<sup>&</sup>lt;sup>35</sup> 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 patent application. Even if the repeal of Section 5 has lifted the bar on some products, it does not follow that the effect of the repeal had a killing effect on living provisions of Section 3(j) of the Patents Act.

Third reasoning of Single Judge was as under:

Section 3(j) of the Patents Act cannot be interpreted without taking into account the effect of changes to Section 2(1)(j)<sup>36</sup> and repeal of Section 5 so as to deprive the patentee of due reward of human skill and ingenuity resulting in human intervention and innovations over and above what occurs in nature ... claim nos. 25 to 27 under the suit patent involve laboratory processes and are not naturally occurring substances which only are to be excluded from the purview of what is an invention by virtue of the provision contained in Section 3(j). These claims being products or processes of biotechnology, thus seem to have been rightly entertained by the Indian Patent office.<sup>37</sup>

This observation of the Single Judge as to conjoint reading of Sections 3(j), 2(1)(j) and 5 is valid. However, the way he applied conjoint reading is *non-sequitur*. Section 2(1)(j) defines 'invention' and Section 3(j) excludes seeds and plants or any part thereof from patentability. On the one hand, Section 2(1)(j) tells us what constitutes an invention and Section 3(j) tells us what does not constitute an invention. On the other hand, Section 5 had provided that product patent for certain chemicals including pharmaceuticals cannot be granted. But the Single Judge without taking the trouble of

interpreting the provisions of Sections 2(1)(j) and 3(j) and without explaining their interplay with Section 5 jumped to the conclusion that only naturally occurring plants and seeds are excluded by Section 3 (j) and products or processes of biotechnology are eligible for the grant of a patent. Section 3(i) nowhere mentions that only naturally occurring seeds and plants are excluded. The Judge was reading what is not written in Section 3 (j). Such a reading of statutory provisions and repeal goes against the basic tenets of statutory construction and renders living statutory provisions redundant and otiose. One of the fundamental principles of statutory construction is presumption against statutory surplusage, i.e. no word of statute is without a purpose, unnecessary, redundant or otiose. At the time of repeal of Section 5 in 2005, Section3 (j) was present in the Patents Act. Had the Parliament of India intended to allow patenting of seeds and plants or any part thereof, it would have also repealed Section 3(j) along with Section 5. But the Parliament of India did not do so. It is trite that repeal of one section of a statute does not have repealing effect on the other sections of the statute unless expressly provided. Section 3(j) is alive and kicking. The repeal of Section 5 does not have any effect whatsoever on the provisions of Section 3(j). If the reasoning of the Single Judge is accounted for, then inventions relating to atomic energy<sup>38</sup> must also be patented despite an explicit statutory prohibition. This reasoning of the Single Judge therefore, cannot withstand the scrutiny of the statutory provisions and legislative intent.

The fourth reasoning of the Single Judge was as under:

Noticeably, the word 'variety' <sup>39</sup> relates to a 'plant grouping' which is not further clarified [...], *prima facie*, 'plant

<sup>&</sup>lt;sup>36</sup> Patents Act (n 2), s 2(1)(j) defines 'invention' to mean 'a new product or process involving an inventive step and capable of industrial application.'

 $<sup>^{\</sup>rm 37}$  Monsanto v Nuziveedu (Del HC) (n 5) 188, para 105.

<sup>&</sup>lt;sup>38</sup> Patents Act (n 2) s 4 provides, 'No patent shall be granted in respect of an invention relating to atomic energy falling within subsection (1) of Section 20 of the Atomic Energy Act 33 of 1962 (India).

<sup>39</sup> Protection of Plant Varieties and Farmers' Rights Act 53 of 2001, s
2 (za) defines a 'variety' to mean 'a plant grouping except micro-

organism within a single botanical taxon of the lowest known rank, which can be-

i.defined by the expression of the characteristics resulting from a given genotype of that plant grouping;

ii.distinguishing from any other plant grouping by expression of at least one of the said characteristics; and

iii.considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation and includes propagating material of such variety, extant variety,

grouping' cannot be equated with a single plant. [...] explanatory notes under the 1991 Act of International Convention for the Protection of New Varieties of Plants (UPOV Convention, 1991), [...] wherein the definition of the expression 'variety' definition whereof under UOPV Convention is *pari materia* identical to the one given in Section 2 (ze) of the (Indian) Protection of Plant Varieties and Farmers' Rights Act 2001 (hereinafter, Plant Act), the para 5 of the said explanatory note being more germane to the issue at hand reading as under:

[5. The definition that a variety means a 'plant grouping' clarifies that the following, for example, do not correspond to the definition of a variety:

A single plant; (however, an existing variety may be represented by a single plant or part(s) of a plant, provided that such a plant or part(s) of the plant could be used to propagate the variety);

A trait (e.g. diseased resistance, flower color);

A chemical or other substance (e.g. oil, DNA);

A plant breeding technology (e.g. tissue culture).

The above explanation, particularly the clarification, highlights that the diseased resistant trait or a chemical or other substance like DNA are not meant to be covered within the meaning of the expression 'variety', the development of which is protected by the Plant Varieties Act.

Thus, the invention which is the subject matter of suit patent is not same as development of a variety within the meaning of Plant Varieties  $Act [...]^{40}$ 

This observation of the Single Judge suffers from following infirmities. First, India is not a Member of UPOV and has enacted a law for protection of plant in compliance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>41</sup> So, UPOV and the (Indian) Plant Act cannot be described as statute *pari materia*. Second, the Single Judge ignored the first example, given in

the UPOV explanation, that if a single plant can be used to propagate a variety, it is a variety. In the present case, the patented plant was used to propagate Bt. cotton variety of the plant. Third, 'plant grouping' cannot be equated with 'single plant'. Even if it is a valid proposition, this logic cannot be extended to facts of present case. This case is about cultivation of a Bt. cotton crop and not about cultivation of a single plant of Bt. cotton. The Bt. cotton variety of plant is nonetheless a variety. No farmer cultivates only a single plant. If that be the case, the invention of Monsanto will be useless for agriculture, propagation and cultivation. If it was a single plant and not a variety, why did Monsanto enter into an agreement with the Indian companies? It is not disputed that Indian companies were selling cotton seeds containing Bt. trait to Indian farmers who were cultivating and propagating Bt. cotton variety in their farms. Reliance on the explanatory note of UPOV by the Single Judge was selective as it ignored first part of the explanation and relied on the other irrelevant parts thereof.

The fifth reasoning of the Single Judge was, '[T]he argument of denial of 'use' of the plaintiffs' patented technology does not come across as valid in the face of admission that the cotton varieties or hybrids developed by them do exhibit the Bt. trait.'42 It is not in dispute that cotton varieties exhibit the Bt. trait. But it is equally true that Indian companies have not used NAS or patented technology of Monsanto as such. Further, the fourth reasoning refutes the third reasoning. In the third reasoning, he holds that plant grouping cannot be equated with single plant. Whereas in the fourth reasoning, he holds that cotton varieties do exhibit the Bt. trait. Therefore, either plants expressing Bt. trait are varieties or they are not varieties. For the purposes of 'use', according to the Single Judge, the invention of Monsanto is a plant variety. However, for the purposes of registration under the (Indian) Plant Act they are not varieties. This is a classic example of blowing hot and cold simultaneously.

transgenic variety, farmers' variety and essentially derived variety.'

<sup>&</sup>lt;sup>40</sup> Monsanto v Nuziveedu (Del HC) (n 5) 188-189, paras 107-109.

<sup>&</sup>lt;sup>41</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

<sup>[</sup>hereinafter TRIPS Agreement]

<sup>&</sup>lt;a href="https://www.wto.org/english/docs\_e/legal\_e/27-trips.pdf">https://www.wto.org/english/docs\_e/legal\_e/27-trips.pdf</a> accessed 12 December 2019.

<sup>&</sup>lt;sup>42</sup> Monsanto v Nuziveedu (Del HC) (n 5) 189, para 109.

On the following points, both the Single Judge and the Division Bench were on the same page:

[...] Cotton Seeds Price (Control) Order, 2015<sup>43</sup> promulgated by the Central Government ... provide not only the 'law' but also reflect the 'public policy' of the State and, thus, the 'consideration' of the agreement between the parties in order to be lawful, within the meaning of Section 23 of the Contract Act<sup>44</sup>must be in accord with such law and public policy and not be opposed or in derogation thereof.

[P]laintiffs were duty bound to consider the request of the Defendants as made by the communications beginning July 2015, for modification of the terms as to the rate of trait fee payable. [...]

Since the plaintiffs did not adhere to their obligation under the contract the demand of payment under the contract terms being not lawful, it apparently being higher than the trait fee permitted by the law in force, the Defendants could not have been found to be in default or to have breached their obligations ... As a sequitur, the termination of the sub-license agreements by communications ... appears *prima facie* to be illegal and arbitrary [...].

[S]o long as the sub-license agreements continue to be in force, or do not come to an end, by efflux of time, or upon being lawfully terminated, the Defendants cannot be injuncted against the use of the suit patent or the trademarks, such right of the Defendants to continued use of suit patent or trademarks not being unconditional.]

The Single Judge further observed:

[Parties shall remain bound by their respective contractual obligations and shall be entitled to all the contractual rights except as to the trait value payable thereunder.

Defendants shall be liable to tender, and pay, the trait fee to the plaintiffs, for the use of the suit patent and trademarks, at such rates as are in accord with the prevalent local laws, as in force or revised from time to time and upon being suitably notified, be obliged to execute necessary documents so as to render the contract(s) in accord with the 'GM Technology (GM trait) Licensing Agreement' as prescribed under the 'Licensing and Formats for GM Technology Agreement Guidelines, 2016', notified by the Government of India.]<sup>45</sup>

Both Monsanto and the Indian companies filed appeals against the Order of the Single Judge before the Division Bench of the Delhi High Court. Monsanto's appeal regarding continuance of the sub-license agreement was dismissed by the Division Bench. The appeal of Indian companies against the Order of Single Judge holding the patent prima facie valid was admitted by the Division Bench. The Division Bench declared Monsanto's patent invalid and revoked the same. Surprisingly, the Division Bench noted that parties had agreed that main issue concerning the legality of patent can be finally decided on the basis of material on record (28 volumes of documents).46 It must be reiterated that parties did not consent for a summary judgment before the Single Judge. The observation of Division Bench that the parties had agreed for a final decision was found to be baseless by the Supreme Court which set aside the decision of the Division Bench.

The most important issue in the opinion of the Division Bench was: whether the process described in Monsanto's nucleotide sequence in its claims 25-27, which were granted patent, resulting in isolation of the Cry2Ab gene, its synthetization and insertion into plant cell, resulting in donor transgenic seeds and plants, fall within the exceptions covered under Section 3(j) of the Patents Act.<sup>47</sup> Division Bench gave the

<sup>&</sup>lt;sup>43</sup> Monsanto v Nuziveedu (Del HC) (n 5) 195, para 128.

<sup>&</sup>lt;sup>44</sup> The Indian Contract Act 1872, s 23 reads as under:

The consideration or object of an agreement is lawful, unless—
it is forbidden by law: or

is of such a nature that, if permitted, it would defeat the provisions of any law; or is fraudulent; or

involves or implies, injury to the person or property of another; or

the Court regards it as immoral, or opposed to public policy.

In each of these cases, the consideration or object of an agreement is said to be unlawful. Every agreement of which the object or consideration is unlawful is void.

<sup>&</sup>lt;sup>45</sup> Monsanto v Nuziveedu (Del HC) (n 5) 197-198, para 134.

<sup>&</sup>lt;sup>46</sup> Nuziveedu v Monsanto (Del HC) (n 6) 22, para 22.

<sup>&</sup>lt;sup>47</sup> ibid 35, para 59.

answer in affirmative and declared Monsanto's patent invalid.

The first reasoning of the Division Bench was that, '[r]epeal of Section 5<sup>48</sup> 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 Single Judge are diametrically opposite to each other. A moot question concerns the effect of the repealed Section 5 on Section 3(j) of Patents Act. Section 5 did remove the embargo on product patents, but it did not remove the embargo imposed by Section 3(j). Section 5 would not have been repealed, but to bring the provisions of the (Indian) Patents Act in compliance with the provisions of the TRIPS Agreement. On one hand, Article 27.1 of the TRIPS Agreement requires that product and process patents be available in all fields of technology without any discrimination. On the other hand, Article 27.3(b) of the TRIPS Agreement allows Members to protect plants by patents or by an effective sui generis system or by any combination thereof. India could have opted to protect plants by patents or by a combination of patents and an effective sui generis system. Accordingly, India opted for an effective sui generis system and enacted the Protection of Plant Varieties and Farmers' Right Act 2001. The Division Bench also read the effect of the repeal of Section 5 on Section3 (j). However, the approach of the Division Bench was directly and inversely opposite to the approach of the Single Judge. In the opinion of the Division Bench, even if a process or product fulfils all other requirements of patentability but does not meet the threshold requirement of Section 3(j), that product or process is not eligible for patent protection. The Division Bench on this point is clearly correct for three related reasons. One, the first and foremost requirement of patentability in India is that a product or process must pass the threshold requirement of patent eligible subject matter. Plants, seeds or any part thereof are explicitly excluded from patentability by Section 3(j). Two, the effect of the repealed section cannot be known

without reading other provisions of the Patents Act in general and Section3 (j) in particular. Three, the dead provisions of the Act cannot control and limit the scope of living provisions of the Act.

Second reasoning of Division Bench was as under:

As the precise definition of a microorganism has not been enacted by Parliament, the ordinary meaning of that expression, gleaned from dictionaries would apply. The discussion about the subject patent discloses that the nucleic acid sequence which is the invention in question (the Cry2AB gene) has no existence of its own; it is of use, after introgression at a particular place, none else. Even thereafter, the seed material has to undergo further steps of hybridization to suit local conditions. Therefore, these products are not 'microorganisms' and consequently excluded from the exclusion clause in Section3 (j).<sup>50</sup>

It is common knowledge in microbiology that NAS is not a microorganism in and of itself. An invented microorganism is the only patent eligible subject matter under Section 3(j). Since NAS is not a microorganism, it cannot be patented. It is also common knowledge in microbiology that every life form in the ultimate analysis is a chemical. However, the converse is not true, i.e. every chemical entity is not a living entity. The argument that NAS is a microorganism was, therefore, rightly rejected by the Division Bench.

<sup>&</sup>lt;sup>48</sup> See n 33.

<sup>&</sup>lt;sup>49</sup> Nuziveedu v Monsanto (Del HC) (n 6) 29-32, paras 39-48.

<sup>&</sup>lt;sup>50</sup> Nuziveedu v Monsanto (Del HC) (n 6) 43, para 79.

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 Treaty<sup>51</sup> and Section10 (4)<sup>52</sup> of the Patents Act.' Depositing of microorganism is a condition precedent for grant of patent on inventions involving biological material under Section 10(4)<sup>54</sup> 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.<sup>55</sup>

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.' <sup>56</sup> 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

provisions, legislative intent and statutory scheme. There may be a counter argument that through gene editing, the inserted NAS may be separated from the host seed or host plant. Theoretically and technically, it may be possible but it is a practical impossibility to separate NAS from all the plants of which it has become a part by cross-pollination. Hence, the reasoning of the Division Bench is sound.

The sixth reasoning of the Division Bench was, '[t]he plant variety being a transgenic variety containing invented NAS are protectable under the Protection of Plant Varieties and Farmers' Rights Act 2001.'57 A transgenic variety<sup>58</sup> is a variety under the provisions of Indian Plant Act and hence can be registered as a new variety thereunder. This reasoning of the Division Bench is in tune with the legislative intent and provisions of the TRIPS Agreement. This reasoning is also in tune with public policy adopted by Parliament of India through Section 3(j) of the Patents Act and the Plant Act.

The seventh reasoning of the Division Bench was that the 'Protection of Plant Varieties and Farmers' Rights Act 2001<sup>59</sup> has an overriding effect by virtue of Section 92.<sup>60</sup> This observation simply means that what is covered by the (Indian) Plant Act cannot get protection under the (Indian) Patents Act. The Plant Act expressly covers transgenic varieties of plants. The Patents Act otherwise expressly excludes plants. It is trite law that if text of statute is explicit, the text is conclusive. There is a problem neither of ambiguity nor of vagueness either in the provisions of Section 3(j) of the Patents Act or in the provisions of the Plant Act. It appeals to reason and fairness that one must seek protection under the

<sup>&</sup>lt;sup>51</sup> Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, art 7 <a href="https://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/wo">https://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/wo</a> inf 12.pdf> accessed 8 March 2019.

<sup>&</sup>lt;sup>52</sup> Patents Act (n 2), s 10(4). 'Contents of specification. Every complete specification shall-

<sup>(</sup>a) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing [the material to an international depository authority under the Budapest Treaty] and by fulfilling the following conditions, namely [...]'

<sup>&</sup>lt;sup>53</sup> Nuziveedu v Monsanto (Del HC) (n 6) 43-45, paras 80-83.

<sup>&</sup>lt;sup>54</sup> See n 52.

<sup>&</sup>lt;sup>55</sup> Nuziveedu v Monsanto (Del HC) (n 6) 51, para 98; Division Bench also relied on European Patent Convention, art 53(b), rule 26(5) and judicial interpretation of these provisions, para 86-91

<sup>&</sup>lt;sup>56</sup> ibid 51-52, paras 99-100.

<sup>&</sup>lt;sup>57</sup> ibid 53-56, paras 102-105.

<sup>&</sup>lt;sup>58</sup> The Protection of Plant Varieties and Farmers' Rights Act 2001 (India), s 2 (za).

<sup>59</sup> ibid.

<sup>60</sup> Nuziveedu v Monsanto (Del HC) (n 6) 55, para 105.

law, which is offering the protection. It is a curious case for Monsanto to seek refuge under a law that explicitly bars the entry of plants and seeds.

The eighth reasoning of the Division Bench was that '[P]atent protection and plant variety ... are not complimentary, but exclusive, in the case of all processes and products falling under Section 3 (j) of the Patents Act.' This simply means that the field covered by the (Indian) Patents Act and (Indian) Plant Act are clearly demarcated and there is no overlap between the two statutes. If a thing is protectable under the (Indian) Patents Act it cannot be protected under the (Indian) Plant Act, and vice versa. The Division Bench further observed:

The absence of a patent results in the lack of property in the use of CryAb2 and the consequent lack of control by Monsanto about its use by others, like Nuziveedu, who might have acquired it under agreement, lawfully, developed their varieties or breeds and sold it to the farming community. The grant of injunction is rendered untenable in these circumstances.

This is a public interest element that the court cannot be blind to. In the ultimate event of Nuziveedu failing in its counter-claim, the harm that might befall Monsanto during the pendent lite period is compensable, monetarily. In these circumstances, the court is of opinion that pending trial of the suit, the directions of the learned single judge do not call for interference.

The subject patent falls within the exclusion spelt out by Section3 (j) of the Patents Act; the subject patent and the claims covered by it are consequently held to be unpatentable. Nuziveedu's counter-claim is therefore, entitled to succeed and is consequently allowed.

Monsanto's Suit ... to the extent it seeks enforcement of the subject patent, is dismissed. However, the suit can proceed with respect to the claim for damages and other reliefs, in the light of the sub-license termination notices issued.

The learned Single Judge's directions to Monsanto to continue with its obligations under the sub-license agreements, including consequential orders with respect to payment and receipt of trade value, are upheld.

Monsanto can apply for registration under the Protection of Plant Varieties and farmers' Rights Act 2001 (within three months of this judgment); ..., the benefit of its previous patent can be granted to it, for the purposes of the said Act in respect of determination of prior publication provisions and requirements.<sup>62</sup>

The Division Bench revoked Monsanto's patent and also set aside the ad interim injunction granted by the Single Judge. Against the decision of the Division Bench Monsanto, filed an appeal by way of Special Leave Petition under Article 136 of the Constitution of India before the Supreme Court. 63 The arguments of Monsanto may be summarized as: (i) NAS is a microorganism hence not excluded by Section 3(j), hence patent has been validly granted; (ii) NAS being a microorganism, cannot be protected under the Plant Act; and (iii) single plant cannot be variety, hence no protection can be claimed under the Plant Act<sup>64</sup>. On the other hand, the Indian companies argued: (i) NAS being part of the seed or of the plant is excluded by Section 3 (j); (ii) expression of Bt. genes in the seed is an essentially biological process; (iii) that the alleged invention neither involves an inventive step nor is capable of industrial application; (iv) Monsanto has neither deposited biological material with IDA nor obtained approval of the National Biodiversity Authority established under the (Indian) Biological Diversity Act 2002;65 (v) Indian companies have neither sold the NAS in vial nor are they making it in laboratory, hence there cannot be any infringement of patent; and (vi) the new plant variety of Monsanto can be protected under the (Indian) Plant Act. 66

<sup>61</sup> Nuziveedu v Monsanto (Del HC) (n 6) 56, para 107.

<sup>&</sup>lt;sup>62</sup> ibid 60-61, paras 114-116.

<sup>&</sup>lt;sup>63</sup> Monsanto v Nuziveedu (SC) (n 15).

<sup>64</sup> ibid 385-389, paras 7-17.

 $<sup>^{65}</sup>$  The Biological Diversity Act 2002 (Act 18 of 2003) (India).

<sup>&</sup>lt;sup>66</sup> Monsanto v Nuziveedu (SC) (n 15) 385-389, paras 7-17.

In the light of the analysis of the judgments of the 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 counter-claim 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 had exceeded its jurisdiction and their decision without jurisdiction was a nullity in law. The Supreme Court set aside the decision of Division Bench observing,

[T]he issue for existence of patent, patent exclusion under Section 3 (j) was a heavily mixed question of law and facts requiring formal proof and expert evidence to be considered at the hearing of the suit.<sup>68</sup>

Neither a pure question of fact nor a mixed question of law and facts can be decided without trial. The Division Bench for reasons known to itself formed an opinion without any basis that parties had agreed for final decision on validity of patent based on the available record. Such an approach was liable to be set aside. Only experts in the field of agro-biotechnology can testify if an invented NAS after being inserted into a seed or plant becomes part of the seed or plant or not. The Division Bench, however, had chosen to decide the case based on available documents. The Supreme Court noted,

[P]laintiffs have never and could not have consented to summary judgement. The consent was given only to decide whether patent was infringed so as to allow or disallow the relief of interim injunction. <sup>69</sup>

Consent for a limited purpose cannot be consent for all purposes. On this point also, the approach of the Division Bench was erroneous. The Supreme Court further noted,

[W]hether 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.<sup>70</sup>

The Supreme Court was astonished to note,

[P]rocess claims were not in issue, yet the Division Bench held them to be bad.'71 This was an error by the Division Bench on the face of the record. Division Bench exceeded its jurisdiction and invalidated process claims though Indian companies did not challenge their validity in the counter-claim. There does not seem to exist any plausible reason for invalidating the process claims. It is trite that a court cannot decide a question not raised before it.

The Supreme Court expressed serious concern over the approach of Division Bench and observed thus:

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. 72

Had the Division Bench confined itself to examine the validity of the interim order passed by the Single Judge, there would not have been any error of jurisdiction. The Division Bench could have reversed the holding of Single Judge concerning prima facie validity of patent. In such a scenario, the Supreme Court would have had an opportunity to express its opinion on the prima facie validity of the patent and could not have had the choice of remaining silent on the issue. But for the erroneous approach of the Division Bench, the Supreme Court could not do what it could. Had the scenario een

<sup>&</sup>lt;sup>67</sup> ibid 385, para 7.

<sup>&</sup>lt;sup>68</sup> Monsanto v Nuziveedu (SC) (n 15) 385, para 7.

<sup>&</sup>lt;sup>69</sup> ibid 385, para 8.

<sup>&</sup>lt;sup>70</sup> ibid 391, para 22.

<sup>&</sup>lt;sup>71</sup> ibid 385, para 8.

<sup>72</sup> ibid 392, para 24.

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. <sup>73</sup>

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 moot question is: if plant or any part of the plant is not eligible for patent but still the Patent Office has granted a 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? It is trite law that what cannot be done directly cannot be done indirectly.

# 3. EXCLUSION OF PLANTS FROM PATENTABILITY AND PUBLIC POLICY

Now we address the question: whether statutory exclusion of plant, seeds or any part thereof and essentially biological processes from patent eligible subject matter, promotes public policy and interest of farmers. Optional exclusion of plants from patentability by Article 27.3(b)74 of the TRIPS Agreement not only shows the recognition of the concerns of Members as to the patentability of plants but it also recognizes the fact that WTO Members have different socioeconomic and political situations and therefore one size will not fit all. Members have the liberty to choose from the menu of Article 27.3(b) to protect and promote their respective public policy. What may be public policy of one Member may not be public policy of another Member. It is true that we are not living in an equal and flat world. We are living in an unequal and uneven world, though we are striving to make it equal. Until inequality is removed, one rule for all may have a devastating effect. We must respect diversity and differences and this is one of the lessons of TRIPS. In accordance with the provisions of Article 27.3(b), India seeks to provide an effective sui generis system for protection of plants by enacting Protection of Plant Varieties and Farmers' Rights Act 2001. In India, there is a fear against patents in general, and against patenting of plants and seeds in particular. The approach of other WTO Members are different from that of India. The United States of America (US) has a different story to offer. US farmers successfully lobbied their Congress for enactment of the Plant Patent Act 1930,75 for the protection

<sup>&</sup>lt;sup>73</sup> Monsanto v Nuziveedu (SC) (n 15) 389, para 18.

<sup>&</sup>lt;sup>74</sup> TRIPS Agreement (n 41) art 27.3(b). 'Members may also exclude from patentability...plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant

varieties either by patents, or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement'

<sup>&</sup>lt;sup>75</sup> United States Code: Plant Patents, 35 USC 161-164.

of asexually (grafting and sporting etc.) reproduced plants, arguing that agriculture cannot be discriminated against industry. In the US, there are three types of intellectual property rights protection available for plants: (i) the Plant Patent Act 1930 for asexually reproduced plants; (ii) the Plant Variety Protection Act 1970;<sup>76</sup> and (iii) the Utility Patents because of *J.E.M. Ag Supply Inc. v Pioneer Hi-Bred International Inc.*<sup>77</sup>

Flexibility allowed by the TRIPS Agreement under Article 27.3(b) gives Members an option to exclude plants from patenting and to protect plants by an effective sui generis system. This article argues that patenting of all new technology, including seed and plant without discrimination, should be encouraged. Arguments against patenting new seeds and plants seem to be weak for the following reasons. One, a patent does not confer a positive right to make or sell the patented product. Making and selling of certain patented products including genetically modified seeds are subject to approval from a competent authority. Two, there is no necessary connection between patents and high prices of patented products. Governments have tremendous power to regulate prices of patented products. Governments also have power to acquire patented inventions for public purposes. The (Indian) Patents Act also allows compulsory licensing of patented products. Three, biotechnological inventions are always subject to approvals of appropriate authorities appointed by Governments. Four, there are no conclusive studies to show that suicides committed by farmers in India are directly related to cultivation of Bt. cotton crops. Ineffective laws and policy paralysis related to farming and agriculture seem to be the main reasons for farmers' distress and suicide. Five, it is nobody's case that the patent system is the only method of encouraging invention. Nevertheless, patent have proved to be the most effective tool for encouraging invention. Six, agro-biotechnology has the potential to come up with new transgenic plants. What if a genetic engineer succeeds in inventing a transgenic bitter gourd plant, having taste of an apple and aroma of jasmine? What if a genetic engineer succeeds in inventing a transgenic sugarcane plant having the property of controlling blood sugar levels? What if a genetic engineer succeeds in increasing the yield of wheat, rice, or any other plant by tenfold? Such inventions will be revolutionary in nature. Such plants can be protected under the provisions of the Protection of Plant Varieties and Farmers' Rights Act 2001. The question is whether such protection will be sufficient to reward the skill, human intervention and ingenuity of the genetic engineer. The answer is a clear no, because such a protection is neither proportional nor fair to the human intervention and ingenuity involved in such type of inventions. In this regard, the three-pronged approach of US law seems to be more proportional, commensurate, fair and equitable to encourage human intervention and ingenuity.

In view of the above, it is suggested that the provisions of Section 3(j) of the Patents Act should be amended and the words, 'plant, seed or any part thereof' should be repealed therefrom. Such an amendment will encourage scientists to invent transgenic plants, which may revolutionize farming. Such a technology can also be used to feed billions.

Against the aforementioned arguments, the most compelling counter argument is that the Indian farmers have been exchanging seeds for generations and if they resort to cultivation of Bt. cotton seeds, they may be compelled to buy fresh seeds which poor Indian farmers cannot afford. A recent study published in the journal *Nature Plants* and reported in a newspaper claims that Bt. cotton only increased cost of cultivation and higher output is due to other

<sup>&</sup>lt;sup>76</sup> United States Code: Plant Variety Protection, 7 USC 2321-2582.

<sup>&</sup>lt;sup>77</sup> J.E.M. Ag Supply Inc v Pioneer Hi-Bred International Inc, 534 US 124 (2001).

<sup>&</sup>lt;sup>78</sup> Vasant P Gandhi and N V Namboodri, 'Economics of Bt. Cotton vis a vis Non-Bt. Cotton in India: A Study Across Four Major Cotton Growing States' (2009) IIM Ahmedabad, 9

<sup>&</sup>lt;a href="https://www.iima.ac.in/c/document\_library/get\_file?uuid=9c05f">https://www.iima.ac.in/c/document\_library/get\_file?uuid=9c05f</a>

<sup>432-28</sup>c1-4e4a-b485-8d808e37d1a4&groupId=62390> accessed 20 April 2020.

<sup>&</sup>lt;sup>79</sup> T V Jayan, 'Bt. Cotton only Increased Cost of Cultivation: Study' (*Hindu Business Line,* India, 16 March 2020)
<a href="https://www.thehindubusinessline.com/economy/agribusiness/bt-cotton-only-increased-cost-of-cultivation-study/article31083583.ece">https://www.thehindubusinessline.com/economy/agribusiness/bt-cotton-only-increased-cost-of-cultivation-study/article31083583.ece</a> accessed 19 April 2020.

factors. However, another report in the same newspaper questions the findings in *Nature Planet* and claims that Bt. technology has made cotton farming more sustainable.<sup>80</sup> A related report in another newspaper<sup>81</sup> claims that farmers fear loss, not arrest and seed illegal Bt. cotton. It may be said that there are contradictory reports about cultivation of Bt. cotton seeds. But farming of Bt. cotton seeds seems to be very popular amongst Indian farmers.

In view of the above, arguments against patenting of plants and seeds seem to be too weak. It is suggested that India should either go for patenting of plant and seeds or should go for a combination of patent and an effective *sui generis* system for the protection of plants. At the same time, India should also try to implement the existing laws in an effective manner and should also develop policies for protecting and promoting the interests of farmers.

It is submitted that crop failure, including the crop of Bt. cotton, is generally due to poverty, inadequate irrigation and adverse environmental conditions. It is a well-known fact that Bt. cotton's roots are very short and therefore require continuous irrigation. Inadequate availability of water is the main reason for failure of the Bt. cotton crop. Indian authorities charged with the responsibility of appraising and approving genetically modified crops are more to be blamed, than Monsanto for the farmers' suicide, if anyone is to be blamed at all.

### 4. CONCLUSIONS

The three courts were of the opinion that Monsanto was wrong in terminating the sub-license agreement because the trait value stipulated in the agreement had become unlawful consideration due to notification of Governments. The Single Judge of the Delhi High Court was clearly right in applying the procedural law of pleadings and trials. At the same time, the

approach of the Single Judge seems to be erroneous in interpretation and application of substantive patent law. The Single Judge of the Delhi High Court confined the scope of Section 3(j) of the (Indian) Patents Act to naturally occurring plants and seeds — a limitation not envisaged by said Act. His opinion that the patent was *prima facie* valid seems to be against the provisions of the (Indian) Patents Act. It is not *res integra* that the whole statute must be read word by word, section by section, and clause by clause to arrive at the statutory meaning. What is explicitly excluded cannot be introduced through the back door by judicial interpretation. Moreover, a repealed section of legislation does not render invalid any surviving section of legislation. Had the Parliament of India wanted to repeal Section3 (j), it would have done so.

The approach of the Division Bench was clearly wrong on application of procedural law of trial and hearing. The Division Bench decided a question which was not before it. It was a decision without jurisdiction. A decision without jurisdiction is a nullity in law. The appeal before the Division Bench was on a limited ground regarding grant of an interim injunction. The approach of the Division Bench as to statutory provisions and application of substantive patent law seems to be clinching if one ignores the procedural law of trial and hearing. The problem is that procedural law cannot be ignored. Had the Division Bench, without deciding the substantive question of law, held that the patent was prima facie invalid as the subject matter is explicitly excluded by legislation, the Supreme Court would have perhaps upheld the decision of the Division Bench and reversed the decision of the Single Judge. Even if the Supreme Court had reversed the decision of the Division Bench, at least it would have expressed an opinion as to the validity or otherwise of the patent.

<sup>&</sup>lt;sup>80</sup> GT Gujar, Bhagirath Choudhary and CD Mayee, 'Bt. technology has made cotton farming more sustainable' (*Business Line*, India, 17 April 2020)

<sup>&</sup>lt;https://www.thehindubusinessline.com/economy/agri-business/bt-technology-has-made-cotton-farming-more-sustainable/article31363602.ece> accessed 21 April 2020.

<sup>&</sup>lt;sup>81</sup> Jayashree Bhosale, 'Farmers Fear Loss, Not Arrest, and Seed Illegal Bt. cotton' (*Economic Times*, India, 20 June 2019)
<a href="https://economictimes.indiatimes.com/markets/commodities/news/farmers-fear-loss-not-arrest-and-seed-illegal-bt-cotton/articleshow/69867576.cms">https://economictimes.indiatimes.com/markets/commodities/news/farmers-fear-loss-not-arrest-and-seed-illegal-bt-cotton/articleshow/69867576.cms</a> accessed 21 April 2020.

The Supreme Court knew that patent is going to expire within a few months, on 4 November 2019. Instead of remanding the matter to the Single Judge for trial, it could have decided the substantive question of law. However, the Supreme Court did not have the luxury of conducting the trial as it is the court of final appeal and is not a court of facts in a patent case. The absence of answers to substantial question of law, however, will definitely create legal uncertainty. It is most likely that this mixed question of law and facts would receive conflicting answers from various High Courts in India if there are cases involving the patenting of invented NAS, whether inserted in a seed or not.

According to TRIPS, Members are at liberty to protect plants by patent or by an effective sui generis system or by any combination thereof. Any WTO Member, like India, is free to not provide patent protection to plants. Hence, the provisions of Section 3(j) of the Patents Act are in consonance with the provisions of the TRIPS Agreement. These provisions, in the wisdom of the Parliament of India, are in public interest and farmers' interest. Moreover, in compliance with the provisions of TRIPS, India has enacted the Protection of Plant Varieties and Farmers' Rights Act 2001, which has provisions regarding breeders' rights, farmers' rights and researchers' rights. Public policy must trump private commercial interests. However, it is suggested that to encourage invention in the field of agro-biotechnology has potential to not only increase crop yield, but also produce crops fit and healthy for human and animal consumption. Hence, patenting of invented seeds and plants should be allowed and the provisions of Section 3(j) should be suitably amended. In the alternative, India should explore the possibility of opting a combination of patents and an effective *sui generis* system for the protection of plants. At the same time, India should also try to implement the existing laws in an effective manner and develop policies for protecting and promoting the interests of farmers. The preeminent need of the hour is that the Government of India commission empirical studies to assess the benefits and burdens of patenting of seeds and plants. Theoretical and doctrinal studies are not going to serve the purpose.

#### **BIBLIOGRAPHY**

Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) <a href="https://www.wto.org/english/docs\_e/legal\_e/27-trips.pdf">https://www.wto.org/english/docs\_e/legal\_e/27-trips.pdf</a> Accessed 12 December 2019

Bhosale J, 'Farmers fear loss, not arrest, and seed illegal Bt. cotton' (*Economic Times*, India, 20 June 2019) <a href="https://economictimes.indiatimes.com/markets/commodities/news/farmers-fear-loss-not-arrest-and-seed-illegal-bt-cotton/articleshow/69867576.cms">https://economictimes.indiatimes.com/markets/commodities/news/farmers-fear-loss-not-arrest-and-seed-illegal-bt-cotton/articleshow/69867576.cms</a> Accessed 21 April 2020

Aryan A, 'SC Overturns Delhi HC Ruling, Grants Bt. Cotton
Patent to Monsanto' (*Business Standard*, India, 8 January
2019) <a href="https://www.business-standard.com/article/markets/sc-overturns-delhi-hc-ruling-grants-bt-cotton-patent-to-monsanto-119010801126\_1.html">https://www.business-standard.com/article/markets/sc-overturns-delhi-hc-ruling-grants-bt-cotton-patent-to-monsanto-119010801126\_1.html</a> Accessed 8 January 2019

Budapest Treaty on the International Recognition of the
Deposit of Microorganisms for the Purposes of Patent
Procedure (9 August 1980)
<a href="https://www.wipo.int/export/sites/www/treaties/en/regist">https://www.wipo.int/export/sites/www/treaties/en/regist</a>
ration/budapest/pdf/wo\_inf\_12.pdf> Accessed 8 March
2019

Gandhi VP and Namboodri NV, 'Economics of Bt. Cotton vis a vis Non-Bt. Cotton in India: A Study Across Four Major Cotton Growing States' (2009) IIM Ahmedabad, 9 <a href="https://www.iima.ac.in/c/document\_library/get\_file?uuid=9c05f432-28c1-4e4a-b485-8d808e37d1a4&groupId=62390">https://www.iima.ac.in/c/document\_library/get\_file?uuid=9c05f432-28c1-4e4a-b485-8d808e37d1a4&groupId=62390</a> Accessed 20 April 2020

Gujar GT, Choudhary B and Mayee CD, 'Bt. technology has made cotton farming more sustainable' (*BusinessLine*, India, 17 April 2020)

<a href="https://www.thehindubusinessline.com/economy/agri-business/bt-technology-has-made-cotton-farming-more-sustainable/article31363602.ece">https://www.thehindubusinessline.com/economy/agri-business/bt-technology-has-made-cotton-farming-more-sustainable/article31363602.ece</a> Accessed 21 April 2020

'India's Top Court allows Monsanto to Claim Patents on GM Cotton-company Source' (*Reuters*, New Delhi, 8 January 2019) <a href="https://reuters.com/article/india-monsanto/indias-">https://reuters.com/article/india-monsanto/indias-</a> top-court-allows-monsanto-to-claim-patents-on-gm-cottoncompany-source-idUSD8N1SS00K> Accessed 8 January 2019

patent/articleshow/63713854.cms?from=mdr> Accessed 8 January 2019

Jayan TV, 'Bt. cotton only increased cost of cultivation: Study' (Hindu Business Line, India, 16 March 2020) <a href="https://www.thehindubusinessline.com/economy/agri-">https://www.thehindubusinessline.com/economy/agri-</a> business/bt-cotton-only-increased-cost-of-cultivationstudy/article31083583.ece> Accessed 19 April 2020

Sheriff K, 'The Bt. Cotton Dispute in Delhi HC and SC: What the latest order means' (The Indian Express, India, 8 January 2019) <a href="https://indianexpress.com/article/explained/the-bt-">https://indianexpress.com/article/explained/the-bt-</a> cotton-dispute-in-delhi-hc-and-sc-what-the-latest-ordermeans-5547531/> Accessed 8 January 2019

J.E.M. Ag Supply Inc. v Pioneer Hi-Bred International Inc., 534 US 124 (2001)

The Biological Diversity Act 2002 (No. 18 of 2003) (India)

'Monsanto Patent Victory on GM Cotton Seeds can Aggravate Agrarian Crisis' (Hindustan Times, India, 8 January 2019) patent-victory-on-gm-cotton-seeds-can-aggravate-agrariancrisis/story-045Xf1MejmdHBBjNJMpSzJ.html> Accessed 8

The Environment (Protection) Act (No. 29 of 1986) (India)

<a href="https://www.hindustantimes.com/india-news/monsanto-">https://www.hindustantimes.com/india-news/monsanto-</a> January 2019

The Indian Contract Act (Act No. 9 of 1872) (India)

Monsanto Technology LLC v Nuziveedu Seeds Ltd., 2017 (70) PTC 145 [Del]

The Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms Genetically Engineered Organisms or Cells Rules 1989 (India)

Monsanto Technology LLC v Nuziveedu Seeds Ltd., [2019] 3 SCC 381

The Patents Act 39 of 1970 (India)

The Constitution of India 1950

Nuziveedu Seeds Ltd. v Monsanto Technology LLC, 2018 (74) PTC 12 [Del]

The Patents (Amendment) Act (No. 17 of 1999) (India)

Rajagopal K, 'Supreme Court backs Monsanto on GM Cotton Patents' (The Hindu, India, 8 January 2019) <a href="https://www.thehindu.com/news/national/supreme-court-">https://www.thehindu.com/news/national/supreme-court-</a> The Protection of Plant Varieties and Farmers' Rights Act (No. 53 of 2001) (India)

Trivedi U, 'GM Cotton: Monsanto wins patent war in India as

backs-monsanto-on-gm-cottonpayments/article25940071.ece> Accessed 8 January 2019 SC rules in its favour' Business Standard (India, 8 January 2019) <a href="https://www.business-">https://www.business-</a> standard.com/article/companies/gm-cotton-monsantowins-patent-war-in-india-as-sc-rules-in-its-favour-119010800376\_1.html> Accessed 8 January 2019

Sally M, 'Delhi High Court dismisses Monsanto plea to enforce Bt. Cotton Seed Patent' Economic Times (India, 8 January 2019)

US Code - Plant Patent Act 1930 [35 USC 161-164]

<a href="https://economictimes.indiatimes.com/news/economy/agr">https://economictimes.indiatimes.com/news/economy/agr</a> iculture/delhi-high-court-dismisses-monsanto-plea-toenforce-bt-cotton-seedUS Code - Plant Variety Protection Act 1970 [7 USC 2321-2582]

World Intellectual Property Organization, 'Budapest Treaty on the International Recognition of the Deposit of

Microorganisms for the Purposes of Patent Procedure –
Note by the Secretariat' WO/INF/12 REV. 26 (WIPO, Geneva,
1 May 2019)
<a href="https://wipo.int/export/sites/www/treaties/en/registratio">https://wipo.int/export/sites/www/treaties/en/registratio</a>
n/budapest/pdf/wo\_inf\_12.pdf> Accessed 8 March 2019