

**Globalisation and the International Governance of Modern Biotechnology**

**Development of IPR Regime in India with Reference to Agricultural  
Biotechnology**

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This paper was prepared for a project on *Globalisation and the International Governance of Modern Biotechnology*, which is part of the *Globalisation and Poverty* programme, a three year programme of research, funded by the Department for International Development, exploring the linkages between globalisation processes and poverty.

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## **Table of Contents**

<b>I Introduction</b>	<b>4</b>
<b>II Patent Law Regime</b>	<b>7</b>
<b>III Protection of Biological Resources</b>	<b>13</b>
<b>III Protection of Biological Resources</b>	<b>13</b>
<b>IV Protection of Plant Varieties</b>	<b>17</b>
<b>V Concluding Analysis:</b>	<b>27</b>
<b>Bibliography</b>	<b>32</b>
<b>Annex I</b>	<b>34</b>
<b>Annex II</b>	<b>36</b>
<b>Annex III</b>	<b>37</b>

## I INTRODUCTION\*

This paper surveys debates over the evolution of intellectual property rights laws in India as they relate to agricultural biotechnology. This has been an area subject to significant developments over recent years, and one in which many new and emerging norms remain untested.

Scientific advancements in agricultural biotechnology, aiming at enhancement of food production have been expected to contribute to making food more nutritious and improve the food security position of India.<sup>1</sup> They are also expected to increase the productivity of land and thus reduce the pressure to extend the acreage under cultivation.<sup>2</sup> However fears have been expressed that the benefits of biotechnology could be outweighed by the risks involved.<sup>3</sup> One of the main fears is that affording intellectual property protection to agricultural biotechnology would drastically affect the economic situation of farmers to the extent of endangering food security. However, the divergence of various interests has hindered the formulation of a clear policy on protection of biotechnological innovation. Realising the “successes in agriculture...., biotechnology...” and “major national achievements” in terms of “very significant increase in food production”, science and technology leading to “new norms of intellectual property rights”, and in *The Science and Technology Policy 2003*, the Government of India has declared as its policy objectives:

- to ensure food, agricultural, nutritional, environmental, water, health and energy security of the people on a sustainable basis,
- to mount a direct and sustained effort on the alleviation of poverty, enhancing livelihood security, removal of hunger and malnutrition,
- to establish an Intellectual property Rights regime which maximises the incentives for the generation and protection of intellectual property by all types of inventors. The regime would also provide a strong, supportive and comprehensive policy environment for speedy and effective domestic commercialisation of such inventions so as to be maximal in the public interest.<sup>4</sup>

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\* This is a pre-final draft subject to review and revision. Research input for this paper was provided by N. Senthil Vannan, with the assistance of Vandana Pai, Jyostna Balakrishnan, Shyamkrishna Balganes, Nidhi Tandon and Vibin Natarajan.

1 See *Science and Technology Policy 2001, Implementation Strategy* (Draft Document: Action Plan: version 3) available at [www.cionline.org/busserv/biotechnology/policy .htm](http://www.cionline.org/busserv/biotechnology/policy.htm). (visited on 29-10-2001).

2, See: Manju Sharma, "India: Biotechnology Research & Development", G.J. Persley and M. M. Lantin, (Eds.), *Agricultural Biotechnology and the Poor: An International Conference on Biotechnology*, pp. 51-57.

3 See Vandana Shiva, *Patents: Myths and Reality* (New Delhi-Penguin), 2001.

<sup>4</sup>Science and technology Policy 2003, available at: <http://www.dst.gov.in/doc/STP2003.doc>. The Policy provides, *inter alia*:

### *Indigenous Resources and Traditional Knowledge:*

Indigenous knowledge, based on our long and rich tradition, would be further developed and harnessed for the purpose of wealth and employment generation. Innovative systems to document, protect, evaluate and to learn from India's rich heritage of traditional knowledge of the natural resources of land, water and bio-diversity will be strengthened and enlarged. Development of technologies that add value to India's indigenous resources and which provide holistic and optimal solutions that are suited to Indian social-cultural-economic ethos will be developed. A concerted plan to intensify research on

The remainder of this introduction provides some historical context for recent developments.

## **Food Security**

The aim of agricultural policies has been to provide food for all. The concept of food security has undergone a shift from the emphasis on availability of food<sup>5</sup> to access to food.<sup>6</sup> If food security is the aim, intellectual property rights which primarily determine economic accessibility of food crops assume paramount importance. Indian policymakers are now therefore being forced to pay greater consideration to the economic management of food security rather than merely the technical aspects. To understand this shift in perspective we will have to go back to the green revolution.

## **Green Revolution**

The government's policy adopted during the green revolution in India wherein public funded research institutions were involved in extensive research, gave an impetus to farming communities to adopt the new technology for agricultural development. The green revolution markedly reduced the costs of farming. The development of High Yielding Varieties was said to have transformed the face of Indian Agriculture.<sup>7</sup> The

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traditional systems of medicine, so as to contribute to fundamental advances in health care, and leading to commercialisation of effective products will be undertaken; appropriate norms of validation and standardisation will be enforced. A purposeful programme to enhance the Indian share of the global herbal product market will be initiated. (para. 9)

### *Generation and Management of Intellectual Property*

Intellectual Property Rights (IPR), have to be viewed, not as a self-contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programmes will be encouraged and promoted.

The process of globalisation is leading to situations where the collective knowledge of societies normally used for common good is converted to proprietary knowledge for commercial profit of a few. Action will be taken to protect our indigenous knowledge systems, primarily through national policies, supplemented by supportive international action. For this purpose, IPR systems which specially protect scientific discoveries and technological innovations arising out of such traditional knowledge will be designed and effectively implemented.

Our legislation with regard to Patents, Copyrights and other forms of Intellectual Property will ensure that maximum incentives are provided for individual inventors, and to our scientific and technological community, to undertake large scale and rapid commercialisation, at home and abroad.

The development of skills and competence to manage IPR and leveraging its influence will be given a major thrust. This is an area calling for significant technological insights and legal expertise and will be handled differently from the present, and with high priority. (para. 11)

<sup>5</sup> *Report of the World Food Conference* New York, 5-16 November 1974", (Rome: United Nations, 1975); See also W. Maxwell, and M. Smith "Household food security :a conceptual review", in S. Maxwell and T. Frankengurger (eds), *Household Food Security: Concepts, Indicators, Measurements: A Technical Review* (New York: 1992) wherein as many 200 definitions of "food security" has been analysed.

<sup>6</sup> Amartya Sen's theory laid emphasis in 1981 itself on entitlement failures and argued that 'scarcity is the characteristic of people not having enough. It is not the characteristic of there not being enough. While the latter can be the cause of the former, it is one of many causes', see A.K. Sen, *Poverty and Famines: An Essay on Entitlement and Deprivation*, (Oxford: Clarendon Press, 1981).

<sup>7</sup> Some however commented on the urban biases of the Green Revolution inasmuch as it benefited only the richer farmers while bypassing the poorer and marginal farmers. See John Meller, "The functions of Agricultural price in Economic Development", *Indian Journal of Agricultural Economics*, Vol. 1, 1968

policies of funding the scientific community by the international foundations<sup>8</sup> led to the evolution of High Yielding Varieties (HYV). The Indian Government was quick to recognise the potential of this technological development and give it full backing.<sup>9</sup> However the spread of this variety was constrained by environmental factors.

The benefit of the research was made available for the public welfare, and the public sector played a key role in the processes. Rights over varieties were not monopolised by any private entity nor were there any move to propertise the rights. The public interest was paramount. This is the reason why the Patent Law in India for a long time consistently excluded plant and plant varieties from the purview of patentability. But that is not the case with the advances in modern biotechnology. So the question which we in India need to ask and understand is why there has been this shift towards asserting property rights over inventions in the field of modern biotechnology<sup>10</sup> as opposed to the public spiritedness that existed in the context of the green revolution. More specifically in the context of this paper, the question can be framed as a problem of defining the factors that influence the shaping of the legislations in this field, and as a problem of identifying the players who have a role in the process of formulation of policy in this area.

One reason for the increasing propertisation of the inventions of modern biotechnology is the increasing involvement of the private sector in research and development in this area. Private sector involvement can be traced in three phases after independence.<sup>11</sup> The general trend appears to be a shift in spending with respect to R&D from public sector to private sector<sup>12</sup> despite the fact that public sector

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<sup>8</sup> For example, Rockefeller and Ford Foundation grants to scientists in Phillipines and Mexico.

<sup>9</sup> Dr. Norman E. Borlaug, the U.S. agronomist who pioneered research in HYV and was awarded the Nobel Peace Prize had observed that the Indian Minister for agriculture at the time “was the first high official to recognise the significance of the new wheat strains and willing to take the risk involved in importing 18.000 tonnes of dwarf Mexican varieties. This act initiated the beginning of a green revolution in Asia”.

<sup>10</sup> Even in the case of modern agricultural biotechnology, India resisted for quite sometime the introduction of intellectual property protection. An example is the avenue taken by the Plant Varieties Protection legislation through the Indian political process, see further below.

<sup>11</sup> *First phase*: In the period immediately following independence, government policy encouraged the importation of technology for commercial purposes. This stimulated the private sector to undertake the research on imported fertilisers, pesticides and machinery to ensure adaptation to local conditions. Starting in the early 1960s however the scope for this kind of adaptation was restricted by controls placed on the imports of foreign technology and on foreign investment to India. As a result, India developed its own production capacity for these technologies, often in public sector companies. *Second phase*: Indigenous private sector development and investment in R&D was discouraged by the policy environment of the period, particularly the 1972 Patents Act, which restricted intellectual property rights to agricultural technology. *Third phase*: The liberalisation of technology importation and foreign investment that began in 1991 marked the start of the third phase, in which encouragement was once again given to the private sector. See Andrew Hall, *et al.*, *Public-private sector interaction in the Indian Agricultural Research System: and Innovation System Perspective on Institutional Reform* available at [www.cabi-publishing.org/bookshop/readingroom/085799600/0851996000ch.pdf](http://www.cabi-publishing.org/bookshop/readingroom/085799600/0851996000ch.pdf) visited on 20-10-2002.

<sup>12</sup> Despite the growth of Indian economy being dependent on agricultural performance, even in 1997 not much public investment has been made on its development. There had been a steady declaration in public investment in gross capital formation in agriculture. In 1980-81, the public investment as a percentage of gross capital formation in agriculture was 38.7 percent which fell to 16.2% in 1996-97. During this period the share of private investment, however, rose from 61.3% to 83.8%. This rise is attributed mostly to better terms of trade offered by the government to agriculture vis-a-vis industry.

industries are more numerous and engage in a greater number of research projects. The Government of India, recognising the importance of interaction between private and public institutions, and hence in its Science and Technology Policy 2003, has declared as its objectives: “to encourage research and innovation in areas of relevance for the economy and society, particularly by promoting close and productive interaction between private and public institutions in science and technology”. The Policy further declares that “sectors such as agriculture...would be accorded highest priority” and that “key leverage technologies such as ...biotechnology.... would be given special importance”.<sup>13</sup>

## II PATENT LAW REGIME

### Policy Formulation

The patent system is designed to encourage and maintain a continuous flow of inventions.<sup>14</sup> The patent law governed the inventions in India since 1856.<sup>15</sup> In India, the Controller of Patents, Designs, and Trademarks works under the Ministry of Commerce & Industry, Department of Industrial Policy & Promotion. The issue of patenting of agricultural biotechnology is a matter concerned with the Department of Industrial Policy and Promotion, Ministry of Agriculture, Department of Biotechnology, and the Ministry of Environment and Forests. The Department of Biotechnology may have to act as the nodal agency inviting opinion from various stakeholders in identifying the kind of protection the biotechnological inventions require. The Department of Industrial Policy and Promotion is concerned with the changes in the patent system.

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The fall in public sector investment was attributed to increase in expenditure to meet higher subsidies on food, fertilisers, electricity, irrigation, credit and other farm inputs rather than creating assets.

<b>Gross Capital Formation in Agriculture (At 1993-94 prices in Rs. Crores)</b>					
<b>Year</b>	<b>Gross Capital Formation</b>			<b>Per Cent Share</b>	
	<b>Public</b>	<b>Private</b>	<b>Total</b>	<b>Public</b>	<b>Private</b>
1993-94	4468	11377	15845	28.2	71.8
1994-95	4970	13244	18214	27.3	72.7
1995-96	4776	15168	19944	23.9	76.1
1996-97	4347	15555	19902	21.8	78.2
1997-98	4416	16579	20995	21.0	79.0

SOURCE : available at <http://www.indiatrades.com>. (visited on 17-11-2002)

<sup>13</sup> See, <http://dst.gov.in/doc/STP2003.doc>

<sup>14</sup> Report on the Revision of the Patent Law, by Rajagopala Ayyangar, September, 1959, p.10.

‘Inventions breeds inventions and thus the pace of inventive activity is accelerated’

<sup>15</sup> The Act of 1856 on protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years. Subsequently, in 1859 the Act was modified as Act xv; patent monopolies called exclusive privileges (making, selling and using inventions in India and authorising others to do so for 14 years from date of filing specification). This was followed by Patents & Designs Protection Act 1872, Protection of Inventions Act.1883, Inventions & Designs Act 1888, Indian Patents & Designs act. 1911. In the year 1972 The Patents Act (act 39 of 1970) came into force on 20<sup>th</sup> April 1972. See, <http://patentoffice.nic.in/ipr/patent/patofficeadd.htm>

The impact of the WTO TRIPS Agreement prompted the adoption of certain changes to the patent legislation. The Minister of Commerce and Industry,<sup>16</sup> while presenting the Bill stated that Indian choice relating to TRIPS had been one of “take-it-or-leave-it”, as part of a package of agreements. The obligation had to be balanced with many domestic interests. The decision of the Appellate Body of the WTO in the case between India and USA further had an impact on legislation in the country.<sup>17</sup> Although the decision of the Appellate Body culminated in the First Amendment to the Patent Act, several concerns were not answered. The issues that had to be addressed were brought forth in the Second Amendment. The amendment indicated the need for balancing international obligations with national interest. The Minister identified the pillars on which the Bill stands such as public interest, public health and nutrition, national interest, national security, protection of traditional knowledge and environment. He further said that the discovery of any living thing or non-living thing would not be patented. Similarly a micro-organism cannot be patented. However, the process by which the micro-organism has been developed can be patented if it meets the criteria for invention.

In debates over the Bill to amend the Patent Act. the priority to be given to biodiversity protection was expressed by Shri Rupchand Pal.<sup>18</sup> Mr. Mani Shankar Aiyar<sup>19</sup> emphasised that there was need to ensure that genetic technology is not merely seen in terms of a profit motive but also that its social, developmental, and environmental consequences were fully taken into consideration. He referred to the example of *Bt* cotton and the long-term environmental loss that was likely to be caused apart from the immediate economic gains. Protection of bio-resources, and food security of the poor were key issues among the six critical points highlighted by Shri Subodh Mohite.<sup>20</sup> The concern for protecting traditional knowledge and the issue of the influence of multi-national corporations (MNCs) were highlighted by Mr. Ajoy Chakraborty.<sup>21</sup>

### **Patenting of Life Forms**

Living things were not considered patentable in India in light of the public religious and moral sentiments.<sup>22</sup> According to the multitude of Indian beliefs, such a right is

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<sup>16</sup> Mr. Murasoli Maran, then Minister of Commerce & Industry in Mr. A.B.Vajpayee’s cabinet, belongs to National Democratic Alliance, available at <http://164.100.24.167/rsdebate/synopsis/195/509052002.htm>. Also available at [http://commin.nic.in/doc/wto\\_May\\_2002.pdf](http://commin.nic.in/doc/wto_May_2002.pdf).

<sup>17</sup> WT/DS 50/AB/R available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/distabase-wto-members2\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/distabase-wto-members2_e.htm). See further below.

<sup>18</sup> Shri. Rupchand Pal is the Member of Parliament from Hooghly constituency and belongs to CPM party of India. The details of the debate is available at : <http://alfa.nic.in/lsdeb/ls12/ses4/4009039902.htm>

<sup>19</sup> Mr. Mani Shankar is the Member of Parliament from Mayiladuthurai constituency and belongs to Congress (I) party of India.

<sup>20</sup> Shri. Subodh Mohite is the Member of Parliament from Ramtek constituency and belongs to Congress Party. The details of the debate is available at: <http://alfa.nic.in/lsdeb/ls13/ses9/140502.html>

<sup>21</sup> Mr. Ajoy Chakraborty is a Member of Parliament and belongs to Communist Party of India.

<sup>22</sup> V.R. Krishna Iyer, “Human health and patent law”, *Frontline*, Oct. 14, 2000.



vested only in God. Any departure would outrage the sense of morality of the Indian people.<sup>23</sup>

S.2(j) of the Patents Act 1970 provided that any “substance produced by manufacture” was considered to be an invention provided it was new and useful. The Act expressly excluded from patenting

*“a method of agriculture or horticulture; or any process for the medicinal, surgical, curative, prophylactic or other treatment of animals or plants to render human beings or any process for a similar treatment of animals or plants to render them.....”*<sup>24</sup>

The Act was silent with respect to patenting of living subject matter. Furthermore the Patents Act 1970 strengthened governmental control in what were viewed as sensitive areas in two important ways:

- i. It rejected outright product patents in the field of drugs, food and outputs of chemical processes.
- ii. It included provisions for compulsory licenses in the public/national interest.<sup>25</sup>

Thus the 1970 Act balanced rights and obligations to ensure that patent monopolies were not established.<sup>26</sup>

### **Patent office directive**

In the absence of any express provision excluding from patentability living subject matter, there was no uniform interpretation of the provisions of the Patents Act by the different patent offices. As a consequence of this, the Controller General of Patents, Designs, and Trademarks in 1991 through an executive order<sup>27</sup> took a specific stand that no patents should be granted in respect of living subject matter. Accordingly there was a bar on the patenting of the process or product of any life form including micro-organisms, plants and animals, and parts thereof irrespective of how these inventions had been made. The instruction prohibited production of such substances by way of gene therapy, tissue culture, cell fusion, etc., from patentability. It allowed patents only for processes or methods of production of tangible and non-living substances such as enzymes, antibiotics, insulin, hormones, interferon, etc.

The aim of the instruction was to institute a uniformity of practice in respect of the examination and grant of biotech applications. The circular thus categorically

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<sup>23</sup> Suman Sahai, “Intellectual Property Rights and Community Rights” in Suman Sahai (Ed.) in *Bioresources and Biotechnology* (New Delhi: Gene Campaign, 1999) at 127; See also Justice N. Rajagopala Ayyangar in his report stated that, “*the precise provisions of Patent Act will have to be designed with special reference to the economic conditions of the country, the state of its scientific and technological advance and its future needs and other relevant factors and so as to minimise if not to eliminate the abuses to which a system of patent monopoly is capable of being put*”, and continued that he would suggest the retention of the patent system that has survived the test for a century. *Report on the Revision of the Patent Law* (New Delhi: Government of India, 1959).

<sup>24</sup> Section 3(h) and (i) of the Patent Act 1970.

<sup>25</sup> See Chapter 16, S.84-S.98, Patents Act, 1970.

<sup>26</sup> V.R. Krishna Iyer, “Human health and patent law”, *Frontline*, Oct. 14, 2000.

<sup>27</sup> Office Instruction No.1 of 1991, dated 15.07.1991.

indicated that the living things ought not to be patented. This attitude was in part at least due to the moral and ethical objections associated with patenting life.<sup>28</sup>

### **The decision in Dimminaco case<sup>29</sup>**

In the *Dimminaco* case<sup>30</sup> the question of accepting a patent application for the process of creating a vaccine against Bursitis was answered in the negative by the Patent Office. The reason offered by the Patent Office was that section 2(j)(i) of the Patent Act precluded the word “manufacture” from including the production of vaccines using micro-organisms and therefore a process patent could not be granted to such a technique. Reference to the grant of patents for live cells, virus and micro-organisms by various branch offices was countered by the respondents on the ground that the micro-organisms in these applications had been lyophilized (freeze dried) and therefore could not be considered to be living. But this argument was not accepted by Court. The Court said that lyophilisation was in fact a method of preservation and therefore indicated that the living organisms were in fact very much alive. The judgment has assumed importance since the Patents Amendment Act 2002 allows micro-organisms, but not other living substances, to be patented. Even after the Act is given effect to it may be influenced by the interpretation in the *Dimminaco* case. There is no statutory bar to accepting a manner of manufacture as being a patentable invention even if it contains a living organism, provided the process is new and results in a useful product.

The judgment thus clarified that process patents could be granted though the end product contains living organisms and in spite of the fact that the process itself made use of micro-organisms as bioreactors.

### **Obligations under TRIPS and India’s Response**

Biotechnology innovations are capable of satisfying the requirements for patentability. The crux of the patent debate, however, has never really been the ability of biotechnology to satisfy the requirements. The debate has centered primarily on whether we should reject patents for biotechnology for social reasons, regardless of their novelty, utility, and non-obviousness.

Article 27(2) of TRIPS is often cited as a means of justifying the exclusion from patentability of living organisms. Article 27(2) enables WTO Members to exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided such exclusion is not made merely because the exploitation is prohibited by their law. India has had a strong religious and cultural tradition which opposes patenting of life forms. It has therefore been argued that Article 27.2 of TRIPS could be used to justify exclusion from patentability of living subject matter.

The first attempt made by the Government of India to amend the Patent Act in 1995, lapsed in Parliament. Consequently the US filed a case against India through the

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<sup>28</sup> See S.2(j), Patents Act, 1970.

<sup>29</sup> *Dimminaco A.G v. Controller of Patent, Designs and ors.* IPLR 2002 July 255.

<sup>30</sup> *Id*

dispute settlement mechanism of the WTO. The WTO Appellate Body issued an adverse finding against India.<sup>31</sup> In order to comply with the WTO ruling, the Government of India enacted in 1999 the Patents (Amendment) Act, establishing a mailbox facility to accept product patent applications from 1 January 1995 onwards, and to provide exclusive marketing rights (EMR) to such applicants.<sup>32</sup>

The amended legislation also provided for changes in the scope of patentable inventions, grant of new rights, extension of the term of protection, provision for reversal of burden of proof in case of process patent infringement, and conditions for compulsory licenses.<sup>33</sup>

Section 3(j) of the Patents Act that had provided that no patents could be claimed for treatment of plants to render them free of disease or to increase their economic value has been amended as to exclude “plants” from its purview.<sup>34</sup> Thus patents can now be granted for a process for treatment of plants, which renders them free of disease or increases their economic value.<sup>35</sup> The effect of the present amendment can be illustrated through the instance of a patent not being available for the cottonseed, which contains the *Bt* gene,<sup>36</sup> while the process of engineering the gene into the seed would be patentable.<sup>37</sup> This is because of the argument that the *Bt* gene is primarily a treatment, which makes the cotton plant more resistant to the bollworm (a pest to which it would otherwise be susceptible) and also increases its economic value. The process of achieving this result is patentable under section 3(i). Once a patent is granted, no other person would be allowed to utilise the same process to develop seeds with this gene, without a license from the patentee.

India has complied with its obligation under Article 27.3 (a) TRIPS by deleting the word “plants” from section 3(i) which excludes “any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings *or any process for a similar treatment of animals* to render them free of disease or to increase their economic value or that of their products” from the scope of patentability. India has also satisfied her obligation to give effect to Article 27.3(b) by incorporating Section 3(j), excluding plants and animals (in whole or any part thereof)

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<sup>31</sup> DS.50/AB/R, December 1997.

<sup>32</sup> Srividhya Raghavan, “Patent Amendments in India in the Wake of TRIPS”, *CASRIP Newsletter* (Winter), 2001. The Act provided EMRs and created a ‘*mailbox system*’ for patent applications for a period of five years or until the patent is granted or rejected, whichever is earlier. If the applicant had already filed an application for his or her invention in any convention country and a patent or EMR had been granted in that country on or after 1 January 1995, the applicant would be eligible to file for patent to pharmaceutical and agrochemical products in India. These patent applications will be kept pending. When India changes its patent law as per WTO recommendations, the pending patent application will be eligible for product patent. Until such patent is granted or rejected for a period of five years (whichever is less), the applicant will be granted EMRs in India if the application is found eligible.

<sup>33</sup> Dr N.S., Gopalakrishnan, *The Patents (Second Amendment) Bill, 1999 - An Analysis*, <http://ebc-india.com/lawyer/articles/2001v1a2.htm> (visited on 12/08/2001).

<sup>34</sup> See for further information: Annex I

<sup>35</sup> See for comments : Ramanna, Anitha, “Policy Implications of India’s Patent Reforms: Patent Applications in the Post-1995 Era”, *Economic and Political Weekly*, May 25, 2002, p. 2065.

<sup>36</sup> No patent can be granted with respect to seeds - Section 3 (j) of the Patents Act, 1970.

<sup>37</sup> Rao, Niranjana C., “Patents for Biotechnology Inventions in TRIPS”, *Economic and Political Weekly*, June 01, 2002, available at <<http://www.epw.org.in>>

other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals the exclusion in Section 3(j) from the scope of patentability. In addition it has given effect to the exception through the Protection of Plant Varieties and Farmers' Rights Act 2001 (see further below). On the whole, the obligation under Article 27.3 has been discharged by India. However, in the process, it diluted the idea of excluding completely plants from patent protection as appears to be underlying Article 27.3. This is because the net result of granting patent protection to treatment of plants is likely to end up in protection for the plant itself. It is questionable whether this dilution is favourable to biotechnological inventions or not.<sup>38</sup>

In addition, section 5 of the Patents Act provides that no patent can be granted for any "substance intended for use or capable of being used as food". The rationale for this provision is that the first priority of the government is to ensure availability of adequate food to each and every Indian citizen. As this is one of the basic amenities in life, it would be against public interest to grant monopoly rights to individuals. However, the Act has narrowed the definition of 'food' by inserting the phrase 'for human consumption'.<sup>39</sup> Under the earlier definition, 'food' was defined as 'any article of nourishment'. Thus, by implication the new definition excludes articles of nourishment not for human consumption, i.e. fodder for animals. Animal fodder is as important as food for humans in an agrarian economy like India, and patentability could cause great hardship.

Some of the NGOs have expressed the opinion that India should avoid patenting on micro-organisms by invoking the clauses of *ordre public* and offence to prevailing norms of morality.<sup>40</sup>

The Patent Amendment Act of 2002 is yet to come into force and is likely to come into force during March /April 2003.

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<sup>38</sup> See Ravishankar A. and Sunil Archak, "Intellectual Property Rights and Agricultural Technology: Interplay and Implications for India", *Economic and Political Weekly*, July 1, 2000, p. 2446, available at <<http://www.epw.org.in>>

<sup>39</sup> Section 2 (g): "Food" means any article of nourishment for human consumption and also includes any substance intended for the use of infants, invalids or convalescents as an article of food or drink.

<sup>40</sup> See: Suman Sahai, *Intellectual Property Rights and IPRs* (New Delhi: Gene Campaign, 1999) at 127

### III PROTECTION OF BIOLOGICAL RESOURCES

#### Policy Formulation Process

India has been playing an active role in the international conservation of biodiversity, as illustrated in its country report to the U.N. Commission on Sustainable Development.<sup>41</sup> India's positive response to the principles enshrined in the Convention on Biological Diversity (CBD), relating to the rights over the genetic resources *per se* and to the technologies that are based on those genetic resources, is amply reflected in the Biodiversity Bill, 2002.<sup>42</sup> This provides for the rights of traditional communities who have been the custodians of genetic resources, and have the knowledge to exploit them in a sustainable manner,<sup>43</sup> measures to conserve and sustainably use biological resources, including habitat and species protection (such as declaration of biodiversity Heritage Sites), environmental impact assessments of all projects which could harm biodiversity, and integration of biodiversity into all sectoral plans, programs and policies. Regulation of access to biological resources by Indian nationals for conservation and to stop over-exploitation (e.g. of medicinal plants), while exempting local communities from unnecessary restrictions is also provided in the Indian bill.<sup>44</sup>

Even before the adoption of the CBD,<sup>45</sup> the initiation of consultations on the protection of biodiversity came from the NGOs although the CBD does not explicitly require the participation of the non-governmental sector in policy making. The Ministry of Environment and Forests (MoEF) responded positively.<sup>46</sup> The consultative process led to the establishment of an expert group that gave its report making recommendations for a Biodiversity Law in India.

The participation of NGOs was so significant that a Draft Law on Biodiversity was framed by Gene Campaign leading to effective National Consultation Seminars<sup>47</sup> and the establishment of a committee under the leadership of MSSRF.<sup>48</sup> The final version of the Biological Diversity Bill discussed and debated by the committee was released by the MoEF for public comments and wide ranging consultations were held with

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<sup>41</sup> Available at: <http://www.un.org/esa/earthsummit/india-cp.htm> (visited on 20/11/02).

<sup>42</sup> For further information see: Annex II. The Bill was passed on 11 December 2002, and is now the Biodiversity Act 2002, No 93. of 2002, available at: <http://www.envfor.nic.in/legis/legis.html>.

<sup>43</sup> Article 8 (j) CBD

<sup>44</sup> Clause 7

<sup>45</sup> India signed the Convention on Biological Diversity on 5th June 1992, and ratified it on 18th February 1994. For discussion of the issues considered by India as predominant at the negotiations before the Convention, see Rajan, Mukund Govind, *Global Environmental Politics-India and the North-South*.

<sup>46</sup> R.V.Anuradha, Bansuri Taneja and Ashish Kothari, *Experiences with Biodiversity Policy-Making and Community Registers in India*, February 2001, International Institute for Environment and Development (IIED), [www.iied.org](http://www.iied.org) (visited on 20/11/02).

<sup>47</sup> The major themes that emerged out of these seminars were:

- a) biodiversity legislation,
- b) the macro-strategy on biodiversity,
- c) sustainable use and biotechnology, and
- d) indigenous knowledge systems and benefit-sharing.

<sup>48</sup> M.S.Swaminathan Research Foundation, based in Chennai headed by renowned Scientist Dr.M.S.Swaminathan.

representatives of scientific and academic institutions, the Confederation of Indian Industry, the relevant government ministries and leading NGOs.

The Indian commitment was evident from its budget proposal of 1999-2000 for the proposed establishment of a National Bio-resources Board (NBB) as well as for the proposal to set up a National Innovation Foundation (NIF). The NBB consists of representatives from the Ministries of Environment and Forests, Agriculture, Department of Biotechnology and non-governmental experts. The object of mobilising intellectual property protection and converting innovations into viable business opportunities was sought to be realised through establishment of NIF.

Despite such concrete efforts, the Biodiversity Bill took a very long time to reach the take-off stage in view of political uncertainties at the central Government level and lack of continuity of officials and functionaries in the concerned Ministries. It is criticised that there was lack of political commitment to the formulation of law and action plan as well as divergent views between various participants made it difficult to arrive at a consensus.<sup>49</sup>

### **Emergence of Biodiversity Law**

The establishment of the Swaminathan Committee heralded a change in the focus of the Biodiversity Bill. The basic concern focused earlier on the rights of indigenous communities shifted towards the prevention of unauthorised use of biological resources by foreign individuals, institutions and companies. NGOs were apprehensive that the new focus would dilute the right to safeguard the knowledge of local and indigenous communities.<sup>50</sup> The representatives from industry felt that finished products should not be included in the law and also suggested that the law should mandate Material Transfer Agreements. It is an indication of clear polarisation of interests between NGOs and industries. At the same time the Bill was considered to be a compromise between extreme views advocated by industries and NGOs.

The proposed multi-stakeholder National Biodiversity Authority (NBA) has been conferred with the power of opposing the grant of patents on a substance process derived from the biological resources from within the country, The NBA is also provided with discretion to decide the extent of benefit sharing amongst the stakeholders.<sup>51</sup>

The Bill is problematic in its treatment of gene banks. Though the Bill provides for collaborative research it is understood to follow exclusionary policy under the Bill,<sup>52</sup>

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<sup>49</sup> Shri Manoj Bhattacharya speaking in Rajya Sabha stated that “this Bill should have been brought seven to eight years back. It has been inordinately delayed. In fact, for 200 years, the biodiversity of our country had been directly looted by the British imperialism”. See

<http://rajyasabha.nic.in/rsdebate/synopsis/197/11122002.htm>

<sup>50</sup> See supra note 46.

<sup>51</sup> The only test case in India for benefit sharing is that of the Kani tribe in South India. For a detailed analysis of the case see Rekha Ramani, “Market Realities v. Indigenous Equities”, 26 *Brooklyn J. Int'l L.* 1147 (Lexis).

<sup>52</sup> Philippe Cullet, "Property Rights over Biological Resources: India's Proposed Legislative Framework", 4 *Journal of World Intellectual Property* (March 2001).

and could adversely affect the development of gene banks such as the Consultative Group on International Agricultural Research (CGIAR). Such gene banks have an important role to play as they facilitate sharing of resources especially in the field of agriculture. These were the Centres which provided some of the green revolution varieties that had significant impacts on overall food production. Research undertaken in these Centres is responsible for many scientific breakthroughs and the present policy of each country to preserve its biodiversity by asserting sovereign rights over its resources may have potentially disastrous effects, especially for the food security of the world. Cullet argues that a blanket ban on all foreign use may be counter-productive. Access to India's biological resources would enable small and less developed countries to foster the fulfillment of basic food and health needs. Further, such a provision will lead to adoption of similar provisions by other developing countries. However this argument is not tenable. Because, providing free access to these international research institutions may serve as a backdoor entry and there is the possibility of the multi-national corporations obtaining access in an indirect way. Further, the composition and nature of these institutions are also changing.<sup>53</sup>

The draft Biodiversity Bill reflects differential treatment for Indians<sup>54</sup> and foreign persons seeking access.<sup>55</sup> However, overall, the involvement of industry in the biodiversity law and policy processes was much limited.<sup>56</sup>

The Bill is not without shortcomings. Despite the fact that it was NGOs that took the initiative and they were the only active participants in the process of formulation of the policy and legislation, NGOs rarely stood united on various issues. There was lack of informed debate among the local and tribal communities as no consultations were held at the village level, being conducted instead in Delhi. Further there were different priorities that were emphasised by the different departments of the government and hence coordination in implementation would be the casualty.

In debates on the Bill, fears were expressed by the Members in Rajya Sabha<sup>57</sup> that National Biodiversity Authority and the State Biodiversity Boards would be comprised mainly of bureaucrats and the defect of these two bodies was the over-concentration of bureaucrats, and whatever rights and authorities are given, were taken away by the Central Government. Saif-ud-din soz expressed fears that

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<sup>53</sup> For example, the Syngenta Foundation for Sustainable Agriculture (wholly owned by Syngenta - the world's largest agrochemical corporation) became the newest member of CGIAR this year. At its 32nd Annual General Meeting (AGM02) that was held at Makati Shangri- La in Manila from Oct 30-Nov 1, and the first to be held outside Washington DC, the above announcement was made by the CGIAR chair, Ian Johnson. Available at <http://www.gene.ch/genet/2002/Nov/msg00019.html> also available at <http://www.cgiar.org/members/index.html>

<sup>54</sup> Federation of Indian Chamber of Commerce and Industry (FICCI), and the Ayurvedic Drug Manufacturer's Association (ADMA) also participated both directly and vocalised their interests through relevant government ministries and departments such as the Ministry of Commerce, the Ministry of Industry and the Department of Indian Systems of Medicine and Homeopathy (ISMH).

<sup>55</sup> The domestic industry lobby brought pressure to safeguard their interests. They argued that domestic research on biodiversity ought to be encouraged, and that it would be easier to monitor and regulate their activities, being confined to India.

<sup>56</sup> For a description of industry's grievances with the Biodiversity Bill see 'No surprises, tonnes of diversity in biodiversity bill', Times of India, New Delhi, 18th April, 2001.

<sup>57</sup> See <http://rajyasabha.nic.in/rsdebate/synopsis/197/11122002.htm>

multinationals would be here to stay and they were concerned with commerce rather than India's future.<sup>58</sup>

B.P.Apte strongly criticised the Bill as not guaranteeing the protection of the community intellectual rights. He further expressed his concern that the Bill itself would end up being a highway for those who would patent Indian traditional uses for two reasons—for not being vigilant and for functioning in the same bureaucratic manner.<sup>59</sup>

On the whole, the consultative process adopted by the Ministry in the formulation of the biodiversity law has been acclaimed as very progressive. It involved a high level of debate and generated a wealth of information. It is worth noting that there is no legal mandate in India, or any pre-determined mechanism, for consultation with all stakeholders affected by a law.

### **Biosafety**

In 1989 the Government of India issued the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells,<sup>60</sup> which to date comprises India's biosafety law. These Rules needed updating pursuant to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, signed by India on 23 January 2001. There is an urgent need to bring the Rules up to date with the international scientific knowledge, information and experience on biotechnology.<sup>61</sup>

The Government of India itself admitted in the second report to the CBD, there are not adequate mechanisms in the country to deal with potentially hazardous technology.<sup>62</sup> For instance, open field trials of Monsanto's transgenic cotton have been allowed by the Department of Biotechnology without proper approval of the Genetic Engineering Approval Committee of the Ministry of Environment and Forests.<sup>63</sup> Highlighting the possible risks to human and ecological health, as well as the need of clear jurisdiction in the biotechnology and regulatory system a writ petition was filed in the Indian Supreme Court challenging these open field trials.<sup>64</sup> The matter is still pending before the Supreme court. In the meanwhile, transgenic *Bt* cotton was found to be growing in the Western State of Gujarat late last year without the Centre or the State governments having given permission for the same. With such an apparent bypass of the regulatory system, posing risks to the natural environment and divided Centre and State opinions on the manner in which it should be dealt with, the debate on whether India should adopt transgenics in agriculture has been rekindled anew. There has been an aggressive propaganda by multinational agribusiness corporations

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<sup>58</sup> Id.

<sup>59</sup> Id.

<sup>60</sup> Framed under Sections 6,8 and 25 of the Environment Protection Act, (1986) Act and issued on December 5, 1989.

<sup>61</sup> Shalini Bhutani & Ashish Kothari, "Rio's Decade: Reassessing The 1992 Earth Summit: Reassessing The 1992 Biodiversity Convention: The Biodiversity Rights Of Developing Nations: A Perspective From India", 32 *Golden Gate U.L. Rev.* 587.

<sup>62</sup> Available at: <http://www.biodiv.org/doc/world/in/in-nr-02en.doc>, pp. 79-80.

<sup>63</sup> Biswajit Dhar "Regulating Biotechnology in India", paper for FIELD / IDS project *Globalisation and the International Governance of Modern Biotechnology*

<sup>64</sup> *RFSTE v. Union of India*, Writ Petition Civil No.71 (1999).



selling genetically engineered crops/products and by government circles in India. In the midst of this propaganda effort, several NGOs are continually stressing biosafety concerns.

The whole concept of the green revolution that revolved round germplasm conservation and its improvement through R & D, as well as the entry of private seed industry into the field, has functioned as the driving intensity in the formulation of Seeds Policy in India. The Patent Act did not specifically address seeds. The National Seeds Policy 2001 has endowed a framework for ensuring the growth of the Seed Sector in a liberalised economic environment. The object is to 'provide the Indian farmers with a wide range of superior seed varieties and planting materials in adequate quantities'.

The amended Patent Act<sup>65</sup> provides that plants and animals in whole or in part, other than micro-organisms, but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals, are non-patentable. Thus even after the present amendment seeds are expressly excluded from the purview of patentable subject matter.

#### **IV PROTECTION OF PLANT VARIETIES**

##### **Background & Policy Formulation**

As noted above, plant genetic resources were not subject to any IPR protection in India until recently. However, India was an active member of the FAO Commission on Plant Genetic Resources, which developed the International Undertaking on Plant Genetic Resources (IUPGR). This arrangement provided for the deposit of plant germplasm in international gene banks, which could be freely exchanged between countries. The main concern was that developed countries were exploiting the system for their advantage. Firstly, it was argued that most of the world's base crop collections and deposits of germplasm were held in the developed world, even though most of the accessions had come from the developing world. Secondly, while traditional varieties and farmers' varieties were treated as being the 'common heritage of humankind', the plant breeders in developed countries were securing IPR protection for their varieties (many a time developed from traditional varieties).<sup>66</sup> In response to a decision to revise the International Undertaking to bring it into line with the provisions of the CBD on access to genetic resources and benefit sharing, the Commission on Genetic Resource for Food and Agriculture adopted a revised text on 1st July 2001, which was submitted to the 31<sup>st</sup> Session of the Food and Agriculture Conference. It was here that the International Treaty on Plant Genetic Resources for Food and Agriculture<sup>67</sup> was adopted on 3<sup>rd</sup> November 2001. India signed and ratified the treaty on 10<sup>th</sup> June 2002.

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<sup>65</sup> See: Section 3(j) of Patent Act, 1970 (as amended in 2002)

<sup>66</sup> See: Graham Dutfield, "TRIPS-related aspects of Traditional Knowledge", 33 *Case W. Res. J. Int'l L.* 233 (2001).

<sup>67</sup> Objectives of the Treaty: The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security, available at <http://www.fao.org/Legal/TREATIES/033t-e.htm>.

Even though India did not provide IPRs over plant varieties, its own folk and traditional varieties, as part of the gene banks, were being used for research to develop new plant varieties in developed countries. The introduction of Plant Breeders' Rights (PBRs) into Indian agricultural dynamics should be seen in the above context.

The Protection of Plant Varieties and Farmers' Rights Act, 2001 has been enacted in pursuance to Article 27.3(b) of the TRIPS Agreement which requires WTO Members to provide for the protection of plant varieties either through patents or through a *sui generis* regime or a combination thereof. The Patents Act 1970 excluded plant varieties from the purview of protection. Thus TRIPS required India to put in place a *sui generis* regime for protection for protection of plant varieties.

The initial draft Plant Varieties Bill, which was introduced in Parliament in December 1999, had generated a lot of criticism among NGOs and farmers' lobbies.<sup>68</sup> A Joint Parliamentary Committee was then appointed in 1999. This Committee visited 15 States and recorded oral evidence of representatives of farmers, experts, individuals etc. and received 132 memoranda containing suggestions. However, certain quarters have criticised this process as being non-transparent and conducted in a very hurried manner.<sup>69</sup>

The then Agriculture Minister, while introducing the Protection of Plant Varieties and Farmers' Rights Bill in the Parliament, explained thus:

The concept of Plant Breeders' rights arises from the need to provide incentives to plant breeders engaged in the creative work of research which sustains agricultural progress through returns on investments made in research and to persuade the researcher to share the benefits of his creativity with society. A system of plant breeders' rights encourages better and mission-oriented research for development of varieties that are fully suited to a given agro-climatic region.

India has developed commendable strength in agricultural research. Indian breeders working, mainly, in the public research system have developed a large number of new varieties. In the absence of plant breeders' rights, these varieties would be freely available to others for exploitation. New varieties developed on the basis of these varieties could get protected in other countries without any benefit accruing to Indian institutions/organisations, whereas the availability of varieties developed in countries which provide for plant breeders' rights would be restricted in India. Therefore, putting in place a system of plant breeders' rights through law in India provides protection to the plant varieties developed by public research system. A system of the plant breeders' rights in the country would also encourage foreign companies to organise buy-back production of seeds in India for export to their countries without any fear of unauthorised use of their genetic material.

The objective of the proposed legislation is to give a significant thrust to agricultural growth by providing an effective system for the protection of plant

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<sup>68</sup> Some of the most vociferous critics of the initial draft were Ashish Kothari of Kalpavriksh, Suman Sahai of Gene Campaign and farmers' lobbies like Kisan Watch. See for example: Ashish Kothari, "Agro-Biodiversity: The Future of Indian Agriculture", <http://www.mtnforum.org>, visited on August 29, 2002.

<sup>69</sup> The public hearings held by the Joint Parliamentary Committee were allegedly said to have been conducted in a highly hurried manner and not as per rules set out for public hearings. See: Dhruva Das Gupta, "Redefining farmers' rights", <http://www.expressindia.com/fe/daily/20000503/fco30031.html>, visited on 22<sup>nd</sup> November, 2002.

varieties and farmers' rights which will stimulate investments for research and development, both in the public and the private sectors, for the development of new plant varieties by ensuring appropriate returns on such investment. It will also facilitate the growth of the seed industry in the country through domestic and foreign investment which will ensure the availability of high quality seeds and planting material to Indian farmers. The proposed legislation recognises the role of farmers as cultivators and conservers and the contribution of traditional, rural and tribal communities to the country's agro biodiversity by rewarding them for their contribution through benefit sharing and protecting the traditional rights of the farmers.<sup>70</sup>

The Indian Parliament passed the Protection of Plant Varieties and Farmers' Rights Act (PPVFRA) in 2001, but, at the time of writing, it is yet to come into force. The debates in the Upper House of the Indian Parliament over the Bill indicate a deep-rooted concern about the hasty manner in which the Bill was being passed, especially in the context of India still having time, until 2005 under TRIPS, for setting in place a regime for protection of plant varieties.<sup>71</sup> The debates also indicate that there was considerable concern expressed by members belonging to a wide political spectrum on the detrimental effect that a law in its present form would have on the farmers and Indian agriculture.<sup>72</sup>

Among the two schools of thought in India regarding adoption of *sui generis* plant variety protection, one school favours the adoption of a UPOV model of plant varieties protection, whereas the second school advocates a non-UPOV frame work for protection of Breeder's Rights which could also uphold rights of local communities conserving the germplasm which forms the foundation of protection of plant varieties. The second school is associated with Green movement in India.<sup>73</sup> India being a rich mega diversity country and having a rich storehouse of land races of principal agricultural crops and also because it has strong R&D base in conventional methods of plant breeding methods, has adopted a *sui generis* protection system in the PPVFRA.<sup>74</sup>

Agricultural research in India has been characterised by public funded research. The Green Revolution in the 1970s was spurred by public sector research and thus the High Yielding Varieties, which were developed, were available to all farmers. With the introduction of PBRs, there would be exclusivity in agricultural technology and poor farmers might be bypassed by the technological changes.<sup>75</sup>

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<sup>70</sup> MKS/GS/5.05/3U-1 - 28.8.2001

<sup>71</sup> Article 65(4) of the TRIPS agreement provides that in cases where a developing country Member is obliged by the TRIPS Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, it may delay the application of the provisions on product patents to such areas of technology for an additional period of five years.

<sup>72</sup> Some of the most vociferous critics of the Bill were Mr.A.R.Kidwai of the Indian National Congress, and Mr.Biplab Dasgupta of the Communist Party of India (Marxist). It is notable that both of these persons were part of the Join Parliamentary Committee, which looked into the Bill and they recorded their dissent to the Report which was ultimately sent by the Committee to the Parliament.

<sup>73</sup> See A. Damodaran, "Regulating Transgenic plants in India: Biosafety, Plant variety protection and Beyond, *EPW*, March 27, 1999. pp.A34.

<sup>74</sup> *Id.*

<sup>75</sup> See generally: Asha Krishnakumar, "Livelihood Security must be the bottom line: Interview with Dr.M.S.Swaminathan", *Frontline*, February 16, 2001, at 112.

### **Protection of Plant Varieties and Farmer's Rights Act**

The Protection of Plant Varieties and Farmers' Rights Act has substantial aspects derived from the International Union for the Protection of New Varieties of Plants (UPOV) at the same time departing from it in certain fundamental ways as will be described below.<sup>76</sup> This was possible because India is not a signatory to the UPOV and the TRIPS agreement too did not mandate for accession to the UPOV.<sup>77</sup> Thus India was able to use this flexibility and incorporate the many safeguard provisions and positive farmers' rights into the Plant Varieties Act.

However, the Indian Government recently announced its intention to sign the UPOV. The official reason put forward by the Government for signing the UPOV is that doing so would guarantee international recognition for Indian plant varieties and that it is also necessary to acquire skills and material resources for plant breeding. The Minister, while replying to a question stated on the floor of Rajya Sabha in July 2002 that

Joining UPOV would be in the interest of our farmers as this would, *inter alia*, facilitate greater investment in research for the development of new plant varieties; in order to ensure the availability of quality seeds to farmers; obviate the need to enter into a large number of bilateral agreements with other countries for mutual recognition of plant breeders' rights; enable Indian plant breeders to secure protection in all Convention countries with minimal formalities and costs, etc.<sup>78</sup>

If India does indeed become a member of the UPOV, there would be substantial repercussions. This is because although the PPVFRA, 2001 follows the same model of protection as that of the UPOV, many safeguards and balances have been incorporated into the Act, such as provisions relating to farmers' rights that might run contrary to UPOV.<sup>79</sup>

It is criticised that this move appears to be in response to international pressure and pressure from the powerful commercial plant breeders. Activists have criticised the view of the Government. Suman Sahai of Gene Campaign commented:

“The argument presented by the government is not only bogus, it is shameful- that joining UPOV was necessary to acquire skills and material resources for plant breeding. If the scientists of the ICAR are so stupid that we need outside skills, let us first close down ICAR. If the intention is to give unlimited rights to biotechnology companies like Monsanto at the cost of Indian farmers, let the government make a statement in Parliament that that is the purpose of joining UPOV. In all the

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<sup>76</sup> The UPOV came into existence in 1978 and was subsequently revised in 1991. For further information see Annex 3.

<sup>77</sup> The TRIPS Agreement does not make any reference to the UPOV. This can be contrasted with other international agreements like the Paris Convention and the Rome Convention with which the TRIPS requires compliance. See: Article 1(3), TRIPS Agreement.

<sup>78</sup> <http://164.100.24.167/rsdebate/synopsis.htm>.

<sup>79</sup> While the PPVFRA will not be nullified, as asserted by the Minister in the Upper House, it would require substantial amendments in areas like farmers' rights, for India to be in compliance with its obligations under the UPOV.

arguments presented by the government, the word Farmer finds no mention. It is only the Breeder and the company whose rights and interests are discussed".<sup>80</sup>

### **Plant Breeders' Rights**

The criteria for protection and the rights given to plant breeders under the PPVFRA and the UPOV 1991 are very similar.<sup>81</sup> To enjoy protection, the variety should conform to the criteria of being novel, distinctive, uniform and stable<sup>82</sup> and the rights, which accrue on protection, include the exclusive right to produce, sell, market, distribute, import or export the variety.<sup>83</sup> The scope of rights under the UPOV 1991 are wider to the extent that the breeders' rights extend over the harvested material and the products made from the harvested material which are obtained from the unauthorised use of the propagating material.<sup>84</sup> Indian law does not have any such provision. India prefers the less stringent version of UPOV 1978 whereby Plant Breeders' Rights are conferred only over "reproductive" and vegetative propagating materials of the protected variety.<sup>85</sup>

Varieties capable of enjoying protection under the PPVFRA include extant varieties (i.e., varieties pre-existing the commencement of the Act), farmers' varieties, essentially derived varieties and new varieties.<sup>86</sup> These rights accrue upon registration.<sup>87</sup> It is noteworthy that under the UPOV extant varieties and farmers' varieties do not enjoy protection. The importance of recognising extant varieties as being capable of protection lies in the fact that India has a rich variety of plants being traditionally produced, and which pre-exist the coming into force of the Act. It would therefore afford a mechanism of protecting these varieties. Even if India does become a party to the UPOV, there would be no international recognition of protected extant varieties, registered in India. Hence, the provision of protecting extant varieties would not be contrary to the UPOV

The maximum duration of protection under the Plant Varieties Act currently is 18 years in the case of trees and vines, 15 years from the date of notification in the case of extant variety and 15 years from the date of registration in the case of a new variety.<sup>88</sup> This is in sharp contrast to the UPOV 1991, which requires much longer terms of protection.<sup>89</sup> The concern has been that after a reasonable duration of protection, the variety should be available to be freely used by farmers. To this extent, India preferred to adopt Article 8 of UPOV 1978.

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<sup>80</sup> . Dr. Suman Sahai: PRESS NOTE, 6 June, 2002, "Govt. sells out farmers to MNCs - Ready to join

<sup>81</sup> See: Annex 3

<sup>82</sup> Section 15(1). The terms 'novel', 'distinctive', 'stable' and 'uniform' are in turn defined in Section 15(3) of the Act.

<sup>83</sup> Section 28, Plant Varieties Act.

<sup>84</sup> Article 14, UPOV.

<sup>85</sup> See A. Damodaran, *supra*, note 73.

<sup>86</sup> Section 2(za), Plant Varieties Act.

<sup>87</sup> Section 28, Plant Varieties Act.

<sup>88</sup> Section 24(6), Plant Varieties Act.

<sup>89</sup> Article 19 of the UPOV, 1991 provides for a minimum period of protection of 20 years for varieties and a period of 25 years for trees & vines.

The scope of Plant Breeders' Rights (PBRs) under the Act is to some extent diluted (compared to the UPOV 1991) also by the nature of farmers' exemption and the concept of farmers' rights as is embodied under the Act. Thus we see that an effort has been made to balance the interests of farmers, and commercial plant breeders while delineating the scope of plant breeders' rights under the Act.

### **Farmers' Rights**

International recognition of farmers' rights is found in the International Treaty on Plant Genetic Resources for Food and Agriculture.

The PPVFRA confers on farmers the right to register a variety that has been developed or bred by the farmer in a like manner as a breeder of a variety.<sup>90</sup> The rationale for this is to prove the point that monopoly IPRs are not restricted to large seed companies and commercial plant breeders, but can be acquired by ordinary farmers as well. It is difficult for farmers' varieties to fulfill the criteria of being stable and uniform. Thus while technically farmers' varieties can be protected and farmers can acquire IPRs over their varieties, the system of PBRs which has been developed to protect varieties developed in laboratories, is inherently unsuitable to protect varieties which develop and evolve *in situ*. UPOV does not contain a similar provision.

Farmers who are engaged in the conservation of genetic resources of landraces and wild relatives are entitled for reward for *in situ* conservation and preservation. These farmers would be entitled to benefit sharing under Section 26 of the PPVFRA if such varieties have contributed to the development of a new variety. However, this provision has been criticised on the ground that it would be very difficult to secure such benefits as the process of placing a claim and establishing entitlement is a very burdensome. A majority of Indian farmers may not be in a position to do all this given their economic and educational status.

Farmers are also entitled to compensation from breeders if the propagating material sold to the farmers does not show the expected performance in given conditions which have been disclosed by the breeders.<sup>91</sup> However, the importance of such a provision is underlined by lessons from past incidents. During the late nineties, farmers in Andhra Pradesh, Karnataka and Maharashtra borrowed huge amounts of money for using seeds and pesticides in the cultivation for export purposes. However, bad quality seeds led to huge crop failures. What followed was large-scale indebtedness and suicides due to non-repayment of loans. The vulnerability of the small Indian farmer, especially to the risks of producing cash crops for the export market is clear.<sup>92</sup> This seems to be the motivation behind this provision. However, it has considerably irked the industry as being too onerous. The UPOV 1991 has no

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<sup>90</sup> Section 2(c), Plant Varieties Act, which defines "breeders" includes within its purview farmers and groups of farmers. Moreover, Section 39(1)(i) Plant Varieties Act specifically provides that farmers are entitled to register new varieties in the same way as breeders.

<sup>91</sup> Section 39(2), PV Act.

<sup>92</sup> For details, see: Ranja Sengupta, A Betrayal of Trust: India sets out to join the UPOV, [http://www.kisanwatch.org/eng/analysis/june02/an\\_UPOV\\_3.htm](http://www.kisanwatch.org/eng/analysis/june02/an_UPOV_3.htm), visited on November 5, 2002.

such provisions and in the event that it joins UPOV, India might be asked to revise this since they could be interpreted to be violative of the breeders' rights.

### **Farmers' Exemption & Innocent Infringement**

A farmer is entitled to save, use, sow and resow, exchange, share or sell his farm produce including seeds which would be protected under the Act, provided that the seed is not branded.<sup>93</sup> This provision thus recognises and legitimises the practice of trade in seeds (even protected seeds) between farmers in villages and towns, prevalent in India for centuries, and to some extent dilutes the monopolistic stronghold of the PBRs by diluting the exclusive right to sell the protected seeds. Exchange of seeds between farmers allows them to plant and grow crops they want to cultivate by trading one variety of seed for another.<sup>94</sup> This provision is especially beneficial for poor farmers, as it enables them to borrow or buy seeds from other farmers cheaply.

Moreover exclusive marketing rights for the breeders or seed companies would have promoted crops, which are commercially most viable, gradually effacing many traditional varieties, and methods of mixed cropping.<sup>95</sup> Thus this provision is of crucial importance even though it is merely declaratory. Farmers' exemption under the UPOV does not provide for the sale of the propagating material.

Section 42 of the Act protects innocent infringement, i.e., when the farmer was unaware of the existence of the right. Though the rule under the PPVFRA is open to subjective interpretations and arbitrary rulings. It also places the burden on the farmer to prove that at the time of the infringement, he was unaware of the existence of the right. Despite these shortcomings, it still remains a genuine attempt to understand the situation of the farmers and their vulnerability.

### **Rights of Communities**

In addition to farmers' rights, rights of communities have also been given some recognition. Any claim attributable to the contribution of the people of that village or local community, in the evolution of any variety for the purpose of staking a claim on behalf of such village or local community, can be made to the authority, which on finding such a contribution to be "significant", will notify a certain amount to be paid as compensation.<sup>96</sup> However, the burden of claiming benefit sharing<sup>97</sup> or compensation<sup>98</sup> is on the claimant. Concerns<sup>99</sup> have been expressed about whether the information about the registration of a given variety will reach the communities or farmers concerned, especially since claims can only be filed at the post registration stage. This is a very important provision for a gene-rich country like India. In India, despite a lack of clarity and cumbersome nature of the benefit claiming process, this rule clearly recognises community rights and attempts to prevent biopiracy.

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<sup>93</sup> Section 39(1)(iv), PPVFRA

<sup>94</sup> See Rajeev Dhavan, "The Right to Seed", *The Hindu*, March 21, 2001, at 8.

<sup>95</sup> Poornima Sampath, "Protection of Plant Varieties and Farmers' Rights Bill, 2000", 2 *IJEL* 1 (2001) 123.

<sup>96</sup> Section 41, PPVFRA

<sup>97</sup> Section 26(1), PPVFRA.

<sup>98</sup> Section 41(1), PPVFRA

<sup>99</sup> For more details, see: Philippe Cullet, "Protection of Plant Varieties", *The Hindu*, March 1, 2001, at 4.

## Public Interest Provisions

The UPOV Convention does not contain any provision relating to compulsory licensing or exclusion of varieties. However, Article 17 of the UPOV lays down that no restriction other than those expressly laid down in the UPOV Convention may be imposed on the rights of the breeder other than in the name of public interest. Thus these provisions might be sustained on this ground even if India does become a party to the UPOV.

1. Compulsory Licensing: The UPOV does not contain any provision for compulsory licensing. The grounds<sup>100</sup> based on which a compulsory license can be granted are:

- When the '*reasonable requirements*' of the public for seed or other propagating material have not been satisfied;<sup>101</sup> or
- The seed or other propagating material of the variety is *not available to the public at a reasonable price*.

In the above circumstances, a compulsory license can be granted for the production, distribution and sale of the seed or other propagating material of the variety. As shown in the Table, the UPOV does not contain a similar provision. This provision is particularly relevant in a country like India in the context of drought conditions.

2. Exclusion of certain varieties from protection: It is provided that no registration shall be made under the Act in cases where prevention of commercial exploitation of such variety is necessary to protect public order or public morality or human, animal and plant life and health or to avoid serious prejudice to the environment.<sup>102</sup>

This provision is extremely important in view of the fact that a number of crop varieties of rice, wheat, pulses and other food crops are essential to protect the food security of the country.<sup>103</sup> It has been suggested that this provision must be effectively used in order to ensure that the varieties, which constitute and cater to the food needs of the poor, are not afforded protection.<sup>104</sup> Moreover, under the Indian law, registration of a plant variety is not allowed if the variety in question involves any technology such as Genetic Use Restriction Technology ("Terminator Technology") which is injurious to the life or health of humans, animals or plants.<sup>105</sup>

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<sup>100</sup> These are embodied in Section 47 PPVFRA.

<sup>101</sup> Section 47 PPVFRA sets out the circumstances in which the requirements of the public are deemed not to have been satisfied.

<sup>102</sup> Section 29(1), PPVFRA.

<sup>103</sup> See generally: Ashish Kothari, "Agro-Biodiversity: The Future of Indian Agriculture", <http://www.mtnforum.org>, visited on August 29, 2002.

<sup>104</sup> Lawrence Surendra and N.S.Goplalkrishnan, "Intellectual Property, Seeds: The Future of Farmers and Farming", (1995) 5 SCC (Journal) 10.

<sup>105</sup> See: Sec-29(3) of PPVFRA 2001, which states that Notwithstanding anything contained under sub-section (2) above and sub-sections (1) and (2) of section 15, no variety of any genera or species, which involves any technology including which is injurious to the life or health of human beings, animals or plants shall be registered under this Act. *Explanation* - For the purpose of this sub-section, the expression any technology' includes genetically use restriction technology and terminator technology.



India, in adopting PPVFRA has chosen the path of *sui generis* plant varieties protection. It is viewed that UPOV 1978 is more suitable to Indian situation in terms of “Breeder’s exemption” and “farmers’ privilege” than UPOV 1991, and also because Indian breeders have developed new cereals and non-cereal varieties. Even if UPOV allows accession to 1978 version, developing countries would be pulled into UPOV process. Reading Article 31 and Article 14 of UPOV 1991, it is possible for a breeder from a UPOV 1991 country to authorise export of his protected plant varieties to a researcher in a non-UPOV country. The researcher can generate an essentially derived variety. UPOV 1978 and UPOV 1991, not being compartmentalised regimes, UPOV 1991 is bound to predominate over its preceding 1978 and 1961 versions.<sup>106</sup>

### **Views of Stakeholders<sup>107</sup>**

The NGOs and activists have expressed the view that India is emulating the Biotechnology policy of UK, US, EU in formulating her policy and law on biotechnology. India also seems to be influenced by international institutions like the UN agencies/donor agencies who have used the carrot of joint collaboration in research and also foreign direct investment.

As regards the question of *adequacy* of the protection in respect of India’s economic and social interest, it was opined that these policies and law are not adequate to shield India’s farmers and biodiversity. While India’s IPR regime is in tune with the international requirements, what is not acceptable is that such an IPR regime will ultimately negatively impact the country’s economy. NGOs demand a framework that protects India’s economic and social interests. Since the biotech industries are profit driven and they focus on producing commercially lucrative transgenic crops, and not necessarily those crops which may be less lucrative but aim at improving the nutritional status of the citizenry. Referring to the case of cassava, an activist stated that despite it being a staple food for at least 300 million people in Africa, no biotechnology company made any effort to improve the crop yield and production. It was only after they found cassava to be a feed substitute for the pig industry in the US that four food and biotechnology companies have begun researching on cassava. This shows, according to him, how animals take precedence over humans when it comes to economics.

One activist further stated “Moreover, the tall claims by the seed companies are not always true. The United States Department of Agriculture and the US government having been pushing the transgenic crops into the third world claiming that they have been tested for safety in their country. However, this is not a guarantee against technological failure or environmental disaster. It is a well-established fact that the extent of hunger and malnutrition that prevails in India is not due to lack of food production but is the result of yawning gaps in reaching food to the vulnerable sections of the society. Or else, there appears to be no justification in allowing the

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<sup>106</sup> See, A.Damodaran, “Plant wealth of India: Economic dimensions of Patenting and Plant Varieties protection”, Biodiversity, conservation and Utilisation of Spices, Medicinal and Aromatic Plants Indian Institute of Spices Research, Calicut, 1999, pp. 322-333.

<sup>107</sup> The research team, as a part of its study, sent questionnaires to various stakeholders and collected opinion from these groups

export of ten million tonnes of surplus wheat in May, 2002 and that too at a time when more than 200 million people go hungry everyday”.

Responding to the question of how they evaluate the *role of current IPR* regime, a number of respondents said that it only reinforces the control of the multinational industries over the seed. IPR protection will increase the price of seeds and this would put them beyond the reach of poor farmers. Further the consequent increase in seed price will also put the food grains beyond the purchase power of the ordinary consumers. In fact, India has no mechanism to ensure that the national interest for biotech research remain safe under the IPR regime that is perceived as having been thrust on India. In response to a question about the UPOV and the present Protection of Plant Varieties and Farmers' Rights Act 2001, several NGOs and activists expressed their opinion, that there are two categories of IPRs that have a direct impact on the erosion of prior rights of communities: patents and plant breeders' rights. Plant breeders' rights negate the contribution of Third World farmers as breeders and hence undermine farmers' rights. Patents allow the usurpation of indigenous knowledge as a western invention through minor tinkering. The UPOV Convention is seen as a Western device by Indian NGOs, which along with patenting leads to biopiracy. This form of intellectual property rights protection, referred to as a plant breeders' rights, is being promoted as the most favourable form of adoption under the *sui generis* option for developing nations by the developed nations. But according to the 1991 revision of the UPOV Convention, newly introduced clauses severely restrict farmers' rights by removing all rights for them to save seed for sowing for the following year, as well as removing researchers' rights to save the seed of new protected varieties. The protected variety may still be used as an initial source of variation for the creation of new varieties but such new varieties cannot be marketed or sold without the plant breeders' rights' holder allowing it. Further, UPOV is a monopoly system that embodies the philosophy of the industrialised north who want to protect the interests of corporate biotechnology and powerful seed companies. If India does not evolve its own *sui generis* system centered on community intellectual rights of farmers and adopts the UPOV model, a rights regime will have been created that protects the rights of the seed industry but offers no protection to the rights of farmers. This in turn will allow a free flow of agricultural biodiversity based on centuries of breeding from the fields of Indian farmers, while the farmers have to pay royalties to the seed industry for the varieties derived from farmers' varieties.

It was further opined that the UPOV system is not in India's interest for the following reasons:

Firstly, it is too expensive. The cost of testing, approval and acquiring a UPOV authorised Breeder's Rights Certificate will cost about two to three lakhs at least. This could even go upto ten lakh rupees. Such high rates preclude the participation of all but the largest seed companies. It will be unaffordable for any small company, farmers' co-operative or farmers or breeders. Secondly, UPOV cannot be accepted by a developing country like India because it is based on the philosophy of the industrialised nations where it was developed and where the primary goal is to protect the interest of the powerful seed companies who are the breeders. In UPOV, rights are granted only to the breeder, and there is nothing for the farmer.

Thirdly, UPOV laws are formulated by nations, which are industrialised, not agricultural economies. In these countries the farming community is by and large rich and constitutes about 2-7 per cent of the population. These countries do not have large number of small and marginal farmers like India. In Europe, agriculture is purely a commercial activity, but in India it is a source of livelihood. These farmers are the ones who have nurtured the genetic resources, which the breeder wants to capture under Breeder's rights.

On the question of free trade and liberalisation, the response was that IPR regimes in the context of 'free trade' and 'trade liberalisation' become instruments of piracy in three ways: Firstly, by *resource piracy* in which the biological and natural resources of communities and the country are freely taken, without recognition or permission, and are used to build up global economies. For example, the transfer of *basmati* varieties of rice from India to build up the rice economy of the US; the free flow of neem seeds from the farms, fields and commons to corporations like W. R. Grace for export. Secondly, by *intellectual and cultural piracy* in which the cultural and intellectual heritage of communities and the country is freely taken without recognition or permission and is used for claiming IPRs such as patents, and trademarks even though the primary innovation and creativity has not taken place through corporate investment. For instance, the use by US corporations of the trade name 'basmati' for their aromatic rice. Thirdly, through *economic piracy* in which the domestic and international markets are usurped through the use of trade names and IPRs, thereby destroying local economies and national economies where the original innovation took place and hence wiping out the livelihoods and economic survival of millions. For example. US rice traders usurping European markets; rice usurping the US market from small-scale Indian producers of neem based biopesticides. In response to a question on bio-resource management policy in India today an activist said that at present India's biotechnology policy seems more focused on safeguarding the interests of the various stakeholders and protecting India's rich resources. Thus the Biodiversity Bill, Traditional Knowledge Bill, etc are primarily concerned with the conservation of the knowledge and resources indigenous to India and seek to ensure that traditional users of such knowledge are made 'benefit sharers' in any commercial exploitation of such knowledge.

## **V CONCLUDING ANALYSIS:**

It is obvious that the policy formulation process in the Indian intellectual property regime for agricultural biotechnology is characterised by a lack of cohesion among policy objectives and the absence of a coordinated effort to facilitate the balancing of the interests involved in the process, which are varied and often conflicting.

The lack of coordination is characterised by the very effort to introduce legislative instruments premised on policy goals and conceptual foundations that are overlapping. The Ministry of Agriculture has drafted the Protection of Plant Varieties and Farmers' Rights Bill; the Ministry of Environment, the Biodiversity Bill; the Ministry of Science and Technology, the Patents (Second Amendment) Act, and the Ministry of Human Resource Development has been attempting at formulation of the Traditional Knowledge Protection Bill. Each of these instruments evidences a certain dominant interest, which is sought to be protected under the regime in question.

The Protection of Plant Varieties Act emphasises the creation of property rights entitled the plant breeder's right aimed primarily at protecting commercial interests

such as those of large seed companies and commercial cultivators.<sup>108</sup> The regime does also seek to provide for a minimal form of protection for farmers engaged in traditional forms of innovation.<sup>109</sup> Innovations such as these would also form an integral component of India's biological diversity, a subject that is sought to be protected under the Biodiversity Bill.<sup>110</sup> In addition to these, a completely independent regulatory regime for traditional knowledge is being mooted (though there does exist some confusion regarding the exact shape such a regime should take). It should therefore be obvious that traditional innovation can form the subject matter of protection under three independent regimes.<sup>111</sup>

Each of these regimes is premised on different or differing conceptual foundations. The Biodiversity Bill is based on the principle of 'national sovereignty over natural resources' and operates as a regime regulating access to and removal of Biological Resources from a certain territory.<sup>112</sup> The concept of the public domain is central to the regime. The PPVFRA, in contrast, envisages a property rights model and is a variant of the traditional plant breeders' rights regime. Even in the context of farmer's rights, the right is in the nature of a proprietary claim. It should therefore be clear that these regimes cannot easily co-exist since they seek to protect the same subject matter but operate on fundamentally divergent principles. Little effort has actually been spent in bringing together the various stakeholders to address these overlaps.

Representatives of the various ministries are, however, of the belief that the level of co-ordination that currently exists is more than sufficient.<sup>113</sup> Under the existent system, a Ministry first constitutes an expert committee which is responsible for the drafting of the instrument. This committee invites representations from different stakeholders and agencies and then submits its recommendations to the Ministry for further action. In most cases, the recommendations are accompanied by a draft instrument in order to expedite the entire process. The committee is not under any obligation to favour or give effect to any specific interest group. Once these recommendations and the draft instrument are handed over to the principal Ministry, the Ministry is at liberty to invite suggestions from other Ministries and Departments which it considers interested or affected by the policy or legislation in question. It is therefore possible for a Ministry to completely ignore an agency or department in the actual policy formation process unless that agency/organisation takes an interest by submitting recommendations of its own volition. Given the excessive workload that

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<sup>108</sup> Section 24-28 of the Protection of Plant Varieties and Farmers' Right Act, 2001.

<sup>109</sup> Section 39 of the PVPFRA

<sup>110</sup> Biological Diversity Bill 2000

<sup>111</sup> Under the Biological Diversity Bill, farmer and community rights under Plant Varieties Act, as non-inventions/ground for opposition and revocation under patent law as well as the proposed independent Traditional Knowledge regime.

<sup>112</sup> The preamble of the Biological Diversity Bill states: "A Bill to provide for conservation of Biological Diversity, sustainable use of its components and suitable sharing of the benefits arising out of the use of the biological resources and for matters connected therewith or incidental thereto....".

<sup>113</sup> The research team had discussions with the officials of the Department of Biotechnology. They stated that there are at different levels interdepartmental co-ordination committees constituted that meet regularly. The official also indicated that the Department of Biotechnology plays a major role in policy formulations by making suitable recommendations on any issue taken up by the government affecting biotechnology.

most Government agencies already experience, it is highly unlikely for any Ministry to submit recommendations without being called upon to do so.

In situations where co-ordination among Government agencies is found to be insufficient, it is unrealistic to expect a high degree of co-ordination between Government agencies and private agencies and private entities. Most private stakeholders are of the opinion that there are some Ministries in which a specific interest is given precedence over others.

A segmented approach, in the absence of proper co-ordination, is capable of resulting in greater confusion in the legislative process and the possibility of conflicting policy goals. This seems to have occurred in the Indian context.

The views of some NGOs have on developments in India's IPR regime in relation to biotechnology have been outlined in the preceding section. Added to this scenario is the role of *international organisations*; inter-governmental, such as the WTO and WIPO, as well as institutions such as the CGIAR. The influence and importance of inter-governmental agencies on domestic policy is conspicuous. The TRIPS Agreement alone is responsible for about six new legislative instruments being introduced in the Indian context.<sup>114</sup>

In the process of implementation of international obligations, the Ministries act within their own official framework. The result being inability to formulate a single national policy that is representative of the various Indian interests involved. An analogy may be drawn to the process of economic reform that occurred in 1991 which, though initially driven by international pressure, was nevertheless transformed into a process of national development suited to the Indian context.<sup>115</sup> This is yet to occur in the Indian intellectual property system. What is responsible for this?

The range and diversity of interests in the Indian biotechnology sector is one of the reasons for this shortfall. The dominant players include members of the industrial and scientific communities, NGOs and, by far quantitatively the largest, the farming communities. Not all of these interests are adequately represented in every policy formulation process. Nevertheless, each does find representation in the overall system. The net effect is a profusion of policies within the legal system, many of which are incapable of mutual co-existence.

The conclusion that can therefore be drawn is that India lacks a cohesive policy formulation process for the intellectual property regime in general, and the agricultural biotechnology sector in particular. The inability of the Government to provide a common platform for differing viewpoints and interests to coalesce and negotiate is responsible for the same.

At the outset, while it may be difficult to balance some of these interests, it nevertheless is essential to at least attempt to do so by bringing them together. Allowing each interest to function independently would be detrimental to India's

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<sup>114</sup> The Geographical Indications of Goods( Registration and protection) Act 1999, The Protection of Plant Varieties and Farmers Rights Act 2001, The Trademarks Act 1999, The Designs Act 2000, The Semi-Conductor Integrated Circuit Layout Design Act 2000 and The Patents [Second Amendment] Act 2002.

<sup>115</sup> See, Ravishankar .A and Sunil Archak, "Intellectual Property Rights and Agricultural Technology, Interplay and Implication for India". *EPW*, July, 1 2000.

national development and more importantly, to its bargaining strategy in international organisations.

While it may be beyond the scope of the present undertaking to suggest a concrete process by which this can occur, it may not be out of place to make a few generalised observations on the shape that an ideal, coordinated and transparent policy formulation process should take.

- The formulation process should be spearheaded by an Inter-Ministerial Coordination Committee on Intellectual Property consisting of representatives of every Central Ministry.
- The formulation process on any specific IPR related issues shall be initiated by the concerned Department / Ministry but left under the control of Inter-Ministerial coordination Committee on Intellectual Property. This would ensure that no interest is promoted over others and that free debate occurs in the process.

The effect of such process would be:

- a) The creation of cohesive policy frameworks for different sectors and a common policy framework around a legal area, i.e. intellectual property.
- b) Enhanced co-ordination neutrality and transparency in the formulation process.
- c) An independent process for new interests and stakeholders to participate without having to lobby for political support.

The patent law has still given priority to the community interests rather than to the monopoly private rights. By excluding from patentable inventions the life forms and inventions based on traditional knowledge, considering traditional knowledge or non-reference to the country of origin as grounds of opposition, Indian patent law has favoured keeping certain interests in the public domain. The idea of a compromise between the extremes of public domain and private monopoly seems to be the option that is being favoured here.

The concern of the State in safeguarding the genetic resources through establishment of National Authorities and benefit sharing processes is on the anvil. Though the role of the proposed Authority is confusing, controversial and overlapping, and at the same time the extraterritorial jurisdiction of the Authority is doubtful, a committed step in this direction is a positive sign.

Farmers' rights and rights of communities are regarded as a counterbalance to the introduction of private, monopoly IPRs into Indian agricultural dynamics. However, many concerns have been expressed as to whether in reality these provisions will actually benefit farmers and communities and tilt the balance in their favour. This is especially so in the context of India where majority of the farming community is poor and illiterate.

Moreover, the manner in which the PPVFRA has been passed seems to reflect anxiety to protect and boost private industry interests. The initial draft of the Bill had evoked

extensive protests from NGOs pressurising the government to dilute private industry interests to some extent by incorporating farmers' rights and rights of communities. India's decision to become a party to the UPOV will have substantial repercussions on the compliance of the PPVFRA with international obligations as a number of aspects of the Act appear to be contrary to the UPOV, which is loaded heavily in favour of the rights of breeders. The move by the Ministry of Agriculture within the Government and the seed industry from outside favouring the accession of India to UPOV, has been countered by NGOs—notably Dr. Suman Sahai of Gene-Campaign, who has filed writ petition before the High Court of New Delhi.

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**ANNEX I**

<b>International convention</b>	<b>National legislation/Bill</b>	<b>Driving Interest</b>	<b>Compliance with</b>	<b>Adequacy/ Deficiency w.r.t. national interest</b>
Agreement on Trade Related Aspects of Intellectual Property Rights [TRIPS]	Patent Act, 1970 as amended in 1999 and 2002	National interest: Inter-National obligations under TRIPS	TRIPS Agreement (First Amendment) Act, 1999 which came into force in March 1999. The Patents (Second Amendment) Act, 2002, The regime of Exclusive Marketing Rights (EMR) introduced by the Patents (Amendment) Act, 1999, has not yet been abolished. Another amendment to the Indian Patents Act, 1970 will be necessary by the end of 2004 to replace the EMR system and introduce product patents	Adequate/
Article 2 of TRIPS agreement dealing with Patentable Subject Matter	Section 2(j) & Section 2(Ja) of Patent Act, 1970 as amended in 2002	To provide necessary safeguards for the protection of public interest, national security, biodiversity, traditional knowledge etc.,	The standard principles adopted right from initial stage of patent law.	Adequate. The NUN test (Novel, useful and non-obvious) has been clearly incorporated into the Act.  Adequate. Reinforces the novelty test that must be applied to biotechnological inventions
Article:27.2 of TRIPS	Section 3 of Patent Act 1970 as amended in 2002 (b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment	Agricultural and Farmer's lobby, NGOs		The flexibility provided are not being exploited completely nor protection obtained. {compulsory licensing]

Article 27.3	Sec 2 of Patent Act 1970 as amended in 2002 (h) a method of agriculture or horticulture; (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.	Agricultural and Farmer's lobby and NGOs		Adequate. Protects traditional farming practices existing in India and other Farmers' Rights.
Article 27.3	(p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.	NGOs	Apart from provisions in Patent Act on patentable inventions, for opposition no separate legislation is made.	Inadequate. A separate legislation to be enacted to protect traditional knowledge in India.
Article 27.3	Section 5: Inventions where only methods or processes of manufacture patentable.	Industry (especially Pharmaceutical companies)		It was in the national interest of India not to allow product patents for food, medicines, drugs and other chemical compounds during the 1970s in order to promote industry and provide cheap access to those substances. However, under the TRIPS Agreement, by Jan. 1, 2005 India will have to grant both product and process patents to all patentable inventions.  However, the distinction between biological, biochemical and microbiological processes remains blurred.

**ANNEX II**

<b>International Convention</b>	<b>National Legislation/Bill</b>	<b>Driving Interest</b>	<b>Compliance with International Obligation</b>	<b>Adequacy/ Deficiency with respect to National Interests</b>
Article 6 of CBD	Section 36 of Biodiversity Act 2002: Central Government to develop National strategies, plans etc., for conservation, etc., of biological diversity.	Social interest/ Government	The Convention Article has been reproduced almost verbatim in the provisions of the Bill.  Substantial compliance	The Bill evidences the commitment of the Government towards conservation of biodiversity.  The establishment of Biodiversity Boards, Heritage sites, etc under the Bill are some of the concrete measures adopted by the Government to implement this commitment.
Article 19 of CBD : Handling of Biotechnology and Distribution of its Benefits	Section 21 of Biodiversity Act 2002: Determination of equitable benefit sharing by National Biodiversity Authority.	Social interest/ Government	The Bill discharges its obligations under the Convention by requiring benefit sharing for resources sourced from India.  However, the Bill is silent with respect to the obligations of parties who have secured biological material from outside India for purposes of research in India. India is developing a strong bio-tech industry and it may be necessary for us to deal with situations of bio-piracy by Indian companies outside India.	The sole aim of the Bill is to conserve the biological resources of India.  One criticism of the provision on benefit sharing under the Bill is that it vests too much of discretion in the hands of the NBA which may be detrimental to the interests of the benefit claimers.
Article 19 of CBD : Handling of Biotechnology and Distribution of its Benefits	Section 36 of Biodiversity Act 2002: Central Government to develop National strategies, plans etc., for conservation, etc., of biological diversity.	Government	The Act addresses the requirement of bio-safety by providing for EIA and disclosure requirements.	India has not yet formulated a comprehensive bio-safety code which is an urgent need of the hour, especially in light of proliferation of GMOs.

Article 8 of CBD: In-situ Conservation	Sec-36 of Biodiversity Act 2002: Central Government to develop National strategies, plans etc., for conservation, etc., of biological diversity.	Social interest/ Government	Efforts have been initiated to draft a Bill dealing with Traditional Knowledge in India.  Substantial compliance.	India is a country which is rich in the traditional knowledge of its communities and the Bill recognises this fact and seeks to protect the same.
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### ANNEX III

<b>International Convention</b>	<b>National legislation / Bill</b>	<b>Driving Interest</b>	<b>Compliance with International Obligations</b>	<b>Adequacy/ Deficiency w.r.t national interest</b>
International Convention for the Protection of New Varieties of Plants (UPOV)	Protection of Plant Varieties and Farmers' Rights Act, 2001. (PPVFRA)		<b>UPOV</b> is not applicable since India is not a signatory to it.	
Article 14 of the UPOV: Scope of Breeders' Rights	Section 28 of PPVFRA 2001	Concern about balancing protection of plant varieties with interests of farmers		Varies with perspective held and the interests involved. The interests involved are: Farmers & NGOs Industry Food Security
Article 20 of UPOV: Kinds of varieties which can enjoy protection	Section 2(za) of PPVFRA 2001	Concern for protecting India's rich repository of traditional varieties.		Doubts have been expressed as to whether at a practical level, such provisions will have much significance since extant & farmers' varieties will have to satisfy the criteria of stability & uniformity in order to secure protection.
Article 19 of the UPOV: Duration of Protection.	Section 24(6) of PPVFRA 2001: provides for a maximum period of protection of 18 years in the case of trees & vines, 15 years from the date of notification in the case of extant	Concern of ensuring that once the breeder has had the opportunity to yield benefits from the protected variety, it should after a reasonable time be available for free use by farmers.		While the industry would want longer terms of protection, a certain kind of balance of interests seems to have been worked out under the Act.

	variety and 15 years from the date of registration in the case of a new variety.			
No provision for Farmers' Rights under the UPOV. However, Art 9 of International Treaty on Plant Genetic Resources for Food and Agriculture recognises farmers' rights.	Section 39, PPVFRA, rights to: register a new variety reward for <i>in situ</i> conservation which has contributed to the development of new variety compensation from breeder for bad seeds and crop failure	In response to protests by farmers' and NGOs to initial draft Bill was tilted heavily in favour of breeders.		Concerns have been expressed that right to register not practically very significant since farmers' varieties not amenable on-farm varieties  Reward to individual farmers-very burdensome process of placing a claim & establishing entitlement. Indian farmers may not be in a position to do all this.
Article 15(2) of UPOV: The authorities have the right to limit the breeders' right.  No provision exempting innocent infringement	Section 39(1) & Section 42 PPVFRA: Farmers' Exemption & provision for innocent infringement	Concern about safeguarding practices of exchange between farmers & protecting their interests	Deviation from the UPOV to the extent that farmers have the right to commercially sell and exchange branded form the seeds though not in its	Are adequate from the perspective of farmers. However, concern has been expressed that it might be difficult for the farmer to establish innocent infringement.
Rights of Communities No provision for this under the UPOV	Section 41 PPVFRA: Right to compensation if they show substantial contribution towards development of a new variety	Recognition of traditional knowledge		Concerns have been expressed as to whether the benefits will actually pass on to the farmers under the existent benefit sharing mechanism, which places the entire burden on the communities to make the claim and establish their contribution
No Public Interest provisions (compulsory licensing and exclusion of	Section 47 PPVFRA: provision for compulsory licenses Section 29(1) PPVFRA:	Food security & safety concerns		Provisions could, if effectively implemented could go a long way in securing these objectives

certain varieties): Except art 17	Exclusion of certain varieties Section 29(3) PPVFRA: restriction of terminator technology have been barred from protection			
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