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Assessing the economic implications of different models for implementing the requirement to protect plant varieties

A case study of India

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As the author of the report, the views and ideas expressed here are my personal and reasoned views; no other person or institutions bears any responsibility for its contents. Comments are welcome and can be directed at the address below.

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ABBREVIATIONS

Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CRO	Contract Research Organization
EDV	Essentially-derived Variety
FAO	Food and Agriculture Organization
FCE	Full-time Equivalent
GMO	Genetically-modified Organisms
ICAR	Indian Council for Agricultural Research
IP	Intellectual Property
IPRs	Intellectual Property Right(s)
MNC	Multi-national corporation
NBA	National Biodiversity Authority
NSC	National Seeds Corporation, Ltd.
OPV	Open-pollinated Varieties
PBR	Plant Breeders' Right
PVP	Plant Variety Protection
SAI	Seed Association of India
SAU	State Agricultural University
SBB	State Biodiversity Board
SSC	State Seed Corporations
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants

EXECUTIVE SUMMARY

Introduction

This is a study of the 'impacts' of implementing Article 27.3(b) of the TRIPs Agreement in India. The study looks at how various international obligations are translated into the architecture of domestic law and analyses the concomitant economic changes that have occurred in plant breeding and the seed industry. India is a useful choice as it a large farming community (65% of the population are dependent on agriculture), an active movement on these issues and an increasingly diverse seed industry with active (often, leading) private sector presence. At the TRIPs Council, India has regularly championed the rights of farmers and the integration of norms and principles from the Convention on Biological Diversity into obligations at the World Trade Organisation. Consequently, studying the way in which this obligation to the TRIPs Agreement is domestically implemented can be a prism into how different domestic (and international) constituencies are handled. The Report analyses the regulatory framework, focussing primarily on the *Protection of Plant Varieties and Farmers' Right Act, 2001*. As the system is still to be operational, the economic analysis looks at the structural changes that have occurred in the plant breeding and seed industry over the last two decades.

Legal Framework

The *Protection of Plant Varieties and Farmers' Right Act*, in specific, and the wider regulatory space concerning plant materials, in general, are driven by a complex set of principles which are not entirely compatible. At one level there are obligations to the TRIPs Agreement and at another level there are the interests of farmers and farming communities. Within these potentially competing pressures, the Act makes a serious attempt at integrating norms and principles of the Convention on Biological Diversity. This is visible in the requirement for a declaration of prior informed consent, i.e. breeding material has been lawfully acquired (section 18(1)(h), the Act). Further, there are provisions for community rights and a gene fund to make operational farmers' rights.

In many ways the Indian legislation pioneers a path that is different and distinct from the dominant template for the protection of plant varieties as mapped out by UPOV. This is evident in the script itself. Beyond the evident absence of 'plant breeders' right' in the title, the right to a breeder follows the successful registration of a variety which "shall confer an exclusive right on the breeder" (cf. section 28(1), the Act). A more substantive difference is in the conditions for registration of a variety. While adopting a similar template of 'novelty, distinctness, uniformity and stability', the Act differs by its requirement for 'essential characteristics'. To explain, the requirement for distinctness requires the variety to be "clearly distinguishable by *at least one essential* characteristic from any other variety whose existence is a matter of common knowledge" (section 15(3)(b), the Act, emphasis added). 'Essential characteristics' is defined in Article 2 (of the Act) to encompass characteristics that "contribute to the principal features, performance or value of the plant variety"; thus substantively different from the procedural treatment of UPOV.

The scope of protection is similar to the scope offered under the 1978 Act of UPOV. The difference is its categorisation of the UPOV exemption for breeders as a 'researchers' right'; thus awarding it a particularly important status. However, it is in providing farmers' rights that the Indian law truly pioneers a different path. The following components constitute farmers' rights:

- A farmer who has bred or developed a new variety shall be entitled to registration and treatment (i.e. protection) in a manner akin to a breeder
- A farmers' variety is entitled to be registered if it fulfils all requirements
- A farmer engaged in conservation and improvement of genetic resources shall be entitled to recognition and reward from the Gene Fund
- A farmer is entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a protected variety provided that the farmer does not sell branded seed of the variety.

There are other provisions that support farmers' rights, such as protection against innocent infringement (section 42). Farmers are protected from alleged infringement when it can be established that "at the time of such infringement [the farmer] was not aware of the existence of such right" (section 42(i), the Act).

An authority is to be set up to administer the Act. The Act also provides for various public interest measures which include a comprehensive ban on varieties that include technologies that are injurious life and health of human beings, animals or plants.

Given the historicity of the Patent Act, 1970, there is no explicit mention of biotechnology or phraseology that might allude to the attempts to demarcate the micro- from the macro-biological as pioneered in the Strasbourg Convention. However, in Section 2, where various definitions are expressed, inventions are said to mean "any new and useful […] (i) art, process, method or manner of manufacture; […] (ii) machine, apparatus or other article; […] (iii) substance produced by manufacture, […] and includes any new and useful improvement of any of them, and an alleged invention" (section 2(j), Patent Act, 1970). Chapter II sets out 'Inventions not patentable' which includes 'prophylactic processes for treatment of humans, animals or plants' and excludes 'a method of agriculture or horticulture'. Despite these provisions, case law (e.g. Agracetus transgenic cotton patent dispute of 1994) demonstrates the problems in administering this exclusion.

Following the TRIPs Agreement, the *Patent Act, 1970* underwent three revisions. In the Second amendment, a new clause, 3(j) was inserted: "plants and animals in whole or any part thereof other than micro-organism but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals;". This paved the way for the *sui generis* option for the protection of plant varieties. It was in the Third amendment that Section 5 (which identified non-patentable inventions) was deleted. Now, patents on microorganisms are possible.

Seed Market Regulations are another sphere of regulations. The 1980s form a watershed in the transformation of the Indian seed industry. In 1983 a policy to release publicly bred varieties to the private sector was introduced. In 1987 there was a

marked relaxation of industrial licensing regulations and in 1988 a new seed policy was announced. The latter allowed private sector companies to enter the industry across a range of crops and also relaxed the constraints on seed imports.

In 2004 a Seed Bill was introduced in Parliament that seeks to replace the *Seed Act, 1966*. It proposes for all varieties to be registered and meet certain prescribed minimum standards. In establishing these standards, there are measures to back the consumer (i.e. farmer) from fraudulent seedsmen. To promote certified seeds and the certification process, it allows for self-certification. The report reviews some of the proposals and notes the concern of commentators of a lack of consistency between these provisions and those present in the *Plant Variety and Farmers' Rights Act*.

Economic Impacts

The seed industry has historically been the reserve of the public sector – framed by the establishment of the National Seed Corporation in 1963 and the success of the World Bank funded Tarai Seed Development Project that launched the high-yielding varieties in the 1960s. Yet, in the 1960s, small private seed companies were set up – many with technical training from the Rockefeller Foundation and the US Agency for International Development. By 1985, it is estimated that of the 420,000 metric tonnes of seed, the public sector produced 240,000 metric tonnes. The private sector has focussed on crops that have been successfully hybridised: sorghum, pearl millet, maize, cotton, sunflower, and some oilseeds. Many of the seed firms had fledging plant breeding operations and dependent substantially on publicly bred germ plasm – and at times finished varieties. Yet, through the years, the private sector has grown in size and accounted for leading shares. One estimate indicated that hybrid seed market shares of 40% in maize, 70% in pearl millet, 90% in sorghum and over 90% in vegetables. In the early 1990s, data suggests that over 40 seed companies have turnovers valued at US$500,000. A key large player is the Maharashtra Hybrid Company (Mahyco) valued in the 1990s at over US$14Mn. Following the liberalisation and other policy changes in the late 1980s, the seed industry has been subject to a phase of mergers and acquisitions initiated by MNCs resulting in significant consolidation: Monsanto has acquired a 26% stake in Mayhco, Agrevo controls 100% of Proagro, Emergent Genetics has acquired 74% stake in Mahendra Hybrids and Pioneer Hybrid has a 51% stake in SPIC. More recent data would suggest a deeper level of mergers and acquisitions. Recent estimates give the (organised) private sector a 67% market share that is valued at US$3.6Bn.

Private sector R&D spending is estimated at having doubled between 1988 and 1996. Without doubt this research is also driven by its focus on 'proprietary' hybrids – evidenced by the increasing rate of release of hybrid varieties that has accelerated. For example, of the 110 maize hybrids released between 1991/97, 93 were from the private sector. There have been substantial investments in agricultural biotechnology with the private sector investments estimated at US$10.62Bn. This outstrips the public sector investments of US$7.37Bn.

For some indigenous firms these structural transformations are difficult to handle. In particular, a fear of technological dependence may be appearing. This builds on their dependence on the public sector for germplasm. However, there are other firms that have entered into technological alliances or form part of the M&A activity.

The research finds the public sector in a complicated position having to confront difficult policy options. There is an opportunity to re-draw the relationship with the

private sector. Equally, there are opportunities of using PBRs as an instrument for cost-recovery and revenue generation. Within this mix, a particular observation is striking. In as much as the private sector will tend to focus on hybrids, there is a strong mandate for research on OPVs and on crops and regions that will remain neglected, such as rice and wheat – the two key food crops of the country. It is clear from the Act that the public sector will seek PBRs on their varieties. Thus, the issue of how these varieties will be licensed to seed firms remains. In making its decision, the public sector should take cognition of the impact of this decision on the competitive structure of the industry. The relatively low seed-to-grain price ratio in India is testimony to the elaborate and competent network of seed growers and seed firms. A licensing policy that compromises this network and leads to the exit of seed firms could potentially make the seed market non-competitive.

1 INTRODUCTION

This is a study that focuses on the 'impacts' of implementing Article 27.3(b) of the Trade-Related Intellectual Property Rights Agreement (TRIPs Agreement) in India. Unlike some of the other studies that constitute this work package, this is based on secondary literature. India presents a useful site for a case study on plant variety protection for a variety of reasons. Amongst countries in the Global South, it stands out for its strong resistance to IPRs, in general, and IPRs in plants, in specific. During the Uruguay Round negotiations, there were regular protests against the provisions concerning IPRs in plant varieties. With a strong farmers' movement and engaged civil society organisations it is useful to note that the eventual law is reflective of these views. Moreover, at the TRIPs Council and other multilateral fora (e.g. Convention on Biological Diversity), India tends to advocate the position of farming communities and traditional knowledge holders. It is also the case that the country boasts a very capable scientific community. Following the regulatory changes of the 1980s/90s, the seed and plant breeding industry has flourished. Thus, a demand for strong IPRs is also found domestically. For that matter, public sector workers and institutions are also *demandeurs*. The public sector, *Council for Scientific and Industrial Research*, is the leading patentee from 'developing countries' using the Patent Cooperation Treaty system.

These different factors place varying pressures on the government as it implements its obligation to different multilateral institutions. There is no *a priori* reason to assume that these pressures are either consistent or overlapping. Consequently, studying the way in which this obligation to the TRIPs Agreement is domestically implemented can be a prism into how different domestic (and international) constituencies are handled. The relevant law was passed in 2001 and came into force only in 2003. Thus, there is no

data and existing studies tend to reflect on the structural changes that have taken place in the wake of the 1980s/90s reforms. A similar focus is adopted here.

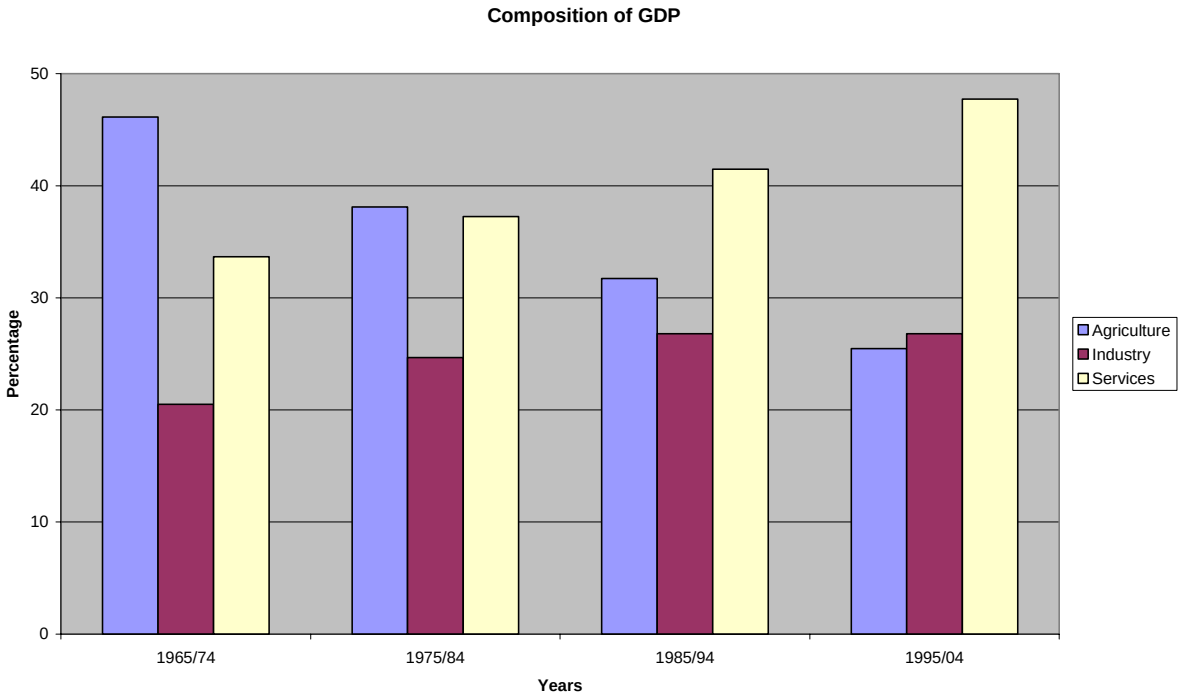
The report begins with an overview of the state of the economy drawing particular attention to agriculture. This overview also provides information about the state of the seed industry and plant breeding. This is followed by an analysis of the national legislative framework in the area of plant material where particular attention is devoted to plant breeder's rights. Other complementary regulations, such as the patent system, seed certification schemes, and biodiversity laws are also analysed. Section 4 presents the main data analysis where emergent trends in the seed and plant breeding industry are identified and studied.

2 BACKGROUND

2.1 *Macroeconomic Context*

It is quite natural to marvel at the contemporary economic *miracle* of India's rapid economic growth marked by annual growth of GDP in excess of 6% in the 1994/04 period. This is quite in contrast to the roughly 4% per annum growth of the 1960s/70s – a rate that has derisively been termed the 'Hindu rate of growth'. This economic performance has been a service sector lead growth, which in the last decade has grown at rates in excess of 9%, though averaging 8.1% in 1994/04. In terms of GDP and over a longer time horizon, it is evident that the service sector has played an increasingly important role (Figure 1).

Figure 1: Sectoral Composition of GDP, 1965-2004



The service sector has grown rapidly and substantially. For example, when 'reforms' were initiated in the early 1990s the size of the sector was US$97.56Bn (1990) and now in 2004 it is estimated at US$278.07Bn; a growth of 185%[1]. Between 1975/84 and 1995/04, the size of the service sector increased by over 250%, increasing from US$51.17Bn to US$142.02Bn[2]. In the same time, agriculture increased by 77% from US$57.9Bn to 102.65Bn. The share of the three sectors in 2004 puts this transformation in perspective: agriculture 21%, industry 27% and service 52%. The strong growth of the economy has also been reflected in improvements in per capita

[1] These figures are in constant US$ (2000).

[2] These figures are in constant US$ (2000).

incomes, which in the last decade (1995/04) has grown at 4.3% per annum. Per capita incomes have increased from US$350 (1995) to US$538 (2004)[3].

Agriculture in India is diversified in terms of the crops, the agroclimatic condition and its production activities. A dominant feature of the agricultural landscape is the presence of small holders (less than 2 hectares): small holders account for 80% of total farm holdings and occupy 40% of total agricultural land area. Reflective of this is the fact that agriculture provides a livelihood for over 65% of the population (Government of India, 2005). Total agricultural production is dominated by crop production, which accounts for 75% of agricultural production with the balance constituted by livestock production. Food grain production contributes the largest share of agricultural production, accounting for around 65% of gross cropped area. The two main crops are rice and wheat: approximately 75% of food grain production and 55-60% of gross cropped area. Maize, another key crop that has also attracted significant private sector activity (see below), accounts for 3-4% of gross cropped area. Food grains production has steadily increased from the 1960s. The adoption of the 'seed-fertiliser' technology package directed at irrigated lands, i.e. the Green Revolution, led to an increase in production from 82 million tonnes in 1961 to 108.4 million tonnes in 1971 (Table 1).

Table 1 Economic Indicators in Agriculture

	1961	**1971**	**1981**	**1991**	**2002**
Net cropped area (Mn ha)	133.2	140.3	140.0	143.0	141.1
Fertiliser use (kg/ha)	1.9	13.1	31.8	67.4	89.8
Food grain production (Mn tonnes)	82.0	108.4	129.6	176.4	212.0
%age total production:					

[3] These are in constant US$ (2000). Comparable figures in constant Rupees are Rs10, 083 and Rs15, 491.

Crops	82.4	84.4	81.4	74.7	71.2
Livestock	17.6	15.6	18.6	25.3	28.8
Average size of holding (ha)	2.69	2.30	1.84	1.57	1.06(a)
%age agriculture in:					
Total export value	44.3	36.8	36.5	22.5	12.4
Total import value	36.4	37.0	18.3	11.3	6.2
(a) 2002-03, Central Statistical Office of India *Source*: Economic Survey, various years					

During the same period, the use of fertiliser increased from 1.9 to 13.1 kg/ha. Wider adoption of these high-response varieties and their adaptation to rain-fed areas also were critical in widening their adoption. Thus, in the 1980s, agricultural production and productivity continued to rise. Yet, many of these technological interventions have not either penetrated wider into or been directed at adverse agroclimatic conditions.

Table 2 Average Growth Rates

Five year Plan	Growth rate of Agriculture & Allied Sectors	Overall GDP growth rate
Seventh Plan (1985-1990)	3.2	6.0
Eight Plan (1992-1997)	4.7	6.7
Ninth Plan (1997-2002)	2.1	5.5
2002-03*	-7.0	4.0
* Provisional		
Source: Economic Survey 2004/05		

This could be a factor accounting for the post-reform period of deceleration in agriculture. The average annual growth rate in agriculture (and allied sectors) declined from 4.7% during the Eight Plan (1992-97) to 2.1% during the Ninth Plan (1997-2002) while provisional figures for 2002-03 are -7.0% (Table 2).

A constant feature of the *Economic Surveys* concerning agriculture is India's dependency on climatic conditions, in particular, erratic, delayed and uneven rainfall. This is reflected in agricultural yields. Yields in rice increased from 2329 kg/ha in 1989 to 2929 kg/ha in 1999, crossing the 3 tonnes/ha mark thereafter. In wheat, yields

increased from 1870 kg/ha in 1985 to 2559 kg/ha and 2.71 tonnes/ha in 2004 (Table 3). It is the slowdown in yields that lies behind the deceleration. The *Economic Survey 2004-05* notes that "[P]romoting more rapid agricultural growth is important not only to achieve higher economic growth, but also to life large number of households in rural areas out of the poverty and unemployment circle" (Government of India, 2005, paragraph 8.55).

Table 3 Crop Yields (tonnes/hectare)

Crops	1985	1990	1995	2000	2004
Rice	2.33	2.63	2.78	2.85	3.04
Wheat	1.87	2.12	2.56	2.78	2.71
Maize	1.15	1.52	1.48	1.82	1.88
Source: Economic Survey (various)					

A final feature of the agriculture sector is its trade performance. Agricultural exports include a wide and varied portfolio that includes pulses, rice, wheat, cereals, tobacco, sugar, poultry and dairy products, horticulture, spices, tea/coffee, processed vegetables and fruits. These may be categorised into three groups: raw products, semi-raw products and processed and ready-to-eat products (Government of India, 2001). Major exports are cereals (Basmati and non-Basmati rice), spices, cashew, tea/coffee, tobacco and marine products. The share of agriculture in export has declined from its high of 44% in 1961 to about 12% in 2002 (Table 4).

Table 4 Export of Agricultural Products

	1996-97		1998-99		2002-03		2004-05 (Apr.-Sept.)	
	Million US dollar	Percent share of agri-exports	Million US dollar	Percent share of agri-exports	Million US dollar	Percent share of agri-exports	Million US dollar	Percent share of agri-exports
Tea	292	4.3	538	9.0	343.6	5.1	197.2	5.6
Coffee	402	5.9	411	6.8	205.5	3.1	111.0	3.2
Cereals*	1 104	16.2	1 495	24.9				

Rice					1 218.1	18.1	456.3	13.0
Wheat					363.6	5.4	220.7	6.3
Oil Meals	985	14.4	461	7.7	308.8	4.6	298.4	8.5
Marine Products	1 129	16.5	1 038	17.3	1 431.6	21.3	549.5	15.6
Cashew	362	5.3	387	6.4	424.2	6.3	240.2	6.8
Fruits & Vegetables	208	3.0	183	3.1	300.2	4.5	200.5	5.7
Agricultural Exports	6 828	100.0	6 014	100.0	6 734	100.0	3 511	100.0
Total Exports	33 470		33 218		52 719.4		36 235	
Agri-export as per cent of total exports	20.4		18.1		12.8		9.7	
* Disaggregation of cereals began in 2002-2003 *Source:* Economic Survey 2000/01 and 2004/05								

Though the total value of agricultural exports has increased in recent years, rising from US$6.7Bn to US$7.5Bn between 2002-03 and 2003-04, the country's share in world trade is just about 1%. The government has recognised this situation and identified the following constraints (Government of India, op. cit.): conflicting domestic policies and interests, higher domestic prices and limited market intelligence. The Foreign Trade Policy 2004-09 has placed a priority on boosting agricultural exports.

2.2 *Plant Breeding*

The significance of varietal improvements and good quality seeds was recognised by the *Royal Commission on Agriculture* (est. 1928). The Commission placed emphasis on the production and distribution of high quality seeds; however, little was done to implement its action plan (Singh et al., 1995, p9). In its post-colonial incarnation as the *National Commission on Agriculture* that policy and institutional action takes place, such as the formation of the *National Seeds Corporation Ltd.* in 1963 (see below). Though, a key institution in the plant breeding sector, the *Indian Council for Agricultural Research* was established in 1929 and has over the years become the principal agency planning and coordinating plant breeding research in India. This now occurs through a broad network of 48 central institutes, 5 national bureaus, 32 national

research centres, 12 project directorates and 62 all-India coordinated research projects[4]. It's a vast network that has manpower of about 30,000 personnel, of which nearly 6500 are scientific posts and 8000 are technical posts. ICAR promotes research, education and extension education in 39 State Agricultural Universities (SAUs), 5 Deemed Universities, 1 Central Agricultural University for the North-Eastern Hills Region and 4 Central Universities by giving financial assistance in different forms. The SAUs, initiated on the recommendation of two Indo-US reviews in 1955 and 1960, were modelled on the land grant colleges of the US. The first SAU was established in 1963 in Pantnagar, Uttar Pradesh and presently there are 39 SAUs and one Central agricultural university (http://www.icar.org.in/sau.htm). Finally, there are the *Krishi Vigyan Kendras* (KVKs, i.e., agricultural science centres), over 260, that are responsible for the transfer of new technologies and practices to farmers.

An example of how this large and expansive network of public agricultural research works is best seen from the perspective of a crop. In 1957 the Coordinated Maize Improvement Programme[5] was initiated with the support of Rockefeller Foundation[6]. Given the diverse agroclimatic conditions, the Directorate has established 27 commodity-specific maize research programmes throughout the country. Public investment in maize research has been substantial; however, it is difficult to delineate the particular amount devoted to maize research.

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[4] The All-India Coordinated Research Projects were started in 1957 with maize and funded by the Rockefeller Foundation.

[5] Now the Directorate of Maize Research.

[6] This paragraph is based on Singh, Pal & Morris (1997) and Singh, Kumar & Singh (2002).

Table 5 Investments in Maize Research, 1999

Particulars	Public sector research	Private sector maize research		
		National companies	Multinational companies	Total private sector
Number of research programmes	30	18	5	23
Maize research personnel				
Senior-level scientists	33.0	42.0	8.5	50.5
FTEs	102	71	16	87
Researchers engaged in (per cent)				
Germplasm improvement	78	95	96	95
Crop management research	17	5	4	5
Other/unknown	5	0	0	0
Annual budget (Rs. Million)	42.3	27.1	37.5	64.6
Source: Singh et al. (2002)				

An alternative proxy used is full-time equivalent scientists at the senior level (FTEs) (Table 5). Thus, in 1999, there were 30 public research programmes that employed 102 FTEs and the majority (78%) were employed in plant breeding, 17% in crop management research and 5% in research and extension work.

Table 6 Research Intensity of Public Agricultural R&E Funding

Indicator	1961-63	1971-73	1981-83	1991-93	1997-99
R&E expenditure					
Constant local currency units (billion 1999 rupees)	2.697	6.576	7.892	14.335	17.885
Total expenditure (million 1999 international dollars)	312	760	912	1 657	2 068
Research expenditure as percentage of AgGDP	0.11	0.22	0.23	0.28	0.31
Source: Pal and Byerlee (2006)					

The ICAR receives funds from the Government of India and from proceeds of the agricultural proceeds cess. In 1995/96, the ICAR budget was of Rs.56Mn. Its revised budget estimate for 2004/05 was Rs.17, 533Mn. ICAR institutes account for less than 40% of the national expenditure on agricultural research and extension (Pal & Byerlee, 2006)[7]. Total (public) funding has increased in real terms from $284Mn in 1961 to

[7] The rest of the paragraph is based on Pal and Byerlee (2006).

$2893Mn in 2000[8]; thus registering a 10-fold increase in four decades. While impressive, other indicators point towards underinvestment in India. In particular, post-1990 the 'intensity of research funding'[9] has stagnated and stabilised around 0.3 (Table 6). This compares unfavourably with either the global average of 1.04 or China's estimate of 0.43.

The private sector has had a presence in the plant breeding and seed sector since the 1920s; though, in the early years the activities were mainly devoted to importing seeds for vegetable and flower production (Rao, 1997, p48). Even post-independence activity was relatively modest with one scholar finding only 9 R&D-based seed companies in 1985 (Agrawal, 1990) and increasing to 40 in 1995 (Rao, op. cit.). Others recognise the turbulence in the industry and note that "India's private maize breeding programmes are still in their infancy; approximately half have been launched since the seed policy reforms were introduced during the late 1980s" (Singh, et al., 2002, p435). One aspect of this turbulence is the entry/exit of seed companies and accompanying consolidation within the industry that is largely on account of MNCs buying into Indian seed companies. Thus, by 2001, these were the key movements: Monsanto has acquired a 26% stake in Mayhco, Agrevo controls 100% of Proagro, Emergent Genetics has acquired 74% stake in Mahendra Hybrids and Pioneer Hybrid a 51% stake in SPIC (Rangnekar, 2003).

Private plant breeding has a diverse crop presence with one estimate of about 122 varieties/hybrids (through 1995): 55 in vegetables, 39 in millets, 13 in cotton, 9 in

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[8] These figures are in 1999 international dollars.

[9] Agricultural research expenditures as a share of agricultural GDP (AgGDP).

oilseeds, 4 in fodder crops and 2 in pulses (Agrawal, 1996). Basant (1995) suggests that Indian private breeding companies spend about 4% of their sales revenues on R&D and this compares well internationally. However, other studies provide a broader spectrum of R&D intensity that averages about 2.6% across the industry (Rao, 1997). Other commentators conducting survey-based empirical studies provide evidence of the structural changes that have occurred in the Indian seed industry. Pray et al. (2001) compare the performance of private investment in the Indian seed industry at two points in time, viz. 1987 and 1995 to discern the impact of the 1980s reforms (Table 7).

Table 7 Economic Characteristics of Private Sector Seed Companies

	Average Sales (Rs. Million)	Average Number of Employees	Average R&D (Rs. Million)	R&D to Sales Ratio (%age)	R&D to Employee Ratio (Rs. Million)
Entrants[1]:					
Large (5)	174	70	10.0	5.75	0.143
Small (15)	17	14	0.7	4.12	0.050
Incumbents[2]:					
Large (7)	282	313	11.0	3.90	0.035
Small (20)	41	72	0.9	2.20	0.013

Source: Rangnekar (2003)

[1] Entrants are firms that entered the seed industry after 1987, totalling 20.

[2] Incumbents are firms in existence prior to 1987 regulatory changes, totalling 27.

Note: (a) number of firms in each class are reported in brackets, (b) total firms in survey = 47, (c) all R&D figures are nominal.

Three claims are made: there has been an increase in the R&D effort, the higher R&D ratio of entrants suggests that reforms have stimulated research intensity, and the fall in concentration ratios supports a claim for increased diversity of technology suppliers. Rangnekar (2003) finds the evidence less compelling and suggests that a higher R&D

ratio for entrants is simply on account of the high start-up investments and potentially lower sales upon market entry. Yet, the diversification of technology suppliers is an important observation. Further, increased funding by private sources is evident. Basant and Ramaswami (2001) find that funding by private and state-owned enterprises has doubled from US$24Mn in 1985 to US$51Mn (in 1995 dollars).

The evidence from maize corroborates the point of a widening pool of technology suppliers (Table 5). By 1997, the private sector employed 87 FTEs with much of the activity devoted to germplasm improvement (95%) and limited attention to crop management (5%). Between 1961 and 1993, the private sector developed 80 varieties and they were all hybrids. In contrast, the public sector released 96 varieties of which 27% were hybrids. As Morris et al. (1998) note, the primary differences in the breeding programmes is notable here. Thus, apart from breeding open-pollinated varieties, public breeding is also directed at wider range of agroclimatic conditions. A key element to the sustainability of diverse technology suppliers is the germplasm used. Privately bred varieties are substantially based on publicly developed germplasm much of it sourced nationally (33%) and from international public sources (25%). This corroborates early work on the transformations in the seed industry where Basant (1995) concludes: “Much of the genetic material, self- and open-pollinated varieties and the inbred lines used by the private sector is obtained from the Indian public sector research institutions or the International Agricultural Centres” (p26). This places the issue of future access in question and draws attention to the licensing/royalty policy that public agriculture will adopt in the future.

A final feature of the section focuses on developments in agricultural biotechnology. India was one of the few countries in the Global South to recognise and act on the importance of this technological development. In 1982 the National Biotechnology

Promotion Board was established as the nodal agency to lead biotechnology research. In 1986, the Board was later restructured to become the Department of Biotechnology (Dhar, 2002). Overall, there are several public agencies that have programmes supporting biotechnology, such as the Department for Scientific and Industrial Research, the Department of Science and Technology, the Indian Council for Agricultural Research and the Indian Council for Medical Research (Chaturvedi, 2005)[10]. Resource allocation has increased from US$3133Mn in 1990/91 to US$8579Mn in 2004/05 (Table 8).

Table 8 Funding of Biotechnology in India

	1999	2002
Private Sector	3122	10616
Public Sector*	6768	7368
*2000/01; 2002/03 Source: Chaturvedi (2005)		

It is in this sector that the private sector has been active either in terms of institutional designs for sourcing finance (e.g. venture capital) or technology (e.g. contract research organisations). The latter is a particular phenomenon and one data source suggests that around 60% of the firms in biotechnology are either small start-ups or CROs. Private sector investments in biotechnology have increased from US$3.1Bn to US$10.62Bn between 1999 and 2002 respectively (Table 8). Thus, outstripping the investments made by public agencies.

[10] The balance of this paragraph is based on Chaturvedi (2005).

2.3 *The Seed Industry*

The significance of quality seeds was initially recognised by a colonial body, the *Royal Commission on Agriculture* (1928), which sought changes to improve the production and distribution of quality seeds. However, little was done till the post-independence *National Commission on Agriculture* presented an action plan in the 1960s (Singh et al., 1995, p9-10). This began with the establishment of the *National Seeds Corporation, Ltd.* (NSC) in 1963 which was mandated with production and distribution of good quality seeds. Subsequently, the *Seeds Act, 1966* was passed to lay the foundations for a regulatory system to prescribe quality standards, certify seeds, and set standards and oversight institutions for the production and distribution of seeds (cf. section 3.3). A little before these developments was the *effective* start of what became the Green Revolution. In 1957, with the support of the Rockefeller Foundation, the *All India Coordinated Maize Improvement Programme* was initiated (Rao, 1997, p42). This led to the introduction of the dwarf (and high-response) maize varieties which were gradually adapted to Indian conditions. In a few years the programme expanded to sorghum and millet and by the mid-1960s to wheat and rice. As these new developments occurred there was a broadening of the seed system through expanding the NSCs and developing a network of *State Seed Corporations* (SSCs). Pal & Tripp (2002) recognise the deeper significance of the network of SSCs that were set up to delivering good quality (Green Revolution) seeds. Not only was a high-standard of seeds generally maintained, but it also led to the formation of a network of experienced seed growers. Further, a strong competitive element was developed in the seed sector, which is reflected in the relatively low seed-to-grain price ratio (Pal & Tripp, op. cit.).

The liberalisation of the economy that began in the 1980s and continued through into the early part of 1990s initiated a significant transformation of the seed industry. In

1988, the government announced the *New Policy on Seed Development* and simultaneously, there were changes to the *Industries Development and Regulation Act, 1956* and revisions to controls on import/export of seeds. Lastly, in 1991 a new *Industrial Policy (1991)* allowed for automatic approval for foreign technology and equity in select spheres of the seed industry. These changes provided a crucial impetus to the private sector, which had only organised themselves under the *Seed Association of India* in 1985. A large number of MNCs entered India after these changes: Cargill, Sandoz, Continental Grains, Ciba-Geigy, Pioneer Hi-Bred, and Hoechst (Pandey & Chaturvedi, 1993). Reviewing the list of approved technical and foreign collaborations (up to 1993); Rao (1997) concludes that they are both entirely devoted to hybrid seeds and limited adaptive R&D. Given the technological dependence of Indian seed companies, Rao contends that domestic companies are needed to deliver technical developments. Over the years the private sector has recorded impressive growth in the seed sector; thus, by the early 1990s, it is said to account for 40% in maize, 70% in pearl millet, 90% in sorghum, and over 90% in vegetable seeds (Pandey & Chaturvedi, 1993)[11]. Most of this growth has come from hybrid seeds and it is fair to note that the private sector has been quick to adopt public sector varietal developments, such as cotton hybrids that made India the world leader in cotton hybrid seed production (Louwaars et al., 2005, p54).

Without diminishing the transformation, it is useful to bear in mind the unreliability of data. As Singh et al. (2002, p440) note, “Public seed agencies and private companies both have reasons to conceal the truth about their sales”. Thus, it is not surprising to find alarmingly different assessments. For example, Pray et al. (1991) finds more than

[11] These are rough estimates of the share of the commercial seed market.

70 seed companies operating whilst Pandey (1994) contends that there are some 500 seed companies. Another qualifier to the estimates is that they tend to focus only on 'commercial seed' sales. While it is difficult to be accurate, many commentators suggest that 'informal' seed sector provides for 75% of the market. Others suggest that 62% of total seed requirement is through the informal sector. In some cases, such as rice, nearly 90% is home-saved or locally acquired (Louwaars et al., 2005, p61).

Table 9 Market Shares in Maize Seed Sector

	1981-83	1985-87	1990-92	1997-99
OPVs				
Public	167	811	658	388
Private	0	193	485	608
Hybrids				
Public	4675	2436	2326	1322
Private	378	705	6267	32295
Source: Singh et al. (2002)				

With these qualifiers in mind, the growth of the private seed sector in maize remains impressive (Table 9). Clearly, the private sector now dominates the seed market and this is overwhelmingly on account of hybrid seed sales. While the private sector has also made substantive inroads into OPVs, it is also the case that OPVs account for a shrinking share of the total maize seed market. The evidence corresponds with the increasing plant breeding activities of the private sector (Table 5). However, not only does the private sector depend substantially on the public sector for germplasm, but it is also systematically multiplying public sector varieties.

The Indian seed industry is a large and diverse entity and as Louwaars et al. (2005, p92) observe, there is no single or easy indicator to capture the industry. Basant (1995), following other contributors, suggests a six-level classification of the Indian seed industry: seed firms without R&D; seed firms with R&D; seed firms with foreign collaborations; MNC subsidiaries; joint-sector firms; and, public sector firms. Clearly,

firms will be differently impacted with the ongoing policy changes and structural transformations: “firms without R&D facilities may either have to develop these facilities or develop linkages with domestic and/or foreign companies that are technologically dynamic” (Basant, 1995, p27).

3 THE LEGAL FRAMEWORK FOR PROTECTING PLANT MATERIAL

Much like the complex global rules and provisions concerning plant material, the domestic architecture of law in India is complicated. This includes different intellectual property laws, seed market regulations and legislation concerning biological diversity and biosafety as well. The national legal framework for PBRs is set out in the *Protection of Plant Varieties and Farmers’ Rights Act, 2001* (henceforth, the Act) which came into force with the passage of the *Protection of Plant Varieties and Farmers’ Rights Rules, 2003* (henceforth, the Rules). This is our primary focus. Other laws and regulations that are analysed include the patent provisions concerning plant material, seed certification, and regulations concerning biodiversity and biosafety.

3.1 *The Protection of Plant Varieties and Farmers’ Rights Act, 2001*

The Act is driven by a complex set of principles which are not entirely compatible: establishing an effective system for the protection of plant varieties, protection of the rights of farmers and breeders and encouraging the development of new varieties of plants. No doubt, as expressed in the Act’s preamble, primary need for compliance with obligations to the TRIPs Agreement (viz. Article 27.3(b)) did drive the legislation. While this is true, it is also the case that discussions concerning PBRs in India were initiated prior to the completion of the Uruguay Round (see Rangnekar, 1998). For instance, in 1990 a committee constituted by the Indian Council for Agricultural Research published a report on the appropriateness of gene patents and PBRs (Anon., 1990). A few

years later a technical mission from the FAO submitted a report titled 'Plant Breeders' Rights: India' (Anon., 1993). All this suggests that there were, in some quarters, domestic interest in PBRs. Reflecting this, the Act, is premised on an understanding that IPRs constitute an incentive effect that will stimulate public and private investments in research and development (see, the Preamble of the Act)[12]. Contrasting this presumption are the underpinning principles of the Act that seek to provide Farmers' Rights. Here, the Act refers to the expression of Farmers' Rights as espoused in the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture. India has been an active supporter of the Treaty[13] and its predecessor, the International Undertaking. Though, potentially in conflict, the Government of India has been in 'closed door' discussions with UPOV on possible membership. While consultations and meetings have taken place as early as 1997, the formal request for initiating accession was taken by the Cabinet in May 2002 and conveyed to UPOV by letter in June 2002. An Indian NGO, *Gene Campaign*, filed a public-interest litigation in October 2002 claiming that the Cabinet's decision is unconstitutional and in conflict with provisions in the Act (Anon., 2002). Every effort has been made by UPOV to accommodate India[14].

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[12] The inclusion of the 'public' here remains equally puzzling and unexplained. Like in the case of Kenya and for that matter various UPOV member countries (e.g. USA, UK, France, etc.), the public sector is allowed to apply for PBRs. This is ostensibly a defensive strategy of keeping publicly bred varieties in circulation, i.e. resisting private appropriation of the same, whilst also enabling cost recovery at a time of diminishing funding for public sector agricultural activities.

[13] India signed and ratified the International Treaty in June 2002 and the treaty came into force on 29 June 2004 following the deposit of the ratification by the 40th country.

[14] In 1997, UPOV decided to allow accession to the 1978 Act, despite it being closed, to those countries who had sought its advice on conformity prior to the entry into force of the 1991 Act. This special provision was open till 24 April 1999. However, at its 33rd Ordinary Session in October 1999, it decided to make further special provisions for allowing accession to the 1978 Act for India, Nicaragua and Zimbabwe. While it is not clear whether any final date for accession has been set by UPOV, the 2000 Annual Report states that accession talks are on-going.

In October 2002, UPOV's Consultative Committee reviewed the Act and sought various clarifications from India (UPOV, 2003, paragraphs 11-2) which were received and reviewed in October 2004 (UPOV, 2005, paragraph 22). In November 2005, a two day meeting between UPOV officials and Indian government officials that included the Chair of the Plant Variety and Farmers' Rights Authority (UPOV, 2006, paragraph 96). It is within these competing interests and objectives that the provisions in the Act and the Rules need to be reviewed.

Administration

The administration of the PBRs and FRs system is to be the responsibility of the Protection of Plant Varieties and Farmers' Rights Authority (cf. Chapter II, the Act). In particular, it is the duty of this body to "promote, by such measures as it thinks fit, the encouragement for the development of new varieties of plants and to protect the rights of the farmers and breeders" (section 8(1), the Act). This includes, among others, to ensure the registration of extant varieties, prepare documentation of the registered varieties, the indexing and cataloguing of farmers' varieties, collecting statistics concerning plant varieties, ensuring adequate seed supply of registered varieties and maintaining the Register (cf. section 8(2), the Act). Specific importance is given to the establishment of a Plant Varieties Registry (cf. Section 12, the Act) and the development of a very detailed National Register of Plant Varieties (cf. section 13, the Act; section 23, the Rules)[15]. The Authority is to be constituted by a Chairperson and fifteen members (section 3(4), the Act). Nine of these fifteen are civil servants (e.g.

[15] Elsewhere we discuss the requirements for registering a variety and the relevant provisions in Chapter III of the Act.

Agricultural Commissioner, Department of Agriculture and Cooperation; Joint Secretary, Seeds, Department of Agriculture and Cooperation) and an additional two are to be State government representatives (cf. section 3(5)(b), the Act). Other members include a representative each from National or state level farmers' organisation, tribal organisations, the seed industry, agricultural universities, and National or State level women's organisation. The Authority will establish a standing committee to advice on matters concerning farmers' rights (section 3(7), the Act).

The application procedures for a PBR are laid out in Section 6 of the Rules. In typical bureaucratic style, all applications – and for that matter any representation – shall be filed in triplicate (section 3(a), the Rules); though there are also additional provisions for filing the same via electronic mail (section 4, the Rules). The application can be made by any person claiming to be the breeder of the variety or successor or assignee thereof (section 16(1)(a)-(c), the Act). Similarly, any farmer, farmer group or community of farmers may be the applicant (section 16(1)(d), the Act). All applications are required to include specific and detailed documentation that includes, among others, the denomination of the variety, passport data, required fees and description of the variety (section 18, the Act). There are two important additional requirements. One concerns a declaration that the variety does not contain any gene or gene sequence involving terminator technology (section 18(1)(c), the Act). And the other constitutes a declaration of prior informed consent, i.e. breeding material has been lawfully acquired (section 18(1)(h), the Act). The application fees and other fees are given in table 10. Noticeable therein is an attempt to establish a differential pricing structure based on the applicant, viz. lower fees for individuals and educational institutions and higher fees for commercial enterprises.

Table 10 Cost of Plant Breeders' Rights

Test fees	50,000[1]
Annual renewal fees (per year), for:	
Individuals	5,000
Educational institutions	7,000
Commercial enterprises	10,000
Application for registering as agent/licensee	10,000
Registration of essentially derived varieties, for:	
Individuals	5,000
Educational institutions	7,000
Commercial enterprises	10,000
Application for variation/cancellation of registration, for:	
Individuals	3,000
Educational institutions	5,000
Commercial enterprises	7,000
Notice of opposition	1,500
Application for benefit sharing	5,000
Source: Protection of Plant Varieties and Farmers' Rights Rules, 2003 Notes All monetary values in Indian Rupees [1] Dependent on nature and type of test, this is the maximum amount.	

All varieties submitted for registration are required to go through various tests as elaborated in section 19 of the Act. Within three months of the advertising of the application for registration, any person may express opposition to the application (section 21(2), the Act). The grounds for opposition include: grant of certificate will be against public interest, the variety may have adverse environmental effect, the person opposing the application is entitled to be the breeder (rather than the applicant), among others (section 21(3), the Act). Necessary formalities and fees for opposing the application are spelt out in section 31 of the Rules. Successfully completing the requirements for registration, such as fulfilling the requirements for novelty, distinctness, uniformity and stability (discussed below) and overcoming any opposition, leads to registration of the variety. Registration "shall confer an exclusive right on the breeder" (cf. section 28(1), the Act) (discussed below). Chapter VIII of the Act makes broad and detailed provisions for a Plant Varieties Protection Appellate Tribunal to exercise the "jurisdiction, powers and authority" spelled out in this Act (section 54, the

Act). The members of the Tribunal will include judicial and technical members (section 55, the Act). The Tribunal will hear appeals to orders and decisions of the Plant Varieties and Farmers' Rights Authority that relate to the registration of a variety, claims on benefit sharing, compulsory licensing, and payment of compensation, among others (section 56, the Act). The decisions of the Tribunal shall be executable as a decree of a civil court (section 57(5), the Act).

Conditions for registering a variety

In many ways the Indian legislation pioneers a path that is different and distinct from the dominant template for the protection of plant varieties as mapped out by UPOV and national implementing legislations of its member countries. While some of these differences are briefly noted here, it is the case that in a key area, the conditions for registering a variety, the legislation makes some attempt to deviate from the UPOV template. The requirements in the Indian legislation apply to all varieties valid for registry, viz., plant varieties, extant varieties, essentially derived varieties, and farmers' varieties. Section 15(1) follows the UPOV approach of requiring tests for novelty, distinctness, uniformity and stability. To begin, the notion of novelty in section 15(3)(a) is 'identical' to what UPOV in its various acts establishes as 'commercial' novelty. In the Indian law, extant varieties are exempt from this requirement. The other requirement for distinctness, uniformity and stability (DUS) as spelt out in section 15(3) of the Act are largely similar to UPOV apart from a potentially important expression of 'essential' characteristics. For example, the requirement for distinctness requires the variety to be "clearly distinguishable by *at least one essential* characteristic from any other variety whose existence is a matter of common knowledge" (section 15(3)(b), the Act, emphasis added). This 'essential characteristic' must be sufficiently uniform and remain unchanged after repeated propagation. In drawing focus on 'essential characteristic',

the Act takes inspiration from the 1978 Act of UPOV, where Article 6(1)(a) requires the variety to be "clearly distinguishable by *one or more important characteristics* from any other variety whose existence is a matter of common knowledge at the time when protection is applied for" (emphasis added). The italicised phrase was deleted in the 1991 Act of UPOV. It is useful to note that some UPOV members (e.g. France and Czechoslovakia) had this in their national laws that implemented the 1978 Act (Rangnekar, 2002). However, UPOV clarifies that the procedural work interpreted this requirement as 'important for distinguishing characteristics'; thus, should not be confused with an assessment of the value conferred by the variety (UPOV, 1996, p26). It is too early to pass judgement on how the conditions for registering a variety might translate in practice because the system for field trials is not yet public. To an extent, the attempts to seek UPOV membership might result in a similar procedural interpretation. On the contrary, 'essential characteristics' is defined in Article 2 (of the Act) to encompass characteristics that "contribute to the principal features, performance or value of the plant variety"; thus substantively different from the procedural explanation of UPOV. This, among other provisions, is one of the fault-lines where conformity with the 1978 Act of UPOV remains lacking.

Essentially derived varieties

Section 2(i) of the Act defines essentially derived variety (EDVs) in primarily phenotypical terms. Thus, an EDV is noted in terms of an 'initial variety' where it is predominately derived for the initial variety and retains the expression of essential characteristics related to the genotype of the initial variety. Further, while the EDV is clearly distinguishable from the initial variety, it conforms to the initial variety in its expression of the essential characteristics related to the initial varieties genotype. The notion of EDVs was introduced into the global architecture of PVP law in the 1991

Act of UPOV (article 14.5), which the (Indian) Act closely adheres to. The introduction of EDVs was directed at curtailing the activity of cosmetic breeding – the breeding of nominally differentiated varieties that are otherwise identical. However, the 1991 Act of UPOV, through a de facto inclusion of EDVs within the scope of PBRs, strengthens the borders of already protected varieties by widening their genetic space beyond their morphological space. A less ambiguous demarcation of the borders of a variety requires a notion of 'genetic conformity', which must necessarily correspond to breeding methods and the variety's method of propagation (Lange, 1993). The Indian Act makes for an interesting difference from this practice. To begin, it is possible to register an EDV if it meets the primary requirement for novelty, distinctness, uniformity and stability and also has the necessary documentation spelt out in section 18 (the Act). Naturally, there is a requirement for authorization from the breeder of the initial variety (section 23(6), the Act). Importantly, where the initial variety is a farmers' variety, consent will be required from the farmer, farmers' group or community of farmers that have contributed to the preservation or development of the variety (section 43, the Act). Provisions concerning EDVs suggest that there are important differences in some of the motive forces behind the Indian legislation when compared to either UPOV or national implementing legislations of member countries. In this instance, rather being driven by a need to curb cosmetic breeding, the Indian legislation appears to place priority on forestalling biopiracy.

Extant varieties

Earlier it was noted that extant varieties can also be registered, which is a provision not to be found in UPOV. However, a precedent can be found in the amnesty offered to extant public varieties in Kenya in 2001 (cf. Kenya case study). The Act defines extant varieties as those varieties that are available in India and have been notified under

Section 5 of the Seeds Act, 1966 (section 2(j), the Act). It also includes varieties in the public domain and farmers' varieties. The Act and the Rules provide for a three year amnesty within which registration of extant varieties will occur. Such varieties must also fulfil the requirements for novelty, distinctness, uniformity and stability and other documentation. The Act places an additional twist by making provisions for the rights conferred upon registration to be deemed to be held by the government. This will be the case where a breeder or their successor does not make a claim (section 28(1), the Act).

The scope of protection

Successful registration of a variety confers a right to the breeder. This is an exclusive right to "produce, sell, market, distribute, import or export the variety" (section 28(1), the Act). While this scope includes transactions that go beyond those notified in the scope in the 1978 Act of UPOV (see article 5(1)), it can be argued that the scope is comparatively limited. To explain, the scope under the Indian Act hinges on 'the variety' whereas in the 1978 Act of UPOV it hinges on the 'reproductive or vegetative propagating material, as such, of the variety'. There is an important distinction between the two – and it is felt that case law, possibly in the not too distant future, may clarify the limits to the rights conferred. At issue will be the meaning of the definition for variety provided in Article 2(za) of the Act.

The duration of 'registration' – and hence the rights conferred – are initially for a period of nine years for trees and vines and six years in the case of other crops (section 26(6), the Act). These periods of registration may be subsequently renewed – and the Rules provide for the necessary procedures and fees (see table 10). The Act also spells out maximum registration durations (section 24(6)): eighteen years for trees and vines,

fifteen years for extant varieties, and fifteen years for other crops.

Akin to UPOV there are limits to the rights conferred that allow for the use of the variety as a source of initial variation; though with some principled differences. The 1978 Act of UPOV allows for the use of a protected variety as a source of initial variation with some restrictions (see article 5(3)). In the 1991 Act of UPOV this exists as a compulsory exception – again circumscribed by some requirements. The Indian legislation differs in denominating this provision as the 'Researchers' Rights' (section 30, the Act) – thus awarding it a particular status beyond an exception to the rights conferred to a breeder. Similar to UPOV, it allows for the variety to be used for experimental purposes and as a source of initial variation. Akin to the 1978 Act of UPOV, the use is circumscribed and authorisation of the breeder is required where the repeated use of the variety is required as parental material for the commercial production of the newly developed variety (section 30, the Act). This is directed at the breeding of hybrid varieties.

Farmers' Rights

If there is one aspect of the Indian Act that has received wide spread attention it is its provisions for farmers' rights. Swaminathan notes this specifically and states that "India's law is unique in the sense that it is the first time anywhere in the world that the rights of both breeders and farmers have received integrated attention" (quoted in Ramanna, 2006). Introducing farmers' rights has been problematic, difficult and highly contested (Seshia, 2001; Ramanna, 2006). Ramanna (ibid.), reviewing the literature, identifies various components to farmers' rights: the right to seeds of registered varieties, the right to register own varieties, the right to reward and recognition through the national gene fund, the right to benefit sharing, the right to information and compensation for crop failure, right to compensation for undisclosed use of traditional

varieties, the right to adequate availability of registered propagating material, exemption from most fees, and protection through provisions for innocent infringement. Many of these overlap – and in legal terms, all of these are not rights in the sense of the term or configured exclusively for farmers to avail of. Section 39 of the Act specifies farmers' rights as including the following:

- A farmer who has bred or developed a new variety shall be entitled to registration and treatment (i.e. protection) in a manner akin to a breeder

- A farmers' variety is entitled to be registered if it fulfils all requirements

- A farmer engaged in conservation and improvement of genetic resources shall be entitled to recognition and reward from the Gene Fund

- A farmer is entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a protected variety provided that the farmer does not sell branded seed of the variety.

The latter two components of section 39 are remarkable in translating global rhetoric and legal architecture into the framework for national practice. These two provisions capture elements of the debate surrounding the FAO's International Treaty (and its predecessor the International Undertaking) and the Convention on Biological Diversity. One would not be entirely off the mark by hazarding a guess that provisions for farmers' rights must be the most difficult element in negotiating India's accession to UPOV even under the 1978 Act.

In addition to the express mention of farmers' rights as above, the Act also has provisions for 'rights of communities' (section 41). This includes a right to claim

benefits for the contributions made to the evolution of a variety, in particular compensation to be drawn from the Gene Fund. In line with FAO's attempts at establishing an International Gene Fund to make Farmers' Rights operational, the Indian Act proposes a (national) Gene Fund (section 45). The sources of income for the Gene Fund come from benefit sharing arrangements with respect to EDVs, annual contributions by way of royalty (cf. section 35(1), the Act), compensation payments (cf. section 41(4), the Act), and contributions from any national or international source. The Act in section 46 and accompanying rules (see section 70, the Rules) set out the conditions and provisions for schemes and uses of the revenues deposited in the Gene Fund.

How the Gene Fund is made operational, resourced and used will be a critical test for giving reality to farmers' rights and the rights of communities. The Act and accompanying Rules provide a framework for setting up benefit sharing arrangements. For example, section 26(2) establishes that "any person or group of persons or firm or governmental or non-governmental organisation" can submit a claim for benefit sharing. While the breeder of the variety in question can challenge the claim for benefit sharing, once a decision is made by the Authority confirming the validity of the claim, a specific amount will be indicated (section 26(3)-(6), the Act). In determining the amount of benefit sharing, the Authority will be guided by the extent and use of the genetic material of the claimant and the commercial utility and demand in the market for the variety (section 26(5), the Act). Additional principles are expressed in section 43 of the Rules.

Another element that, as noted earlier, is considered a component of farmers' rights is protection against innocent infringement (section 42). Farmers are protected from alleged infringement when it can be established that "at the time of such

infringement [the farmer] was not aware of the existence of such right" (section 42(i), the Act).

Public Interest Provisions

There are many provisions that are directed at protecting 'public' interest. These relate to protection against environmental harm, provisions for compulsory licensing, and prohibitions on protecting varieties that incorporate harmful technologies. For example, there are provisions similar to the exceptions noted in Article 27(2) of the TRIPs Agreement that allow for exceptions on those technologies where the commercial exploitation may harm public order or morality. Thus, section 29(1) of the Act provides for a similar framework. Yet, the Indian Act makes for a comprehensive prohibition on varieties which involve any technology that is injurious to the life and health of human beings, animals, or plants (section 29(3), the Act). Further, specific reference is made to genetic use restriction technologies and terminator technologies. Finally, Chapter VII provides for compulsory licenses. Principally, the provisions are triggered by 'public requirement' not being met.

3.2 *The Protection of Plant Material through Patents*

The *Patent Act, 1970* has been widely documented and commented upon. In particular, scholars, activists, and policy analysts have noted its historical significance in reversing regressive legislations in a post-colonial setting and how it, along with other policy interventions, enabled the domestic pharmaceutical industry to grow and diversify. The *Patent Act, 1970* is better situated in the then new ideas of development and decolonisation and the changing regulatory practices in other areas of the Global South, notably Latin America. These countries explored space that existed for the autonomous determination of the domestic architecture of IP law. Simultaneously,

these countries collectively attempted to modify global IP architecture (Sell, 1998). The Patent Act, 1970 was the consequence of a long and deliberative dialogue (Rangnekar, 2006). A significant rationale for amending the colonial Patents and Design Act, 1911 was grounded in what Justice Ayyangar – the author the defining *Report on the Revision of the Patent Law* (1959) – calls compatibility with national interest: "the precise provisions of the Patent Act will have to be designed with special references 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 part" (Ayyangar, 1959). While there are many remarkable features in the *Patent Act, 1970* our focus here is on provisions concerning plant material. In Section 2, where various definitions are expressed, inventions are said to mean "any new and useful […] (i) art, process, method or manner of manufacture; […] (ii) machine, apparatus or other article; […] (iii) substance produced by manufacture, […] and includes any new and useful improvement of any of them, and an alleged invention" (section 2(j), *Patent Act, 1970*). In clarifying the ambit of patents, Chapter II is titled 'Inventions not patentable'. A long list of exclusion is articulated that includes inventions that are frivolous, inventions injurious to public health or contrary to morality, mere discoveries and medical, surgical, or prophylactic processes for treatment of humans, animals or plants. Of particular relevance is section 3(h) which excludes 'a method of agriculture or horticulture'. This is remarkable in that previously the *Paris Convention*, in article 1(3), clarified that 'industrial property' is to include a wide range of subject matter that encompasses agriculture, flower, fruits and tobacco leaf. No doubt, legal practice in some jurisdiction already provided for patents in some areas of plant material whilst plant varieties were protected through a *sui generis* law (see Bent et al., 1987 for a

discussion).

Given the historicity of the *Patent Act, 1970* there is no explicit mention of biotechnology or phraseology that might allude to the attempts to demarcate the micro- from the macro-biological as pioneered in the Strasbourg Convention. In fact, there is no reference to micro-organisms, genes or gene sequences. In light of this, it might be suggested that the *Patent Act, 1970* is silent – or at least, ambiguous – about the patentability of particular categories of plant material. Not surprisingly legal practice on this differed between patent offices and examiners. A pertinent example is the grant of patent number 168950 to *Agracetus* in May 1992[16]. The patent, titled 'Methods of producing transformed cotton cells by tissue culture, was similar to the US patents (No. 5004873) titled 'Genetic engineering of cotton cells and lines' with some claims being dropped. It remains confusing how this patent was accepted and granted given the exclusions in Section 3(h) & 3(i). As the US grants were read to include specie-wide claims, i.e., encompassing any genetically engineered cotton seed, it raised opposition, including from the US Department of Agriculture leading to a challenge on its grant (Mestel, 1994). The US Patent and Trademark Office withdrew both patents in December 1994. In India, the government initiated action under section 66 listing environmental and health reasons for the revocation of the patent leading to its revocation in October 1994.

It was only as late as 1991 that the Controller General of Patents, Designs and Trademarks issued an executive order[17] aimed at establishing common practice. The

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[16] The discussion of the patent is based on Rao (1997), unless indicated otherwise.

[17] Office Instruction No. 1 of 1991, dated 15th July 1991.

executive order established a prohibition on process and product patents on living forms, including microorganisms, plants and animals and their parts thereof. It allowed patents for processes or methods of production of tangible and non-living substances such as enzymes, antibiotics, insulin, hormones, etc. This directive took support from the general prohibition on patents on particular subject matter on ethical and moral grounds (cf. Section 2(j), the Patent Act, 1970). It is here that the decision in *Dimminaco A.G. v. Controller of Patent, Designs, and Ors* (AID No 1, Calcutta High Court) clarifies the situation[18]. Dimminaco, a Swiss company, had applied for a patent of process involving the manufacture of a vaccine for infectious bursitis in poultry. The Controller rejected the application on the grounds that section 2(j)(i) defines 'manufacture' to exclude the production of vaccines. It was also indicated that earlier grants of patents for live cells and microorganisms was possible as the subject matter had been lyophilized (i.e. freeze dried); thus, construed as 'not living'. Hence, the application was rejected. In April 2002, Justice Ashok Kumar Ganguly passed judgement that set aside the decision of the Controller and ordered the acceptance of Dimminaco's patent application. The Court observed that in the absence of a definition of expressions like "manner of manufacture" or "substance", the normal dictionary meaning of these words should be used. Consequently, accepting applications where the end-product is a commercial commodity. As a result, the Controller reviewed the patent application which was then successfully granted (cf. Indian Patent 187970). Following this case law, it might be concluded that process patents are possible even where the end product encompasses living organisms and that the process involves microorganisms.

[18] The discussion here is based on Ramakrishna (2002).

The completion of the TRIPs Agreement and with India being a signatory, there were a number of changes to be made to the *Patent Act, 1970* – each with their respective binding deadline. Having availed of the additional transitional period for particular technologies, India faced an obligation to put in place by 1 January, 1995 mechanisms for receiving product patent applications in these exempt technologies (i.e., the 'mail-box' requirement, Article 70.8) and allow for the grant of exclusive marketing rights (Article 70.9). The second was an obligation to come into compliance with TRIPs at the end of the five-year transitional period available for developing countries (Article 65.2), i.e. by 1 January, 2000. The final obligation/deadline was to come into full compliance at the end of the additional transitional period; thus offer patents in those exempt technologies by 1 January, 2005. It is the second amendment to the *Patent Act, 1970* that is of primary relevance to the topic.

The *Patent (Second Amendment) Bill, 1999* was introduced in the Rajya Sabha on 20 December 1999 and was soon enough referred to a Joint Parliamentary Committee of both the Houses of Parliament. The Committee held 39 meeting, received 42 memoranda, and heard oral testimonies from 51 witnesses and 19 individuals and organisations. Additionally, the Committee also visited a number of countries[19]. Preparing a report of its finding (in December 2001), the Joint Parliamentary Committee revised the Bill and recommended its adoption. This was ultimately passed by both Houses of Parliament and received Presidential assent on 25th June 2002.

[19] These visits included Argentina, Brazil, Canada, China, Japan and Korea. Some scholars remained dismayed that the tour did not include the USA despite a visit to Canada (Ragavan, 2002).

The *Patent (Second Amendment) Act, 2002* (henceforth, the *Second Amendment*) makes for a comprehensive revision to the section titled 'inventions, which are not patentable'; in particular, there are more than fifteen changes to Section 3. These changes include introduction of an exclusion that is akin to, but different from, Article 27(2) of the TRIPs Agreement, and an elaborate list of non-patentable inventions (e.g. abstract theory, mathematical or business methods, computer programmes, and topography of integrated circuits, among others). Two particular changes are relevant to the subject. First, in clause 3(i), the words 'or plants' have been deleted so that the exclusion from patentability reads as follows: "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". This allows for process patents in plant material. Second, the *Second Amendment* introduced an entirely new clause, 3(j), which presents the following exclusion from patentability: plants and animals in whole or any part thereof other than micro-organism but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals. Collectively, these two amendments present the situation of permitting process patents involving plant material whilst prohibiting product patents. To explain using an example from Ramakrishna (2002), while a patent for cottonseed engineered to include the *Bt* gene is not permitted the process of engineering the gene into the cottonseed is patentable. The prohibition on product patents is further strengthened by Clause 5, 'Inventions where only methods or processes of manufacture patentable. Here, in paragraph 1, there is a prohibition on patenting of inventions "claiming substances intended for use, or capable of being used, as food or as medicine or drug". No doubt, 'food' is somewhat narrowly defined in clause 2(g) (Ramakrishna, 2002); thus, circumscribing the prohibition on product patents. The extent of the non-

patentability of certain subject matter and the delimitation of process/product patents remains unclear. That said, there are no doubts as to the patentability of microorganisms. To explain, microbiological processes are patentable, patents for microbiological products are not 'yet' possible, i.e. postponed till the third amendment when the final deadline for full compliance comes around (see below).

It is important to note that the *Second Amendment* introduces key changes to the patent application and examination process with the objective of forestalling biopiracy. Section 25 is amendment with the insertion of new clauses that require (a) checking for proper disclosure of geographical origin of the biological material used in the invention and (b) the claims in the application are checked in light of oral knowledge and practice in India and elsewhere. In particular, these are set out as legitimate grounds for opposition of a patent application.

The Second Amendment also makes for interesting reading on translating Article 27(2) of the TRIPs Agreement into domestic IP architecture. In Section 3 the following clause has been introduced: "(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment". A quick reading would suggest that this maps well onto the Article 27(2). However, in TRIPs there is an expression that the exclusion is not a blanket 'ban' on particular technologies. Specifically, it provides for exclusions from patents for specific inventions – those where their commercial exploitation pose a particular risk (e.g. letter bomb, terminator) – and not entire categories of inventions (e.g. GMOs) like in the case of Article 27(3). Further, there is a contingency – commercial exploitation. In the sense, non-patentability can be granted only when the commercial exploitation needs to be prevented to protect the 'other interests' (public order, morality, etc.); thus the source

of risk is the commercial exploitation of the technology under consideration. Keeping all this in mind, the construction of clause (b) is seen to have a broader canvas through its inclusion of “primary or intended use” in addition to the TRIPs-expressed “commercial exploitation”.

The final patent-related obligation, product patents in exempt technologies, was to be enacted through the Patents (Amendment) Bill, 2003, but this lapsed with the dissolution of Parliament. The new government, the Congress- led and Left-backed, United Progressive Alliance decided to introduce a marginally revised version of the same as the Patents (Amendment) Ordinance, 2004 (Ord. No. 7 of 2004) (henceforth, the Ordinance) in light of the 1 January, 2005 deadline. The issues raised in light of the draft Bill were largely devoted to two broad areas: (a) conditions for grant of patent and relevant procedures (e.g. pre- and post-grant opposition), and (b) using the Doha provisions for access to medicine (e.g. export of generic medicines, etc.) (Rangnekar, 2006). Focus on the changing definition of invention existed, but were muted. The relevant change made in the Patents (Amendment) Act, 2005 was to delete Section 5 of the Patent Act, 1970. Consequently, the proviso that denied the granting of product patents in particular technological areas was removed.

3.3 *Other Regulatory Measures*

Seed Market Regulations

Effectively the only, and definitely the ultimate, delivery vehicle for the developments achieved in plant breeding are *seeds*. A key element of seed market legislations is to ensure that varietal improvements are retained through the seed multiplication stages and delivered to the farmer. Given the information asymmetries in the market for seeds, akin to similar problems in the market for durable goods, the regulations seek

to focus on certification and labelling. The present day legal foundation for regulating the seed market is found in the *Central Seeds Act, 1966* (Singh et al., 2002). This Act sought to retain control over the seed of most staple food crops in the public sector and the private sector was active in vegetable and flower seeds. Thus, for example, the *National Seed Corporation* (est. 1963) was mandated with the bulk import and production of high-yielding varieties (of the Green Revolution) and promotion of good standards in processing, storage and distribution of quality seed. The Act prescribed certification standards and enforcement was delegated to state government agencies. In policy terms, the 1980s form a watershed in the transformation of the Indian seed industry. In 1983 a policy to release publicly bred varieties to the private sector for multiplication was introduced, which was followed by a marked relaxation of industrial licensing regulations in 1987 that also allowed the entry of foreign companies. Eventually in 1988, the *New Policy on Seed Development* was announced with the articulated objective of "provid[ing] the Indian farmer the best seeds and plant materials available in the world to increase productivity, farm incomes and export earnings". With these objectives, the measures introduced were broadly directed at putting most seeds on open general license, reducing import duties and freeing up the import of particular equipment (Pandey and Chaturvedi, 1993; Basant, 1995):

- Import of vegetable, flower and fruit seeds placed on open general license
- Import of oilseed, pulses and coarse cereal seeds allowed, initially for a two year period but contingent on foreign company having a collaborative arrangement with an Indian company that allows transfer of parental breeding material.
- Decrease of import duties (approx. from 95% to 15%) for import of seeds and seed production equipment

Alongside this opening up, the Policy continued to maintain non-tariff controls on seeds

and equipment imports, such as the demand for quarantine regulations. Further, import of wheat and paddy seeds continued to be prohibited (Basant, 1995). In 2002 another policy change was made that eventually allowed the import and export of all seeds, subject to all imported seeds being registered (Ramaswami, 2002). In 2004, the Government introduced the *Seeds Bill, 2004* which on passage will replace the *Seeds Act, 1966*[20]. Some of the proposals include the following:

- All commercial seeds have to be registered; thus meeting prescribed standards
- Failure to meet given standards allows the farmer to claim compensation (under the *Consumer Protection Act, 1986*)
- Self-certification by accredited agencies and certification by recognised foreign agencies is permitted
- Every seed producer and dealer across all crops will have to be registered
- Farmers can continue to use and sell their seeds and planting material, provided they do not use the brand name and that they meet the minimum standards applicable to registered seeds.

Concerns have been expressed regarding the interface between the *Seeds Bill, 2004* and the Act (see below). For example, while the Act provides farmers' rights that allow for saving, using, sowing, resowing, exchanging, sharing and selling the seed of a protected variety with the contingency that the brand name is not used. Measures in the *Seeds Bill, 2004* limit this by requiring sale of seed by a farmer to meet certain minimum standards of germination and purity. These interface issues aside, there is need for the Bill because it introduces measures for transgenic seeds.

Biodiversity Regulations

[20] The discussion is based on Anon. (nd) and Madhavan and Sanyal (2006), unless indicated otherwise.

Having ratified the Convention on Biological Diversity in February 1994, India introduced the *Biological Diversity Act, 2002* and the *Biological Diversity Rules, 2004*. What is remarkable about this regulation is the deliberative process of law making and the high level of inclusiveness achieved in scripting the law (Anuradha et al., 2001). National consultation seminars, lead by a civil society group, the *Gene Campaign*, were followed by a committee under the leadership of the MS Swaminathan Research Foundation. The draft produced was then made public and opened for comments (Anuradha et al., op. cit.). Equally significant was the experience with the *National Biodiversity Strategy Action Plan*, a programme to elaborate State level plans as provisioned in the *Biological Diversity Act, 2002*. This was coordinated by a tripartite group involving a civil society organisation (Kalpavriksh), the government (Ministry of Environment and Forests) and industry (Biotech Consortium India, Ltd.)[21]. However, as the government failed to 'publish' the report, Kalpavriksh decided to release the report.

Primary authority at the federal level resides in the National Biodiversity Authority (NBA), which is based in Chennai and is under the leadership of Dr Kanniyan. The NBA is assisted at the provincial level by State Biodiversity Boards (SBB). At the local level there are Biodiversity Management Committees. The latter are to be involved in the conservation, sustainable use and documentation of local biodiversity; however, according to the *Biological Diversity Rules, 2004* their main function is the preparation of People's Biodiversity Registers. The SBB is vested with the power of dealing with citizens who seek to access and use biological diversity and associated traditional knowledge. However, it is the NBA that deals with issues concerning IPRs on subject

[21] Details of the process and relevant documentation are available at the website of the NGO, Kalpavriksh http://www.kalpavriksh.org/f5/f5.1/pubbd; last accessed 28th November 2006.

matter that involves biological resources and associated traditional knowledge. The NBA also is the nodal point for any non-citizen who seeks to access and use biological resources and associated traditional knowledge. Both the NBA and the SBB are to be involved in ensuring that equitable benefit sharing arrangements are established with the granting of access. Akin to the Gene Fund of the *Protection of Plant Variety and Farmers' Right Act*, there are provisions for national, state-level and local biodiversity funds based on the granting of access to biological resources which will be used to support the benefit sharing ideals of this regulation.

A key objective grounding the *Biological Diversity Act, 2002* is stopping 'biopiracy'. This reflects the experience with the grant of patents (and PBRs) in other jurisdictions that encompass biological resources and associated traditional knowledge from the country (e.g. neem, turmeric, Basmati, chickpeas). Different measures exist to meet the objective. Thus, NBA is vested with the power of representing the country in international litigation to oppose the grant of IPRs on material/knowledge accessed and obtained in India. On the other hand, prior informed consent principles exist that see the NBA being the relevant authority reviewing requests for using biological resources and associated knowledge.

The CBD and national implementing legislations have generally been criticised for condoning the use of IPRs and engaging in a commercialisation of biological resources. This applies to the Indian legislation as well (Cullet & Raja, 2004). It has also been criticised for the primacy accorded to establishing national sovereignty over biological resources (Apte, 2006). In doing so, it completely obliterates common property arrangements and other communitarian systems of controlling access and use of biological resources. In particular, Apte (op. cit., p101) notes that the legal status of

People's Biodiversity Registers remains uncertain and ambiguous.

Biosafety Regulation[22]

In 1989 the Government issued the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms and Cells* which at that point established the principles of biosafety regulations in India. Beyond elaborate rules, this also introduced the institutional structure for biosafety policy and regulation. A six tier structure was proposed that included bodies like the Recombinant DNA Advisory Committee, the Institutional Biosafety Committee, the Genetic Engineering Approval Committee and State and District level biotechnology coordination committees. Following the ratification of the *Convention on Biological Diversity*, in particular the Cartagena Protocol, there was a need to revise these rules. The Department for Biotechnology revised the guidelines to provide for the safe handling of genetically modified organisms (GMOs) in research, the deliberate release of GMOs and the shipment and import of GMOs for research. While this exists on paper, the government admitted in its *Second National Report to the Convention on Biological Diversity* the inadequacy of resources and capacity to deal with GMOs (Government of India, 2001b, esp. pp79-83). This is reflective of a deeper institutional conundrum: the absence of any permanent secretariat to deal with GMO trials and the institutionally complex architecture noted earlier.

Up until late 2005, only one commercial trial of a GM crop was approved – *Bt* cotton in March 2002. Though, there are 22 GM plants being tested in India (Chaturvedi, 2005).

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[22] The discussion here is based on Chaturvedi (2005) and Dhar (2002).

This follows initial approval to Mahyco[23] by the Department for Biotechnology in 1995 to import cotton seed containing the *Bt Cry 1Ac* gene and subsequent trials from 1996. In July 2000, the Genetic Engineering Approvals Committee gave the green signal to large scale field trials. Finally, in March 2002 came the approval for commercial cultivation of three *Bt* cotton varieties – no doubt, with various conditions that include cultivation surrounded by a refuge, the sale of *Bt* cotton seeds with seeds of non-*Bt* cotton seeds (for the refuge), etc.

Reflected in the government's admission to the CBD are reports of the unauthorised sowing of GM crops. This was initially reported in 1997 with respect to GM eggplant; however, subsequent news of several hundred hectares of unapproved *Bt* cotton in Gujarat has become controversial[24]. A local seed company, Navbharat Seeds Pvt. Ltd., had supplied cotton seed which was found to carry the *Bt Cry 1Ac* gene. To resolve this public policy disaster the government set up a 'Taskforce on the Application of Biotechnology in Agriculture' under the chairmanship of MS Swaminathan. The Report (in 2004) recommends two separate 'panels' to deal with agricultural/food biotechnology and pharma/medical biotechnology respectively. While strongly promoting the application of biotechnology for crop development it categorically bars GM research in crops of trade value (e.g. Basmati rice, Darjeeling tea). A key recommendation is for the allocation of Rs120Mn[25] for building capacity for evaluation and application of biotechnology.

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[23] Initially an independent seed company, it is now an affiliate of Monsanto.

[24] Reportedly, over 11,000 hectares with cultivation since 1998.

[25] Approximately, USD13.3Mn at 2003 purchasing power parity rates.

4 THE IMPACTS OF PBRS

As the PBRs system is not yet functional, it becomes superfluous to consider the 'impacts of PBRs'. That essential fact aside, there has been much turbulence in the seed and plant breeding sector (cf. section 2.2, 2.3) with significant regulatory changes, revisions in the public-private interface and the entry of MNCs in the sector. It is with that backdrop that this section reviews some of the areas of concern that relate to the introduction of PBRs.

4.1 *Research and Development*

There is a presumption that introduction of PBRs will provide further incentives to the private sector to increase investments in plant breeding and thus lead to an increasing provision of plant varieties (Pray, 1990; Pal & Tripp, 2002). To a great extent, the evidence reported in sections 2.2 and 2.3 provide a compelling reason to accept this presumption. The opening up of the seed industry and wider economic reforms has witnessed increased private sector activity in the industry. Through the 1990s, the private sector has broadened its portfolio of crops and geographical areas of activities. The number of firms has also increased. For example, in 1987/88 there were 12 firms active in pearl millet and by 1997/98 this increased to 25 (Table XXX). In sorghum the increase was from 10 to 15 in the same period. Along side the increase in the number of firms has been an increase in the number of plant varieties. In pearl millet the number of varieties increased from 54 in 1995 to 66 in 1998; though only 14 private sector varieties accounted for area shares in excess of 2% (Dhar, 2002). In sorghum the number of private varieties nearly doubled to 41; yet, only 6 had area shares in excess of 2%. Even while a handful of varieties secure market shares it is clear that privately bred varieties have a dominant market share (Table 11).

Table 11 Market Share in Hybrid Seeds

	1990-91		1996-98	
	Public Sector	**Private Sector**	**Public Sector**	**Private Sector**
Pearl Millet	24,000	6,000	10,000	11,000
Sorghum	7,000	7,000	5,000	11,200
Maize	12,000	6,000	2,000	18,000
Sunflower	500	4,500	200	7,800
Cotton	4,000	1,500	5,000	5,000
Note: all values in tonnes Source: Seed Association of India (1998)				

Table 11 gives the market shares of public and private hybrid varieties for 19909/91 and 1997/98. Momentarily disregarding the point that these are hybrids, it is clear that in a short period the private sector has come to occupy a leading position in these crops. In particular cases, such as sunflower, it has always been the main provider of plant varieties. On the other hand, in maize it has increased its activities to account for 90% of the market. The fact that these crops have been successfully hybridised has been acknowledged. Thus, Basant (1995, p26) observes that hybridisation provides the firms with some “natural protection” and enables a higher margin on sales.

Table 12 Indian Seed Market Shares

	1994-95		1998-99		2003-04	
	Market Size (USD Mn, PPP)	**Market Share (%)**	**Market Size (USD Mn, PPP)**	**Market Share (%)**	**Market Size (USD Mn, PPP)**	**Market Share (%)**
Public Sector	612	40	672	25	1162	22
Private Sector, organised	540	35	1617	60	3593	67
Private Sector, unorganised	386	25	404	15	581	11
Total	**1538**	**100**	**2694**	**100**	**5336**	**100**
Source: Chaturvedi (2005)						

Beyond hybrids, the private sector has come to occupy the leading share in the seed market (Table 12). In less than a decade the size of the seed market has increased

more than 3 times from US$1.5Bn to US$5.3Bn[26]. However, the real significant feature is the substantial growth of the (organised) private sector from 35% in 1994/95 to 67% in 2003/04. Remarkable as this is, it is useful to remember that a significant share of the seed market – often the larger segment – is locally sourced either through saved seeds, or farmer-to-farmer exchanges or other 'informal' sources. Estimates for this segment range widely from about 60% to nearly 90% for rice (section 2.3).

Questions remain regarding the impacts of this growth of the private sector, particularly as this growth has occurred at the same time that agriculture in India has experienced deceleration (cf. section 2.1). While there may not be any direct causality between the two, the fact remains that increased private sector breeding activity and seed market presence has not translated into arresting/reversing the deceleration. In this respect, Chaturvedi (2005, p34-5) observes that indigenous firms are under heavy pressure to technologically improve their seeds. Apart from user demand, firms are also facing competitive pressures from new entrants, in particular MNCs. Three broad solutions are being tried (Chaturvedi, op. cit.):

- *Internal biotechnology breeding programmes:* Large, indigenous firms, KJ Agri-genetics and Indo-American Hybrids, have invested in biotechnology. Difficulties in securing the necessary manpower to build the necessary absorptive capacity are being experienced.

- *Technology alliances with MNCs:* Some seeds companies, like Mahyco Seeds, have gone for tie-up with MNCs, like Monsanto, to access useful genes for

[26] These estimates are in millions of US dollars at PPP.

developing transgenic varieties. However, in this case the local breeding is at the low-end of the technology spectrum as it only involves back-crossing.

- *New start-ups:* Firms like Meta Helix and Avesthagen have emerged with a strong science base; thus, presenting the option of contract research organisation.

Outside the biotechnology world, it seems that seed firms are looking at the PBR system as a means for protecting hybrids (Louwaars, et al., 2005, pp89-90). An attraction of PBRs is that it may enhance protection by making it easier to litigate against 'theft'. In general, Louwaars et al. (2005, p92) suggest that few seed companies will move into non-hybrids, in part because of the broad protection offered to farmers. The possibility of OPVs exists only where firms have already established brand loyalty.

4.2 *The Case of the Public Sector*

The introduction of PBRs is recognised as dually generating opportunities for the public sector to reorient its funding patterns and activities while also raising concerns about the deepening institutional division of labour between the public and the private sector (Godden, 1982; Kloppenburg, 1988). No doubt, reflective of a neoliberal ethic, pressure continues to be applied on the public sector to *cut-back* and leave the market for the private sector. Simultaneously, the introduction of PBRs raises a variety of policy questions concerning the relationship between the public and the private sector. For instance, what might be the modalities of releasing publicly bred varieties? Often, allowing the public sector to protect varieties through PBRs is presented as a strategy against misappropriation (Rangnekar, 2006). Yet, this is simply an issue of improving

the rigours of assessment in the administering office. With or without PBRs, the public sector also has to decide on its varietal release policy. This has serious implications for the competitiveness of the seed industry as it allows smaller seed companies with limited or no internal breeding programmes to remain in the market; thus, ensuring a diversity of technology suppliers (Godden, 1984). In essence, a wide licensing policy would help dissipate any allocative and distributional inefficiencies arising out of the grant of protection. Reflecting these different predilections, the *Indian Council on Agricultural Research* (1990) presented a strong mandate for public sector plant breeding premised on a "healthy competition" with the private sector. Another formative idea regarding public sector policy was the recommendation of the FAO study (Anon., 1993) that PBRs could generate royalty sharing schemes for public sector breeders as a means to motivate and retain personnel.

Thus, the introduction of PBRs and other regulatory changes discussed above in section 3 present an opportunity to review the performance of the public sector in plant breeding and seed production. As well noted, the performance has been mixed and the financial stability of some operations fragile (Pal & Tripp, 2002). The difficult choice concerns whether to cull some of the operations and, as often suggested (e.g. Ravishankar & Archak, 2000), focus only on basic plant breeding. In this framework, the public sector would also be advised to withdraw from seed multiplication and distribution. Others are more cautious and suggest a renewed mandate that is premised on a delicate balance between *efficiency* and *equity* (e.g. Singh et al., 1995). There is a pragmatic recognition that, following the regulatory reforms, the private sector has attracted away some of the breeders from the public sector; thus, making the likelihood of similar historical rates of developing/releasing varieties difficult. Even within this focus on personnel, Singh et al. (1995, p18) recognise that the "cost of

developing the human capital employed in the private sector is largely borne by the government"; thus, recommending some payment by the private sector for this 'subsidy'. The situation is more complicated for two particularly interrelated reasons: (a) the underinvestment in research particularly because of its high social rate of return and (b) the increasing consolidation in the 'life science' industries.

It is often suggested that the dual movements of increasing private sector activities and the public sector seeking IPRs can create perverse incentives (Oehmke, et al., 2000). There is a direct stimulus from a cost-recovery and revenue-generating objective that would direct research towards more financially lucrative varieties and agroclimatic conditions. While this may play the role of being a subsidy to other research, finding the 'right' balance is neither easy nor guaranteed. On the other hand, there are the indirect influences generated by the growing interaction with the private sector. Apart from the possibilities of personnel being attracted out of the public sector, there will be some influences on the orientation of research and also on the access to research products. At issue is the very rationale for public sector institutions, in particular accountability, research orientation and impact on the access to publicly produced technologies.

Seeds are the essential delivery mechanism for developments in plant breeding. For that matter, even developments in biotechnology are largely delivered to farmers through new seeds. For example, Mahyco's *Bt* cotton varieties in India were breed through traditional back-crossing with the gene's acquired from Monsanto – a rather low-end technological act (Chaturvedi, 2005, p35). This places a premium on having locally adapted and widely adopted varieties that could be potential carriers for these novel technologies. There is evidence that private sector firms are unlikely to consider developing OPVs because of the provisions for farmers' rights in the PBRs law; thus, indicating that there might be little effect of the PBRs legislation on non-hybrid plant

breeding (Louwaars et al., 2005, p92). This raises the case of key food crops – rice, wheat and pulses.

This is not to say that the private sector is not either interested in or active in non-hybrid crops. Here, evidence from the rice seed industry in Andhra Pradesh is insightful. Ironically, the private sector undertakes no breeding activity and the crop is not a typical high-value/low-volume crop, and yet, seed production is increasingly conducted by the private sector (Tripp and Pal, 2002). A number of factors explain this phenomenon: (a) large captive market of 3.5Mn hectare rice cultivation, with regular seed purchase by farmers, (b) rice seed production is relatively simple and does not require substantial investments, (c) availability of experienced seed growers (in Northern Telangana) and storage and processing facilities, and importantly, (d) availability of breeders' seed from the public sector. Importantly, the viability of many seed companies is crucially contingent on securing free access to publicly developed varieties. This case points to another aspect of the public sector – access to its breeding material. Needless to say, the continued sustainability of rice seed firms would depend on the terms of access to the publicly bred varieties.

Earlier it was noted that the historical development of the breeding and seed industry in India, particularly during the Green Revolution, laid the foundation for a network of experienced seed growers, distributors and the State Seed Corporations (cf. section 2.3). This massive infrastructural and social investment has enabled the private sector to enter the seed industry. The presence of efficient competitiveness in the seed industry is reflected in the comparatively low seed-to-grain price ratio (Pal & Tripp, 2002. Pal & Tripp (op cit) note a number of factors with respect to the low seed-to-grain price ratio that includes the access to publicly bred parental lines, the network of seed growers and the presence of the public sector in the sector. They remain sceptical of

a policy that licenses varieties to the highest bidder as it might lead to increased concentration in the seed market (pp446-47). A policy favouring non-exclusive licenses would protect the presence of seed companies with limited plant breeding and also lower entry costs into the seed sector; essentially, a policy promoting a diversity of technology suppliers and a broad industry structure.

5 CONCLUSION

The review of India's law and the potential impacts provides useful observations and lessons. Two broad observations are of key importance to this report. First, is the construction of domestic law which uniquely provides for farmers' rights and breeders' rights. Notable is the interfacing of principles and provisions between the different regulatory instruments, such as between the *Biological Diversity Act* and the *Patent Act*. Second, are the structural transformations that have occurred in the plant breeding and seed industry that accompanied the reforms of the 1980s. Notable is the growth of the private sector in hybrids (of particular crops), seed multiplication and biotechnology.

The legal architecture regarding plants that has emerged in India is unique in many senses. The long and deliberative process through which the different regulations developed is difficult to emulate. Despite criticisms concerning some aspects of the law, the deliberative process has given a strong sense of purchase amongst many constituencies. This participation is well reflected in provisions and textual orientation. Thus, for example, MS Swaminathan commends the *Protection of Plant Varieties and Farmers Rights Act* for being globally unique in accommodating the interests of both groups within a single law. However, this law is equally significant for charting a relatively unique path in differing from the UPOV template that has dominated the regulatory landscape of plant variety protection. While retaining the UPOV template of

DUS, the Indian law differs in requiring varieties to distinguish themselves in at least one essential characteristic. The difference from UPOV is also marked by text. Thus, the exemption to use a protected variety as a source of initial variation, something that exits in UPOV, is set out as a researchers' *right*, rather than an exception to the right conferred on breeders.

The architecture of laws also exhibit interconnections that are considered useful. This follows the analysis of the different laws and regulations that have been introduced to implement obligations to the WTO and the CBD. Thus, there are disclosure requirements in the patent laws that bring to bear the provisions of the *Biological Diversity Act*. The Gene Fund has also been set up and it should provide financial resources for Farmers' Rights.

As the PBRs system has not yet becoming operational, the research focussed on the structural transformations that are occurring in the seed and plant breeding industry. Following the reforms to the seed industry in the 1980s and the economy-wide reforms of the 1990s, the sector has experienced significant turbulence. The private sector is a mix of very diverse firms with varying competency and capabilities in plant breeding. However, it has been able to displace the public sector in the (hybrid) seed market for many crops. The reforms that allowed publicly bred varieties to be multiplied by the private sector have been a factor in this transformation. For instance, in Andhra Pradesh, the rice seed market which is mainly provided for by the private sector consists of publicly bred varieties. Even in the area of biotechnology there have been substantive developments in the private sector. With the amendments to the patent law now clarifying that microorganisms are patentable and the genetically modified plants being field trialled (and a few commercially grown); there is all likelihood of this sector to grow. Some seed firms will find themselves in the vulnerable position of

technological dependence. Further, it seems unlikely that firms will invest in non-hybrids; thus, the two main food crops – wheat and rice – will remain neglected by the private sector.

The changes to the seed and plant breeding sector have raised many questions for the public sector. A range of issues are to be confronted, such as the retention of personnel, strategies for cost recovery, and protection for and licensing of publicly bred varieties. The research finds that for long a preference of maintaining a presence in the market, to generate 'healthy competition', has configured the public sector's response to these policy options. Thus, not only can the public sector seek PBRs but there are provisions for protecting extant varieties. However, in deciding on their licensing policy, the public sector will need to consider the deeper impact of each option. The experienced network of seed growers and the proliferation of State Seed Corporations and the easy access to public varieties has translated into a competitive seed industry. This is manifested in the low seed-to-grain ratio. The viability of many seed firms, particularly new entrants with no breeding capacity, and the competitiveness of the industry seriously depends on maintaining relatively easy (and cheap) access to publicly bred varieties.

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