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The Public-Private Debate in Agricultural Biotechnology and New Trends in the IPR Regime: Challenges before Developing Countries

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I Introduction

In past few years, agriculture in most of the developing countries has been getting exposed to an entirely new set of technologies, the developments in the area of biotechnology in particular. This frontier technology becomes particularly important in developing country agriculture with stagnating productivity growth and crops confronting many biotic and abiotic stresses. The constraints on productivity in developing country agriculture have become much more acute since late eighties, when green revolution varieties reached their maximum yield potential. The advancements in biotechnology seem to offer, a way out, of this impasse by opening an opportunity to attain higher productivity with sustainable development of agriculture in these countries.

The developments in biotechnology, however, have been accompanied by a stronger intellectual property rights (IPR) regime. In fact, with the advancements in this technology stronger instruments are being used for the protection of technology which are highly exclusionist in their approach. This may pose severe challenges for the developing countries as advances in this technology are largely in the private sector and these new trends in the IPR regime seems to foreclose the entry of public sector in this domain. This is happening despite of the fact that a large number of developing countries have agreed to a relatively newer IPR regime at the WTO forum. In fact, coverage of agricultural sector through an IPR regime is a recent phenomenon in the developing countries.

In this context, several issues pertaining to the role of government and space for public sector supported R&D in agriculture have been raised. The rapid economic development in many developing countries such as South East Asian countries, have demonstrated that national technological capability remains a key factor in competitiveness. The dynamism with which countries develop and use new technologies defines their paths of technological development.

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This dynamism reflects on the cumulative pattern of production and skills acquired over time and sketches out their technological trajectories. Thus one idea has been that public sector R&D institutions should develop more strength and competence in the realm of the frontier technologies. Thus the emergence of biotechnology is also accompanied by an intense debate on techno-globalism vis-à-vis the role of nation-state in technological development.

The increasing role of knowledge in agricultural production and the growing challenge of environment management in particular has to be acknowledged. This trend suggests that it has become increasingly important to bring dynamism in the functioning of the science and technology system at the national level. While the existence of a strong physical infrastructure is necessary for the development of an effective S&T system, the critical factors remain the institutional set-up that supports this system and the cohesion between the overall developmental objectives and the R&D endeavours in different streams. In fact, these factors play a far more significant role in frontier technologies, biotechnology, in particular than in case of any of the traditional technologies.

This paper is an attempt to look into these aspects more closely, as several achievements in biotechnology promises to take agricultural system out from the various technological challenges, it is facing in the developing countries. Section II discuss the promises biotechnology made in the last decade or so while section III attempts to briefly present the broad contours of the private-public debate in agriculture. Growth of agricultural biotechnology and share of private sector is discussed in Section IV. Various facets of IPR regime are discussed in section V. The last section summarizes the discussion.

II Biotechnology- A Panacea for Growth!

The potential of plant biotechnology for agriculture includes a diverse range of techniques, which appear to offer scope to help solve some of the problems of developing countries, particularly since they provide potential tools to solve agronomic problems. In fact, many developing countries, including India, launched a series of programmes to take advantage of this opportunity.[1] The Convention on Biological Diversity (CBD), 1992, defined biotechnology as, "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses." This technology facilitates plant breeders to monitor the outcomes of conventional crossings and selection, allow useful genes to be identified and cloned and make it possible for genes from the same species to be utilised more quickly and precisely than do the methods of traditional plant breeding. But most attention now is focussed on transfer of genes between different species only, transgenic crops are often called as GMOs.[2] Though the scope of plant biotechnology is very wide, now the attention is on transfer of genes between different species to develop transgenic crops. There is a vast body of literature available which discusses the probable advantages of biotechnology[3]. Fransman (1994) has taken some stalk of many ex-ante studies, but ex-post evaluation, particularly of economic returns makes the inferences clearer.

II.1 Cost-Reduction

It is puzzling to find that they are very few ex-post studies to substantiate the expected gains from biotechnology especially in context of developing countries. Pray et.al. (2001) have attempted to analyse the impact of Bt cotton in China. The study finds that, Bt varieties reduced cost of cotton production by 20 to 23 per cent over new non-Bt varieties, while prices were almost same for both. To obtain higher or similar yields non-Bt farmers had to spend more money on inputs and labour. Table 1 shows that though farms saved several hundred RMBs per hectare on seed costs by growing non Bt seed, they had to spend at least 1200 RMB more per hectare for purchasing pesticides. As spraying in insecticides is a labour intensive process, more labour costs amounting to an increase of 1500 to 2400 RMB per hectare are involved. Need to mention that along with this, other costs such as that of irrigation, plastic, fertiliser, plant growth regulator, etc. also go up. The last two columns of Table 1 show that the cost of producing a kilogram of BT variety seed cotton (say, using 33 B) is only 80 per cent of the cost of producing a kilogram of non Bt cotton and GK 12, another Bt cotton variety has 77 per cent of the cost of non Bt cotton. Similarly, Paarlberg (2001) attempted a study on US soybean. He found that, in US, farmers growing genetically modified soybean, could reduce their chemical costs by 10 to 40 per cent.

So far, the most widely used transgenic cereal varieties achieve cost saving by incorporating characteristics that eliminate the need for using specific inputs of production. One example is the varieties containing genes that code for the toxin produced by *Bacillus thuringiensis* (Bt). In this case, the farmer saves by eliminating the need for spraying against particular pests. There may be a cost saving, either with respect to the herbicides that are actually used or with respect to the differential cost of spraying as opposed to cultivating. And, to the extent that this could help reduce crop production losses to weeds, its yield implications may be significant.

Table 1: Comparison between Production Costs of Bt and non Bt Varieties of Cotton in China

Variety	Input Costs (RMB[a]/ha)					Total Cost	
	Seed (1)	Pesticide (2)	Labour (3)	Other inputs[b] (4)	Total Cost[c] (5)	RMB/ Kg[c] (6)	As % of 9418 (7)
Bt Cotton							
33B	547	244	5433	4476	10701	3.19	80
SGK321	571	131	3698	5911	10311	NA	NA
GK 12	359	337	5391	4379	10466	3.09	77
Other Bt Varieties	522	355	4513	3772	9161	2.68	67
Non Bt Cotton							
Bollworm Resistant Varieties	960	258	5525	4531	11273	4.45	112
Susceptible Varieties	327	1799	6418	4784	13327	4.09	103
Non Bt Susceptible Variety 9418	306	1996	6912	5073	14288	3.99	100

Notes: a. One US dollar = RMB 8.3
b. Fertiliser, plastic, irrigation expenses, growth regulators, plowing expenses (the only mechanised operation), and land taxes. It does not include cost of irrigation equipment or land, which are owned by the villages.
c. Authors conducted an F test and found that non Bt variety 9418 was statistically different from the Bt varieties.
Source: Pray et.al. (2001)

II.2 Yield Enhancement

Biotechnology offers several ways by which average yields can be directly increased. One is through improvements in the "architecture" of the plant to enable it to absorb more photosynthetic energy or convert a larger portion of that energy into grain rather than stem or leaf. This was, in essence, the "Green Revolution" approach of breeding dwarfing genes into plants so that the plants could make better use of fertiliser and water and produce more grain. This approach is being pursued again in the new rice architecture being studied by the International Rice Research Institute (IRRI), as well as by some private sector interests undertaking research in the fundamental mechanisms that control plant architecture. Another approach, for climates where this is useful, is to modify the plant for a shorter growing season by enhancing its efficiency in the use of fertilizer, pesticides and water. Molecular hybridization has also been demonstrated to increase the productivity of several crops, including rice and wheat, by 15 to 20 per cent[4]. But it must be noted that the on-farm yield improvements observed so far have been for transgenic varieties developed to reduce on-farm production costs rather than for the purpose of increasing yields.

However, it is not yet clear whether yield increasing experiences so far reflect a one-time advance, or the first stage of a continuing increase in yields. Considering that there are many new technologies that will, over time, be applicable for plant improvements and/or integrated into plants, the most reasonable conjecture is that the new technologies will continue to provide yield increases, that these will be introduced on a regular basis, and that each of the associated yield increases will be somewhat more than historical trends[5].

II.3 Improves Nutritional Value

There are many possibilities by which biotechnology improves the nutritional value of cereals by enhancing the presence of special nutrients or chemicals. A commercial example is the increase in the levels of biotin (vitamin H) for application in animal and human nutrition.

Biotechnology has been targeted at rice and tried used to improve upon rice to meet the Vitamin A and iron deficiencies. Vitamin A deficiency, which also interferes with the bio-availability of iron, affects 413 Million children worldwide i.e. 7 per cent of the world population. Rice endosperm does not contain any pro-vitamin A. However, through different techniques transgenic plants carrying the genes produced seeds with yellow endosperm have been developed. The biochemical analysis has confirmed that this yellow color indicates the presence of pro-vitamin A[6]. Public sector breeders have also been looking into similar special purpose applications, such as inserting genes so that vitamin A and iron becomes available through the consumption of rice[7].

Among the potentially more important applications for specific markets, are those that seek to improve the quality of feed crops. New varieties of transgenic maize that contain higher oil levels to boost energy and improve feeding efficiency or have characteristics to reduce phosphorous in animal waste are examples that are currently under development[8]. In an interesting development, that is, certainly relevant to feed grains, is a patent covering the insertion of a protein into plants, when eaten would facilitate control of animal parasites.

II.4 New Traits

Biotechnology in food grains has addressed development of a single trait only. This has mostly been herbicide and pesticide tolerance. However recently some companies like Garst Seeds, a subsidiary of Advanta, have developed maize hybrids, which can tolerate two different classes of chemical herbicides.[9] In the United States, currently about 20 per cent of the maize production is destined for such markets, with the production of high-fructose corn syrup and of alcohol being the largest of a number of the industrial uses[10]. Maize and sorghum are among the crops that produces a high yield of starch/energy per hectare, and are the leading temperate zone crops for this purpose. In essence, it has become possible to vary the feed or starch production characteristic of important crop plants within wide bounds, making it possible to use almost any starch producing plant for many industrial purposes.

There are also other non-traditional uses of cereal crops, the most important example of which is cellulose, clearly available from other sources, but perhaps usefully produced in grain cultivation under certain circumstances. These developments may have significance for rice and other cereals, which are more widely grown in developing countries. To the extent that imported cereals are priced higher than those domestically grown, using starch and other traits from domestically produced bio-engineered cereals in developing country industries could lead to costs savings and boost farm incomes. Another important possibility is genetically altering crop plants for the production of proteins of pharmacological significance. Some of the patens in this area have wide applicability to different products, including for example, to the production of maize. One patent has very broad claims, but its examples emphasize production in rice. Several of the patents mention production of specific products, not all of which are therapeutic. However, commercial applications of these technologies are not yet widely available.

III Constraints on Public Research

The agricultural sector in the developing countries is passing through a difficult phase. The challenges range from the post-green revolution stagnation in primary agricultural crops to large scale malnutrition and declining R&D allocations. There are some constraints almost all the developing countries are grappling with. A brief review of these constraints is being attempted in what follows.

One of the major constraints agriculture is facing in most of the developing countries relates to farm productivity. Green revolution contributed to achieving higher yields. The semi-dwarf high-yielding varieties of wheat and rice in the late 1960s in South and Southeast Asia revolutionised productivity growth. The higher growth rates were achieved also through the development and adoption of improved technologies, and appropriate government policies and programmes for widely disseminating the improved varieties. Productivity in most of the food crops has been stagnating since early 90s (Table 2).[11] Lowering of productivity growth in agriculture would have a bearing on per capita food availability especially for the growing population in developing Asia, where population is expected to grow to 3726 million by the year 2010[12].

Table 2: Productivity of Different Food Crops in Selected Countries (Kg/hectares)

Commodity	Country	1979-81	1989-91	1995	1996	1997	1999
Cereals	Thailand	1917	2149	2527	2293	2268	2459
	China	3029	4192	4664	4093	4844	4882
	Sri Lanka	2464	2924	3053	3015	3802	3156
	United States	4154	4583	4645	5185	5299	5735
	India	1324	2191	2140	2180	2232	2264
Wheat	China	2047	3112	3541	3734	4087	3969
	Pakistan	1566	1844	2081	2018	2053	2162
	United States	2291	2388	2408	2442	2673	2872
	Argentina	1547	1987	1937	2259	2520	2500
	India	1545	2216	2559	2493	2654	2583
Rice Paddy	Thailand	1494	2098	2441	2172	2143	2327
	China	4244	5613	6022	6206	6331	6321
	Pakistan	2466	2309	2752	2868	2827	2875
	Sri Lanka	2555	3026	3159	3123	3954	3247
	United States	5167	6356	6301	6860	6609	6622
	India	1858	2619	2784	2846	2915	2929
Source: FAO Production Year Book, various years							

Table 3: Average Annual Agricultural Research Expenditure

Countries	Agricultural research expenditures 1971-75	1976-80	1981-85	1986-90	1995	Annual growth 1971-80	1981-93
	(million 1985 international dollars)[a]					*(percentage)*	
Bangladesh	51.7	68.8	111.2	131.0	123.8[d]	**6.8**	**2.7**
China	576.9	842.5	1165.3	1460.0	1867.6[c]	**8.4**	**4.8**
India	404.4	657.6	874.6	1296.5	1561.8[c]	**9.9**	**7.5**
Indonesia	61.6	108.0	147.2	202.4	208.2[c]	**9.5**	**6.2**
Pakistan	74.6	111.6	165.7	201.8	198.3[d]	**8.5**	**3.5**
Sri Lanka	19.4	31.8	37.3	31.3	35.5[c]	**9.6**	**-1.3**
Malaysia	42.7	91.2	124.5	151.0	170.5[d]	**16.1**	**3.6**
Thailand	119.4	143.8	196.9	245.6	428.0[c]	**3.9**	**8.3**

Notes

a. To obtain an internationally comparable measure of the volume of resources used for research, research expenditures were complied in local currency units, then deflated to base year 1985 with a local GDP deflator (World Bank 1995), and finally converted to 1985 international dollars using 1985 purchasing power parities indexes (PPPs) (Summers and Heston 1991).
b. Growth rates were calculated using a least squares regression method.
c. 1990 figure
d. 1992 figure
e. 1993 figure

Source: Tabor (ed.) 1998, ISNAR.

Another major constrain is the lowering of R&D allocations for the agricultural sector in developing countries. In light of capital-intensive biotechnologies, this has become a major source of worry. As Table 3 shows, allocations for agriculture R&D have grown over the years in most of the developing countries. In case of Asian developing countries, the growth rate has been much higher between 1970-80 but has slowed down in late 80s. The sharp decline in allocations for agriculture R&D Sri Lanka is very intriguing. Similarly, in case of Bangladesh growth rate has been on the decline, from 6.8 per cent during the seventies to 2.7 per cent after 1980. In addition, there is a shift in the financing of agricultural research from public to private sector in these countries. This is in continuation of an already established trend in the developed countries where the basic R&D, which has always been seen as an exclusive domain of public research has attracted lot of private interest in the realm of plant genomics and other frontier areas of biotechnology. Now more than $300 million are being spent by private firms on sequencing of genes of different plants. The explanations for this may be attempted at two levels. One comes from the wider international setting within which newer technologies are coming up, while the other one is purely an endogenous factor reflecting on the capability of a developing country public sector *per se*.

Kalaitzandonakes (1999) explains that private investment in knowledge generation and transfer has increased because knowledge assets are gradually becoming less public in nature. The changing nature of economy from, ‘material based’ to ‘knowledge based’ with a stronger intellectual property regime covering biological systems has largely brought in this transformation. On the other hand Kumar and Sidharthan (1997) explain that the ongoing structural adjustment programmes have severely affected the ability of developing countries to support public R&D budget while Tabor (1998) observes that decline in public spending reflects a lack of public confidence in the ability of the public research system to play a meaningful role in agricultural development.

The relevance of this technology for developing countries has to be seen in the light of two factors. The first pertains to the priorities that agro-biotech research has seen thus far, and the second relates to the possibilities of access of small farmers to this technology.

The integration of biotechnology in the overall agriculture research context. As plant breeding has been the major tool for agriculture R&D since the early sixties, so the question then would be relating to the factors that determine the maximum mix of biotechnology and traditional methods in plant breeding programmes of the future. The first determinant emanates from the very perception of usefulness of genes accessible from incompatible species. For instance, the Round-up tolerance and Bt genes from bacteria have benefited crop production in many ways. The second determinant is the relative cost of using biotechnology and traditional plant breeding methods for cultivar development. The relative cost factor becomes more important when both traditional technique and biotechnology can help in cultivar development.

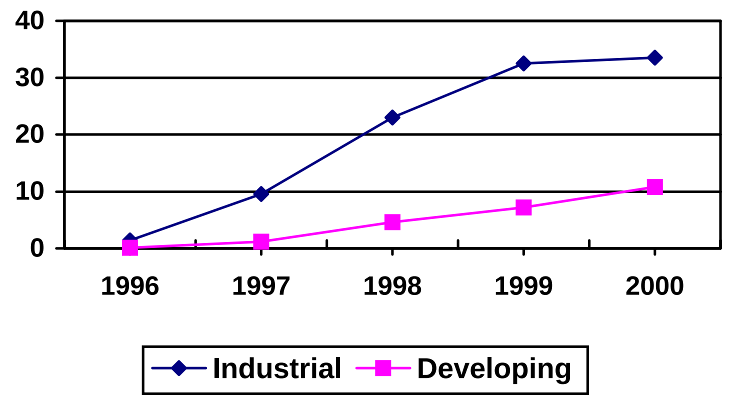
The direction of public sector research was in keeping with the basic objective of achieving larger access to advanced technology for insuring food security through both food crops and commercial crops. Therefore, public sector research took a balanced view, giving full attention to the crops linked with the food security of a developing country. The latter is particularly important in most developing countries given that small farmers form a large proportion of the farming communities in these countries. One aspect that needs to be kept in view while dealing with the agricultural sector in the developing countries is that the farming community comprises mostly of resource poor small and marginal farmers. They work in a typical 'low external input sustainable agriculture' (LEISA) production model. This model, by its own nature is sustainable, however, the challenge before the modern technology is to enhance the productivity of such farms without adversely affecting their sustainability. The location-specific dimension, while working out any strategy for R&D support demands that it should have involvement of the local resources as local knowledge and local biodiversity. This approach only would provide a sustainable agricultural system.

As is clear from the earlier section, emergence of biotechnology has given lot of hope to the developing countries. However, the international environment in which these technologies are being developed is considerably different from the one which saw the adoption of the "Green Revolution".[13] The most significant difference is that unlike the Green Revolution varieties, which were primarily developed in the public funded organisations, developments of the biotechnology are being spearheaded by commercial companies, as we would see in the following section. However, the level of research, development and use of biotechnology in the public sector, in most of the developing countries, has been much higher than that in the private sector, though this picture is changing very fast.

IV Growth in Biotechnology

In last one decade or so the rate of transfer of biotechnology to the field has gone up many times. Figure 1 shows the relative hectarage of transgenic crops in industrial and developing countries during the period 1996-2000. In the developed countries it has gone up from 1.4 million hectares in 1996 to 33.5 million hectares in 2000 amounting to a growth of 96 per cent while the proportion of transgenic crops in developing countries has increased from 0.1 million hectares to 10.8 million hectares in the same period. The area under GMO in the developing countries grew at a rate of 14 per cent in 1997 to 16 per cent in 1998 and 18 per cent by 1999. In 2000, it showed a rise of 24 per cent. Table 4 gives the country-specific details. The total area under transgenic crops at present is 44.2 million hectares. Out of this, USA and Canada among the developed

Figure 1: Global Area of Transgenic Crops, 1997 to 2000: Industrial and Developing Countries (million hectares)



Source: ISAAA (2001)

countries and Argentina and China among the developing countries show a wider adoption of this technology. Developing countries have almost 11 million hectares under transgenic crop cultivation. Table 4 also shows that smaller Latin America and CIS countries are among other developing countries who have embarked on the GM adoption path in the last two years.

Accordingly, the global market of biotechnology has grown rapidly in the last few years. In 1995 it was at $75 million while in 1998 it was $1.5 billion. This is now being projected to $6 billion by 2005. This period has also seen a very rapid rise in acquisition, alliances and mergers. There are several factors responsible for these initiatives. James (1998) explains that those firms having larger status in pharmaceuticals/biotechnology are now entering in agricultural sector. As a result, there has been major meager and acquisitions among major firms world wide. Table 5 lists major 25 acquisitions and alliances, which alone are worth $17 billion.

Table 4: Global Area of Transgenic Crops 1996-2000 by Country (Million Hectares)

Country	1996	1997	1998	1999	2000
USA	1.5	8.1	20.5	28.7	30.3
Argentina	0.1	1.4	4.3	6.7	10
Canada	0.1	1.3	2.8	4	3
China	1.1	1.8	---	2.3	2.5
South Africa	---	---	<0.1	0.1	0.2
Australia	0.1	0.1	0.1	0.1	0.2
Romania	---	---	---	0.1	0.1
Mexico	0.1	0.1	<0.1	0.1	0.1
Bulgaria	---	---	---	---	0.1
Spain	---	---	<0.1	0.1	0.1
Germany	---	---	---	---	0.1
France	---	---	<0.1	0.1	0.1
Portugal	---	---	---	0.1	---
Ukraine	---	---	---	0.1	---
Uruguay	---	---	---	---	0.1
Total	**3.0**	**12.8**	**27.8**	**42.5**	**46.9**

Source: ISAAA Briefing Papers (Various Issues)

Table 5 lists three major mergers worth $13 billion. As the list of acquisitions show Monsanto has emerged as the biggest player in the game. In the process, it has acquired some of the largest firms in the US commodity markets and holds important patents. For instance, DeKalb has 11 per cent of US commodity market with lots of important patents. Similarly, Delta & Pineland is the largest US company for cotton seeds. Monsanto has also acquired international seed operations of Cargill for $1.4 billion. Cargill specialised in seeds of corn, sunflower, rapeseed, soyabean, alfalfa, sorghum, wheat and hybrid rice in 51 countries. Unilever owned Plant Breeding International Cambridge Ltd. (PBIC), earlier a public research institute has also been bought by Monsanto. PBIC largely focuses on cereal varieties and potato.

Among the mergers one finds creation of Novartis is a major step towards tapping of synergies in the biotechnology business. Ciba and Sandoz have merged their pesticide and seed business of $ 5 bn. to take form of Novartis. Similarly, the merger of Hoechst and Rhone Poulenc to form Aventis was to achieve better operational efficiency. Aventis now has an R&D budget of $3 billion and annual sales of $ 20 billion all over the world.

V Facets of TRIPs Regime

Over the years, TRIPs, has emerged as one of the most widely debated WTO agreement. The emergence of biotechnology has further intensified the debate. The writings have largely been focussed on the Article 27.3(b) of WTO agreement on TRIPs, which requires developing countries to provide either patents or an "effective *sui-generis*" protection for the ownership of plant varieties by the year 2000. For the least developed countries, the deadline is extended uptil the year 2005.

Though the US and other developed countries proposed a formal review of this article, resistance from other trading nations did not allow for the proposed review, in the WTO. This is of course a temporary relief. If at all this review is pushed back on the formal agenda, it would not come up before the next round of negotiations, which is in 2001-2, and even if it is taken up, it is not likely to be concluded before the completion of the round which would be by 2005 only.[14] There is a large body of literature defining the concept *sui-generis* and whether UPOV 1978 or 1991 is of greater relevance for the developing countries,[15] a detailed discussion of that is outside the scope of the paper.

Table 5: Biotechnology-driven Acquisitions, Alliances and Mergers (1995-98)

Company/Partners	**Corporations Involved/Activity**	**Estimated Value ($ billion)**
Acquisitions and Alliances		
Monsanto	Agracetus, Asgrow, Calgene, DeKalb, Delta & Pine Land, Holdens, Sementes Agroceres, selected International Seeds Operations of Cargill, Plant Breeding International Cambridge (PBIC) (acquisitions)	8.6
Pioneer/Dupont	Joint Venture to form "Optimum Quality Products"	1.7
DuPont	Protein Technologies Inc.-soybean miller and processor (acquisitions)	1.5
AgrEvo	PGS, Sun Seeds. Cargill North America (acquisition)	1.5
Seminis (ELM/Pulsar)	Asgrow, Petoseed, Royal Sluis, DNAP, Hungong and ChoonAng, Nath Slusi (acquisitions) LSL Biotechnologies (alliance)	1.2
Dow AgroSciences	Mycogen, Performance Plants, Brazil Hibrido & Others	0.8
Cargill/Monsanto	R&D joint venture; $100 million per year from each	0.2
Others	Includes Crop Genomics Acquisitions and Alliances	1.5
	Total	**17.0**
Merger		
Ciba/Sandoz	Novartis created, with seed/pesticide sales of approximately $5 billion	5.0
Hoechst/Rhone Poulenc	Aventis created, with agricultural sales of AgrEvo and Rhone Poluenc Agro exceeding $ 4.5 billion annually	4.5
Zeneca and Van der Have	ADVANTA with annual sales of seed plus pesticides from Zeneca of approximately $3.5 billion	3.5
	Total	**13.0**

Source: ISAAA (1998)

But, the pertinent question is what agenda developing countries should pursue and to what extent it is technologically tenable. An answer to this should only guide the future course of action for the developing countries not only with respect to TRIPs negotiations but also their IPR policy in general. In this context, it needs to be mentioned at the outset that the increasing importance of genetic engineering in agricultural research across the world, a continued increase in genetically modified organisms (GMOs) and the ability to patent plants has actually reduced the importance of plant variety protection and consequently of the *sui-generis* system within the IPR regime.

Here it would be interesting to take a stock of the broad trends in the intellectual property regime at the level of individual developed countries. Till recently, life forms used to be exempted from patenting. However, developments in biotechnology are compelling for revising the approach towards the intellectual property regime. These policy changes have largely been taking place in the USA, but now European Union and Japan are also all set to closely follow in this race. Accordingly, various national governments are bringing in changes in the national laws in order to protect and encourage investments in biotechnology. These policy changes have further widened the scope of the ongoing debate. Now it covers a wide range of issues such as the range of product patents and the patentability of genes, gene-sequences and parts of gene-sequences derived from humans, animals, plants or microorganisms. The added aspect is of the relationship between the patent system and the plant variety system. Moreover, patenting, especially of human body parts, has posed an ethical limit for biotechnology itself. In the following sections we attempt to analyze some of these prominent trends in the patenting regime.

V.1 Moving from PVP to Plant Patents

In recent past, plant variety protection (PVP) and the patents have emerged as two important forms of intellectual property rights. In context of developing countries, PVP has been there for some time but patents for plants is a recent phenomenon. As Table 6 shows both patent and PVP provide exclusive monopoly rights over a creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for 15-20 years. The criteria for a patent are novelty, inventiveness (non-obviousness), utility, and reproducibility. Although patents were designed for industrial application, with biotechnology, patent offices now grant patents on microorganisms and, in some countries, on all life forms.

The intellectual property regime for plant variety protection emerged with a strong commitment for public interest in mind. The whole provision for compulsory licensing was introduced with this intention only. Under this provision of compulsory licensing a holder of plant breeders' rights can neither refuse any applicant nor can offer unreasonable terms for this. Plant variety protection has worked well as a mechanism to promote the interests of the plant breeders for developing new varieties through giving them proprietary rights on the one hand and as a custodian of public rights of access and use of genetic material on the other hand. PVP gives patent-like rights to plant breeders. What gets protected in this case is the genetic makeup of a specific plant variety. The criteria for protection are different: novelty, distinctness, uniformity, and stability. PVP laws can provide exemptions for breeders, allowing them to use protected varieties for further breeding, and for farmers, allowing them to save seeds from their harvest. In plant breeding, thus PVP is the weaker sister of patenting mainly because of these exemptions. PVR also encourages cross licensing between a holder of PVR and a holder of a patent. Under the breeders' exemption of plant variety rights anyone may use protected material for breeding purposes. However, the patent regime does not reciprocate this.

As Table 6 shows, in the patent regime the interpretation of research exemption is much narrower than that of the breeders' exemption in PVR. Thus, for instance, if a breeder wants to produce a new variety and needs a compulsory cross-license from a patent holder, the breeder has to demonstrate that the breeding programme will produce a technical progress, but all results of a breeding programme, take a long span of research and development effort, so how can we demonstrate the technical progress right in the beginning? Thus cross licensing for a plant breeder, hardly means anything.[16] Thus for all practical purposes PVR ends up protecting small advances in the breeding process while patent regime would actually lead the protection of bigger leaps in technological achievements.

In Europe, animal and plant varieties have always been excluded from patentability under Article 53 (b) of the European Patent Convention (EPC). This convention was signed in 1973. The term "variety" was not defined in the EPC. As plant varieties could be protected either through the existing national laws (plant breeders' right) or through the UPOV convention. With this, European Patent Office started establishing the fact that plant varieties fall under the jurisdiction of the patent regime. One of the major reasons sited for slow growth of biotechnology industry in Europe is the lack of certainty concerning intellectual property protection for biotechnology inventions[17]. The proponents of biotechnology suggest that the conflicts between the ethical aspects of technology development vis-à-vis commercial gains from technology have not allowed the growth of this industry. The Novartis decision (Decision G01/98) seems to confirm this. The decision suggests that plant varieties are not patentable but patent on a genus is possible. The genus is made up of species and sub-species and varieties. This mean that patents control of varieties is acquired through the proprietary control of genus. In the Novartis case, at issue, were the claims to plants containing a gene conferring resistance to plant pathogens. The Technical Board of Appeal referred the question to the Enlarged Board of Appeal.[18]

Table 6: Agreement on Trade Related Aspects of Intellectual Property (TRIPs), US Utility Patent Protection, the European Patent Convention (EPC) and the International Convention on the Protection of New Varieties of Plants (UPOV)

	TRIPs Agreement	**US Utility Patent**	**European Patent Convention**	**UPOV Convention 1991**
Granting Criteria	Novelty, Inventive step and Industrial Applicability	Novelty, Non-obviousness, Utility	Novelty, Inventive Step, Industrial Application	New, Distinct, Uniform and Stable
Industrial Applicability/Utility	Not defined	Advantage over the Prior art	The invention must be capable of industrial application-this includes agricultural use but does not include methods of human treatment	Not a requirement
Distinctness	Not defined even as a requirement for the *sui generis* system of protection mandated for plant varieties under Article 27 (3) (b)	Not a requirement	Not a requirement	The variety must be clearly distinguishable in its essential characteristics from other varieties, which are a matter of common knowledge (e.g. protected by a plant variety right) at the time of application.
Extent of Protection	a) Where the subject matter of the patent is a product the right allows the holder to prevent third parties, not having the consent of the holder using, offering for sale, selling or importing the product b) Patent holder can deny usage of the process he has developed or even the sale of product of that process	a) Right to prevent all others from using the invention. b) Protection extends to all biological materials genes to genotype	a) Right to prevent all others from using the invention b) Broad claims are not permitted c) Protection extends to all biological materials, genes to genotype and includes plant groupings but not plant variety	a) Right to produce, reproduce, sale or stock any plant variety b) Right to extends to harvested material and other products obtained from material of the variety provided
Farmers Privilege	Not specific-but possibly permitted via Article 30	Not permitted	Not permitted	Optional Contracting Parties may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeders' right in relation to any variety in order to permit farmers to use for propagating purposes
Breeders/Research Exemption	Not specific-but possibly permitted via Article 30	Free use of protected material for research purposes is permitted but only where it is for non-commercial purposes.	No-but such an exemption is usually provided in the national patent laws of Member States of the EPC.	Yes-non-infringing act include a) acts done privately and for non-commercial purposes b) acts done for experimental purpose and for breeding
Compulsory Licences	Yes, but only where a) the applicant has requested for and been refused a licence from the patent holder b) the use for which the applicant wishes to use the protected invention	No, although the ability of the patent holder (the licensor) to dictate the terms of any licence s/he chooses to grant are subject to extensive restrictions via the common law doctrine of patent misuse and anti-trust		Not mentioned as such Article 17 states that 1) Except where expressly provided in this Convention, non Contracting Party may restrict the

	is non-exclusive c) the use is predominantly within the domestic market d) the licence holder pays an adequate remuneration Where the licence is needed in order to exploit a second patented invention which is dependent then a licence will be granted only where 1) the invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; 2) the owner o the first patent is entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and 3) the use in respect of the first patent is non-assignable except with the assignment of the second patent. Each case is assessed on its individual merits, it is non-assignable, it is subject to termination when the circumstances change and any decision is subject to judicial review	laws		free exercise of a breeders' right for reasons other than of public interest 2) When any such restriction has the effect of authorising a third party to perform any act for which the breeders' authorisation is required, the Contracting Party concerned shall take all measures necessary to ensure that the breeder receives equitable remuneration
Duration of Protection	20 years from the date of filing	20 years from the date of filing	20 years from the date of filing	30 years for trees and vines, 25 years for all other varieties (Article 19)

Source: US Department of Agriculture Economics Research Service (1998)

The Board found that a claim in which plant varieties are not claimed is not excluded from patentability under Article 53 (b), even though it may embrace plant varieties. The Board further concluded that inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the European Patent Convention if they met the all other requirements of patentability.

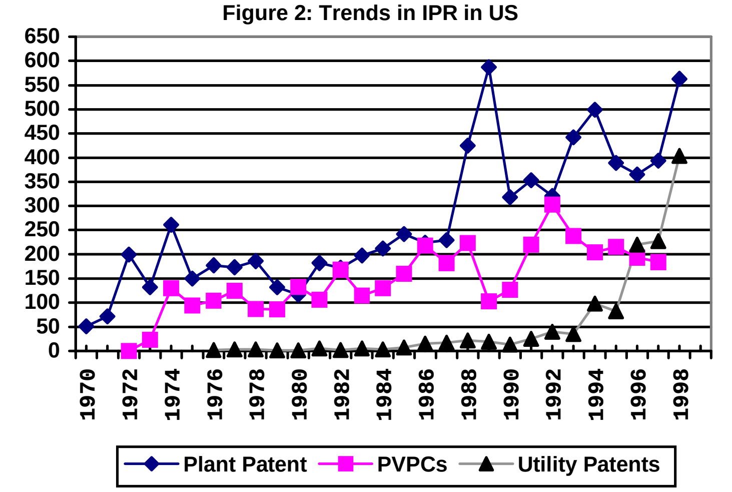
However, a directive from European Community on the protection of biotechnology inventions (Directive 98/44EC) contains specific provisions on the patentability of genetically engineered biological material including plants and animals. This marks a major departure from earlier practice in the European Union. The directive was adopted by the European Union on July 6, 1998 and all the necessary amendments were rectified by the EU on September 1, 1999. The most significant feature of the directive is the provision pertaining to the patentability of the biological material including inventions relating to plant and animal varieties, human body and sequences or partial sequences of genes[19]. The individual member states of the EU have two years to amend their national laws to bring them into conformity with Directive[20]. The explanatory notice published in the OJ EPO records that since the early 1980's, the EPO has received about 15000 applications in the field of biotechnology, for which about 3000 patents have been granted. 1500 applications relate to transgenic plants 600 to transgenic animals and 2000 to DNA sequences. The Biotech Directive had to be implemented into national law by 30 July 2000.

Germany has demanded that this directive is inadequate for promotion of biotechnology and in order to retain competitiveness of European biotechnology industry the directive should be further strengthened and tightened up. Most of the implementation was done by the UK through the Statutory Instrument (SI) 2000/2037. UK law is largely compatible with the Biotech Directive already. UK is attempting some balancing act between PVP and patents. There were one or two areas where changes are required. In particular, there needed to be introduced, into the patent law, derogations, equivalent to the derogations in the plant varieties legislation, to enable farmers to save and use seed on their own farms. A cross-licensing provision also needed to be introduced to both acts between plant variety rights and patent rights where the invention or plant variety constitutes "significant technical progress" over the other right and could not be exploited without infringing the protection conferred on the other rightholder. "Significant technical progress" is a high hurdle to overcome. This part of the Directive is still to be implemented. Although these compulsory licence provisions are proposed to give recompense to the other rights holder, they also require the applicant for the compulsory licence to cross-license its own rights to the person from whom it is seeking the compulsory licence.[21] The UK SI has produced new schedules in order to ensure uniformity between the UK patent legislation and the Biotech Directive, the Patents Act and Rules to set out clearly the provisions of the Biotech Directive in national legislation. There is minor tinkering with the Patents Act itself and the Government is taking this opportunity to ensure compliance with TRIPs (Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods-part of the last round of the General Agreement on Tariffs and Trade) and the recent changes to the EPC.

V.2 *Emergence of Utility Patents*

In the US the extension of IPR's to new plant varieties and biological inventions, including the development of biotechnologies, has stimulated private companies to invest in plant breeding[22]. The Plant Patent Act of 1930 and the Plant Variety Protection Act (PVPA) of 1970 established plant breeders' rights for new plants and plant varieties. In 1980, a Supreme Court decision (*Diamond v. Chakraboarty)* authorized the use of patents for biological inventions, specifically microorganisms. Several recent decisions by the Patent and Trademark Office broadened the use of patents for plants and created space for Utility Patents (ex parte Hibberd in 1985) and animals (ex parte Allen in 1987). Utility patents are for any, "new and useful process machine, manufacture, composition of matter or any new and useful improvement therefor." Utility patents can protect all the parts of the plants including genes, seeds' physiological and physical traits. As Table 6 shows utility Patents have a larger coverage than PVPs in the sense that they cover not just a single variety as in PVP 3 but also all other varieties having same traits and functional properties. Further, in utility patent not only a single claim is allowed but it also provides protection for covering plant parts including flowers, fruits and cuttings, etc. Apart from this, protection is not dependent on whether the plant is sexually produced or asexually produced.

Figure 2: Trends in IPR in US



Source: USDAER (2000)

As a result, private-sector research expenditures for plant breeding have increased from $6 million in 1960 to $400 million in 1992 (Klotz. Fugile, and Pray, 1995; Fugile, Klotz, and Gill, 1995). Nearly 70 per cent of private-sector plant breeding research expenditures in 1989 was for corn, vegetables, and soybean. Private firms have also reacted to changes in IPR's by investing heavily in biotechnology techniques.

The number of Plant Patents, Plant Variety Protection Certificates (PVPC's) and Utility Patents issued over the last 25 years has risen (Figure 2). The PVPA stimulated the development of new field crop varieties. By the end of 1994, 3,306 PVPC's had been issued for new crop varieties. The number of PVPC's issued for new varieties of field crops, grasses, and vegetables climbed up from 153 in 1971-74 to 992 in 1991-94. New soybean, corn and vegetable varieties accounted for 56 per cent of total PVPC's awarded. The private sector own approximately 87 per cent of the total PVPC's issued. Oats was the only crop of which the public sector held a higher share of PVPC's. However, Utility Patents are the most difficult to obtain and have been awarded primarily for new biotechnology innovations, such as genetically engineered varieties. The number of utility patents issued has grown up very rapidly in the US. By December 1994, 324 Utility Patents had been issued for new plants or plant parts and 38 were issued for animals. As with PVPC's, most utility Patents were awarded to the private sector (Fugile, Klotz, and Gill, 1995). Thus, IPR has encouraged the private sector to develop new agricultural technologies by enabling firms to capture greater share of the commercial value of their inventions.

V.3 Patenting of Research Tools

One of the major trends in the patenting which is emerging in US patent system is their broad nature. At times, it is even encompassing research tools necessary for further downstream research and development. Some of the research tools, patenting of which have attracted attention are expressed sequence tags (ESTs), restriction enzymes, screening systems, technique related to DNA sequencing and single nucleotide polymorphisms (SNPs). [23] As these research tools by definition have the power to control the downstream research of pharmaceuticals, they can wield an extremely large influence when patented. The problem of broad patenting is actually grown over the years. For instance, Agracetus patent on all transgenic cotton (US patent 5, 159, 135) or similar patents on all transgenic soybean. Some of these patents are subject to reexamination or litigation to determine their validity. Similarly, a new US patent awarded to Monsanto in 2001, giving an exclusive monopoly right on crucial method identifying modified plant cells in laboratory. US Patent No. 6, 174, 724 covers all practical methods of making transformed plants that employ antibiotic resistance markers. The technique has been used in virtually all commercial GM crops. An earlier patent granted to another major US firm, Syngenta, covered a marker, which enables plants cell transformation and selection without the use of antibiotic resistance marker. This technology was first developed in a very small firm Danisco in Denmark. This company sold the patent to Sandoz in 1998, which later became Novartis, which in 2000 became Syngenta.[24]

These issues can give rise to several policy challenges when seen in context of developing countries. It may just foreclose entry of the late comers in the technology race, which would eventually affect public sector research endeavors, as is mostly practised in the developing countries. While when seen in larger context of investment in research in developing such techniques, patents seems to be the only way to recover the investment. However, the need seems to be to analyse the research trends in the overall context of social requirement as with individual technological features of research tools, the scope of the technology and its contribution to society may differ. For instance, in developing countries ensuring a higher crop yield for adequate food supply would always be a priority over the necessity of developing a drug required for life style diseases.

The problem of EST patents having severe implications for future progress of genomic industries is also being seriously analysed in Japan. The opinion which is emerging there, suggests that, the utility of ESTs will not be recognised from the mere disclosure of a general function i.e. capability of use as a research tool, and such EST inventions will not be patented.[25] However, utility of EST can be recognised if it can be used as a probe for a gene encoding a specific useful protein or that it can be used as a tool to diagnose a specific disease.

VI Concluding Observations

The post Green Revolution, agriculture production scenario seems to pose several challenges for food security in developing countries. It is high time that agricultural R&D plans prioritise investment on new technologies so as to rightly balance or rather supplement the traditional techniques with new technologies such as biotechnology. However, the opinion about biotechnology among the developing countries is mixed. There are experts who actually enlist several factors why biotechnology *per se*, is not the right technology to ensure food security and reduce poverty in the developing countries. They even go up to the extent of saying that biotechnology is a technology that has been shaped by a narrow range of private interests – interests that are incompatible with the demands of an ecologically sound and socially – just agriculture.

Thus the issues that the advent of this technology raises, covers a much wider canvass. The ethical dimension of the genetically modified organisms (GMOs) have further confounded the ongoing confusion on the relevance of biotechnology for the developing countries. In the last decade or so, the transnational corporations have emerged as a major source of biotechnology products. This trend has, probably, further contributed to the concerns among the developing countries as reports about bio-piracy galore. These concerns have got reflected in the wider debate being initiated to assess the relevance of this technology for developing countries.

In such a scenario, it may not be entirely misplaced, to observe that, since biotechnology is a frontier technology, upcoming in a dynamic international environment, it probably requires an altogether different approach to ensure the growth of the technology along with the desired socio-economic goals. Thus it poses a two-fold challenge, on one hand, the growth of technology has to be ensured and on the other, policies would have to be evolved not only to restrict its adverse implications but also for ensuring growth in the agricultural sector. Any imbalance between the two may offset the wider developmental impetus, the agricultural sector needs at this point.

The WTO TRIPs regime article 27.3 (b) refers to have either a patent regime or an effective *sui generis* system for protection of plant varieties. In last decade or so, the developing countries have strongly debated the various aspects of *sui generis* system and what actually constitutes it. However, as is evident from the earlier sections the varietial protection is being attempted through much more stronger patent regime, which do not allow any kind of exemption and is much narrower in its scope than the plant patents or plant variety protection. There is a continuous growth in what is called the utility patents in the US while the Biotechnology Directive of EU has suggested a similar mechanism for the protection of biotechnological inventions in the Europe. Along with this there is also a growing trend of patenting the research tools as well. Thus in light of the developments in biotechnology the profile of patent regime is fast changing in the developed countries. Needless to mention that a large part of this research is emanating from the private sector.

These changes would have severe implications for the developing countries. More so when they are already struggling with the implementational hurdles of the TRIPs regime. There are many developing countries, including India, which have yet to put in place national legislations to position themselves vis-à-vis the international negotiations at the WTO. India has come out with several drafts of biodiversity and patent laws but they have yet to see light of the day. There have been several reasons for this delay but now it seems to be clear that it would not only adversely affect the access to technology per se but the patenting of research tools would also exclude the late comers in the technology race from imitation or even from product development in any other form.

In this context, the role of public research institutions becomes very relevant. In developing countries productivity levels have yet to move anyway closer to the ones achieved in the developed countries. This requires not only the continuation of all budgetary support for the public research institutions in the developing countries but if required even increasing them to meet the demand. It is also important to ensure that public plant breeders/laboratories have access to the best science and germplasm. Similarly capacity in public plant breeding should be enhanced. This increased capacity should be directed towards those crops, which are not likely to attract private investment. Over last so many years public plant breeding programmes have evolved with a free exchange of germplasm and cooperative scientific endeavours.

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