

## Analysis of Opportunities and Challenges in IPR and Agriculture in the Indian Context

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This paper assimilates and contributes to the current state of IPR knowledge and proprietary products in the Indian jurisdiction. The influence of international IPR domain and influx of proprietary foreign technology products on Indian agricultural technology profile *vis-à-vis* the plight of the national players is discussed, particularly, with respect to patenting in plant biotechnology/transgenics. The factual scenario under the national PPV&FR regime is narrated. This paper also analyses the recent foreign interests in respect of patenting in the areas of animal vaccines and diagnostics *vis-à-vis* the existing strength of the national system, which needs to be maintained.

**Keywords:** IPR, agriculture, patent, PPV&FR, transgenic, technology transfer, licensing, vaccines, diagnostics

The TRIPS Agreement, Article 65, had allowed a total transition period of 10 years (January 1995 – December 2004) to the developing country members for extending product patent protection in their respective territory to the areas of technology that were not protectable earlier. During the transition period, the member countries provided an agreed mail box arrangement for receiving patent applications filed by foreign nationals for such products. Thus, India received mail box applications as per the Patents (Amendment) Act, 1999 for inventions in the areas of food and chemical (including biochemical and biotechnological) substances, also related to agriculture. Many of these patent applications filed in India during that period were the national phase entries

of the international applications earlier filed elsewhere by the applicants under the Patent Cooperation Treaty (PCT applications).

### Foreign Proprietary Technologies in Indian Landscape

There is a bounty of foreign proprietary technologies in the field of agricultural biotechnology that have been recently added to the Indian landscape. For example, a simple search in the Indian patent office database<sup>1</sup> for ‘transgenic plant’ in the abstract revealed more than 50 patents granted to as many as 35 applicants (Table 1), including foreign (22 companies, 8 universities and research organizations, and 2 individuals), and Indian

Table 1—Granted Indian patents for ‘transgenic plant’ categorized by patentees as on 1 March 2011

Foreign companies	Cropdesign N V, Monsanto Technologies LLC, Syngenta Participations Ag, Pioneer Hi-Bred International Inc, BASF Plant Science, Bayer Bioscience, Centocor Inc, Japan Tobacco Inc, Meristem Therapeutics, Senesco Technologies Inc, Agrivida Inc, Avestha Gengraine Technologies Pvt Ltd, Chromagenics B V, Dow Agrosciences LLC, E I Du Pont De Nemours & Co, Fraunhofer-Gesellschaft Zur Forderung Der Angewandten Forschung E V, Kweek-En Researchbedrijf Agrico BV, LTA Resource Management Maxygen Inc, Nippon Paper Industries Co Ltd, Protalix Ltd, Warner-Lambert Company LLC
Foreign universities/ Institutes	Auburn University, Bar Ilan University, Texas Tech University, The University of Chicago, University of Central Florida, The Hebrew University of Jerusalem, Leibniz-Institut fur Pflanzengenetik und kulturpflanzenforschung (IPK), Max-Planck Gesellschaft
Indian universities/ Institutes	ICAR (Indian Agricultural Research Institute), Bose Institute, Tamil Nadu Agricultural University
Foreign individuals	Raab R Michael, Yeh Shyi-Dong

Source: Compiled data from <http://ipindia.nic.in/...> patent search

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(3 institutes and universities). Fig. 1a provides the applicant/sector-wise distribution of the patents in this area, whereas Fig. 1b reveals that, of the identified patents, 22 were mail box applications.

Some of the interesting patents granted to multinational companies, viz., Monsanto include ‘Cotton event Mon 88913 and compositions and methods for detection thereof’, ‘Novel plant promoters for use in early seed development’, and ‘DNA constructs and methods to enhance the production of commercially viable transgenic plants’.

The search also showed that 18 of the published applications were filed by Monsanto before 2005 (mail box applications) and the company had 144 published applications as on 1 March 2011 related to transgenic plants. A Monsanto application on ‘Identification of seeds or plants using phenotypic markers’ filed in Chennai patent office was also abandoned under Section 21 of the Patents Act, 1970, perhaps strategically, since the company had chosen not to file a reply to the objections made by patent examiner within the stipulated time. Nevertheless, some of the key Monsanto applications that are under examination or awaiting examination include, Cotton event Mon15985 for the BollGard-II technology, Cotton event Mon88913, Corn plant and seed corresponding to transgenic event Mon89034, Corn plant Mon88017, Soybean event Mon89788 and methods for detection thereof, Methods for improving the yield of cucumber plants, Transgenic crop plants with improved stress tolerance, Methods for incorporating multiple genes in a crop plant, Methods and compositions to enhance plant breeding, High throughput screening, Methods for producing hybrid seed, Method for selection of transformed cells, and Method and apparatus for substantially isolating plant tissues, etc.

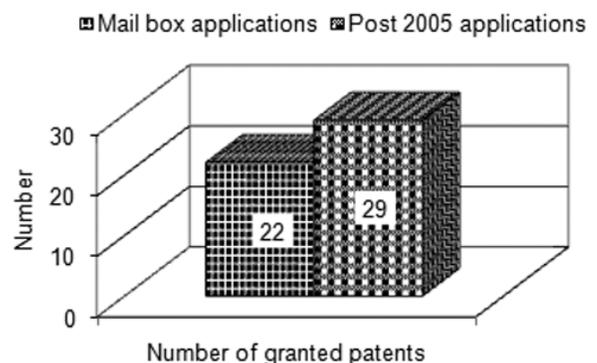
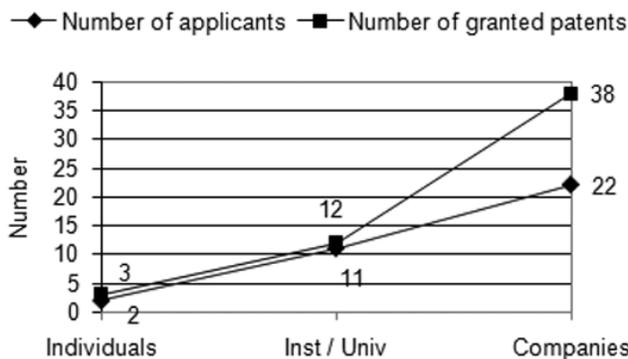
Thus, given ‘competitiveness’ as the buzz word under the global IPR domain, the national agricultural research system in India is now expected to re-prioritize and undertake research on those key areas that may yield technology profile specifically suited to Indian situations, and complement the international proprietary technologies protected in the country.

Nevertheless, there is also an opportunity before the public sector research system to harness the benefits of their intellectual property in the international market where adaptation of these novel technologies under similar agroclimatic conditions would be high.

### Indian Proprietary Agricultural Technology Profile

#### Patents

The Indian Council of Agricultural Research (ICAR) is the IP leader with over 60 granted patents in various field of plant and animal science, including biotechnology, dairy technology, animal disease diagnostics, and therapeutics, engineering and post harvest processing, and environmental science. Other patentees in core agriculture fields include universities, Indian institutes of technology, and other research organizations and institutions like Council of Scientific and Industrial Research (CSIR), Defence Research and Development Organization (DRDO), Bose Institute, etc. Quite a few patents have been granted to individual inventors for inventions such as: An improved agriculture harrow disk, Tractor mounted multipurpose deep trencher, a preparation for enhancing yield in agriculture and horticulture, a composition for enhancing nitrogen fixation in legumes, etc.



Source: Compiled data from [http://ipindia.nic.in/...](http://ipindia.nic.in/) patent search

Fig. 1a—Granted Indian patents for ‘transgenic plant’ (by applicant/sector)

Fig. 1b—Granted Indian patents for ‘transgenic plant’ (by timeline)

However, unlike the proprietary foreign technology used in agriculture in India, in the recent times, commercialization of Indian proprietary (patented) technologies is rather low to almost none. This situation requires further insight and efforts towards patent landscaping, IP audit, valuation and negotiation for commercialization within the country despite an already intense, extravagant capacity building and human resource development effort being already made by all concerned. It is time to focus on the *niche* areas where the national R&D strength lies and help the world, particularly the developing world, in meeting their present and future agriculture technology needs through effective partnerships with multinationals where possible.

#### Plant Varieties

A sizeable number of 2220 applications for the protection of plant varieties in the country have been recorded by the plant variety registry.<sup>2</sup> Of these, 2119 applications (extant = 1222, new = 841, EDV = 1, farmer = 55) were made up to 31 December 2010 and a further 101 applications, mainly new in 2011. In contrast to this sizeable number, the number of extant varieties registered (certificates issued) were a meager 217 (Table 2), including the three farmer varieties registered as extant varieties. Further, only two certificates were issued to private sector for their new varieties registered.

Not only are the titles granted to plant varieties so far in India are a few, a critical examination reveals that the registered and protected extant varieties

Table 2—Extant varieties registered in India (as on 1 March 2011)

Grantee	Number of plant variety titles granted
<b>Public Sector</b>	
Indian Council of Agricultural Research	186
Orissa University of Agricultural & Technology	7
Birsa Agricultural University	2
Dr Panjabrao Deshmukh Krishi Vidyapeeth	3
<b>Private Seed Companies</b>	
New Nandi Seeds Corp	7
JK Agrigenetics	4
Maharashtra Hybrid Seeds Co Ltd	2
Ajeet Seeds Ltd	2
Vikram Seeds Ltd	1
<b>Farmers</b>	
Individuals	3
<b>Total</b>	<b>217</b>

Source: Compiled data from <http://www.planauthority.gov.in/>

have so far not been subject to any licensing and cross-licensing, for the purpose of promoting R&D on well adapted Indian crop varieties in food crops (cereals, millet and legumes). Since Indian plant variety legislation had provided a fairly long transition period for the registration and protection of the existing varietal products, it could be a lack of confidence and negotiation capacity that the proponents of a unique idea of the extant variety protection in the country have not been able to steer the intended purpose to a logical conclusion. On the other hand, copies of the germplasm of these registered extant varieties are being freely used by all sectors from the already available public domain, including the international gene banks and nurseries.

Therefore, unless an appropriate corrective measure is taken at this stage, which may include a voluntary license by ICAR or compulsory license by the Protection of Plant Variety and Farmers' Rights Authority (PPV&FRA), this gap is likely to be recorded as a historic legislative extravaganza and an error under the PPV&FR jurisprudence.

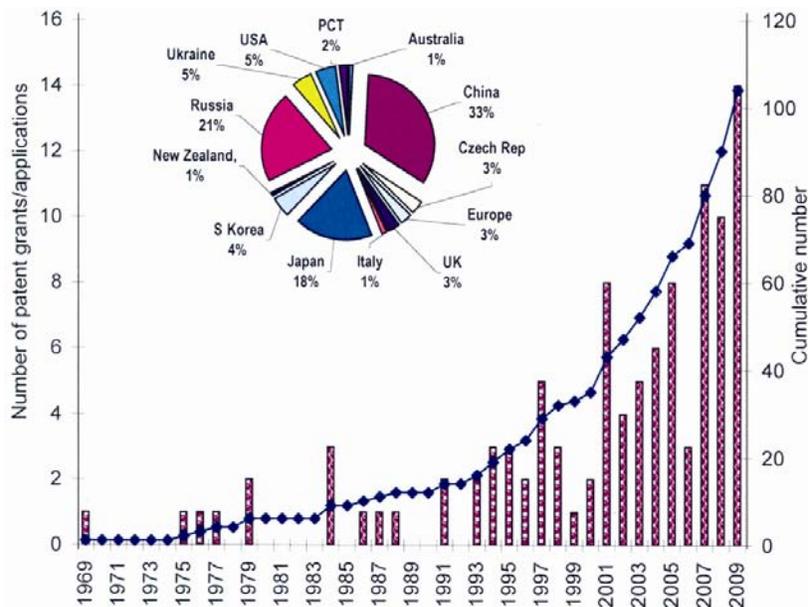
#### Other Areas of Indian Technology Affected by Current IPR Domain

Patenting activities in the public research system in the country based on animal science research are relatively new. However, the fast changing global scenario for the patenting activities in fields such as animal vaccine and diagnostics is a matter of similar concern and challenge. The private sector has been invited to commercialize public sector technologies, including those covered under patent applications, in an array of fields, namely, vaccines, diagnostics, peptides, primer sequences, antigens, synthetic gene, transfer vector, immune-prophylactic, and immune-sensor apparatus. A quick search and analysis was conducted<sup>3</sup> to illustrate the published patent applications and granted patents in various countries. Fig. 2 shows that a total of 104 patents/published applications could be retrieved for the index words 'animal and vaccine' searched in 'title' or 'abstract'. The patenting trend in this field of technology was shown to increase globally in the past 3 years. China, Russia and Japan have been the dominating countries that received 35, 22 and 19 patent applications, respectively, in field of animal vaccine, whereas, South Korea, USA and Ukraine received 5 applications each. Besides, European Patent Office, UK and Czech Republic received 3 applications each, and Italy, Australia and New Zealand also figured in

the list with one application each. Only 2 international applications were filed under the PCT, in this field, which shows that there is more country-specific interest in the exclusive marketing of IP protected vaccines, with East Asian and Eurasian (erstwhile Soviet Union) countries in the lead. Interestingly, despite the fact that world's leading companies in

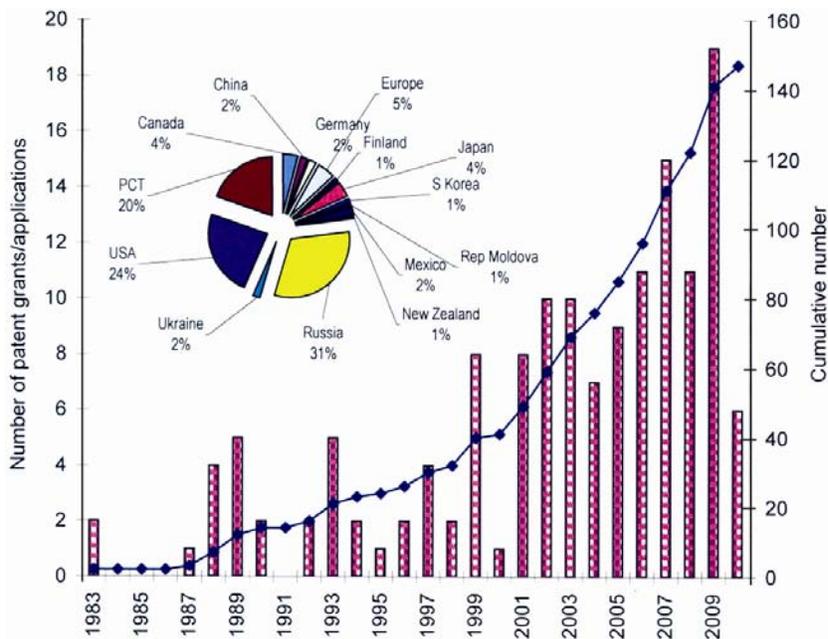
pharmaceuticals hail from USA and Europe, where commercial dairying is also sizeable, the interest in patenting in the area of animal vaccines has been rather low.

A similar search and analysis for patenting in animal diagnostics (Fig. 3) showed 147 patent applications/granted patents since 1983. Russia led



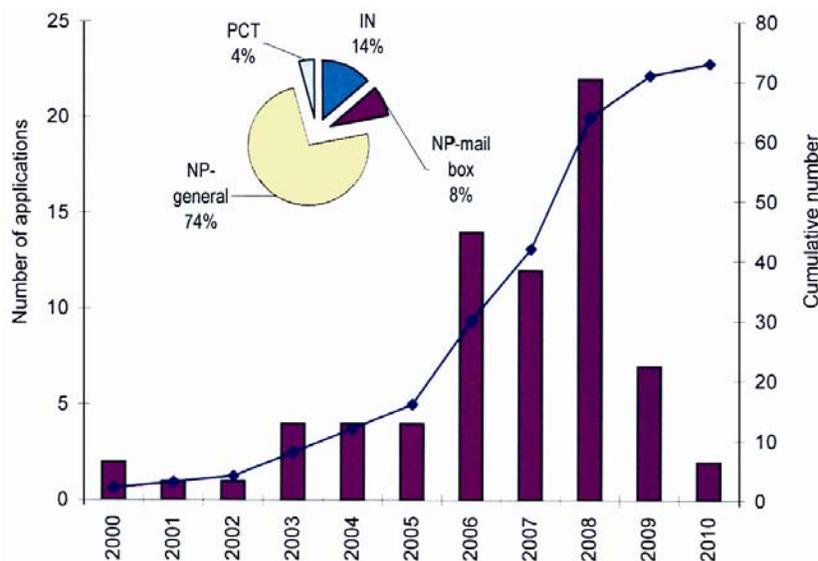
Source: Compiled based on data from <http://ep.espacenet.com/>

Fig. 2—Patenting activity in the field of animal vaccine in various countries (1969-2009)



Source: Compiled based on data from <http://ep.espacenet.com/>

Fig. 3—Patenting activity in the area of animal diagnostics in various countries (1983-2010)



Source: Compiled based on data from <http://ep.espacenet.com/>

Fig. 4—Patenting activity in animal vaccine and diagnostics in India

the table with 46 patent applications/granted patents whereas China (3 applications) and Japan (6 applications), which had high ranking in patenting of animal vaccines (Fig. 2) did not receive much attention for patenting in animal diagnostic field. On the other hand, there was predominant interest in filing applications and hence marketing of animal diagnostic products in USA (35 applications) and under the PCT (29 applications). Europe and Canada also indicated a fairly high marketing interest in animal diagnostics, although the patenting activity in animal vaccines in these jurisdictions was negligible.

The Indian scenario with respect to patenting activity in animal vaccine is illustrated in Fig. 4. Out of 73 published applications/granted patents, the highest number (22) was published in 2008. Further, 82 per cent of the patenting interest in animal vaccine was shown by foreign applicants through filing of 60 national phase applications under the PCT. This included 6 applications filed prior to 2005, i.e. under the mail box arrangement. Only 10 (14 per cent) new applications were directly filed as applications for Indian patents, and 3 international applications filed in India under the PCT, i.e., with Indian Patent Office as the receiving office. A total of 49 applicants were involved in the patenting activity. This included seven public sector organizations, like the ICAR, CSIR, and DRDO. Seven foreign universities also

filed applications in India for animal vaccines. Some private companies were the other applicants.

### Conclusion

The foregoing discussion has only one lesson, which is a corollary to the lesson learnt in case of deployment of registered extant varieties through soft and/or cross-licences. The existing strength of the national public research system in the development and commercial use in veterinary applications need to be timely consolidated and further developed. This attempt to dissect issues on IPR in the field of agriculture may give an initial idea to persons having ordinary skill in the art to become more IPR compatible in their research approach. It is quite clear that India, although sufficiently meets the domestic requirement of animal vaccines, has not been on the global map of patenting activity in animal vaccine and diagnostic fields. However, the past leadership in generic products in the selected fields may have to be maintained through conscious efforts in the present competitive era, under the IPR regime.

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