



Brainstorming Meeting

Harnessing Intellectual Property to Stimulate Agricultural Growth

Central Library, IARI, New Delhi

27 July, 2018

Proceedings

Context

Globally, the nations that laid significant emphasis on scaling, incentivizing and protecting innovations have progressed much faster than the others. In India, research in plant breeding during mid-nineteen sixties enabled the country to achieve Green Revolution. This was one of the most significant achievements leading to household food security as well as reduction in poverty and hunger. However, an ever-increasing population, shrinking agricultural land holdings, overexploitation of natural resources and adverse impacts of climate change are posing serious threats to India's food security and sustainability. While over the last five decades, food grains production has increased more than five-fold to around 284.4 million tonnes (mt), India still would need about 345 mt of food grains by 2030, which based on the present production trends, may rather be difficult to achieve.

In addition, the problem of hunger and malnutrition is far more serious. India currently has around 20 per cent population facing an abject poverty and almost 40 per cent children below five years of age are stunted and malnourished. Hence, the country not only needs food security but also household nutritional security. Therefore, there is an urgent need to give a major thrust to scaling-up innovations that can ensure better food, nutritional and environmental security in the diverse agro-ecological regions of the country.

In this context, innovations in biotechnology provide a range of opportunities to increase crop productivity and ensure sustainability of the production systems. However, research in modern biotechnology, such as GM technology, is relatively expensive. It also requires regulatory compliance which involves lengthy testing procedures before approval and release of final products.

Presently in India, Patents (Amendments) Act, 2005 (Patents Act) and Protection of Plant Varieties and Farmers' Rights Act (PPV&FRA), 2001 are the two regulatory systems for intellectual property (IP) protection in agriculture. Innovations in identification, isolation and application of novel gene sequences and their products are protected under the Patents Act. Patents are mainly granted on products and processes that meet the patentability criteria of novelty, inventive step and utility. Further, a patented technology is invariably licensed between the parties through mutually agreed bilateral contracts. Accordingly, so far GM technology innovations and products thereof have been provided protection under the Patents Act.

On the contrary, the new plant varieties and farmer conserved varieties are protected by 'registration' under PPV&FRA after fulfilling the criteria of distinctiveness, uniformity and stability (DUS). In their case, the provision and modalities of benefit sharing exist in PPV&FRA. Hence, both public and private sector organizations/seed companies have been granted patents on gene technologies and have also been granted registration of crop varieties

under PPV&FRA thus safeguarding the interests of the innovators. In the process, thus far around 3,000 plant varieties have been protected under PPV&FRA and about 1,000 gene sequences that may have application through incorporation in seeds/plant variety/hybrids have been protected under the Patents Act.

However, this understanding of the two acts with respect to the protection granted to plant biotechnological innovations in the background of new varieties has been questioned legally, especially in view of Section 3(j) of the Patent Act, according to which plants and animals other than microorganisms but including, varieties and species and essentially biological processes for production of plants and animals are non-patentable. Recently, in this context, Hon. Delhi High Court as per decision of 11 April 2018 ruled that since a synthesized gene sequence inserted into a plant genome has become a part of the plant and its functioning is an essentially biological process, it is to be considered as a part of plant only and hence such innovation cannot be patented under the Patents Act .

In view of this, a need has obviously arisen to have a clarity as to how the Breeders' Rights granted under PPV&FRA for new varieties developed through plant breeding can co-exist with Patent Rights granted under Patents Act for biotechnological innovations, including incorporation and expression of novel gene sequences in plants and their products, in a transgenic variety developed through plant breeding.

Brainstorming Meeting

To address the above issues through an in-depth dialogue among the concerned stakeholders, a one-day brainstorming meeting on “Harnessing Intellectual Property to Stimulate Agricultural Growth” was organized by the Trust for Advancement of Agricultural Science (TAAS) on 27 July 2018 at the Central Library, Indian Agricultural Research Institute (IARI), New Delhi. A total of 51 senior officials from Indian Council of Agricultural Research (ICAR), Department of Biotechnology (DBT), the Protection of Plant Varieties and Farmers' Rights Authority, National Research Development Council (NRDC), Technology Information Forecasting and Assessment Council (TIFAC), Consultative Group of International Agricultural Research (CGIAR) Centers, Asia-Pacific Association of Agricultural Research Institutions (APAARI), South Asia Biotechnology Centre (SABC), intellectual property (IP) legal experts, biotechnologists, plant breeders, and representatives of seed associations participated actively in the brainstorming meeting and presented their viewpoints on the subject. The meeting was organized with the following objectives:

- To discuss and understand the scope of IP protection of biological innovations under the Patents (Amendments) Act, 2005 as well as under the Protection of Plant Varieties and Farmers Rights Act (PPV&FRA) 2001
- To have better understanding of the possible grey/overlapping areas of IP protection, especially those of biological inventions
- To recommend/suggest measures to ensure proper incentives and rewards to researchers and to have an effective compliance relating to IPRs for accelerating agricultural research and innovation for development (ARI4D)

Major Recommendations

1. Incentives for Innovations

- Biotechnological innovations, especially those that involve huge development and commercialization costs, would need to generate proportionate financial returns in order to ensure continued investment in innovations and greater benefits to farmers and

the society. Hence, the development and introduction of desirable traits and new varieties using biotechnology must continue receiving high priority and the needed incentives through protection under both Patents Act and PPV&FRA be in place.

- Indian agriculture in the present context needs innovations such as Bt technology that led to a dramatic increase in both cotton production and profitability. Disruptive technologies, while threatening the market value of previous technologies and products, certainly help in benefitting the farmers as well as the consumers. Such technologies at times may result in monopoly. To safeguard against this, both the public and private sector research institutions must be strengthened to ensure healthy competition.
- Rapid advances are being made by the global seed and biotechnology industry towards identifying and utilizing new genes and developing novel gene modification technologies and products. It is recommended that the Indian national agricultural research system and the seed sector should substantially enhance their ARI4D in such technologies and cooperate to synergize both technology and product development as well as to promote healthy competition especially to guard against possible technology and price monopoly.
- For the benefit of both R&D investors and end-user farmers/consumers, the concerned IP related statutory bodies and the Ministries of Commerce & Industries and Agriculture and Farmers Welfare, in consultation with public and private sector organizations/stakeholders must proactively revisit the existing rules, laws and acts on the subject of innovations in agriculture. Where necessary, required amendments need to be brought about to create an enabling environment to encourage new innovations and their adoption and to achieve faster the goal of 'Make in India'.

2. Revisiting Legal Provisions

(a) Patents Act

- Section 3(j) of the Patents Act presently excludes plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals from patenting. This Section seems to have been introduced in 2002 as an amendment in the Patents Act of 1970, as a consequence of harmonisation for protection provided to plant varieties under the PPV&FRA, which got enacted in 2001.
- It is well established that DNA modification technology and related variety development is quite distinct from the conventional plant breeding and involves several artificial processes or products that otherwise do not occur in nature. These include: use of microbial or synthetically manipulated genes, development of DNA construct having the gene of interest and other DNA modification technologies like CRISPER-Cas 9, and transfer of the artificial gene construct into a host plant DNA through artificial transformation techniques. These innovations, therefore, should not be treated as essentially biological processes, with no provision of IP protection on them once transferred into a variety.
- Hence, it is recommended that Section 3(j) of Patent Act be revisited and its coverage clarified on scientific and logical grounds considering the actual processes involved and to protect the interest of innovators relating to genetic modifications and concerned varietal developments. Such clarity is necessary since similar biotechnological processes and products thereof (e.g. insulin, antibiotics, etc.) are in use in pharmaceutical industry. Hence, innovation of similar kind in agricultural

biotechnology need not be put to any disadvantage, especially when the gene expression is manifested after the incorporation in a plant/variety. This being fundamental for the growth of agricultural innovations, biological innovations must be protected through required legal provisions. .

(b) PPV&FRA

- PPV&FRA is a unique *suigeneis* system of protection of plant varieties that also protects the rights of farmers as variety developers and conservers of agricultural biodiversity. However, the Act in its present form does not accord protection to genes, gene constructs and related biotechnological processes and products. Hence, there is need to revisit the law and address the following:
 - PPV&FRA defines a ‘variety’ as, “.. *a plant grouping except microorganism within a single botanical taxon of the lowest known rank, which can be - (i) defined by the expression of the characteristics resulting from a given genotype of that plant grouping; (ii) distinguished from any other plant grouping by expression of at least one of the said characteristics; and (iii) considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation, and includes propagating material of such variety, extant variety, transgenic variety, farmers’ variety and essentially derived variety*”. The Act specifically excludes microorganisms from the definition of a variety. Hence, the processes and products of microorganism manipulation, as may be involved in the development of gene constructs, are out of its domain. Further, a gene though conferring a trait to the plant does not qualify by itself for protection under PPV&FRA till the particular genotype carrying the transformation event is distinguishable from other known varieties on the basis of descriptors specific to the essential characteristics of the crop species. Consequently, processes of plant transformation also cannot be protected under the Act which, thus should be protected under Patents Act
 - The general process of benefit sharing under PPV&FRA is limited to a registered variety only where the claim is that it has been derived from a previously existing variety (Section 26/1). Hence, no claims for the use of any previously existing variety is possible under the law if the beneficiary does not register the variety so evolved. Also, the amount of benefit sharing has to be decided by the Authority (Section 26/5), and the amount has first to be deposited in the National Gene Fund (Section 45/1a) from which the payments are to be made to the claimant. This mechanism is quite different from the prevalent licensing and sublicensing arrangement of patented genes or gene construct technologies under agreements between two parties.
 - Currently, irrespective of whether it is an approved GM variety or otherwise, any variety registered under PPV&FRA can be used by other breeders to develop new varieties, except for its repeated use where permission from the developer of registered variety is required (Section 30). Thus, this exemption under Researcher’s Rights does not permit maintenance of any IP right by the inventor for use of the GM event for development of a new or an essentially derived variety. This aspect has to be examined and needed amendment, as necessary, should be brought about in the Act to ensure mutual advantages to both GM event inventor and the user plant breeder in the case of GM event usage.

In view of above concerns, it is recommended that PVP&FRA in its present form would obviously require revision to remove ambiguity related to overlap or coexistence with the Patents Act and to ensure necessary protection to genetic modifications related processes under the Patents Act while continuing to protect new plant varieties developed through plant breeding taking advantage of biotechnology inventions especially under the PPV&FRA.

3. General Recommendations

- An exercise on needed harmonization of PPV&FRA with Patent Act and the Biological Diversity Act 2002 is needed with respect to community rights, awarding biodiversity conservers, and identifying biodiversity hot spots to avoid disagreement and duplication of efforts.
- PPV&FR Authority should develop an information portal which can be accessible to the breeders, trait developers, farmers, communities and public at large on all registered varieties, their source parental lines, traits descriptors and related information.
- An online system of filing application for registration of new varieties by the PPV&FRA, including community varieties, should be developed on priority to facilitate application process, follow-up action and needed guidance.
- Section 29(3) related to exclusion of certain varieties from registration was brought in primarily to prevent the perpetuation of products of Genetic Use Restriction Technology (GURT) or Terminator Technology which are likely to be injurious to life or health of humans or animals. There is scope for misinterpretation of the clause, “...no variety of any genera or species which involves any technology which is injurious to the life or health of human beings, animals or plants shall be registered under this Act”. For example, the incorporation of male sterility could be misinterpreted as being injurious to the life of plant since pollen is otherwise needed for sexual reproduction. Deletion or appropriate amendment of this section is, therefore, required to prevent any misinterpretation.
- All the registered varieties and hybrids (with their parents) must be DNA fingerprinted. The fingerprint and other key information should also be encoded on each seed bag before sale in order to enable verification of its authenticity and genetic purity. This step is critical to ensure providing authentic seed to the farmers.
- The importance of ethics in science need not be re-emphasized. A healthy seed industry with a global reach cannot be expected without technology acquisition and profit sharing. In this regard, declaration under section 18(h) of PPV&FRA, of having acquired the parent genetic material lawfully, must be insisted upon for needed transparency and to ensure benefit sharing.

PROGRAM

09:30-10:55	Inaugural Session <i>Chair: Dr. R. S. Paroda</i>	
09:30-09:40	Welcome and Overview	Dr. R.S. Paroda, TAAS
09:40-09:50	Enabling Biotech Innovations in Agriculture	Dr. T. Mohapatra, ICAR
09:50-10:00	Incentives for Biotech Innovations	Dr. S.R. Rao, DBT
10:00-10:15	Current Issues Relating to Intellectual Property in Agriculture	Dr. Malathi Lakshmikumaran
10:15-10:30	Patenting of Biotech Innovations in Agriculture	Dr. K.S. Kardam, IP India
10:30-10:45	Protection of Plant Varieties and Farmers' Rights	Dr. K. V. Prabhu, PPV&FRA
10:45-10:55	Remarks by Chair	
10:55-11:20	Group Photo and Tea Break	
11:20-13:00	Panel Discussion: Harnessing Intellectual Property – Stakeholders' Views <i>Co-Chairs: Dr. R.B. Singh and Dr. K.V. Prabhu</i>	
11:20-11:30	Prof. Deepak Pental, Delhi University	
11:30-11:40	Dr. Sanjeev Saxena, ICAR	
11:40-11:50	Mr. M. Prabhakar Rao, NSAI	
11:50-12:00	Dr. Ram Kaundinya, FSII	
12:00-12:10	Dr. Paresh Verma, AAI	
12:10-12:20	Dr. Bhagirath Choudhary, SABC	
12:20-12:50	General Discussion	
12:50-13:00	Remarks by Co-Chairs	
13:00-14:15	Lunch Break	
14:15-16:25	Round Table Interaction on Way Forward <i>Co-Chairs: Dr. R. S. Paroda and Dr. R. B. Singh</i> Feedback from Participants Remarks by Co-Chairs	
16:25-16:30	Vote of Thanks by Convenor	Dr. J.L. Karihaloo, TAAS
16:30	Tea	

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