



Brainstorming Meeting on Harnessing Intellectual Property to Stimulate Agricultural Growth

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Proceedings & Recommendations

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Acronyms and Abbreviations

APAARI	Asia-Pacific Association of Agricultural Research Institutions
ARI4D	Agricultural Research and Innovation for Development
CGIAR	Consultative Group of International Agricultural Research
DBT	Department of Biotechnology
DUS	Distinctiveness, Uniformity and Stability
GM	Genetically Modified
GURT	Genetic Use Restriction Technology
IARI	Indian Agricultural Research Institute
ICAR	Indian Council of Agricultural Research
IP	Intellectual Property
Mt	Million Tonnes
NRDC	National Research Development Council
PPV&FRA	Protection of Plant Varieties and Farmers' Rights Act
R&D	Research and Development
SABC	South Asia Biotechnology Centre
TAAS	Trust for Advancement of Agricultural Sciences
TIFAC	Technology Information Forecasting and Assessment Council

Proceedings & Recommendations

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 genetically modified (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 Sciences (TAAS) on 27 July 2018 at the Central Library, Indian Agricultural Research Institute (IARI), New Delhi. The Technical Program (Annexure I) comprised of Inaugural Session, Panel Discussion and Round Table Interaction on Way Forward. A total of 51 senior officials (Annexure II) from Indian Council of

Agricultural Research (ICAR), Department of Biotechnology (DBT), the Protection of Plant Varieties and Farmers' Rights Authority (PPV&FRA), 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 need to 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 Patents 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.

Technical Program

09:30-10:55 Inaugural Session

Chair: Dr. R.S. Paroda

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 Lakshmikumar
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	<i>Group Photo and Tea Break</i>	

11:20-13:00 Panel Discussion: Harnessing Intellectual Property - Stakeholders' Views

Co-Chairs: Dr. R.B. Singh and Dr. K.V. Prabhu

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**

14:15-16:30 **Round Table Interaction on Way Forward**
Co-Chairs: Dr. R.S. Paroda and Dr. R.B. Singh

Feedback from Participants

Remarks by Co-Chairs

Vote of Thanks by Convenor

Dr. J.L. Karihaloo,
TAAS

16:30 **Tea**

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Trust for Advancement of Agricultural Sciences (TAAS)

GOAL

An accelerated movement for harnessing agricultural science for the welfare of people.

MISSION

To promote growth and advancement of agriculture through scientific interactions and partnerships with stakeholders.

OBJECTIVES

- To act as think tank on key policy issues relating to agricultural research for development (AR4D).
- Organizing seminars and special lectures on emerging issues and new developments in agriculture.
- To institute national awards for the outstanding contributions to Indian agriculture by the scientists of Indian and other origin abroad.
- Facilitating partnerships with non-resident agricultural scientists visiting India for short period.

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Dr. R.S. Paroda

Secretary
Dr. N.N. Singh

Members
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Dr. A.K. Srivastava
Dr. (Mrs.) Rita Sharma
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- National Workshop on Outscaling Farm Innovation - Proceedings and Recommendations, September 3-5, 2013.
- Brainstorming Workshop on Soybean for Household Food and Nutritional Security - Proceedings and Recommendations, March 21-22, 2014.
- The Eight Foundation Day Lecture on “Sustainable Agricultural Development - IFAD's Experiences” by Dr. Kanayo F. Nwanze, President, IFAD, August 5, 2014.
- Need for Linking Research with Extension for Accelerated Agricultural Growth in Asia - Strategy Paper by Dr. R.S. Paroda, September 25, 2014.
- Global Conference on Women in Agriculture - Proceedings and Recommendations, March 13-15, 2015.
- Brainstorming Workshop on Upscaling Quality Protein Maize for Nutritional Security - Recommendations, May 21-22, 2015.
- The Ninth Foundation Day Lecture on “21st Century Challenges and Research Opportunity for Sustainable Maize and Wheat Production” by Dr. Thomas A. Lumpkin, Former DG, CIMMYT, September 28, 2015.
- National Dialogue on Efficient Management for Improving Soil Health - New Delhi Soil Health Declaration - 2015, September 28-29, 2015.
- Regional Consultation on Agroforestry: The Way Forward - New Delhi Action Plan on Agroforestry 2015, October 8-10, 2015.
- National Dialogue on Innovative Extension Systems for Farmers' Empowerment and Welfare - Road Map for an Innovative Agricultural Extension System, December 17-19, 2015.
- Round Table Discussion on Promoting Biotech Innovations in Agriculture and Related Issues - Proceedings & Recommendations, August 4, 2016.
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- Delhi Declaration on Agrobiodiversity Management – Outcome of International Agrobiodiversity Congress 2016, November 6-9, 2016.
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- Regional Policy Dialogue on Scaling Conservation Agriculture for Sustainable Intensification, Dhaka, Bangladesh, September 8-9, 2017.
- Policy Brief on Scaling Conservation Agriculture in South Asia, September, 2017.
- Retrospect and Prospect of Doubling Maize Production and Farmers' Income – Strategy Paper by Dr. N.N. Singh, September 10, 2017.
- Indian Agriculture for Achieving Sustainable Development Goals - Strategy Paper by Dr. R.S. Paroda, October, 2017.
- Policy Brief on Efficient Potassium Management in Indian Agriculture - August, 2017.
- Strategy for Doubling Farmers' Income - Strategy Paper by Dr. R.S. Paroda, February, 2018.
- Livestock Development in India - Strategy Paper by Dr. A.K. Srivastava, Member, ASRB & Trustee, TAAS, February, 2018.
- Policy Brief on Agricultural Policies and Investment Priorities for Managing Natural Resources, Climate Change and Air Pollution - April, 2018.
- Women Empowerment for Agricultural Development - Strategy Paper by Dr. R.S. Paroda, May, 2018.



Progress Through Science

Trust for Advancement of Agricultural Sciences (TAAS)

The Trust for Advancement of Agricultural Sciences (TAAS) was established on 17 October 2002. Its mission is to promote growth and advancement of agriculture through scientific interactions and partnerships. The major objectives are: (i) to act as think tank on key policy issues relating to agricultural research for development, (ii) organizing seminars and special lectures on emerging issues and new development in agriculture sciences in different regions of India, (iii) instituting national awards for the outstanding contributions to Indian agriculture by the scientists of Indian origin, and (iv) facilitating partnerships with non-resident Indian agricultural scientists. The main activities include organizing foundation day lectures, special lectures, brain storming sessions/symposia/seminars/ workshops on important themes, developing strategy papers on key policy matters, promoting farmers' innovations and conferring Dr. M.S. Swaminathan Award for Leadership in Agriculture. For more details, please visit: www.taas.in

TAAS Publications on Innovations

1. Stakeholders' Interface on GM Food Crops, 19 May, 2011
2. Brainstorming Workshop on "Up-scaling Quality Protein Maize for Nutritional Security", 20-21 May, 2015
3. Roundtable Discussion on "Promoting Biotech Innovations in Agriculture and Related Issues", 4 August, 2016
4. Policy Dialogue on "Incentives and Strategies for Scaling-out Innovations for Smallholder Farmers", 30-31 October, 2017