



REVIEW ARTICLE

India's compliance with the international IPR regime – A case of plant genetic resources

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Abstract

The Indian subcontinent is one of the eight Primary Vavilsonian Centers of crop origin and ranks second after the Chinese centre regarding crop origin. The region has 117 crop species, including rice, millet and legumes. India is also one of the 17 megadiverse countries of the world. Studies show that India has made an excellent contribution to Svalbard Global Seed Vault compared to any individual Gene Bank. Owing to its rich biodiversity, the country must enforce the best governance system for its Plant Genetic Resources (PGRs) for food and agriculture under the International Intellectual Property Regime. Though developed at a relatively slower pace than other IPRs, India's two key legislations - the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV & FRA) and the Geographical Indications Act, 1999 (GIA), which offer legal protection to its PGRs. Complementing these legislations, the Biological Diversity Act (2002), amended in 2023, BDA ensures access to genetic resources and the fair and equitable sharing of benefits from their utilization. The Indian *sui-generis* legislation for plant variety protection has a unique component: Farmers' Rights. This article briefly reviews India's compliance with the international IPR regime, using PGRs as a case study.

Keywords: biological diversity act; geographical indications act; intellectual property rights; plant genetic resources; protection of plant varieties and farmers' rights act

Introduction

The International Undertaking on Plant Genetic Resources defines plant genetic resources as the reproductive or vegetative propagating materials of: 1) cultivated varieties and newly developed varieties; 2) obsolete cultivars; 3) primitive cultivars (landraces); 4) wild and weed species near relatives of cultivated varieties; and, 5) special genetic stocks (including elite and current breeders' lines and mutants. Human engagement with agriculture began nearly 10000 years ago, as the Rubbish-Heap hypothesis suggested, marking a transition from foraging to cultivation. Many plant genetic resources must have been generated by natural means or conscious or unconscious selection. They adapted to different conditions later, including through human migration. Studies indicate that humans have utilized only a fraction of global flora for food production, with just 150 plant species fulfilling most caloric requirements. Genetic resources comprising native landraces, local selections, elite cultivars and wild relatives of crop plants are the essential raw materials to meet crop improvement programmes' current and future needs (1). Centres of origin for cultivated plants (Fig. 1) are predominantly found in mountainous regions between the Tropic of Capricorn (23°28') south of the equator and about 45

°N of the equator in the old world and between Cancer and Capricorn in the new world (2, 3). An intriguing question arises: Why were plants domesticated in certain areas but not in others? One possible explanation suggests: "We observe a paradox: while considerable wild plant diversity exists up to 45-50 °N latitude in Europe, Asia and North America and southward to 35-40 °S in the southern continents (excluding desert and semi-desert areas), domestication of potential crop plants occurred primarily within specific regions between 45 °N and 30 °S" (4).

Agrobiodiversity – The Indian hotspot

The Indian subcontinent is one of the eight primary crop origin and domestication centres, including rice, millet and legume (3). At least 166 crop plants and about 320 species of wild relatives of cultivated plants had originated here. India is considered a "cradle of agrobiodiversity", as the region is in the confluence of Indo-Malayan, Palaeartic and Ethiopian biogeographic realms. It is also observed that the fertile Indo-Gangetic plains have attracted human migration, which has resulted in different civilizations (5, 6). The Indian subcontinent, thus, is "a crucible of tropical, temperate and semi-arid floristic elements" (7). The Indian subcontinent is one of the 17 megadiverse regions of the world, with three



Fig. 1. The Eight Primary Centres of Crop Origin identified by N. I. Vavilov. 1) Chinese; 2) Indian & Indo-Malayan; 3) Inner Asiatic; 4) Asia Minor; 5) Mediterranean; 6) Abyssinian; 7) South Mexican and Central American; 8) South America Andes region, Chilean & Brazilian-Paraguayian (2).

biodiversity hotspots (8). The angiosperm diversity of the country represents 6 % of the world's known flowering plants (9). There are 25 micro-hotspots identified in the country and the endemic species in such hotspots singly represent 33 % of the total flora (10). India has 21 identified agroecological regions, varying in crop-growing from 90 to 270 days. An admixture of soil profiles also offers different ecological niches for different crops (11). Over the years, the farmers of India have been developing and sustaining a good variety of crops to suit these different habitats and ecological conditions (7). The National Gene Bank, New Delhi, has a collection of 469320 accessions as of November 2024 (12). India's contribution to the global platter is also remarkable (Table 1) (13). India has also developed its legal measures to protect biodiversity under international agreements and there is an urgent demand for an "inquiry into the access and benefit sharing provisions that appreciates the efforts of the farmers" (14).

Why should the PGRs be governed?

Farmers have been using and sharing seeds for years. Studies show that they also continuously contributed to evolving new varieties that fit the changing conditions. The open flows of plant germplasm caused the spread of agriculture and must have been driven by "imperialism, colonization, emigration, trade, development assistance and climate change" (15). The rediscovery of Mendelian works in the early twentieth century truly ignited scientific breeding efforts (16, 17). Exclusive ownership rights over plant varieties came in 1930 in the USA. The Paris Convention on the Protection of New Varieties of Plants, UPOV of 1961 gave Breeders' Rights over plant varieties. TRIPS came later in 1994, The Convention on Biological Diversity in 1992 and The International Treaty on Plant Genetic Resources for Food and Agriculture in 2001. The objectives were multi-faceted, including protecting both breeders' and farmers' rights over PGRs. The greatest diversity of PGRs is in

Table 1. Indian germplasm on the global platter (13)

S. No.	Agency (Gene bank)	Total accessions of PGRs	PGR accessions of Indian - origin	% of PGR accessions of Indian - origin	Remarks
1	CGIAR gene bank	720733	62920	8.73 %	Available to researchers for crop improvement programmes
2	446 organizations represented in Genesys	28027770	100607	3.78 %	No information is available on accessibility
3	Svalbard global seed vault (SGSV)	824625	66339 (50 % traditional varieties or landraces)	8.04 %	The Mean value of germplasm accessions to SGSV by individual gene banks is 13744. India has contributed 4.85 times. However, only 25 direct submissions exist and 24 national and international gene banks have made all others.

India provided 91, 403 accessions to other countries/gene banks for 38 years from 1976

the tropical and subtropical areas, where most developing countries are situated. When seeds are deposited in germplasm banks, often in developed countries, whom do these belong to: the originating countries, the storing country, or humanity at large? Suppose the new varieties obtained are the result of applying technology to raw genetic materials. Why are the rights of the technology providers recognized rather than those of the materials providers? Many such crucial questions were posed during the lengthy negotiations coordinated by the Food and Agricultural Organization – FAO in the 1960s and the answers that came up during the early years of the PGR negotiations were not convincing (18).

The International Treaty on Plant Genetic Resources for Food & Agriculture (ITPGRFA)

ITPGRFA of the Food and Agricultural Organization) covers food and forage crops in the public domain and advocates for the Breeders'/Farmers' Rights, subject to national legislation (19). It also provides a Multilateral System (MLS) of Access and Benefit Sharing (ABS) to facilitate the exchange of PGRs. On the other hand, the Convention on Biological Diversity (CBD) provides a bilateral system of agreements for accessing PGRs. The interdependence of countries on PGRs is a key rationale for creating the MLS, an impact study from Nepal revealed. It was also pointed out that "most people or countries are unaware of the current and future importance of interdependence and how the flow of genetic materials between countries contributes to national food security" (20). In India, the Union Ministry of Agriculture & Farmers Welfare is the nodal agency that implements it.

Intellectual Property and related rights

According to the World Intellectual Property Organization (WIPO), Intellectual Property (IP) refers to "creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce." Intellectual Property Rights (IPRs) are protected by laws that enable people to earn financial benefits from what they invent. There are more than 25 international treaties on IP, as

administered by WIPO. Plant varieties have long been considered Intellectual Property (IP), but legal protection has evolved more slowly than in other areas of IP law (22). The concern for providing food security to their people may have influenced many countries to keep plant varieties out of IPR protection for a long time (23). In India, IPRs have been in discussion since Act VI of 1856 on protecting inventions based on the British Patent Law of 1852 (24). Tables 2 and 3 indicate the types of IPRs and other related rights available in India with particular reference to those in which the governance of PGRs is involved.

Governance of plant genetic resources in India - The three-pronged strategy

Given the above mentioned situations regarding India's rich biodiversity and willingness to provide genetic resources to the global pool, the country must enforce the best governance system for its Plant Genetic Resources (PGRs) under the International Intellectual Property Regime. Though developed at a relatively slower pace than other IPRs, India primarily has two related legislations - the Geographical Indications Act, 1999 – GIA (25). The second one is the Protection of Plant Varieties and Farmers' Rights Act, 2001 - PPV & FRA (26). These legislations offers legal protection to its PGRs. Like an 'umbrella legislation', the Biological Diversity Act (2002, with amendments in 2023), BDA ensures access to genetic resources and the fair and equitable sharing of benefits from their utilization (27). Plants and animals in whole or any part, as well as species (other than microorganisms), are not patentable in India. The Indian *sui-generis* legislation for plant variety protection has a unique component: The Farmer's Rights. This component considers farmers' rights with those of breeders, recognizing their contributions to conserving and improving plant genetic resources, a feature uncommon in other plant varieties protection systems. This article further provides a brief about the PGR governance in India, a kind of 'three-pronged strategy' that includes geographical indicators and plant variety rights under the umbrella of the BDA.

Table 2. Comparative account - Types of IPRs and related rights in India (Authors' compilation)

Sr. No.	Category	Type	Acts (With various amendments)	Rules (With various amendments)	Plant Genetic Resources included or not
1	IPR	Patents*	Patents Act, 1970	Patents Rules, 2003	No
2		Copyright	Copyright Act, 1957	Copyright Rules, 1958 & 2013	No
3		Designs	Designs Act, 2000	Designs Rules, 2001, 2008 & 2014	No
4		Trademark	Trade Marks Act 1999	Trade Marks Rules, 2002	No
5		Geographical Indication	The Geographical Indications of Goods (Registration & Protection) Act, 1999	The Geographical Indications of Goods (Registration and Protection) (Amendment) Rules, 2002	Yes
6		New/ Extant Plant varieties/Farmers' rights on PGRs	Protection of Plant Varieties and Farmers' Rights Act, 2001	Protection of Plant Varieties and Farmers' Rights Rules, 2002	Yes
7	Others	Biodiversity	Biological Diversity Act, 2002 & with amendments in 2023	Biological Diversity Rules, 2004	Yes
8		Traditional knowledge, Traditional cultural expressions and genetic resources	Not available	Not available	Yes

* "Plants and animals in whole or any part and species (other than microorganisms)" are not patentable in India

Table 3. IPR/Related Rights for governance of PGRs - The Indian system - Comparison (Authors' compilation)

Sr. No.	Category	Characteristics/criteria	Type		Exclusive rights	ABS provisions
			Process	Product/goods		
1	Geographical indications	Indication provided for agricultural/natural/manufactured goods that originate/are processed from a definite geographical territory; goods with exceptional quality or reputation.	Not applicable	Yes	Legal protection that prevents unauthorized use of GIs	No
2	New/Extant plant varieties/Farmers' rights on PGRs	For the protection of plant varieties, the rights of farmers and breeders; Distinctiveness, uniqueness and stability of the variety are important	Not applicable	New varieties/Extant varieties/Farmers' varieties/Varieties of common knowledge	Exclusive rights to register the varieties	Yes
3	Biodiversity	For "the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of their benefits; the diversity to be recorded in Peoples' Biodiversity Registers	Not applicable	Not applicable	Benefit claims for the commercial use of biological resources.	Yes

The Geographical Indications (GIs)

WIPO defines Geographical Indication (GI) as "a sign used on products with a specific geographical origin and possess qualities or a reputation due to that origin. To function as a GI, a sign must identify a product as originating in a given place." The Trade-Related Aspects of Intellectual Property Rights (TRIPS) defines Geographical Indication (GI) as "indications which identify a good as originating in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristics of the good is essentially attributable to its geographical origin." (Article 22.1 of the TRIPS Agreement) (28). The Geographical Indications of Goods (Registration and Protection) Act, 1999 of India is administered by the Office of the Controller General of Patents, Designs & Trademarks under the Ministry of Commerce and Industry. Goods under Geographical Indicators are classified into 34 classes. GIs that are agricultural and related products primarily fall under in classes 29, 30 and 31. As of 1st December 2024, there are 643 registered GIs, of which 200 are agricultural products. The GIs can be provided to either a 'producer', a 'Registered proprietor', or an 'authorized user' (25).

New/Extant plant varieties: The Protection of Plant Varieties and Farmers' Rights Act of India (PPV & FRA, 2001)

As the Farmers' Rights Project describes, the political use of the 'Farmers' Rights' concept emerged as "a countermove to the increased demand for plant breeders' rights," as voiced in international negotiations (29). In 1983, the concept was first brought to the international negotiations in the Council of FAO chaired by Prof. M. S. Swaminathan. There were three options for India to protect the IPR on plant varieties in response to Article 27(3) (b) of TRIPS. It could be 1) a patent, 2) an effective '*sui-generis*' system, or 3) a combination. The discussions on Plant Breeders' Rights in India were initiated in the Second Seed Seminar 1989, organized by the Seed Association of India (30). Pioneers observe that "the very idea behind the Indian legislation with respect to Agrobiodiversity was to point out that farmers and breeders are allies in the struggle for sustainable food security and that their rights must be mutually reinforcing and not be antagonistic" (31, 32). The PPV & FR Act of India was

enacted on 30th October 2001 (26). The Act is meant for "providing the establishment of an effective system for the protection of plant varieties, the rights of farmers and plant breeders (researchers also) and to encourage the development of new varieties of plants". The Protection of Plant Varieties and Farmers' Rights Authority (PPV & FR Authority) under the Ministry of Agriculture and Farmers' Welfare.

Four types of plant varieties can be registered under the provision of this Act, they are:

1. New variety: "A new variety registered under the Act".
2. Extant variety: "Available in India, notified under Section 5 of the Seed Act, 1966".
3. Farmers' variety: "Traditionally been cultivated and developed by the farmers, in the public domain, or a wild relative or landrace about which farmers possess common knowledge" and
4. Essentially derived variety (EDV): "Any variety that has been derived from a new, extant or farmers' variety that has been registered under the Act".

Farmers' rights

The PPV & FR Act defines farmers in three roles: "cultivators, conservers and breeders". Nine rights were given to the farmers by the Act, including the right to seeds and the right to receive rewards and recognition for their conservation efforts (9). The provision of registration of Farmers' Varieties allows the farmers "to register those varieties cultivated and evolved or bred by them, wild relatives, or landraces about which the farmers possess common knowledge." Section 26 of the Act provides for sharing the commercial gains from registered varieties. As of December 2024, 8385 varieties have already been given registration certificates (Fig. 2) (33). The Plant Genome Saviour Community Recognitions and Awards given by the PPV & FR Authority annually by inviting applications are for the rural and tribal farming communities, groups, or individuals engaged in the conservation, improvement and preservation of genetic resources of plants and their wild relatives.

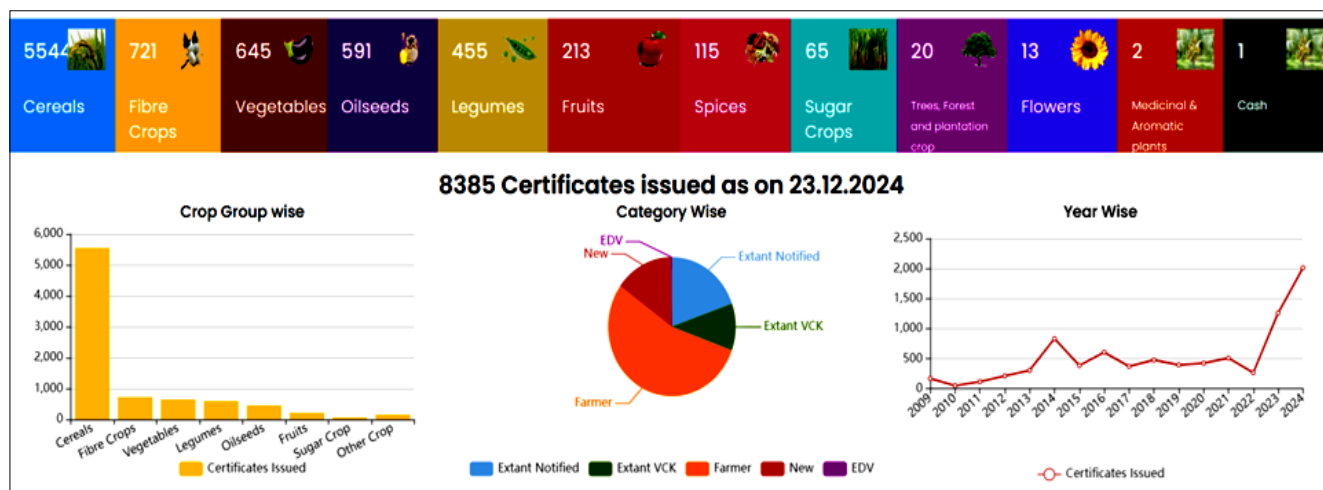


Fig. 2. Details of registered varieties under PPV & FR Act, December 2024 (33).

Governance of Biodiversity/PGRs under the Convention on Biological Diversity (CBD) and the Nagoya Protocol: The Biological Diversity Act, 2002, 2023 & The Indian ABS System

The Convention on Biological Diversity (CBD) which entered into force on 29 December 1993, is the only international instrument comprehensively addressing the sustainable use of biological diversity and directs the parties to ensure the ABS system (34). Nagoya Protocol on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization" to the CBD was adopted in 2010 in Nagoya, Japan and entered into force on 12 October 2014. As demanded by Article 6 of the CBD, to develop national policies, strategies, plans or programmes for the conservation and sustainable use of biological diversity, India enacted The Biological Diversity Act in 2002 and its Rules in 2004 (27). The Biological Diversity Act, 2002 (BDA) mandates implementing the Act through a decentralized system focusing on "the

conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising from the utilization of biological resources". India is at the top among the 134 parties of the Nagoya Protocol that have brought various Legislative, Administrative and Policy measures in biodiversity (CBD). The National Biodiversity Authority (NBA) under the Ministry of Environment, Forest and Climate Change administers the BDA through a three-tier structure that comprises the authority itself as the secretariat, State-level Biodiversity Boards and the local self-government-level Biodiversity Management Committees. The ABS process in India is rigorous and takes an 18-step path (Fig. 3) (35). It commences with a paid application to the NBA to access biological resources. The applicants are bound to comply with the Material Transfer Agreement and deposit royalty to the NBA fund, which would be passed to the conservers of the resources. During 2020-21 alone, the NBA has collected an amount of Rs. 84098477 as royalty (36).

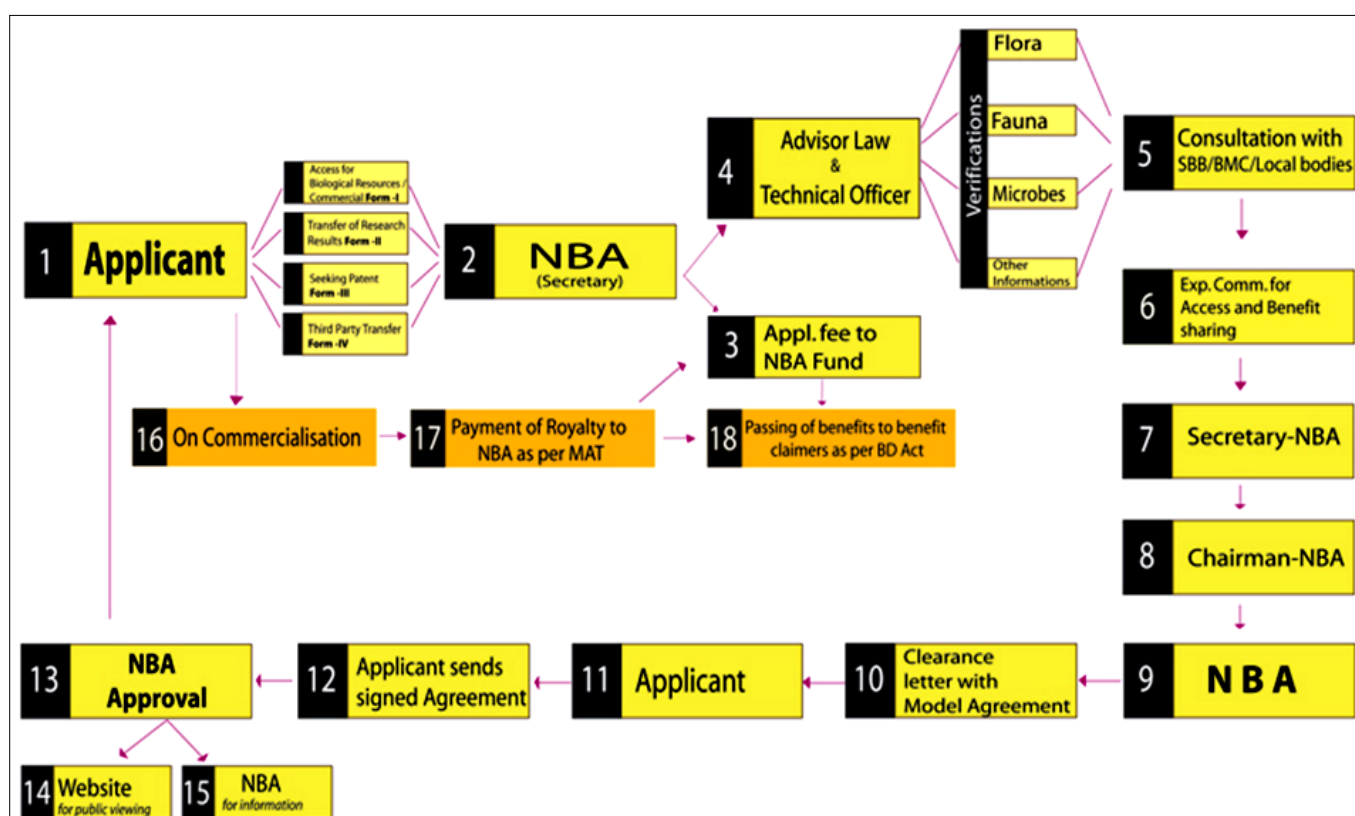


Fig. 3. ABS process in India (35).

The Biological Diversity (Amendment) Bill, 2021: Concerns and the 2023 Amendment Act

The Biological Diversity (Amendment) Bill was passed on 25th July 2023, which brought several changes to the Principal Act. The Act of 2023 was aimed to address the concerns raised by different stakeholders, including research, pharma and industry sectors. The following is a chronicle of the notable changes consolidated by experts (37).

Definitions

In several provisions of the Act, the 'equitable sharing' of benefits has been changed to include 'fair and equitable' sharing, which adheres to the obligations in the Nagoya Protocol. Many key terms such as 'biological resources' 'access (of biological resources)', 'derivatives (of biological resources)', 'bio-survey', 'benefit claimers' and 'Non-Indian Entity (who access the biological resources)' have been defined more clearly. It also represents India's territorial extent.

Recognition

The Act of 2023 recognizes 'codified traditional knowledge', especially in the health sector.

Other provisions

Foreign entities should require prior approval to secure exclusive rights to biological resources, while Indian entities need only a registration with the NBA, thus simplifying the provision. There is a shift from imprisonment to increased financial penalties in the case of penalties.

The amendment mainly aimed to facilitate trade and the enhanced use of biological resources rather than promote biological diversity. Quoting legal experts and environmental campaigners, it was observed that "the amendment could magnify commercial exploitation of the country's ecosystems and harm the communities that depend on them" (38). Though it "enhanced community participation in the decision-making processes" under the Act, it may also enable corporate interests over public concerns. There is also a view that "the private sector's use of traditional knowledge and the relaxation of benefit-sharing rules for encouraging Indian medicine may result in the indiscriminate use of biological resources" (37).

Discussion

Indian *sui generis* system – The prospects

There are different voices regarding seed-related treaties and negotiations like TRIPS, UPOV and ITPGRFA. A global citizen report has even urged the declaration of Article 27.3 (b) of TRIPS as 'immoral' as the patenting of crop varieties sucks in crop genetic diversity from the farming communities and restricts the resulting varieties into circulating only among the rich. There could also be concerns over the patented genes passing to natural varieties (39). The Global Citizens Alliance for Seed Freedom assumed the TRIPS agreement was a corporate solution to the issue of farmers saving their seeds. Some noted that reductionist, mechanistic science and a legal framework for privatizing seed and knowledge of the seed would reinforce each other, destroy diversity and deny farmers innovation and breeding. It may also create seed monopolies and can be called

'an assault on seeds.' Such provisions impose an arsenal of legality that undemocratically criminalizes farmers' seed sharing (40). The 'Seed Freedom communities' across the globe have argued for seed freedom. It is the freedom of diverse species to evolve, as is the freedom of human communities to reclaim open-source seeds as commons. As the seeds are the source of life, the embodiment of bio-cultural diversity, Seed Freedom is the birthright of every form of life, it is the birthright of every farmer and food producer and it is also the basis of Food Freedom, argues the Seed Freedom Community (40). It was also observed that possibilities are there, such as IPR protection, which would hamper the farmers' customary rights (23). Many of the seed-saver groups in the country were convinced that this kind of European-styled IPR was neither useful nor desirable in their context (41). Studies also pointed out that IPR-based approaches are unlikely to provide significant economic returns to farming communities and may promote a shift from farmer-centered agriculture (42, 43). The PPV & FR Act can be considered a progressive legislation (44). However, the word 'progressive' can be misleading and placing farmers' rights within the case of IPR is a backward step. The progressive farmer movements are steps ahead in discussing seed sovereignty (45). As a pioneer in protecting farmers' rights, India is duly bound to closely monitor the effectiveness of this regime for the benefit of the farming communities at large (46). A 'bottom-up' approach was suggested to improve the situation and realize the concept (47). The Act should need constant citizen vigilance to keep it 'pro-farmer' in its implementation and compliance with such a system can always burden small/marginal farmers (48). We must also continue analyzing the impact of the registration of farmers' varieties on their livelihoods and the social benefits the right intended to generate (49). The farmers should not be put under an obligation to comply with legislation that has administrative complexities. Monitoring the use of the farmers' varieties against the infringement of rights will also have to be discussed seriously.

Indian BD Act - The prospects

It is also worth noting that India produced the celebrated ABS experimental model through the case of the plant *Trichopus zeylanicus* used by the Kani tribal community of the Western Ghats. Since it was a 'pre-Biological Diversity Act era' model, it had many limitations, such as a chaotic benefit-sharing arrangement with no coordination among the actors involved (50). The question is, "How do the international and national guidelines help communities and conservation?" We may need to wait to see that the benefit sharing is realized fairly and equitably (51). The conservation of the environment/biodiversity needs to be primarily through activities at the grassroots level through local self-governments, coordinated at the state and monitored at the national level. Though there are some contrasting views on implementing the BD Act, India has established a comprehensive system to realize the objectives of the CBD and the country's actions have been recognized globally (52, 53).

ABS for traditional PGRs: The provisions and the prospects

Section 26 of the PPV & FR Act assures that "a fair share of benefit from the commercial gains of a registered variety should go back to the breeders or farmers who have provided the base genetic resources". Some exemptions are provided

under the BD Act to promote the use of bioresources for research and non-commercial use. Section 6 of the BD Act, 2002, states that the application for IPRs should not be made without the approval of the NBA. However, this provision "shall not apply to any person applying for any right under the PPV & FRA" (54). 'Conventional breeding or traditional practice in any agriculture, horticulture, poultry, dairy farming, animal husbandry, beekeeping, etc.' are exempted from access to bioresources as per section 2(f) of the BD Act. The BD Act defines 'commercial utilization' as the "end uses of resources for drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic interventions" (27). Biodiversity governance has been on a pure conservation and science-oriented path. It is "heading to a multi-faceted path ranging from a 'global commons' perspective to a national sovereignty perspective, preservation-centred action to sustainable use-based action, ecological inferences to economic linkages, science-based decision-making to decision-making that looks for scientific rationale, state-centred management approaches to community-centred management approaches" (55).

Is the Indian *sui generis* system for the legal protection of PGRs 'effective'?

While critically examining the Protection of Plant Varieties and Farmers' Rights Bill of 1999 (before it got into an Act), many concerns were shared regarding the implementation of the same provisions. It was noted that combining breeders' and farmers' rights could be "faulty and would not help to protect the interests of the said groups in the context of globalization". The study further argued that India must go for protection for breeders under the Indian Patent Act along with a *sui generis* law to protect the farmers' interests (23). Another opinion was that "India is duly bound to closely monitor the effectiveness of this regime as a pioneer and role model in protecting farmers' rights" (46). After 20 years of enactment of the Act, the picture is now getting clearer. Two fundamental questions regarding the implementation of the Act are as follows:

Question 1. "How effective is combining Breeders' and Farmers' rights in a single legislation?"

Question 2. "How can we ensure the farmers are not obligated to go after the legislation with procedural complexities?"

Conclusion

Given India's rich biodiversity and its role in contributing genetic resources to the global pool, it is essential to strengthen governance mechanisms for its PGRs under the current international IP regime. The Geographical Indications and Plant Variety Rights, under the umbrella of the Biological Diversity Act, share common objectives of conserving biodiversity and protecting its rights. For effective biodiversity governance, these systems should coexist and complement each other. While examining the provisions of the PPV & FRA and GIA, two of the key questions could be, 'Would that be fair enough if those PGRs protected under the GI Act could be primarily registered with the PPV & FR Act?' and 'What could be the take of the BD Act in the protection of the rights over PGRs for food and agriculture?' Further research is recommended to

address these questions and to evaluate the potential of ABS provisions under these Acts.

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Authors' contributions

PP conceptualized the study as a part of his PhD research in the framework provided by BV and SMT and contributed to the original draft preparation. BV supervised the study and contributed to the manuscript review and editing. SMT supervised the study and contributed to the manuscript review and editing. All authors read and approved the final manuscript.

Compliance with ethical standards

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