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Plant Breeding and Intellectual Property Rights in Nepal

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Abstract

This article examines the adoption of plant breeders' rights (PBR), also known as intellectual property rights (IPR), pertaining to plant breeding and genetics in various nations. Its main goal is to offer direction for the growth of an organized and competitive plant breeding industry in Nepal. The paper seeks to analyze the mechanisms that ensure adequate protection of intellectual property and returns on investment in plant breeding, drawing on international practices and treaties like the Convention on Biodiversity, Trade Related Aspect of Intellectual Property (TRIPS), and the International Union for the Protection of New Varieties of Plants (UPOV). The paper presents case studies to demonstrate how these issues are addressed by looking at the current IPR landscape in Asia, Europe, and North America. These results are the basis of policy recommendations to aid Nepal in developing a strong plant breeding industry.

Keywords: Biodiversity, Geographical Indication, Intellectual Property, Plant breeders' rights, Plant breeding, UPOV

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1. Introduction

Plant breeding has a significant role in increasing crop yield. It is estimated that about 60% of yield gain is due to plant breeding and genetic improvement over the years in agriculture (Ci et al., 2011; Hallauer, 2007; Rozman et al., 1996; Schulthess et al., 2022). Plant breeding and related research started in Nepal in Khumaltar in 1951. More systematic research was initiated with the establishment of commodity programs in 1971 (Joshi, 2017). While plant breeding is an important business in Europe and America, it has yet to develop well in Nepal. Various components of plant breeding, including germplasm management, its maintenance and utilization, and the use of modern tools of plant breeding, are yet to be utilized. As a result, plant breeding has not progressed as much as it could develop in Nepal.

The current situation of plant breeding in the private sector is almost non-existent. Plant Breeding leads to the formation of plant variety or varieties which is referred to a specific group of plants within a particular botanical category, distinguished by the expression of certain characteristics resulting from a specific genotype or combination of genotypes. The protection of these plant varieties has been an important obligation aftermath the introductions of Trade Related Aspect of Intellectual Property framework within the regime of World Trade Organization, which recognized production of Plant Variety as an intellectual activity subject to protection under the rights of Intellectual Property. The intellectual property, which is the creation of intellectual activities that may give a noble product accepts plant building as one of its facetes. In plant breeding, there are a lot of intellectual activities because it has science and art involved, including the innovation, efforts of the breeders within it leading to increased interest and debate within the Plant Variety Protection (PVP) right within the Intellectual Property Rights. Thus, the paper seeks to analyze the mechanisms that ensure adequate protection of intellectual property and returns on investment in plant breeding, drawing on international practices and treaties like the Convention on Biodiversity, TRIPS, and the International Union for the Protection of New Varieties of Plants (UPOV). The paper presents case studies to demonstrate how these issues are addressed by looking at the current IPR landscape in Asia, Europe, and North America.

2. Conventions Associated with IPR

The IPR has received international attention, even in the United Nations forum. To safeguard traditional knowledge and prevent biopiracy, two global agreements were established: the Convention on Biological Diversity (CBD) in 1992 and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

in 2001. These agreements urge participating nations to enable resource access in a way that promotes the preservation and sustainable utilization of biological resources. Additionally, they aim to safeguard the rights of local communities, indigenous groups, and farmers.

The Convention on Biological Diversity was opened for signature in 1992 at the United Nations Conference and entered into force in 1993. The Convention's had three objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits from utilizing genetic resources (Secretariat of the Convention on Biological Diversity, 2011). Although the idea was conceptualized in the 1990s, it took more than a decade to develop the detailed procedure and adopt the articles only after the Nagoya convention. The convention advanced the third objective by providing a legal basis for sharing genetic resources. The protocol also has the provision to foster and protect traditional knowledge. These provisions will benefit the indigenous and local communities by utilizing genetic resources. Overall, the protocol aims to enhance the contribution of biological diversity for sustainable development and human well-being. There are 36 articles in this protocol (Secretariat of the Convention on Biological Diversity, 2011). The primary emphasis is to access and utilize genetic resources and share ownership. The Nagoya convention has provided the basis for the rights in the available genetic resources in the country. It provides the framework to initiate the discussion and drafting of laws related to plant breeding rights. This law should provide protection, development, and the utilization of available genetic resources. Some of the countries have already benefited from the provisions of the protocol of this convention. Nepal should move ahead quickly, drafting and implementing the laws as soon as possible.

After more than 15 sessions of the FAO Committee on Genetic Resources and its subsidiary bodies, ITPGRFA was approved during the FAO conference in 2001. The Treaty was introduced to harmonise the International Undertaking on Plant Genetic Resources signed in 1983 with CBD. The Treaty came into force on 29 June 2004 and, until now, 116 countries have ratified it. Nepal ratified ITPGRFA on 2 January 2007. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) holds great significance for breeders, as it recognizes their pivotal role in developing new plant varieties for food and agriculture. The treaty grants breeders access to a diverse range of plant genetic resources, housed in gene banks worldwide, enabling them to enhance crop productivity and create improved varieties with desirable traits. The ITPGRFA specifically focuses on plant

genetic resources for food and agriculture, encompassing 64 resources that are vital for food security. The treaty acknowledges the contributions of farmers in preserving, enhancing, and providing these resources, while recognizing their rights to benefit from such contributions through a multilateral system. Farmers are acknowledged as custodians of plant genetic resources, and Article 9 explicitly recognizes their rights to use, exchange, and sell farm-saved seeds and other propagating materials.

Furthermore, the treaty places a strong emphasis on farmers' rights to traditional knowledge, participation in benefit sharing, and involvement in national decision-making processes. It mandates contracting parties to safeguard and promote farmers' rights in accordance with their specific needs and priorities, while considering their national legal frameworks. Farmers are also considered in the treaty's provisions related to general obligations and financial resources. Breeders derive significant benefits from the ITPGRFA as it grants them access to a wide array of plant genetic resources for the development of improved crop varieties. Simultaneously, it acknowledges and protects the rights of farmers, as well as their participation in resource conservation and utilization.

The International Union for the Protection of New Varieties of Plants (UPOV) was established in 1961 and has provided broad guidelines for adopting PVP (https://www.upov.int/members/en/). This was founded in Europe, considering the plant breeding activities on the continent. It prepared the outline to protect intellectual property and provided the necessary guidelines. After the subsequent conventions, they modified their provisions, particularly in 1978 and 1991. The PVP via UPOV is a harmonized system that awards IPR to organizations in its 78 member countries. Distinctness (D), uniformity (U), and stability (S) are the basis for a new variety, which can be tested by measuring phenotypic traits in multi-location trials, molecular marker-based testing systems, or sequence-based testing systems. They can verify the traits by one or more than one testing systems collected from multiple locations. It should be noted that PVP is more common in Europe, whereas the plant patenting system is standard practice in the United States of America (USA). Plant patenting was started in the 1930s in asexually propagated crops. The provision of the same system was extended by the court ruling in the rest of the crops in 1984, which covers the plant patent system. Both systems are equally valid and can be recognized anywhere in the world. Some of the components of the system are compared below in Table 1.

Table 1: Criteria for recognizing a novel crop variety to issue a license under UPOV and plant pattern system (Tripp et al., 2007).

Criteria	UPOV 1978	UPOV 1991	Utility Patents (USA)
Requirements	Novelty (in trade) Distinctness Uniformity Stability	Novelty (in trade) Distinctness Uniformity Stability	Novelty (in the invention) Utility Non-obviousness Industrial application
Seed saving	Allowed for private and non-commercial use	For use on own holding only	Not allowed without the consent of the patent holder
Seed exchange	Allowed for non-commercial use	Not allowed without the consent of the right holder	Not allowed without the consent of the patent holder
Breeder's exemption	Use in breeding allowed	Use in breeding allowed (but sharing rights in case of essentially derived varieties-EDVs)	Not allowed without the consent of the patent holder

The PBR or PVP has led to good harmonization within the European Union (EU) (Dons, 2013). About 80 countries have signed UPOV 1978 or 1991 or adopted UPOV guidelines (https://www.upov.int/members/en/).

The Agreement on Trade-Related Aspects of Intellectual Property Rights by the World Trade Organization states that countries shall provide for the protection of plant varieties either by patents or an effective system of the country's choice (sui generis system), or a combination of the two approaches. Such an effective sui generis system was established in 1961 and revised in 1978 and 1991. The rationale premised behind plant variety protection in TRIPS is the requirement to support innovation, economic growth, fair competition, biodiversity preservation, and food security.

3. Biodiversity and Geographical Indication (GI)

Nepal is very rich in Plant biodiversity. This is an enormous resource for agriculture improvement. It is estimated that about 2000 plant species need to be utilized for the

benefit of Nepali farmers (Baul & McDonald, 2014; Paudel et al., 2011). These species are rich in medicinal value, nutritional importance, disease resistance, and other traits of agricultural importance. Some species are yet to be characterized well. The Nagoya Convention has addressed the issue of biodiversity and its utilization, as mentioned above. Based on that, Nepal can benefit from its rich biodiversity.

A geographical indication (GI) is a sign (or name) used on products with a specific geographical origin and possessing unique qualities or a reputation associated with the outcome of the origin (Baul & McDonald, 2014; Paudel et al., 2011). Its significance is for business purposes. Examples are Basmati rice, Citrus, Coffee, Jumli beans, Jumli rice, Junar, and many more. Nepal has not realized the benefits of these unique local germplasms. Several countries have filed and obtained the license of GI recognition for agriculture and related products. Nepal needs to progress a lot in this process. This is the area to work on by capturing the legal framework.

4. Legal Framework of IPR

4.1 International Legal Framework for Plant Breeding and Plant Variety Protection

The ratification of the Biodiversity Convention by Nepal establishes a fundamental framework for the conservation and utilization of biological resources. It confirms Nepal's sovereignty over its biological resources but also recognizes the concept of "common concern," indicating that the protection of biodiversity in Nepal is important for the country and the international community as a whole. In the context of plant variety protection, the Convention's provisions on access to biological resources and the sharing of benefits become relevant. It establishes that countries providing micro-organisms, plants, or animals for commercial use have the right to receive a fair share of the benefits derived from their utilization. This aspect emphasizes the importance of recognizing and protecting the rights of those who contribute to developing and conserving plant varieties. Furthermore, the Biodiversity Convention addresses the relationship between the management of biological resources and intellectual property rights. Article 16 of the Convention specifically states that intellectual property rights should not undermine the functioning of the Convention. This recognition ensures that the protection of intellectual property rights, including plant breeders' rights, should be in harmony with the goals and principles of biodiversity conservation and the fair and equitable sharing of benefits.

Therefore, Nepal's ratification of the Biodiversity Convention provides a broader context for considering plant variety protection. It underscores the importance of ensuring that intellectual property rights, including rights related to plant varieties,

align with the objectives of conserving biodiversity and promoting equitable sharing of benefits derived from the use of biological resources. Similarly, Nepal has also ratified the Plant Genetic Resources for Food and Agriculture (PGRFA) Treaty. This treaty aligns closely with the principles of the Biodiversity Convention and emphasizes the interconnected goals of conservation, sustainable use, and benefit sharing. The overarching objective of the PGRFA Treaty is to promote sustainable agriculture and ensure food security. The significance of the PGRFA Treaty lies in its transformative impact on the legal status of plant genetic resources in international law. Unlike its predecessor, the 1983 International Undertaking, which primarily focused on resource sharing, the PGRFA Treaty affirms the sovereign rights of states over their Plant-Originating Farming Systems (PORFA). Moreover, the treaty acknowledges the introduction of intellectual property rights in relation to these resources.

From a plant breeder's standpoint, one of the key contributions of the PGRFA Treaty is its emphasis on the role of farmers and their significant contribution to the conservation of agro-biodiversity. The treaty recognizes the rights of farmers over their tangible assets, such as seeds, as well as their rights to a lesser extent concerning traditional knowledge. Overall, the ratification of the PGRFA Treaty by Nepal provides a favorable legal framework that acknowledges the importance of sustainable agriculture, food security, and the rights of farmers in relation to plant genetic resources. This treaty complements the objectives of the Biodiversity Convention and reinforces the recognition of intellectual property rights within the context of plant breeding and genetic resource utilization. Nepal is not Party to UPOV.

According to the TRIPS Art. 27.3(b), new plant varieties should be protected by patents, by an effective sui-generis system, or a combination of both. The Options for the protection of plant varieties in TRIPS are enlisted as:

a. WTO Members can choose to protect plant varieties through patents
b. WTO Members can develop an effective sui generis system to protect plant varieties. This means they should bring an effective national law that grants IPR over new plant varieties through breeders' rights certificates.
c. WTO Members can develop a system that gives patents and plant breeders' rights certificates to protect plant varieties.

During Nepal's accession process to the World Trade Organization (WTO), it made a conscious decision to establish a distinctive framework for safeguarding plant varieties known as a sui generis system. Under this system, the creators of new plant varietes are granted certificates of plant breeders' rights instead of patents. The *Sui*

Generis system, chosen by Nepal offers a range of possibilities, allowing Nepal a significant flexibility in designing its own mechanisms for protecting plant varieties taking into account of various factors, including the level of economic development, available resources, agricultural and industrial policies, the state of its public and private research capabilities, as well as the unique needs and circumstances of small-scale farmers and indigenous communities in Nepal.

4.2 *Lex Generalis* of IPR in Nepal

Nepal is a signatory to the 1886 Berne Convention, 1883 Paris Convention, and World Intellectual Property Organization (WIPO). On April 23, 2004, Nepal became WTO's 147th member as first least developed country (LDC) member of the organization, becoming party to TRIPS. Wherein, Nepal was allowed a 10-year transitional period to improve its system and legal arrangement to make itself able to implement the basic requirements outlined in the TRIPS Agreement during the accession discussions. Nepal, now enjoys the benefits and extended transitional period for LDCs until 1 January 2033. Prior to joining the WTO, Nepal had two legislations viz. the Copyright Act of 2002 and the Patent, Design, and Trademark Act of 1965, which have continued to be the major IP laws in Nepal up until this point showcasing the present structure of present IPR not adhering to global norms and procedures.

The concept of Plant Variety Protection, Breeder's right are not recognized within these legislative framework. Provided that, the Constitution of Nepal has included Intellectual Property Right as Fundamental Right under Article 25, Right to Property. Moreover, the promulgation of Intellectual Property Policy, 2017 can be show casted as the initiation of Policy and Legislative Reform in the Intellectual Property Regime in Nepal. The objective of the Intellectual Property (IP) Policy is to encourage the protection, promotion, and development of IP while ensuring a balanced IP system, creating awareness about the social, economic, and cultural aspects of IP, promoting the commercialization of IP, and strengthening the legal, administrative, and human resources for effective IP protection and enforcement. With the preview of these objectives, the Policy recognizes unconventional signs for trademark registration, emphasizing the protection of well-known trademarks, and advocates for legal frameworks to safeguard various IP rights including the newer dimension of IP such as PVP. The policy also acknowledges the contributions of indigenous people, seeks to protect traditional knowledge, and supports innovation through utility models emphasizing the importance of compulsory licensing, IP audit, and valuation methods. However, the policy falls short in seeing Nepal's status as an LDC and its flexibilities under the TRIPS.

4.3 *Lex Specialis* Framework of Plant Variety Protection in Nepal

The Intellectual Property Policy of Nepal, 2017, recognizes the significance of providing legal protection for various aspects such as geographical indications, plant variety protection, trade secrets, biodiversity, integrated circuits, traditional knowledge, and traditional cultural expressions. It emphasizes the need for safeguarding these intellectual property (IP) rights through sui generis models, which are uniquely tailored mechanisms acknowledging the invaluable contributions of indigenous people towards preserving and sustainably utilizing biodiversity. It calls for justly rewarding indigenous communities for their efforts in this regard through fair benefit sharing. The policy seeks to address the issues highlighted therein by enacting laws within a two-year timeframe, which has been the case of a major failure in implementation and execution.

Unlike other jurisdictions, there no specific policy or lex specialis for plant breeding and genetics in Nepal. However, The Seed Act, 2045 has defined the breeder as "*a person, organization or body which brings into use any variety of the crops by breeding or selecting it for the first time*." The act, in Section 3, has envisioned the National Seeds Board in to carry following major functions relating to plant variety protection, including the approval, release and registration of the Seeds of new variety as prescribed along with testing of the specialty, uniformity, and permanency of the Seeds of new Variety and grant the right of ownership to the Breeder as prescribed. Moreover, the provision of "restriction for imports of seed variety which cause damage to the agricultural activities in Nepal" is progressive in terms of farmers right, protecting the famers discards the treaty obligation of "National Treatment" within TRIPS. However, certain lacunas in the act require readdressed, including the provisions on granting ownership rights to breeders needing improvement in clarity and structure. The scope and procedures for claiming ownership rights are undefined, causing confusion to the breeders to acquire their rights. Registration of new plant varieties is required, and there are restrictions on marketing unregistered and unmodified seeds, which necessitate a letter of permission creating extra procedural hurdles for breeders leading to demotivation on innovation and improvisation.

Although punishments are established for violating legal provisions in the act, they do not address infringements of ownership rights explicitly. Furthermore, there is a provision for granting ownership rights to traditional local varieties, but the specific details are unspecified. Similarly, Nepal Government, aiming to provide compensation in case of faulty and misrepresented seeds provided by breeders, has introduced Seed Compensation Directive, 2073. The compensation shall be provided as determined by Evaluation Committee envisioned within the directive. Furthermore, National

Seed Vision (2013- 2025) has also recognized a sui-generis method to strike a balance with breeders right. Nepal had drafted the two-draft bill: Access to Genetic Resources and Benefit Sharing, 2002 and Plant Variety Protection and Farmers Rights bill, 2008, which could not be passed by the Parliament and are now repealed.

4.4 Practices of IPR in Various Countries

Plant breeders change the genetic makeup of crops so that new cultivars have a higher yield and quality and are better adapted to the needs of farmers, food processors, and consumers. The plant breeding industry is one of the most innovative sectors in the world. It is estimated that 15 to 25% of turnover is used for research and development, a figure far higher than most other industrial sectors where R&D plays an important role. This explains why IPR is such a crucial issue in plant breeding. New inventions and creations of cultivars must be effectively protected so that the plant breeder can realize a fair return on investment and therefore has an incentive for additional investments in the future (Dons, 2013). This is all about supporting future investment and fostering the breeding industry. A comparative cost analysis is presented in Table 2 to give some idea about how much effort it involves before getting the certificate of a variety by fulfilling the DUS (distinctness, uniformity, and stability) requirements.

Table 2: Relative cost associated with the application fee, a plant variety protection license, and a patenting system in China, Europe, and the United States (Tripp et al., 2007).

Item	China	EU	US
Application	$217	$1,115	$432
Testing	$556	$1,490	$3,220
Granting of rights	-	-	$682
Cost of PVP and ten years of protection	$3,340	$7,780	$4,344
Cost of PVP and 15 years of protection	$5,687	$10,480	$4,344

We describe the examples of intellectual property rights in various countries below. Although UPOV provides the main framework, countries have used intellectual property rights based on the needs of their own country. Regardless of the practice, they follow the main core value of distinctness, uniformity, and stability (DUS) for a new variety. Regarding the use of the IPR, they have modified it based on the involvement of plant breeder and their need. That's where they are specific to the national need, availability of the germplasm in the country, plant breeding

requirement, plant breeders' participation, and national agriculture situation. Obtaining the UPOV certificate, getting membership, and preparing IPR-related legislations are centered on these issues. Utility patents generally provide 20 years of IP protection, while the length of protection under PVP is limited to the time it takes to create a distinct new variety from the germplasm introduced by the original research. Dawson et al. (2018) suggest that PVP rules are weaker than utility patents due to the breeders' and farmers' exemptions. However, they also mention that stricter PVP rules may restrain access to germplasm, slow innovation, and decrease research and development (R&D) (Dawson et al., 2018).

4.4.1 Scenarios of UPOV in Asia, Africa, and South America

There are very few UPOV member countries from the developing world. As of April 2006, UPOV membership for industrialized countries included eight countries under the 1978 convention and 18 under the 1991 convention. The membership for countries classified as developing, newly industrialized, or economies in transition was 17 (1978) and 15 (1991) (Tripp et al., 2007). Several other countries are at various stages of the application process (Dawson et al., 2018). No countries in sub-Saharan Africa, South or Southeast Asia (except Singapore), or Latin America joined UPOV in 1991. The African Intellectual Property Organization (OAPI) system represents a harmonized regional approach to PVP in which one application covers all member countries. This is similar to the service of the European Community Plant Variety Office (CPVO), although separate national PVP systems also exist in member countries. Several developing countries that belong to UPOV 1978 (e.g., Colombia and Kenya) are considering changes in their legislation to make it more consistent with UPOV 1991(Tripp et al., 2007). Other scenarios and systems developed in other developing countries are presented in Table 3.

Table 3: Some of the legal provisions and their scope of coverage in various developing countries for protecting plant breeders' rights UPOV systems (Tripp et al., 2007).

Country	Legislation	Scope of Coverage	Plant variety patents
China	Regulation of the PRC on the Protection of New Varieties of Plants (1999). Member of UPOV (1978) since 2000.	Forty-one crops are currently eligible. Certificates have been issued for 15 species through 2004.	Hybrids may fall under the scope of patents for a breeding or selection methodology.

Country	Legislation	Scope of Coverage	Plant variety patents
Columbia	Member of UPOV (1978) since 1996. Law 243 (1995) establishes PVP. Resolution 2046 (2003) defines limitations on seed saving.	All crops were eligible for practice certificates issued for seven cereals and 15 horticultural crops.	Plant varieties cannot be patented, but transgenic varieties may be patented because they are not found in nature.
India	The protection of Plant Varieties and Farmers' Right Act (2001) establishes PVP. Application to join UPOV (1978) pending. Implementation began in 2005.	No crops were excluded, but the exemption for varieties whose commercial exploitation would be a danger to public order, public and health.	No patents of plant varieties are allowed.
Kenya	Seed and Plant Varieties Act (Cap 326) was amended in 1991 and 1994 to establish PVP. Kenya joined UPOV (1978) in	No crops excluded; applications have been accepted for 31 field crops and 23 horticultural crops.	No patents of plant varieties allowed
Uganda	Draft Plant Variety Protection Act is still before Parliament. It defines PVP as well as farmer and community rights.	No crops are excluded in the draft bill	No patents of plant varieties allowed

4.4.2 Scenarios of UPOV in Europe

European Patent Convention (EPC) takes account of UPOV. The EC regulations and rules that make up the Community Plant Variety Rights (CPVR) have protected the innovative breeding companies in all EU Member States for about 15 years, although there are some differences between crops. Transgenic plants have yet to become a commercial success in the EU, and governments have typically funded much of the basic work of introducing exotic germplasm, which has primarily been directed towards specific quality or disease and insect resistance genes (Lence et al.,

2016). Therefore, the traditional breeding programs conducted by the private sector in the EU are typically favored under a PVP system. The situation makes patenting in Europe complicated. If the process of sexual crossing and selection includes an additional step of a technical nature, including genome modification affecting a trait, this can be patentable. Many seed companies, policymakers, and scientists in the EU favor PVP, while those in the US favor patent laws (Lence et al., 2016). There may be circumstances under which both perspectives are correct. Patents can incentivize firms to conduct expensive and long-lasting research programs leading to the development of transgenic plants or novel varieties and introducing exotic germplasm into commercial products by the private sector.

4.4.3 North America

Canada enacted the plant breeders rights (PBR) Act in 1990 based on the 1978 revision of the UPOV convention (Carew et al., 2017). The Act was amended and updated in 2015. Under the revised PBR, it was extended from 18 to 25 years for fruit trees and vine varieties and 20 years for other crops. The PBR system allows farm-saved seed use, while plant breeders can use germplasm in new breeding activities in Canada (Carew et al., 2017). Plant varieties can be protected in the USA under a system of plant patents, utility patents, or the PVPA. The Plant Patent Act (1930) gives patent protection to new varieties of non-tuberous asexually propagated plants in the USA (Pardey et al., 2013). The US Supreme Court ruling of 1984 covered seeds under the same Act. The PVP in the USA provides IP protection for breeders of new varieties.

4.4.4 Experience of Nepal

Developing countries like Nepal needs to establish an appropriate PVP system as a part of a broader, improved national seed systems, issues such as the 'patenting of food crops' may put of technology ownership and restrictions on farmer seed systems, there are issues such as the 'patenting of food crops' that may put small farmers off being denied access to their seed. To address all these issues, Nepal should be able to integrate the PVP system into the national seed system and address the issues raised by the national agriculture and seed system plan. This will avoid any possible questions related to the PVP.

While the Nepalese Seed Act permits anyone to apply for variety registration and release, the National Seed Board imposes stringent requirements on applicants, including the possession of at least an MSc degree and the availability of breeding infrastructure that meets specific criteria. The registration of the improved '*Pokhareli Jethobudho*' was made possible through the establishment of the community project

known as the "Fewa Seed Producers Group system," which supplied farming communities throughout the Pokhara valley. The registration mechanism for such agricultural biodiversity by farmers should be accumulating to their rights.

Moreover, there is a risk that such varieties may later be claimed as the intellectual property of breeding companies, thereby leading to the practice of "bioprospecting." In this process, farmers' prior informed consent is not considered. Consequently, farmers bear the consequences of this situation, as the existing seed legislation fails to support local farmers in registering their seeds, primarily due to the rules that oblige them to fulfill specific technical and infrastructural requirements.

5. Conclusions and Policy Recommendations

We should have a strong PVP-related law in place to encourage public and private sectors investment in Plant breeding and genetics programs in Nepal. However, it should also make balance farmer's rights also make the balance with farmer's right and traditional knowledge of the communities of Nepal. Nepal government and policymakers should view PVP as a tool for achieving national agricultural development goals. However, the country should cross-check the bio piracy. Nepal shall duly adopt the international mechanism wherein the IPR applicants are obligated to reveal the origin of biological resources and the related traditional knowledge (TK), while also presenting evidence of Access and Benefit Sharing (ABS) and Prior Informed Consent (PIC) agreements empower the country to regulate unauthorized entry into agricultural biodiversity and associated knowledge effectively. As a result, it acts as a safeguard against the risks of bio-piracy and the inappropriate exploitation of local or traditional knowledge.

The PVP should be part of a broader strategy for developing a commercial seed system in Nepal. While adopting the PVP policy and approach, we should watch the strategy of India and China closely, which can influence the national IPR policy significantly.

We strongly suggest that stakeholders of Nepal's agriculture research and development, including the Ministry of Agriculture, Nepal Agriculture Research Council, universities (Agriculture and Forestry University and Tribhuvan University), private seed industries, and growers' associations, should be involved in developing the PVP act, including farmers' rights and IPR. Such a legal framework should be broad enough to accommodate the potential novel traits developed or introduced in the country from abroad by biotechnological tools, including genetic transformation, genome editing, or any other advanced tools for the genetic improvement of crop plants. Adopting IPR laws by the government will be critical to encouraging private

sector investment in plant breeding and biotechnology. It will play a very important role in protecting our natural germplasm in agriculture, medicinal, and forest-related natural resources. Amendment of the Seed Act, To enhance understanding and effectiveness, is necessary and it must have clearly defined scope and procedures for claiming ownership rights, specific details about granting ownership rights to traditional local varieties and additionally, incorporate punishments specifically related to the infringement of ownership rights would strengthen the legal framework and discourage violations.

The carefully outlined legal provisions can also encourage private and public sectors to work together for national development by fostering the plant breeding industry in the long run. A sovereign and agriculture-based country like Nepal should have our strong IPR law for a healthy and productive agricultural system. The carefully outlined legal provisions can also encourage private and public sectors to work together for national development by fostering the plant breeding industry in the long run. Briefly, we need:

a. Strategy and action plan for effective implementation of IPR in relation to plant breeding, genetics, and agrobiodiversity.
b. To discuss drafting the PVP, breeder's rights, and farmer's rights and its approval and make specific legislation for the protection and promotion of breeder's rights paralleling balancing the farmer's right and traditional knowledge.
c. Immediate legal action is to protect against the loss of native genetic resources because many imported exotic technologies are replacing native genetic resources and traditional technologies, and there is a trend of losing IPR along with these losses.
d. Law, regulation, and guidelines because IPR policy exists, but due to a lack of related legal systems, none of the breeding-related IPRs, including geographical indication, are licensed and protected.
e. To initiate incentive mechanisms for breeders, geneticists, and conservationists.
f. To develop simple and practical working guidelines suitable to all relevant stakeholders, including farmers.

Authors Contribution

Dilip R. Panthee: Conceiving ideas; formulation of overarching research goals and aims; Development or design of methodology; Conducting a research and investigation process, specifically data/evidence collection; Report initial draft/review/ final draft polishing.

Khusi R. Tiwari: Conceiving ideas; formulation of overarching research goals and aims; Development or design of methodology; Conducting a research and investigation process, specifically data/evidence collection; Report initial draft/review/ final draft polishing.

Bal K. Joshi: Conceiving ideas; formulation of overarching research goals and aims; Development or design of methodology; Conducting a research and investigation process, specifically data/evidence collection; Report initial draft/review/ final draft polishing.

Kalidas Subedi: Conceiving ideas; formulation of overarching research goals and aims; Development or design of methodology; Conducting a research and investigation process, specifically data/evidence collection; Report initial draft/review/ final draft polishing.

Pooja Panthee: Review of final draft and polishing.

Conflict of Interest

The authors declared no conflict of interest.

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