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ETHICAL AND REGULATORY IMPLICATIONS OF INTELLECTUAL PROPERTY IN ADVANCED SEED TECHNOLOGIES

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ABSTRACT

The swift progress in agricultural biotechnology, genetics and high-throughput phenotyping has completely transformed the process of creating enhanced seed varieties. Nevertheless, the convergence of these technologies with intellectual property (IP) rights gives rise to intricate ethical and legal issues that need to be resolved in order to establish an all-encompassing and enduring agricultural system. This review article examines the function of intellectual property rights in motivating research and development, while simultaneously emphasizing the possible restrictions on accessing genetic resources and the necessity for fair distribution of benefits. The delicate equilibrium between the rights of breeders and the needs of farmers is a crucial matter, especially when considering the rights of farmers to save, utilize, trade and vend seeds which they have conserved from their own farms. The discussion also encompasses ethical concerns related to advanced seed technology, including perceived hazards to human health and the environment, as well as moral and ethical objections. In order to tackle these concerns, other regulatory frameworks have been established, such as biosafety standards and intellectual property rights (IPR) regulations. Nevertheless, there is a requirement for agricultural policies that are more comprehensive and sustainable in order to encourage transparency, involvement of all parties concerned and the establishment of alternative intellectual property models that strike a balance between innovation and accessibility. Stronger farmers' rights, fair sharing of gains and safeguards for health and ecosystems can be the foundation for a creative and equitable farming system. The evaluation concludes with a call for cooperation between politicians, scientists and other stakeholders on the road to a sustainable and food-secure future.

KEYWORDS: IPR, Ethical, Regulatory mechanism, Farmers Rights, PVP, Advanced seed technologies

1. INTRODUCTION TO IPR IN SEED TECHNOLOGIES

Over the last century and a half, much of the plant genetic diversity that once fed the world has disappeared, largely because agriculture industrialised and control of the seed business became concentrated in a few hands (OECD, 2018). Agricultural operations play a paramount role in the welfare of diverse stakeholders, encompassing producers, consumers, economies and ecosystems. Given the continuous consolidation of the seed industry, coupled with the decline in biodiversity and limited availability of plant genetic resources due to seed privatization, the very future of the global human population becomes progressively uncertain. Large businesses and other variety creators had strong IPR on seeds and genetic features, based on twentieth-century legislation and court rulings, although such protection was initially meant to reward breeders and provide growers more variations to choose from. The result has been a market in which a few of corporations control around 60% of the worldwide seed supply (Howard, 2015). By 2020, 4

transnational businesses dominated the agrichemical and seed industries (Mary Ann Hendrickson et al, 2020) determining the direction of plant breeding and the farming options available to growers and vulnerable communities. These businesses have tended to breed for even stands, high harvests and resistance to agrochemicals, often at the expense of diversity, local adaptation and low-input performance — exactly the attributes that help crops cope with environmental stress. As the climate becomes less predictable, the stable seasons, soils and water supplies that supported monoculture will become harder to rely on. In response, smaller seed firms, plant breeders and community seed keepers are trying to protect and widen the genetic base of crops. Their work needs money for land, equipment and labour, and many of them end up turning to the same IPR tools that have historically narrowed crop diversity. Because applying IPR to living organisms is still relatively new and poorly settled in law, it is unclear how diversity-oriented growers should protect their seed and their livelihoods. Conventional IPR were designed for fixed inventions, and fitting them to self-reproducing organisms has proved difficult; in the United States, repeated legislative experiments have left a confusing set of overlapping regimes (Mark D. Janis, 2002). This review examines the social, economic and environmental problems that arise from market concentration and from exclusionary patenting of plant genetic resources, including the rapid loss of plant biodiversity. In the US, seed IPR can mean a patent from the USPTO, a certificate from the PVP office run by the USDA, private contracts, or protective arrangements built by non-profits and community bodies such as the Open Source Seed Initiative (OSSI), seed libraries and seed swaps. Many seed originators lack the experience or funds to work through the legal system, and initiatives such as OSSI try to keep seed, as a living resource, from falling under the control of a few owners. At the same time, IPR remain an important driver of innovation in seed technology. Advances in genetics, biotechnology and high-throughput phenotyping have improved variety development, seed quality, seed production, processing and seed health. We discuss how IP affects these innovations, access to genetic resources, how breeders' claims can be weighed against what farmers need, and the policy options for an inclusive and sustainable agricultural system.

1.1 Historical Context

Although people have cultivated plants for roughly 10,000 years, formal law on seed ownership is less than a century old. Plant breeding and seed technologies have progressed rapidly and policy has struggled to keep pace (Jenny and Paulina, 2022). [Figure 1: History of seed and intellectual property rights (figure to be inserted). For much of history farmers had selected and conserved seed for themselves and this activity was the foundation of modern plant breedingPlant breeding and seed technologies have evolved rapidly and policy has struggled to keep up (Jenny and Paulina, 2022). [Figure 1: History of seed and intellectual property rights (figure to be inserted). For most of history farmers selected and conserved their own seed, and this activity was the foundation of modern plant breeding. Such practices were essentially unregulated until the twentieth century. Backed by public figures such as Thomas Edison, the US Congress approved plant patent legislation in 1930, the first law anywhere to reward breeders for new plants; it covered asexually propagated plants but excluded tuber crops such as potato to prevent monopolies over staple foods [Blakeney, 2007]. The first such patent followed in August 1931, when Henry Bosenberg was rewarded for a new climbing rose. UPOV, set up in 1961, gave countries a common international model that tried to reconcile the interests of breeders and farmers and to keep germplasm moving between programmes [Blakeney, 2007]. Hybrid seed and the Green Revolution of the 1950s and 1960s then transformed farming, and in 1970 the US passed its Plant Variety Protection Act, which brought seed-propagated crops under protection for the first time [UPOV.1970]. Because farmers can replant non-hybrid seed year after year, seed companies argued that they could not recover their breeding costs; the PVP framework therefore gradually narrowed the saving of protected seed while keeping a breeders' exemption, so that a protected variety could still serve as parent material for a new and distinct one. Commentators warned that this would encourage consolidation, as large breeding programmes absorbed or closed smaller independent breeders and farmer-to-farmer exchange declined.

The finding of Mendelian genetics in 1900, however, had already shifted the improvement of crops from farmers and seed custodians to professional scientists, although landraces and heirloom varieties established by agricultural communities still form the basis of much current breeding. A significant moment was the Diamond v. Chakrabarty case in 1980 which confirmed that live creatures could be copyrighted, leading to patents on genetically modified seed [Blakeney, 2007; Meghwal et al., 2023]. In 1985 the USPTO granted a patent on a herbicide-tolerant transgenic tobacco plant [Ref USPTO]. From 1995, the WTO's agreement on trade-related IP (TRIPS) obliged member states to meet baseline levels of IP protection, plant varieties included, and required members to protect biotechnological inventions. These developments increased the market power of large firms and raised concerns about smallholders' access to seed and the biodiversity of the developing countries in which UPOV and TRIPS were often seen as serving the interests of multinational corporations and a narrow range of high-yielding varieties (HYV) [Meghwal et al., 2023; Downes, G., 2004].

In the twenty-first century, consolidation has continued alongside sharper debate. In 2001, the FAO's plant treaty (ITPGRFA) was agreed, promoting the sustainable conservation, exchange and use of agricultural genetic resources by countries. The US Supreme Court upheld the patent on Monsanto's genetically altered soybean in a 2013 case, Bowman v. Monsanto Co., and this decision, together with the Bayer-Monsanto merger, increased fears about market

power in seeds and agrochemicals. Some countries have responded with legislation trying to balance the interests of breeders and producers. India's 2001 law on plant varieties and the rights of farmers (PPVFR Act) allows growers to retain and exchange seed under certain conditions [Blakeney, 2007]. More recently, CRISPR editing of genes has generated new problems around the patentability of native features and increased interest in open source seed initiatives and the value of traditional knowledge and farmers' variety [Meghwal, et al., 2023; Downes, G., 2004]. In sum, the history of seed IPR is the history of law, technology and economics influencing each other, and the way that innovation, access and sustainability are balanced in the future will determine a great deal about the future of agriculture.

1.2 Importance of IPR in Agriculture and Biotechnology

IPR is very important in agriculture and biotech: it protects inventions, attracts investment, and shapes markets. Exclusive rights let corporations recover research and development expenditures, which is vital for genetically modified (GM) crops, which need huge investments (Pray, C. E., & Nagarajan, L. 2018). Companies are more likely to spend when competitors cannot simply imitate their work leading to more efficient and resilient cultivars that both benefit farmers and customers (Piesse, J., & Thirtle, C. (2009). Khor, M. 2015). IPs can contribute to food security by protecting novel varieties that are resistant to insects, diseases and climate stress. However, the same rights may also limit smallholders' access to seed and an effective system must balance the interest of breeders against the needs of farmers (Koo, B. 2017; Alston, J. M., & Pardey, P. G. (2014)). Strong IPR have also restructured the seed sector, resulting in concentration among big agribusinesses. Concentration can lead to less competition and higher seed costs, and policymakers need to understand these impacts to avoid monopolistic behavior (Ghosh, A. (2019); Khor, M. (2015)). The TRIPS Agreement has an impact on national IPR laws and hence on the ability of a country to pursue its own agricultural goals. Moreover, IPR increasingly determine whether commerce in agricultural products is facilitated or hampered (Qaim, M. (2016); Van Wijk, J., & van der Meer, M. (2017)). Another problem is biodiversity: if only a few high-yielding varieties are grown, traditional types that are important for sustainable farming may disappear. Therefore IPR systems need to be designed to balance innovation with conservation (Koo, B. (2017); Alston, J. M., & Pardey, P. G. (2014)). Approaches that involve farmers, researchers and industry together are likely to produce fairer and more sustainable results (Ghosh, A. (2019); Qaim, M. (2016)).

2. Types of IPR: Relevant to Seed Technology

Four kinds of IPR matter most in the seed sector: patents, plant variety protection (PVP), trade secrets and trademarks. Each serves a different purpose and affects breeders, companies and farmers in different ways.

2.1 Patents

A patent lets its owner stop others from making, using or selling the protected invention, normally for two decades. In the seed sector, patents may cover GM organisms, breeding methods, genetic modifications and novel plant traits [Chowdhury, P, 2017; Khorsed Zaman, 2021]. They reward inventors and, in return, require public disclosure of the invention. They can also restrict access to key technologies and encourage monopolistic practices [Mendoza, R.M. (2020)][Andersen, P., & Cohen, M. (2002)], and gene patents in particular have been criticised for limiting farmers' ability to save and replant seed [Mendoza, R.M. (2020)][Mercedes Campi & Alessandro Nuvolari (2020)]. Strong patent protection helped bring transgenic crops to market in the United States by encouraging companies to invest in biotechnology. However, market power concentrated in a few firms can raise seed prices and reduce competition and variety choice [Moss, D.L. (2013)]. Patented traits also clash with seed saving; the spread of Roundup Ready® soybean, for example, imposed restrictions that changed farmers' customary practice [Mascarenhas, M., & Busch, L., 2006]. Licensing fees and the risk of infringement suits add further barriers for small farmers and new market entrants [Singh, K. (2017); Ferrari, V.E et al. 2019].

2.2 Plant Variety Protection (PVP)

Under PVP, a breeder obtains exclusive control of a registered variety in the form of Plant Breeders' Rights (PBR) [Khorsed Zaman, 2021; Andersen, P., & Cohen, M. (2002)]. India chose its own model through the PPVFR Act of 2001, which protects breeders and farmers within a single law. Once a variety is registered, the certificate holder (the breeder or anyone acting on the breeder's behalf, such as a licensee) alone may multiply, market, distribute, import or export it. Applications go to the Registrar of the PPV&FR Authority in New Delhi, and four groups of varieties qualify: new, extant, farmers' and essentially derived varieties (EDVs). For a new variety, the applicant must show novelty together with distinctness, uniformity and stability. The Authority will refuse a variety if blocking its commercial use is needed on grounds of public order or morality, the health of people, animals or plants, or serious environmental damage, and it will also refuse varieties that carry harmful seed-sterility technologies (often called GURT or terminator technology). Protection runs for 18 years from registration for trees and vines, 15 years from the date of Gazette notification for extant varieties already notified under the Seeds Act, 1966, and 15 years from registration for all other crops. UPOV 1991 sets longer minimum periods of 20 to 25 years. Since TRIPS, and with bilateral trade agreements requiring protection beyond the TRIPS minimum, PVP laws throughout the world have become stronger and more similar. The extent to which each country has gone depends on its legal capacity, trained

staff, the weight of agriculture in its economy and its openness to trade [Khorsed Zaman, 2021]. In trying to harmonize the interests of breeders and farmers, India adopted a mixed strategy where the Patents Act covered the genetic inventions and the PPVFR Act covered varieties [Dash, M.S. (2015)]. PVP provides legal redress where the variety is used without permission but it is difficult to enforce because it is not always easy to distinguish between a new variation and an existing one. PVP may also be of little benefit to smallholders who rely on indigenous varieties or cannot purchase commercial seed [Rai, M., & Mauria, S. (2004) ; Singh, K. (2017)].

2.3 Trade Secrets

A trade secret is any concealed commercial expertise that puts a corporation ahead of its competitors. In seed companies this often includes hybrid parent lines, breeding processes, marker panels, or seed production recipes. No registration is needed and the protection is valid for as long as the knowledge stays confidential, even if the exclusivity is less strong than for a patent or a PVP certificate [Andersen, P., & Cohen, M. (2002)]. If a rival independently discovers the information or reverse-engineers the information, the protection is removed and legal action is feasible only when misappropriation or theft can be demonstrated [Rai, M., & Mauria, S. 2004].

2.4 Trademarks in Seed Branding

Trademarks enable seed companies to differentiate themselves in a congested marketplace. Besides the source of the seed, a trademark also indicates quality and reliability to the farmers and agribusinesses (Pajic, 2020). When several items have the same characteristics, a strong brand can affect a purchase choice (Hasanah et al., 2023). Names such as Pioneer are commonly linked with some performance criteria. The quality of the seed has a great impact on production and profit; hence, farmers generally rely on brand image (Tahir et al., 2022; Kanojia et al., 2023). Furthermore, trademarks illustrate the qualities of products, such as endurance to dry spells or to plant disease. Registration grants the owner exclusive use of the mark in commerce and the right to sue infringers, shielding the brand from inferior imitations (Tahir et al., 2022). Trademarks are no less of a problem. A mark can lose protection if it becomes the generic name for a product, which can happen when a variety name widely embraced comes to stand for an entire class of seed. Trademark legislation is different in different countries, thus companies must manage protection on a market-by-market basis. Companies also have to be careful not to use marks that mislead purchasers about the nature of GM crops and unambiguous labeling is vital for consumer trust. Litigation over Roundup Ready® soybean, especially Monsanto v. Schmeiser, highlighted the need for seed IP protection in the courts (Auriol et al., 2023), whereas Pioneer shows how continuous investment in research and branding may lead to market supremacy. Sound trademark strategy will remain important in building lasting ties with farmers as biotechnology and customer preferences shift (Bourexi et al., 2017).

3. International Framework for Seed-Related IPR

The international legal framework for IPR on seeds has experienced significant developments in recent decades, as governments seek to strike a balance between innovation in biotechnology and the rights of farmers and food security. In the middle is the TRIPS Agreement . On either side are many regional and international accords . The major IPR instruments are patents for inventions such as GM characteristics, PVP for new varieties and trademarks for seed brands and symbols. They want to enhance investment in research and at the same time ensure good quality seed is available to farmers. Several international bodies also govern seed trade and quality: seed moving across borders is certified under the OECD Seed Schemes, sampling and testing follow the rules of ISTA (the International Seed Testing Association), UPOV protects new varieties, the International Seed Federation (ISF) issues trade and arbitration rules, and FAO instruments cover plant health, phytosanitary measures, access and benefit sharing, and pesticide use. Because the system pursues both strong protection and broad access, continuing dialogue at local, national and international levels is needed, together with approaches that respect local conditions while meeting global norms.

3.1 TRIPS Agreement

Countries and companies increasingly wanted their IP respected abroad, and this drove a series of international agreements. GATT, created in 1947, cut tariffs and other trade barriers through reciprocal concessions over eight negotiating rounds; the last of these, the Uruguay Round, brought farm trade into the system, and in 1995 the WTO took over GATT's role. TRIPS came into effect on the first day of 1995 and remains the broadest multilateral treaty on IP, laying down shared rules on how each kind of IP is to be protected and enforced. Its Article 27.3(b) lets members keep plants and animals (though not microorganisms) out of patent law, provided that plant varieties are still protected, whether by patents, by a workable sui generis law, or by both. India, Thailand and a number of other countries have chosen not to patent plant varieties and rely on sui generis legislation instead.

3.2 UPOV Convention

UPOV is a Geneva-based intergovernmental body created by the 1961 convention on new plant varieties, and the convention has since been amended three times, in 1972, 1978 and 1991. Its purpose is to promote a working PVP system that rewards the development of new varieties for the wider benefit of society. The convention lists the acts that need the breeder's permission, chiefly in relation to propagating material and, in some circumstances, to the harvest; put simply, nobody may multiply a protected variety for sale without the breeder's consent. Protection is

available only for a variety that is new, clearly different from varieties already known, consistent across plants and true over generations, and that has an acceptable name. Three uses fall outside the right: private use for non-commercial ends, experimentation, and the breeding of further varieties.

3.3 Convention on Biological Diversity (CBD)

Countries began signing the CBD at the 1992 Rio Earth Summit (5 June), and it took legal effect on 29 December 1993. No other international treaty treats biodiversity as comprehensively. It pursues three aims together: keeping biological diversity intact, using its parts sustainably, and dividing the gains from genetic resources fairly. It was also the first treaty to declare the conservation of biodiversity a concern shared by all humanity. Parties are legally bound by it, and it deals with the origin and value of natural resources and traditional knowledge and with the rights attached to them. India gave effect to the CBD through its Biological Diversity Act, 2002; under this Act, any IPR application that draws on Indian bioresources needs the prior consent of the National Biodiversity Authority (NBA), and India may oppose IPR granted in other countries over such material. Under the CBD's Access and Benefit-Sharing (ABS) framework, the terms on which genetic material is obtained, and how the resulting gains are divided, are agreed between users and the provider country. These rules also reach the knowledge held by indigenous and local communities: Article 8(j) commits Parties to protect and maintain such knowledge and to share its rewards with the approval of the communities concerned. The Cartagena Protocol on Biosafety, agreed in January 2000, became the first worldwide instrument on moving, handling and using living modified organisms (LMOs) whose release could harm biodiversity or human health. It set up an Advance Informed Agreement procedure for LMOs meant for release into the environment and rests on precaution and risk assessment. The Nagoya Protocol, agreed in Japan in October 2010 and binding since October 2014, is the CBD's second protocol. It gives benefit sharing a firmer legal footing and makes the rules for access more predictable for both providers and users of genetic material.

3.4 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The FAO plant treaty eases the movement of seed and germplasm of food crops between countries and supports research needed for climate-smart farming and food security (Belay et al., 2023). It is binding on its members and governs how plant genetic resources for food and agriculture (PGRFA) are accessed and how gains from them are shared (Aubry, 2023); in India it has to be applied together with the Biological Diversity Act and the Nagoya Protocol (Simkin et al., 2022). Breeders may claim IPR over new varieties bred from material taken from the treaty's Multilateral System (MLS), but if the resulting product cannot be freely used for further research and breeding, the breeder has to pay a share into a common benefit-sharing fund, which industry and donors may also support voluntarily. The money and other benefits from this fund go mainly to farmers in developing countries. The treaty further lists steps that governments are expected to take to give effect to farmers' rights, among them safeguarding the traditional knowledge linked to PGRFA (Singh et al., 2022).

4. Patents under advanced Seed Technology

Patenting in advanced seed technology increasingly concerns seed treatment, seed enhancement and genetic modification aimed at better seed quality, germination and stress resilience, all of which are important for food security and climate adaptation (Bamakan, Nezhadsistani, Bodaghi, & Qu, 2022; Reddy et al., 2022; Sorgato et al., 2020). The effects of these patents reach beyond individual crops to agricultural practice and policy (Blum et al., 2022; Setsoafia, Ma, & Renwick, 2022). Patents encourage collaboration between universities and industry, and the protection they offer allows companies to fund long-term research that may address global food challenges (Auriol, Biancini, & Paillacar, 2023; Tacconelli et al., 2017). Studies show that improved varieties can raise yields and farm incomes (Shelar et al., 2023), and genome editing tools such as CRISPR-Cas9 have brought new precision to crop improvement (Miladinovic et al., 2021). Bringing a biotech trait such as herbicide tolerance or insect resistance to market involves long phases of discovery, testing and regulatory review in many countries, which is one reason patents are considered important for such technologies (Fischhoff & Cline, 2009). Patents cut both ways (Speckbacher & Wabnegg, 2020). Bringing one new GM trait to market has been put at roughly US$136 million, which is used to justify a period of exclusivity (Lemarié, Baghdasaryan, & Campens, 2017). At the same time, broad utility patents have contributed to consolidation of the seed industry and fewer choices for farmers (Ilin & Shi, 2021). Companies also utilize private agreements, mixing trade secrets over hybrid parent lines with restricted licences that dictate how seed is used and reproduced, thus exerting control beyond the reach of PVP or patents alone (Nashkova, 2023; Pereira et al., 2019). Broad patents can restrict access to genetic resources needed by public breeders and developing countries, and have generated concerns about biopiracy where genetic material from underdeveloped countries is patented without adequate benefit sharing (Kim, 2023). Researchers and breeders need to understand the different scope of utility patents, plant patents and PVP certificates (Trappey et al., 2021), but consolidation can make it difficult to identify current patent holders even with resources such as Google Patents (Vetokhin et al., 2023). OSSIs, for example, utilize licences that maintain varieties publicly available for further breeding (McNaughton, 2017). Editing genes brings up the open topic of whether modified plants without foreign DNA should be patentable (Cheng et al., 2020).

4.1 Patentable Subject Matter in Seed Innovation

Seed-related patenting in India is regulated by three instruments: the Patents Act of 1970, the PPVFR Act of 2001 and the country's commitments under TRIPS (Tyagi, A.P et al., 2013). In 2005, amendments were passed to extend patent protection to new compounds created by incremental improvements, with implications for GM seed [Wani, T.A. (2008)]. The PPVFR Act creates a sui generis PVP system separate from patent law, however the two systems overlap and sometimes conflict [Thikkavarapu, P.R, 2018]. A patentable invention should be new, should include an inventive step that an expert would not find obvious and should have practical utility [Rao, M.B., & Guru, M.V. (2010)]. For example, there is confusion concerning GM seed that might be covered by both regulations because of the overlap. Critics are calling for tighter protection of farmers' rights, arguing that seed patents could discourage smallholders from conserving seed and increasing their dependence on multinationals [Wani, T.A. (2008); Archana 2018]. TRIPS demands the protection of biotechnological inventions. India's different farming systems require a personalized approach, which takes into account the local biodiversity and farmer practices [Thikkavarapu, P.R, 2018; Wani, T.A. (2008)].

4.2 Gene Patents and Genetically Modified Organisms (GMO)

Genetic engineering is used to give crops better yield, tolerance of dry conditions and protection against insects (Zheng et al. 2022); the term GMO covers any plant, animal or microbe whose genome has been changed by such methods (Evanega, Conrow, Adams, & Lynas, 2022; Hu, Wang, Chen, & Wang, 2023). Selective breeding has shaped crops and animals for centuries (Berseth, 2022), but direct modification can add traits absent from the species (Singhania, Patel, Tsai, Chen, & Dong, 2021; Pan et al., 2022) far faster than conventional crossing, helping crops tolerate poor conditions, improving nutrition and reducing pesticide use (Anthony et al., 2023; Ignatova, Babak, & Bagirova, 2020; KhokharVoytas et al., 2023; Crespo-Herrera et al., 2018; Bravo & Soberón, 2023). Their wide use, however, has ethical and ecological dimensions (Lin et al., 2023; Schmidt et al., 2022; Santarelli, 2021). GM crops can be patented because their engineered genetic changes do not occur in nature (Turaeva & Asomova, 2023). The crop must be innovative, non-obvious and valuable for it to qualify (Tack et al., 2020; Kim et al., 2023). Patent enforcement here is a balance between rewarding scientists and enabling monopolies over agricultural resources (Rowbottom, 2023; Andreea-Ion et al., 2021). The patents on life forms lead to problems about who owns organisms and the impact on biodiversity (Kovak, Blaustein-Rejto, and Qaim 2022; Cortez et al., 2021; Simkin, Seto, McDonald, & Jetz, 2022). The monopolies can restrict farmers' access to seed and their independence (Alam et al., 2023). Laws differ widely between countries (Auriol, Biancini, & Paillacar, 2023), and approval requires thorough environmental and health evaluation. Disputes often pit large biotechnology firms against small farmers over seed saving, and concentration of seed diversity in a few companies has broader implications for food security, agricultural diversity and the ethics of biotechnology (Trail et al., 2022; Al-Tohamy et al., 2022; None, 2021; Borsa et al., 2023).

Bt cotton reached Indian farms in the 2002-03 season. Its insecticidal protein, active against bollworm, is coded by a gene taken from Bacillus thuringiensis, a common soil microbe. It is still the sole transgenic crop cleared for commercial farming in the country, and India now ranks fourth in global GM crop area and second in cotton output (Quan & Wu, 2023). India's apex biotech regulator, GEAC, later cleared GM mustard DMH-11 (Dhara Mustard Hybrid-11) for environmental release; the hybrid was bred at the University of Delhi with a bacterial gene system that makes the crop easier to hybridise. The breeders claimed a 25-30% yield advantage over non-hybrid mustard, which several NGOs challenged (Misra et al., 2012), and the clearance covered seed production and field testing following ICAR norms ahead of any commercial launch. Bt brinjal, bred by Mahyco together with the agricultural universities at Dharwad and Coimbatore, was approved by the GEAC but then halted by a moratorium in 2010 (Akinbo et al., 2021). Familiar international cases are Golden Rice, bred to accumulate beta-carotene and so reduce vitamin A deficiency (Steur, De, Stein, & Demont, 2022; Sajovic et al., 2022), virus-resistant papaya that saved papaya farming in Hawaii (Premchand et al., 2023), the slow-ripening Flavr Savr tomato (Ishii, 2017), and cassava engineered against viral disease (Huang et al., 2023). India's legal base for GMO regulation is the Environment (Protection) Act of 1986, administered by the environment ministry (MoEFCC) (Venkatasubramanian, 2019). The GEAC, a statutory committee within that ministry, must clear any import, export, movement, production, use or marketing of GMOs, and food made from GM crops is in addition subject to the national food regulator (FSSAI), which was created under the food safety law of 2006. The Biological Diversity Act, 2002 requires anyone using Indian bioresources for GMO research or business to obtain prior permission and sign a benefit-sharing agreement with the NBA (Santo et al., 2023), while the Plant Quarantine Order of 2003 controls the cross-border movement of GM plants and plant material.

4.3 CRISPR and Genome Editing Technology

By allowing targeted and efficient changes to DNA, CRISPR-Cas tools have changed how plants are bred; they help scientists locate the genes behind complex traits, tap unused diversity and introduce beneficial mutations for higher yield, better disease resistance and stronger stress tolerance. The CRISPR patent landscape is complex and varies by region; in Australia, for instance, many filings exist but local contributions are few, showing the difficulties smaller innovators face. In soybean, groundnut, cowpea, chickpea and other legumes, editing has improved seed nutrient content and tolerance to both pests and environmental stress (Ahmad, 2023; Sangari, M.G et al., 2024). Methods

refined in animal germline stem cells may be adapted to plants [Decker et al., 2024], and the newer bridge RNA editing approach, which links two DNA segments, could allow larger genome changes than current CRISPR tools [Parums DV, 2024].

Editing can produce disease-resistant crops that need fewer pesticides and can improve nutritional and functional quality (Veillet et al., 2020; Ku & Ha, 2020). Newer tools such as prime editing allow still more precise changes. Rapid growth in these technologies has led to many patent filings and grants on CRISPR-Cas and related tools, so innovators must work through a crowded patent landscape to use them effectively. How technology and patent law develop together will strongly influence the future of agricultural biotechnology [Ahmad, 2023; Veillet et al., 2020; Ku & Ha, 2020; Ercolano & Wang, 2023; Maximiano MR, 2021].

4.4 Breeding Techniques and Algorithms

In vitro methods such as haploid breeding and somatic hybridisation, together with molecular markers, have made breeding more efficient and precise (Dunwell, 2009). Linking these methods with computing and artificial intelligence (AI) may shorten the time needed to breed productive cultivars that cope with a changing climate. The term "Breeding 4.0" reflects the rapid growth of omics data and informatics, and machine learning is expected to be central to developing climate-adapted crops (Khan et al., 2022; Yoosefzadeh-Najafabadi et al., 2023). A key benefit of AI is better prediction of crop performance. Models trained on historical and environmental data can forecast how varieties will perform, help identify superior parents and shorten selection cycles. AI models fed with satellite images, sensor data and historical records can also forecast pest and disease outbreaks, supporting early management and the breeding of resistant varieties (Khan et al., 2022; Gardiner Krishna, 2021; Yoosefzadeh-Najafabadi et al., 2023). Challenges remain: crop performance depends on complex interactions among genes, environment and stresses, which makes prediction difficult, and high-quality diverse data and computing power are not available to everyone.

5. Plant Variety Protection Systems

5.1 UPOV, sui generis system and Plant Breeders' Rights

Building PVP regimes has been a difficult process shaped by legal, political and economic factors. UPOV has been central to the sui generis model of PBR, which many countries have adopted with varying degrees of enforcement. In Asia, the development of PVP has been long and often contested (Lertdhamtewe, 2013); many countries were at first reluctant to grant such rights, but TRIPS obligations led to a range of legislative models. New biotechnological breeding methods have also forced regulators and scholars to rethink how such plants should be classified and governed. Transgenic plants and agricultural biotechnologies may involve many components, each subject to different IP and property rights (Lusser et al., 2012), so securing freedom to operate has become a major concern for public and private researchers. Infringement weakens incentives for research, and because monitoring and enforcement are costly, some actors may infringe whenever it pays to do so (Giannakas, 2002). A clear understanding of PVP regimes, the UPOV Convention and infringement is therefore essential for researchers, legislators and other stakeholders.

5.2 Distinctness, Uniformity, Stability (DUS) and Value for Cultivation and Use (VCU) Criteria

PVP is based on 4 tests (novelty, distinctness, uniformity, stability) and many nations add a value for cultivation and use (VCU) test before a variety is released. Together they help to manage crop diversity and regulate breeding (Poteete et al., 2010). The PBR grant is based on the DUS. A variety is distinct if it is clearly distinguishable from any other variety by at least one morphological, molecular or other attribute. Uniformity means that plants of the variety will show the same characteristics so farmers may expect consistent growth, yield and disease response. A variety is stable if the traits of the variety remain unchanged across multiple generations. A variety whose traits drift loses value for the producer. These parameters are said to favor homogeneous high-yield cultivars over more diversified landraces (Lertdhamtewe, 2013). DUS testing combines field trials and laboratory analysis, with DNA markers, particularly SNPs (single nucleotide polymorphisms), now allowing a more accurate evaluation of distinctness and uniformity, making testing more reliable and efficient as the number of varieties increases (Yu JK and Chung 2021; Achard et al. 2020). VCU testing evaluates agronomic value in multi-location trials compared to standard cultivars. It evaluates agronomic performance (yield, disease resistance and adaptation), economic feasibility (whether the advantages outweigh input costs like as fertilizer and water at current prices) and consumer acceptance (flavour, nutrition and appearance). VCU assessment is accelerated and performance prediction is increasingly made using molecular and biochemical markers.

DUS and VCU are related but distinct. A variety with strong VCU will not get PVP if it fails DUS and a distinct and stable variety with poor yield or disease resistance may not be commercially viable. These principles are recognized by UPOV, an international body that supports the seed trade. Detailed requirements change from country to country, depending on local tastes and farming traditions. Large field experiments involve time, land and money that can be a burden to small breeding programs, and molecular approaches demand equipment and expertise not available to all. The VCU emphasis on productivity and commercial performance may also devalue local adaptability, nutritional quality and cultural relevance. Genome editing adds another layer of intricacy, as it tests the existing definitions of genetic change. Any reform of DUS and VCU testing should therefore weigh what crop diversity means socially,

ecologically and culturally, alongside new technology (Scossa et al., 2020; McCouch et al., 2020; Lertdhamtewe, 2013; Lusser et al., 2012).

5.3 Essentially Derived Varieties (EDV)

Within UPOV, the EDV idea is meant to stop breeders' rights from either stifling or being undercut by follow-on breeding. An EDV is bred mainly from an initial variety (IV) and keeps the core characteristics that the IV owes to its genetic make-up, while differing in a few traits introduced by the breeding method. EDVs can arise from conventional breeding, mutation breeding, marker-assisted selection or gene editing, and the degree to which essential traits are retained determines whether a variety counts as an EDV. Extending protection to such varieties encourages investment, especially as new breeding techniques (NBTs) advance quickly (Kloepper et al., 2021), and it tackles free-riding, where others profit from a breeder's work without compensation (Gervais, 2020). At the same time, the breeder's exemption still allows initial varieties to be used for further breeding, which maintains an active breeding environment.

The application of the principle has been problematic. The wording of UPOV on EDVs is often considered vague, causing uncertainty among breeders and lawyers regarding which varieties are eligible and generating discussions on interpretation (Kloepper et al., 2021). Setting genetic similarity thresholds is similarly tricky. The calibration concept defines thresholds based on similarity among closely related genotypes. The tails principle uses percentiles within a reference population. The pedigree principle uses breeding procedures proven to create EDVs. None of these is as good across species. Because NBTs typically create variations that retain most of the original DNA, it is legally questionable if they are EDVs or stand-alone varieties (Kloepper et al., 2021), which complicates issues. Updating definitions for EDV and involving stakeholders to address these issues will assist PVP systems encourage innovation and continue access to genetic resources.

5.4 Farmers' Rights and Farm-Saved Seeds

Farmers' Rights, a concept which came out of global discussions in the 1980s, is currently at the center of the PVP debate. It recognizes a farmer's right to save, exchange and sell seed, a practice that promotes crop diversification and household food security. ITPGRFA (FAO, 2001) specifically acknowledges these rights and they are especially relevant for smallholders reliant on traditional seed systems. TRIPS requires the protection of plant types, but allows actions to be taken in accordance with Farmers' Rights (WTO, 1994) and nations have interpreted this differently. The PPV&FR Act (2001) of India provides legal recognition to breeders as well as farmers and farmers are free to retain, replant, share and market farm-saved seed and the legislation recognizes their role in protecting crop diversity (PPV&FR Act, 2001). Farmers' Rights are included in Bangladesh's PVP statute but have been criticized for insufficient enforcement (Rahman & Rahman, 2020), and shortcomings in implementation are also apparent in Pakistan's emerging system (Khan et al., 2024).

The conflict is that breeders want protection so that they can fund research but farmers rely on traditional seed saving and sharing, and severe IP regulations may prevent farmers from conserving seed of hybrid or patented crops (Gervais, 2020). Although Farmers' Rights are protected by law, many smallholders are unaware of these rights or lack the legal support to assert them, leaving them vulnerable to abuse by larger seed firms. The lines between traditional breeding and patented inventions get blurred with NBTs such as CRISPR, leading to concerns over farmers' capacity to conserve seed from such crops (Kloepper et al., 2021). Governments can reinforce Farmers' Rights with clear and enforceable restrictions on conserving, utilizing, exchanging and selling seed at local level, and awareness programs outlining legal rights under national laws and international treaties. Discussions with the organizations of farmers, breeders, lawmakers and legal experts can help to resolve conflicting interests. Investment in research on traditional varieties and sustainable farming, and support for community seed banks can help improve farmers' access to diversified seed while safeguarding agricultural biodiversity.

6. Emerging Technologies and IPR Challenges

6.1 Synthetic Biology in Seed Development

Synthetic biology is revolutionizing seed creation with precision genetic design that can boost production, resilience and sustainability but it also poses significant IP problems. Sequencing has become cheaper and bioinformatics better, revealing much more about which genes influence valuable crop qualities. Tools such as CRISPR-Cas9 allow genes to be introduced or removed to improve performance (Basso et al. 2020), for example to give drought resistance or improved nutrition. Synthetic genomics, which designs and constructs new biological parts and systems, may someday develop wholly new plant kinds adapted to certain conditions or markets, while automated high-throughput screening permits rapid testing of genetic modifications.There is controversy about patenting in synthetic biology, particularly in relation to natural sequences or traditional breeding methods. The Nagoya Protocol's provisions on access to genetic resources and benefit sharing potentially block the use of samples from developing nations [Bagley, M.A., 2016]. IPR can spur innovation, but it can also restrict access to vital technology, especially for smallholders who could be deterred by expensive license payments. The co-existence of TRIPS and CBD makes things much more complex. How both can co-exist without hampering innovation is a matter of debate (Bagley, M.A., 2016; Minssen T 2015).

6.2 Artificial Intelligence (AI) and Machine Learning (ML)

Seed quality testing is important for seed lot selection and it is also used to determine the viability, vigor and genetic purity of seed lots. Conventional germination, purity and vigor tests give information necessary for decision-making and regulatory compliance (ISTA, 1999), but are labor-intensive, need specialized personnel and may not predict field performance across settings (Filho, 2015). AI/ML provide new methods. Spectral imaging (multi- and hyperspectral) is a fast non-destructive method to detect viability, vigor and infection and hyperspectral systems can also sort variations and identify faults more rapidly than manual inspection (Kumar et al., 2015; Kong et al., 2019; Mahesh et al., 2018, Collins et al, 2025). ML can analyze big imaging datasets to predict seed performance and autonomous robots are being developed with imaging systems to capture phenotypic data as plants grow (KWS, 2024). The application of these methods with networked field sensors enables constant crop monitoring and facilitates site-specific management. Computer vision has improved the objectivity and repeatability of germination testing (Dell Aquila, 2009; Nguyen et al., 2018; Masteling et al., 2020). Low cost RGB camera systems were used to develop SeedGerm, an automated open-source ML tool (Colmer et al., 2020). Hyperspectral imaging paired with ML has predicted germination or vigor in maize, barley, rice, wheat and soybean with c. 85-95% accuracy (Feng et al., 2019). Automated methods can also distinguish pure seed from contaminants (Zhao et al., 2022), and identify insects, fungal infection and physical damage so that problems are handled early (ElMasry et al., 2019). AI also muddies ownership and its unclear where rights should lie, if artificial intelligence systems help invent things – with the inventor of the AI, or the researcher who uses it. Many nations still require a human inventor, leaving AI-generated inventions in a legal void that can discourage investment (iPleaders, 2024). Farmers are also hesitant to share data due to fear of abuse because the current patent system does not sufficiently secure raw agricultural data (CIGI, 2024). But to let AI-driven seed research flourish, we need updated legal structures that protect the interests of stakeholders.

6.3 Block chain for Seed Traceability and IP Management

Beyond banking, blockchain is drawing interest in agricultural and IP management. Blockchain-based traceability solutions can help address longstanding concerns of food quality, safety, and supply chain transparency (Bosona & Gebresenbet, 2023). Because the ledger is decentralized, tamper-proof and transparent, it can record every movement and transaction of a seed lot from the production plot to sale, without the need for intermediaries. Link it to IoT sensors that track ambient conditions, storage temperature and logistics and you have a complete and verified product history. These similar qualities make blockchain a promising instrument for the registration, monitoring and enforcement of rights over plant varieties and genetic resources (Kamilaris et al., 2019). In practice, blockchain traceability can eliminate counterfeit seed and provide farmers confidence in its quality. In India, such systems have traced seeds from source to buyer and increased trust amongst parties (TraceX, 2024). Data once recorded cannot be changed, ensuring reliable records of seed quality, manufacturing processes and certification. A buyer can scan a QR code linked to the ledger and instantly discover the origin of a seed lot and how it was tested (TRST01, 2021). India's agriculture ministry recently launched SATHI (Seed Traceability, Authentication and Holistic Inventory), a single online system that tracks seed through production, quality inspections and certification. A blockchain record can also be used as evidence when a new variety or technology was produced and how, which can assist in infringement claims, and intelligent contracts can assist with licensing and royalty payments. However, challenges remain. Many countries have strong laws on software patents, making it impossible to secure blockchain innovations (Invntree, 2024). Also, the need for big databases brings up issues regarding who owns the data and how people may fairly access genetic data (Williamson & Leonelli, 2022).

7. Ethical Considerations and Controversies

Consumers, environmental groups and faith organisations have all voiced ethical objections to advanced seed technologies. Most of these concern possible harm to people and ecosystems, and whether it is right to alter genetic material at all.

7.1 Risks to Human, animal Health, flora and fauna

As the world's population grows, so does demand for food, fuel and fibre, and farming needs new solutions to keep pace. A major concern about advanced seed technologies is their possible effect on health and the environment. Critics argue that GMOs might have unintended effects, such as new allergens or gene transfer to non-target organisms (Domingo & Bordonaba, 2011), and although many studies have examined GMO safety, long-term effects are still debated. Genome editing offers promising solutions but also raises questions about how IPR interact with human, animal and environmental health. Questions remain about allergenicity and long-term effects of GM foods, about the adequacy of current assessments, and about effects of GM feed on livestock reproduction and immunity. Herbicide-tolerant crops may increase herbicide use, harming non-target plants, while gene flow to wild relatives threatens native flora and heavy chemical inputs may affect soil microbes and fertility. Patented GM seed can also narrow smallholders' access to diverse genetic material and deepen dependence on annual seed purchases from a few corporations. These issues, together with the morality of patenting living organisms, call for continuing dialogue to support responsible innovation (KWS, 2024; Kumar et al., 2024; Glover et al., 2023).

7.2 Moral and Ethical issues

There are others who oppose contemporary seed technologies on moral grounds, believing that genetic modification is “playing God” or going against nature (Comstock, 2000). Such positions are generally rooted in religious or philosophical ideas on the sanctity of life and, while not scientific statements, they do represent values that should be taken into account in the development and use of technologies. Critics say patenting GM seed raises problems about ownership of living creatures and turns nature into a commodity and diminishes the intrinsic value of life (Bold Patents). This type of commodification can consolidate control over essential resources in the hands of a few businesses and diminish seed saving, threatening food sovereignty in poorer nations where farmers depend on unpatented traditional varieties. Terminator technology, which creates sterile seed, has been attacked for making farmers dependent on multinational firms and forcing them to buy seed each season, thus compromising their autonomy and economic stability (Guebert, 2001). Herbicide-tolerant crops have also been associated with increasing herbicide use with impacts on non-target species and ecosystems (Guebert, 2001). Cultural viewpoints matter, too: in many places, farming techniques are linked to cultural identity, and Western-style patent regimes may be viewed as alien impositions that clash with local values (Purdue e-Pubs, 2024). These topics demonstrate the connection between innovation, business interests, environmental sustainability and social justice.

7.3 Access to Genetic Resources and Benefit Sharing

ABS raises difficult ethical considerations regarding who benefits when IPR govern the products of biotechnology. The Nagoya Protocol gives each state ownership of the genetic material inside its boundaries, raising issues of fairness for the indigenous people and farmers who have tended that material for generations (WIPO, 2023). From an ethical standpoint, these communities are entitled to a fair share of the benefits and access should be based on their free and informed permission, obtained through an open and respectful procedure. Failure to get such consent may lead to exploitation and erode confidence between researchers and communities (Purdue e-Pubs, 2024). Many cultures view genetic resources as heritage rather than commodities, and ABS agreements need to respect these values and customary knowledge (WIPO, 2023). Patents on biological beings are particularly controversial when goods are generated from traditional knowledge without adequate remuneration to its custodians. By contrast, the complex bilateral agreements under the Nagoya Protocol have decreased germplasm sharing, which may impede crop breeding and jeopardize food security (PMC, 2023). This sets up a contradiction between the protection of local rights and the promotion of worldwide agricultural prosperity. The concentration of patents on genetic resources in a few multinationals also carries the risk of marginalizing smallholders and indigenous groups, who may not be able to pay for access to important genetic material (WIPO, 2023).

7.4 Traditional Knowledge and Farmers' Varieties

Traditional knowledge (TK) includes the traditions, innovations and abilities of indigenous cultures developed over centuries and its protection is important for cultural heritage and biodiversity. Today’s IPR systems tend to ignore these contributions leading to biopiracy, when corporations patent TK without consent or pay (Amity International Journal, 2017). The right to save, exchange and sell seed is vital to farm livelihoods and household food security but rigid IPR can threaten this; an ethical approach should balance the rights of breeders with the rights of farmers (Purdue e-Pubs, 2024). IPR compels farmers to commercial varieties, leaving traditional kinds behind, decreasing the number of crop types and making farms less resilient to pests and a changing climate (PMC, 2023). Indigenous groups typically lack the political leverage or legal ability to make fair agreements (Purdue e-Pubs, 2024). Solutions to these concerns should include equitable sharing of benefits, respect of farmers’ rights and protection against biopiracy.

7.5 Food Security vs IPR Protection

The heart of the ethical dilemma is a tension between innovation and access to improved seed. IPRs boost research by establishing exclusive rights, but they can also prevent farmers from accessing germplasm, especially in the poorest nations, and can pit breeders against growers who depend on a wide choice of seed." Traditionally, farmers have stored and exchanged seed, which encourages biodiversity and adapts crops to local conditions. Stringent IPR regimes limiting these activities undermine the autonomy of farmers and food production (Purdue e-Pubs, 2024). Fair sharing of benefits is also important. The Nagoya Protocol envisages benefits from the use of genetic material accruing to communities who have conserved it, yet a lot of indigenous communities are still getting nothing in return (WIPO, 2011). A limited number of multinational companies hold most seed types and GMO patents, restricting agricultural diversity and possibly farmers’ choices, and threatening food security (Bold Patents, n.d.) . Loss of biodiversity is detrimental to resilience to pests and climate change and proprietary varieties can divert farmers from native types (PMC, 2023). It is especially difficult for developing nations to comply with international IP requirements and maintain indigenous farming practices and food security (Purdue e-Pubs, 2024).

7.6 Biopiracy and Misappropriation of Genetic Resources

Biopiracy is the unauthorized patenting of biological material and associated TK. This is a major ethical concern as biotechnology is ever more dependent on genetic resources that have been conserved by indigenous populations over extended periods of time. In that companies have traditionally patented indigenous plants and their use without authorization or payment, substantial injustice has been caused (WIPO, 2023). Ethical frameworks must recognize the

rights of these communities, involve them in decisions about their own resources, and assure informed consent that is effectively communicated and practiced during research and commercialization (Purdue e-Pubs, 2024). Equitable benefit-sharing agreements are also essential; the Nagoya Protocol is supportive of this notion (WIPO, 2011), although implementation is often poor and exploitation occurs. A well-known example is the neem case, when a US firm patented a product based on a tree that Indian farmers had used for centuries, illustrating how IPR can trigger the exploitation of indigenous knowledge rather than its protection (Think Landscape, 2024). Another dimension is provided by digital sequence information (DSI), in that genetic sequences can now be retrieved and used digitally without access to specimens. Such 'digital biopiracy' may not be covered by existing laws, hence requiring revised regulations (Opinio Juris, 2024). And enforcement is inconsistent. Many poorer countries simply lack the laws, institutions or resources to prevent multinational businesses from abusing their genetic richness, which poses issues of justice in global trade (PMC, 2023). IP regimes should be rethought to combat biopiracy, indigenous rights prioritized, informed consent ensured and systems established for equitable benefit sharing that honor TK and foster innovation.

8. Regulatory Framework and Enforcement of Seed-Related IPR

8.1 Bio-safety regulations

Biosafety is the potential or actual risk that an organism presents to human, animal and plant health, either through direct infection or indirect environmental impact. Biosafety rules on seeds seek to decrease hazards from GMOs and LMOs by preventing accidental release, minimizing contamination and assessing dangers to biodiversity, and may also take into account socio-economic implications. India’s system is based on the 1986 environment protection law and the 1989 Rules on harmful microorganisms and genetically modified organisms or cells with the Cartagena Protocol as the worldwide standard. Six entities are responsible for this. They are: RDAC (advisory), RCGM (review of genetic manipulation), GEAC (appraisal and approval), state-level coordination committees (SBCC), district committees (DLC) and biosafety committees inside each institution (IBSC). The RCGM grants research import permits after evaluating safety data and need. The GEAC regulates imports for wider usage and quarantine regulations are applicable to any biological material. Rules on farmer seed saving vary by country, with UPOV 1978 allowing it but UPOV 1991 not. India’s PPVFR Act is quite permissive in that it allows growers to keep, reuse, swap and even sell seed of protected varieties as long as it is not sold under a brand name. The boundaries of allowed seed saving and the impact on the commercial seed business are still a matter of controversy. Biosafety rules govern transgenic crops through characterisation of the genetic background, field testing and approval before release, but biosafety authorities focus on environmental and public health matters and usually cannot enforce IPR. PVP gives breeders control over the production and marketing of their varieties, patents can cover genes, editing techniques and tools, and companies may hold inbred lines as trade secrets. Stronger IPR may encourage private investment in breeding, although evidence linking PVP to greater private sector activity is mixed, and income from IPR may pull national agricultural research institutes (NARIs) away from their public mission. Biosafety rules and IPR have different aims but can complement each other. In Argentina, Monsanto used PVP and biosafety rules to control access to Roundup Ready soybean in the absence of patent protection; control of illegal Bt cotton cultivation in India has relied on seed legislation; and CIMMYT's Striga-resistant maize required resolving IPR on herbicide resistance genes through partnerships with companies. Seed sector policy should therefore treat biosafety and IPR together, promoting innovation while ensuring environmental sustainability and fair access to seed.

8.2 IPR and regulations

IPR and legislation in the seed business have a significant impact on food security, innovation and the rights of farmers and seed producers. One of the major problems especially in poorer nations is the conflict between the private rights of breeders and the common rights of farming communities (Ramanna, 2005). Agriculture for a long time remained mainly outside global IP regulations, as seed and crop germplasm were seen as a common asset. Since then, the growth of biotechnology and worldwide seed markets has intensified pressure to establish and enforce PBR, sometimes at the expense of traditional methods and community seed systems. How successfully PBR function depends on the broader economic and legal framework including the strength of market institutions and the judiciary. Where property rights are not well defined, there is less motivation to spend because innovations can be replicated without paying. Some countries have experimented with alternate methods whereby communities hold joint rights in their TK and indigenous germplasm (Haghiri and Phillips, 2003). The seed systems of smallholder farmers are also influenced by national seed legislation and the prioritization of commercial seed networks over informal seed systems has increased worries over loss of agrobiodiversity. Even where laws exist, enforcement is typically inadequate. The Indian seed industry cites to limited understanding of seed IPR among enforcement agencies and to delayed court procedures (Indian Seeds Industry Advocates, 2023). However, enforcement must respect farmers’ customary seed saving and exchange to safeguard biodiversity and food security (Agriculture Post, 2023).

8.3 Detection of IPR Infringement

Seed IPR detection and enforcement is vital for the protection of breeders and farmers. TRIPS provides basic global standards that affect national PVP and patent laws, whereas the CBD and its Nagoya Protocol require that indigenous populations get a fair return when their genetic material is utilized (WIPO, 2011). In India, the PPVFR Act protects breeders and farmers alike, permitting registration of new varieties while recognizing farmers' rights to store and trade seeds (Purdue e-Pubs, 2024), while FSSAI rules help examine risks of novel seed technology before commercial acceptance (Agriculture Post, 2023). Monitoring seed production and marketing channels for unauthorized use of protected kinds or TK is necessary for detection of infringement. The Indian seed sector needs local law enforcement who know about seed identification and case registration since their involvement can prevent IP theft and the unlawful manufacture of unlicensed GM seed. Training programs can help officials identify violation. The experts pointed to major hurdles such as the lack of robust IP protections, the conflict between farmers' and breeders' rights, and the sluggish legal processes (Times of India, 2024). An effective enforcement approach should respect the rights of the breeders and farmers to conserve biodiversity and stimulate innovation (Indian Seeds Industry Advocates, 2024).

8.4 Legal Remedies and Dispute Resolution

Seed IPR cannot be implemented in practice without practical remedies and mechanisms of settling disputes. Courts can grant injunctions to prohibit infringing activities and avoid additional harm to the rights holder (Times of India, 2024). Damages may also be awarded to rights holders to put them back in the economic position they would have been in had the infringement not happened (Indian Seeds Industry Advocates, 2024), while courts may order an account of profits to ensure infringers do not profit from unlawful action (Purdue e-Pubs, 2024). With the complexity of agricultural IP disputes, parties are increasingly turning to mediation, arbitration and other out-of-court settlement alternatives, which tend to be speedier than litigation and help protect commercial relationships (Agriculture Post, 2023). Training law enforcement officers to identify infringement and register complaints and simplifying court procedures for IP matters will speed up rulings and promote compliance (Indian Seeds Industry Advocates, 2024).

8.5 Case Studies of Major Seed IPR Litigations

Several cases have highlighted the difficulties of seed IPR litigation. In Bowman v. Monsanto, farmer Vernon Bowman purchased commodity soybean from a grain elevator, sowed it and preserved seed from the ensuing Roundup Ready crop. Monsanto sued for infringement and won. The US Supreme Court said that when a farmer buys copyrighted seed, he does not therefore get the right to generate fresh copies of that seed by planting a crop. The case shows the dichotomy between patent rights and customary seed saving. India's battles over the unauthorized replication and sale of Bt cotton seed demonstrated the difficulty of enforcing IPR when many farmers do not know their rights and obligations, and led to requests for better enforcement and farmer education. Syngenta and grain handler Bunge had disputes over GM maize that was not yet certified in some export countries, highlighting the complexity of seed and grain supply chains and raising questions about the obligations of distributors (Agriculture Post, 2023).

9. Conclusion and Future Trends

Seed IPR management the key to balancing innovation, farmers' rights and biodiversity conservation Seed IPR's history is a microcosm of a larger battle between corporate interests and the old ways of farming. UPOV's PVP regulations provide breeders with exclusive rights but could limit farmers' traditional practice of seed saving and sharing. TRIPS has forced developing countries to adopt IP standards of industrialized countries, with possible consequences to local biodiversity and food sovereignty. The seed sovereignty movement is gaining momentum and challenging corporate control over seeds. It emphasizes the value of agrobiodiversity and the role of farmers in crop diversity. Getting this balance right is crucial to food security and sustainable farming as conditions change. Policymakers need frameworks that protect breeders, support farmers' rights and maintain biodiversity. The rapid breakthroughs in genetic engineering and related biotechnologies require a revision of existing IPR regimes to ensure protection of new varieties for food security and sustainability, while ensuring fair access for smallholders. IPR global harmonization can promote efficiency and trade but often ignores the local farming traditions. Developing nations struggle to achieve stringent criteria under agreements such as TRIPS. Future policy should acknowledge the progress made by breeders and the traditions of farmers, for example through farmer exemptions and community seed banks. Policies that are designed with the input of farmers, academics and industry are more likely to be inclusive and to represent the interests of all actors in the seed chain, and the sharing of experience between nations helps guide harmonization that respects local systems. New patterns also need to be observed. DIY biotechnology based on CRISPR expands experimental access, but creates biosecurity and ethical concerns that require flexible, balanced rules. Low-income countries might require compulsory licensing or similar access measures. And further consolidation in agricultural biotechnology demands strong competition law enforcement and thorough monitoring of mergers. Public-private partnership and well-targeted public funding can ensure that research on food security and sustainability is generally accessible.

The need to adjust IPR systems to climate-resilient agriculture is becoming more pressing. Traditional knowledge is an important resource for climate adaptation, and IPR regimes should protect indigenous and local knowledge, while also permitting its fair use in modern innovation, perhaps via dedicated organizations that reward communities for their efforts. Open-access techniques that share genetic resources and research results can help increase innovation and fair access to resilience technology. IPR regulations must be flexible to react rapidly to new scientific data and environmental conditions, avoid monopolization of genetic resources, and promote equitable licensing that allows farmers to use better varieties without exorbitant prices or restrictions on storing seed. Finally, the alignment of IPR rules with national and international climate goals, with the cooperation of governments, industry and farming communities, will be fundamental for an agricultural system that is innovative and just.

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