TALLINN UNIVERSITY OF TECHNOLOGY School of Business and Governance Department of Law

Hajna Szücs

GROWING THREATS TO PLANT BREEDING FROM INTELLECTUAL PROPERTY LAWS

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Supervisor: Pawan Kumar Dutt, MA

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I hereby declare that I have compiled the thesis independently and all works, important standpoints and data by other authors have been properly referenced and the same paper has not been previously presented for grading.

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ABSTRACT

Intellectual property rights on living organisms such as seeds have drastically developed over the last few decades affecting farmers and breeders of all sizes. Despite the possibility to prohibit patents on seeds originating from essentially biological processes according to 27(3)b of the TRIPS agreement, there is a lack of clarity regarding that in the EU. As a result, in recent years there has been an increasing number of successful patent applications in the EU that affect seeds of essentially biological processes.

The TRIPS agreement also gave rise to the UPOV Convention that has been implemented into the plant variety protection system used in Europe. Provisions of the Convention that describe the requirements for the registration of plant varieties restrict the types of seeds allowed on the market. There are additional controversies in the case of essentially derived varieties that may be developed by farmers and breeders as a result of the farmers' exemption. The legal consequences of these laws can have implications for the rights of farmers to save, sell and improve their seeds.

The research goes into the international and EU patent and plant variety protection rules and will cover how international treaties on farmers' rights are implemented into the intellectual property laws of the EU. The research will include a comparison of the situation in different countries to discover solutions to the problematic areas pointed out in the paper.

Keywords: TRIPS Agreement, intellectual property rights, essentially biological processes, plant variety protection, peasants' rights

LIST OF ABBREVIATIONS

CBD	Convention on Biological Diversity
CESCR	Committee on Economic, Social and Cultural Rights
CJEU	Court of Justice of the European Union
CPVO	Community Plant Variety Office
DUS	distinctness, uniformity, stability
EDV	essentially derived variety
EPO	European Patent Office
EU	European Union
IV	initial variety
NBT	new breeding technologies
PPVFR	Protection of Plant Varieties and Farmers' Rights Act
TRIPS	The Agreement of Trade-Related Aspects of Intellectual Property Rights
UNDROP	United Nations Declaration on the Rights of Indigenous People
UPOV	International Union for the Protection of New Varieties of Plants
WTO	World Trade Organization

INTRODUCTION

Regardless of the size and the locations of farmers, whether they are small-scale local farms or huge operations with thousands of hectares, they all share the common characteristic of relying on seeds. Before the introduction of intellectual property rights, all seeds used to be part of the commons with farmers having full sovereignty to replant and develop the seeds they were using. The last century has markedly changed the agricultural sector with the rise of new technologies and legal developments such as patents which makes it practically illegal for farmers who do not own the patent or permission from the owner to replant the seeds.¹ The new changes these days are slowly ending thousands of years of traditions despite the fact that the patented plant varieties of today are at least in some part also the fruits of the historical hard work of farmers which was based on a system of free seeds.²

On the other hand, intellectual property rights, and especially patents, play an essential role in today's modern world because technology, as it is known today, could not have developed without them. It is widely known that patents provide the core motive for people to innovate by giving assurance that their investments will see returns. While there are variations in the success rates of patents in particular based on the different economic sectors and geographical locations, their necessary function in research and development is not up for debate.³ Inventions in the area of agriculture by developing new varieties have always been one of the key tasks of farmers not only to achieve more desirable produce but also for achieving resistance against certain diseases that could have had detrimental consequences for the harvest and to better adapt the plants for the local climate. Farmers and biotech companies alike work hard to develop plant varieties that are better equipped to handle periods of droughts and other extreme weather conditions such as heatwaves which are increasingly prevalent in Europe. Since the work they do is crucial for ensuring food

¹Muzaka, V. (2021). Stealing the common from the goose: The emergence of Farmers' Rights and their implementation in India and Brazil. *Journal of Agrarian Change*, 21, 356-359.

²Kloppenburg, J. (2010). Impeding Dispossession, Enabling Repossession: Biological Open Source and the Recovery of Seed Sovereignty. *Journal of Agrarian Change*, 10(3), 370-372.

³Sampat, B. N. (2018). A Survey of Empirical Evidence on Patents and Innovation. *National Bureau of Economic Research Working Papers*, No. 25383.

security, they deserve reward for their hard work in the form of receiving protection and monetary returns for their seeds.⁴

It is not news for most people that the rapid development in technology is also constantly bringing unique challenges and new issues to the tables of legislators. Patents granted on plant seeds are an area in biotechnology where the laws and regulations in the European Union (EU) as well as their interpretation have gone through multiple changes. Legislative decisions in the EU as well as the practice of the European Patent Office (EPO) have had substantial impacts and continue to play a key role in determining the scope of patent protections as well as other plant protections. ⁵ In addition, the Court of Justice of the European Union (CJEU) and national courts have also greatly contributed to current policies and rules.⁶ Such changes will also be inevitable in the future to bring more certainty about the extent of rights breeders have and the protections farmers can enjoy who are often vulnerable when they face large undertakings that hold intellectual property rights on seeds that farmers sow.⁷

There are clear trends in this area in the EU today that show the topicality of the issue. First, the EPO has been granting thousands of patents in recent years even if there are controversies regarding whether or not they are allowed according to EU patenting rules. The various cases represent an ongoing issue that has no definite solution in sight. In addition, challenges such as droughts and severe weather conditions already place an ever-increasing pressure on farmers who feel threatened by the increasing number of seed patents granted in the EU that in many cases extend protection for the seeds that they have developed.⁸ Secondly, the new EU regulation that extends the plant variety registration to organic seeds has raised awareness on the deficiencies of the current plant variety protection system as well that is used not only in the EU but also worldwide.⁹ Overall, one of the main questions in this regard is what the needed efforts are to make current patent and plant variety protection rules compatible with conventions aimed at protecting the rights of small-scale farmers.

⁴Brzezinski, B. (2022, Oct 04) Like it or not, gene-edited crops are coming to the EU. Politico. Retrieved March 14, 2023, from https://www.politico.eu/article/gene-edited-crop-eu-climate-change-drought-agriculture/.

⁵ NPOS Patents on Plant Genes Report 2022, p. 23-27.

⁶ Manno, R. (2021). The development of the CJEU case law in plant variety rights. *Stockholm Intellectual Property Law Review*, 1(3), 28-35.

⁷ Howard, P.H. (2015). Intellectual Property and Consolidation in the Seed Industry. *Crop Science*, 55, 2489- 2490.

⁸ NPOS Patents on Plant Genes Report 2022, *supra nota* 5, p. 30-31.

⁹ Batur, F., Bocci, R., Bartha, B. (2021). Marketing Farmers' Varieties in Europe: Encouraging Pathways with Missing Links for the Recognition and Support of Farmer Seed Systems. *Agronomy*, 11(11), 2162, p. 3-4.

The question is not whether plant varieties in agriculture should be protected or whether complete unrestricted access to seeds and plant materials would be more beneficial. As mentioned before, breeders and biotech companies play an important role in ensuring the development of quality seeds especially in the EU, and intellectual property rights and protections continue to ensure their existence. The real question is rather: in what ways are intellectual property protections adequate and in what ways could they be excessive in relation to the right to access and save seeds, especially for farmers who are less powerful compared to large breeding undertakings that might have more resources at their disposal?

1. INTELLECTUAL PROPERTY RIGHTS ON PLANTS IN THE EU

Ever since the beginning of agriculture, farmers have used various natural selection methods to improve the quality of their crops and to develop characteristics that transformed the plants to become more resistant to diseases and climate conditions in their environments. The cultivated crops known today are a result of thousands of years of hard work, experimenting, and discoveries. Farmers have always taken pride in the seeds they have produced which naturally resulted in the need to develop systems that offer some sort of protection and rights in the seeds they have developed over time.¹⁰

Today, farmers who develop new varieties have access to two main sources of protection among some other alternative ways as well. The first method in Europe and the one used by the great majority of traditional farms is to register and obtain plant variety protection.¹¹ While this form of protection offers an effective way to secure farmers' and breeders' economic interests and livelihoods, it leaves the possibilities open for other farmers to develop new varieties using the protected seeds as well.¹² On the other hand, the second option is to file a claim for a patent in which case the EPO would view the seed as an invention and give way for the breeder to receive exclusive protections if the requirements are fulfilled. These rights are far more comprehensive compared to those conferred by plant variety protections.¹³

1.1. Patent protections on plants

Perhaps the most significant instrument to introduce patents on living organisms was the drafting and adoption of the TRIPS agreement which opened the doors for the possibility to issue patents

¹⁰ Louwaars, N., De Jonge, B. (2021). Regulating Seeds – A Challenging Task. Agronomy, 11, 2324, p. 1-4.

¹¹ Community Plant Variety Office Report 2022.

¹² Kiewiet, B. (2005). Plant Variety Protection in the European Community. World Patent Information, 27, 322.

¹³ Smulders, M. J. M., van de Weil, C. C. M, Lotz, L. A. P. (2021). The Use of Intellectual Property Systems in Plant Breeding for Ensuring Deployment of Good Agricultural Practices. *Agronomy*, 11, 1163, p. 2-4.

on living organisms that would also affect plants and their seeds' genetic material.¹⁴ Article 27(3)b of the document extends the scope of patentable matters to biological inventions while also including a less than straightforward exemption for countries to exempt living organisms that have been derived by essentially biological processes from the patenting requirement.¹⁵ While many feel that getting rid of the entire patent system for biological inventions is the right way because of moral issues as well as conflicts with the rights of vulnerable people, it might do more harm than good. Instead, a better way is to look at the problems with the current patent rules and modify those in a way that responds to current concerns.¹⁶

Applicable rules for patenting in the EU include the European Patent Convention as well as the EU Directive on the legal protection of biotechnological inventions 98/44/EC. The Convention applies the prohibition on organisms derived by essentially biological processes as described in article 53(b) of the Convention.¹⁷ The EPO consisting of 38 member states has control over patent applications. While the EPO is separate from the EU, the rules and decisions affect all EU member states since they are also all parties to the convention.¹⁸ The extent of patents in the EU, however, may also be determined by the case law of the CJEU. According to the outcome of *Monsanto v. Cefetera*, the extent of gene patents must be limited to the living material and cannot cover its processed and derived versions of the product. The decision was made regarding the issue of whether the patented herbicide-resistant soy could be imported to the EU as soybean meal. The decision had a retroactive effect and automatically limited the scope of patents even before the time of judgment.¹⁹

1.2. The plant variety protection system in the EU

Plant variety protection is an intellectual property right for plants that is issued by the Community Plant Variety Protection Office (CPVO) and is valid throughout the territory of the EU if the variety fulfills the requirements set out in the Council Regulation (EC) No 2100/94 on Community

¹⁴ Tappeser, B., Baier, A. (2000). Who Owns Biological Diversity? A Brief Description over the Rights to Biological Diversity in the North-South Context. Öko-Institut Freiburg, 18.

¹⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights.

¹⁶ Dutfield, G. (2002). Sharing the Benefits of Biodiversity: Is there a Role for the Patent System. *Journal of World Intellectual Property*, 5(6), 929-931.

¹⁷ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, art. 53(b).; Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p 13-21, art. 5.

¹⁸ Schmulders (2021), *supra nota* 13, p. 2-3.

¹⁹ Court Decision, 6. 7. 2010, Monsanto Technology LLC v Cefetra BV and Others, Case C-428/08, EU:C:2010:402.

plant variety rights.²⁰ The Regulation is also referred to as the Basic Regulation since it lays down some basic definitions and a detailed and all-encompassing criterion. These requirements are also found in the International Union for the Protection of New Varieties of Plants Convention (UPOV) since the plant variety rights in the EU were initially framed according to this international instrument.²¹ The protections granted by the regulation are different from patents as discussed above and are much more commonly used for plants obtained by traditional farming practices that have been used by farmers for generations.²²

The three main aspects for eligibility are also called the DUS requirements which stand for distinctness, uniformity, and stability and are covered by the technical examination procedures of the CPVO.²³ This means that the applicant for the protection must be able to show that the plant is adequately distinguishable from all other protected varieties, is generally uniform in its characteristics, and is stable in a way that does not change in its characteristics after repeated propagation.²⁴ In addition to the technical aspects, formal and substantive examinations are also carried out to check the conditions for entitlement or determine the novelty of the plant which is generally vested in the first applicant to evaluate it. ²⁵ The office then also examines if the variety to be registered is likely to mislead or cause confusion when approving the variety denomination that the applicant proposes.²⁶ Once the conditions of the regulation are met, the applicant receives a certificate that grants several rights to reproduce the variety, sell, and to export or import the plant among other various other rights as well.²⁷

Others can only use the protected material for planting or can sell the harvested material if they acquire the authorization of the holder of plant variety protection rights or check whether the owner is capable to exercise his rights.²⁸ In the landmark case of *Club de Variedades Vegetales Protegidasthe* by the CJEU, the court gave an important ruling that would shape the scope of plant variety protection rights. The question of the case was whether or not plant variety protection rights

²⁰ Community Plant Variety Office Report 2022, supra nota 11.

²¹ Bostyn, S. J.R. (2021). Towards a Fair Scope of Protection for Plant Breeders' Rights in an Era of New Breeding Techniques: Proposals for a Modernization of the Essentially Derived Variety Concept. *Agronomy*, 11, 1511, p. 3.

²² Kiewiet, B. (2003, November). *Relation between PVP and Patents on Biotechnology*. [Conference Presentation] Community Plant Variety Office.

²³ Community Plant Variety Office Report 2022, *supra nota* 11.

²⁴ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 01.9.1994, p 1-30, Art 7.

²⁵ *Ibid*, Art 10.

²⁶ *Ibid*, Art 63.

²⁷ *Ibid*, Art 62.

²⁸ *Ibid*, Art 13.

would affect the case of a farmer who purchased a type of mandarin plant and planted it during the period that the application was made by the owner but before the protection was finalized and officially granted. The court, found among other things, that such a situation cannot be regarded as unauthorized use including in those cases where the harvest takes place after the protection enters into force.²⁹

A significant characteristic of the plant variety protection system that distinguishes it from patents is that it also incorporates the concept of farmers' privilege or the exemption to freely use the seeds for discovering new varieties.³⁰ While both patents and plant breeder rights serve the primary purpose of safeguarding the interests of breeders by granting them exclusive rights in the produce, third-party use for experimenting is only permitted in the case of plant variety protection in order to balance out the strict limitations that exclusive rights have on other farmers.³¹ Because the farmers' privilege enables farmers to develop new varieties from the existing materials without notifying or asking for permission from the owner, the farmers' exemption consequently also makes it possible to claim protection for the newly developed variety. Since the farmers' exemption has the potential to offer an excessively wide scope of freedom for developers and too little protection for the initial breeder even if the changes made to the variety are negligible, the UPOV has introduced the concept of essentially derived varieties (EDVs).³² The same concept has been implemented also into the Basic Regulation in the EU in article 87(2)(h).³³

It does not take special knowledge to achieve the "distinctiveness" criteria as it may even occur due to random mutagenesis. This means that varieties that are essentially obtained from the initial variety (IVs) require the consent of the initial owner before the new breeder may commercialize it but still obtains all other rights related to development according to the rights given in chapter V of the UPOV Convention.³⁴ The current definition for EDVs as per the Conventions is that it is "predominantly derived from the initial variety … while retaining the expression of the essential

²⁹ Court Decision, 19.12.2019, *Club de Variedades Vegetales Protegidas v Adolfo Juan Martínez Sanchís*, Case C-176/18, EU:C:2019:1131.

³⁰ Council Regulation (EC) No 2100/94, *supra nota* 22, Art. 15.

³¹ Nguyen, H. B. H., Lindroos, K. W. (2021). The Regulation of Farmer's Privilege Under Vietnamese IP Law and the Law of the European Union. *ICC*, 52, 678-680.

³² Würtenberger, G. (2013). Legal perspectives on Essentially Derived Varieties. *Revista Electronica do IBPI*, 8, 200-202.

³³ Council Regulation (EC) No 2100/94, supra nota 22, Art. 87(2)h.

³⁴ Bostyn, S. J.R. (2021). Supra nota 19, p. 12.

characteristics that result from the genotype", is distinguishable from the initial variety but still contains the same essential characteristics of the genotype of the essential variety.³⁵

1.3. Option of open source for plants

In an attempt to solve the problems posed by the disadvantages of plant variety protections and patents, a system was proposed and developed that at first sight seems like a stark contrast to the purpose and rationale of the two above. In fact, The Open Source Seed Initiative which began in 2012 does not aim to provide protection to farmers but rather seeks to counterbalance the increasing power of large companies and the privatization of seeds.³⁶ The initiative is also a response to the views of many that the current legal trends put far more emphasis on the enforcement of the rights of owners while offering inadequate protection for the rights of users.³⁷

The Open-Source Initiative was developed following the example of the open-source software and enables anyone without restrictions to grow the seeds they obtained while at the same time effectively prohibiting anyone from claiming patents or plant variety protections on those seeds. In addition, the recipients of the seeds are also under the obligation to make developments of those seeds open source and accessible to all, starting a process that has no ends because it will apply to all offspring of the seed. There is a special licensing method for enforcing and ensuring the three open access rules. The nature of open-source licensing is unlike ordinary licenses but the basis rests in contract law in that the giver discloses the conditions and the recipient then agrees and pledges to follow the terms of the license. ³⁸ There is even an example of such an open-source contract provided by the website of the Open Source Seeds which now operates worldwide.³⁹ Although the movement was initially born in the USA, the possibility to enforce the licensing rules under German contract law has enabled it to grow and become a global movement. Still, the lack of studies and legal cases casts serious doubts on its guarantees for the seeds to remain free and the contract to be enforced.⁴⁰

³⁵ International Convention for the Protection of New Varieties of Plants Art. 14(5).

³⁶ Louwaars, N. (2019). Open Source Seed, a Revolution in Breeding or Yet Another Attack on the Breeder's Exemption?. *Frontiers in Plant Science*, 10, 1127, p. 1-4.

³⁷ Frediksson, M. (2021). Open Source Seeds and the Revitalization of Local Knowledge. *Sustainability*, 13, 12270, p. 9.

³⁸Kotschi, J., Rapf, K. (2016). Liberating seeds with an Open Source Seed (OSS) Licence. Agrecol Working Paper.

³⁹ Open Source Seeds. *The Open Source Seed License*. Retrieved April 19, 2023, from <u>https://www.opensourceseeds.org/en/open-source-seed-licence</u>.

⁴⁰ Louwaars, N. (2019). Supra nota 34, p. 11.

2. THE RIGHT TO SAVE AND REPLANT SEEDS

Thanks can be given to the farmer ancestors and indigenous people working and developing their seeds for thousands of years for all the various cultivated plants known today, including fruits and vegetables. Beginning with the corn that originates from Native Americans who developed it from various wild grasses to the commonly known potatoes today that have much lower toxicity thanks to South American indigenous people, all these developments occurred due to the possibility to sow and cultivate thousands of varieties for each plant.⁴¹ While genetic diversity used to be increasing exponentially, this trend has been reversing since modern times with the introduction of more homogenous varieties. In addition, the wide range of legal regimes from multi and bilateral international agreements to national laws which govern seeds and ownership over them has made it vital to include the right to seeds and the traditional knowledge of indigenous people as human rights.⁴²

2.1 Human rights of peasants

Human rights are at least equal if not higher than other international instruments. Some argue that human rights have primacy over WTO law because WTO laws only provide a means to such an end of eventually realizing human rights such as raising the living standards of the people.⁴³ Still, whatever the case may be, the Committee on Economic, Social and Cultural Rights concluded that human rights are not comparable in nature to intellectual property rights, since while the first is fundamental and universal for all individuals and in some instances communities, the latter is just the states' means of encouraging creativity and innovation which cannot be brought to the same level. In addition, intellectual property rights cannot be regarded as timeless since they are only applied for a period of time, may be revoked, and are primarily directed towards the protection of

 ⁴¹ Eckles, A. (2021, September 22). What's Growin On: the History and Politics of Seed Saving. Retrieved March 24.2022, from https://www.denverlibrary.org/blog/books/heidie/whats-growin-history-and-politics-seed-saving.
⁴² Walter, S., KU School of Law. (2021). Legal Regimes Governing Seed. *The Global Restoration Project Working*

Paper.

⁴³ Dr. Yigzaw, D. A. (2015). Hierary of Norms: The Case for the primacy of Human Rights Over WTO Law. *Suffolk Transnational Law Review*, 38(1), 33-68.

business, personal interests and investments.⁴⁴ Since states have pledged in connection to the United Nations Declaration on the Rights of Indigenous People (UNDROP) to realize the rights of peasants even when legislating in the area of intellectual property law, international and national laws must be adopted accommodating human rights and not vice versa.⁴⁵

The rights of farmers are protected by the UNDROP and include all those individuals called peasants who either alone or as communities are involved in small-scale agricultural production.⁴⁶ It is applicable for a wide range of activities from fishing to even pastoralism and covers also those hired workers who work for these peasants.⁴⁷ The right to seeds and even the right to biological diversity are both specifically protected by the instrument. Peasants as described above are granted the right to " (...) conserve, use, maintain and develop their own seeds and genetic resources or those of their choice". Furthermore, to " (...) save, store, transport, exchange, donate, sell and reuse farm-saved seeds, crops, and propagating material."⁴⁸

When it comes to human rights, the most basic principle that states bear is the obligation to also ensure the protection of these rights.⁴⁹ States party to the UNDROP have committed themselves to "respect, protect and fulfill the right to seeds" as well as to support peasant's seeds systems, facilitate peasants' decision-making in issues that relate to their use of seeds and agricultural research that benefits them as per article 2(1).⁵⁰ The obligations of the states, therefore, do not end by merely removing barriers to exercising the rights, but they also mean that states must promote and encourage by their action that the peasant seed system may thrive.⁵¹ State policies should strive to realize these rights by granting access and possibilities to use resources and technologies taking into account the wide range of circumstances farmers may have.⁵²

⁴⁴ Committee on Economic, Social and Cultural Rights (CESCR), General Comment no 17.

⁴⁵ Golay, C., Bessa, A. (2019). The Right To Seeds In Europe: The United Nations Declaration on the Rights of Peasants and Other People Working In Rural Areas and The Protection of The Right To Seeds In Europe. *Geneva Academy*, p. 51.

⁴⁶ United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas, 73/165, art. 1, p 1.

⁴⁷ *Ibid* 46, art. 1, p 2-3.

⁴⁸ *Ibid* 46, art. 22, p 2-3.

⁴⁹ Golay, C., Bessa, A. (2019), supra nota 43, p 37.

⁵⁰ UNDROP, *supra nota* 46, art. 2, p 1.

⁵¹ Golay, C., Bessa, A. (2019), supra nota 43, p. 20.

⁵² Tsioumani, Elsa. (2021). *Fair and Equitable Benefit-Sharing in Agriculture: Reinventing Agrarian Justice*. Earthscan Studies in Natural Resource Management, p. 75-76.

Finally, the UNDROP also recognizes the rights arising from access and benefit sharing of seeds protected in various international conventions as human rights.⁵³ This includes the Nagoya protocol that further specifies the benefit-sharing obligations of users of genetic resources that originate from traditional knowledge and local communities.⁵⁴ This protocol is also connected to the third objective of the Convention on Biological Diversity (CBD) of fair and equitable sharing of benefits arising from genetic resources.⁵⁵ It also lays down the rules to ensure the transparency of the origin of resources and that informed consent has been obtained before the use of those in question.⁵⁶ Furthermore, it also requires "as far as possible, not to restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities."⁵⁷

2.2. Implementation of farmers' rights in Europe

In order to protect the seeds in the hands of peasants, some but not all, EU countries have enacted the farmers' exemption in their legislation as an exemption from plant variety protection although with only a limited scope. ⁵⁸ In addition, the EU has been quite successful in taking preventative steps to avoid the risks of cross-contamination of peasants' seeds with genetically modified varieties that would have especially jeopardized the integrity of organic seeds. The EU legislation has made it possible to ban genetically modified seeds and 17 member states have already lived with this possibility. The Commission also has issued special rules that place strict requirements on the labeling and traceability of these crops.⁵⁹

The Nagoya protocol which lays down rules for access and benefit sharing of genetic resources is crucial for indigenous people and peasants to ensure that they get their fair share of benefits that others obtain when exploiting those resources. For more harmonized rules, the EU has implemented the access and benefit sharing (ABS) regulation for adopting the rules in the protocol

⁵³ UNDROP, supra nota 44, art. 19.

⁵⁴ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization to the Convention on Biological Diversity, art. 5, p 5.

⁵⁵ Convention on Biological Diversity, art. 1, p 3.

⁵⁶ Tehran, M. Y. (2016). The Nagoya Protocol and Indigenous Peoples. *The International Indigenous Journal*, 7(2), 6.

⁵⁷ CBD, *supra nota* 54, art. 12, p 4.

⁵⁸ Priti, V. (2017). The Breeder's Exception to Patient Rights as a New Type of Research Exception. *R&S*, p. 109-116.

⁵⁹ Golay, C., Batur, F. (2021). Practical Manual on The Right to Seeds in Europe: The United Nations Declaration on The Rights of Peasants and Other People Working in Rural Areas and The Right to Seeds in Europe. *Geneva Academy*, p. 33-34.

mainly with the aims to facilitate research and development and the internal market.⁶⁰ The regulation consists of a due diligence provision which usually covers the obligation of users to obtain an internationally recognized certificate that varies from country to country.⁶¹ Besides establishing the certification requirement for the obtaining of research funding or for the commercialization of products in the end stages, the certificate is not necessary to obtain patents because doing so would have made the Nagoya protocol binding for the EU's biotechnological inventions directive.⁶²

Other mechanisms for the EU to implement peasants' rights include the way of listening to these groups in the decision-making and ensuring that existing laws that affect their rights are in accordance with international instruments such as the Nagoya Protocol or the UNDROPS.⁶³ The European Commission has put in place the "Have Your Say" portal that enables farmers to leave feedback and make their voices heard on issues that involve legislation of the EU and implementation of rules that affect them.⁶⁴ While the EU has highly advanced feedback mechanisms in general, important implementations of the UNDROPS regarding the rights to save, sell and access local seeds as well as to control and develop these on their own should be manifested in the accommodation of these into current UPOV based rules and patent laws. The next section will be concerned specifically with the existing gaps and conflicts in the implementation of peasants' rights within these areas in the EU.

⁶² Coolsaet, B., Batur, F., Broggiato, A., Pitseys, J., Dedeurwaerdere, T. (2015), supra nota 57, p. 405.

⁶⁰ Coolsaet, B., Batur, F., Broggiato, A., Pitseys, J., Dedeurwaerdere, T. (2015). Implementing the Nagoya Protocol: Comparing Access and Benefit-sharing Regimes in Europe. *Hotei Publishing*, p. 378.

⁶¹ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, OJ L 150, 20.5.2014, p. 59-71, art. 4.

 ⁶³ 2013/767/EU: Commission Decision of 16 December 2013 setting up a framework for civil dialogue in matters covered by the common agricultural policy and repealing Decision 2004/391/EC, OJ L 338, 17.12.2013, p. 115-117.
⁶⁴ Golay, C., Batur, F. (2021), *supra nota* 56, p. 39.

3. THE CONLFICT OF FARMERS' RIGHTS AND INTELLECTUAL PROPERTY RIGHTS IN EUROPE

Some of the main areas of concern include the increasing number of successful patent applications on seeds obtained through controversial methods as well as the extent of these protections that can severely limit farmers' ability to exercise their rights.⁶⁵ While the rights of farmers and the privileges granted by the plant variety protection are important considerations, it is important to examine how both patent and plant variety rules are able to fulfill their effective function of protecting the rights breeders and farmers have in their seeds. The narrow scope of plant variety protection makes it difficult for many farmers working with unconventional varieties to make a living and obtain the same benefits for their hard work as others.⁶⁶ The rise of technology in the form of new breeding technologies (NBTs) that enable breeders with the right tools to develop new varieties within a much shorter period of time than ever before. While it might have taken a traditional farmer a decade to develop his plant variety in earlier times, it is now possible to do the same within a year or two.⁶⁷ As a result, experts around the world are calling for urgent action in this area because the notion of plant variety protection is becoming meaningless.⁶⁸

3.1 The patenting of essentially biological varieties and their effects on farmers

As discussed in the first section, article 27(3)b of the TRIPS Agreement generally allows for exceptions from the mandatory patents if the seeds are the result of essentially biological processes. The exemption is applied in the EU Patent Convention as well, although, an exact definition of what these processes entail is still not provided leaving many potential questions open. Although patents may only be granted on genetic sequences which are the results of biotechnological

⁶⁵ NPOS Patents on Plant Genes Report 2022, *supra nota* 5, p. 11-12.

⁶⁶ Mariani, S. (2021). Law-Driven Innovation in Cereal Varieties: The Role of Plant Variety Protection and Seed Marketing legislation in the European Union. *Sustainability*, 12, 8049, p. 2.

⁶⁷ Kock, M. A. (2021). Essentially Derived Varieties in View of New Breeding Technologies – Plant Breeders' Rights at a Crossroads. *GRUR International*, 70(1), 12-14.

⁶⁸ Smith, J. S. C. (2021). The Future of Essentially Derived Variety (EDV) Status: Predominantly More Explanations or Essential Change. *Agronomy*, 11(6), 1261, p. 10.

inventions, the EPO is entrusted with the task to decide the claims on a case by case basis and determine whether or not the particular claim already falls outside of the scope of patentable objects.⁶⁹ Unclear rules make it possible for companies to abuse patenting rules and obtain patents for conventionally bred plants as has been done in the case of as many as 1500 patent claims in the last 10 years. Such patents can have devastating consequences on farmers since protected traits can extend to hundreds of other varieties as well as severely limiting and even excluding the farmers' privilege which applies to seeds protected by the variety protections in similar cases. In addition, the practice shows that it is large companies that benefit from patenting rules since they are most frequently submitting claims to the EPO while traditional farmers generally tend to stick with the more familiar plant variety protections.⁷⁰

A great victory for traditional farmers came with the final decision of the Enlarged Board of Appeal of the EPO in 2017 which reinforced and finalized the rule that no patents may be obtained on seeds originating exclusively from essential biological processes.⁷¹ This was followed by two cases where the EPO decided that essentially biological processes can be patented.⁷² Although the decision attempted to mark the end of the controversy and debate between large companies and smaller farmers, new patent claims show that the problem is still far from being solved completely. One of these claims in patent application WO2021000878 granted for Asian soy with resistance to soy rust includes around 5000 naturally occurring genetic variations that farmers cannot use in the development of their own varieties. Because no difference is made currently between randomly generated mutations versus those achieved by technical means in the practice guidelines of the Administrative Council of the EPO, patents such as those above are currently a reality.⁷³ Farmers affected by the protection must face complicated legal hurdles to find out to which extent they may use the genes of the plant and the constant uncertainty of whether or not the seeds they possess already contain the protected expressions or traits and may be challenged and sued by the owner.⁷⁴

While the protection of genes resulting from essentially biological processes is one of the most controversial ones, big corporations are known to use several other tactics to take advantage of the

⁶⁹ Kock, M. A. (2007). Essentially biological processes: the interpretation of the exception under Article 53(b) of the European patent Convention. *Journal of Intellectual property Law & Practice*, 2(5), 286-289.

⁷⁰ NPOS Patents on Plant Genes Report 2022, *supra nota* 5, p. 10.

⁷¹ Court decision, 14. 05. 2020, Pepper (follow-up to "Tomatoes II" and "Broccoli II, G 0003/19, ECLI:EP:BA:2020:G000319.20200514.

⁷² Court decision, 25. 03. 2015, G0002/12, ECLI:EP:BA:2015:G000212.20150325.; Court decision, 25. 03. 2015, G0002/13, ECLI:EP:BA:2015:G000213.20150325.

⁷³ NPOS Patents on Plant Genes Report 2022, *supra nota* 5, p. 6.

⁷⁴ NPOS Patents on Plant Genes Report 2022, *supra nota* 5, p. 6.

legal loopholes in the rules. One other way is by asserting wide claims to include all plants transformed by the technology. The other is reach-through claims that also protect the offspring of the plants created by the technologies and blocking patents aimed at preventing others from claiming protection on their own inventions. Thus, the web of patents that companies can achieve can seriously hurt research and development, especially in the agricultural sector which was originally not developed relying on intellectual property rights as they are known today.⁷⁵

3.2. Disadvantages of plant variety protection system for farmers

While plant variety protection is generally considered to be an effective way to balance the interests of farmers and is enjoying popularity among breeders, it highly favors conventional seeds over organic ones. The DUS requirements" are vital for the purposes to make sure that the marketed seeds fulfill the minimum requirements to ensure their quality for the buyers, especially in conventional agriculture.⁷⁶ The Common Catalogue was created for the purpose of supplementing the UPOV rules to provide a list of all the plant varieties that confirm these quality checks. However, organic varieties require the selection and breeding of different varieties which are also more resilient due to their heterogeneous nature.⁷⁷

The DUS characteristics were developed for the needs of commercial, high-input breeding systems and leave little to no room for low-input and diverse varieties that perform better in ways that require different testing.⁷⁸ Because organic seeds often do not fulfill the uniformity criteria according to the directive, the farmer cannot register the seeds and market them under these rules or is often forced to use conventional seeds on their organic farms.⁷⁹ The restrictions are creating a landscape in Europe where there are numerous breeders like farmers and small seed producers who cannot sell their products.⁸⁰ Therefore, the inadequate and lack of protection of heterogenous organic plant materials present a significant gap in the current plant variety protection rules. This

⁷⁵Howard, P.H. (2015), supra nota 7, p. 2492.

⁷⁶ Benefits of Plant Variety Protection (June 2010). World Intellectual Property Organization. Retrieved April 19, 2023, from: <u>https://www.wipo.int/wipo_magazine/en/2010/03/article_0007.html</u>

⁷⁷ Mariani, S. (2021), supra nota 63, p. 6-11.

⁷⁸ Final Report: acquis on the marketing of seed and plant propagating material (S&PM). (2008). European Commission.

⁷⁹ Kotschi, J., Schrimpf, B., Waters-Bayer, A., Horneburg, B. (2022). Financing Organic Plant Breeding – New Economic Models for Seed as a Commons. *Sustainability*, 14(16), 10023, p. 3.

⁸⁰ Kloppenburg, J. (2014). Re-purposing the master's tools: the open source seed initiative and the struggle for seed sovereignty. *Journal of Peasant Studies*, 41(6), 1231, p.

could be especially concerning becuase of the EU's aspiration is to significantly increase the hectares of agricultural land dedicated to organic farming.⁸¹

3.2.1. The challenges with organic seeds as heterogeneous materials

Because of long negotiations and countless petitions from organic producers in the EU, particularly in Germany, the new Directive 2018/848 which entered into force at the beginning of 2022, has finally made it possible for producers to register their seeds as "organic heterogenous material."⁸² The moment was celebrated as a remarkable milestone and victory in the organic community since the extended new rules would finally enable farmers to market their seeds which are not considered homogenous based on the DUS requirements" criteria under the plant variety protection rules. This means that responsible officials of member states can be notified of organic heterogenous seeds, given that the farmer is able to give adequate information about the description of the plant such as characteristics that are typical for the group as well as the breeding methods used.⁸³

This was the success also with a type of organic rye produced called Baldachin at the Dottenfelderhof farm which was among the first to be registered under the new rules for registration.⁸⁴ Because the registration of organic heterogeneous materials does not offer neither plant variety protection nor any other forms of protection but only serves the purpose of receiving the necessary permission for selling the seeds, they are considered to be as common property. Although these seeds are technically open source already because of the lack of protections, the breeders still placed an open source license on it in order to ensure that future developments of the seeds could remain free of gene manipulation and patents as well.⁸⁵ In addition, German local farmers are also signing up their seeds to the OSSI in hopes that selling 'free seeds' could potentially increase their revenue for the organic seeds and can provide a basis for collecting donations for the cause they are supporting.⁸⁶

⁸¹ Mariani, S. (2021), supra nota 63, p. 2.

⁸² Verein Arche Noah (May 31. 2019) POSITIONSPAPIER "Biologisches Heterogenes Material" in der Bio-Verordnung 2018/848: Delegierter Rechtsakt der Europäischen Kommission & Nationale Umsetzung des Meldesystems.

⁸³ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, OJ L150, 14.6.2018, p.1, art. 13, p a-b.

⁸⁴ Bella. (2022, July 14). Ein Roggen, der uns allen gehört – gemeinsam die ökologische Züchtung stärken. Retrieved April 04. 2023, from https://opensourceseeds.org/blog/community-finanziert-gemeinsam-den-ersten-open-source-roggen.

⁸⁵ Frediksson, M. (2021), *supra nota* 35, p. 12-14.

⁸⁶ Louwaars, N. (2019), *supra nota* 34, p. 3.

While most members of the initiative are there due to their beliefs in the advocacy of farmers' rights, they admit that there is an equal need to reward farmers for the development of new varieties.⁸⁷ At this point, the open source initiative offers ideas that people can follow but it is just a set of principles that anyone can use. It is yet to be seen whether it could develop into something that is effective, fully enforceable, generates income, and grants true freedom to farmers.⁸⁸ In short, the DUS requirements in the CPVR are not adequately fulfilling the rights granted by the UNDROP. This is especially visible in that the CPVR regime does not grant active rights to farmers to save and replant their seeds, but merely provides some exemptions.⁸⁹

3.2.2. Uncertainties surrounding essentially derived varieties and their effects on farmers and breeders in the EU

Another growing problem in the EU and with the current plant variety protections based on the UPOV 1992 Convention is the unclear definition of what constitutes an essentially derived variety (EDV) and how to differentiate it from initial varieties (IV). Despite the definition for EDVs, many consider it nearly impossible to tell at what point a variety is no longer considered essentially derived and what may or may not be considered essential characteristics anymore.⁹⁰ In addition, the explanatory notes that accompany the definition in an attempt to give further clarity are contradictory in themselves and give rise to a wide range of interpretations which leads to legal uncertainty for those working in breeding. According to the UPOV's explanatory notes, the differences between IVs and EDVs should be "one or very few" but also that EDVs must maintain all essential characteristics or otherwise they cannot fall into this category.⁹¹

The conflicting interpretations are illustrated in the Dutch case, *Million Stars v Blancanieves*. While the lower court found that 17 of 21 phenotypic characteristics were different between the two varieties and that they were the result of the act of derivation, another court came to a different conclusion.⁹² The Dutch Court of Appeals instead determined that the latter variety is not an EDV because of the large number of differences after reviewing phenotypical (outer appearance) data. Another issue was the determination of the burden of proof which was on the plaintiff to prove

⁸⁷ Kloppenburg, J. (2014), supra nota 76, p. 1227.

⁸⁸ Montenegro de Wit, Maywa. (2019). Beating the bounds: how does 'open source' become a seed of commons?. *The Journal of Peasant Studies*, 46(1), 73-74.

⁸⁹ May, L. (September 5, 2022). Seed Sovereignty in the European Union. Let's Liberate Diversity. Retrieved April 20, 2023, from <u>https://liberatediversity.org/seed-sovereignty-in-the-european-union/</u>.

⁹⁰ Würtenberger, G. (2013), *supra nota* 30, p. 204-205.

⁹¹ UPOV/EXN/EDV/2 Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, p. 6.

⁹² Astée Flowers B.V. v Danziger 'Dan'Flower Farm(2005) 198763, Court of TheHague (July 13 2005).

essential derivation according to Dutch law.⁹³ Interestingly, the Israeli court that examined the same case came to the conclusion that Blancanieves is indeed an essentially derived variety by reversing the burden of proof and by considering and accepting genetic differences as arguments in addition to phenotypical similarities.⁹⁴

Weaknesses of the system relating to EDVs in Europe come from the lack of established rules regarding registration and that much of the decision-making is left for the parties to decide. For example, there is no authority in charge of the determination of EDV status but rather it is the breeder of the IV who has to claim EDV status for a variety and has the burden of proof for ownership.⁹⁵ Then, in the absence of rules and tests, the first breeder is left alone to argue for his benefits and reach an agreement with the second breeder. If the dispute is not resolved and court intervention is necessary, then the court bases its decision on what has been decided between breeders internationally.⁹⁶ This situation creates a good breeding ground for disputes that put a strain on breeders and farmers who argue that they lack the financial means and the time to be in the courtrooms.⁹⁷

The tensions in this regard are expected to escalate in the future because it is still not certain how to categorize new breeding technologies (NBTs) in the sense that whether the results of the techniques would be EDVs or not. Following the rules of minimal to no differences in the determination of EDV status, NBTs may often not be compliant with the criterion because the purpose of the process itself is to change the essential characteristics of the plant. The issue here is that these NBTs such as all the subtypes of CRISPR/Cas have the capability to change plants significantly without altering their genome. In addition, the very nature of the technologies is to rely exclusively on the initial variety.⁹⁸ As a result, new technologies in development have the possibility to undermine the purpose of EDVs to protect and reward breeders' hard work in

⁹³ Danziger Dan'Flower Farm v Astée Flowers B.V.(2009) 105.003.932/01, Court of Appeal, The Hague (29 December 2009).

⁹⁴ Danzinger Flower Farm v Hanania Azulai and Astee Flowers B.V.(2009) 1228/03, District Court, Tel-Aviv-Jaffa.

⁹⁵ Adhikari, K., Jefferson, D. (Eds.). (2019). *Intellectual Property Law and Plant Protection: Challenges and Developments in Asia.* Taylor & Francis Group, p. 53-56.

⁹⁶ Kiewiet, B. (2006, April). Essentially Derived varieties. Adaptation of presentation for Plantum NL.

⁹⁷ Danziger, M. (2019). Impact of EDV Concept on Plant Breeding: Outlook for ornamental plants. *Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy. Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy*, 30.10.2019, Geneva, (48-55). UPOV, Geneva, Switzerland.

⁹⁸ Krieger, E., De Keyser, E., De Riek, J. (2020) Do New Breeding Techniques in Ornamentals and Fruits Lead to Essentially Derived Varieties?. *Frontiers in Plant Science*, 10, 1612, p. 8-9.

developing their initial varieties as well as giving large companies with advanced technologies an advantage over small-scale farmers.⁹⁹

Experts are divided in their opinion regarding how to handle the issue. There are those who advocate for a more inclusive interpretation of EDVs and others who argue for more extensive rights for IVs. As such, there is a view that if a new variety is derived only from one single variety (parent) then it is simply not independent of that initial variety and the developer should seek consent from the owner. According to this view, the number of differences should not be the decisive factor in determining the status of EDVs.¹⁰⁰ Other on the hand, others find that considering NBTs as essentially derived can hamper innovation as well since the owners of EDVs cannot claim the same benefits.¹⁰¹

The issues with EDVs also affect peasants' rights which extends to problems faced by small-scale farming communities. First, it restricts small-scale farmers to sell varieties that they have developed to be suitable for their local environments which can have implications for local farming communities that rely on the exchange of farm-saved seeds. However, farmers may be negatively affected by inadequate protections as a result of a narrow interpretation of the notion of the EDVs. The other serious problem is that larger breeders and tech companies may use the material of farmer-developed seeds if they are registered and then reap profits off of it after making a few insignificant changes.¹⁰²

⁹⁹ Bostyn, S. J.R. (2021), *supra nota* 19, p. 1-2.

¹⁰⁰ Danziger, M. (2019), supra nota 93, p. 51-53.

¹⁰¹ Kock, M. A. (2021), supra nota 64, p. 12-14.

¹⁰² Smith, C., Bragdon, S. H. (2016). The relationship between intellectual property rights and small-scale farmer innovation. *Quaker United Nations Office*, p. 17-20.

4. COMPARATIVE ANALYSIS OF SOLUTIONS FROM DIFFERENT COUNTRIES

The next section is going to focus on countries that have developed provisions, or mechanisms in their legal system that have offered a solution for the rights of farmers in the area of patents and plant variety protection. Because of the widely known issues in both patent law and plant variety protection law, some countries offer valuable insights into the way that they have handled the situation and may become a source of inspiration for the EU. The new patent law in France is one of the great examples regarding how to restrict the scope of patents which would not only favor small-scale farmers and breeders who work with conventional methods but would benefit the industry through rules that bring more certainty. Clarifying definitions is important for plant variety protection as well. Since essentially derived varieties can be abused easily, clear rules are needed for these issues.¹⁰³

The Protection of Plant Varieties and Farmers' Right Act, 2001 (PPVFR) in India is one of the very few examples of an effective plant variety protection system that can be compared to the UPOV system used worldwide.¹⁰⁴ The previous pandemic that resulted in disruptions of imports in developing countries has shown the importance of a system that local farmers and provides local farmers with the conditions to thrive. Such a system is especially useful for developing countries where there is even more emphasis and need for local farmers than in the EU.¹⁰⁵ Still, the flexibility of the Indian plant variety protection with its multiple options for protection might be useful for organic and other non-conventional farmers and breeders within the EU as well.¹⁰⁶

¹⁰³ Kock, M. A. (2021), *supra nota* 64, p. 22-23.

¹⁰⁴ May, L. (September 5, 2022), *supra nota* 85.

¹⁰⁵ Chuma-Okoro, H., Oluwasemilore, A. I. (2022). Intellectual property rights, agricultural biotechnology and food self-sufficiency: strengthening the Nigerian intellectual property legal framework for food-self sufficiency in the aftermath of a global pandemic. *International Review of Law, Computers & Technology*, 36(1), 48-54.

¹⁰⁶ Moonka, R., Mukherjee, S. (2018). Trips Flexibilities and India's Plant Variety Protection Regime: The Way Forward. *BRICS Law Journal*, 5(1), 122-124.

4.1. Protection for farmers from excessive patenting

As one of the countries in the EU, France has incorporated into its legislation the clause which intends to solve the threat that the new gene technologies pose on the characteristics of essentially derived varieties. It states in article 10 of Law No. 2016-1087 of 8 August 2016 for the Reconquest of Biodiversity, Nature and Landscapes, "protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological materials possessing those specific characteristics, obtained independently from the patented biological material and through essentially biological process, neither to biological materials obtained from the latter through propagation or multiplication".¹⁰⁷

The provision was rightly added to the French patent law after the controversial case of Gautier Semences who ran a family business of developing seeds but had to face Rijk Zwaan, another breeder with the patent claim EP 0921720 that included the resistance from a disease that occurs in lettuce as a result of a specific gene expression. The outcome was that Gautier Semences had to enter a license agreement with Rijk Zwaan because he was selling a lettuce variety that contained the above-mentioned characteristic protected by the patent. This was despite the fact that he had been selling the lettuce a long time before the patent claim. Rikj Zwaan was allowed to do so because the current legislation which was also in force in France at the time offered no limitations to patents even in cases where the patented biological materials existed even before Rikj Zwaan filed the patent.¹⁰⁸

4.2. Alternative Plant Variety protection systems for more benefit for small-scale farmers

In stark contrast to the results of the examination above regarding how Europe's CPVR system fails to do enough to protect the rights enshrined in the UNDROPS despite the obligation to bring intellectual property rights in harmony with peasants' rights, the PPVFR seems to do greater justice to these rights. As a member of the WTO, India was also under the obligation to comply with the TRIPS requirements and adopt a patent or sui generis law to protect the right to seeds. While most countries, including Europe, opted to use the widely used UPOV sui generis system,

¹⁰⁷ LOI no 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (1), Journal Officiel de la République Francaise, Aug. 9. 2016, art. 10.

¹⁰⁸ Biological patents: an endangered species (November 14. 2016). Patent my French! Retrieved February 02, 2023, from <u>https://patentmyfrench.com/biological-patents-endangered/</u>.

India decided to develop one on its own.¹⁰⁹ The PPVFR Act has successfully achieved to balance both breeders' and farmers' rights fulfilling Art. 27.3(b) of the TRIPS and has proved to be successful under the UNDROPS as well. According to the evaluation, the act sufficiently protects farmers' self-determination to save, sell and resow seeds, protection requirements are adjusted to their individual breeding methods and the system enforces the fair sharing of benefits of the use of resources in the possession of rural people.¹¹⁰

The main success of the PPVFR lays in the uniquely strong rights of farmers to save, use, sow, exchange, and sell their seeds even if they are protected with registration. Here, it is only required that the farmer does not resell the seeds under the breeder's brand for the protection of his interests in accordance with the protected privileges accorded to him.¹¹¹ While there are exclusive rights to registered varieties, there are also robust safeguards to enforce farmers' rights. Farmers are awarded sufficient legal certainty to exercise these basic rights by the provision which protects them against innocent infringements under article 42. If a farmer can show evidence that he was not aware of the protected variety of the seeds at the time of the infringing activity, any claims of the claimant will be dismissed on those grounds.¹¹²

Despite some key differences, the PPVFR contains significant similarities to the UPOV system. Firstly, in order to register new varieties, it is necessary for them to be novel, distinctive, and uniform in a similar way as according to the DUS requirements. To prove the novelty of the seed, the breeder must disclose information about where the material was obtained before the registration.¹¹³ This enables farmers and indigenous communities to be recognized in the registration process which is followed by the exclusive rights over the registered seeds for the farmers to enjoy.¹¹⁴ In addition, it is possible to be exempted from the novelty rules if farmers wish to protect a variety that is not new by applying for an extant variety. In this case, the uniformity requirements are more flexible and open new possibilities even for farmers would also apply in these cases as well. Although the novelty requirement demands the certification of origin of the

¹⁰⁹ Singh, M., Kamal, P. K. K. (2022, April 5). Emergence of plant variety protection in India. Retrieved April 18, 2023, from <u>https://www.managingip.com/article/2a5d15ejam5bo2n1mvq4g/emergence-of-plant-variety-protection-in-india</u>

¹¹⁰ May, L. (September 5, 2022), *supra nota* 85.

¹¹¹ The Protection of Plant Varieties and Farmers' Rights Act, 2001, art. 39, p 1(iv).

¹¹² *Ibid*, art. 42.

¹¹³ *Ibid*, art. 40.

¹¹⁴ *Ibid*, art. 28.

seed which facilitates benefit sharing, the main concerns regarding how small farmers can protect their seeds without having the means to fulfill expectations that only large breeders can achieve is still unclear.¹¹⁵

4.3. Approaches toward clear rules in the extent of rights farmers and breeders have in IVs and EDVs

Now that the need for straightforward rules for initial and essentially derived varieties has been established, it is helpful to look at countries where the same concepts are successfully used with little room for uncertainty. When defining rules, it is necessary to choose between a narrower or a wider interpretation for initial varieties. Both of these routes have important consequences that will necessarily favor either new breeders by lowering a threshold for varieties that have been modified or by favoring the owner of the initial varieties. In the examples below, Australia has taken a stricter approach while the Indian plant variety protection system has built in a more balanced system which still accords more rights to the initial breeders.¹¹⁶

4.3.1. Stronger protection of the rights of IV owners in India

Although India is unique in that it does not use the UPOV system, the notion of essential derivation had to be included in its PPVFR provisions. Moreover, the criterion for EDVs is very similar to that in the UPOV in that in that EDVs also need to fulfill the DUS criteria as laid out in article 15.¹¹⁷ This means that they need to have one distinctive characteristic but should otherwise be for the most part in conformity with the initial variety. The provisions here do not state exactly to what extent conformity is needed but an extensive guideline is available for more certainty. The focus and the deciding factor in decision making is based more on genotypic data rather than relying primarily on the phenotypes (outward expressions) of the plant as it is done elsewhere such as in Europe.¹¹⁸ This means that breeders must possess all the necessary documentation including the breeding records and be prepared for the necessity to gather extensive amounts of data. The Indian approach is similar to the Australian one in that the responsible office determines if a variety is EDV unlike in Europe. A key difference lies perhaps in that the guidelines serve the purpose of

¹¹⁵ Moonka, R., Mukherjee, S. (2018), *supra nota* 102, p. 124-126.

¹¹⁶ Kock, M. A. (2021), supra nota 64, p. 22-23.

¹¹⁷ The Protection of Plant Varieties and Farmers' Rights Act, 2001, *supra nota* 107, art. 23, p 7.

¹¹⁸ Elangovan, M. (2010). Essential derivation of varieties and the imminent challenges to Indian Plant Breeders. *Electronic Journal of Plant Breeding*, 1(4), 1257-1264.

extending IV protection to the EDV by requiring the consent of the breeder before registering the EDV.¹¹⁹

4.3.2. Extension of the rights of the breeders of EDVs in Australia

Australia, being one of the countries that have adopted the UPOV Convention, has chosen to take a narrow interpretation regarding EDVs in an attempt to solve the uncertainty surrounding conflicting interpretations in their plant variety protection system. Narrow interpretation means more freedom for plant varieties including those developed by NBTs and less protection for breeders because it creates a stricter criterion for the definition of EDVs so that many plant varieties would fall outside of its scope. The Australian plant variety protection focuses on the determination of essential characteristics and allows differences only in essential characteristics to still consider the variety EDV. Even if there is a difference in only one essential characteristic, the rule makes it clear that it is already a new variety that can be protected and commercialized accordingly. These limits make it possible for breeders to receive guarantees only in cases of "cosmetic breeding" but it doesn't affect those cases where the new variety is clearly based on one single initial variety.¹²⁰

This approach is already faulty in that very often having one difference in essential characteristics does not automatically mean that the variety is distinguishable from others, and it would be false not to consider it EDV.¹²¹ The use of "bright line" test has resulted in several claims for EDVs to be rejected ever since its implementation. One example was in the case *Sir Walter' v 'B12'* where the breeder claimed that shorter internodes in the plant variety developed by another breeder are merely cosmetic and thus an EDV. However, the second breeder was able to refute this claim by using evidence that shorter internodes serve other functions as well such as increasing the wear tolerance of plants. Because short internodes were essential characteristics according to the Australian Plant Breeder's Rights Act 1994, and since they were not cosmetic, the EDV claim was rejected.¹²² As the example illustrates, Australia has put a system in place which greatly increases efficiency with straightforward rules that brings clarity and simplification.¹²³ However, it is still a

¹¹⁹ Kock, M. A. (2021), supra nota 64, p. 22-23.

¹²⁰ Kock, M. A. (2021), *supra nota* 64, p. 22-23.

¹²¹ Brown, E. (2019). Impact of EDV Concept on Plant Breeding: Outlook for fruit. *Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy. Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy*, 30.10.2019, Geneva, (63). UPOV, Geneva, Switzerland.

¹²² Waterhouse, D. (2013, October 22). Experience on essentially derived varieties in Australia [Conference presentation]. UPOV Seminar on essentially derived varieties (EDVs). Retrieved April 18, 2023, from <u>https://www.upov.int/meetings/en/doc details.jsp?meeting id=29782&doc id=253313</u>. ¹²³ Kock, M. A. (2021), *supra nota* 64, p. 22-23.

question if it undermines the purpose of the EDV provisions which was originally put in place to protect the original breeder from a too broad application of the farmers' exemption.¹²⁴

¹²⁴ Würtenberger, G. (2013), *supra nota* 30, p. 201-202.

CONCLUSION

The aim of the present thesis has been to research the main deficiencies of current patents and plant variety protection rules in the EU in relation to seeds and new legal trends in this area. Controversies were examined in those legal rules that are based on the UPOV 1991 as well as the TRIPS agreement that is also widely implemented all around the world. Because of its widespread application, the relevant practices of selected countries were compared to give an overview of possible alternative approaches as well as their strengths and weaknesses. The intention was also to analyze whether or not rules related to intellectual property rights in the areas above are in harmony with international conventions that the EU is a member of such as the UNDROP and Nagoya protocols that specify peasants' rights.

The results of the findings showed that the prohibition to patent plant materials obtained via essentially biological processes enshrined in article 53 of the European Patent Convention is not enforced adequately. This is manifested in the decisions and practices of the EPO that are leading to the undermining of the right to save, sell and replant seeds based on article 22(2-3) of the UNDROP because the nature of the granted patents can affect and restrict farmers in using the varieties, they have obtained through traditional breeding practices. The EPO does this both by actually granting patents that result from essentially biological processes and by granting patents that would claim protections for genetic materials that are also the result of essentially biological processes. The solution to it lies in the source of the problem which is the unclear definition of what constitutes essentially biological processes and to what extent patent should have an effect in the case of plants. The example of France is noteworthy in the way that it has implemented the provision in its patent law that sets limits to patent protections so that they do not extend to those materials that have been obtained through essentially biological processes. This restriction is a good and most likely workable solution for the EU as a whole and member states to consider.

The research has also identified problematic areas with the PVP system in the EU, especially in the current DUS requirements according to article 7 of the Basic Regulation. It sets forth serious obstacles for farmers in making a living from organic and other traditional and heirloom varieties which is again in contrast to article 22(2-3) of the UNDROP. As a side note, it is questionable how

the EU would achieve its sustainability goals and food security with the current rules favoring commercial varieties. Although it was difficult to find alternative examples since much of the world is using the UPOV 1991 based PVP just like the EU, the Indian PVP system may offer some valuable insights into the way they attempt to balance the rights of the breeders and the need to have trustworthy seeds on the market. Besides the same DUS requirements, there are also rights to save and exchange seeds as well as to offer protection for small-scale farmers' and indigenous people's seeds that do not conform to the standard criteria. The Indian approach that creates various categories of seeds such as for the special extant varieties with a slight adjustment of requirements might be an inspiring example for the EU. Although there is no complete solution in the Indian approach either, extant varieties for farmers have lower DUS requirements in order to grant them access to the protections they deserve for non-standard varieties. A similar solution of multiple categories of plant variety protections with varying requirements is needed for the EU to make sure that organic farmers not only have the right to put their heterogeneous varieties on the market but also to benefit from the plant variety protection that secures financial returns.

New technologies are especially relevant from the intellectual property viewpoint because of the rapid changes and developments that can even nullify the effects, or the aims laws have for regulating protections. According to the research, the definition and regulation of essentially derived varieties are unclear, and their application has already had a confusing effect on breeders and farmers alike. From the comparative analysis, it is clear that straightforward definitions such as those applied in Australia and India bring certainty and reduce disputes between farmers as well as bring more certainty to the rights, they have either in EDVs or IVs. Still, while clear rules are necessary for EDV rights, it is necessary to determine whether member states would adopt a rather strict interpretation that would grant broad rights to EDV developers or whether the approach places more emphasis on the right of the breeder of initial variety. The question is a sensitive one that requires the careful balancing of rights when deciding between a narrow or broad interpretation. While more rights to IV owners seems to be a more fair solution to the problem if innovation is supported too as in the Indian approach, the EU still needs to consider vulnerable farmers such as those operating on a small scale to make sure that clear EDV rules are also in line with international conventions such as the UNDROP.

Overall, the EU has a well-developed system for the protection of intellectual property rights as well as a reputation to respect human rights. Still, the two areas of concern in patenting and Community plant variety protection raise concerns over how they are compatible with current international conventions. For these reasons, seeds have become the area of concern of many NGOs in the EU as they try to argue for the protection of farmers, especially in organic and small-scale operations who are weaker compared to large companies with highly advanced technology and legal knowledge to advocate for themselves. While patents and plant variety protection rights are needed for large breeding operations as well as to keep innovation alive, the EU needs to balance these rights, especially in the areas of seeds that constitute a special area of intellectual property rights.

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