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Master's thesis, 85p., 1 appendix

Master Degree Programme in Law and Information Society

December 2019

As food insecurity continues to be a cardinal concern in Africa, many alternatives including, the use of GMOs have been proposed as an exemplar for addressing the challenge. While a single measure may not be enough, this paper, in brief, looks at the use of Genetically modified organisms as a mechanism for combating food insecurity in Africa, particularly the role intellectual property plays as the new fulcrum in the biotech industry debates.

As a growing field, GMOs are regulated differently across the world. The paper first looks at the various international and regional regulatory frameworks that govern GMO, their general outlook, how they came into being, and how they are affecting the systems being crafted and implemented in Africa. Specifically, the CBD-CPB, TRIPS agreement, and UPOV convention are considered together with the different regulatory approaches that the US and EU have adopted on GMO even though both have similar intellectual property protections for biotech innovations.

The question of how GMOs should be protected to guarantee rights of developers while not hindering access to food is further analysed under the scope, objectives, and exceptions of plant patents and other sui-generis protection models that are available to African countries in their quest to have a balanced system that works. The paper concludes that although biotechnological improvements have stabilized the breeding process and fortified the demand for patent protections, sui-generis protection may be more suitable for the African food production climate. And luckily, nations need not reinvent the wheel instead.

KEYWORDS: Genetically Modified Organisms; Intellectual Property; Access to food; Food Security; Patents in Africa; Sui-generis Protection in Africa; Plant Variety Protections; Africa

GENETICALLY MODIFIED FOOD, INTELLECTUAL PROPERTY, AND FOOD SECURITY IN AFRICA.

Abstract

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ABBREVIATIONS

Art.	Article
AU	African Union
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biodiversity
CPVR	Community Plant Variety Rights
EBoA	Enlarged Board of Appeal
EPC	European Patent Convention
EPO	European Patent Office
EPO	Economic Partnership Agreement
EU	European Union
FAO	Food and Agriculture Organization
GM	Genetic Modification
GMO	Genetically Modified Organisms
GURT	Genetic Use Restriction Technology
IP	Intellectual Property
IPRs	Intellectual Property Rights
LMO	Living Modified Organisms
PBR	Plant Breeders Rights
PPVFR	Plant Protection Variety and Farmers Rights
PVP	Plant Variety Protection
TRIPs	Trade-Related Aspects of Intellectual Property Agreement
UPOV	The Union for the Protection of New Varieties of Plants
US	United States of America
WTO	World Trade Organization

Lipton (1999) argued that Too many people still have no or too little to eat.

1.0 INTRODUCTION

In 2018, the United Nations estimated that most of the over 783 million people who live below the poverty line are either in Africa or southern Asia. Its studies over the same period also estimated that about 233 million (from the 175 million in 2010) of the 795 million people worldwide who are either hungry or undernourished are in Africa; particularly Sub-Saharan Africa.[1] And even though trend analysis over the past decade indicates that the world food crisis has improved, food insecurity is an existential threat to Africa and other areas of the world.[2] This notwithstanding, in 2007, many African countries amidst high food insecurity concerns, rejected food aid from the UN because it contained Genetically Modified Organisms (GMOs). The rejection raises at least two critical issues: acceptability of GM (despite its potential for solving hunger) and; the framework that will facilitate the short term flow and long term growth of GM.[3] This research looks at the role GMO play in ensuring food security as well as the challenges it brings.

Food security is realized "*when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life*."[4] This concept can be applied at the family/ household level as well as the national, regional, and global levels. To achieve household food security, the concerns of the individuals within the household is the focus. Food insecurity as such exists when physical, social and economic factors limit access to food.[5] The Ryerson Centre also integrates access to foods that are culturally acceptable and in a way that human dignity is upheld into the meaning of food security.[6] Food security, therefore, goes beyond

[1] The State of Food Insecurity in the World 2016. Meeting the 2015 International Hunger Targets: Taking Stock of Uneven Progress (FAO, IFAD and WFP, 2015) p. 8. https://www.worldhunger.org/africa-hunger-poverty-facts/, http://www.un.org/en/sections/issues-depth/poverty/

[2] The State of Food Security and Nutrition in the World. Building Climate Resilience for food security and nutrition 2018, ISBN 978-92-5-13057-3 FOA Report.

[3] Jamil K. 2018, Biotechnology - a Solution To Hunger? https://www.un.org/en/chronicle/article/biotechnology-solution-hunger

[4] Anema, A., Fielden, S. J., Shurgold, S., Ding, E., Messina, J., Jones, J. E., ... & Hogg, R. S. (2016). Association between food insecurity and procurement methods among people living with HIV in a high resource setting. *PloS one*, *11*(8), e0157630..

[5] Rome Declaration on World Food Security and World Food Summit Plan of Action, adopted at the World Food Summit, Rome, 13–17 November 1996, at http://www.fao.org/docrep/003/w3613e/w3613e00.HTM.

[6] Vahabi, M., & Damba, C. (2013). Perceived barriers in accessing food among recent Latin American immigrants in Toronto. *International journal for equity in health*, *12*(1), 1.

merely providing food to malnourished or undernourished people to include other cultural and religious considerations.

Previous Food Security Summit discussions focused on availability and overlooked the core element of access under the presumption that the poor countries would be able to afford food once they were available for purchase. It was the FAO summit in 1983 that, however, brought attention to the need to consider the challenges at both the demand and supply sides. Subsequent debates on the subject broadened the concept of access to include the notion of sufficient food, food safety, nutritional balance and cultural appropriateness. The concept of food security was expanded and accordingly re-defined in view of this. Recent food security studies have, in addition to access, identified availability, acceptability, adequacy and the agencies that facilitate food security realisation as critical factors.[7]

The reasons for food insecurity are varied and diverse, many have suggested that Population growth, farming practices, limited farm inputs, inadequate storage facilities, weak market structures, transport and distribution network from insufficient infrastructure such as roads are the leading causes.[8] Others contend that the unfavourable commodity pricing mechanism rather than the type of seed remains the biggest obstacle for farmers despite the enormous food insecurity and poverty concerns on the continent.[9] These challenges are not isolated but very intertwined in many respects. For example, the traditional labour-intensive farming practices encouraged people to procreate in many communities; having many children implied having more hands to work, yet, the farm produces are left to rot because of the poor transport network.

So far, many studies have established a direct correlation between food security and development. It is therefore not surprising that food security has been central in the developmental strategies of the African region with 12 out of the 17 UN SDGs, for instance, reflecting the central role of nutrition in sustainable development.[10] This centrality is borne out of the nature of resources within the continent. That is the vast expanse of the land remains cultivable in spite of the number of deserts, and the population are mainly farmers in rural areas

[7] Vahabi, M. & Damba C. ib
[8] PRESENT SITUATION OF AGRICULTURE. (n.d.). Retrieved from http://www.fao.org/3/Y0491e/y0491e02.htm.
[9] Sasson, A. (2012) Food security for Africa: an urgent global challenge. *Agric & Food Secur* 1, 2 doi:10.1186/2048-7010-1-2. Also see Kofi Annan former UN secretary general on food security.
[10] The Sustainable Development Goals Report 2019 United Nations

where agriculture is the primary source of sustenance and employment.[11] Nevertheless, the current state of the food industry challenges the traditional ways of solving malnutrition. As such, several studies from organisations and researchers from all fields - economics, politics, agriculture, and the likes are continually developing new approaches and techniques that could be devised to ensure food security within the African region. Genetic Modification (GM) is one of the new ways suggested by many.[12]

A GMO is an organism that scientists have altered by introducing alien genes or by modifying a plants genetic structure. The process generates proteins that give the modified organism new properties.[13] Genetic Modification (GM) or Genetic Engineering (GE), is not just a modern version of the natural breeding process that we have known and practised for many thousands of years where plants and animals with the best attributes are used in producing offsprings, instead, it is a new way of creating living organisms that could never occur in nature artificially. GM, therefore, involves the mechanism that enables desirable characteristics or genetic makeups which occurs naturally to be developed through modern biotechnology techniques called gene technology.[14] GMO include Living Modified Organism (LMO) and material obtained through LMO-based manufacturing and processing, as well as organisms not capable of reproduction or breeding.

The genetics of living cells, organisms and materials are synthetically altered by lab techniques to give them new properties that make plants resistant to diseases, insect, rodents, or drought. Other mechanisms make plants less susceptible to herbicides while others aim to enhance the quality of food or their nutritional value. Some varieties are also more friendly to the environment and could also increase the capacity of plants to deal with harsh weather.[15] But the GM option is, however, not without controversy, opponents argue that GMO presents unknown perils to humans, animals and biodiversity.

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[11] Voortman, R. L., Sonneveld, B. G., & Keyzer, M. A. (2003). African land ecology: Opportunities and constraints for agricultural development. *Ambio: A Journal of the Human environment*, *32*(5), 367-374.
[12] Ib note 3
[13] Esvelt, K. M., Smidler, A. L., Catteruccia, F., & Church, G. M. (2014). Emerging technology: concerning RNA-guided gene drives for the alteration of wild populations. *Elife*, *3*, e03401.
[14] Cockburn, A. (2002). Assuring the safety of genetically modified (GM) foods: the importance of an holistic, integrative approach. *Journal of Biotechnology*, *98*(1), 79-106.
[15] FAO "FAO director-general stresses benefits of biotechnology in fighting hunger and malnutrition and calls for open debate on potential risks" (press release, 14 May 2001), available at: http://www.fao.org/WAICENT/OIS/PRESS_NE/PRESSENG/2001/pren0131.htm (last accessed 20 March 2017).

Some commentators have opined that GM is not an appropriate measure for reasons like sustainability, they maintain that GM is an insufficient tool for curbing world hunger because its quick "technofix" and emphasis on monocultures has the potential of frustrating food sustainability and biodiversity efforts and will in the worsen world hunger in the distant future.[16] Others argue GM crops increase the use of pesticides and herbicides because Gm crops become resistant to weed killers forcing farmers to use more and more, which in turn kills other vegetation and wildlife. This irreversibly diminishes biodiversity, contaminate and mutate wild plants, and undermine traditional agricultural practices. Some believe that GM is being used as a tool for corporate entities to take over global food supply which then increases hunger and poverty because farmers would get locked into buying seed GMO companies and only benefit large-scale entities and not small-scale farmers.[17]

The general acceptance of GM in several areas have been low, perceptions, exaggerated fear and conflicting messages have been a significant reason for this. While lobbyists are overstating the gains, critics are overstating the risks. The African continent has historically been slow in undertaking self-tailored research as well as in accepting new agricultural techniques and technologies. New ways such as Genetically Modified (GM) foods have not been an exception even thought the use of GM products across the globe had increased exponentially since it was introduced in the 1990s.

The above notwithstanding, many continue to argue that GM has the ability to revolutionise agriculture in a manner that guarantees sustainable growth and food security.[18] But while issues such as the effect on biodiversity, health, among others may still be unresolved, the concerns Intellectual Property (IP) raises is one that is not only continually gaining centrality in GM discussions but responsible for shifting the current discourse on today's GM especially as a tool for combating food insecurity. This challenge of IP in GM is unique for several reasons; one is the newness of the area, the shifting landscape, and the leading players and interests that come to play.[19]

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[16] Strauss D. M. (2007), *Defying Nature: The Ethical Implications of Genetically Modified Plants,* 3 J. FOOD L. & POL'Y 1, 8–9 (discussing the failed promise of this technology and presenting an ethical framework in support of labeling and monitoring) [hereinafter Strauss, *Ethical Implications*].

[17] Weis, A. J., & Weis, T. (2007). *The global food economy: The battle for the future of farming*. Zed Books.

[18] Kariyawasam K. (2009), Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on world Agriculture, researchgate.net page 9

[19] Strauss, D. M. (2009). The application of TRIPS to GMOs: international intellectual property rights and biotechnology. *Stan. J. Int'l L.*, *45*, 287.

Today, Intellectual property is widely considered as the needed mechanism that will incentivise and promotes innovation in the public and private sector.[20] Unlike the early renaissance, crop science research in general and specifically GM, have moved from the public pro-bono into the private-profit sector.[21] This move has been accompanied by the institution and adaption several laws and techniques that will protect private IP rights, and creating a whole new challenge for developing countries.[22] IP potentially affects all aspects of the food chain; from the selection of seeds, breeding, farming, among others, especially GM foods. That is why the current perimeter in the battle over genetically modified organisms are showing under Intellectual Property Rights (IPRs).[23]

Taking cognisance of the general controversies surrounding GMOs, with particular emphasis on Africa, this paper looks at the role IP plays in the GM industry and how this intersection affect access to food. The pecuniary nature of Africa's development by itself raises issues fundamental issues for analysis. The nature of resources and the role agriculture plays in this area as the primary source of employment and sustenance makes the introduction of IP enveloped GM into Africa a complicated one. Africa's internal and external relations with other nations and organisations, coupled with its international obligations, have severe implications on access to food, food security, and development.

Therefore, the central question is, how can IP be modelled within the GM industry to improve food security? That is, how can the continent get the right mix of measures that ensures access to food and related genetic materials; transfer and development of biotechnology easier for food security purposes, from the policy space permissible within International commitments, treaty obligations, and bilateral agreement — synopsis and justification of the problem.

1.2 METHODOLOGY AND SOURCES

This paper employs the Legal formal research method in assessing the position and development of the law on GM and its impact on access. It will mainly analyse the agreements,

[20] Williams, H. L. (2013). Intellectual property rights and innovation: Evidence from the human genome. *Journal of Political Economy*, *121*(1), 1-27.
[21] The earlier poverty reduction strategies between 1965 and 1984 that was said to be partly caused by the expansion of food staples production through poverty-oriented agricultural research particularly pro bono agricultural research that caused food staples to increase.
[22] Lybbert, T. J., & Sumner, D. A. (2012). Agricultural technologies for climate change in developing countries: Policy options for innovation and technology diffusion. *Food Policy*, *37*(1), 114-123.
[23] Strauss D. M id

conventions, regulations, acts, directives, case-laws, and legislation governing intellectual property in GM for food and the biotechnological industry. Literature by scholars on IP, empirical data and findings from scientists and reputable institutions on GM, within the confines of access to food will also be considered.

Although the paper is mainly qualitative, the running approach will be looking at the development and history; the current position of the law and how it is being implemented, together with; the effects of the laws on access to protected material to ensure food security.

1.3 LIMITATION AND SIGNIFICANCE

The GM debate is one that transcends disciplines, so is the scope and target of IP, this paper, however, focuses on the role IP plays within the GM and plant genetic industry. As such, the discussion in this paper narrows in on this intersection at the expense of the other equally important issues like health and safety, that have continually dominated this spectrum.

IP is another broad area, however only the IPRs that mainly impacts the food chain is the centre of our attention (patents and sui-generis protections). Even though the ultimate end of this paper is the impact that IPR in GM have on Access to Food, the discussion focuses on food crops and not animals. 85% of the food is crop-based. Crop varieties like hybrid crops that may not fall under typical GM crops are still considered under this study due to the role IP plays in that area as well.

Again, even though the issue of food insecurity is a global treat that many countries face, particularly developing countries, the area of this study is the African continent, it is essential to note that the presence or threat may not be the same for all the African countries. Other challenges like political instability, corruption, that plague the region is also not the subject of this paper.

1.4 OUTLINE

This paper contains five chapters. The first chapter contains the introduction that has the problem statement and the background to the study; methodology; limitations and significance as well as; the outline of the study. The introduction gives background to the study by navigating the concepts and developments of food security to GMO, a component of the biotechnological industry, as an option in curbing food insecurity, its controversies, and challenges; before most importantly introduce the connection between GMO and Intellectual

Property; and finally, the synopsis and justification of the problem. The main objectives of the paper are also explained together with the Methodology and limitation of the study are then given, before an overview of the research is presented.

The second chapter then centres on GMO regulations worldwide with the role Africa plays in the development of the law; the specific interventions towards Africa; and its impact on Africa as the underlining theme. It begins by looking at the major international treaties designed specifically or tangentially to address the issues and concerns of the GM industry. The Cartagena Protocol on Biosafety, TRIPS agreement which as the foremost IP treaty globally, UPOV Convention, as well as the ITCGR, will be assessed before the EU-US regimes for regulating GM. The bilateral and multilateral trade relations of countries in Africa and the rest of the world generate enormous benefits for all parties, how trade partners regulate GMOs is therefore imperative on any considerations the region contemplates.

The effects these protocols and systems have on the continents food security are enormous, the continent's affiliation with the EU and the US remain a significant policy determinant. While the United States considers GMOs as a significant element of the biotechnology industry, the EU has been quite cautious in wholly accepting GM. Agriculture in Africa is not only for consumption but also a means of livelihood support, the effect of the seemingly divergent approach by the African countries' significant partners and donors amid their respective positions and international treaties create a quagmire that needs to be navigated. Regulatory issues like labelling, acceptability and trust are also considered under this chapter.

With the divide on the acceptability of GMOs in Africa on going, the need to craft IP protection for GMOs that are responsive to both the demands of the region and the positioning of other IP regimes becomes imperative. Chapter Three, therefore, makes an inquiry based on the fundamental question of how has and should GMOs be protected in general and Africa in particular? Plants, animals, microorganisms and other organisms with modified genetic makeup via genetic engineering or transgenic technology are all included under GM, and they differ from plant varieties. Plant varieties are obtained from natural biological processes; however, due to technological advancements, it is difficult to distinguish between the two. The rift between patent and sui-generis protection is manifested in the European scenario, but are they the only rights to be considered under the circumstances? The issues of ownership and control, liability and intent, infringement, biopiracy, GURTs amongst others are very crucial, and a significant consideration in the type of protection.

The protocols that regulate GMOs internationally impact policies within the continent on several counts; however, the role Intellectual Property plays in terms of food and genetic resources is of paramount concern in this research. Chapter four focuses on access, and begins by looking at what access is within the context of the law, access to food is considered as a human right issue but is it a sufficient ground to break IPR? Foreign IPR holders dominate the current system. The compass is, therefore, on how countries can access protected GM materials, that is, the flexibilities within the law, by which policies can be fashioned out, albeit dependent on the type of protection. The actual implementations of the flexibilities for access are assessed to see how countries have indeed utilised the spaces given through their incorporation of treaty obligations in national laws. And then finally we look at other alternatives proposed for the facilitation of access to food

Chapter five concludes on food security; that is how the observations in this paper affect food security in Africa. It summarises the comments within the paper and makes recommendations for public policymakers, rightsholders, farmers, and the general populace on the IP aspects of GMO and how it can influence access to food. The table in chapter 2 shows the number of treaties that each African country is a party to.

Regulating GM's across territories: it is through the law, that GMOs come to exist in the particular way they do in the world.

2.0 REGULATING GENETIC MODIFICATION

As a developing field, Genetically Modified Organisms are regulated differently across the globe; from their inception in the laboratory through to their use by consumers, a genetically modified plant undergoes different restrictions and approvals processes. There are not just different rules for different types of GMOs; different rules applies to GM that humans eat and for animal feed. GM regulations also vary as much between treaties as amongst national legislations. A genetically modified plant may, for example, be sanctioned for general use in the United States, but only as feed for animals by member states of the EU, or may not be sanctioned for any in Japan.[24] Even though the politics of regulating the risks of GMOs remain an active and incomplete project, the intersection of GMOs and the different fields of law, in particular, Intellectual property, have evolved into one rich area of research.

In this chapter, the treaties and legislation that governs GM are the point of focus, with particular emphasis on IP treaties related to GM. We look at how different jurisdictions have and continue to regulate GM foods and their Intellectual property outlook. This is done by assessing the regulatory frameworks that govern GM; how they came about; what treaties apply in certain countries; their potential effects, and the Intellectual Property clauses. The contributions of Africa, the specific interventions aimed at Africa and the general outcomes regulating GM as well as, sections of the law relating to the transfer and exchange of resources are all considered since food security goes beyond access to food.

Internationally, GM features in many treaties and agreements, whiles the Convention of Biological Diversity's (CBD) Cartagena Protocol Biodiversity (CPB) looks at the transfer of GM, the Sanitary and Phytosanitary Measures (SPS Agreement) that the WTO oversees focuses on trading GMO internationally. Other agreements such as the TRIPS, the FAO's ITGRC, and UPOV of WIPO also play vital roles in shaping the regulatory framework of GMs. Each treaty has its aims and objectives and may sometimes relate differently to similar situations. Regions like EU, US, and developing countries have also been approaching GM

[24] Holm, S. (2015). When They Don't Want Your Corn: The Most Effective Tort Claims for Plaintiffs Harmed by Seed Companies Whose Genetically Engineered Seeds Produced More Problems Than Profits. *Hamline L. Rev.*, *38*, 557.

regulations differently. The United States and the European Union, for example, have a shared interest of providing healthy foods and a reliable regime of regulation, yet, each has chosen different paths when it comes to the surge in GM food and feeds for animals available. Other countries, mostly developing ones, are also in the formative phase when it comes to GM regulation, with a number of them inching toward the middle of the US EU ends.[25]

Again, IP has in recent times been one primary consideration in the GM regulation discuss, as such, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement by has been a crucial instrument for GM regulations. We start by looking at some international treaties, before looking at the US and EU, since in their efforts to design a responsive system for regulating biotechnology, many of the countries in Africa come up against the might and influence of both the US and the European Community aside treaty obligations. After which the various regulatory issues such as the institutions and capacities they required, Trust and Acceptability, traceability and labelling are also considered within the policy space left for nations. The traceability and labelling requirements, for instance, have forced a number of developing countries to refrain from GM crops, this is because they fear to lose the European Community markets over issues such as improper segregation of GM and non-GM products.

2.1 INTERNATIONAL TREATIES (CBD/CPB: TRIPS: ITGRC, UPOV)

2.1.**1 The Convention on Biological Diversity (CBD): The Cartagena Protocol on Biodiversity (CPB).**

Genetic Modification as a subset of the biotech industry since its introduction in the 1990s has been regulated at the International level by different instruments. These regulations have undergone several phases, but to date, The Cartagena Protocol on Biosafety (CPB), remains the sole international regulatory protocol that was specifically created to forestall the risks biotechnology has on biological diversity.[26] It is one of the significant protocols under the Convention on Biological Diversity established by the UN.[27] The CPB seeks to regulate the

[25] Patterson, L. A., & Josling, T. (2002). Regulating biotechnology: comparing EU and US approaches. *Environmental policy in the European Union*, 183-200.

[26] The CBD has various sub-programs and agreement: Cartagena Protocol on Biodiversity; Global Strategy for Plant Conservation: Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization

[27] On 29 January 2000, the Conference of the Parties to the Convention on Biological Diversity adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety. It is a legally binding

supervision, usage and movement "living modified organisms" (LMOs) in the way that restricts the possible adverse effects on biodiversity. The potential risks posed by LMOs are to be controlled with the creation of an advance informed agreement (AIA) procedure.[28]

The CPB generally governs how GMOs are transported across borders, the safety measures needed, and grounds on which governments should decide on whether or not to allow GM into their countries. It concedes that biodiversity goes beyond plants, animals, and microorganisms and their ecological community. The CPB prioritises people and the necessities of life like food, shelter, medicines, and activities that pollute the environment.[29] Most African states are among the 193 countries that are parties to the CPB, and therefore, only allowed to develop laws stricter than those set out in the CPB. The Precautionary Principle (PP) which underlines the convention stems from the declaration's demand for a halt or suspension on approvals in order to prevent environmental degradation in areas where the possibility of severe or permanent damage is likely, even if scientific data is inconclusive.[30] It is on this premise that other international regimes concerning GMOs and several African states argue. And many of the countries that are sceptical about GMOs justify their slowness in accepting GMOs into their markets when the health uncertainties and environmental concerns cannot be entirely dismissed on this principle. The GM industry, however, claims that rejecting GMOs without sound scientific proof of proven harm is unreasonable.

Sections such as article 20(4) emphasis the extent to which developing country implementing their commitments under this Convention is incumbent on developed country parties fulfilling their obligations. Obligations relating to financial resources and transfer of technology, economic and social development, as well as the eradication of poverty, are the primary and overriding priorities of the developing nations/parties. Even though Intellectual property interests were not a non-negotiable issue when the CBD's was being formed, the treaty by its nature and the aftermath implementation has evoked severe IPRs concerns. Helfer (2004) argued that "a careful examination of the CBD shows that any intellectual property rights

convention that recognizes the conservation of biological diversity is a common concern of humankind and is an integral part of development process. It covers all species, ecosystem, genetic resources.

[28] This procedure ensures that countries are provided with the information necessary to make informed decisions before agreeing to the importation of each organism into their territory.

[29] CBD, *About the CBD*, *available at* http://www.biodiv.org/convention/default.shtml

[30] U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, at 6, U.N. Doc. A/CONF.151/26/Rev. 1 (Jan. 1, 1993). *See* Commisión Nacional de Recursos Fitogenéticos, Frequently Asked Questions About the Cartagena Protocol on Biosafety, http://www.conarefi.ucr.ac.cr/Bioseguridad1.htm

system that is at variance with the CBD's objectives should be must be accordingly be adjusted."[31] The convention also incorporates the importance of protecting third-party and society interest when protecting inventions in plant materials, especially with the proliferation of IP rights, biopiracy, and commercial realities. As a result, some countries especially developing ones, have tried to use CBD structures to harmonise their intellectual property systems.

Even though the importance of biodiversity and EU legal rules in protecting it was underlined in case C-59/11 Association Kokopelli v Graines Baumaux SAS EU where the advocate general raised the EU obligations under the CBD,[32] the CPB seems to focus on the adverse effects that LMOs potentially pose to the environment, and the destruction to biodiversity as the commercialisation and utilisation of Genetic Resources are held mainly by private entities, at the expense of facilitating the technology transfers that developing countries were promised.[33]

2.1.2 Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The World Trade Organization (WTO) emerged as the governing body for global trade from 1995 and has approached GMOs as a trade issue rather than a safety one. However, its Sanitary and Phytosanitary (SPS) Agreement guides the health and safety of GMO. Contrary to the CBD, the SPS demands that risk assessments results from the most current science should be the basis for decisions. The Agreement delineates measures that members should use in protecting and safeguarding the health of people, animal, and plant life. These measures include risks associated with the additives and contaminants that are used in food as well as the impact that the entry or spread of pests, and either disease-carrying or causing organisms have in general.[34]

The core aim of the SPS Agreement is to stop countries from creating measures that are protectionist in nature under the pretence of health and safety. Thus, the agreement streamlines health and safety standards across the board and requires members who adopt higher protective

[31] Helfer R. L, (2004), *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 24, n.10.
[32] Association Kokopelli v Graines Baumaux SAS EU. C2012;447
[33] Lawson C, 2012, *Regulating Genetic Resources: Access and Benefit-sharing in International Law* (Edward Elgar).
[34] Gonzalez, C. G. (2006). Genetically modified organisms and justice: the international environmental justice implications of biotechnology. *Geo. Int'l Envtl. L. Rev.*, *19*, 583.

measures to justify their decision scientific evidence. Accordingly, and contrary to the CDB precautionary principle, GMOs, are not be rejected without solid scientific reasoning. Moreover, the WTO's agreement on Technical Barriers to Trade also prohibits the rejection of GMOs without any scientific proof of harm.[35] Countries like USA, Canada and Argentina in the past instituted actions against the European Union under the SPS when some EU member states banned particular GMOs because they thought they were unsafe. And the WTO ruled that the scientifically adduced evidence of harm was lacking; therefore, the ban was not justified.[36]

Trade-Related Intellectual Property Rights (TRIPS) is another critical agreement the WTO have that is currently affecting GM hugely.[37] TRIPS have upon its inception been either an inescapable consideration for or the bedrock upon which several other treaties and legislations hinges on and its clauses affects the biotech industry significantly. Although Trips is an agreement on the IP aspects of trade and not directly a GM regulation, it is one agreement that has a far-reaching impact on GM and plant varieties. The Trips agreement has been a tool for shaping the biotech and for the matter the GM industry.[38]

Before TRIPS, the Paris Convention, which came about in 1883, was the most accessible intellectual property accord that nations subscribed to. The convention relied on the principle of national treatment, as it did not have uniform standards for protecting intellectual property rights. National treatment meant that both goods of home and foreign applications are given the same, and one is not discriminated against the other. However, each country was allowed to set its intellectual property system. Later the Patent Cooperation Treaty was concluded in 1970 to augment the Paris Convention, and it introduced a centralised process for all application on utility patent.[39]

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[35] Löfstedt, R. E., Fischhoff, B., & Fischhoff, I. R. (2002). Precautionary principles: General definitions and specific applications to genetically modified organisms. *Journal of Policy Analysis and Management: The Journal of the Association for Public Policy Analysis and Management*, *21*(3), 381-407.

[36] International law governing GMOs. http://safsc.org.za/wp-content/uploads/2015/09/int-law-governing-SA-GMO.pdf

[37] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a treaty that is generally recognized as the most robust embodiment of intellectual property rights was enacted in 1994.

[38] the vigorous efforts and pressure of Biotechnology companies for recognition and enforcement of the rights to their seeds in the international community, securing intellectual property protection for its agricultural industry was a major goal of the United States during the TRIPS negotiation

[39]Kawamura, S. (2011). GMO trade in the context of TRIPS: From the perspective of an autopoietic system analysis. *Ritsumeikan Journal of International Affairs*, *10*, 243-268.

However, intending to promote and facilitate international trade, TRIPS sets out general principles and minimum standards which are binding on all its members. It's negotiators also consciously left room for manoeuvre so that governments can accustom domestic IP laws and policies to safeguard critical national interests. Member countries have to enact the necessary legal framework that includes the set minimum regulations. These standards include, amongst others, a minimum patent period of 20 years; provision for product patents; and the protection to [pharmaceutical] test data from 'unfair commercial use'. Members are further compelled to protect plant varieties either by patents, an effective *sui generis* system or by any combination.

The patent articles set *"any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*" as patentable subject matters.[40] This provision expands the patent scope to include all aspects of the biotech industry. GMO's requires at the very least some form of gene modification and TRIPS extends protection to genetic materials that have been modified at the cellular level, but not to the whole genetically modified plant.[41]

TRIPs also categorise nations according to their stage of developments. Most of the countries in Africa are either developing or least developed that had to commit to protecting and enforcing IP rights before they will be admitted by the convention and by extension, global trade. [42] This prerequisite was to insisted by developed countries as a way of protecting their domestic interests beyond their territories and in other countries. However, by 2015, 34 disputes had cited the TRIPS Agreement, developing countries instituted 26 of those cases against developed, contrary to earlier predictions. Some developing countries have successfully gain access to agricultural and services markets in some developed countries through WTO disputes using TRIPS.[43]

[40] ANNEX 1C AGREEMENT ON TRADE-RELATED ASPECTS OF .... https://www.wto.org/english/docs_e/legal_e/27-trips.pdf. TRIPS' recognizes is that living things may be patented; there is no general exclusion for microorganisms, and even developers of plant varieties (but not animals) must receive some sort of intellectual property protection for their "inventions." it further demands that patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

[41] Kawamaru, S. Id

[42] Correa, C. (2007). Intellectual property in LDCs: Strategies for enhancing technology transfer and dissemination. *Background Paper*, (4).

[43] Report Changing the face of IP trade and Policy Making, 20 years of Trips 2015

So far, the impact of TRIPs in the biotech industry of countries in Africa has been enormous, particularly with the introduction of TRIP plus.[44] Nonetheless, TRIPS is still considered by some critics as a breach of the ideals of many nations and been cited as the reason for some developing countries desiring to create their agreements that will be more responsive to their national interests and traditional practices.[45] Most developed countries for decades had the opportunity to freely debated the need and how to protect plant material, without external pressures or influences, developing countries, on the contrary, have not had a history of debating this issue. Rather, all discussion has been limited to implementation within the context of the TRIPs agreement. Many countries in African are implementing TRIPs to the letter, but it is important to note that the likelihood of any intellectual property system that has not been redefined to accommodate the social, cultural and economic needs of the people succeeding is low.[46]

2.1.3 The Union for the Protection of New Varieties of Plant Convention (UPOV)

The UPOV Convention is another treaty that explicitly makes mention of the genetical modification/engineering of plant varieties and goes further in granting intellectual property rights for them. The Convention was first introduced in 1967 but has undergone several changes, its latest act was in 1991, and it is this act that, as reflective of its era, acknowledges GM crops and the protection they need. UPOV's latest changes acknowledged the dynamic nature of the biotechnology and Plant Variety industry and how they are affected by IP. Its plant protection system has been the alternative to patent that many countries have employed.

UPOV's membership comprises of both developed and developing nations. Currently, over 76 countries worldwide are parties to the convention. South Africa, Egypt, Kenya and the ARIPO members are the countries in Africa that are officially are parties to the UPOV.[47] However, the number of African countries that have their plant variety laws crafted as the UPOV model run

[44] The United States concerned that resort to this provision could weaken intellectual property rights of their biotech products, pressured developing countries into entering additional treaties, referred to as "TRIPS-plus" bilateral agreements. These "TRIPS-plus" agreements do not only contain more stringent intellectual property standards, but also enjoined developing countries to implement TRIPS more quickly than the specified transition periods, or require adherence to other multilateral intellectual property agreements.
[45] Kawamaru S. ib
[46] Gervais, D. J. (2001). The internationalization of intellectual property: new challenges from the very old and the very new. *Fordham Intell. Prop. Media & Ent. LJ*, *12*, 929.
[47]ARIPO members Benin, Burkina Faso, Cameroon, Cental African Republic, Shad, Comoros , Congo, Cote d'Ivoire, Equitorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo. https://www.upov.int/export/sites/upov/member/en/pdf/pub423.pdf

above the official figure. Some researchers, like Meienberg F (2015), have argued that UPOV negatively affects agriculture in developing countries.[48] Plant variety protection, as expressed in the 1991 act, for example, impede farmers because it does not allow them to replant the seeds they have saved. Therefore, some countries like India will have lots of problems when they decide to join UPOV, especially with their active farmer's rights. Kenya's example also shows how UPOV is export-oriented since the majority of varieties are horticultural crops.

2.2 REGIONAL REGULATORY SYSTEMS

2.2.1 UNITED STATES

In the United States, GM products are everywhere, as the majority of food products sold in the market contains gm. A 2007 study found that about 91% of all soybeans, 87% of cotton and 73% of corn, for example, contained strains that were genetically modified.[49] Even though some environmental hazards and human health risk issues continue to be raised, GM regulation is comparatively relaxed mainly because US government considers GM as an essential economic asset and the vibrancy of the biotech industry. The biotech companies wield enormous power that has been used to shape the law in their favour.[50]

In general, regulatory approvals or licenses are needed before GMOs are cultivated, distributed, sold or consumed. Crops are grouped into several categories, and this determines how they are regulated and the type of license needed. Agricultural plants, for example, are classified under conventional, genetically modified, organic and the combinations thereof such as conventional plants that are not genetically engineered, conventional crops that are genetically engineered; or purely organic.[51] In addition, genetically engineered crops are further divided based on what

[48] Correa, C. M., Shashikant, S., & Meienberg, F. (2015). Plant variety protection in developing countries: A tool for designing a sui generis plant variety protection system: An alternative to UPOV 1991. *By: Association for Plant Breeding for the benefit of society (APBREBES) and its member organizations: Berne declaration, the development fund, SEARICE and third world network*.
[49] ibid
[50] Strauss, D. M. (2009). The application of TRIPS to GMOs: international intellectual property rights and biotechnology. *Stan. J. Int'l L.*, *45*, 287.
[51] Holm S. (2015) "When They Don't Want Your Corn: The Most Effective Tort Claims for Plaintiffs Harmed by Seed Companies Whose Genetically Engineered Seeds Produced More Problems Than Profits," *Hamline Law Review*: Vol. 38: Iss. 3, Article 6. Available at: http://digitalcommons.hamline.edu/hlr/vol38/iss3/6

they are being used for (food, feed, ethanol), whether they can be exported to certain countries and the purpose of use (experiment). A gm technology can also be approved for no use at all.[52]

Currently, the United States Department of Agric. USDA, Environmental Protection Agency (EPA), Animal and Plant Health Inspection Service (APHIS), and the Food and Drugs Administration FDA, are the four central institutions that regulate the GM and biotech industry. The intended use generally determines the supervisory agency.[53] The FDA, for example, regulates GMOs that are used in food, while the EPA responsible for the effect of GMO used as pesticides on the environment, using the Federal Insecticide, Fungicide, and Rodenticide Act. The USDA also regulates plant pests and noxious weeds through the Plant Protection Act.

GM may be released in so far as they meet some six primary criteria are met. The criteria first require that plant species are determined and that the transgenes must be stable and capable of being integrated. The function of the transgenes must also be known and must not result in the production of an infectious substance like a virus. Furthermore, any introduced sequence that is derived from plant viruses must pose the risk of creating new plant viruses. And finally, the plant must not contain genetic material derived from an animal or human pathogen. Producers are currently not required to label GM food in the US, but National Bioengineered Food Disclosure Standard (2016) law which comes into effect from 2020 will make it mandatory for companies to put a text on the packaging, a symbol or an electronic link that shows that the product or part of it is biologically engineered

Within the United States, patenting genetic modifications are not only allowed but actively encouraged. This is because judicial pronouncements, legislative acts and policy initiatives over the last five decades have thoroughly changed the jurisprudence of IP in the biotech sector. These changes have allowed genetically modified organisms and plant genetic resources to be protected as under patents and at the same time strengthening other *sui generis* intellectual property regimes such as PBRs. Consequently, the number of patents for agricultural biotech has risen exponentially.[54] Interestingly the US holds a number of patents in joint ventures, but

[52] ibid

[53] Sec *Coordinated Framework for Regulation of Biotechnology,* 51 Fed. Reg. 23,302.

[54] Under plant technology, a total of 2,976 patents was awarded as of 2000.68% of which occurred in the most recent four-year period.12 Similarly, 66% of the 4,129 total patents for genetic transformations were awarded between 1996 and 2000.13 Out of all U.S. agricultural biotechnology patents awarded, most have been awarded to U.S. firms (4,331), followed by non-U.S. firms (3,051) and U.S. nonprofits (2,344).

private companies hold the bulk of patents. Monsanto, for instance, currently owns or licenses more than 90% of the genetically modified seeds globally.[55]

Internationally, the US, as a champion of granting IP for GM and a global leader in the GM industry, continually seeks to export its standards to other areas with no exception to Africa. Their biotech industry is believed to be the main force behind the TRIPS agreement, but the evolving nature of the industry due to new developments resulting from new laws and court decisions needs to be internationalised as well.[56] And this being done through trade agreements that aim to synchronise other practices with US standards. The African Growth and Opportunities Act (AGOA) of 2000 is one free trade agreement that hugely impacts GM regulations.[57]

2.2.2 GMOs AND THE EUROPEAN UNION

Unlike the US, the growth of Genetically Modifications and plant genetic industry across Europe has been relatively steady as the marketing and cultivation of GM seeds have been low. Currently, less than 1% of arable lands are under GMO cultivation even though the EU allows it. However, considerable amounts of GM products like maize and soybeans are imported and used mostly as animal feed within the EU.[58] The European Union have been very conservative in its approach to regulating GMOs mainly to public perception reasons.[25] Notwithstanding, in order to ensure that GM takes place in safe conditions, the European Union has set up a legal framework consisting of a number of directives, regulations and institutions to oversee the modern biotechnology industry and its advancement.

The framework aims to regulate GMOs in Europe by protecting not only human and animal health but the environment as well. It introduces high safety assessments standards for any GMOs introduced on the market by establishing harmonised procedures that are *efficient, fast and transparent for the risk assessment* and authorisation. The Union have so far been

[55] Rifkin J. (1998) HARNESSING THE GENE AND REMAKING THE WORLD: THE BIOTECH CENTURY 68 (describing the seed industry as a global $15 billion industry).
[56] Their influence on the biotech industry has not only stemmed from their political position but their market share of the GM industry.
[57] Formally known as the Trade and Development Act of 2000, AGOA is a unilateral extension of market access by the United States of America (US) to chosen sub-Saharan Africa countries. It commits 41 African countries to take particular positions in support of the US at the multilateral trade level. The 41 countries were chosen according to eligibility criteria under section 104 of the Act.
[58] In 2015 only one GMO variety, the MON 810, was cultivated in Europe and only 40 GMO based products were imported mainly for animal feed (soya)

employing the precautionary principle through market authorisation requirements and environmental assessment conditions to restrict GM. The WTO expert panels decision in 2006, for example, showed how widespread moratoriums on approval and marketing of GMO foods were used between 1999 and 2004.[59]

Member states have the autonomy in allowing the GMOs cultivation within their borders, and can, therefore, restrict or ban GM cultivation if their socio-economic impacts on agricultural practices and others are harmful. Although before 2015, only health reasons had been cited for restrictions.[60] They can also consign the cultivation of GMOs to demarcated areas within their territories, but the conversation on whether a Member State can ban its sale and use entirely threatens the free movement of goods across the EU's internal borders.[61] If a Member State elects to grow gm, it is up to that state to decide if it will allow GM crops to be planted along-side non-GM crops determine the distances between them; currently, they vary from 5 to 600 meters.[62]

European Commission and the European Food and Safety Authority are the central bodies responsible for GMO regulations.[63] The EC deals with the drafting of proposals for granting or refusing authorisation,[64] while the EFSA preoccupies itself with the Scientific assessment conducted on public health and other scientific considerations. EFSA examines emerging issues and new hazards by updating assessment methods and approaches.[65] The EFSA also conduct extensive, case-by-case, science-based food evaluation in order to respond to enquiries from the other EU institutions and the Member States in a manner backed by sound science.

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[59] In 2006, the WTO dispute settlement panel issued its final decision (the EC-Biotech decision) in the complaint brought by the United States, Canada, and Argentina against the European Communities (EC) over the EC's alleged moratorium on the approval and marketing of agricultural and food products containing genetically modified organisms (GMOs) findings determined that the EC's moratorium was against Annex C(1)(a) and Article 8 of the SPS Agreement, which prohibit "undue delay" in product approval procedures.

[60] Hartung, U., & Schaub, S. (2018). The Regulation of Genetically Modified Organisms on a Local Level: Exploring the Determinants of Cultivation Bans. *Sustainability*, *10*(10), 3392.

[61] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_068_R_0001

[62] Pearce, B., Woodward, L., & Sanders, R. (2006). Engineering Coexistence.

[63] Brussels, 07.10.2002 COM(2002) 545 final REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Development and implications of patent law in the field of biotechnology and genetic engineering http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2002/0545/COM_COM(2002)0545_EN.pdf

[64] Davison, J. (2010). GM plants: science, politics and EC regulations. *Plant Science*, *178*(2), 94-98.

[65] How the EFSA works, https://www.efsa.europa.eu/en/about/howwework

The Legal protection of Biotech inventions is mainly guaranteed under Directive 98/44/EC, the European Patent Convention and other legislation like Directive 2009/41/EC which deals with the contained use of GM micro-organisms and Regulation (EC) 1946/2003 which concerns the transboundary movements of GMOs. Directive 2001/18/EC also regulates how GMOs are dispersed into the environment while Regulation (EC) 1829/2003 governs genetically modified food and feed. However, to ensure that consumers and other interests make informed choices, the traceability and labelling rules for food and feed that GMOs are managed by Regulation (EC) 1830/2003. This regulation stipulates that every GMO must be labelled except when its GMO content is beneath 0.9%.[66] In addition, the Commission Implementing Decision (EU) 2018/1790 repealing Decision 2002/623/EC[67] has repealed the Guidance Notes of 2002,[68] but with regards to the Environmental Risk Assessment (ERA) of genetically modified organisms, the Commission Directive (EU) 2018/350 has amended Directive 2001/18/EC,[69] in order to ensure that ERA requirements are keeping up with scientific developments and technical progress.

Recent studies have shown that although this framework comes at severe costs, its impact on other regions of the world is equally immense. The EU's internal and external rule-making affects its trade partners. The EU uses bilateral trade agreements (BTA) and some of its internal legislation as a mechanism to influence developments in developing countries and other multilateral agreement.[70] For instances, several researchers have observed that developing countries ability to utilise the flexibilities in TRIPS, is severely hampered by other trade agreements. The EU, in particular, has an Economic Partnership Agreement with Africa, in which stricter and enhanced IP updates that may not necessarily be conducive for promoting access to food, medicines, and development, in general, are drafted for African nations to

[66] GMO legislation - Food Safety - European Commission. https://ec.europa.eu/food/plant/gmo/legislation_en

[67] : Publication of Commission Implementing Decision (EU) 2018/1790 of 16 November 2018, repealing Decision 2002/623/EC, establishing guidance notes on the environmental risk assessment of genetically modified organisms.

[68] To reduces the number of guidance documents that operators and competent authorities need to take into account, when carrying out an environmental risk assessment under Annex II to Directive 2001/18/EC.

[69] Publication of Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC, concerning the environmental risk assessment (ERA) of GMOs.

[70] Acquah, D. O. (2017). Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development. (page 48) argued that How they negatively affect access. He uses the Common Commercial Policy analyse expansion in Trips, the redesign in EU trade policy. Customs regulation, does the updated regulation appropriately ensure balance in Access.

consider in addition to, the developments from CJEU. Most of which has not been favourable for Africa.[71]

So far, some African countries are parties to the EPA, and much of Africa's agricultural produce is still destined for Europe markets. The refusal of many African countries in taking the UN "aid" in 2007 for example, was not only due to the potential effect GMO had on human health and environmental but also the EU's attitude towards GMOs and food safety rules.[72]

2.2.3 AFRICA

Since regulations of Genetically Modification started in the 1990s, many countries have gone through the process of formation, gradual modification, and evolution of their rules; however, with the exception of some few countries in Africa, the majority seem to still be at the formation stages even though GM crops are being cultivated, consumed, and traded in large quantities within their territories and on the international markets.[73] While the majority of nations are silent of the subject, South Africa, Burkina Faso and Sudan are the main countries that are commercially exploring GMO even though a number of other countries like Algeria outrightly bans GMOs within their territories.

The Africa Union, as a supranational body is yet to implement a protocol that comprehensively addresses GM in general nor GM-IP in spite of its resolve in its 2006 Decision EX.CL/Dec.26(III) to have a common stand on modern biotechnology. The decision acknowledged that biotechnology could help increase production, yet opposing views have delayed the assessment and adoption of GM technologies for this purpose. The absence of a clear path from the AU has led to two things happening; first, nations having to fall on bilateral and multilateral agreements like sub-regional directives, other trade agreements and international treaties for direction. Second, GM companies having had to employ stringent

[71]The CJEU in 2001 ruled that there is no provision in the CBD which requires that the conditions for the grant of a patent for biotechnological inventions should include the consideration of the interests of the country from which the genetic resource originates or the existence of measures for transferring technology and that by virtue of Article 1(2) of Directive 98/44/EC, the Member States are required to apply the Directive in accordance with the obligations they have undertaken as regards biological diversity

[72] Strauss, D. M. (2008). Feast or famine: the impact of the WTO decision favoring the US biotechnology industry in the EU ban of genetically modified foods. *Am. Bus. LJ*, *45*, 775.

[73] Crops like maize, cotton, cassava are some of the gm variety grown and in which countries Burkina Faso, Egypt, South Africa, and Sudan, the rest have been slow in adopting GM for various reasons, trade, health, regulation.

measures like licensing and GURT to ensure the protection of their products. Both effects impact severely on food security within the region. The African Free Trade Agreement which recently came into force, however, directs AU minister to submit for adoption a draft that detail among other the continent's policy for Competition, Investment, and Intellectual Property Rights.[74]

Many African nations are part of international treaties either individually or as a block. About 52 of the 54 countries parties to the TRIPS agreement and over 40 African countries are also parties the Cartagena Protocol on Biosafety and its mother convention the CBD which regulates the cross-border movement of GMOs. The Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the UPOV are some of the other treaties that many African countries are parties to. These treaties provide broad guidelines that often require specific structures and institutions to oversee implementation. Most of the countries in Africa are nonetheless still developing the needed structures and institutions while the few others that have managed to set up the structures required are non-functioning therefore unable to access the full complement or benefits from these treaties.

Other sub-regional bodies in Africa like SADC, ECOWAS, COMESA, EAC also exist within the continent.[75] None of these regional groupings has enacted any comprehensive policy on GM yet, but they seem to be more ahead in the process of securing one than the AU. ECOWAS, for example, has an Action plan that aims to check biotechnology and biosafety developments for its members.[76] The plan resolved to expand productivity to levels that genuinely affects the development process by expanding the market for agricultural products in West Africa. It sought to promote the regional markets and the integration of the West African agriculture into the global market via the strengthening of regulatory systems and a product quality approach; Elimination of trade barriers; Resolution of the intellectual property issues to promote technological development while taking the many socio-economic contexts and roles of agriculture into account. The action plan beheld member states to avoid being in contradiction

[74] ASSEMBLY OF THE UNION Tenth Extraordinary Session 21 March .... https://au.int/sites/default/files/decisions/34055-ext_assembly_dec_1x_e26_march.pdf

[75] The major African regions developed guidelines and policies to move the process forward.
SADC established an advisory committee in 2003 to focus on handling of food aid, policies and regulations, capacity building, and public awareness. However, this committee seems to have been dormant for the past several years.
The AU policy guidelines attempt to guide member states in establishing public awareness, biosafety strategy, harmonization, participation in international negotiations, and stakeholder collaboration.

[76] During the ministers meeting of ECOWAS in 2007 action plan

with the international agreements in other to benefit from the GMOs by adapting their national legislation with the help of the African Intellectual Property Office.[77]

Notwithstanding the delay of the regional and continental bodies, some individual nations within Africa have been formulating some policies on GMs. Mauritius, for example, enacted a GMO act in 2004. South Africa, being the most vibrant GMO nation in Africa, also has a GMO law. The Mauritius act, however, applies to recombinant nucleic acid techniques that create new combinations of genetic material; methods that introduce alien nucleic acid molecules into an organism of; or cell fusion likes protoplasts, beyond the same taxonomy. Hybridisation techniques that form live cells with the new genetic material combination are also considered under the act but overlook genetic manipulation of human cells or processes that do not use recombinant nucleic acid molecules or genetical modifications. [78]

On the other hand, Algeria, Rwanda and Madagascar amongst many others have bans in place for GM crops. [79] But given the homogeneity of the region, the effect is that the continent stands the risk of an unharmonised policy on GM and the issues thereof. A harmonised regulation that synchronizes the approval system at the regional level and addresses the fragmentation in approaches may be needed to improve access to GM food.

2.3. REGULATORY ISSUES

By creating crops with higher yields, better nutritional value and stronger resistivity to disease, GMs have the potential of improving food security, reducing malnutrition and fighting poverty, but as to whether GM can provide meals that are accepted by all is the question. Many people within the African continent are hungry, but the food provided must be acceptable. Unlike the EU and far from the US, the attitude of Africans towards GM has not been entirely responsive, and a sizeable number are still sceptical about GM for many reasons. The fear of the unknown has been one big reason some researchers assign to this phenomenon.

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[77] *Action 3.2.2.1.1.10: To strengthen existing IP systems in the Member States.* Since the ECOWAS countries also belong to the African Intellectual Property Organization (AIPO), the national representations of these organizations should be mobilized by ECOWAS with a view to not only re-examining the national legislation in order to adapt them to the new global context, but also assist the countries in setting up the administrative and technical institutions in charge of intellectual property issues.

[78] Section 6(3) of the Mauritius GMO act.

[79] Food Related Regulation in Africa Compared to EU and US .... https://www.waystocap.com/blog/food-related-regulation-in-africa-compared-to-eu-and-us/

GM is a relatively new development; thus, most of the long-term effects are still unknown. However, the direct and indirect socio-economic and ecological consequences of GM often contemplated largely accounts for the seeming lack of trust. This notion has been long sustained because many of the African households are small-scale farmers who rely on natural resources, and uncomfortable with farming inputs/practices that increase the vulnerability of its biodiversity.[80] Although nations have different peculiarities, the adverse reports in other country are often exaggerated. The possibility of contamination for endemic or staple food crops gene pools, for example, was not only crucial in South Africa's rejection of research applications on genetically engineered cassava and sorghum, but also the basis debates in other countries. Clapp, J. (2005) also observed that the European rejection of genetically engineered food had made Europe destined exporters who are in the majority in many African countries cautious in adopting GMOs.[81]

Several actors from different quarters have espoused many suggestions regarding ways of improving trust and acceptability of GM in Africa. But institutional capacity is one defining measure. Since profit-driven private entities and not governments and agents responsible for ensuring food security, are directing GM research, the unrest among farmers and consumers are high, because the supervising institutions are inadequate and non-performing. Research shows that both developers and consumers of GM are in many ways comfortable when there are institutions that guarantee the protection of developers' interest on one hand and consumer protection on the other. It is not surprising then that most treaties require the establishment of specific institutions and capacity.

While some treaties may be vague as to the composition and capacity of these institutions, others demand strict compliance. The institutions mostly define the parameters, specify or test gm, decide on disputes, among others within the sector. Many of the GM treaties require the setting up of specific institutions. The CPB requires parties to publish all their decisions on GMOs, on an international website called the Biosafety Clearing-House (BCH) as well as summaries of the scientific safety studies carried out on these GMOs. This information is vital as it informs citizens, governments and industry about decision making on GMOs. This

[80] Moola, S., & Munnik, V. (2007). GMOs in Africa: food and agriculture. *Retrieved March*, *25*, 2012.
[81] Clapp, J., 2005. The political economy of food aid in an era of agricultural biotechnology. Global Governance 11: 467-485.

mechanism helps the public to understand what GMOs are and also encourage public participation and scrutiny.

So far, a number of African countries are in the process of setting up the required institutions, while the others that already have laws that make provision for seed testing stations like Zambia Sudan and Botswana are acquiring some kits to boost their capacity for the GM industry. South Africa, for instance, was able to reject Syngenta's application to import GM maize for ethanol on the grounds of food safety because it had the necessary facility to assess. The African Centre for Technology Studies (ACTS) also coordinated a study that assessed the current IPR practices in select African countries and identified the capacity of institutions in carrying out policy dictates and even simple documentations as a major challenge although the majority of the countries have IP laws.

The effects of many regulations in Africa have been low due to defects in the administrative structure needed for implementation and enforcement.[82] Several studies have also observed that most of the institutions are either non-existent or ill-equipped to carry out their mandate. Some noticed that many national patent offices in Africa, in particular, were inadequately equipped to perform their core functions of examining patent applications and compiling data on patents for the public and other inventors. This, in effect, is facilitating the exploitation of essential genetic resources by foreigners who are protecting ideas and discoveries that are not patentable. [83] While investigating the South African patent system, Pouris (2011) argued that '*granting patents for inventions that are not new or useful or that are obvious, unjustly rewards the patent holder at the expense of real inventors, the consumer and social welfare*' when he was reviewing the patents system in South African. [84]

The example of European Patents Office revoking Monsanto's melon patent EP1962578, issued May 2011 which could potentially restrict access to all breeding material that have the virus resistance similar to the Indian melon is an indication that the need for not just institutions

[82] Mgbeoji P. (2009), Intellectual property rights in Africa: The way ahead. In Armstrong, D. (Ed.). (2009). *Routledge handbook of international law*. Routledge.
[83] Innovation & intellectual property: Collaborative dynamics in Africa EDITORS: Jeremy de Beer, Chris Armstrong, Chidi Oguamanam, Tobias Schonwetter ISBN: 9781919895994 (softcover) PUBLISHER: Open A-I-R, UCT Press, Cape Town, ZAR350 (the electronic version is licensed under a Creative Commons license) PUBLISHED: 2014
[84] Pouris A, (2011) Patents and economic development in South Africa: Managing intellectual property rights. S Afr J Sci. 107(11/12):24-33. http://dx.doi.org/10.4102/sajs.v107i11/12.355

but ones that can examine patent claims and patents granted elsewhere.[85] That is why it was refreshing when South Africa rejected the GM sorghum project on the basis that GM technologies that originate from Africa cannot be patented, and thereby setting limits even pro-GM countries.[86]

One major institution that needs to be equipped the most is the Court systems in Africa. That is a Judiciary system that will appropriately consider the continents peculiarities and give life to its laws is one element worth highlighting. USC has shaped the US system. The CJEU has made several profound judgments that have been telling on the gm industry, the decision on the presence of patented material alone without it performing stated function in Monsanto case has impacted profoundly even at the international level.

Again, the different trade and regulatory directions that the United States and the EU are pursuing over GMOs is obscuring the conversation on the social, economic and environmental implications of GM technology in the developing world. The need to have a policy or at least a clear policy direction is crucial because of the different regulatory approaches by blocs such as the EU and the US; the tension should not sue Africa. The continent needs to fashion out a policy from the current policy space that will premiums the hard and pressing demands of Africa, such as access. And also develop a consistent and coherent policy framework that is in line with the national developmental agenda — the needed expertise to press for more favourable terms while making the most out of the current system.

But in conclusion, while a country-by-country report that provides comprehensively assess capacity of both research institutions and government departments responsible for implementing regulations on GMOs and to contribute meaningfully to discussions on the international stage is needed, the institutional and human resources to research and conduct policy analysis in IPRs available, the directions they are heading, and best practices all need to upgrade.

[85] Mgbeoji, I. (2007). TRIPS and TRIPS plus impacts in Africa.
[86] Africa Flak: Will GM foods keep a hungry continent better fed?. https://africaflak.blogspot.com/2008/03/will-gm-foods-keep-hungry-continent.html

Table 1

COUNTRY	TRIPS	CBD/CPB	UPOV	ITCGR
Algeria	Observer	X	-	X
Angola	X	X	-	X
Benin	X	X	ARIPO	X
Botswana	X	X	-	-
Burkina Faso	X	X	ARIPO	X
Burundi	X	X	-	X
Cabo Verde	X	X	-	X
Cameroon	X	X	ARIPO	X
Central African Republic	X	X	ARIPO	X
Chad	X	X	ARIPO	X
Comoros	Observer	X	ARIPO	-
Congo, DR.	X	X	X	X
Congo, Republic	Yes	X	ARIPO	X
Cote d'Ivoire	Yes	X	ARIPO	X
Djibouti	Yes	X	-	X
Egypt	Yes	X	-	X
Equatorial Guinea	Observer	X	ARIPO	-
Eritrea	X	X	-	X
Eswatini (Swaziland)	X	X	-	X
Ethiopia	Observer	X	-	X
Gabon	X	X	ARIPO	X
The Gambia	Yes	X	-	X
Ghana	Yes	X	-	X
Guinea	Yes	X	ARIPO	X
Guinea-Bissau	Yes	-	ARIPO	X
Kenya	Yes	X	X	X
Lesotho	Yes	X	-	X
Liberia	Yes	X	-	X
Libya	Observer	X	-	X
Madagascar	Yes	X	-	X
Malawi	Yes	X	-	X
Mali	Yes	X	ARIPO	X
Mauritania	Yes	X	ARIPO	X
Mauritius	Yes	X	-	X
Morocco	Yes	X	X	X
Mozambique	Yes	X	-	-
Namibia	Yes	X	-	X
Niger	Yes	X	ARIPO	X
Nigeria	Yes	X	-	X
Rwanda	Yes	X	-	X

Sao Tome and Principe	Observer	X	-	X
Senegal	X	X	ARIPO	X
Seychelles	X	X	-	X
Sierra Leone	X	X	-	X
Somalia	Observer	X	-	-
South Africa	X	X	X	-
South Sudan	Observer	X	-	-
Sudan	Observer	X	-	X
Tanzania	X	-	-	-
Togo	X	X	X	X
Tunisia	X	X	X	X
Uganda	X	X	-	X
Zambia	X	X	-	X
Zimbabwe	X	X	-	X

Source: Summary Table of Membership of the World Intellectual Property Organization (WIPO) and the Treaties Administered by WIPO, plus UPOV, WTO and UN https://www.wipo.int/treaties/en/summary.jsp

3.0. THE INTERSECTION BETWEEN GENETIC MODIFICATION AND INTELLECTUAL PROPERTY

Once considered an isolated and peripheral area of law, recent works have not only placed intellectual property front and centre in the study of law, science, and policy but have considerably broadened the scope of scholarship on intellectual property to include GM and the biotechnology industry.[87] At the same time, the GM debate that initially centred on the politics of regulating its risks is gradually assuming IPR as its new centrality. Even though Intellectual Property impacts on all the points of the food chain IP in food was for a long time under-theorised and had not been taken seriously until recently as the vast majority of IPR and IP studies continued to be about software and others. Today, the GMO discourse is slowly shifting discussions from risk to battling the challenges intellectual property rights poses in the arena. In fine, just as scholarship on GMOs has changed focus in the last two decades, so has the scholarly analysis of Intellectual Property.

Presently, the impact that intellectual property laws have especially on agriculture in developing countries is central, complex and multi-layered. The correlation between intellectual property rights and the type of cultivars/seeds available, rising seed prices, can be predicted easily looking at the way markets work. Other effects, such as the prevalence of bio-piracy and the loss of biodiversity, are in part facilitated by gaps in the treaty framework and the deficiencies in domestic legal regimes.[88] The elements that impact IPRs on the Global South manifests in the displacement of traditional communal farming practices by corporate farming; disruption of established farming practices and food systems; appropriation of the genetic resources by corporate interests in the North; the loss of gene diversity and diminution of genetic variety; and discrimination against the indigenous knowledge developed within communities individually or collectively.[89]

[87] Biagioli, M., Jaszi, P., & Woodmansee, M. (Eds.). (2015). *Making and unmaking intellectual property: creative production in legal and cultural perspective*. University of Chicago Press.
[88] Thampapillai, D. (2015). The Food and Agricultural Organization and Food Security in the Context of International Intellectual Property Rights Protection. *Legal Perspectives on Security Institutions, Cambridge University Press (2015)*, 269-291.
[89] ibid

In this chapter, we centre on the interplay of IP and GM by studying the various Intellectual Property Rights that move along and impact the GM food chain. IPRs such as Patent, Plant Varieties Protection/Breeders' protection, Trademark, Traditional Knowledge, and geographical indications and the likes are sought at different stages of the food supply chain, and countries all over the world are under legal obligations to provide IP protection for that. While the type of protections differs, the prime IPRs in GM such as patent and other Sui generis protections like breeders' rights/plant variety, together with, some significant issues related to IPR protection concerns such as; Infringements and Liability, biopiracy, licensing, in Africa are the probing themes of this chapter.

The principle of Territoriality on which IP operates implies IP rules are applicable only within a jurisdiction. [90] Therefore, the nature and scope of protection can only be guaranteed the extent afforded by the laws within that territory. Economic self-interest has been a central determinant of domestic IP laws and policies. And the use of IPRs as a means of protecting the products of local manufacturing when traded internationally abound. Many territories aim at protecting their interests and citizens, including at the expense of foreigners.[91] Therefore, in our bid to understand and analyse GM-IP in Africa, we will begin by looking at how the IPRs came about and its introduction into Africa before turning to how the IPRs that affect GM is defined, established and operates within applicable treaties. We will then delve into the national legislation and regional systems like the US and EU that despite the territorial nature of IP hugely influences the IP regimes in Africa.

3.1 DEVELOPMENT OF GM- IPR SYSTEM IN AFRICA

Countries over the years have ratified IP treaties and promulgated IP laws in line with national interests, Exports oriented countries have tended to stronger protection that restricts access and causes to inflate pricing for their cultural and scientific products, while import oriented countries have for obvious reasons had weaker protections for imported products.[92] However,

[90] Historically, IP territoriality has denoted three things: conferral of IP rights under the national laws of individual states. 2, restriction of the legal effects of those rights to the territory of their conferring state. 3 is the enforcement of IP rights by the courts of the conferring state applying domestic law.

[91] Drahos, P. (1999). The universality of intellectual property rights: origins and development. *Intellectual property and human rights*, 13-41.

[92] Eg. When Switzerland introduced a patent law in the late 19th century, only to protect those goods in which they had an established manufacturing and export industry. And left the areas where they depended on imports from abroad were left unprotected by patents, enabling continued free public access to chemical inventions patented abroad.

IP was introduced in Africa by colonising European countries, while Britain was exporting in whole its domestic IP laws to its colonies – in some cases with a level of some support by local ordinances,[93] France and other European countries were extending their homegrown IP laws to their territories through assimilation and other measures.[94] The genesis of African countries participating in international treaties was also commissioned in their absence and without their consent.[95] Some postcolonial theorists have suggested that the current state of IP development goes beyond contemporary political and economic circumstances to colonial-era and the systematic neo-colonial arrangements like international multilateral and bilateral agreements that further the external economic control and industrial interests.

Today many African countries are in the process of ratifying, implementing and adapting their national legislation to meet international responsibilities, often without a link between IP and technological developments derived internally.[96] Some researchers have proposed the need to undertake comprehensive sectoral research to ascertain the impact each IPR or IP regime has on the set targets is eminent in order for the people to appreciate the need for it to be protected. The establishment of IP regimes should, therefore, take cognisance of both internal and external dynamics. A balance between access to external resources and the protection of homegrown ones is of the considerable essence, That is why to get a befitting IP protection regime for Africa's food security and beyond, Africa must consider not only the IPRs in other jurisdictions but most importantly its resource endowment, historical, cultural, and socio-economic positioning.

The development of IP framework should be move alongside the indigenous alternative rights/systems since the former's introduction was as Yankey posits not intended to stimulate "indigenous activity, local research and development, innovation or to ensure the adequate transfer of technology, rather its objective was to safeguard the property rights of the machinery

[93] Kongolo, T. (2013). Historical developments of industrial property laws in Africa. *The WIPO Journal, 5 (1)*, 105-117.
[94] French laws until 1962, governed patent rights in the majority of francophone African countries, and the French National Institute for Intellectual Property (INPI) served as the central IP authority.
[95] Acquah, D. O. (2017). Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development. Read Acquah page 183 for details on this.
[96] Brandl, K., Darendeli, I., & Mudambi, R. (2019). Foreign actors and intellectual property protection regulations in developing countries. *Journal of International Business Studies*, *50*(5), 826-846.

technology used in the exploitation of gold and other mineral and human resources in the Colonies."[97]

3.2 IPRS THAT IMPACTS FOOD THE GLOBAL SUPPLY CHAIN

Even though the idea of rewarding agricultural innovations with exclusionary rights can originate from the 1833 Papal Edict, the underlying assumption today is that IPRs are inevitable within the contemporary global setting.[98] IP continues to permeate into new areas as it gaining centrality in existing domains, and a clear example is the role Intellectual Property play in the biotechnology and GM industry. Many European countries began by considering IP protection for plant material and breeding techniques under patent law even though the consensus was against patenting plant materials in general. Now other sui-generis protections like Plant Variety Rights (PVR)/Plant Breeders' Rights are available for GM and plant material industry, yet patents remain the popular IPR. While some developers opt for plant patents, many apply for utility patents.

Today, developing new strains of plant material have evolved. Releasing the new variety now entails incorporating desired features into the variety that is being improved, examing the new variety over a range of habitats over time to establish its stability.[99] Other modern breeding techniques that discover or creates a genetically stable variation for the desired plant attributes like high yield, pests and disease resistivity and stress-resilient are increasingly been employed in the process of selecting from the variations, individual plants possessing the best expression of the desired traits, which has now been added to the traditional breeding methods. These processes are very challenging as it employs several techniques and requires lots of resources to minimise the propensity of spontaneous genetic variation for outcomes often that will have the stability of intellectual products.[100]

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[97] Mengistie, G., & United Nations. Economic Commission for Africa. (2010). *The Patent System in Africa: Its Contribution and Potential in Stimulating Innovation, Technology Transfer, and Fostering Science and Technology*. Economic Commission for Africa.

[98].' Pila and Torremans This edict extended the principles governing the reward and ownership of scientific and literary works in the papal states to 'those works that relate to the progress of agriculture and its techniques

[99] Hansen, M., Busch, L., Burkhardt, J., Lacy, W. B., & Lacy, L. R. (1986). Plant breeding and biotechnology. *BioScience*, *36*(1), 29-39.

[100] See A010/2013 Aurora Srl v Community plant variety Office (26 November 2014) Aurora [4] The inappropriateness of patent in breeding as plant varieties are as much of the products of nature as the creation of individuals.

The introduction of technology into plant and food is forcing countries to revise their IP laws, many nations, including some developed ones, are in the process of carving the right protections. Such states have to couch their protection from the policy space that is allowed within International treaties which and further narrowed by Trade Agreements. Others are in the quagmire of finding an appropriate relationship between the forms of protection as well as the balance between right holders and third-party interest and rights.[101] Getting the right IP mix within the existing global structure, in particular, is an urgent matter in Africa's bid to ensure food security.

The establishment and definition of IPR in many countries often stem from international treaties, the operationalisation of treaty provision has not been entirely the same everywhere. The extent to which the increasing industrialisation of food, private sector dominance of plant breeding research, and gene therapies impacts decision making can account for most of the disparities. The discussion below with focuses on the IPRs and other sui-generis protections used in GM industry, with emphasis on the relationship between them, especially patent and PBRs/PVRs which in the face of changes in technological and economic plant breeding contexts continues to be a difficult one.

Currently, most IP rights in Africa are owned by entities mainly from US and EU,[102] this fact, coupled with the IP chapters of Trade agreements between Africa and other nations makes the understanding of protections in these regimes imperative in any analysis on access to GM and plant genetic material as a viable and effective option in remedying food insecurity. Despite the apparent collision of the general GM regulations, the EU and US seem to have similar IP for GM in both territories.[103]

3.2.1 PATENTS

Patents in general and GM patents in particular as established in treaties, the US-EU patent systems, Origin of African Patent and the developments GM patent. Patent-related issues

Patents are granted on any product or process invented within the field of technology with an established fact that they are novel or unique, and the results from such inventions are capable

[101] Pila and Torremans page 235 The relationship between plant variety and patent protection
[102] Only 6 companies control 95% of gm seed worldwide
[103] Patterson, L. A., & Josling, T. (2002). Regulating biotechnology: comparing EU and US approaches. *Environmental policy in the European Union*, 183-200.

of being used in industrial application. Pila and Ohly define patents as the "limited-term monopoly rights granted in respect of new, inventive, and industrially applicable inventions." Although international treaties establish patents,[104] IP is territorial, and the benefits such as 20 years monopoly that national jurisprudence allow rights holders to block others to use it for gainful, commercial purposes or producing same at other places without appropriate approval.[105]

The scope of protection, the definition of critical elements, as well as the processes and requirements needed for a product or process to have a patent differ depending on the jurisdiction where patent protection is being sought. This disparity can be attributed to the most pervasive IP agreement of today, the TRIPs agreement,[106] which has not only allowed for the grant of patents for everything under its system of trade law but also plagued with a number of interpretation variations and flexibilities, some of which are discussed below.[107]

TRIPS has caused a high increase in the world's protection of intellectual property rights and especially patent technology. This comprises of "any inventions, in every field of technology, whether products or processes, which is new, involve an inventive step and are capable of industrial application."[108] This definition effectively makes innovations from every industry capable of patents. The new biotech additions defeat the lack of technical, industrial, or mechanical properties of plant material inventions arguments and serve as justification for states that grant patents to plant materials and varieties.[109] Currently, although other forms of IPR exists in the GM industry, Patent remains dominant despite the age-old arguments of its inappropriateness. Recent data show that patents continue to be the most popular intellectual property within the biotechnology industry contrary to the boisterous criticisms.

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[104] Internationally, patents have moved through several treaties, since the practice of granting patents for inventions began in Greece - Sicily around 500 BCE, and more so after first general patent statute and patent specification of the 15th and 16th centuries spread across European states and the world. The recognition of patent as exceptions to a general prohibition against 'odious monopolies' in the 17th century and the patent war of the 19th century helped reconciled the major issues such as term of protection, requirements, exclusions thus leading to the first international patent treaty, the Paris convention for the protection of Industrial property of 1883

[105] Article 28 TRIPS

[106] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994).

[107] Trips provide the minimum standards for IP protection and are an inescapable conditionality for joining the WTO.

[108] Dwivedi, D. 2015, "Trips Agreement And Protection Of New Plant Varieties: Issues And Implications For Agricultural Sector In India." Vidhigya, vol. 10, no. 1, INMANTEC Institutions, p. 1.

[109] Sterckx, S. (2017). European patent law and biotechnological inventions. In *Biotechnology, Patents and Morality* (pp. 1-112). Routledge.

The agreement obligates member states to legislate laws that protect and ensure enforcement of rights on matters like plants that can be patented.[110] It also allows member states the choice of protecting subject-matters like plants varieties through patents or a sui generis system, even though a country can adopt both.[111] Because of this, the IP protection for plant and plant materials vary immensely in many counties. Some states have opted for patent protection for plants while others, tend to refuse patent protection for both plants and animals aside micro-organisms organisms. Others also refuse essentially biological processes while allowing non-biological and microbiological method needed in plants or animals production to be protected based on Article 27(3).[112]

States that allow for patenting plant and plant genetic resources gives exclusive rights such as the right to make, offer for sale, sell, and import, in addition to, the rights to prevent others from exploitation if the consent of the patent holder has not been given for a period of 20 years.[113] These rights are mandatory and can only be restricted under conditions like Article 27(2) and Article 31, which establishes a compulsory licensing regime. Whereas Article 31 establishes a Compulsory-licensing system, Article 27(2) allows restrictions based on "*ordre public"* or morality grounds "*provided they are limited, do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the legitimate interests" of the owner of the patent*. "[114]

Some states, on the other hand, exclude patents for plant varieties and provide other sui-generis system forms of protection for them. Several industrialised countries like the US, Japan, Australia, New Zealand, Sweden and the United Kingdom, have taken advantage of this to allow plant breeders the opportunity to protection for new varieties with patent once they meet some other requirements, many developing countries are refusing plant patents (Watal, 2000, p. 149). Countries like India, Thailand, and Malaysia have enacted separate statute applicable exclusively to plant varieties and plant genetic resources. These countries do not grant plant patents do not interpret "Using" as in a sense stated in article 28 (1) of TRIPS to include planting, harvesting, saving, re-planting and exchanging seeds.

[110] Article 27(1): Part II, section 5 of TRIPS concerning availability, scope and use of IPRs.
[111] Article 27.3.b
[112] Example of countries Biodiversity and the Law - docshare.tips. http://docshare.tips/biodiversity-and-the-law-_576253f9b6d87f3b878b495c.html
[113] Article 28 of the TRIPS agreement list the exclusive rights available to a patent-holder
[114] in accordance with article 27 (2),

A variety of a plant refers to the plant grouping, within a single botanical taxon of the lowest known rank, it is defined by the reproducible expression of its distinguishing and other genetic characteristics.[115] Plant varieties can either be developed natural or synthetical. GM is the way many plant varieties of today are developed. TRIPS, however, extends protection to genetic materials that have been modified at the cellular level, and not the whole genetically modified plant [116] This implies that inventors of plant varieties can secure intellectual property protection for their inventions or new products since the law provides for it. This is because living things can be patented and hence there is no apparent rejection for micro-organisms. TRIPS consider Modified genes unavailable in nature, under the ambit of patentable subject matters, as such the denying patents on such genes, is against the TRIPs Agreement.[117] As such, it dictates that states should protect GMO by patent.[118] Critics consider this as a breach of the ideals of many nations, and the reason why some developing countries are fashioning out alternate and parallel treaties that reflects their national interests and cultural beliefs. But protecting plant varieties with a system other than patents raises the challenges application of GM in plants since the application of GM in plants are plant related-invention that generates plant varieties.

Distinguishing between plant varieties, and other plant-related innovations have, therefore, become a challenge for some nations. And this is because several states and regional laws usually do not allow patents for plant varieties while plant-related innovations are covered under patents. For instance, in Europe, article 53(b) of the European Patent Convention prevents the patenting of "plant varieties". However, the European Patent Office has stated that broad patent claims that cover "plants" or an invention bigger beyond a single variety are likely to be patented although such claims might have multiple varieties.[119] Plant breeders' in Europe can, therefore, fashion their patents claim for new plant varieties in a way that receives de facto patent protection.

In conclusion, opinions remain divided between developed and developing states since TRIPs does not expressly mention genes and genetic material whereas developed countries are more open to patents on only isolated or purified genes whereas developing countries do not allow

[115] Art. 2, ITPGRFA also International Treaty on Plant Genetic Resources for Food http://www.fao.org/3/a-i0510e.pdf
[116] Strauss, D. M. (2009). The application of TRIPS to GMOs: international intellectual property rights and biotechnology. *Stan. J. Int'l L.*, *45*, 287.
[117] Article 34
[118] Strauss, D. M. (2009) ib
[119] G 0001/98, Novartis II/Transgenic Plant, 2000; E.P.O.R. 303 para. 3.10; Janis & Kesan, 2001b, p. 35

for patent protection on genes and genetic material. The patentability of genes and genetic material, therefore, depends on the interpretation of "invention" within a jurisdiction, if a state considers genes and genetic material as discovery rather than invention, they will fall outside the scope of subjects that can be protected with patents the TRIPs Agreement. But instead, f genes are considered invented after having been isolated or purified," they would fall within the scope of patentable subject TRIPs suggests."[120]

3.2.1.1 UNITED STATES PATENT

The United States is one destination that has championed the patenting of biotechnology. This action not only been supported by various Acts such as the Plant Patent Act of 1930, and the Plant Variety Protection Act of 1970 and 1994, but also the courts and the effective enforcement strategies put in place by the U.S Patent office.[121] The 1952 Patent Act established utility patents by giving patent holders a wide range of exclusive rights to be exercised for a 20year period if the invention satisfies the novelty, non-obviousness, disclosure, patentable subject matter, and utility requirements.[122] In defining 'patentable' subject matter, section 101 grants utility patents for any new and employable process, machinery, and manufacture products as well as any advancements made to existing processes and products.[123]

The landmark case *Diamond v. Chakrabarty* is credited for bringing living organisms or genetically engineered microorganism into the remit of material that can be patented under § 101. The court believed "Congress intended statutory subject matter to include anything under the sun that is made by man."[124] This judgment invariably extended patents scope to almost everything that does not occur naturally so far as there is an element of human intervention in the invention and can satisfy the requirements of patentability.[125] Again, the Board of Patent Appeals and Interferences extended patentable life forms to plants through the *Ex parte Hibberd cause*, hence, sidestepping the USPTO's refusal of a patent application for a corn plant

[120] Correa, C. M. (2001). Internationalization of the patent system and new technologies. *Wis. Int'l LJ*, *20*, 523.
[121] Section 35 U.S.C. § 161, states that: "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent, therefore . . . ."
[122] U.S. Patent Act of 1952, 35 U.S.C. §§ 101–103 (2000).
[123] Strauss M.
[124] Chakrabarty, 447 U.S. at 303.
[125] *See,* Daniel J. Kevles, *Diamond v. Chakrabarty and Beyond: The Political Economy of Patenting Life*, *in* PRIVATE SCIENCE: BIOTECHNOLOGY AND THE RISE OF THE MOLECULAR SCIENCES, at 65 (Arnold Thackray ed., 1998).

and opening the door for more complex living organisms for a utility patent.[126] However, the *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc. case* ultimately confirmed that plants and seeds could be patented.[127] The court supported the need to protect hybrid corn seeds and new breeds developed. Subsequent decisions have made animals and even mammals a patentable subject matter.

Today, a lot of biotechnology prefer and opt for utility patents instead of plant patents; the USPTO commenced the issuance of Utility patents for both human-made plants and plant elements in the 1980s. Plant breeders prefer utility patent system because of its extensive scope. Even though the seed-saving and research exemptions have been narrowed by recent development in courts, the Plant Variety Protection Act still have both exemptions which make it unattractive for breeders. Utility patents aside protecting plants covers plant genes and include the use of the genetic material of multiple plants which may have multiple uses and traits. The criteria for utility patents vary from plant patents. A plant must be manufactured by humans aside fulfilling the basic requirements utility, novelty, and be non-obvious in the creation to get a utility patent. Plants that are eligible for Utility patent can be propagated from its seed or asexual.[128]

Most developers in the GMO sector usually apply for utility patent instead of plant patents protection for their new and novel and hybrids plants. Players in the GMO sector, usually seek utility patents to protect specific elements such as genes or DNA strands, buds, proteins, pollen or fruit of a plant. Available data also show Utility patents for plant-based chemicals and processes that are used in making these products.

Critics, however, contend that the demand for utility patent further impairs the statutory exemptions meant to safeguard the traditions of the small-scale farmer as well as innovative creations that plant breeders make. But in response, some observers have suggested that the increase in private sector participation in seed production," and "the escalation in biotech utility patents for new varieties are rather boosting research and development activities with tremendous results.

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[126] *Ex parte Hibberd,* 227 U.S.P.Q. 443, 443–44 (Bd. of Pat. App. & Interferences 1985). Also see arte Appeals Rules of Practice Before the BPAI in Ex Parte Appeals The Effective Date: January 23, 2012 on https://www.uspto.gov/sites/default/files/ip/boards/bpai/procedures/og/bpai_ex_parte_rules_slides_final.pdf

[127] *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001), quoting *Chakrabarty*, 447.

[128] Holm, Sarah (2015) "When They Don't Want Your Corn: The Most Effective Tort Claims for Plaintiffs Harmed by Seed Companies Whose Genetically Engineered Seeds Produced More Problems Than Profits," *Hamline Law Review*: Vol. 38: Iss. 3, Article 6. Available at: http://digitalcommons.hamline.edu/hlr/vol38/iss3/6

With the United States being a net exporter of IP, these strong patent protections as manifested in acts and court's interpretations are continually being exported to other countries, and particularly developing countries through trade agreements like NAFTA to update IP laws in other regions. These extensions create difficulties for some critical exemptions, like the research and seed-saving exemptions, are still very relevant in developing countries, especially in Africa since US laws have narrowed them.[129] Moreover, the Plant Variety Protection Act Amendments of 1994 that was enacted to make the original act fall in line with the more robust International Convention for the Protection of New Varieties of Plants tend to have eroded traditions including restricting the rights of farmers' to use, that persists in many African countries. *Asgrow Seed v. Winterboer*. [130]

3.2.1.2 EUROPEAN PATENTS

Aside from the numerous international obligations, the protection of GM and plant material within the EU is primarily regulated by the Directive 98/44/EC (the Biotech Directive).[131] This directive which is the core instrument for the legal protection, management and advancement of the biotech/GM inventions within Europe and together with the European Patent Convention and Plant Variety Rights systems, form the European biotechnology patent framework. In the bid to ensure uniformity, the Biotech Directive has not only been transposed into national legislation of Europe,[132] but it was also through the Decision of the Administrative Council of the European Patent organization (1999) incorporated into the Implementing Regulations to the European Patent Convention. [133] The Boards of Appeal and other quasi-judicial bodies of

[129] *Asgrow Seed v. Winterboer*, 513 U.S. 179 (1995).
[130] Pub. L. No. 103–349, 108 Stat. 3138 (codified as amended at 7 U.S.C. § 2543 (1994))
[131] Directive 98/44/EC
[132] Patent protection in Europe is currently ensured by two systems: the European Patent System and the national patent systems. Even thought there may be some variations, the national patents systems are similar to the European patent system. This is because most of the EU member states have reconciled their national laws to the EU directives on IP rights protection.[132]
[133] Through the application for annulment of Directive 98/44/EC, brought by the Kingdom of the Netherlands, with the support of Italy and Norway of 19 October 1998, the compatibility of the biotech directive with international treaties and agreements like EPC, TRIPS, WIPO CBD, etc. was established. It appeared incontestable that the Directive was fully compatible with the existing deals in the field of biotechnology. In addition, much as the Court did not consider itself competent to assess the validity of the Directive with regard to the European Patent Convention, in that the European Community is not a party to it, it declared itself competent in relation to the legality of the Directive vis-à-vis the Convention on Biological Diversity.
See Rule 23b explicitly lays the Directive 98/44/EC down as a supplementary means of interpreting EPC rules, and hence the relevant provisions of the Convention.

the organization have over the period profited and referred explicitly to Directive 98/44/EC as it functions as the primary framework for the EPC's protection of GMOs.

Both the Biotech Directive and the European Patent Convention (EPC) make plant-related inventions patentable in cases where the technical feasibility of any design is not limited to one variety. Article 3(1) of the Biotech directive explicitly grants patent protection "for new inventions; which involve an inventive step and; which are susceptible of industrial application in products that consists of or contains biological material or a process through which organic materials are produced, processed or used."[134] The Biotech Directive extends patent protection to all material except as stated in Article 5(1) and also defines Biological material as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.[135]

The scope of patents protection conferred by EU patent generally, covers products, processes, and products of processes of all inventions.[136] However, the patent laws in Europe do not cover conventional breeding patents be it the variety itself or the processes by which it is done. Articles 2(2), Art. 4(1)(b): Art. 4(3) Paragraph 1(b) Art. 53(b) EPC are the relevant provisions on the scope of process protection. *In particular, where it is based on the sexual crossing of whole genomes and the subsequent selection of plants, […], remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC.* The directive separates plant and animals improvements that are can be patented from other varieties through how the product concerned is achieved. A plant variety is mostly gained through biological processes (sexual reproduction observable in nature), whereas non-biological processes forming part of genetic engineering leads to transgenic plants and animals.[137]

Patents cannot be granted to biological processes that are considered essential within the EU. And this is in line with Article 27 of TRIPS which only compels members to grant patent

134

135 Article 2(1)(a) og the Biotech directive - definition of Biological material".

136 While Art. 8(2) of the biotech directive: Art. 64(2) EPC extend exclusion from patentability of essentially biological methods for the production of plants to the products directly obtained by such process, the EPO (Enlarged Board of Appeal) argues (as decided in G2/07 and G1/08) that exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have an adverse effect on the allowability of a product claim directed to plants or plant material such as plant parts.

137 In the action for annulment of Directive 98/44/EC, the applicants considered the patentability of plants and animals provisions unclear and ambiguous, and hence a source of legal uncertainty which justified an annulment of the Directive.

protection for non-biological processes.[138] However, through decisions G2/12, and G2/13 the EPO has affirmed that *product-by-process claim for plants or plant material other than a plant variety define as essentially biological process for the production of plants does not preclude such claim per se*.[139] But the enlarged board has ruled that products derived from essentially biological processes like plants or fruits are, therefore, can be granted patent protection even when they are developed from a process that is not patentable . [140]

The above notwithstanding Article 9 Biotech Directive defines the scope of protection for a product containing or consisting of genetic information as: "*However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability.*"[141]

Some commentators have argued that article 9 extends protection to all genetically modified material, except as limited by the two requirements of Article 5(1) - the product first is integrated into another material (plant), and second, the integrated genetic information must perform its stated function.[142] The European Court of Justice Decision court has, however, indicated that although genetic modification of a plant variety is not patentable, an amendment to the broad-spectrum, or species can be protected by a patent.[143] The same court in its decision on 10 December 2001, has also emphasized the granting of patents for inventions relating to a plant variety if they meet the conditions required.[144] The EBA of the EPO has ruled that in principle, plants can be patented if the technical features are not restricted to single plant

[138] *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.J. EUR-Lex L.E.X.I.S. 396 (2010).
[139]
[140]Monsanto Slammed for Violating European Patent Law for GMO .... https://www.ecowatch.com/monsanto-slammed-for-violating-european-patent-law-for-gmo-melon-1882159544.html.
Enlarged Board of Appeal (EBoA) in March 2015 on "broccoli and tomato II G2/12 and G2/13 .
[141] Minssen, T., & Nordberg, A. (2015). The Impact of "Broccoli II" and "Tomatoes II" on European Patents in Conventional Breeding, GMOs, and Synthetic Biology: The Grand Finale of a Juicy Patents Tale?. *Biotechnology Law Report*, *34*(3), 81-98.
[142] Conner, A. J., Glare, T. R., & Nap, J. P. (2003). The release of genetically modified crops into the environment: Part II. Overview of ecological risk assessment. *The Plant Journal*, *33*(1), 19-46.
[143] Points 44 and 45 of the judgment for annulment. Also The Enlarged Board of Appeal of the European Patent Organisation's decision of 20 December 1999 is based mutatis mutandis on the same considerations as contained in Directive 98/44/EC, viz.
[144] The Court rejected the arguments in Point 43 of the judgment and referred to the substance of Article 4 of the Directive,which lays down that a patent cannot be granted for a plant variety, but may be for an invention if its technical feasibility is not confined to a particular plant variety

variation.[145] This ruling implies that within the EU, plant inventions fall under patentable subject matters if that invention can be carried out on several plants.[146]

The CJEU ruled in the Monsanto case that genetic inventions contained in patented products must perform its duty in the material and not be merely present, in order to clarify the scope of the legal protection discussed on biotechnological inventions provided for in Article 9. That is, protection is limited to stated claims and the actual application of the stated claims. Consequently, European biotechnology patent protection is only valid provided that the function of the patented gene is congruent to its indication.[147] Accordingly, a claim to a DNA or genetic modification sequence is enforceable within the EU when the sequence is proficient in executing functions for which it was created.[148] Protection granted under Article 1(2) of Directive 98/44/EC is thereby not absolute. The escape clause that was possibly created by the case's ruling could have a high impact on companies like Monsanto, but some scholars have also suggested it will weaken the attempts for global intellectual harmonization.

Published patent applications, by the European Patent Office from 1995 to date indicate much higher applications in Genetically Modified plants than conventional forms, most of these patents have been secured under a utility patent. Utility patent was only open for cultivars in Europe from 2015. EU utility patent have breeders; exemption[149] France, Germany, Switzerland, and the Netherlands have breeders' exception in their utility patent even though some form of licensing may be needed.

In January 2018, the European Patent Office rescinded the CRISPR-Cas9 patent initiated by the US-based Broad Institute. The decision was based on whether the EPO had the power to decide on Broad's entitlement for priority since the patent originates from the US. By implication, the judgment on this case was likely to affect every industry that employs genetic technology scientifically. The impact of these rulings and the general position of the EU patent

[145] Monsanto Slammed for Violating European Patent Law for GMO .... https://www.ecowatch.com/monsanto-slammed-for-violating-european-patent-law-for-gmo-melon-1882159544.html. The legal definition for invention in Europe is based on the Bundesgerichtshof (German supreme court) in Red Dove X ZB 15/67, [1970] IIC 136, where the court decided that an invention comprising of teaching methodically to utilize controllable natural forces to achieve a causal, perceivable result that can be repeated an arbitrary number of times obtaining the same result each time and the breeding method in issue could not be repeated to produce a dove.
[146] Monsanto Slammed for Violating European Patent Law for GMO https://www.ecowatch.com/monsanto-slammed-for-violating-european-patent-law-for-gmo-melon-1882159544.html
[147] C-428/08 Monsanto Technology LLC, the judgment of 6 July 2010
[148] Biological inventions (Supplementary reading).
https://e-courses.epo.org/wbts_int/litigation/BiologicalInventions.pdf
[149] Initiated by the Plantum (umbrella organization for commercial seed companies in Netherlands)

can in no way be underestimated since EU rule-making affects other countries in immense ways.[150] The EU, in particular, has an Economic Partnership Agreement with Africa, in which stricter and enhanced IP updates that may not necessarily be conducive for promoting access to food, medicines, and development, in general, are drafted for African nations to consider.

3.2.1.3 AFRICAN PATENT.

Many African countries signatories to international treaties and bilateral agreements which have IP clauses that press for a broader patent scope, these treaties and agreements have generally shaped the IP regime in many African countries. Some researchers consider TRIPS and bilateral agreements like the US FTAs and EU's EPAs as the contributors of both the type and scope of patents protection in Africa even though the scope of patent protection seems to differ differs from nation to nation. Several studies on the region indicate that the majority of the countries in Africa granting patent protection for inventions are as a result of treaty obligation or trade agreements.

In accordance with the latitude that TRIPs give in Article 27(3)(b) of the TRIPS Agreement, several developing countries have excluded patents for plants varieties with the intention of providing sui-generis protection. But, TRIPS is unambiguous in demanding patent protections for GMOs. Many African states have been slow in acknowledging the presence of GM in their territories, let alone enact laws for them. Only a few countries that are into GM cultivation are also yet to finalize the regulations on them. Mauritius have a GMO act, but it makes no mention of intellectual property rights.

South Africa's patent laws exclude plant and animal varieties; however, the exclusion does not cover microbiological processes like plants modified through genetic engineering.[151] This exclusion, however, creates a situation where plants and plant products could be the subject of both patents and breeders' rights laws. This dual protection possibility can also be seen in the Ethiopian patents and breeders laws.

Some scholars have opined that patents are western in that they protect formal practices and do not recognize other farming practices and privileges in Africa and other developing countries yet even countries that are not under obligations are being influenced to follow suit. Ethiopia

[150] Acquah D. O. (2017) id
[151] Sileshi, B. (2012). The Possible Overlap between Plant Variety Protection and Patent: Approaches in Africa with Particular Reference to South Africa and Ethiopia. *Haramaya Law Review*, *1*(1), 125-136.

is not a member of TRIPS and is therefore not obliged to follow the provisions TRIPs demands, even though the country acceded to the WTO in 2003. Nonetheless, the patent and plant variety laws that Ethiopia legislated in 1995 and 2005, respectively grant patents that are similar to TRIPS rather than the African Union Model Law or the CBD, to which they are signatories to.[152] Table 3 shows the type of protection each nation offers.

3.2.2. SUI-GENERIS

"Plant breeding is a highly resource-consuming activity. It takes several years to develop a variety and requires a lot of financial resources, equipment, and skilled workforce" (Jördens and Button, 2011).

Although patent continues to dominate, the rationale for granting IP as a mechanism for encouraging developments of new plant material has led to many questioning the inappropriateness of patent protections for food on public interest grounds while advocating for other sui-generis forms of protection.[153] The term sui-generis refers to any "unique" system created to give protection, it gives room for flexibility in the scheme of plant variety protection. Sui-generis plant protection also gives a broader spectrum for policy alternatives since it can even include systems that acknowledge innovators, with or without compensation or individual monopoly rights.[154] A sui-generis IP system is, therefore, a set of rules designed to the particular features of the subject matter for which protection is being given.[155] It is a form of protection TRIPS suggests for protecting plant genetic material aside patents. Sui-generis are different from patents in may regards.[156]

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[152] A Proclamation Concerning Inventions, Minor Inventions and Industrial Designs Proc. No. 123/1995, NEGARIT GAZETA OF THE TRANSITIONAL GOVERNMENT OF ETHIOPIA [hereinafter Patent Proc.]; Plant Breeders' Right Proc. No. 481/2005, FEDERAL NEGARIT GAZETA [hereinafter Plant Breeders' Proc.]. also Ethiopia ratified the CBD on July 4, 1994, and UPOV on October 2, 2005. The country has also ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (2001).

[153] Batur, F., & Dedeurwaerdere, T. (2014). The use of agrobiodiversity for plant improvement and the intellectual property paradigm: institutional fit and legal tools for mass selection, conventional and molecular plant breeding. *Life sciences, society and policy*, *10*(1), 14.

[154] Pila, J., & Torremans, P. (2019). *European intellectual property law*. Oxford University Press, USA.

[155] Correa, C. M., Shashikant, S., & Meienberg, F. (2015). Plant variety protection in developing countries: A tool for designing a sui generis plant variety protection system: An alternative to UPOV 1991. *By: Association for Plant Breeding for the benefit of society (APBREBES) and its member organizations: Berne declaration, the development fund, SEARICE and third world network*.

[156] Protection offered is much less than a patent, even though it is less expensive, and the proof and documentation requirements are less intensive. The types of plants that can be protected are not limited as they are in plant patenting. And farmers can save and reuse seeds from protected plants or sell the seeds for use on other farms in

There are many forms of sui-generis protection as the nature of a sui-generis regime is based on the objectives and prevailing interests. The focal subject often alternates around themes like commercial or farmers' variety; the scope of rights conferrable; the conditions that applicants or rights holders must satisfy; and the recognition of farmers' rights as defined by ITGRFA. These are what Correa has identified as the distinguishing elements of the forms of sui-generis protection.[157] In this section, we look at the types of sui-generis protections available and how each is established in line with Correa's taxonomy. We discuss Plant Breeders' Rights, and Plant Variety Protections as against the Indian, and the African model of protections along the lines of coverage (new, extant, commercial, traditional, wild, farmers variety); protection requirements (novelty, distinctness, Uniformity and stability NDUS); rights conferred; rights holders. These elements form the basis of divergence between the UPOV model and the other sui-generis protection models.

3.2.2.1 PLANT BREEDERS' RIGHTS

Plant breeding programs based on conventional and biotechnological methods require massive investments, both in scientific intelligence and skills, and in economic terms, yet, once a variety is evolved, it is easier to reproduce, multiply or sell the seeds of the improved varieties without the knowledge or consent of the breeder. The concept of plant breeders' rights was thus introduced to strengthen compensation efforts for the commitments and investments. PBRs originated in developed countries where private companies have been essential players in plant breeding research, seed production and marketing.[158] Today PBRs are prominent within international agreement and variants of PBR can be found in different jurisdictions.

The Union for the Protection of New Varieties of Plants (UPOV) Plants Breeders Rights (PBR) system has been the default model many nations adopt in their implementation of a sui generis system of protection for plant varieties as required by TRIPS even though article 27 does not refer to any preexisting legal regime (Correa 2015). UPOV has two models of the sui-generis system , (the 1991 and 1978 models), and states that signed the GATT accord are obliged to

contrast to Article 14 which gives patentee rights to prevent others from producing or reproducing, conditioning for the purpose of propagation, offering for sale, selling or otherwise marketing, exporting, importing, and stocking for any of the purposes for the relevant plant materials.

[157] Correa M, id

[158] Tansey, G. (2011). Whose power to control? Some reflections on seed systems and food security in a changing world. *IDS Bulletin*, *42*(4), 111-120.

choose either the 1978 provisions or the 1991 Convention even though both systems differ on some core issues like farmers rights.[159]

UPOV's Plant breeders' rights are significantly different from patents. The requirement criteria for PBR protection are not rigorous, but the bounds of security or safety granted is quite narrow by way of the exclusive rights and the exceptions and limitations, unlike patents where the requirements that need to be satisfied before a product or process is eligible are high and challenging, albeit for the broader rights. A state may adopt either or both forms of protection depending developmental stage of its plant breeders' industry.

Under the UPOV Convention, the Novelty Distinctness, Uniformity, and Stability criteria are employed to confer exclusive rights to authorise the production or reproduction, cultivation, selling/marketing, exporting and importing, as well as the stocking for any purposes of propagating material of the protected variety,[160] for new varieties over a period 15 to 20 years, based on the type of species. PBR rights do not include traditional varieties, and the 91 model makes farmers' rights optional in article 15(2).

Currently, plant protection other than patents in several countries is based on the UPOV 91 model. Europe, for example, has a Plant Variety Rights Protection that stems from UPOV. Some states such as Thailand and India have, however, enacted versions of sui-generis systems for protecting all plant species and kinds, in compliance with the TRIPs but not necessarily UPOV standards (discussed in 3.1.2.2).[161] This is because many researchers argue that the UPOV, particularly the '91 Convention, is least suited for challenges in developing countries where the majority of the farmer are in the informal seed sector.[162]

3.2.2.2 PLANT VARIETY RIGHTS

Plant Variety Rights (PVR) are sui generis rights conferred on application to breeders of a particular strain of plant material. It is Europe's response to plant patent, and the natural system that evolved in Europe after Netherland and Germany gave breeders exclusionary rights in respect to new strains of plant material depending on the principle of minimum standards and

[159] Group, The Crucible. People, Plants, and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society, International Development Research Centre, 1994. ProQuest eBook Central, http://ebookcentral.Created from kutu on 2019-05-08 04:13:32.
[160] Article 14 lists the rights accorded breeders' under the UPOVconvention
[161] SSRN-id2619763.pdf India, 2001; Thailand, 1999.
[162] National and Regional Plant Variety Protection Legislation .... http://www.apbrebes.org/content/national-and-regional-plant-variety-protection-legislation-developing-countries

national treatment.[163] It is also the reason for the call for EEC members to exclude plant varieties from European patentability as in Article 2(b) SPC and Art 53(b) EPC. The PVR system in Europe without prejudice to the national property protection for variety makes room for a Community Plant Variety Rights (CPVR) system, and breeders must choose between the community and national PVR for any given variety.

PVR allows Union members to recognise new plant variety and requires them to grant breeders' protection on the plant genera and species they develop.[164] The subject matter protectable under CPVR is plant variety; however, a plant is legally defined in EU to include all botanical genera and species, varieties as well as hybrids between them.[165] A variety, on the other hand, means "plant grouping within a single botanical taxon of the lowest known rank".[166] Article 19 gives trees and vines 25 years of protection while other species receive 20 years of protection.[167] A subject matter is required to be capable of definition, distinction, and consideration as a unit to constitute a variety. This adds up to the overall demands of novelty and DUS (distinctness, uniformity, and stability) condition. Even though novelty here is derived from Article 10 of UPOV, it is different from novelty under European Patent law. The former uses commercialize instead of made available to the public.

In the Sakata case, an invention was explained to include not only new developments but the planting, selection, and growing of materials and its development that existed before it became a finished variety as well. The Keith Kirsten case also had the Board of Appeal expanding a variety to include when a person comes across a variety deliberately or by chance, so far as they are conscious that it was a new variety they did not know, and believe the variety to be unknown to other persons as well with or without commercial potential. The same variety can be independently discovered by two or more at the same time.

The CPVR gives exclusive rights similar to utility patents. These rights include the rights to "produce and reproduce, condition for propagation, sell, market, import and export to the

[163] Trommetter, M. (2010). Flexibility in the implementation of intellectual property rights in agricultural biotechnology. *European journal of law and economics*, *30*(3), 223-245.
[164] Article 3 of the PVP
[165] 1991 UPOV Convention Act
[166] Plant grouping consisting of entire plants or parts of plants as far as such are capable of producing entire plants (variety constituents); the expression of characteristics referred to in paragraph 2 of Article 5. Central to the definition is the reference to taxonomic rank, which restricts the subject matter for which CPRVs may be granted to plants positioned at the bottom of the taxonomic hierarchy, immediately beneath the rank of genus
[167] Article 1 of UPOV convention

Community" as well as the piling of a variety harvested. Article 13(2) and 13(5) makes the use of protected varieties in developing non-distinct and hybrid varieties an infringement.[168] However, article 13(8) to 15 of the basic rule tries to provide a balance between the rights of breeders on the one hand, and the interests of farmers and the broader society on the other. These exceptions and limitations articles make public morality, public policy or security, the health and life of humans, animals or plants protections, the protection of industrial or commercial property, the protection of the environment, or the safeguarding of competition of trade or agricultural production legitimate grounds for restricting the rights given to breeders. Article 15(1) also allow farmers to use in their fields propagating materials they get cultivation so far as they are not from a hybrid or synthetic variety.

Farmers privilege under PVR applies only to plants under art. 14(2) (rice, peas, beans, and rye), and even subject to obligations such as the equitable payment remuneration (except small farmers) of a reasonable amount below what the license holder would usually charge within the area.[169] According to the court of justice in case c-242/14 Saatgut-Treuhandverwaltungs GmbH v Gerhard und Jurgen Vogel GbR EU:c:2015:422, while the farmer need not pay the equitable remuneration to the holder in advance of planting the relevant farm-saved seed, nor does the period which she has for paying it to continue indefinitely. Instead, to be able to benefit from Article 14 privilege, the farmer must pay the remuneration before the marketing year for that planting season. Secondly, affected farmers and suppliers of processing services are required to provide information concerning the issues of art 14(3) when the CPVR holder asks.

Currently, most patent-related issues seem to be well resolved in the European context, but a number of concerns regarding plant protection remain hanging, the interface between patent and PVR in defining the scope of product protection is one of such, that is the patent regime to a large extent may be unambiguous since in practice plant varieties are within the scope of patents.[170] But since plant invention can either be protected by patent or PVR, many experts have argued for, at least clarifications, that better distinguishes between the areas of plants inventions that can be patented and plant variety rights, especially inventions relating to plants developed through an essentially biological process.

[168] Bart Kiewiet, Plant variety protection in the European Community, 0172-2190/$ - see front matter _ 2005 Elsevier Ltd. All rights reserved. doi:10.1016/j.wpi.2005.07.006
[169] Article 14(3) outlines two obligations
[170] Addressed in G1/98 see in particular Article 64 EPC; Article 4(2) and Articles 8 and 9 of the biotech directives

In the US, the Plant Variety Protection (PVP) is a certification process which gives breeders control on specific plant varieties invented or discovered. The PVP aims at protecting natural material. As such breeders' rights under PVP excludes “technical processes” employed in the production of the varieties, and therefore, do not extend to breeding methods or systems. While first-generation hybrid varieties are excluded under the act, plants that are propagated by seed and tubers, as well as F1 bacteria, fungi and hybrids all fall within the scope of the PVP

3.2.2.3 THE INDIAN MODEL

India in 2001 enacted the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR, this act established a system for protecting plant varieties, farmers and plant breeders. Its objective was to promote the development and cultivation of new plant varieties. Before the act, India’s patent and design laws (1970) considered all plant genetic resources as public property and did not assign any IP protection for pharmaceuticals, food, and agrochemicals and methods of agriculture and horticulture innovations. The PPVFR act was therefore in response to the Trips agreements requirements, in particular, Article 27.3(b). The PPVFR establishes a dual right system, first for the variety, and then the breeder. The rights granted under the PPVFR are heritable and can also be transferred to others only when the variety is registered.

The PPVFR combines the rights of both breeders and farmers, it protects breeders and at the same time, grants extensive rights to farmers. By this breeders/researchers are allowed to use a protected variety for further breeding/research, while farmers’ rights to sow, re-sow, sell or save seeds of protected variety from their harvest is also guaranteed. The act recognises farmers as cultivators, conservers of agricultural biodiversity, and breeders of plant varieties. It considers farmers as the custodian of the local variety or community as conservers and selectors of germplasms.

The general protection requirements of novelty, distinctness, uniformity and stability,[171] is not applied in all circumstances. The novelty principle, for example, does not apply to extant varieties according to Art 15(2) even though the other requirements must be satisfied; This significantly broadens the scope for to include varieties that have previously been commercialised or offered for sale.

The Indian act also differs with the UPOV on the coverage. It grants protection to categories of varieties, and the PPVFR applies to not only new plant varieties but also varieties developed

[171] Novelty, distinctiveness, and stability are the criteria for the PPVFR

by farmers' under the Extant (domestic and existing) Varieties umbrella. This variety includes plants or materials that have been propagated and developed commonly by farmers as well as the wild-relative or landrace varieties that farmers and the community, in general, have shared knowledge on.[172] Extant varieties/farmers varieties are usually accorded exclusive rights similar to that of new varieties, and given broader exceptions like the ways seeds could be reused, saved, use, sow, re-sow, exchange, share and even sell products, such as seeds of protected varieties.[173] In addition Essentially Derived Varieties (EDV), be it new or extant can be registered.

Breeders' are given 15 years protection term for field crops and 18 years in the case of trees and vines, subject to renewal fees and fulfilment of other condition. Notified varieties also receive fifteen years from the date it was applied for under section 5 of Seeds Act, 1966. A person selling, exporting, importing or producing protected varieties requires the permission of the breeder, failure to do so infringes on the registered license and therefore liable to a fine or imprisonment six months and three years. This also applies in cases where a denomination is deceptively similar or capable of being confused with the denomination of a registered variety.

Farmers on the hand are equally entitled to save, use, sow, re-sow, exchange, or sell produce they obtained from their farms even if they are seeds of a variety that has been registered unrestrictedly. Farmers' can also register their varieties, to secure the exclusive rights to produce, sell, market, distribute, import and export the variety. In addition, they are absolved from all fees relating to any proceedings. Again, in cases where a registered variety is unable to perform the function, it is expected to do, farmers have to the right to demand compensation. Efforts by communities that help to conserve or evolves any variety also need to be compensated when it is being used to develop other varieties.[174] All these rights, together with provisions relating to benefit sharing, can be enforced under Civil and criminal law.

Exception u/30 allows scientists and researchers to have access to the registered variety for experiment or research purposes. Registered varieties can also be used as a primary source of a variety for evolving other varieties without the prior approval of the breeder. However, one needs to seek the permission of the of breeder when developing a new variety for commercial

[172] Article 2(1)
[173] Dhar, B. (2002). Sui generis systems for plant variety protection. *Quaker United Nations Office, Geneva*.
[174] Community Rights (CR) (u/s26).

production involves using a parental line of a protected variety repeatedly. The PPVFR also permits compulsory license in the case where the price of a variety registered is restricting the public from having access .

In conclusion, the extensive liberties with respects to both farmers' and breeders' rights makes it incompatible with neither UPOV 78 nor UPOV 91 since farmers are permitted to sell seed of protected varieties. But India is a WTO member, and its PVPFR is, therefore, an alternative to UPOV that other WTO member can emulate for plant variety protection. The Indian Act is the first in the world to give formal rights to farmers without jeopardising the rights of researchers and breeders.

3.2.2.4 THE AFRICAN MODEL

In 2000, the OAU developed a model that sought to give directions to sovereign states on how to approach plant varieties protections in a way that traditional and indigenous technologies complemented by appropriate modern technologies can be promoted and supported. This model specifically aimed at preventing encroachment into the realm of community livelihood systems in Africa and following the obligations of TRIPS 27(3) for a sui-generis option on one hand and upholding Africa's commitments under the CBD on the other.

Under the African Model, PBRs are formulated in such a way that traditional community innovations and propagating methods are not subverted by modern practices of commercial nature. It protects the rights of breeders, farmers, and communities. The model prioritises access to biological resources by acknowledging that communities have rights over the natural resources, knowledge and technology that they have been developed over generations. And that these endogenous resources are the collective right of the people which takes preeminence over other private rights. It, thus, shares similar objectives with the Indian model and contradicts the aim of international and regional trade and IP organisations in Africa for the establishment of a harmonised PVP law based on UPOV '91.[175]

Premised on the fundamental understanding the survival of all humanity depends on life which is fundamental human right as in Article 9, the model does not allow patents on life nor the exclusive appropriation of parts or derivative of it.[176] Article 28 defines breeders' rights and

[175] Oguamanam, C. (2018). Plant Breeders' Rights, Farmers' Rights and Food Security: Africa's Failure of Resolve and India's Wobbly Leadership. *Indian Journal of Law and Technology, Forthcoming*..
[176] Article 9. *Patents over Life Forms and Biological Processes*

accord it with protection duration term similar to the UPOV standards; however, it departs from the NDUS criteria for protection and sets its protection requirement under Articles 25(2) and 29.[177] With emphases on *Specific attributes identified* by a community as the protection requirement, this model disregards the NDUS criteria. Correa has noted that the unclear nature of the attributes that should be considered and how they are to be determined could cause many ambiguities and competing on claims to ownership.

Breeders' Rights under the African model, however, are restricted by conditions under Farmers' Rights in respect of a plant variety, they also require higher approval criterion that involves statistically valid, multi-locational trials for plant varieties originating from outside a country.[178] Farmers right as in Article 24 is discussed in section 3.3.2.1 of this paper. The model also recognises, protects and supports the natural rights that local communities have like farming practices and IP rights; it provides a system that will facilitate access to biological resources. Moreover, technologies that are derived from the knowledge and traditions of communities must have the consent of that community and the State.[179]

So far, it is yet to be known the number of countries that have taken inspiration from the African model. Correa has noted that this model has not been incorporated into national legislation of member countries. Zambia's attempt to legislate a bill that combined breeders rights and farmers rights in line with the African Model and the ITPGR for example first saw the isolation of both rights and then the passage of only the breeders' rights akin to the UPOV due to international pressures for reasons that the breeders' rights were more urgent. In effect, the Zambian model that began as sui generis bill has no specific provisions on farmers varieties

1) Patents over life forms and biological processes are not recognised and cannot be applied for.
2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.

[177] Article 25(2) A variety with specific attributes identified by a community shall be granted intellectual protection through a variety certificate which does not have to meet the criteria of distinction, uniformity and stability. This variety certificate entitles the community to have the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use without prejudice to the Farmers' Rights set out in this law.

[178] Artile 43 of the African Model

[179] Article 23 *Recognition of Community Intellectual Rights* The Community Intellectual Rights of the local communities, including traditional professional groups, particularly traditional
practioners, shall at all times remain inalienable, and shall be further protected under the mechanism established by this legislation. And argues in clause 3 that Non-registration of any community innovations, practices, knowledge or technologies, is not to mean that these are not protected by Community Intellectual Rights.
4) The publication of a written or oral description of a biological resource and its associated knowledge and information, or the presence of these resources in a genebank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources.

due to constant pressure from private seed developers, international UPOV and external seed companies.[180] This example exposes the enormous role of foreign influence and domestic pressure from seed companies in the enactment of the law process. The African model can still be an inspiration going forward.

In conclusion, tour African countries, aside from the 17 nations that the African Intellectual Property Organization (OAPI) plant breeders' rights system covers have acceded to the UPOV convention.[181] This means that the majority of the countries in Africa that seeks to protect plant variety by means other than patent and are not members of UPOV have the privilege to develop their form of protection along with the African model. The reality, however, is that countries like Ghana, and Malawi who are not members of UPOV, in spite of widespread criticism and protests, have modelled their Plant variety protections along UPOV lines and without fully exploring Trips flexibilities.

There is yet to be any nation in Africa that has modelled its sui-generis protections along with the Indian model. It is also important to note that even though many countries in Africa have tailored their sui-generis protection along the UPOV lines, there are still marked differences between them. Correa has, for instance, indicated that Kenya allows plant breeders' rights to all plant genera and species except algae and bacteria, the laws in Egypt makes it mandatory for the origin of the breeding material and the source of the knowledge used in developing the variety must be revealed. No African state has developed a model unique enough for acknowledgement and replication.

The sui-generis law in itself may not be the solution especially as external pressure do force farmers to abandon the set standards for higher ones in order to gain access to international markets etc. however, Correa has listed of expected elements of a good sui-generis as equity, conservation, preventing misappropriation, dissemination of knowledge, farmers rights, incentive. These elements were deduced from comparing the available sui-generis protection and the rationale for their demand. The potential conflict in policies and regulations like the acknowledgement of Farmers' Rights as expressed in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) has also led to calls for the continent to develop its sui generis protection that will focus on local variety and practices.

[180] Mwila, G. (2016). 17 Commentary on the Zambian Plant Breeder's Rights Act. *Farmers' Crop Varieties and Farmers' Rights*, 319.
[181] Member States of OAPI: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo

3.2.2.4 THE AFRICAN MODEL

In 2000, the OAU developed a model that sought to give directions to sovereign states on how to approach plant varieties protections in a way that traditional and indigenous technologies complemented by appropriate modern technologies can be promoted and supported. This model specifically aimed at preventing encroachment into the realm of community livelihood systems in Africa and following the obligations of TRIPS 27(3) for a sui-generis option on one hand and upholding Africa's commitments under the CBD on the other.

Under the African Model, PBRs are formulated in such a way that Africa's long tradition of community innovations and breeding are not undermined by new norms of commercial nature. It protects the rights of breeders, farmers and the Local Communities. The model prioritises access to biological resources by acknowledging that the rights of local communities over their natural resources, knowledge and technology that have evolved over generations are a collective nature and is, therefore, are a priori rights which takes precedence over rights-based on private interests. It, thus, shares similar objectives with the Indian model and contradicts the aim of international and regional trade and IP organisations in Africa for the establishment of a harmonised PVP law based on UPOV '91.[182]

Premised on the fundamental understanding that all forms of life are the basis for human survival and a fundamental human right as in Article 9, the model prohibits the patenting of life or exclusively appropriating any life form or part or derivative thereof.[183] Article 28 defines breeders' rights and accord it with protection duration term similar to the UPOV standards; however, it departs from the NDUS criteria for protection and sets its protection requirement under Articles 25(2) and 29.[184] With emphases on *Specific attributes identified* by a community as the protection requirement, this model disregards the NDUS criteria. Correa has noted that

[182] Oguamanam, C. (2018). Plant Breeders' Rights, Farmers' Rights and Food Security: Africa's Failure of Resolve and India's Wobbly Leadership. *Indian Journal of Law and Technology, Forthcoming*..

[183] Article 9. *Patents over Life Forms and Biological Processes*

1) Patents over life forms and biological processes are not recognised and cannot be applied for.

2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.

[184] Article 25(2) A variety with specific attributes identified by a community shall be granted intellectual protection through a variety certificate which does not have to meet the criteria of distinction, uniformity and stability. This variety certificate entitles the community to have the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use without prejudice to the Farmers' Rights set out in this law.

the unclear nature of the attributes that should be considered and how they are to be determined might lead to significant uncertainty and competing claims about ownership.

Breeders' Rights under the African model, however, are subject to the conditions provided in the Farmers' Rights in respect of a plant variety, they also require higher approval criterion that involves statistically valid, multi-locational trials for plant varieties originating from outside a country.[185] Farmers right as in Article 24 is discussed in section 3.3.2.1 of this paper. The model also recognises, protects and supports the inalienable rights of local communities including farming communities and their IP rights by providing an appropriate system of access to biological resources, community knowledge-based technologies are subject to the prior informed consent of the State and the concerned local communities.[186]

So far, it is yet to be known the number of countries that have taken inspiration from the African model. Correa has noted that this model could not make its way into the national legislation of member countries. Zambia's attempt to legislate a bill that combined breeders rights and farmers rights in line with the African Model and the ITPGR for example first saw the isolation of both rights and then the passage of only the breeders' rights akin to the UPOV due to international pressures for reasons that the breeders' rights were more urgent. In effect, the Zambian model that began as sui generis bill has no specific provisions on farmers varieties due to constant pressure from private seed developers, international UPOV and external seed companies.[187] This example exposes the enormous role of foreign influence and local pressure from seed companies in the enactment of the law process. The African model can still be an inspiration going forward.

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[187] Mwila, G. (2016). 17 Commentary on the Zambian Plant Breeder's Rights Act. *Farmers' Crop Varieties and Farmers' Rights*, 319.

[188] Member States of OAPI: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo

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3.3 IPR RELATED ISSUES

3.3.1 FARMERS RIGHTS

The concept of farmers' rights was advanced to counter-balance the property-based response to the imbalance between Northern intellectual property rights and rights of Southern farmers; it aims to vest quasi-intellectual property rights in the latter.[189] Over the years, IPRs in agriculture have been conferring rights on Northern actors while the contribution of Southern

[189] Thampapillai, D. (2015). The Food and Agricultural Organization and Food Security in the Context of International Intellectual Property Rights Protection. *Legal Perspectives on Security Institutions, Cambridge University Press (2015)*, 269-291.

farmers has gone uncompensated.[190] Within the same period, international trade has affected domestic farming by disrupting traditional farming practices and jeopardising food security. Accordingly, farmer's rights are often advanced to recognise the contributions of farmers to plant genetic resources development and conservation as well as food security. [191]

The first international instrument to effectively allude to farmer's rights is the non-binding agreement on Plant Genetic Resources, developed by the Food and Agricultural Organisation in 1989. It's Resolution 5/89 brought farmer's rights within the framework of International Undertakings. This came about as the Global South sought for an open-access approach to plant genetic resources that will counteract the Breeders' Rights created by UPOV. However, the Resolution and the original text of the agreement embodied two separate approaches to farmer's rights. The first being the common heritage of humankind stated in Article 1 of the Undertaking, and the second, the privilege or property-based approach that linked farmer's rights to new IP concepts like traditional knowledge. While the former benefits farmers by preserving access and diversity, the latter method provides a basis for farmers to either receive compensation for their efforts or to be afforded concessions relative to traditional farming practices.[192]

The clear difference between western IP and FR is the former lacks the level of enforceability within intellectual property rights. This inadequacy provides food security institutions such as the FAO with a limited range of policy options that they can feasibly pursue. Besides, the non-binding Resolution 5/89 did not specifically define Farmers' right even though FR generally include the right to save, replant and share seeds. These shortfalls made the undertaking an inadequate mechanism for achieving the farmer's rights. Nevertheless, the International Undertaking did influence the drafting of the CBD, and the access and benefit-sharing scheme in the ITPGRFA. The absence of any specific definition of farmer's rights, in turn, impacts upon the content of the rights.

Article 9 of ITPGRFA provides the legal recognition of the concept of farmer's rights, more effective than the International Undertaking or FAO Resolution 5/89. These rights are fundamental to traditional smallholder and subsistence farming. However, while there is some

[190] Cullet, P., Germann, C., Nascimento Muller, A., & Pasadilla, G. (2006). Intellectual property rights, plant genetic resources and traditional knowledge. *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*, 112-151.
[191] Oguamanam, C. (2006). Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous and Local Communities. *Drake J. Agric. L.*, *11*, 273.
[192] ibid

clarity in ITPGRFA as to the form and manner of farmer's rights, the problem of how those rights are to be given effect within international economic laws and treaties like TRIPS lingers. The informal nature of the practices means farmers find it hard to meet specific standards like stability and uniformity set by regimes like UPOV because varieties developed farmers are less stable over time.[193] Some scholars have argued for alternative standards since the strict application of the NDUS requirements often leads to farmers' varieties unqualified for protection.[194]

Farmers rights under India gives the farmer the normal rights to use, sow re-sow, share, exchange, or sell produce from their farms.[195] In addition, farmers are allowed to save but are not allowed to sell branded seed of varieties that are protected under the law. It also sets farmers not only as conservation agents but allow new varieties they develop to be registered and protected in like manner as a breeders' variety,[196] complemented by juicy incentives like exemption from paying fees for registration of farmer's varieties, conducting DUS test, renewal of farmers variety, a fee for the opposition and benefit-sharing claim and no charges in court and administrative proceedings. The act further gives farmers the rights to hold breeders accountable for what they sell. That is getting compensation for the loss caused by poor quality seeds. It also has provision to protect farmers from spurious seeds, unfair marketing practices and exaggerated claims by seed companies and disregard rights for claiming compensation if the breeder willfully and knowingly fails to disclose the actual identity or parental line or knowledge while registering. Farmers are, however, not allowed to sell protected varieties as branded seeds (packaged, labelled in a way that shows that seed is of a variety protected under the act.

However, under the Africa model (articles 24-27), Farmers' Rights recognises Farmers' varieties and breeds and protects same way and manner as the customary practices and laws protect them in their localities, be it formal or not, so far as there are specific attributes peculiar to that community.[197] The DUS criteria do are not applied to farmers rights. And Intellectual protection is granted through a variety certificate which gives community to the exclusive

[193] Correa M. id
[194] Genetic Resources Policy Initiative, 2006, 20-21
[195] Who Will Defend The Indian Farmers' - dailyexcelsior.com. https://www.dailyexcelsior.com/who-will-defend-the-indian-farmers/
[196] Article 39
[197] Biodiversity and the Law - docshare.tips. http://docshare.tips/biodiversity-and-the-law-_576253f9b6d87f3b878b495c.html

rights to save, cultivate, exchange, use, sell or to license a variety's use without prejudice to the Farmers' Rights.

Section 25 in particular accord farmers, individually or collectively, the rights to save, use, exchange and sell farm-saved seed/propagating material of farmers' varieties and even the use of a new breeders' variety protected to develop farmers' varieties. This includes materials from gene banks and plants genetic resource centres.[198] However, farmers are prohibited from putting on sale materials of varieties that are protected under the law on a commercial scale. The Act further limits Breeders' Rights on new varieties on the basis of safeguarding the environment, food and health needs of the people and their communities.[199]

UPOV since 61 allowed farmers to use material they have harvested from protected variety produced in their field for planting without any obligation to the PBR titleholder. This exemption is called the farmers' privilege. The 91 initially didn't mention this, but due to strong opposition, this privilege has been made optional and left members national laws. The privilege only applies to use in one's field and does not extend to seeds produced by another farmer. Hence does not permit of the seed of protected varieties to be exchanged. About 70% of farmers in developing countries depend on seeds produced by farmers, are poor, illiterate and succumb to economic burden if they are forced to pay royalties on seeds they produce and use. Many researchers have regards farmers privilege as different from farmers rights since it has a very narrow scope.[200]

3.3.2 THE CHALLENGES OF IPR IMPLEMENTATION

The introduction and implementation of IPR face many challenges. And from the above, IP in food has not been any different, not to recount the peculiar resistance that GM faces. Some scholars have argued that the current IP system shows serious flaws, which become more apparent when global resources and the developing world are considered. The way GM has been treated by some courts, international bodies and treaties threatens the equitable distribution of resources, biodiversity and the effects on culture and economies of many nations

[198] FNI report 7-2006 - Farmers Rights http://www.readbag.com/fni-no-docpdf-fni-r0706

[199] Recognising the need to conserve the rich biodiversity of https://www.coursehero.com/file/p6bb4cv/Recognising-the-need-to-conserve-the-rich-biodiversity-of-the-continent-the-OAU/

[200] Esteva, G., & Prakash, M. S. (2014). *Grassroots postmodernism: Remaking the soil of cultures*. Zed Books Ltd..

The issues of biopiracy, contamination, licensing, and infringements that IPRs raises threatens the status quo in which farmers who have total control over are the centre of the system, customary practice, access to seed and decision making. Farmers today on top of the restrictions IP comes with have to face the rigid and standardised quality control system designed for large companies if they want to participate in commercial seed production, and this is a huge obstacle. This section attempts to look at how these issues of plant-related IPRs in Africa are framed with possible remedies.

BIOPIRACY is the highly unethical practice where individual and other entities through IPRs commercialise biological materials like plant genetic resource from various countries without compensation. It is often defined as *"the acquisition of biodiversity, be it biological material like plants, animals, microorganism, and their parts, or of traditional knowledge related to that biodiversity, without the prior informed consent of those whose biodiversity or traditional knowledge has been taken"*.[201] Biopiracy is a significant concern in many developing countries and a core part of the IPR resistance movement. But proving biopiracy has been a challenge primarily because contracts with researchers and bioprospectors are usually not public, making the verification of claims difficult even when they are stated patent claims. One can, therefore, not be sure that rules of access and benefit-sharing are mandatory for bioprospectors or their agents.

Monsanto's melon patent, for example, was considered as an act of biopiracy which violated the Indian law and international treaties because the patented resistance feature was not invented by Monsanto, instead just discovered in an Indian melon.[202] The Hoodia biopiracy example where the exclusive rights to the appetite suppressant technology that is based on the traditional knowledge of the people of San, which was developed and patented by the South African Council for Scientific and Industrial Research (CSIR) were awarded epitomised how benefit-sharing and prior informed consent can fail in Africa.

LICENSING - Given the nature of the Plant genetic industry, most IP holders in the GM industry usually resort to licensing instead of an outright sale because of the unique reproductive qualities. Patenting a plant is similar to licensing any other new, or novel

[201] Heong, C. Y. (2006). New report points to widespread biopiracy in Africa. *THIRD WORLD RESURGENCE*, *186*, 17.
[202] Laursen, L. (2012). Monsanto to face biopiracy charges in India.

invention and product since a royalty goes to the nursery or entity that owns the patent each time the patented plant variety sells.[203] Currently, there is a variety of licensing agreements that may be voluntary where the patent holder dictates the terms or Non-voluntary (Compulsory licensing as a mechanism for access to food is discussed further in chapter four of this paper) where lower royalties and transaction costs are offered. Each licensing agreement has its benefits and challenges. A cross-licensing, for instance, is most attractive in complementary patents and blocking patents cases but may not be appropriate for other situations

Companies like Monsanto have different contractual relationships with different types of farmers where farmers who use the seeds are held by *express license restrictions on seed bags, often called bag-tag-license or seed-wrap license*. Certain licensing agreements prevent farmers from carrying out some inveterate practices for profit maximization purposes. Some of the agreements specify that the seed can be used to produce food and feed; such agreements do not permit farmers to save seeds nor replant them after harvest, but rather, they must sell the leftover seed as food or feed and replant.[204] This type of license is likely to cause serious issues in Africa since the norm for most farmers is saving seeds for replanting the following year.

Licensing is a common method used when research exemptions are inadequate. With it, both the license holder and licensee have enough freedom to draft contracts that addresses their issues of interest so far as they are not anti-competitive in nature. However, licensing often tends to limit the rights of farmers who procure license seeds since they can only do things permitted under the license agreements; the license agreements are usually narrower than sales agreements. Even though a one-to-one licensing mechanism is a non-rigid model that leaves room for custom-made use and access in special cases, Overwalle G. (2006) has observed that users are usually the weaker party when negotiating licenses because they do not have assets to offer in return.[205]

INFRINGEMENTS AND LIABILITIES. When the terms of a license are breached, or other IPR infringement happens, the patentee has the right to commence legal action against anyone or bodies who infringe their patents. Exploiting protected materials without the consent of the

[203] Plant Patent | UpCounsel 2019. https://www.upcounsel.com/plant-patent
[204] Jay P. Kesan, (2006) *Licensing Restrictions and Appropriating Market Benefits from Plant Innovation*, 16 Fordham Intell. Prop. Media & Ent. L.J. 1081. Available at: https://ir.lawnet.fordham.edu/iplj/vol16/iss4/3
[205] Van Overwalle, G., Van Zimmeren, E., Verbeure, B., & Matthijs, G. (2006). Models for facilitating access to patents on genetic inventions. *Nature Reviews Genetics*, *7*(2), 143.

owner or performing other acts which may lead to infringement. Articles 44,45,46, and 51 of TRIPS concerns violations of IPRs, these articles specify that members have civil, judicial, and administrative procedures that IPR holders can access in cases of infringements. The system should include remedies to prevent breaches (injunctions), fix damages caused by violations and provide solutions that deter others like fines and forfeitures. Several countries around the world have therefore instituted measures to protect IPRs from violations; however, for many African countries, improving IP systems to suit TRIPS standards comes with substantial financial costs and regulatory burdens.

The main infringement case in the EU has been in Lemon Symphony X ZR 14/07 interpreted Article 13 as extending CPRV beyond the area of protected variety's identity to the area of further tolerance covering its natural or expectable variation. In Melanie X ZR 93/04, the German supreme court decided that the whole plants cannot be seen as harvested material within the meaning of Article 13 since their production does not require any act of harvesting. The ***Monsanto Canada Inc v Schmeiser*** [2004] 1 S.C.R. 902, 2004 SCC 34 deals with innocent infringers. Some have suggested that even though the law demands permanent injunction in infringement cases, innocent infringements and situations where public interest like food security is at stake ought to be exempted. This is particularly important for innocent farmers who violate IPRs unknowingly.

Even though not many Infringements cases have erupted from Africa because the large portion of farmers is yet to diversify, the farming practice is likely to encourage infringements as more protected materials makes its way into the system. The light of the infringement and liability loophole that the pollen-drift case created has called for the need for assessment of the current system in view of the objectives of improving food security and safeguarding the ecosystem, which can be better achieved by encouraging containment. Luckily, the India PPVFR act protects innocent infringement and deems acts of breaches by farmers who genuinely were unaware that the infringed rights occurred when the violations happened as not unlawful.[206]

The debate on how to deal with innocent infringement also brings to the fall the use of Genetic Use Restriction Technology (GURTS). This terminator technology as some calls it was introduced by the seed companies whose bid to protect the returns for their investment, often through contracts that forbid farmers from planting the seeds after harvest failed, particularly in areas where the framework for guaranteeing such protections did not exist. GURT renders

[206] Section 42 in The Protection of Plant Varieties and https://indiankanoon.org/doc/1567805/

harvested seeds virile and not capable of reproducing after one season, or in some cases, "unless sprayed with specific chemicals that activate the right gene." With this technology, second-generation seeds lose the defining characteristics of the original seeds. However, the efficiency of GURT is often counteracted by its effects on the age-old rights of farmers to save seeds for planting and selling in later seasons, Hahn, R. (2012).[207]

Today, many leading seed companies have refrained from GURT, especially after the measure was withdrawn by several international bodies indicted the measure,[208] some continue to argue for it mainly because of the potential of resolving innocent infringements and the inability of some IPR systems to provide enough or cannot effectively enforce contractual clauses. The CBD of the UN by convention bans GURT.[209] UPOV also believed that there are sufficient measures in Conventions and its system to "protect intellectual property rights and that with proper legal protections in place, technologies like 'terminator genes' should not be necessary."[210]

[207] Hahn, R. (2012). Transgenic Crops in Developing Countries-Can New Business Models Make a Difference in Fostering Sustainability and Mitigating Non-Technological Risks from Innovation?. *International Journal of Business Insights and Transformation*, *4*, 30-37.
[208] Oguamanam, C. (2005). Genetic use restriction (or terminator) technologies (Gurts) in agricultural biotechnology: The limits of technological alternatives to intellectual property. *Canadian Journal of Law and Technology*, 59-76.
[209] Lieberman, S., & Gray, T. (2008). The World Trade Organization's Report on the EU's Moratorium on Biotech Products: The Wisdom of the US Challenge to the EU in the WTO. *Global Environmental Politics*, *8*(1), 33-52.
[210] In April 2003, the Convention on Biological Diversity asked the UPOV for comment on the use of Genetic Use Restriction Technologies.

4.0. ACCESS TO FOOD WITHIN THE GM-IP

The problem of food security threatens the health and lives of millions of people in the Global South, while the reasons may be complex and inter-related, access, availability and affordability are crucial points that cannot be circumvented in any discussion.[211] The FOA since 1991 has been consistent in their observations that, world food security is becoming less of a global supply problem, overall stability, and global stock levels, to the challenge of inadequate access to food supplies by the poor and vulnerable groups within a country, caused among other things by lack of purchasing power.[212]

Many researchers point to the changes that agricultural investments witnessed as the roots of the challenge with access to food. Hitherto, new developments were introduced by public institutions and funds, but today, improved ways are generated by private entities who need IPRs in order to secure the returns on their investments.[213] The limited monopoly rights IP confers on food in the form of plants, and animal varieties protections enable IPR holders to determine the price of food, often beyond the budget of the poor, in order to recover their investments. This practice, in effect, raises more significant challenges for access to food and food security since food security. Food security is realised "*when all people at all times have access to sufficient, safe, and nutritious food to maintain a healthy and active life*."[214] Within the context of IP, access to food involves measures that will make protected contents more available to the public. And it involves limiting the monopoly on improved varieties, be it GM or Non-Gm, assigned to rightsholders.

Today, many African countries are not only assuming stronger standards of intellectual property protection in their 'development agendas', but also more extensive harmonisation of

[211] Naseem, A., Spielman, D. J., & Omamo, S. W. (2010). Private-sector investment in R&D: a review of policy options to promote its growth in developing-country agriculture. *Agribusiness*, *26*(1), 143-173.
[212] Ullah, A., Khan, D., Zheng, S., & Ali, U. (2018). Factors influencing the adoption of improved cultivars: a case of peach farmers in Pakistan. *Ciência Rural*, *48*(11).
[213] Clancy, M. S., & Moschini, G. (2017). Intellectual property rights and the ascent of proprietary innovation in agriculture. *Annual Review of Resource Economics*, *9*, 53-74.
[214] World Health Organization Jan 11, 2018, Introduction to Food Access, Food Security, and Food .... https://serc.carleton.edu/integrate/teaching_materials/food_supply/student_materials/1063

standards.[215] While this could be of immense benefit as many argue, the likelihood of it negatively affecting access to food and food security, in general, exists equally.[216] Many researchers, therefore, emphasize that granting IP protection should focus on improving food security and access to food in the long-term.[217] As such, defining the right scope for private rights while safeguarding the concerns of the public when it comes to food security matters should be the primary consideration. Maximising the flexibility for policy space within treaty obligations when adopting IP protection for plants and food material, in general, becomes essential for nations since IPR is now a must globally.

In this chapter, we focus on access to food by looking at how countries have approached the concept of access to food as defined and within the context of Intellectual Property rights by examining and comparing the legal protection for access to food. Since most international treaties operate by establishing legal standards for member states to implement within their territories, the specific requirements, tools, and space for national policy manoeuvres that are available will be perused as we look at how countries in Africa have shaped their regulations in this regard.

The discussion that follows thus focuses on access to plant materials that are protected by the various IPRs; we first look at what access to food means and examines whether food security is a sufficient element in invoking relevant clauses of exceptions in treaties. We then look at the flexibilities or policy space offered by agreements to states and how it is affected by the type of protection provided by nations as a result of national obligations. Before examining and comparing the legal regimes that some African countries have adopted to approach the concept of access to food through the incorporation of the treaty flexibilities in their national laws and then conclude on the effects of legal protection chosen.

[215] Isiko Štrba, S. (2017). Legal and institutional considerations for plant variety protection and food security in African development agendas: solutions from WIPO?. *Journal of Intellectual Property Law & Practice*, *12*(3), 191-205.
[216] Rapp, R. T., & Rozek, R. P. (1990). Benefits and costs of intellectual property protection in developing countries. *Journal of world trade*, *24*(5), 75-102.
[217]Id Isiko Strba, S

4.1. What is access to food? Does IPR restrict access?

Access to food is one of the four elements that need to be addressed to ensure food security. it usually refers to how affordable food is, how they are allocated, as well as, individuals and households choices.[218] The 2001 State of Food Insecurity Summit added the concept of social access to food while the CBD highlights access to genetic resource and benefit-sharing as a way of ensuring equity.[219] The World Health Organization also considered both physical and economic access to food that satisfies the peoples' dietary needs and choices in the definition of access, and have subsequently employed many strategies to prioritise and improve access.[220] Today access to food is "*Determined among consumers by the spatial accessibility and affordability of food retailers - specifically such factors as travel time to shopping, availability of healthy foods, and food prices - relative to the access to transportation and socioeconomic resources of food buyers*".[221]

Since food access is a fluid condition of human consumers, its impact on every person may be different at all times. The issue of access to food manifests differently to people and in places. In low-income areas, it comes as the difficulty in accessing healthy and affordable food retailers that is within reach of one's budget. Getting food that the people are accustomed or have the right nourishing ingredients to eat is also a consideration under access. To both full-time and part-time farmers in many farming communities across Africa, access to food comes in the form of the ability to produce and store enough food year in year out, and this is dependent on factors like access to improved seeds and planting materials.[222] Access to food in Africa, therefore, goes beyond the proximity to food, it includes having access to the inputs (high-yield seeds varieties fertilisers, pesticides,) and technology irrigation, as well as the advantages of specialized crops and large scale farming brings, to the production of food.[223]

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[218] Ericksen, P. J. (2008). Conceptualizing food systems for global environmental change research. *Global environmental change*, *18*(1), 234-245.
[219] Lawson, C., & Downing, S. (2002). It's patently absurd—benefit sharing genetic resources from the sea under UNCLOS, the CBD and TRIPs. *Journal of International Wildlife Law and Policy*, *5*(3), 211-233.
[220] Gregory, P. J., Ingram, J. S., & Brklacich, M. (2005). Climate change and food security. *Philosophical transactions of the Royal Society of London. Series B, Biological sciences*, *360*(1463), 2139–2148. doi:10.1098/rstb.2005.1745. In 2009
[221] https://serc.carleton.edu/integrate/teaching_materials/food_supply/student_materials/1063
[222] ibid
[223] Taylor, M. R., & Cayford, J. (2003). American patent policy, biotechnology, and African agriculture: The case for policy change. *Harv. JL & Tech.*, *17*, 321. African farmers often face difficult growing conditions, and better access to the basic Green Revolution tools can play an important role in improving their productivity.

The current concept of access to food evokes elements that challenge the status quo and provoke governments to be more active in improving access to food in ways that were never conceived. IP as alluded earlier affect access to food in a much severe yet subtle way. It restricts the amount of food that can be produced in the first place, impedes research and in some cases acts as a tool for appropriating agriculture genetics.[224] This is because many of the practices that are done by farmers and others in the cultivation and production of food are restricted by IPRs. An example is how some IPRs hinders the practice whereby farmers replants seeds they harvest from their farms. The use of seeds for breeding improved varieties or research is nowadays also hugely affected by IP.

Some experts have argued that access to food is a fundamental human right under the right to food, which takes priority to many other rights including the IP which is currently one of the main hurdles that obstruct the access to GM foods in particular.[225] Others also maintain that IP in and by itself promotes access since it incentivises and encourages developments that lead to efficient methods and higher output, but the overwhelming majority maintain that IP restricts access to food. And that human rights, and specifically the right to food, is a counterbalancing measure between the need to reward contributions of right holders and the interest of the public in terms of a providing an unceasing food flow.[226] They believe the right to food should guarantee the rights of people to feed themselves in dignity through the provision of enough food that adequately satisfy individual needs.[227]

Right to food as a concept is again a response to the challenges food insecurity places three levels of obligations on states under Article 11 of the International Covenant on Social,

[224] Oguamanam, C. (2006). Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous and Local Communities. *Drake J. Agric. L.*, *11*, 273.
[225] Cullet, P. (2004). Intellectual property rights and food security in the south. *J. World Intell. Prop.*, *7*, 261.
[226] The right to food obliges governments to help people who genuinely cannot get access to food. Under the General Comment no. 12 of the Committee on Economic Social and Cultural Rights (CESC) the *states obligation* is to respect and not arbitrarily prevent people from having access to food; take measures that *protects* and ensures that enterprises or individuals do not deprive individuals of their access to adequate food; *fulfill* (facilitate and provide) by proactively engaging acts that people's access to and utilization of resources and means to ensure their livelihood, including food security.
[227] This right is derived from the International Covenant on Economic, Social and Cultural Rights. the right to food is applicable in 106 countries either via constitutional arrangements of various forms or via direct applicability in law of various international treaties. Right to food is protected under international human rights (art 25 of the Universal Declaration of HR, Art 11of international covenant on economic, social and cultural rights) and humanitarian law. African charter on the rights and welfare of the child, African commission on human and peoples right 2001, and the protocol to the African charter on human and people's rights on the rights of women Maputo protocol art 15). European common agricultural policy and the new common food and Agric policy considers food as a universal human right, and not merely a commodity.

Economic and Cultural Rights: first, the responsibility of preserving existing channels that ensure access, this includes avoiding acts that would jeopardize the current practices that ensure access; second, an obligation to safeguard access to food; and third, an obligation to fulfil the right to food conditions.[228] In the context of seed policies, suggestions have been made that when states allow patent holders to exercise their rights in ways that detrimentally affect farmer's rights in cultivation practices, including access to gm/plant material, that is needed to increase yield so that there will be enough food it amounts to violations.[229] States, therefore, employ different measures to ensure these goals, however, in incorporating the right to food into IP in a way that facilitates access to food, other concerns like IPR and even competition law complicates the issue.[230]

Other commentators also maintain that right to food is not an adequate legal ground that supersedes the right to property such as IP since the discussions do not address the countervailing obligations under international trade law, much less define a clear connection between the right to food and WTO treaties like TRIPS.[231] Right to food under public international law, therefore, must be situated within the broader framework of international law, including international economic law. Moreover, the text of Article 11 of the ICESCR does not create a series of specific obligations for food security. Also, the view expressed on this particular point is usually aspirational rather than determinative.[232]

The above notwithstanding, Article 8(1) of the TRIPS agreement impresses on its members to adopt measures paramount in protecting public health and nutrition while promoting the public interest in areas of extreme importance especially in socio-economic and technological development in a manner consistent with the agreement.[233] This qualification within Article 8 gives Article 27(3)(b) priority should a member state seek to enact a measure that would prejudice rights created under Article 8. This provision is vital, however, international pressures like trade

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[228] The Special Rapporteur on the Right to Food further elaborated on in his 2009 report to the UN General Assembly

[229] Blakeney, M. (2009). *Intellectual property rights and food security*. Cabi. See also, Seed Policies and the Right to Food: Enhancing Agrobiodiversity and Encouraging Innovation: Report of the Special Rapporteur on the Right to Food, Olivier De Schutter, UN Doc A/64/170 (23 July 2009); Conny Almekinders and Niels Louwaars, *Farmers' Seed Production. New Approaches and Practices* (Intermediate Technology Publications, London, 1999).

[230] Van Overwalle, G. (2010). A man of flowers: A reflection on plant patents, the right to food and competition law. *Technology and competition*, 355-372.

[231] Ziegler, J., Golay, C., Mahon, C., & Way, S. (2011). *The fight for the right to food: lessons learned*. Springer.

[232] Nasu, H., & Rubenstein, K. (Eds.). (2015). *Legal perspectives on security institutions*. Cambridge University Press.

[233]TRIPSand pharmaceutical patents. https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

threats, and diplomatic intimidation is making it difficult for developing countries. So far, this provision has been successfully used to mitigate the adverse effects of patents in public health, the same can, therefore, serve as the basis for restricting protections for food.

4.2 HOW CAN COUNTRIES HAVE ACCESS - FLEXIBILITIES/POLICY SPACE

Access, be it to food or related materials, is treated differently across treaties and territories, while some regimes have extensive clauses on how it should be approached, others proffer non-binding and aspirational objectives. This situation is mainly caused by the fact that treaties have to find a balance between creators demanding overprotective regimes and other interest holders lobbying for more open systems. In this section, we look at how access clauses established in the relevant international treaties can and have been implemented in national regulations in some countries, particularly in Africa. The specific interventions and exemptions like compulsory license and research exemption are two flexibilities that are often employed and necessary for access, are assessed across treaties and legislation.

International treaties give guidelines and states have the prerogative in determining the laws within their territory. Consequently, several studies have shown a positive relationship between nations and the conventions they are signatories to. Many countries have chosen to adopt different types of Intellectual property protection for plant varieties, however, as elaborated in chapter 3, the kind of protection offered varies over time and also from country to country, in line with the treaty flexibilities and general interests of the particular country.[234] That is why during treaty negotiation stages countries makes demands in line with their national interest. IP protection with regards to access, therefore, varies from regime to regime

The states that permit IP in food gives temporal monopoly rights to inventors to encourage the creation of new and useful works that benefit society. By this, access is restricted through controlling mechanisms like pricing within the protection span. States invariably limit access to, and the usage of new knowledge by others so that developers will be able to recoup their investments and to encourage more. This implies that the new development becomes available to all after the protected period and within that time, access is mainly dependent on the terms permissible by the law and determined by the right holder.

[234]. Mwila, G. (2016). 17 Commentary on the Zambian Plant Breeder's Rights Act. *Farmers' Crop Varieties and Farmers' Rights*, 319. The Zambian PBR law is a result of local and internation pressures

These Rightsholders are mostly motivated by profits, and there are instances where their legitimate profit-maximising interest conflicts with that of others. In such a case, the legal use of the protected material outside the authorisation of the rights holder depends on the type of protection. IP protection can be from no protection to some category, through tailored protection (sui generis) to stronger protection as in the case of a patent. [235] Even though the idea of no protection may be very unpopular today, many countries have in the past resulted in this mechanism. The Netherland and Germany in the past, for example, did not grant protection for plants,[236] the United States also in the 1930s when they decided not to protect six crops.[237] In the case where a nation chooses not to protect plant genetic material or even GM, access will be unrestrained. However, such a move will be contrary to many existing treaties and conventions and will have many effects on inventions.

4.2.1 TRIPS AND ACCESS TO FOOD

Today, TRIPs as a pro-patent agreement broadens the scope for IP protection with a wide range of protections, yet scholarship on whether TRIPS encourages or restricts access to biotech inventions, in general, remains divided.[238] The minimum standards principle that TRIPs stipulates means that its member states cannot implement any weaker laws. Accordingly, a nation can only protect plants by patents, sui-generis protection or a combination of both.[239] Patent, generally considered as the most robust protection for biotechnological invention gives right of exclusion, this right gives the holder the power to set prices or control access to the patented invention over a period. This means an invention/discovery is available to the general public after the period. Within this period, access to the protected materials is mostly in the purview of the rights holder whose primary motivation is in recouping their investments and not food insecurity issues. Patent, however, grants neither positive nor absolute rights; therefore, rights granted are subject to other regulation or further restrictions.[240]

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[235] The idea of no protection is not new, began in Netherland and Germany and even some crops were excluded in the us in the 1930's

[236] Pila, J., & Torremans, P. (2018). *European intellectual property law*. Oxford University Press, USA.

[237] Crosson, P. R. (2016). *Productivity effects of cropland erosion in the United States*. Routledge.

[238] Clark A.D. Wilson, *The TRIPS Agreement: Is It Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers? 10* J. TECH. L. & POL'Y 243, 261-62 (2005).

[239] Article 27(3)

[240] Osenga, K. (2012). Get the balance right: squaring access with patent protection. *Pac. McGeorge Global Bus. & Dev. LJ*, *25*, 309.

The exponential growth of patents in agricultural biotechnology raises several concerns for research and development of subsistence and speciality crops, and access to the technology that is used in producing food, especially for poor and underprivileged groups, in less developed countries. There are many provisions, including the broad authority in Article 30 that allows patents to be limited. In addition, Article 27.3(b) lays the grounds for plants and animals to be excluded as a patentable subject. The inherent right to determine patentability standards allows countries to define what it considers as novel, inventive step, utility, and disclosure in a way that maximises exposure, minimise discoveries being patented and constrict patent width. This space can also be used in conjunction with the right to grant compulsory licenses.[241] The research exemptions is also a model for facilitating access to patented gene technology. These options give countries the space to address their peculiarities.

TRIPS incorporate a variant of the three-step test that originated from copyright law and applies it to patent law under article 30. This article sets out a cumulative test that a member state must satisfy before it can restrain the rights of patent holders or plant breeders. Even though the WTO leans towards the narrow interpretation of this provision its panel on the Canadian safe harbour provision allowed the practice where pharmaceutical companies that produce generic drugs to manufacture and test drugs before patents expire so that the generic drugs will be available as soon as the patent for the drug expires was based on art 30.[242]

The layers of flexibilities that TRIPS incorporate also allows some countries to implement TRIPS in a way that suits domestic conditions. These flexibilities under Limitation and exclusion clauses thus offer a leeway to access protected materials. So far, no country has a justified their no patent protection for plants under Article that sets patentable subject matters and restriction of patent, even though many scholars have interpreted article 27(3)2 to limit the patent scope in plant genetics with Article 27(2) serving as a basis, for in refusing to grant biotechnology patents on substantial public interest grounds or to safeguard ordre public, well-being of people and their environs.

Other researchers have also proposed ways by which increased access is possible even without triggering the limitation and Exception clauses of Art 27. One such scholar is Geertruini Van

[241] Taylor, M. R., & Cayford, J. (2003). American patent policy, biotechnology, and African agriculture: The case for policy change. *Harv. JL & Tech.*, *17*, 321.
[242] Osenga, K. (2012). Get the balance right: squaring access with patent protection. *Pac. McGeorge Global Bus. & Dev. LJ*, *25*, 309.

Overwalle, and he has offered additional routes like patent pool and clearinghouse mechanisms that can be employed to deal with the quagmire in crop-related patents in order to safeguard the right to food since few countries have utilized the flexibilities of the TRIPS Agreement to use, even though they allow patent for plants and others (discussed in section 4.3).[243]

4.2.1.1 COMPULSORY LICENSE

Article 31 of TRIPS establishes a compulsory licensing framework that gives WTO members room to implement TRIPS-compatible standards more broadly, this framework has in the past been used by states to obtain affordable medicines and can be used to have access to food.[244] A country can invoke compulsory license to permit the use of a patent; it can also authorise third parties to use a patent without the authorisation of the patent holder, but often with compensation. The government-imposed royalty rates are usually paid as compensation; they are, for the most part, lower than the rate a patent owner typically negotiate for. Compulsory license is available to all members, but political pressures and trade sanctions have made countries cautious when using this option.

Countries that initiate compulsory licenses are, however, obliged to consider every permit on its individual merits, as such, the scope and duration of the license should be confined to the purpose for which it was authorized, and it should be done after unsuccessful efforts have been made with the rights holder at a reasonable commercial fees and conditions except under national emergencies, extreme urgency or public non-commercial use. This implies that a license should be in respect of specific technology, not the whole class or category. A government can, therefore, authorise a compulsory licensing for a particular GM variety, but cannot approve a compulsory licensing of all resistance to pathogens and herbicides and for better nutrient profiles

The Doha Declaration which made after TRIPS guides interpreting some of the exceptions needed in the prior negotiation requirement. Even though the declaration is related to public health, its proclamations affirmed the position that member state has the discretion to decide the situations they consider as national emergency or circumstance of extreme urgency. A nation can, therefore, categorise access to food as an urgent problem and invoke the benefits

[243]Van Overwalle, G. (2010). A man of flowers: A reflection on plant patents, the right to food and competition law. *Technology and competition*, 355-372.
[244] Correa, C. M. (2016). Intellectual property: how much room is left for industrial policy?. *Journal of International Commerce, Economics and Policy*, *7*(02), 1650012.

of this clause. Thailand, for example, has stretched this interpretation to the fury of many developed countries by licensing drugs that did not treat infectious diseases nor outbreak prevention.[245]

Even though studies on compulsory licensing have focused mainly on notable factors that affect the issuance of compulsory licensing like local capacity, importing possibilities, and pressure from patent holders' and their threats to leave the market, Son, K (2019) has observed that countries with matured patents systems were more likely to utilise compulsory licensing. Many advanced states have adopted and employed this option throughout history, although recent evidence shows more use by developing countries.[246] Compulsory licensing is not limited to only patents. Thailand's PVP and Indian PPVFR have provisions for compulsory licensing.[247]

The European Parliament, for instance, has passed a resolution regarding the issuance of compulsory licensing for EU members. This resolution is meant to augment the provisions made in Art 29 the basic regulation for granting compulsory licenses for CPVR by CPVO on public interest grounds.[248] The terms governing compulsory licenses are contained in the implementing rules of the basic regulation. It applies to safeguard the life and health of humans, animals or plants; it also aims at maintaining a consistent supply of essentials to the market, and the need to motivate breeders who intend to introduce improved varieties.[249]

Several African countries have since 2001 issued multiple compulsory licenses for various reasons, but mainly under article 31 or Par7 for medicine. In some of the cases, there was no patent filed or granted. An example is the compulsory license Djibouti issued in May 2007 for HIV/AIDS, AVRs also did not have a patent granted when DRC issued the license in 2005. There are also instances where the licenses issued were not executed for the reasons other than no patent like Price discounts, rejected and also voluntary licenses. In Thailand, donations were the reason why the license was not carried out for the imatinib cancer treatment medication while Subscription model for lowering price being implemented accounted for the US non-

[245] The United States listed Thailand in its Special 301 report. Patent holders retaliated by taking drugs off the market in Thailand. Despite these repercussions, Thailand did not back down from its compulsory licenses.
[246] http://tripsflexibilities.medicineslawandpolicy.org/
[247] Son, K. B. (2019). Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis. *Globalization and Health*, *15*(1), 42.
[248] Parliament E. EU options for improving acess to mediciens; 2017
[249] Article 41

execution on the HCV medicines in 2018. In all about 25 African countries have a history of issuing compulsory licenses for various reasons.[250]

In West Africa, some studies have shown that the African Growth and Opportunity Act (AGOA) has been a significant reason for the slow initiation of compulsory licenses. Many countries in Africa are members of AGOA even though the initiative frustrates efforts for compulsory licenses, this is because AGOA highlights the enforcement of stringent IP norms.[251] Ghana's inability to fully implement compulsory licensing in the height of the HIV outbreak in 2004, for example, emanates from the strict and restrictive IP-related provisions in AGOA.[252] Together with section 104, section 111 of the AGOA and similar to 506(A) of the GSP Act, demands that other nations protect IPRs of US firms as stated in subparagraph (5) of section 502(C) of the Trade Act 1974. This measure is a core requirement that determines countries that will have access to US markets as well as benefit from US budgetary support.[253]

Taylor M. R and Cayford J (2003) argue for a policy alternative in the US patent law that will allow nonexclusive licenses to developers who intends to use protected contents improve food security in developing countries. Such provisions, they believe, will improve access because developers will not have to worry about infringements when they are working on food security issues. They also noted that such an alternative would not significantly reduce the incentive of the invention since the royalty provision will ensure that rights holders are compensated in a way that will not make them economically is not worse off.[254]

4.2.1.2 RESEARCH EXEMPTION

Presently, research is a crucial element within the food supply sector, and it is through research that new and acceptable varieties are developed. Many treaties, therefore, acknowledge the

[250] Trips Flexibilities database http://tripsflexibilities.medicineslawandpolicy.org/
[251] Manu, T. (2015). Assessing the potential impact of Intellectual Property Standards in EU and US bilateral trade agreements on compulsory licensing for essential medicines in West African States. *African Journal of International and Comparative Law*, *23*(2), 226-249.
[252] Ibid. Ghana was facing shortages by the end of 2004 and this forced the then Minister of Health to declare a state of emergency, followed by a grant of compulsory licensing on 26 October 2005.15 Since the government of Ghana had declared an emergency situation with respect to the HIV/AIDS epidemic there was no need to negotiate for a voluntary licence from the patent right holder prior to the grant of such a licence. But did not carry out compulsory license. The core reason that prompted Ghana to abrogate its three-year compulsory license too soon stems from the fact that Combivir was patented in the US87 and this meant that such a licence had been contrary to the spirit of AGOA.
[253] ibid
[254] Taylor, M. R., & Cayford, J. (2003). American patent policy, biotechnology, and African agriculture: The case for policy change. *Harv. JL & Tech.*, *17*, 321.

importance of research and safeguards it with an exemption. This is because the intellectual property rights system which was intended to encourage and reward innovation inherently poses a fundamental obstacle for further research, the sheer number of patents that genetic engineers and DNA markers, for example, have to navigate can make research and development of new products costly and unattractive.[255] Research exemptions are therefore needed to provide exceptions to the exclusive rights customarily offered to patents.

By giving researchers designated leeway to use patented materials without fear of infringements, researchers can develop developing cheap and culturally acceptable varieties that can significantly improve access to food. Research exemption is an element of patents law of Europe. The substantial provision, of the European Community Patent Convention, indicates that the rights given for a patent do not carry to deeds which are done for experimental purposes.[256] Research exemption is also standard in some sui-generis protection. However, in the United States, albeit with a very narrow scope of application, research exemption is not stated in patent law; instead, it exists as a product of judicial decision. Over the years this exemption has been the centre of some notable controversies, determining the scale, nature (experiments on versus with) and the ultimate goal of the experiment (commercial versus non-commercial), and where applicable have been a significant challenge.[257]

Some courts in the US have construed the law in general as inherently exempting the use of patented inventions in non-commercial research from infringement. But in the landmark case of *Madey v. Duke University,* for example, the ruling narrowed this interpretation to exclude using patented technology in both commercial research or non-research settings when it opined that "*Regardless of whether an institution or entity is engaged in an endeavour for commercial gain, forasmuch as the act is in furtherance of the alleged infringer's legitimate business and not solely for amusement, to satisfy idle curiosity, or for strict philosophical inquiry, an act may not qualify for the very narrow and strictly limited experimental use defence.*"[258] Overwalle G. has, however, noted that in practice, this exemption is applied less strictly because companies rarely sue researchers.

[255] Zerbe, N. (2008). Sowing the seeds of progress: the agricultural biotechnology debate in Africa. *History Compass*, *6*(2), 404-425.
[256] Van Overwalle, G., Van Zimmeren, E., Verbeure, B., & Matthijs, G. (2006). Models for facilitating access to patents on genetic inventions. *Nature Reviews Genetics*, *7*(2), 143.
[257] ibid
[258] *Madey v. Duke University*, 266 F. Supp. 2d 420 (M.D.N.C. 2001).

Recent studies seem sceptical about the prospects of this exception in the area of Agri-biotechnology.[259] Many believe IPRs hinders the work of researchers who work on varieties for developing countries because of the unwillingness of Western biotechnology companies in providing the needed cooperation. Researchers particular about infringement of the patent are thus compelled to form partnerships with patentholders through Material Transfer Agreements (MTAs) to gain worry-free access to the technologies and technical know-how, this practice is widespread in situations where there are intentions for export. The MTAs in general strictly regulates the use of the technology. Some developing countries have therefore accorded research exemption broader limits while a number of research institutes are also granting free access to gene sequences used for diagnostic testing and other activities and collecting royalties after.

The Indian PPVFR act does not prevent researchers from using registered variety in their works or experiments. It even allows registered varieties to be used as the foundation for developing other varieties, except that the researcher needs to the authorization of the breeder in cases where a variety whose parental line is needed for commercial production is used repeatedly.[260] The African model also recognises the research exemption in general as many nations within the continent have it in their laws. So far, no dispute has arrived over the use of this exemption because of the low level of research within the continent; cooperation and MTAs also account for this. Taylor and Cayford again argue for the laws to exclude the use of biotech patents in research and development aimed at food security in developing countries from the exclusive rights given to patents.[261]

4.2.2 ACCESS IN SUI-GENERIS PROTECTIONS.

Sui-generis protection allows countries to tailor intellectual property protections in a way that the challenges of a country are prioritised. A country that chooses sui-generis protection on plant varieties has a much wider space for manoeuvres. This is because there is no requirement for international standardisation as in the case of patents, neither does the law set demands that it should be compared to patents. Sui-Generis protection is accepted as long as there is some form of protection exist, even if it is not similar to any other country. This implies that each

[259] Covino, D., & Boccia, F. (2016). Potentialities of new agri-biotechnology for sustainable nutrition. *RIVISTA DI STUDI SULLA SOSTENIBILITA'*.
[260] Article 30 of the Indian PPVFR
[261] Taylor, M. R., & Cayford, J. (2003). American patent policy, biotechnology, and African agriculture: The case for policy change. *Harv. JL & Tech.*, *17*, 321.

country is permitted to adopt any kind of protection for plant variety that will benefit the said county; however, many of the countries including countries in Africa that choose this form of protection tend to follow the path of UPOV.

4.2.2.1 UPOV CONVENTION AND ACCESS TO FOOD

Although many researchers question the provisions of UPOV on access to food, it is the most applied sui-generis system currently. The UPOV convention generally does not allow breeders' rights to exceed "*acts done privately and for non-commercial purposes; acts done for experimental purposes and; acts done for breeding other varieties" except in specific cases as enumerated under Article 14(5).* The general interpretations under the convention give broad rights akin to patents to breeders and to a considerable extent limits the rights of others.

UPOV '91, for example, makes farmers rights optional in art 15(2). Subsequently, many states have restricted farmers rights in line with this article. Further interpretation from UPOV council states that not a ban on farmers rights, yet following actions seem to erode farmers rights by the day.[262] Some commentators have suggested that UPOV is the worst form of protection for African nations in terms of access, but increasingly, even countries like Ghana that are not members of UPOV are modelling their sui-generis protection along the UPOV lines.[263]

Article 17 provides the sole grounds on which breeders rights could be restricted in the pursuit of access. It allows restrictions on breeder's rights based on public interest grounds after necessary measures that guarantee the fair and appropriate remuneration for breeders' are satisfied.[264] However, nations that have UPOV inspired PVPs are either unwilling or have not been able to trigger this provision because of external pressures in spite of the eminence of access to food challenges in these countries. Uganda and Tanzania, for example, have different forms of UPOV PBR, yet both worry about access to food.[265]

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[262] Winter, L. (2010). Cultivating Farmers' Rights: Reconciling Food Security, Indigenous Agriculture, and TRIPS. *Vand. J. Transnat'l L.*, *43*, 223.

[263] Acquah, O. D. (2019). The Proposed Plant Breeders Bill of Ghana and the Food Sovereignty Connundrum wpmk-the-proposed-plant-breeders-bill-of-ghana-and-the-food-sovereignty-conundrum.

[264] Restrictions on the Exercise of the Breeder's Right (1) [*Public interest*] Except where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest. (2) [*Equitable remuneration*] When any such restriction has the effect of authorizing a third party to perform any act for which the breeder's authorization is required, the Contracting Party concerned shall take all measures necessary to ensure that the breeder receives equitable remuneration.

[265] Kakooza, A. C. (2016). Plant Variety Protection in Uganda: A Legal Analysis of Emerging Trends. SSRN: https://ssrn.com/abstract=3330283

4.2.2.2 ACCESS TO FOOD; THE AFRICAN MODELS AND OTHER

The African model highlights access to food by giving guaranteeing those broad rights for farmers. It allows farmers to save and use seed from their farm for replanting and encourages the exchange of seeds. The model permits for the use and sale of protected propagating materials for purposes other than commerce, and further allow the cultivation of varieties that are registered as food for household consumption or for the market. Even though these provisions are subject to further conditions under the Farmers' Rights, its impact on ensuring improved access to food is encouraging.[266] In addition, article 31(d) sets forth the research exemption, while article 33 lays the foundation for compulsory licence rights where food security, nutrition or health of people are at risk.[267]

The CBD-CPB has approached access from a different perspective, its provisions like Article 15, looks at access to genetic resources from the viewpoint of States sovereignty (art. 3). States generally have the rights over their natural resources and are therefore entitled to a share of the benefits that accrue from its exploitation. The commercial utilisation of the genetic resources, the technology needed must, therefore, be shared on fair "mutually agreed terms".[268] Article 16 in particular, makes provision for the access and transfer of the technologies that may be a subject of patents and other IPRs to be transferred fairly and in line with the overall objective of the CBD.[269] Other sections such as article 19(4) and 20(4) detail the particulars and unique situation under which developing countries can have broad access, including access to IP related material. A number of developing countries have so far tried to harmonise their IPRs with the biodiversity framework.

4.3 HOW HAVE COUNTRIES UTILIZED THESE FLEXIBILITIES

Even though protection options vary, each option impact on access to food differently, available data show that many countries within Africa provide at the very least, some kind of protection for GM food and plant varieties. The type of protection nations have been offering are in practice affecting the available options for access.

[266] Section 31(2)
[267] Article 33 of the African model Law
[268] Art. 15.7 of CBD
[269] Article 16(2) of the CBD states that its members should recognize that patents and other IPRs can affect the implementation the Convention, as such each should ensure that their obligations to other treaties are supportive of and do not run counter to objectives of the CBD

Given the fact that many countries offer different forms of protection for GM and plant varieties, it is vital to evaluate how they have interpreted and incorporated the options above, especially the ones allowed for in treaties. In practice, a number of African countries have sought to implement the GM and plant variety legislation, yet, the question as to how well have they maximise the flexibilities available under these treaties that they are parties to as well as the factors and interests, of considerations that influence the choices they employ, remains potent. How have African countries applied the flexibilities available? Why? What has been the primary considerations, interests, and influencers?

From chapter 3, we realised that many countries in Africa grants patents to plants and most of them do not only have compulsory license clauses in their regulations but have a history of issuing a number of them. Majority of the countries in Africa have compulsory licensing in their laws, usually under patent law. South Africa however, has CL in both their patent laws and Competition laws. Again, the majority of the countries that have successfully enacted plant variety laws also have compulsory licensing clauses. So far, the majority of the countries in Africa have experiences of issuing compulsory licenses in the health sector, even though a number of them were not executed.[270]

Many African countries have decided to go in for protection such as patent, Plant variety protection, and other sui-generis protections that are not entirely in line with any international treaty, however, concerns are still being raised as to how specific clauses are being interpreted in ways that do not allow broader access. GHANA's Patents Act 657 for example, excludes plant varieties from patents in section 2(g) even though part 2(f) allows for non-biological and microbiological materials to be patented just as in the trips agreement; Section 13 provides for exploitation by gov't and other authorised persons; [271] And Section 14 handles non-voluntary licensing yet, its usage has been a challenge even in the heist of national crisis like the HIV outbreak in the early 2000s.[272] Ghana is also developing a Plant breeders bill that is in line with UPOV even though it is not a member.[273] The bill which was drafted in 2013 employs the typical restrictions of UPOV, even though it is not bound by the UPOV act.

[270] http://tripsflexibilities.medicineslawandpolicy.org/
[271] Patents Act 2003, Act 657
[272] Manu, T. (2015). Assessing the potential impact of Intellectual Property Standards in EU and US bilateral trade agreements on compulsory licensing for essential medicines in West African States. *African Journal of International and Comparative Law*, *23*(2), 226-249.
[273] Plant Breeders Bill of Ghana, drafted in 2013

In conclusion, the implementation of the flexibilities is hindered by BTAs. Lauterpacht, E. (1996) posits that, in being mindful of FDI and access to the perceived lucrative markets, when negotiating Bilateral Trade Agreements, Less Developed Countries have been reluctant in invoking the TRIPS flexibilities even when they have to increase affordable access medicines.[274] His analysis will show the extent to which AGOA has shrunk the policy spaces of other countries that intend to implement compulsory licensing.

4.4 OTHER METHODS THAT CAN BE EMPLOYED

Over the years, the difficulties IP poses to access have caused many inquiries into the subject, and while some researchers are actively looking for new systems that can address the present challenges, others are dedicated to making the current system more responsive. IP as from the above impacts heavily on access to food, and just like IP in other fields has led to many advocating for more effective systems. Open-source, patent pool; clearinghouse, and liability regimes are some methods that have been suggested by a number of researchers as a means of resolving the challenge of access to protected materials relating to food. Even though some of these methods were first introduced in other fields, the likelihood of their successful adoption is high even under patents.

Patent pool, for example, is handy when the quest for access and use of a patented technology requires the permission of different patent holders or multiple patents. Some researchers have suggested that patent pool as a better alternative to compulsory licensing. To these researchers, companies stand a better position and will, therefore, be more willing to corporate that compulsory licensing that often compels them under challenging circumstances. Taking cognizance of the enormity of Intellectual property in the biological diversity industry and the challenge it poses for a pool of patents, the Organisation for Economic Co-operation and Development (OECD) was the first to propose patent pool in genetics. Even though the OECD believed that the concept could work in this field, its proposal was more of a call for stakeholders' perusal and evaluation.

There are a number of risks associated with patent pool mechanism; one is the potential of concealing invalid patents. A single pool could have several patents from different sources, verifying each patent is an arduous task that places enormous work on pool managers. As such,

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Lauterpacht, E. (1996). International law and private foreign investment. *Ind. J. Global Legal Stud.*, *4*, 259. noting that developing countries realized that development required both public government loans as well as private investment flows.

the likelihood of admitting an invalid patent becomes high, given the workload. Secondly, sharing the benefits accrued from the pool among patent holders can also be challenging, even though the worth of each patent can be estimated by experts, the possibility of an unfair benefit-sharing mechanism is usually high. Others have also argued that patent pools can brood cartels that will, in the long run, disrupt the markets with anti-competitive behaviours. The number of pools established so far has been able to manage these challenges mainly because of their moderate sizes. The golden rice pool which enriched rice with β-carotene while allows further genetic improvement suitable for localities, for example, shows that patent-pool can work to the benefit of developing countries.

Clearinghouse mechanism is another means others have suggested that as a way to improve access to the genetic materials needed for food production. The term 'clearing house' was originally a barter system that some banking institutions adopted for their intra-trade activities. The process primarily involved transferring net balance in cash after checks and bills have been evened. This concept is now being employed to include *any mechanism by which providers and users of goods, services and/or information are matched*.[275] So far, the clearinghouse system has been applied in the area of information pertaining to the status of technical attributes of IP. Information Clearinghouse comprises of both free and fee-paying searches like the EPO websites and Patent Lens. Technical exchange clearinghouses also exist to give information about the available technologies, their owners, and an intermediary team for license negotiations and mediation, BirchBod is an example of this type of clearinghouse. For now, the information and technical details available in these clearinghouses not only scattered, but they also represent a small section of the market and can only function in areas where technology can be delineated and valued.[276]

The royalty-collection clearinghouse takes license fees from users on behalf of the patents holders in return for the use of specific technologies or services after which the clearinghouse redistributes the revenue according to an agreed formula. This model has proven its worth and is very common in the copyright industry. The copyright societies that monitor music played on the radio, and other public spaces and events are a prime example of this model. Others

[275] Overwalle G. Plant Patents: From Exclusivity to Inclusivity | CPVO. https://cpvo.europa.eu/en/news-and-events/articles/plant-patents-exclusivity-inclusivity

[276] Birchbob is an internet-based platform that brings together offers and demands for innovations and provides services dedicated to finding and facilitating contacts between technology holders and technology seekers.

include the American Society of Composers, Nordisk Copyright Bureau (NCB), and the Southern African Music Rights Organisation (SAMRO).

Another model available under the clearinghouse mechanism is the open-source model which intends to advance the open flow free exchange of technology. This model is also common within the software and other industries, but it is best for sharing and exchanging unpatented technology. The SNP Consortium is an example of an open-source method. The consortium has established a public directory that gathers human genomes that have not been registered for others who seek to use them in their research. The main challenge for this method is that private entities and research institutes invest so much before a gene is invented or a variety is developed. Therefore, like recoup before they can offer their progress for free under this model. The open-source model can be an excellent compliment to the research exemption.

5.0 CONCLUSIONS AND RECOMMENDATIONS

The technique by which the DNA molecule of living organisms is infused artificially into other organisms called Genetic Modification has revolutionalised the way many things are done. Agricultural practices like breeding, for example, are now undertaking by artificial means to bring improvements. The improvements made through biotech tools include plants' that are resistant to diseases, insects or drought. They also include plants that have higher receptiveness to herbicides or ones with enhanced qualities or upgraded nutritional benefits, as well as plants that produce more harvest. These improvements bring about several benefits like reducing the cost of production; decreasing environmental degradation; and improving the richness of food products that aids in the war on food insecurity, which is a real threat in Africa.

On the other hand, significant concerns are continually being raised. Severe health issues, extinction of some varieties, particularly traditional ones, and the unknown perils to humans, animals and the biodiversity are often pushed forward to counter GM gains. Opponents argue that vital agricultural pollinators, decomposers, vegetation and wildlife are threatened by way of mutation or contamination as plants become more and more resistant and dependent on weedicides, insecticides and pesticides. This many believe cause farmers to become over-reliant on seed corporations.

Several reasons have been attributed to the slowness of Africa in accepting GM foods even though GM crops are traded internationally and being introduced locally by the day. This lag has led many countries in Africa to ignore regulations on GM instead of putting up systems that will curb the ills of GM. Some commentators suggest that it is essential for countries to regulate GM even if they do not allow it within their territories because of the growth and influence GM technology wields.[277] In addition, given the different approaches in regulating GMO that the continent's trade partners have adopted, African countries have to take a stand and cannot be indifferent.

A system that considers the exigencies of the time like while addressing the core issues pertaining to the continent like food security is most needed at this time. Health and safety-related issues were top on the concern list; however, today, GM discourse is dominated by new concerns like IPR. The GM measure inherently heightens the significance of intellectual

[277] Ayele, S. (2007). The legitimation of GMO governance in Africa. *Science and Public Policy*, *34*(4), 239-249.

property protection and the ambiguities of its purpose and effectiveness on GM. This is because agricultural research that used to be funded by the public developed seeds that had improved feature which was made available to farmers as a public good are now being undertaking by private entities rather than the public establishments and universities. As a result of this shift, agricultural research is more and more being considered as private goods which need intellectual property protection. IPRs are necessary for the new biotech movement since investment needs to be recouped, yet the threat that they pose to the traditional practices have been a reason for the unwillingness of many in accepting the GM option.

Intellectual Property, needs to be navigated carefully because even though it threatens the current practices and traditions like farming in Africa, international IP laws offer some space for police maneuvers in addition to the requirements they demand. Both patents and sui-generis protections that TRIPS offer as plants material protection mechanisms have associated challenges. The unresolved issues like farmers rights, licensing, infringements and liabilities are raised on the daily in addition to the appropriation of resources and traditional know-hows ranges high. While patents are too stringent, sui-generis have also been criticised as either at non-compactible with other IPRs or not responsive to the actual concerns' farmers in Africa face, when they are in line with UPOV. However, some commentators have noted that something in the current IP posture needs to change.

These challenges are, however, surmountable with the proper regulatory framework that prioritises the needs, concerns and aspirations of all interests. International treaties have provided broad and general guidelines, but a comparative study of different jurisdictions shows the multiple ways in which GMOs are being approached and regulated. The dichotomy between the US and EU regulatory systems may be a challenge for developing countries that have the US and EU as trade partners, but it also exposes the breadth or range of policy alternatives available for African countries

Even though stability in breeding methods have improved with biotechnologies, Pila and Torremans believe Patent are still be ineffective for plant inventions they often tend to lack the novelty and inventive step patent requirements demand, thereby supporting sui generis rights instead. Many of the countries in Africa provide either patents or sui-generis protection for plants/crops in accordance with TRIPS, even though the number of countries that have finalised their plant variety or breeders bill is less. Such countries stand a higher chance of providing dual protection for GMOs. Currently, some researchers are looking for ways to improve the IP

system to make it more responsive to the present demands. Wijk V and Junne (1992), for example, believes that there is no need for Africa to adopt a patent system for plants rather, hybrid laws that synthesis patent law and copyright protection is more likely to work. To them, such a system will give broader flexibility to inventors than patents, and at the same time, a more limited control than copyright affords.

This is because current IP protection is a private right as such its practices benefit the ones with the economic wherewithal and legal backings at the expense of those without such access. Many scholars have stated that the prevailing IP conventions were not formed to recognise informal innovators intellectual additions and the primary rationale behind the low appreciation for the intellectual reserve of ordinary farmers in developing countries. Therefore, finding the right mix IPRs for plants that prioritises the interests and positions of the continent without stifling investments and other interests is imperative. The effect of sweeping IPR claims discourages investment and innovation as well as restricts access to food.

Access to food as an objective is possible to attain within the available system, the traditional modes like compulsory licensing and research exemptions are permitted under the law and could be employed for this purpose. While the call for indigenous communities to protect properties of food plant that are peculiar to them is on the ascendency, some are advocating for the communities to go in for royalty arrangement that is favourable. Other methods like the proposition by with the proposed methods suggested by Overwalle V. G. (2009) could also be implemented to augment the conventional methods.

So far, the lack of a consistent and comprehensive intellectual property policy across the continent is not only creating many unexamined challenges that derail the progress of the continent but also severely disrupting many developmental goals within countries. Countries are drafting a new law and the ones modifying their existing laws, therefore, needs a much more insightful team that will consider the exigencies of their state vis-a-vis the flexibilities permitted within the law. This is very important because there is a considerable disconnect between IP and national economic-planning goals in many countries. Some have attributed this disconnect to the fact that most of the IP systems in Africa are relics of colonial statutes and decrees whose conceiving aim was not to further the goals of developing the innovative capacity of indigenous contributors or the preservation of the biological diversity of countries in Africa.

In general, more attention needs to be put on the capacity and capacity building within the region. While the need for well-equipped and fully functioning institutions are needed, more education, and the involvement of IP experts, etc. to negotiate competently on the international stage is equally crucial. The complexities of IP is very specialized and demand skilled personnel who are well-informed in the subject, yet there seems to be low participation of professional societies in the discourse within the region. Farmers, breeders, consumers and all interest parties along the food chain needs to be fully educated on how IP works and how each can benefit from it through outreach programs, school curricular, and other dedicated channels

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