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Changing Frameworks of Intellectual Property Rights in Agricultural Biotechnology

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Abstract
Intellectual property (IP) right in agricultural biosciences has experienced a radical change because of resulting technologies and the results of legal innovations. This development depicts an increasing conflict of conflicting forces of innovation incentive on one hand and concerning the global food security together with fair access to the biotechnological resource. As genetically modified organisms (GMOs), gene-editing technologies such as CRISPR and synthetic biology have emerged, patents, plant breeders rights and other intellectual property designs have been expanded and enforced, which brings up vital issues pertaining to ownership, rights of farmers and conservation of biodiversity. This article examines the legal, ethical and socio-economic effects of such a change with a view that worth is given to balance between the protection of the innovators and the benefit of the people in a fast moving industry.

Keywords: ***Intellectual Property Rights, Agricultural Biotechnology, Patent Law, Plant Breeders' Rights, GMOs, CRISPR, Biosafety, Farmers' Rights, Biopiracy, Biodiversity Conservation, Global Food Security, Legal Frameworks.***

1.Introduction
Agricultural innovation has resisted apocalyptic projections of food insufficiency throughout the past 100 years mostly because there has been ongoing government investment in research and development. These technological inventions have been tracked down by good nutrition, productivity and economic yield all over the world. Nevertheless, over the past several decades a paradigm change has occurred to the processes that protect and encourage innovation, especially in the form of the growth of intellectual property (IP) (in the agricultural biosciences). A field that was originally dominated by government agencies and common knowledge, the creation of genetically engineered crop and molecular breeding tools has turned the way access to knowledge and the control over indispensable biological innovations are handled on its head, as privatized concerns have come to the fore. Such transition poses challenging issues of equity, innovation, market concentration and food security all over the world considering that the global IP systems are tightening due to international agreements such as TRIPS (Trade Related Aspects of Intellectual Property Rights) and national patenting policies(1). This paper will delve in the way intellectual property legal and institutional frameworks have developed in the agricultural biotechnology as well as the forces behind these developments, and what it means to the level of innovation, competition as well as development.

Publicly funded institutions were key in the great wins of agricultural science in the 20 th century, the Green Revolution, and the spread of high-yielding crop varieties throughout the world. Provision of agricultural innovation was free as universities, national research programmes and international agricultural centres connected and opened themselves up to innovative broad market access. However, this open model set had its disadvantages especially in driving the interest of private sector participation. Lack of a system by which seed companies could control the ability of farmers to reuse their saved seed eroded such profitability among the seed companies since farmers could resort to self-pollinating crops. Therefore, the investments made by the private companies have been relatively smaller but with the exception of hybrid crops such as maize, which is naturally unable to be replicated by planting the same seed since this is a characteristic of that type of crop genetically.

The legal situation started altering in the mid 20 th century though. One of the earliest acts towards acknowledging the proprietary nature of biological innovation was The U.S. Plant Patent Act of 1930, which conveyed exclusive rights over the asexually-produced crops to the plant varieties. Subsequently, there was the act of Plant Variety Protection Act (PVPA) in 1970, this was to tag sexually propagated plant varieties in the protection too, thus enforcing breeder rights on new and distinct plant varieties. The Union internationally, Union for the Protection

of New Varieties of Plants (UPOV) 1961 however, supplied a multilateral system of harmonization of the plant breeders rights and later impacted on the change of laws in Europe, Latin America, and Asia(2).

An important change occurred in 1980 when the U.S Supreme Court decided the case of Diamond v. Chakrabarty, that confirmed that genetically modified beings could be patented (GMOs). This landmark case expanded the boundaries of utility patents to comprise new forms of life, and initiated a flood of patent applications in the genes, characters, and biotechnological procedures. Similar equivalents, such as the1980 Bayh-Dole Act, and the rights to federally funded research helped to strengthen universities and non-profit organization to commercialize their work furthering the correlation between academic science and the commercial world(3). These changes in legislation initiated the creation of a powerful biotech industry, especially in the United States where investment in genetic engineering by both the government and individual business began to boom.

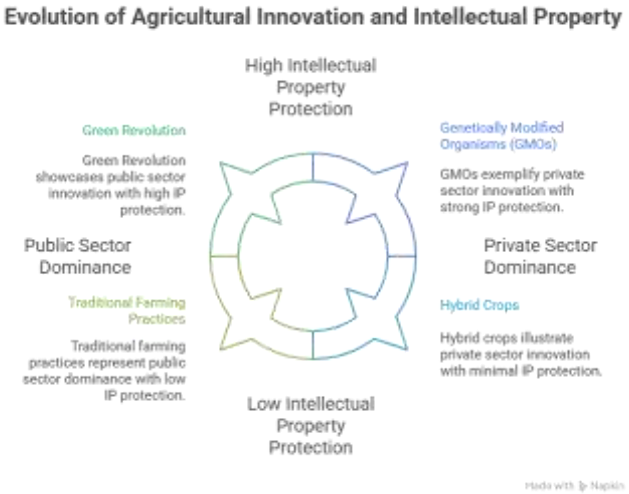

FIGURE 1 Evolution of Agricultural Innovation and Intellectual Property

Although the trend was initially reflected on the domestic level, international frameworks took an interest to reflect the same soon after. In 1994 TRIPS agreement negotiated under the World Trade Organization was signed and required member countries; even the developing nations to apply the minimum level of IP protection. This was not out of local pressure on the need of innovation incentives but received pressure by the developed countries to force the world to comply to its IP claims. As a matter of fact, the global trade was available on the condition of accepting stronger IP regimes. In most developing nations, the process has seen a lot of difficulties; in their laws and ability to enforce the law. In addition, the opponents say that such regimes can restrict the access to genetic resources and technologies needed to provide food security and climate resilience.

The spread of IP rights has also redesigned the organizational structure of area of agricultural biotechnology. The cumulative nature of innovation associated with crop improvement holds that emerging new traits are constructed on the basis of the existing germplasm, tools and techniques. But with the increasing numbers of elements of these innovations turning patentable, the legal situation has now become quite cumbersome, particularly to the researchers in the public, as well as small companies. The effectiveness of the idea of a freedom to operate, which presupposes the opportunity to create and market innovations without violating the IP rights of other organizations, has been undermined. Other technologies like Golden Rice 119 consist of dozens of patented materials and incorporation of such implies the use of the complicated licensing arrangements. These costs of transaction, legal uncertainty and the threat of litigation have become great constraints to entry.

2.Global Expansion of Intellectual Property Systems in Agricultural Innovation

In previous times it was the natural world; plants and animals tended to leave the realm of intellectual property. Exchange and cultivation of naturally occurring species found in various regions of the world were a typical characteristic of innovations in the agricultural sector. This was taken as discovery but not invention and could not be owned and be enjoyed as exclusive as per legal provisions of IP laws. Until the 20th village intellectual property protection in the form of new plant varieties did not exist(4).

In the United States, the most important legal recognition of an innovation involving plants was the Plant Patent Act of 1930. The act was a historic law on agriculture as it provided inventors with protection through exclusive

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right to sexually asexual propagation of the variety of a plant-except the tubers. The act allowed owners of plant patents to ensure that no other person would reproduce, sell, or use the patented plant material and its clones without the owners permission until the time the patent expired. The law was critical in commercial horticulture but was not applied to the major food crops in farming where it was applied in protecting fruit trees, berry plants, vines and the ornament symbolic crops.

The U.S. would later in 1970 expand its cover under the Plant Variety Protection Act (PVPA). Under this Act, rights were introduced to sexually reproduced crops. New plant varieties had to be novel, distinct, uniform and stable to enjoy protection. In their initial stages farmers had freedom to freely exchange or sell small quantities of supremely-constructed seed, which later amendments denied them. But farmers were allowed to save and re-use seed on their own farms- something that still affects the market today. Saved seed cuts down on the chances of the breeder to recover the research and development investment by selling the seed many times thus, competing with commercial seed availability.

Europe was already advanced in protecting the same and they existed using the banners of the International Union for the Protection of New Varieties of Plants (UPOV1961). The revised version of the UPOV (1972) introduced tougher and more enduring ones, the authors extended to 20-25 years, depending on the plant product (in 1978 there was no significant change, and, most importantly, in 1991). The UPOV convention attracted a lot of other countries and introduced similar law on plant variety protection (PVP) based on its methodology. Although the U.S. had plant patents as well as PVP rights most countries relied on PVP as the main legal instrument to protect the asexually as well as the sexually propagated plants(5).

Notably, the majority of PVP systems, such as that covered by UPOV permitted the existing(protected) varieties to act as a platform in the development of newer ones, ensuring continued innovation. Such flexibility was however curbed after the UPOV revision in 1991 when the concept of essentially derived varieties were introduced. This provision limits the exploitation of the protected varieties to create new ones which are closely related, and presumably the breeder is then able to have more control over downstream utilization.

Notwithstanding the legal progress, there are considerable numbers of researchers and analysts who are doubtful concerning the degree to which staple crop breeding tailor-made a major sponsorship through the protection of plant variety. Evidence seems to indicate that PVP schemes, at least in the case of achieving a more formalized and professionalized seed industry, usually resulted in commercializing varieties of cosmetic or economically inconsequential aspects as opposed to any real advancements. The possibility to register minor variations to be guaranteed IP rights may have been the incentive breeders had rather than to spend time and capital in high-impact innovation.

However, commercial breeders have enjoyed extensive application of PVP laws in controlling reproduction and access to markets. They are very useful in restricting uncontrolled seed breeding and preserving valuable parent lines in the hybrid breeding programs. A royalties system of control has developed in Europe and other such countries as Japan that either does not allow seed saving or royalties have to be paid when harvesting a crop of a protected variety(6). When it comes to flowers and specialty crops, royalties are effectively collected at central marketplaces as seen in the Netherlands even when it comes to imports like those in far-away countries of Africa and Latin America.

In Australia, the system has escaped another innovative direction by employing End Point Royalties (EPRs). These are not paid when one is selling his or her seeds, but at crop marketing centers, using the actual output that was harvested on the protected varieties. This system satisfies the capacity of farmers to reserve seed to use themselves, but that breeders should still be paid out of the product sales. This is because in certain Australian crops EPR compliance is of above 80%, indicating that royalty collection can be not only a viable but also efficient process with centralized value chains and proper observer.

But the most radical change happened when utility patents were issued on biological innovation. Diamond v., 1980 U.S. Supreme Court ruling U.S. Supreme Court case Diamond v., 1980 U.S. Supreme Court case The legal turning point was the decision of Chakrabarty which confirmed that it was possible to patent living organisms which are genetically modified. This paved the way to the complete patenting of genetic sequences, means of transformation and biotech derived plant varieties. The patents in utility mode are more potent and far-reaching in terms of control than the PVP legislation as they go beyond the material product to encompass the process adopted and tools

employed in the innovation. In such patents, an inventor gets the sole right to manufacture, use, sell, or even import such invention into the country within up to 20 years punishable by law.

3.Utility Patents and the Global Expansion

The introduction of utility patents signaled the next important step in the securing of innovations as regards to agricultural biotechnology. It reached the breaking point in 1980 when the U.S supplementary court in its landmark judgment in the case of Diamond v. Chakrabarty, supported the propositions that living bodies, artificially produced through human engineering, could be patented using the tool of utility patent. This court decision set the floodgates open to patenting biological inventions that were novel, non-obvious and useful--all qualities with which the typical patent law associated itself(7). By granting stronger and broader legal protection as compared to plant-specific protections like the plant variety rights (PVP), plant patents, the utility patents were more attractive. Such patents would give patent owners complete control over both the organism and the processes or technologies enabled by the organism, and these could be enforced against unauthorized uses, production or commercialization. The change of agricultural science was revolutionary in that way genes, promoters,fertilization techniques, and even whole genetically modified (GM) plantswere now able to be guarded against making use by anybody without official licensing.

In the same year, the U.S Congress enacted the Bayh-Dole Act which gave universities, small business, and non-profit organizations the right to own inventions that are created during federally funded research. This encouraged academic institutions to patent their discoveries and licence them to industry to develop commercially thus setting off a trend of university industry collaborations in biotechnology. Previously government scientists whose interest was mainly to enhance open science started turning to patentable innovations that would attract business. The researching landscape was changed to competitive and there was a race among institutions in order to get monopoly over discoveries. In addition, in 1982, the establishment of the United States court of appeals of the federal circuit centralized patent appeals and reinforced consistency in the application of the patent rulings. These events rendered the United States the most patent-friendly place on the planet and led to the fact that the country became the leader of the changes in the sphere of agricultural biotechnology.

The motivation behind the quest to increase IP protections in agriculture was not only to promote innovation in the future, but also to capture some of the revenues that have already been created in the past through technological innovation. It was the pressure of highly powerful industries that needed patent reform to expand its monopoly and to gain more returns on its investment in research and development such as pharmaceuticals, chemicals, electronics among others. This patent activism wave was never led by the stakeholders in the agricultural sphere but instead engulfed the seed and biotechnology spheres with the concurrent boost in genetic engineering. In the 1990s there existed the legal framework allowing firms to patent both the inputs (e.g., methods of transformations, genes) and the outputs (e.g. GM seeds) that resulted in vertically integrated system of IP, which effectively favored the rights holding firms.

Economists tend to agree that protection of some kind is needed to stimulate research and innovation but there is disagreement as to whether patent systems, especially strong systems are the most efficient way to advance social welfare. There is a huge difference between agriculture innovations and others in the sphere of technology. Most of the benefit falls on consumers in terms of cheaper prices and better food security and not the firms in terms of returns to the market. Therefore, the trade off between the welfare of the population and welfare of an individual in farming is more sensitive. Moreover, the surveys demonstrate that the most industries (excluding pharma and chemistry) judging by the share of companies using patents to secure intellectual resources, relying rather on lead time, trade secret and brand reputation(8). The question is, are high functioning patent systems really necessary, or are they just an unnecessary barrier to knowledge dissemination particularly in an industry where knowledge is build up through accumulated innovation?

The IP revolution that was spearheaded by the U.S was soon extended to the international scene. One force behind this global spread was the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement that was part of the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT) and which has applied to be under the World Trade Organisation (WTO) since 1995. TRIPS compelled all the member countries to have minimum measures of safeguarding an extensive array of intellectual property such as patents, copyrights and plant breeders rights. Notably, this was a binding treaty: the nations that did not abide by the TRIPS requirements could be subject to trade sanctions. Due to the pressure to gain access to the world markets and fend off the

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penalties in terms of punitive trade restrictions, several developing nations reluctantly went by these terms, not particularly because they were eager to protect IPs. The move was a historic first as the developing countries were forced to be patented on a global level.

The TRIPS agreement accord was flexible in agricultural biotechnology to an extent. Article 27.3(b) allowed nations to exclude plants and animals as they conformed towards the establishment of sui generis (unique) system of protection of plant varieties. Although this clause seemed to provide developing countries with some flexibility to adapt IP system to their unique needs, practically, the maneuverability was very limited. These exceptions have been hawed over time by bilateral trade agreements, or what are called TRIPS-Plus agreements, negotiated with the United States, European Union or other larger powers. They have given up their rights to other systems to have better trade relations with many nations. Countries like Jordan, Morocco, Singapore and Chile have readily accepted to IP agreements that further extend the terms of those covered under TRIPS, sometimes including patenting of plant and animal varieties, which are quite controversial and indeed heavily lobbied by multinational agribusiness interests.

4.Technological Advancements and Institutional Shifts

Modern agricultural biotechnology has developed because of the revolutionary investigations of molecular biology conducted in the 1970s and 1980s. Some pioneering research-like the technique of recombinant DNA that was invented by Cohen and Boyer-prepared the way of genetic-molecule manipulation. Although most of these early discoveries were still made in academic or government laboratories, their protection also became more and more covered by patent protection. Patenting of the recombinant DNA methods in 1980 marked the beginning of a new world, in which the biological world and the legal world were to redefine the world of agricultural innovations. Importantly, the multiple early patents largely were licensed cheap non-exclusively which assist in the spreading of ways of the ground.

The early 1990s and 1980s were atypically opportune with regard to innovation in agricultural biotechnology. Federal funding in the U.S., especially by major research agencies such as the National Institutes of Health was generous as far as basic research was concerned. Meanwhile legislative systems encouraged commercialization via intellectual property right. In contrast to conventional breeding in which the phenotypic selection was involved and natural variations were exploited, genetic engineering enabled the direct modification of selected traits. This opened the possibility to engineer resistance to pests and herbicides, and alter the shelf-life, nutrition and yield usually by the selective insertion of a limited number of genes.

Business interest increased fast. Companies that make pharmaceuticals and chemicals were realizing synergies which seemed to exist between human health. These are the companies that started to brand themselves as life science companies. These companies started massive investment in agricultural biotech; they introduced seed development divisions, they purchased intellectual rights and they entered into licensing agreements with the seed manufacturers. Meanwhile venture capital was pouring into startups intended to commercialize university-derived research. The historical pattern of how research in the public sector produced global public goods was changing into a system of hybrid public-private cooperation and the prospect of patent royalties transformed university priorities and the incentives of the academic staff.

By mid-1990s biotechnology made concrete advances. Insect resistant, herbicide resistant, and long shelf life genetically modified crops (e.g. Bt corn, cotton, round up ready soybeans and canola, flavr savr tomatoes) entered the marketplace. These technologies spread swiftly with rapidity being witnessed among farmers particularly in the North American and South American countries. They were very appealing in terms of their efficiency in cutting down the prices of input, ease in managing the crops and better crops produced. By the year 2004, the GM crops had been planted in over 200 million acres world over testifying the wide embrace of the biotechnology solutions to the world of agriculture.

Nevertheless, the lucrative and technological advancement in agricultural biotechnology was accompanied by the emergence of new concerns--especially the legal framework on which all the innovations are based. Patents had not only become central in the innovation incentives, but also in the access to the market. The freedom to work in plant breeding and biotechnology became limited as increasingly biotech traits, tools and components of germplasm were patented. In comparison to what used to happen in the previous decades, the knowledge flow was

not as free in the 1990s attributed to the emergence of complicated networks of intellectual property that would regulate pretty much every aspect of the innovation process.

Contemporary plant breeding is additive and participatory: new cultivars may combine many traits originating in a variety of sources. Those characteristics can be proprietary promoters, choice markers, transformation procedures and genes, which have been patented individually. This layering of intellectual property rights has created what the scholars refer to as patent thicket because the breeders have to navigate through various licenses, keep watch of cross claims, and have to endure legal ambiguity before commercializing a new strain of varieties. The famous one is Golden Rice, a genetically modified crop supplemented with pro-vitamin A. There was the need to access over 40 distinct patents owned by various parties in different jurisdictions.

The cumbersomeness and the expense to deal with such legal knot ties have had structural implications on the industry. The small firms and the public institutions are also under pressure. Not having the legal knowledge or the available funds to negotiate bundled licenses, most choose not to do transgenic research at all or limit themselves to unpatented cropping solutions and techniques. In reaction, big agrochemical and biotechnology firms have sought vertical integration. Instead of issuing licenses on their traits to the independent seed producers, they have bought them outright, as well as acquisitions of biotechnology companies at start-up stage, intellectual property aggregates and even germplasm treasure-housed libraries of elite materials.

By the end of the 90s this trend toward merging in the industry was seen. The companies of seeds that were multiple and regional, turned out to be subsidiaries of companies that went multinational. The concentrate power in the stream, from the discovery and development of genes and traits on the upstream part of the chain and selling and production of the seed or products brought downstream segments of biotech value chain in the hands of firms like Monsanto, DuPont, Syngenta, and Bayer. These corporations were able to secure regulatory control over important technologies and market outlets so that they could hunger out all the value possible through proprietary innovations and at the same time achieve the freedom to operate. In a report published in 2002, it was observed that around half of the patents covering the commercial use of a wide range of agricultural biotechnologies were in the portfolio of four companies, which was so high a degree of concentration that it set few precedents in the agricultural history.

Overall, agricultural biotechnology has existed on the basis of not only a scientific evolution but an institutional one as well. By improving genetic and molecular biology along with major revisions in intellectual property rights, the mechanisms of agricultural innovation creation, control, and distribution have recreated themselves. Although the drive towards use of discoveries in biotechnology as commercial products has been taken up well in the private sector, it has also brought about entry barriers, legal complexity, and concentrated the industry. The dilemma here is making sure that the pace of innovation in agriculture is not only inclusive, sustainable, and in line with world food security agendas.

5.Conclusion

The course of agricultural biotechnology during the last decades has been highly associated with the development of the intellectual property (IP) systems. What started out as a science based on open scientific discussion and research led by the public sector has radically changed into a commercially-driven, IP-based science. Legal innovations in utility patenting, plant variety protections, and international trade regimes have spurred this change most notably in the form of the TRIPS regime invented by the World Trade Organization. Collectively, the transformations have changed the nature of the production and dissemination of agricultural innovations in terms of how these innovations are created, transferred, and received, producing not only astounding technological achievements but also confronting the enormous institutional and ethical issues.

This change is centered on interactions between market structures and innovation incentives. On the one hand, there is also no doubting that stronger IP regimes have spurred the investment in agricultural research by corporate entities. The speed at which genetically modified crops, in particular herbicide-tolerant soy beans and insect-resistant cotton, has been commercialized and the ease at which it has been widely adopted reflects the ability of market-animated innovation when partnered with enforceable rights. In Europe and other parts of the world, private companies have demonstrated their ability to scale the translation of technologies out of the lab and into the field, therefore increasing their rate of productivity, as well as changing the way crops are managed on the continent.

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Nevertheless, these improvements have not been fairly shared. Biotechnology has commercialised a limited number of crops, mostly restricting operations in maize, soybean, cotton and canola where appropriability is high and where markets are strong. These crops enjoy centralised supply chains, concentration of value capturing, large-scale farming structures that allows the reaping of royalty and the enforcing of the IP. By contrast, most of the staple crops that are cultivated in the developing world, including sorghum, millet, cassava, and several pulses, continue to be ignored by biotechnologists because they are not very profitable and are still far flung. This ends up as an expanding innovation gap, in that the private enterprise R&D centers in on high-reward markets, and the government-owned institutions center in on neglected crops and areas.

Besides, the issue of proliferative patents and proprietary technological overlap has added another dimension to the innovation sector of agriculture. Contrary to early days of the Green Revolution where technologies were freely exchanged, the present biotechnology environment is marked by random ownership, legal ambiguity and transaction costs. The problem is aggravated by accretion of intellectual property-based claims known as patent thicketsor patent stacking that makes it hard to commercialize or license existing technology without violating existing rights without possessing them. This has caused mayhem with innovation bottlenecks, less-freedom-to-operate, and greater reliance on negotiated access to proprietary assets.

A few ways can facilitate a more equal future. To start with, to accomplish this, patent pools, open-access licensing systems, and collective R&D consortia should be built to lessen access limitations and decrease transaction costs in the innovations of bio tech industries. Second, nations should contemplate the possibility to introduce the so-called sui generis IP regimes that will acknowledge the informal systems of innovation owned by farmers and traditional breeders, but still take into account the international commitments. Third, international donors and funding agencies ought to invest in the improvement of the capacity to breed in the public sector particularly, in crops and environments where there is low privatization by the private firms.

Lastly, international transparency of IP governance and more accountability on it is obligatory. The policy autonomy of developing countries should not be prevented by trade agreements and bilateral negotiations and the local needs should not be barred in the implementation of flexible IP systems. The future of agricultural IP needs to be less of the one-size-fits-all model, but principles of inclusivity, sustainability, and public good would guide the trend.

To sum up, the intellectual property rights in agricultural biotechnology have evolved both to progress and polarization. It has opened frontiers of scientific possibilities and created class disadvantage simultaneously. With burdens on the global food system mounting up (in terms of population and climate change, scarcity of resources and geopolitical strains), the value of biotechnology will continue to not only rise, but to grow in significance. The redesign of the governance of innovation itself is needed to ensure its gains become broadly shared and not narrowly captured. Intellectual property should not only be commercially instrumental, but also to fulfill the wider objectives of food security, environmental sustainability and social justice.

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Conflicts of interest

The authors have no conflicts of interest to declare

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