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The Co-Evolution of Science and Law in Plant Breeding: Incentives to Innovate and Access to Biological Resources

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This paper analyses the co-evolution of scientific progress and intellectual property protection in plant breeding and the debates generated in its design and implementation. It relates the institutional history to several problems related with incentives to innovate, appropriability of innovation rents, disclosure and cumulativeness, and diffusion and access to biological resources. We identify three main issues that were fiercely discussed along history: firstly, whether plant varieties and other biological resources could be considered as inventions or simple products of nature, secondly, how to provide incentives to plant breeders without preventing access to innovation and looking upon the contribution of farmers to obtain present improved varieties, and, thirdly, the social cost of generating monopolies in plant breeding and agriculture as food producers. These three issues have shaped the debates and remained controversial until our days. The analysis shows that legal and scientific factors evolved at different paces, resulting in different IPRs systems, and giving raise to several problems.

Keywords: Intellectual Property Rights, Plant Breeders' Rights, Patents, Plant Varieties, Biotechnology, Incentives, R&D, Green Revolution, The Plant Patent Act, International Convention for the Protection of New Varieties of Plants, Essentially Derived Variety, The European Patent Convention, Genetic Use Restriction Technologies

Nowadays, plant breeders developing new plant varieties can apply for different types of intellectual property rights (IPRs). However, this is the result of a complex historical process that only recently resulted in the consideration of plants as suitable for intellectual property (IP) protection at a global scale.

Not surprisingly; the evolving role of IPRs is highly controversial. Some of the debates are shared with other sectors. For instance, do IPRs increase the quantity of biological innovations? Which is the social impact of the trade-off between incentives to innovate and access to innovations? Other debates are specific to sectors dealing with living organisms and are related to the morality of their private appropriation. For many years, the consideration of plant varieties as inventions and not mere products of nature was fiercely discussed. Finally, other issues derive from specific features of plant varieties that distinguish them from other types of innovations as many plants are self-replicating maintaining their genetic features.[1]

During the twentieth century, and increasingly in the last two decades, several countries have been implementing or broadening plant variety protection (PVP), with the aim of preventing other breeders to copy them but also of avoiding purchasers to reproduce plants and reuse their seeds.[2] However, this is by no means the only way of protecting biological innovations. Alternative forms such as trade secrets, private contracts, use of reputation, and other marketing strategies, were and are still widely used. Plant breeding was developed for decades without formal IPRs, obtaining and diffusing relevant innovations. Yet, scientific progress has been adding more complexity to the needs of the industry and the design of IPRs systems. In particular, the recent application of genetic engineering to plant breeding created interesting aspects related both with innovation activities and appropriation of innovation rents. In addition, the increasing role of the private sector investment in research and development (R&D), which outpaced public resources, has also played a role in shaping IPRs systems.

While the economic literature on patent protection has been widening in recent years, other types of IPRs, such as plant breeders' rights (PBRs), have been less studied. Most of the literature focuses on cases of study addressing the effect of IPRs on innovation and productivity.[3,4,5] Other authors have analyzed the evolution of IPRs for products of the life

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science industry from a historical or sociological perspective.[6,7,8] Other authors have analyzed PVP in certain countries or periods of time.[9,10]

The aim of this paper is to provide a historical analysis of the co-evolution of plant breeding techniques and PVP, contributing to the more general debate in economics of innovation and IPRs. Taking into account the specificities of plant varieties and related IPRs, this analysis provides an interesting framework to address issues such as: cumulativeness, the trade-off between diffusion and private appropriation of new knowledge, the social costs of monopolies, and the effectiveness and scope of IPRs systems.

The historical overview shows that, beyond advances in science, discussions were driven over the years by similar concerns and, especially, three issues have shaped the debate. The first one is whether plant varieties can be considered as genuine inventions or mere products of nature. The second one is how to use IPRs to provide incentives to plant breeders in order to spur innovation, disclosure, and the development of the industry, without preventing access to biological resources and looking upon the contribution of farmers to present improved plant varieties. The third one is related to the costs of generating monopolies on food security, a key issue for development and social welfare.[11] Finally, the development of more complex scientific knowledge, derived from modern biotechnology, has enriched the debate, but the co-evolution of legal and scientific factors resulting in different IPRs systems did not impede the development of innovations over the centuries.

The rest of the paper is organized as follows. First, we briefly analyze the historical evolution of seed improvement methods from its origins to the present. Then, we present the different means of protection used over the years. Finally, we conclude discussing how the case of IPRs for biological innovations relates with the broader literature on IPRs and innovation.

Improving Plant Varieties: From Natural Selection to Biotechnology

Plant breeding is the science of altering the genetic characteristics of plants in order to improve yields or obtain desired characteristics. Despite plant breeding is a relatively recent activity, plant varieties have been modified since remote times through natural selection in such a way that Charles Darwin claimed that: “Not a few botanists believe that several of our anciently cultivated plants have become so profoundly modified that it is not possible now to recognize their aboriginal parent-forms”.[12]

During the nineteenth century, plant’s improvements were performed by means of trial and error selection, largely based on tacit knowledge, as scientific methods were unknown till the beginning of the twentieth century. Between the seventeenth century and the beginning of the twentieth century, farmers contributed to genetic improvement through artificial selection or selective breeding, i.e. collecting seeds from the best plants and growing them separately to isolate high-yielding and disease resistant strains.[13] Private breeders and public research institutions used to follow very similar procedures. Cross-breeding was a basic technique consisting of crossing different lines with desired traits and selecting the best plants among the offspring. Therefore, selection used to occur ex-post and was based on the phenotype of the plant -the observable characteristics in the performance in the field- rather than on other not expressed features constituting the genotype of the plant. In practice, the pedigree method consisted in starting with a healthy seed, planting it in a fertile soil with the best conditions, and selecting the best seeds of its offspring.[14] Since breeders provided the best conditions for selection, buying seeds instead of self-selecting them was offered to farmers as a more productive option. Farmers, private breeders, and public institutions made significant contributions to seed improvement before the development of more complex technological methods.

The rediscovery of Mendel’s laws in 1900 boosted plant breeding, through the application of scientific selection methods, strengthening the participation of the public sector and encouraging private initiatives.[15] Scientific progress radically changed the process of improving plants making it less dependent on nature and less random.

One of the most relevant breakthroughs was the development of hybrid maize as a result of the work of different agricultural experiment stations in the United States (US) during the 1920s. Since hybrids lose their genetic characteristics in the second generation, they offer a biological protection for breeders, enhancing profit opportunities for private companies, which rapidly launched a new industry of seeds producers.[16] Since the 1930s, farmers started adopting hybrids because they highly raise yields. In this context, public research institutes increased their role in self-pollinating species, which can be replicated by farmers without losing their genetic features. Semi-dwarf wheat with high-yields and disease-resistance constituted another relevant breakthrough. They were obtained in Mexico in the 1940s and were freely diffused together with modern agricultural techniques, giving place to the so-called "Green Revolution".

Towards the 1970s, scientific advances in molecular biology brought about new changes for plant breeding, adding more complex scientific knowledge and making the improvement process of seeds less random. Along with it, there was a shift towards private funding of research. The so-called modern biotechnology or genetic engineering, has provided new tools to genetically modify plants, but also for breeding conventional plant varieties. In some cases, biotechnology has shorten the time for the development of a new plant variety since its genetic characteristics can be known before the plant has finished its biological process.[17] The performance or whether certain characteristics are going to be expressed in a new plant variety can be partly anticipated in the laboratory. One of the most widely known advance is the genetic modification of plants through the introduction of genes from other species into a variety. However, transgenesis is neither the only available tool nor the most used. Other high-tech procedures for improving plant varieties or reducing the time needed for the selection process are mutagenesis, gene mapping, embryo rescue, double haploidization, and selection based on genetic markers.[18] Several authors and institutions see modern biotechnology as a breakthrough and a key to increase productivity, but also genetically improved bioenergy crops could help to mitigate climate change, improve food, feed, and fiber security, and reduce the environmental footprint of agriculture.[19] Conversely, others are less optimistic, especially because thus far biotechnology has not raised yield ceilings beyond the levels achieved using the older methods and because the growth of the industry along with the strengthening of IPRs has had negative consequences, such as market concentration, that can risk food security and biodiversity.

Beyond scientific progress, plant breeding depends on biological processes. As such, it is characterized by a strong and unavoidable path dependence since biological innovation is cumulative and based on upstream enhancements. Innovation in plant breeding is a sequence of small incremental qualitative improvements, which generate a steady and rather modest increase of productivity. Seldom, there are radical innovations such as hybrid corns or semi-dwarf wheat varieties, which produce jumps in productivity trends. More recent technological progress from genetic engineering has produced a breakthrough in the way that plant varieties can be improved despite not producing a high increase in yields.

The development of a new plant variety is costly, subject to local specificities that depend on the ecological characteristics, demands long periods of R&D and, relying on biological factors, presents "extra uncertainty" with respect to innovation in other sectors. Seeds have the characteristics of a quasi-public good given thatthey present, to some extent, non-excludability as many plant varieties can be easily reproduced. Besides, seed technology is non-rival and also hardly excludable. Moreover, seeds can be for farmers both a capital good when used for sowing and a final good when harvested and sell as grain.

Plant breeders have put forward the fact that the self-replicating feature of seeds and horticultural plants make them vulnerable to copy and fraud, arguing that IPRs are necessary for the development of innovation activities. Externalities, indivisibility, and uncertainty in plant breeding call for a discussion on the provision of incentives but also on the access to the improved genetic material.

Protecting Plant Varieties

The evolutionary process of technical change in plant breeding came along with changes in the appropriability mechanisms of innovation rents. For many years plant breeding was developed without formal protection, based on breeders' reputation or secrecy. Later, scientific advances provided a biological protection for some plants, i.e. hybrids. It was only in the 1960s that a special institutional system allowing PVP for all kind of plants through PBRs was created. More recently, living organisms and also plant varieties are being considered in some countries as patentable subject matter.

In a stylized way, we might think PVP as a combination of protection deriving from biological factors, which may be enhanced by scientific developments, and another one emerging from legal factors.[20] Figure 1 shows that these two types of protection can be combined in different ways.

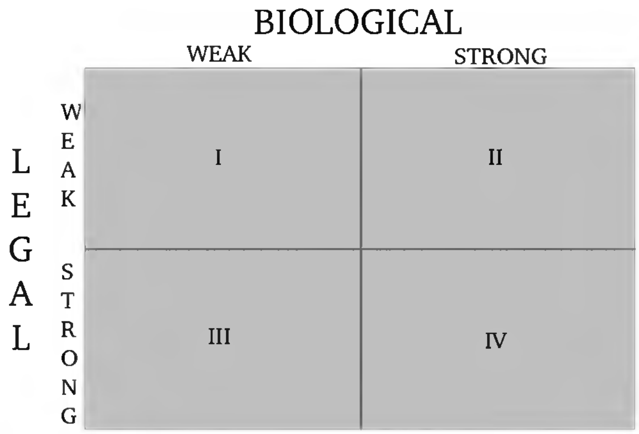

Fig. 1 — Interaction of biological and legal protection

Before and during the nineteenth century, plant varieties could be fairly easily copied and legal instruments preventing copy were not available (I). After the 1920s, hybridization provided biological protection against reproduction in the absence of legal IP protection (II). Since 1930 -for asexually reproduced plants, excluding tuber propagated plants- and since 1968 -for all types of plants-, different IP arrangements were implemented, generating two new cases. Strong legal protection could be combined with weak biological protection -self-pollinated species, such as wheat and soybean- protected by a PBR (III), and with strong biological protection -hybrids- towards the end of the twentieth century when patents and other IPRs became available (IV).

Several combinations of legal and biological protection coexisted in time for different types of seeds. Despite breeders had used the argument that in front of certain technological advances, legal aspects need to evolve, the evolution of scientific advances and legal aspects usually took place at different paces. The interaction of plant breeding science, political and legal factors, as well as different interests has been shaping the process.

Innovation without IPRs

The birth of the plant breeding industry goes back to the nineteenth century, where no formal protection was available. Despite that, many biological innovations were obtained, plant breeding and a market of seeds grew steadily, breeders' associations were set up, seed testing systems were developed and adopted, and national research institutes were established in Europe and the US.

Meanwhile, there was a widespread belief that patents were not suitable for biological innovations because they did not meet the conditions for the granting of a patent: novelty, inventiveness, non-obviousness, and utility. Utility was difficult to prove and, until some scientific advances were reached, breeders were not able to guarantee the quality and the character of the following generations. The inventive step was considered problematic since it was not clear how products of nature could be distinguished from products of nature modified by human intervention. The "product of nature" doctrine in US law, which states that organisms that live in nature cannot be considered as inventions and are not patentable, prevailed up until the 1980s.[21] In the absence of formal IP protection, breeders found alternative methods to profit from their innovations, among which several informal practices.

In Great Britain, breeders dedicated part of their time to establish a good reputation among farmers and the scientific community.[22] To promote the virtues of seeds, breeders used advertising and publications in scientific journals. Breeders' reputation was used to attract farmers and convince them of the benefits of buying new seeds instead of self-replicating them. Breeders also used to sell sealed sacks that deliver by post to farmers in orderto prevent other breeders or seed dealers from copying and selling a variety under a different name. Moreover, a few institutions, such as agricultural societies, contributed to the protection of plant varieties by awarding certificates on the quality of seeds, giving prizes, informing trial results, and publishing debates on the originality of plant varieties.

In France and Italy, horticulturists used to remove the buds from the stems of flowers in order to prevent competitors from taking cuttings. Likewise, in the US, Paul Stark built a cage around his Golden Delicious apple tree to prevent others from taking cuttings or buds.[23] Also, breeders used trademarks to protect their products, the building of good reputation, and pricing strategies that consisted in selling the first new variety at a high price, assuming that they would not be able to charge for subsequent seeds.[24,25] Moreover, they implemented private arrangements imposing contractual obligations upon the purchaser. In addition, the practice of sharing knowledge seems to have been fairly widespread and plant breeders used to attend public discussions in agricultural societies to share their progresses and knowledge spread through networks of personal contacts and other informal channels.[26]

However, enforcing IPRs and demonstrating infringement were difficult tasks at the moment.[27]

Despite these strategies were not always useful in providing IP protection, many biological innovations were obtained establishing the foundation of the next scientific revolution in breeding and productivity growth in agriculture.[28]

The Adoption of Formal Protection

Towards the end of the nineteenth century, horticulturists in the US became the first breeders to claim actively for IP protection. They complained that, without IP protection, it was not possible to receive a proper compensation for their innovations, which were very quickly copied. Horticulturists managed to form a powerful lobbying group and Paul Stark, the discoverer and developer of the Golden Delicious Apple, drafted the first Plant Patent Act.

The Congress started discussing IPRs for plants already in 1885.[7,23] The Committee on Patents of the US House of Representatives focused in three main arguments: the consideration of plant varieties as innovations or mere products of nature; the necessity to provide incentives to breeders considering the need of making plant varieties available; and the social costs of monopolies.

Regarding the first point, pronouncements were initially against the extension of patents considering that, being "natural products", plants were not patentable subject matter.[29,30,31] However, the idea that plants were products of nature regardless of the degree of human intervention was challenged. "It is obvious that nature originally created plants but it cannot be denied that man often controls and directs the natural processes and produces a desired result. In such cases the part played by nature and man cannot be completely separated or weighted or credited to one or the other. Nature in such instances, unaided by man, does not reproduce the new variety true to type".[32] Finally, the Committee agreed that the asexual reproduction of a new variety, even if nature has produced it, constituted and innovation by human agency.

Concerning the second issue, breeders argued that incentives were needed to reduce public expenditures in R&D and spur private innovations, strengthening public health, prosperity, and national defense. Finding no reasons for being excluded from patent protection, they demanded the same legal treatment as mechanical, electrical, or chemical inventions. "No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of fruit or other plant to mankind".[33]

Lastly, the Committee was against the extension of patents to sexually reproduced plants, most of the agricultural crops, and some tubers-propagated plants because: "The experience we have had with the monopolization of patents for inventions, raises grave doubt as to the wisdom of granting patents on new kind of plants of a food-producing nature".[34] However, it was simultaneously argued that food supply was dependent upon the introduction of new plant varieties and incentives were necessary for their development. Food shortages during the First World War were used to illustrate the need of incentives for breeders.

Finally, the Plant Patent Act was enacted in 1930, covering only asexually reproduced plants (excluding tuber propagated plants) invented or discovered in a cultivated area, which could prove to be distinct and new. Unlike utility patents, usefulness was not needed and description requirements were less strict, as a consequence of the specificities of plants compared with manufactured products.

Certainly, plant patents did not escape from criticism. Their main controversial point was how to determine whether a plant was an innovation or a mere product of nature, and how detailed should disclosure be.[35,36] The scope of the patent was also criticized as the right was granted to the plant variety as a unit allowing one single claim, not considering the complex nature of a plant variety, which is composed by different elements.[37,38] Besides, given the weak disclosure requirements, it was questioned whether the Patent Office would have been able to distinguish genuine from counterfeit IP.[6]

The first plant patent, granted to a landscape gardener who developed a bud variation using a number of Van Fleet roses, was already controversial. It was not granted to an inventor but rather to a discoverer, it included a vaguely defined claim that could prevent further innovation, and it protected a variety that was the product of a casual discovery whose contribution could not be compared to the one made by Van Fleet. All these raised doubts on "whether the interest in plant improvement can be rewarded and stimulated through the granting of patents".[39] In fact, only 16% of the new rose varieties created between 1931 and 1970 were patented, American roses continued to be based on European ones, and a significant number of roses were developed by hobbyists before any protection was available.[23]

The Plant Patent Act was created and approved ad hoc to satisfy the needs of innovators of the horticulture industry in the US. As such, it was not the consequence of scientific progress allowing the identification of new varieties creating the necessity of changes in law.[40] It was rather the result of political pressure from a particular group that gained protection for particular plants. Seed producers excluded from the Plant Patent Act continued employing alternative means of protection and started using certification that tested the purity of the bag seeds in contrast with trademarks, which were a guaranty of their performance.[6] Both in the US and the rest of the world, IP protection for agricultural crops remained a minor concern until the 1950s.

Obtaining Biological Protection

Since the beginning of the twentieth century, several research institutes were working in hybridization. The first hybrid corns were obtained in the US and quickly diffused since the 1930s given their yields improvements. Hybrids result from cross-breeding inbred lines which differ in some hereditary factor, they inherit the best features of their parents and have a better yield performance. Yet, due to the so-called heterosis, hybrid's offspring present much lower yields. At different paces, many other countries obtained hybrids adapted to their soil conditions: "Hybrid corn was not a once-and-for-all innovation that could be adopted everywhere. Rather, it was an invention of a new method of innovating, a method of developing superior strains of corn for specific localities".[16]

Hybrids offer a biological protection for the developer for two reasons. First, seeds from hybrids off-springs do not retain their original characteristics and, thus, farmers need to buy hybrid seeds each year, and second, other breeders need access to parent lines for replicating hybrids, which can be protected as trade secrets. This was foreseeing as revolutionary by the pioneer scientists devoted to the development of hybrids: "[I]t is the first time in agricultural history that a seeds man is enabled to gain the full benefit from a desirable origination of his own or something that he has purchased. The man who originates devices to open our boxes of shoe polish or to autograph our camera negatives, is able to patent his product and gain the full reward of his inventiveness. The man who originates a new plant, which may be of incalculable benefit to the whole country, gets nothing –not even fame– for his pains, as the plants can be propagated by anyone. There is correspondingly less incentive for the production of improved types. The utilization of first generation hybrids enables the originator to keep the parental types and give out only the crossed seeds, which are less valuable for continued propagation".[41] Given the greater profit expectations, private breeders rapidly became interested in hybrid corn and,in the following decades, there was a steady increase in the quantity of new hybrids.

The Diffusion of PBRs

Unlike horticulturists in the US, plant breeders of sexually reproduced plants worldwide were not able to constitute a powerful interest group until the 1950s. After the Second World War, Europe achieved self-sufficiency and became an internationally competitive producer of agricultural products while the market of seeds started taking a global dimension.[42] In this context, European breeders and their associations gained influence in discussions about IPRs for plant varieties.

The first international conference was held in Paris in 1957. Breeders faced the serious objection that it is "contrary to the interest of humanity" to allow a monopoly in agricultural products and food because a monopoly might speculate on the needs of consumers.[43] However, they succeeded in demanding a reward for their innovations and the main debate was whether it was better to allow patent protection or to create specific rights. Finally, the decision was to create a *sui generis* system.

In 1961 five European countries (Belgium, France, the Federal Republic of Germany, Italy, and the Netherlands) signed the International Convention for the Protection of New Varieties of Plants, which established the UPOV. Signatory countries had to provide at least 15 years of protection for new plant varieties that proved to be distinctive, uniform, and stable. It took seven years for the founding countries to adopt PVP systems following the guidelines of the Convention, which finally entered into force in 1968.[44] The Convention was revised in 1972 -including minor modifications-, in 1978, and 1991.Other non-European countries also adopted legislation based on the UPOV, like the US that in 1970 enacted the Plant Variety Protection Act to provide PBRs to plant varieties.

Plant breeders' rights are specific rights, which grant breeders exclusive rights on propagating material of new plant varieties. Like patents, PBRs give the right to exclude others from using the protected innovation, but the demands for claiming protection are specific and they consider two relevant exceptions. The first one is the "breeders' exception", which allows breeders to freely use protected plant varieties to conduct research leading to a new plant variety, considering the cumulative nature of innovation in plants. The second one is the "farmers' exception", which allows farmers to use the seeds obtained from seeds of plant varieties they have bought. This exemption recognizes the contribution that farmers had made in the past, and still do, to present plant varieties through artificial selection. Both exceptions impose a limit in the monopoly created by PBRs facilitating access to protected plant varieties.

The 1991 Act of the UPOV Convention restricted these exceptions. The farmers' exception, which was compulsory in the two initial revisions, became optional in the 1991 Act. The breeders' exception is compulsory in all the Conventions, but the last revision limited its scope with the inclusion of the concept of "essentially derived variety" (EDV), which is a variety that is clearly distinguishable from the initial one but retains its essential characteristics. Then, a breeder wishing to obtain an EDV needs an authorization to use the initial variety via a contract or license, paying a right for its experimental use.[45]

The UPOV had a limited number of members until the ratification of the agreement on Trade Related Aspects of Intellectual Property Rights in 1994, which made compulsory patentability of micro-organisms, and non-biological and microbiological processes for the production of plant varieties. It also requires signatory countries to provide an "effective" IP protection system for plant varieties either by patents or *sui generis* systems. Since then, the UPOV system has been diffusing to most developing countries. Only a few countries, like India, Malaysia, and Thailand, have adopted PVP systems that differ from the one proposed by the UPOV, allowing farmers to sale seeds and register their plant varieties, considering the existence of a large number of small-scale farmers actively participating in seed improvement.[46]

This process has triggered several controversies. Advocates of a global harmonized IPRs regime claim that it will provide incentives to develop a more sustainable plant breeding industry and to boosttrade and technology transfer.[47] However, as innovation in plant breeding is location specific, the possibility of transferring plant varieties without any adaptation process is limited. Instead, foreign direct investment or cross-licensing with local breeders may be more likely to happen.

On the other hand, several arguments are put forward and the inadequacy of a uniform system of IPRs for heterogeneous countries is a key issue. The incentives provided by this system encourage an industrial agriculture that may be not suitable for all countries, especially for those with a large number of small farmers producing within systems that are far from the one implied in the UPOV. Also, the system can lead to monoculture, reducing biodiversity, which is an important asset in many developing countries.[48] Other critics target the consequences of the monopolization of biological resources in terms of concentration and the possible negative effects on future innovation.[49,50]

Patenting Plant Varieties and other Genetic Material

During the second half of the twentieth century, the consideration of living organisms as not patentable subject matter was questioned, in particular, given the advances derived from modern biotechnology. Different types of plant varieties resistant to weeds and insects, and withstanding salt, drought, or high and low temperatures, have been developed through the application of different techniques, and genes that confer these characteristics have been patented worldwide. However, also their patentability has been surrounded by controversies and one of them is whether a DNA sequence can be considered a discovery or an invention. Following a long controversial history, DNA manipulation of living organisms currently constitute patentable subject matter in several countries, although patenting of specific plant varieties and whole plants is not allowed in most countries.[51] The present situation regarding patentability of genes and DNA sequences is the result of fierce debates in these countries.

In the US, the lobby of firms involved in chemical and biotechnological research, which were acquiring seed companies, pushed towards the extension of the scope of IPRs.[8] Simultaneously, small farmers, consumer's organizations and social activists, were opposing to the granting of IPRs for living organisms.[6]

In 1980, the US Supreme Court confronted the question of whether living organisms could be eligible for utility patents. The decision in *Diamond* v *Chakrabarty* (1980) implied a turning point ruling that a live human-made micro-organism could be considered patentable subject matter. In 1988, the US granted the Patent No. 4,736,866 to Harvard College for the so-called OncoMouse, which became emblematic reflecting the new favorable situation to patentability of living organisms. In 1985, the US Patent Office started recognizing plants and plat parts as patentable subject matter and, in the case *J.E.M. Ag Supply, Inc.* v *Pioneer Hi-Bred International, Inc.* (2001), the US Supreme Court concluded that all plants are eligible for utility patents. Since then, US plant breeders can apply for a PBR, a utility patent, or both to protect their biological innovations. In addition, for the case of an asexually reproduced plant (excluding tuber propagated plants), they can apply for a plant patent according to the Plant Patent Act of 1930. Despite the complex interplay between PBRs and utility patents, South Korea, Japan, and Australia, also allow double protection.

In the specific case of genes and gene sequences, the US argues that they qualify for potential patenting as compositions of matter, if they are novel, isolated, their molecular structure is known, and if they have substantive and credible utility. In the last decades, utility patents have been issued in the US for plant inbreds, hybrids, plant parts -such as seeds, pollen, fruits, and flowers-, biotechnology methods, genes, DNA sequences, and several other products deriving from plants.[19]

Europe was more reluctant to accept patentability of living organisms.[52] In 1973, the European Patent Convention (EPC), constituted by most members of the European Union, forbade patents on plant and animal varieties, and essentially biological processes for their production, keeping this criteria in the revision of 1991. Plant breeders, especially those involved in biotechnology, were increasingly demanding patent protection, and despite the opposition of non-governmental organizations, consumers, and some European countries, the European Union Biotechnology Directive established common standards for the protection of biotechnological inventions in 1998, extending the protection of patented genetic information in plants to all materials in which the product is incorporated and in which the genetic information is contained, but still confirming that plant varieties are not patentable subject matter.[53] The rules of the EPC were amended to comply with the provisions and, accordingly, the European Patent Office has accepted claims to plants and animals if the technical feasibility is not confined to a particular plant or animal variety.[19]

Certainly, the application of modern biotechnology to agriculture has brought new challenges and complexity for the design, limits, scope, and enforcement of IPRs. A genetically modified (GM) plant variety is constituted by elements that may be protected by different rights. A significant number of patents related to biotechnological innovations is for processes or methods, which are used to develop new plant varieties. In addition, genetic materials and gene fragments may also be patented, while plant varieties do not always qualify for patent protection. All this creates contradictions and overlapping, and current legislation in many countries presents several unsolved questions.

One contradiction derives from the fact that patents do not consider breeders' and farmers' exemptions. Thus, patenting a gene creates an unbalanced situation between the owner of a plant variety and the owner of a gene, where the former does not have access to the gene without a license, the latter may legally access the plant variety without the breeders' authorization. Moreover, a similar problem arises with farmers' right of saving seeds because patents protecting a gene do not consider it, creating a contradiction in the scope and limitations of IPRs. Frequently, these contradictions have been addressed by using private contracts or special regulations in addition to existing acts related with IPRs.[54] Some countries, like France and Germany, have incorporated breeder exemption clauses in their patent laws.[55]

Another concern is related with the allowance of patents for relevant research tools and to the fact that a new plant variety can be composed by a set of innovations protected by different rights and different owners, which may need to be involved in contracts or licenses. This could lead to the "tragedy of the anticommons", which may arise when scientific commons are fragmented and appropriated by private firms with the right to exclude others from using them, hindering future research and slowing the pace of downstream innovation.[56,57]

Moreover, there are doubts concerning the influence of patent protection in the development of biotechnology. The mere existence of patents may hardly lead to more innovation and productivity, especially since a plant must be different but not better than existing ones to apply for patent protection. A recent analysis has shown that, in the US, most patented hybrid corns, including GM, did not improve significantly on prior ones. From a sample of 315 patent-hybrid pairs, only 141 (45%) have higher yields and, on average, new hybrids produced 0.81% less corn than existing hybrids.[58] Lastly, also in biotechnology, there are other available tools to protect innovations. Trade secrecy and asymmetries in knowledge assets are widely used means of protection. Another one is the use of private contracts either to enforce existing IPRs or to substitute them. Some examples are explicit licenses signed by buyers, which restrict resale or use of the material in breeding or sowing; bag label contracts and "material transfer agreements", which define the rights and obligations of recipients with respect to these materials; or "Technology Use Agreements", which restrict the use of plant genetic material.[59]

In addition, there are several initiatives using open-source and "copyleft" in agricultural biotechnology.[60] Most of them promote an alternative use of the patent system that may contribute to preserve free access to research tools, to help public sector technologies to reach developing countries by decreasing IP barriers, improving commercialization strategies, and increasing technology transfer.[61,62]

Further "Biological" Protection?

Another kind of biological IP protection may derive from the use of the so-called Genetic Use Restriction Technologies (GURTs). There are two types: variety-level (V-GURTs) and trait-level (T-GURTs). The first one makes second generation of seeds to be sterile by the introduction of a gene, known as terminator, in their genomes. The second one involves the external application of inducers, for instance, chemicals to trigger the expression of some specific traits in plant varieties. Both methods were developed in the 1990s by a cooperative research between the Agricultural Research Service of the US Department of Agriculture and the company Delta and Pine Land, and patented in the US in 1998.[63] The public awareness of the potential negative impacts of these technologies on genetic diversity, innovation, and the society, generated strong criticism. Finally, plant varieties with GURTs were not released to the market.

Despite plant varieties resulting from the application of V-GURTs are similar to hybrids in the fact that they can be used only once, an important difference is that hybrids have increased productivity, while V-GURTs do not search improvement of yields. In the case of T-GURTs, the use of seeds by farmers is tied to the purchase of another input to the developer. These technologies can be applied to all kind of seeds preventing not only propagation but also germination. Therefore, the scope, implications, and mechanism greatly differ from hybrids.[64]

Conclusion

In recent years, academic interest and controversies around the effect of IPRs on innovation and economic development have increased. Some of the main discussions regard the recent tightening and global diffusion of IPRs, the broadening of patent scope, the efficiency of IPRs as incentives to innovate, the social costs of generating monopolies, and the effect of IPRs on access to knowledge.[65]

IP protection for plant varieties shares many of the controversies revolving around other forms of IPRs. Some of them are similar to those raised during the "patent controversy" of the nineteenth century.[66] On the contrary, other issues are specific to plant varieties.

Protecting plants and other living organisms with IPRs presents complexities and ambiguities. One clear problem relates to the definition of the scope of IPRs. It is not easy to determine the precise moment and the inventor of a certain innovation because they often emerge from research performed by several actors even in different locations or time. Plants are complex organisms composed of several parts and they contain a historically evolved genetic program coded in their DNA.[67] All in all, there may be vague boundaries for two or more enforceable IPRs on close innovations.

Generally speaking, innovations are the result of the application of knowledge that leads to the creation of new goods or methods. Knowledge is, to a certain extent, easy to be replicated and appropriated by others, although its replication depends on capabilities and presents some degree of tacitness.[68] In addition, knowledge presents indivisibilities and innovation activities are costly and risky. Indivisibility, inappropriability, and uncertainty derive in a "market failure" that may prevent optimal resource allocation and appropriation of innovation rents in perfect competition.[69] Thus, IPRs are usually seen as the best available incentive to solve this problem.

However, there is a trade-off emerging from IPRs. While in some cases, IPRs might provide incentives to innovate, at the same time, they prevent access to knowledge, which might hinder future innovation and limit its diffusion.[70] This trade-off is particularly important in the case of plant varieties for two reasons. Firstly, because cumulativeness plays a key role since innovation necessarily depends on access to existing genetic material. Secondly, granting access to knowledge contained in seeds is a sensitive matter given the concerns related to the private appropriation of living organisms and the contribution that farmers have done to present plant varieties.

Considering this, breeders' and farmers' exceptions were introduced to lessen the problems of impeding cumulative innovation and access to knowledge. The exceptions address two controversial aspects of IPRs in any sector. The first one is the impediment of cumulative knowledge. The second one regards the control after sale of what others do with the knowledge contained in the protected device. In addition, these exceptions aim to impose a limit to the monopoly power that derives from IPRs. Along with the strengthening of IPRs, both exceptions were limited in the last decades. The farmers' exception is optional and the breeders' exception is now limited by the introduction of EDV, which, in principle, was introduced to discourage the creation of plant varieties with minor changes. However, this may have important effects in future research. While it may be an incentive for earlier innovators, doubts may be raised regarding whether it leaves place for enough profit for the second innovator. Besides, the fear of infringing a PBR may dissuade research or limit it to situations of "inventing around", still generating minor changes but increasing market shares.

The evolutionary process of improving and protecting plant varieties has been shaped by the fact that they contain the material that allows for their reproduction. This characteristic has driven plant breeders to demand IP protection, aiming to: (i) avoid being copied by other breeders or seed dealers, and (ii) prevent purchasers from reproducing plants.

Both issues are also faced by innovators in other industries. To some extent, plant breeding can be compared with the industry of books, software or music, where the price of creating new devices is high but their copies are almost costless and it is difficult to prevent their replication. However, the problem was exacerbated in plant breeding not only by the facility with which plants can be copied or propagated but also because the ability to demonstrate whether a variety has been copied was quite difficult with the technological tools available for many years. Both the possibility of reproducing plants and of proving the authenticity of a plant variety have changed along with scientific progress. These and other issues have been fiercely discussed since the nineteenth century. In particular, three main issues seem to be still unsolved and further complicated by recent technological changes.

Invention* v *Product of Nature

Legally, the "product of nature" doctrine prevailed until recently. Initial discussions regarded the innovation character of a plant variety. More recently, rather than questioning the inventiveness of a biological innovation, controversies have become related to the limits of the innovation. The recent application of biotechnology has added more complexity since plant varieties may now be composed of several parts subject to be protected by different IPRs with different scopes and limitations. Moreover, how to demonstrate authenticity of a plant variety was questioned until the development of new technologies that now allow accurate identification. Besides, the contribution of farmers and nature to present plant varieties may not be recognized when granting an IPR to a new development. Finally, the extended scope of patents has raised moral and ethical concerns related with the private appropriation of living organisms.

Incentives* v *Access

Providing incentives to innovate without hindering access to innovations has been fiercely discussed. Two factors exacerbate the problem in plant breeding. From the side of the users, there is a concern in recognizing farmers' contribution to plant improvement through artificial selection. From the side of the innovator, the strong cumulative character of innovation implies that there is an unavoidable path dependence, and a necessity to access past innovations to obtain further innovations. Thus, IPRs might hinder future biological innovations more than in other sectors. Recent patentability of products and processes that are used to develop new plant varieties has raised new concerns.

Social Costs of Monopolies

By providing a temporary monopoly, IPRs impose social costs because monopolists sell less at higher prices and because the market power they hold may lead them to innovate less. This is highly problematic in plant breeding and agriculture since monopolization of genetic resources can affect food production. Concerns regarding firms controlling food supply can be found in different historical frameworks. Until the 1960s, the issue was relevant for developed countries, which had gone through international conflicts after which they sought to attain self-sufficiency in food production. Later, this problem became more relevant for developing countries since food production and distribution is a major problem affecting a large share of their populations.

Discussions regarding PVP have been developing for more than a century. However, most issues remained controversial until our days, revealing the complexity of providing IPRs for living organisms. From a long run perspective, it is possible to identify different means of protection for biological innovations. This process has evolved from no formal protection towards strong IPRs systems in the present. However, the early development of plant breeding took place in the absence of formal IP protection or within weak IPRs systems. Several authors have shown that dramatic biological gains were made in plant improvements during the nineteenth century, despite they were not always visible because they helped maintaining productivity rather than increasing it.[3,4,18] As R&D costs and complexity increase, the need of proper incentives gains relevance, but access to innovations remains clearly important. The degree of protection and appropriation of innovation rents in plant breeding has been determined by the interplay of legal and natural factors together with political and social factors. In general, institutions, such as IPRs, do not evolve at the same pace than scientific progress. Even though different degrees of appropriation were in place over the years and countries, plant breeding has been growing, obtaining biological innovations. The longstanding and still open debate calls for a discussion on which IP protection system could better suit different countries and agricultural systems. A difficult balance between the provision of incentives and the access to genetic material is needed. But also, IP protection should help achieving -or at least not risk- food security and biodiversity.

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