Genetically Modified Seeds, Intellectual Property Protection and the Role of Law in Transnational Perspective

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Abstract

This paper tries to provide a fresh insight on a highly disputed, although very sectorial topic, represented by intellectual property protection on genetically modified seed and, in general, on agricultural biotechnology products. Both because of the wide employ of seeds and plant varieties in agriculture and for the international relevance of intellectual property protection, domestic perspectives on this very topic soon become obsolete, partial and useless. Intellectual property protection on agricultural biotechnology products is a charged topic for a number of reasons. First of all, seeds are the starting point of very complex value chains in all economies. That does not relate exclusively to food. Indeed, plants have now a role in a wide number of very diverse industries such as biofuels or textiles or construction materials. Most of all, seeds are indispensable for the production of vegetables, for a large part of the worldwide population the primary, if not exclusive, ingredient of the daily diet.

1 Introduction

This paper is a first attempt to provide a new legal perspective about the intersection of intellectual property protection and contract techniques to manage the use of seeds in agriculture, and, more specifically, genetically modified seeds that show resistance to pesticides, have higher yield and are less exposed to climate hurdles.

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There is a heated debate on biotechnology applied to agriculture. Intellectual property protection is one of the controversial issues involved, since the agro-business in most advanced economies is strongly incentivized by, and heavily relying on, patents. Less developed countries suffer from costly access to agricultural technologies needed to improve productivity. At the same time, such countries experience a paradox, since their territories are usually rich in terms of biodiversity and significant varieties. What can be eventually subject to genetic modifications and patented by large biotech companies comes indeed from those countries. Bio-piracy is one of those almost unregulated practices that end up being a serious wound for populations of less developed countries and a negative externality for the world population at large.

The main question that this paper aims to discuss is whether law as a technique to regulate and balance the interests of parties involved (farmers, communities, agro-bio companies) can have an effective role in governing the several models of agriculture and can be instrumental in supporting alternative business models that could co-exist with the current agro-bio business also in less developed countries. If law cannot be a factor of competitiveness for states (without triggering the usual race to the bottom), at least legal solutions can introduce strategies of differentiation among states, towards different models of economic growth.

2 The Problem: Intellectual Property Applied to Seeds

Seeds are an extremely important element of any eco-system as they are at the beginning of life, as far as the vegetal world is concerned. Access to seeds is a precondition for a number of farming activities which are primarily, but not exclusively, aimed at providing food to people. They include also the production of biofuels or of textiles and other critical raw materials. No matter how small a seed is, it is the initial ingredient of large, extended and complex value chains for all countries.

Because of the increase in the worldwide population and the alleged constant need for food, it has been thought that biotechnology applied to agriculture would have brought significant advancements in terms of pesticide resistant, high yield varieties that would have required less land, less water, less pesticides and less fertilizers to grow.[1] To achieve those purposes, technology can act, and has an impact, at different levels of the value chain of agriculture-based products.[2] Seeds are the primary asset and the starting point of the chain; acting at that level appeared

[1]The world population is expected to grow from the current 6.4 billion people to 9.3 billion in 2050, with a yearly growth of 77 million.

[2]For instance, researchers have been experimenting natural, eco-compatible polymers to reduce consumption of water. See, for instance, Demitri et al. (2013).

as particularly fruitful for agricultural biotechnology and techniques of genetic engineering have soon proved effective.[3]

The problem with biotechnological research (not necessarily referred only to the seed industry) is its cost and the need for expensive and complex instrumentation and procedures to deal with the extraordinarily complex structure of living organisms. Just as an example, researchers from the United States Department of Agriculture have recently announced the sequencing of the wheat genome. It has been an incredibly intense task, as it turned out that the wheat (*Triticum aestivum*) has between 94,000 and 96,000 genes, which is five times the size of the human genome.[4] Large investments have been made for an achievement that is an initial step to use genetic information to improve productivity and resistance.[5]

Unless states provide funding *ex ante* for intensive research and development activities mainly to public research organizations and academic institutions, most investments are undertaken by private companies that strongly rely on *ex post* exclusivity via intellectual property protection to ensure a return on investment for their research efforts.[6] In this regard, the evolution of the relationship between technology and intellectual property rights is no different from other fields, in all possible respects.[7] If, indeed, the private industry is championing the use of exclusive rights to ensure *ex post* incentives to investments in biotechnological research (with all the implications in terms of lobbying on governments in order to strengthen and possibly expand the scope of protection), small farmers and less developed countries protest against the use of intellectual property in this segment of agriculture and, particularly, on seeds.[8] Protection increases prices, that for the poorest populations is the real barrier in accessing seeds and, consequently, food.

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[3]But a ruthful critique to agricultural biotechnology comes from the influential work of Altieri (2015).

[4]See Brenchley et al. (2012).

[5]Bread wheat is a crucial crop for human life, since it accounts for 20 % of the calories consumed by humans. The current threat for wheat is a fungal disease identified as Ug99 (also known as stem rust), which is responsible for severe losses of crops in Africa, Asia and the Middle East since 1999. The study of the genome becomes instrumental to identify techniques that make wheat more resistant.

[6]There have been situations in which intellectual property protection has been sought also where the recurrence of an invention was doubtful, although investments for discovery had been significant. It is the case of the *Myriad Genetics* case, where the applicant tried to retain patent protection on two genes (BRCA1 and BRCA2) sequenced (an activity that required intense effort) even if the genes where not technically invented. See *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. (2013).

[7]At least in the United States, the federal government has had a crucial role in supplying farmers with seeds for over 100 years, before the private industry took over and started lobbying for increased intellectual property protection. For a detailed account of the evolution of the industry, see Center for Food Safety & Save Our Seeds, *Seed Giants vs. Farmers*, Washington, D.C., 2013, 13 (reporting that by the turn of the 19th Century the U.S. Department of Agriculture had distributed over a billion bags of seeds to farmers in the United States).

[8]The problem is not a new one. It had been already described by Busch et al. (1990).

Hard words are spoken and the difficulty of finding an equilibrium has been portrayed as a "seed war".[9]

Also from this perspective, things are apparently not different from other fields of the technology, and most remarkably in the field of software and digital creations. The assumption is that some resources (and, in this case, the germplasm of seeds) are commons and should be shielded by any attempt to extend proprietary rights on them. Yet, a closer look at the problem reveals that the situation is way more complex than in other sectors where supporters and critics of intellectual property protection are at war.

Access to seeds is considered a pre-condition for a number of practices in communities of farmers (mostly selecting the best seeds from the best plants, saving them for the next season—a practice also termed "brown-bagging"—and exchanging with seeds from other farmers), aimed at preserving biodiversity and increasing productivity by natural selection techniques. Across generations of seeds, varieties have been naturally improved and have become heritage of those communities. Such practices are basically inexpensive, not artificial (as cross pollination occurs naturally) and do not alter natural ecosystems where such seeds are employed. Most importantly, there are no exclusive rights at play that somehow constrain use. Actually, the exchange of seeds is an exchange of opportunities for improved local productions on smaller and larges scales.

Intellectual property protection kicks in when the selection process is triggered and achieved by means of biotechnological methods by manipulating the genetic information of the plant. The basic assumption is that the level of productivity should be increased and natural techniques of selection do not serve this purpose adequately (or timely, since they follow the time scale of nature and seasons). Moreover, because of atmospheric and bacteriological agents, plants should be made more resistant and genetic engineering is instrumental to that goal.

Exclusive rights applied to seeds means that the use of such fundamental ingredients of farming can (and in fact is) now heavily influenced by the intellectual property owner. Consequently, access to seeds is conditioned and practices of conservation and exchange of seeds become essentially forbidden to the extent they frustrate the interest of owners and do not earn their consent.

There are additional problems caused by the combined use of genetically modified seeds and intellectual property protection. First of all, since engineered seeds are resistant to pesticides, the selection process makes then dominant over time; other less resistant varieties are doomed to gradually disappear. In short, biodiversity is at jeopardy and varieties that may have important properties can get lost. Furthermore, since many agricultural regimes end up becoming monoculture, they are less resilient and intrinsically vulnerable to events and pests that might destroy them altogether. And since monoculture is at the opposite of rotation, land is doomed to a progressive impoverishment, which in turn justifies the massive resort to chemical fertilizers. Of course, biotechnology is at work here to make sure

[9]For an uncompromising reading see Shiva (2015).

that all this does not happen, but more resistant varieties come at the cost of more expensive access to protected technology; the problem, in a sense, is only postponed and the case for agricultural biotechnology is reinforced.

There are also ethical, technological and inevitably legal discussions about the opportunity of using transgenic varieties to produce food; science has not been able so far to clearly define whether there is a genuine risk for human health and for nature coming from use of genetically modified plants.[10] No matter how important this discussion is, its scope goes beyond the aim of this paper, which is to deal with genetically modified seeds from the perspective of the incentives created by intellectual property protection regimes and their impact at transnational level. After all, if given applications of biotech are risky for health it is not a matter that depends directly on intellectual property and the focus should be rather on the nature and results of biotechnology applied to food.

Intellectual property protection applied to genetically modified seeds appears problematic in a number of respects. As we have seen, exclusive rights provide the legal infrastructure for the industry to limit those practices that are at odds with the proprietary prerogatives and that would reduce the profitability of trade in seeds. Conflicts arise among supporters and opponents as in any other field of technology and there is a movement that equals seeds to commons and urges to reconsider the use of intellectual property in agriculture, where a commons regime is more consistent with agricultural practices, particularly in smaller communities of farmers. Moreover, there is also the suspect (somehow documented by evidence) that agricultural biotechnology is over-incentivized by intellectual property protection. The outcome is an apparent (and dangerous) diversion of the original purpose of the policy, which is no longer to support investments to improve agriculture, but to increase profitability, even when there is no technical problem to be solved, by artificially creating or reinforcing the rationale for biotechnological investments and, consequently, intellectual property protection.[11]

2.1 The Problem with Exhaustion of Rights

There is one peculiarity of biotechnological inventions that, when referred to genetically modified seeds, is a major source of legal problems for any patent policy, as well as for rights holders. Biotechnological inventions can refer to

[10]One remarkable case involves the production of transgenic corn in Italy. Until recently, there have been cases brought before administrative judges to challenge the decision of health authorities to deny authorization to put in commerce and employ in agriculture transgenic varieties. See, for instance, T.a.r. Lazio 23 Aprile, 2014, n. 4410, in *Ambiente*, 2014, 548, confirmed by Cons. Stato 6 febbraio 2015, n. 605 (not yet published).

[11]See Center for Food Safety & Save Our Seeds, *Seed Giants vs. Farmers*, cit., 15.

organisms that have the ability to be self-reproducing[12]; in other words, alike other inventions in different fields of technology, they are living matter.

The root of the problem is straightforward. The general rationale behind intellectual property rights is simple: imitation of a protected item is infringement. Protected items can be bought and used and even resold downstream or donated, but cannot be generally reproduced without permission of the intellectual property owner. The first sale of a protected good causes exhaustion of protection, in connection with the payment of a consideration (a supra-competitive price) that is supposed to compensate the inventor for its investments. Typically, exhaustion does not affect the limitation to create copies of the protected items, even if such items have been lawfully acquired in exchange for a price.

But what if the protected technological good can create copies of itself, by reproducing the features that are subject to patent protection? Does the exhaustion effect still take place or it never does? And in the latter case, can the patent owner control the technology all along the value chain, no matter how it is used, by whom, how many times, for whatever purposes until the patent is in force?

These interrogatives are clearly technology-specific; they refer to biotechnology and, as far as genetically modified seeds are concerned, they pose a serious issue for patent policy.[13] Limiting protection to the first sale would be probably not enough in terms of incentives for the agro-bio industry. On the other hand, accepting the fact that protection is never exhausted turns out to be a multifaceted problem, first in terms of overprotection and costs that the public at large may be called to bear, second for the discrimination among technologies, that could have an impact on industries and markets.[14] This is a puzzle that requires legal solution and although each legal system can come up with its own solution, the consequences and the effects of each choice can go well beyond the national borders. Regulation can have direct internal impact (benefitting the intellectual property holder or farmers), but it has also certainly external effects by influencing at transnational level the choice of the industry to commercialize given technologies and to extend the operations in given countries. In this respect, the link among intellectual property protection, international trade and foreign direct investments is clear and strong. Regulation of

[12]This feature is recognized as structurally distinctive for biotechnologies; see for instance art. 2, par. 1, lett. (a) of European Directive 98/44/EC.

[13]For a discussion on the alternative options, see Downing-Howk (2004).

[14]One remarkable difference that emerges in considering exhaustion of rights relates to software, that, alike seeds, is not self-reproducing but, like seeds, can be "generative" of further products by preserving a constant trait. Quite interestingly, the U.S. Supreme Court held that a sale of a product that incorporates a software process technology causes the exhaustion effect. See *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008). For a comment on the decision see also *The Doctrine of Patent Exhaustion: The Impact of* Quanta Computer, Inc. v. LG Elecs., Inc., in 14 *Va. J.L. Tech.* 273, 283 (2009). Software and seeds have been considered showing some common traits by Leaven (2008), that criticizes the different conclusions on exhaustion. But the argument of similarity goes back to the opinion of the advocate general Mischo in the European case *SPRL Louis Erauw-Jacquery c. La Hesbignonne SC* (in *ECR*, 1988, 1919).

intellectual property has effects on other policies and affects other aspects of the market.

More importantly, if exclusive rights are persistent for self-reproducing technologies, the right holders can continue ruling about the way the technology can be used, thus perpetuating their will (not only their exclusive rights) downstream and imposing models to users that might further limit farmers' freedom. This power might go well beyond what is needed in terms of incentives for the industry.

3 Contracts for the Circulation of Genetically Modified Seeds

Intuitively, coupled with the problem of patent protection for genetically modified seeds is the use of contracts to control the value chain by intellectual property owners and to reduce the risks of farmers' behaviors that would seriously harm the protection and reduce the profitability of innovative technologies.

Proprietary protection is a necessary condition to be rewarded and receive incentives to invest in genetically modified varieties. But it is not sufficient. The intrinsic limitation of exhaustion is, so to say, a genetic trait of patent protection, and a very troublesome one. Moreover, there are several farming practices that require a further level of restriction not allowed by patents, but certainly available through contractual terms. Since exhaustion effects come from sales, and sales are contracts, one way to control circulation is precisely to act on sales terms and conditions, by conforming the use of purchased seeds to the commercial strategy of the rights holder.

To fully understand the use of contract to control the circulation and the use of seeds it is worth recalling that genetically modified seeds are commodities bought by farmers for sowing. What is protected is not the seed *per se* (that is, the portion of physical matter), but the process technology that is responsible for the definitive modification of the germplasm as it results in the genetic information eventually contained in the seed.[15] Purchasing the seed also implies accessing the technology, which is an inseparable feature of the seed.

In order to prevent exhaustion of patent protection that insists on the technology, the agro-bio industry has come up with an ingenuous mechanism that relies on contracts. Thus, when farmers buy seeds in bulk (typically packed in bags of different size), the transaction is construed as a complex contract that blends a sale (of the seed as such) and a license (of the incorporated proprietary technology).

Terms and conditions of the license are typically fine-printed on sealed bags and a more specific clause warns purchasers that opening the bag and using the seeds signifies acceptance. Those familiar with software technology contracts will recognize a mechanism of contract formation that is analogous to shrink-wrap licenses and that might raise the same doubts about the meaning of the consent exchanged

[15]Because of the nature of technology (a process), protection extends to the outcome of the process, that is the genetically modified seed.

(to be sure, the mechanism is also termed "bag-tag" or "seed-wrap" licensing, by analogy with other –wrap like agreements).[16] Patent and technology owners are thus able to impose unilaterally contractual terms to the purchaser that is at the same time a licensee of the technology subject to rights and obligations concerning its use.[17]

More in details, contract terms require the farmer to use the seeds only for one season and not to replant second generation seeds (that is, seeds that come from plants that are grown by sowing the seeds purchased in the first place). Moreover, the farmer cannot exchange the seeds with other seeds, whether his own or third parties'. If seeds are exchanged and used for replanting, the recipient of the seeds is an infringer (because patent protection is still effective and the terms of the agreement are enforceable), while the provider is in breach of the license. The recipient can then be pursued not on contractual ground, because technically there is no relationship between him and the technology owner (no privity), but because he is accessing a piece of intellectual property without consent where the protected feature is still subject to exclusive rights. All these contractual prohibitions are made possible by the fact that the first sale (that includes a license) has not technically caused exhaustion.[18] Here again, it has to be recalled the difference between biotechnology and software technology.[19]

Once purchased, seeds are then used for sowing, but since plants coming from seeds yield seeds on their turn, and the variety is genetically modified, the next generation of seeds is identical to the former and still featuring the proprietary traits. Needless to say, exhaustion is prevented by the fact that the embedded technology is licensed and not sold and contractual terms can introduce in the contractual relationships the whole set of limitations that have been previously mentioned.

To a mind not exposed to legal sophistications, such mechanisms can appear as artificial and complex; and so they are. Their effectiveness results from the combination of proprietary rights and contract techniques whose immediate outcome is

[16]The seed-wrap licensing practice has been approved by a number of lower courts in the United States and then affirmed by the U.S. Supreme Court in *J.E.M. v. Pioneer*, 534 U.S. 124 (2001) at 145.

[17]The context is of a typical business-to-business transaction, with standardized terms unilaterally written and imposed to farmers by the owner of the critical (intellectual property protected) resource.

[18]The International Seed Federation has expressed its view on the topic of exhaustion by stating that there should be no exception for farm-saved seeds under any form of intellectual property right (see *ISF View on Intellectual Property*, Rio de Janeiro, 2012, 26).

[19]And it is a difference that comparatively is stronger in Europe than in the U.S., after the ECJ decision in *UsedSoft GmbH v. Oracle International Corp.* (ECJ 3 July 2012, C-128/11), that has interpreted the European directive on software as meaning that the right of distribution of a copy of a computer program is exhausted if the copyright holder who has authorized, even free of charge, the downloading of that copy from the internet onto a data carrier has also conferred, in return for payment of a fee intended to enable him to obtain a remuneration corresponding to the economic value of the copy of the work of which he is the proprietor, a right to use that copy for an unlimited period. For a comment, Göbel (2012).

to perpetuate patent protection across generations of seeds and to subject farmers to the intellectual property rights of the growers.

The combined effect of contracts and property comes at the inevitable cost of forcing contracts as mechanisms to control circulation and use of seeds. The mechanism is effective to the extent the terms and conditions of the agreement are enforceable, but the enforceability has to be tested against legal theories on contract formation at national level. Since contract law is still largely national, the viability of contractual solutions by intellectual property owners cannot be affirmed once and for all legal systems. Although there is a trend to consider such arrangements as valid, still occasionally some courts might object to their enforceability.[20]

As a matter of fact, through the mentioned combination of intellectual property and contracts, the agro-bio industry is able to retain absolute control of the value chain and to extend its powers to connected market (such as that for chemical products, including pesticides, herbicides and fertilizers). Going back to the mainstream arguments of the debate, without intellectual property there would not be any new genetically modified variety. If exhaustion effects worked as in any other instance of intellectual property protection, the incentives would be reduced (if not eliminated), as the first sale of a self-replicating technology would then make it available to anyone at no cost. The use of seed-wrap licenses relies on, and at the same time reinforces, patent protection on seeds.

Negative externalities are apparent. Without intellectual property protection, downstream activities implying the use of seeds would be unfettered and common practices of saving, exchanging and replanting seeds would be perfectly lawful. Resort to intellectual property is a real game changer and a large part of negative effects (starting from loss of biodiversity) comes from the operation of this mechanism and should become part of the equation for balancing grants of exclusive rights with social benefits to access.

4 Normative Framework that Applies to Genetically Modified Seeds and How It Deals with the Problems Above

The agro-bio industry has an interest in applying uniformly the solutions devised at contractual level to prevent exhaustion, reinforce intellectual property protection, manage risks and increase profitability. In a globalized world, such solutions can be seen as a genuine expression of a new *lex mercatoria* or, more brutally, the attempt of multinational corporations to opt out from a legal system and to impose their own laws. To the extent national courts enforce such contractual arrangements, they give a pass to them to freely circulate in the market as legally viable solutions and to propagate into other legal systems (when circulation of models is path dependent).

[20]For a discussion of techniques of contract formation in comparative perspective see Granieri (2015).

Pressures to modify intellectual property laws in a more favorable way to industry, although powerful (because of the lobbies), have limited effect since international treaties within the Word Intellectual Property Organization require consensus, that is more and more difficult to obtain for the opposition of those countries that are negatively affected by the practice of multinational corporations.[21] On the other hand, contract law remains mostly a national matter and it shows more flexibility; empty spaces left by legislators can be easily filled in by private ordering and freedom of contracts.

The legal question then is to see which are the limits of private autonomy when dealing with intellectual property protection on genetically modified seeds. The question does not have a general and abstract answer. It must be dealt with still under the state laws where contracts are used by the industry to engineer solutions that are consistent with its own goals.

In a number of recent cases, Monsanto—which is one of the few large multinational corporations in the field, epitomizing the archetype of the globalized player in the agro-bio market[22]—has been testing for some time now from a legal standpoint the enforceability of its contractual arrangements for the distribution of patented genetically modified seeds. In particular, the company owns patents related to soy modified with DNA-recombinants techniques that make the seeds resistant to herbicides and, more specifically, to glysophate-based products (also patented and sold by the same corporation).[23] This technology is worldwide known as the Roundup Ready®.

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[21]As a matter of fact, the Doha Development Round negotiations started in 2001 are still blocked and agriculture is one of the most relevant dealbreakers.

[22]According to some sources, Monsanto is responsible for the commercialization of 90 % of all genetically modified organisms worldwide. It has been also the topic for a documentary by Robin (2015), where all the major critiques towards the company are counted by the author.

[23]In at least one case, Monsanto's patent claims are direct to a method for controlling weeds with its technology. See US patent n. 5,352,605 its reissue RE39,247 (claim 32): «A method for selectively controlling weeds in a field containing a crop having plant crop seeds or plants comprising the steps of: (a) planting the crop seeds or plants which are glyphosate-tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant, the DNA molecule having: (i) a promoter which functions in plant cells to cause the production of an RNA sequence, (ii) a structural DNA sequence that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence domains: -R-X.sub.1-H-X.sub.2-E-(SEQ ID NO:37), in which X.sub.1 is G, S, T, C, Y, N, Q, D or E; X.sub.2 is S or T; and -G-D-K-X.sub.3-(SEQ ID NO:38), in which X.sub.3 is S or T; and -S-A-Q-X.sub.4-K-(SEQ ID NO:39), in which X.sub.4 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V; and -N-X.sub.5-T-R-(SEQ ID NO:40), in which X.sub.5 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, P, S, T, W, Y or V, .Iadd. provided that when X.sub.1 is D, X.sub.2 is T, X.sub.3 is S, and X.sub.4 is V, then X.sub.5 is A, R, N, D, C, Q, E, G, H, I, L, K, M, F, S, T, W, Y or V.Iaddend.; and (iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the EPSPS enzyme to enhance the glyphosate tolerance of the crop plant transformed with the DNA molecule; and (b) applying to the crop and weeds in the field a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop».

Monsanto uses a double channel to distribute its products: directly via farmers and, indirectly, via growers that are responsible for duplication and sale to farmers. In both cases Monsanto uses a standard form contract, called the Monsanto Technology Steward Agreement (Monsanto TSA) under which the several technologies owned by the company are licensed to growers and farmers. Monsanto TSA is a single-use license, meaning that the purchaser of the seed is allowed to use the seeds «solely for a single planting of a commercial crop» (art. 4.f). Additionally it introduces a number of limitations concerning saving, transferring, cleaning or conducting research on patented seeds. Second generation seeds (those obtained by planting the purchased seeds) can be sold as commodity seeds to local grain elevators, that typically do not suffer limitations in reselling such seeds.

In the U.S. case *Monsanto v. Bowman*, a farmer had bought for years patented seeds from growers licensed by Monsanto, complying with the licensing terms. Due to the need of a second (and riskier) sowing in the same year, Bowman starts acquiring lower price seeds from a local elevator and starts mixing those seeds with third generation seeds (clearly breaching the terms of the Monsanto TSA).[24] When Monsanto brings an action against Bowman, the farmer raises, among other things, the defense of exhaustion of rights: purchasing seeds from those who do not suffer limitations (such as grain elevators) should trigger the application of the first-sale doctrine and return freedom of operation to the farmer.

Bowman's argument is not accepted by the district court and by the court of appeals. The Supreme Court of the United States granted *certiorari* and there was a feeling that the appellate decision might be overturned in favor of the farmer. But an unanimous court ruled once again in favor of Monsanto.

Since at least 1992, U.S. courts have supported the practice of Monsanto to tie a sale and a license and to introduce post-sale restrictions to farmers when purchasing patented seeds. In one case, judges justified such practices with the need to protect public health and to limit exposure to products liability. The same rationale has been applied by the U.S. Court of Appeals for the Federal Circuit to all self-reproducing biotechnological innovations.[25] *Bowman* does not come as a surprise, nor the judges' sentence that applying the first sale doctrine to the derivatives (generations) of self-reproducing technologies «would eviscerate the rights of the patent holder».

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[24]Because genetically-modified seeds are resistant to glysophate, while natural seeds are not, Monsanto's agents can easily verify whether one field is planted with natural or modified seeds. Spraying herbicides will kill the natural plants and weeds and will keep alive genetically modified varieties. If the farmer cannot show the bag where the seeds were stored, he is clearly an infringer. Monsanto has been also criticized for the forceful manners of its agents in collecting evidence, sometimes trespassing farmers' property. Monsanto's practices are also described by Johns (2009, p. 16). Enforcement techniques can produce false positives in case of the so called blown-by seeds, that is, situations in which genetically modified varieties are found in fields where seeds had not been used intentionally by farmers, but brought by the wind from adjacent fields.

[25]U.S. courts introduced the distinction between conditioned and not conditioned sales; exhaustion only applies to the latter and not in all cases in which the seller has put conditions in the terms of the agreement, which is exactly the case with seed-wrap licenses.

The U.S. Supreme Court had requested an opinion to the Solicitor General before issuing the decision in *Bowman* and this circumstance had been interpreted as if the Court would be ready to reverse the Court of Appeals' opinion and introduce a principle that applies the exhaustion principle also for self-replicating technologies.[26] But it was not the case. An unanimous Court reinforced the position that «[t]he exhaustion doctrine is limited to the "particular item" sold to avoid just such a mismatch between invention and reward». The first sale of the seed does not terminate the rights of the holder: «"a second creation" of the patented item "call[s] the monopoly, conferred by the patent grant, into play for a second time"».[27] The problem, one could just add, is in the fact that the monopoly could be called into play for the entire life of the patent and no matter how many generations of seeds are grown.

Importantly, the Court was clear to say that the power to prevent the use of second generation seeds stems directly from the kind of patent protection that attaches to biotechnological inventions and it is not dependent on contract terms. Hence, such terms are perfectly valid, as they are not aimed at unlawfully extending the exclusive rights granted by the patent.

4.1 Life After *Bowman* and European Union Law

Bowman is an interesting case, for a number of reasons. First of all, it reached the Supreme Court and it won a nine-zero opinion that is a strong signal about the practice of Monsanto and seed owners, thus setting a precedent that might have an influence even outside the jurisdiction of the United States.[28] Secondly, it endorses a different treatment for biotechnological innovations concerning self-reproducing technologies, that in fact are never subject to exhaustion, thus becoming stronger and more pervasive than any other innovation, but also raising the issue of consistency between intellectual property policy and other values (such as the promotion of biodiversity). Thirdly, it shows how, in the U.S. legal system, the sources of law interact on this very topic, where contract law remains essentially state law, whereas patent protection is federal law; enforcement of contracts for circulation of intellectual property rights is somehow influenced, at state level, by federal laws and this has also been considered as an area of potential friction at the interface of state and federal regulation. The U.S. case provides a good benchmark for

[26]According to Duffy (2010), the request of an opinion is an element that typically predicts the decision to grant *certiorari* to reverse the case. Empirical data on the relationship between requests of opinion and decisions are available in Thompson and Wachtell (2009).

[27]The Court of Appeals had been more cautious and justice Kagan affirmed that the decision did not aim to apply to all instances of «self-replicating products», although «such inventions are becoming even more prevalent, complex, and diverse»; see *Monsanto Co. v. Bowman*, 657 F.3d 1341 (Fed. Cir. 2011).

[28]Importantly, national solutions about exhaustion are extremely important because international sources, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), refuse to deal with this topic and leave it up to states sovereignty.

European regulation, where the creation of an internal market by EU legislation has been jeopardized in many occasions by contractual practices that were deemed to be enforceable under state laws.

On the territories of the European Union the situation, at legal level, shows some differences, at least as far as genetically modified seeds are concerned. There might be political and economic reasons that justify the European view of the problem; after all, the main agro-bio companies are U.S. multinationals and the European industry, with few remarkable exceptions, lags behind. But it might well be that a casual legal difference provides the basis for a strategy of legal differentiation at regional level, that might compensate the negative externalities produced, at international level, by a more relaxed treatment of contracts for the circulation of intellectual property rights on genetically modified seeds.

The principle of exhaustion, created initially by case law, has been instrumental in supporting the process of market integration in Europe, by limiting the power of intellectual property owners and the ability for them to control the circulation of goods downstream once a merchandise has been put in commerce on the European territory.[29] It has been then incorporated into patent laws (and intellectual property laws in general).

Since 1988, in *Erauw-Jacquery*, the European Court of Justice acknowledged that some restrictions in license agreements were necessary (and thus exempted by antitrust laws) in order to protect the investment of companies, since «the development of the basic lines may involve considerable financial commitment».[30] The Court joined the argument of advocate general Mischo, that some contractual restrictions are required «to control the destination and the use of the basic seed; otherwise [the owner] would risk the de facto loss of the exclusive rights granted to him in respect of the new varieties which he has developed».[31]

The issue of exhaustion for patent rights on biotechnological inventions is now dealt with under EC Directive 98/44 (art. 10) and the solution is not devoid of difficulties, entangled as it is into general statements and specific exceptions. More in details, art. 11 of the Directive states, by way of exception to the general principle of protection, that the sale or other forms of commercialization of plant propagating material [*scil.*: seeds] to a farmer, by the holder of the patent or with his consent, for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of EC Regulation 2100/94 (see, *infra*, next paragraph). In light of the mandatory nature of

[29]For a discussion of the current dimension of exhaustion in European Union law, see Schovsbo, *The Exhaustion of Rights and Common Principles of European Intellectual Property Law*, in Ohly (edited by), *Common Principles of European Intellectual Property Law*, Tübingen, 2012, 169.

[30]ECJ 19 April 1988, C-27/87, *SPRL Louis Erauw-Jacquery c. La Hesbignonne SC*, in *ECR*, 1988, 1919.

[31]Opinion of Advocate General Mischo of 9 December 1987, *SPRL Louis Erauw-Jacquery c. La Hesbignonne SC,* par. 11 (in *ECR*, 1988, 1919).

Article 11, single-use licenses in Europe are not enforceable if they aim to take away from farmers the freedom granted by the Directive.

The relevant side of the provision, for what matters with respect to the purpose of this paper, is that the exhaustion only applies to the extent seeds are used (also for replanting) for internal purposes and not to put them in trade. Exchange of seeds is not allowed because that practice would imply a use that is by the farmer but not on his own farm. The ability to multiply the seeds for internal purposes has a positive impact on farming, to the extent it allows the farmer to deal with genetically modified seeds and with their derivatives without necessarily being forced to purchase seeds every season. Moreover, the farmer can mix his own seeds with those purchased or with second generation seeds and promote, a least internally, biodiversity.[32]

4.2 Concurring Forms of Protection: Utility Patents and Plant Variety Registration (UPOV)

At an international level, a relevant source for intellectual property protection of plant varieties is the International Convention for the Protection of New Varieties of Plants (UPOV convention). The convention has been introduced also in the European Union with EC Regulation 2100/94 on Community Plant Variety Rights. Importantly, as stated in art. 1 of the Regulation, its provisions are the sole and exclusive form of protection for plant varieties in Europe.[33]

Plant varieties can be reproduced by natural techniques (for instance, by mere cutting) and such circumstance is again a source of vulnerability for protection. The extent to which exhaustion limits protection for breeders is defined in art. 16 of the UPOV convention. The breeder's right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of art.14 (5) (concerning varieties which are essentially derived from the protected variety), which has been sold or otherwise marketed by the breeder or with his consent in the territory of one Contracting Party concerned, or any material derived from the said material, unless such acts (i) involve further propagation of the variety in question or (ii) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes.

[32]The interpretation of the Directive followed by the European Court of Justice is consistent with the purpose to maintain a difficult equilibrium for all the interests involved in this matter. For instance, in *Monsanto v. Cefetra*, the ECJ stated that art. 9 of the Directive define a level of harmonization that does not allow national Member States to increase the level of protection; see ECJ July 6, 2010, C-428/08.

[33]The protection for plant varieties is also available in the U.S. with the Plant Varieties Protection Act (PVPA). The relationship between utility patents and plant varieties patents has been discussed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* 534 U.S. 124 (2001). The case is discussed by Daniels (2003), Rives (2001), Nilles (2000).

Many Contracting States, including the European Union (as signatory party of the Convention) within Regulation 2100/94, have adopted the solution that allows to restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety that is essentially derived by the one protected. Regulation 2100/94 limits this possibility to the varieties listed in art. 14.2.

Also in these sources there has been an attempt to reconcile a policy of incentives with the need not to excessively restrict farmer's freedom, at least with respect to activities that can be considered "private" and that are presumptively of limited impact on the market.[34]

There appears to be a divide between the U.S. law on agro-bio inventions and the extent of patent protection, on the one side, and the European solution, coupled with the international sources, on the other side. The U.S. system adopts a position of absolute protection for innovators in biotechnological agriculture and accepts unconditionally all the implications, including the use of contracts (and unilaterally imposed terms) to further limit farmers' freedom, if such freedom can pose a threat to the exclusive rights of right holders or weakens his business model. Moreover, the lack of exhaustion effects in case of self-reproducing matter is considered a built-in feature of intellectual property protection. An uncompromising faith into the incentives' structure of patent laws seems to justify the policy.

On the other side, the European Union and many other countries, even if aware of the difficulties in striking the right balance, are more in favor of a limited freedom of farmers, by allowing exhaustion in circumstances where private use can be reasonably accepted.

5 International Laws and the Interface Between Intellectual Property Policy and Contract: The Nagoya Protocol

The topic of genetically modified seeds cuts across other relevant aspects concerning the international regime of trade in those fields where seeds are at the beginning of the value chain. The values at play are not necessarily only those of the biotech industry or of farmers. As it should be clear, to the extent biodiversity is essential to ecosystems, the need to preserve non-genetically modified varieties (while not discouraging biotechnological researches) is also extremely important for the public at large. Moreover, outside most developed nations there is a kind of agriculture that is inspired by communitarian values and that mixes elements of cultural, economic, sometimes religious dimension.[35]

[34]To some extent, the grower can limit the ability of farmers to do certain things by contractual restrictions, but without relying on property rights. Acts contrary to the restrictions only qualify as breach of contracts, not as infringement.

[35]See Ferran (2014).

When the destruction of biodiversity if feared as a possible consequence of an indiscriminate use of stronger and more resistant varieties, all those values come to play altogether and finding a balance point can be near to impossible. Preserving biodiversity implies also a responsible use of the intellectual property rights at national level and an enforcement of contracts that does not extend unreasonably the powers conferred upon rights holders by intellectual property regimes. Differences in legal systems, in this respect, are not necessarily a negative thing, as it will be clarified in the next paragraphs.

Biodiversity can be at risk not only as a consequence of the introduction and massive use of genetically modified varieties, but also by unauthorized access to natural resources of communities where the environment is still rich and pristine, compared to more industrialized and intensively cultivated territories. Such access has often turned into biopiracy and to practices that have been identified as "predation" or neo-colonialism, in line with the warlike terminology mentioned at the beginning.

In a sense, it sounds as a vivid paradox the fact that even the most advanced research of developed countries needs access to local and poorly codified knowledge generated at community level in less developed countries by a slow and steady accumulation that lasted for centuries, if not for a 1000 years.[36] The impact of such access is sometimes dreadful, because resources are appropriated, modified, subjected to intellectual property rights and then sold as new products to local farmers, for whom such resources used to be free. Biodiversity is compromised, a regime of commons is destroyed, resources become exclusive and other communitarian values are overridden.

In order to preserve biodiversity and combat biopiracy, member states which are part of the Convention on Biodiversity eventually introduced a specific international instrument, that is the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.[37] The purpose of the Protocol is to make sure that genetic resources are accessed under consent of the communities they belong to and that utilization of genetic resources allows a fair and equitable share of benefits to such communities.[38]

The European Union has signed the Protocol on June 23, 2011 and has approved it on May 16, 2014 with a specific regulation. In October 2012, the European Commission presented a proposal for an EU Access and Benefit Sharing

[36]One often quoted example of biopiracy is the case for the "devil's claw" (*Harpagophytum procumbens*), an herb native of the eastern and southern Africa that local communities of the San people used as an anti-inflammatory and now widely employed in the pharmaceutical industry.

[37]The Protocol was adopted on October 29, 2010. See Tania Bubela, E. Richard Gold, *Genetic Resources and Traditional Knowledge. Case studies and Conflicting Interests*, EE, 2013. Catherine Rodhes, *Governance of Genetic Resources*, EE, 2013. Charles Lawson, *Regulating Genetic Resources*, EE, 2012.

[38]Levidow and Carr (1997), reported that unpaid royalties to less developed countries amount to 5.4 billion USD.

(ABS) Regulation to implement the mandatory elements of the Nagoya Protocol for the European Union. The European Parliament and the Council adopted the new EU Regulation (No 511/2014) on 16 April 2014. It has entered into force on 9 June 2014. Entry into force of Regulation 511/2014 was made dependent on the entry into force of the Protocol, which happened at its fiftieth ratification.[39]

The main provisions of the regulation (art. 4, 5 and 7), concerning obligations in the use and transfer of genetic resources will only become applicable one year after the entry into force of the Nagoya Protocol. Regulation 511/2014 implements the mandatory parts of the Protocol (basically a repetition of its main provisions), whereas a further implementing regulation is currently being worked out, although it is not yet clear when this is going to be adopted.[40]

One of the pillars in the policy of the Protocol is about due diligence efforts that each private party has to exercise when receiving a genetic material, to make sure the relevant provisions of the Protocol have been complied with.[41] As a consequence, a significant role for the functioning of the Protocol is expected by Member States of the EU, which will have the role of cooperating with the Commission to lower, as much as possible, the due diligence costs associated with access to genetic resources and traditional knowledge.[42]

Since seeds are genetic materials, under the terms of the Protocol, the use of seeds and the genetic manipulation of plant varieties will be now subject to the provisions of the Protocol. Hopefully, exotic varieties will not be appropriated and modified without the consent of the local communities and phenomena of reverse technology transfer will be avoided.[43] Nothing in the Protocol prevents individuals

[39]As of the date of this writing (February 2015), the Protocol has been ratified by 59 States, out of the 196 Parties of the CBD.

[40]There might be coordination problems in implementing the Protocol in Europe that might eventually jeopardize its effectiveness. The European Union is one of the signatories of the agreement, together with European Members States. Since several measures will depend on states, there is the genuine risk that institutional activisms of the European Union will collide with prerogative of Member States in implementing the instrument.

[41]Importantly, the protocol also refers to, and protect, the traditional knowledge associated with genetic resources (see art. 7 of the Nagoya Protocol). Traditional knowledge is for genetic resources what complementary know-how is for a patented technology. It resides in indigenous and local communities and is part of their tradition.

[42]Due diligence is the pillar of the Protocol as far as circulation of genetic resources is concerned. In each transaction, each party belonging to an implementing state will be subject to the duty to ascertain whether the resource has been lawfully acquired (that is, in compliance with the principle of access). In the past, it was suggested that one solution to ease the identification of the origin of resources was force applicants to declare the source of the material in the patent application. The solution had been opposed, as burdensome, by the International Seed Federation (*Disclosure of Origin in Intellectual Property Protection Applications*, Bangalore, 2003). Very likely it will be considered again as a possible way to mitigate the duty of due diligence.

[43]Reverse technology transfer is the situation in which a state is supposed to pay to access resources that are subject to proprietary rights of a third party, although such resources were originally from the recipient state.

and companies to resort to intellectual property protection for genetic resources that have been appropriated, if the owner of the resource consented to access.

Furthermore, the legal relevance of the Protocol for genetically modified seeds lies in the fact that genetic resources (including traditional know how) are subject to the mechanism of consent and to an international property rights regime. There is nothing inherently against intellectual property in the Protocol and nothing conclusive about the superiority of legal solutions to find an equilibrium about values at play. To the extent consensus is required, there is an implicit acknowledgement that those resources are proprietary resources and cannot be freely appropriated or modified or exchanged. The Protocol aims at fighting biopiracy with the same legal weapons that are conventionally used in Western countries: property and contracts. The alternative option, one based on an international liability rule, would have been better than the *status quo*, but less respectful of sovereignty of less developed states.[44]

On a less positive note, unfortunately the Protocol is an international instrument, whose application at national level depends on voluntary implementation by states and although the level of acceptance is high, it should be underscored that the most enthusiastic acceptance comes obviously from less developed countries. As it holds for the CBD, one of the most important states in the world is not part of the Protocol, that is, the United States. Thus, a very large portion of the world (one of the most industrialized countries and the homeland of the most powerful agro-bio industries) does not recognize and apply the principles of the Protocol, thus introducing a wound to the underlying policy and escaping the international regime of liability for access to genetic resources.[45] The fact the U.S. are not part of the Protocol is a big weakness to the overall international legal framework, because as a matter of fact the main players of the genetically modified seed market are U.S. multinational corporations. The Protocol here might prove less effective, but if corporations are no longer generally free to appropriate genetic resources in biodiverse environments, it is a first bulwark against plunder that nevertheless will impact on individual conducts and business models. The Protocol is undeniably part of the legal framework in which the issue of genetically modified seeds must be deal with.

[44]The *status quo* is represented by a situation in which seed grabbing is actually practiced as in an era of colonialism land grabbing was justified by a doctrine of *terra nullius*. The Protocol recognizes sovereignty over national resources and rebuts the principle of free appropriability of common resources. A solution that is close to liability rule was adopted by a number of national legislations in the U.S., where farmers are allowed to use second generation seeds for sowing, by compensating the rights holders, as reported by Leaven, *The Misinterpretation of the Patent*, cit., 140.

[45]Since 1996, the U.S. territory is the land that is cultivated more than others with genetically modified varieties, followed by Argentina, Canada, Brazil, China and South Africa.

6 Negative Externalities

Differences in the legal framework that states create to govern the behavior of players working on the value chain of seeds generate inevitable international externalities. One remarkable example is represented by the U.S. position towards the Nagoya Protocol. The option not to regulate the access to third parties' genetic resources provides an advantage to the national industry, but projects costs on less developed countries and on other states that joined the Protocol. Overall, the international trade is affected and the purposes of the Protocol might be frustrated or strongly limited. The effectiveness of international legal instruments is inevitably dependent on the widest acceptance.

Adopting a paradigm of regulatory competition on the very topic of agricultural biotechnology can lead to the conclusion that, in order to attract the biotech industry, state regulation should be more friendly for businesses, even if this choice would harm farmers by increasing the costs to access seeds or by limiting their ability to save and exchange seeds. At international level, the Nagoya protocol is a set of mandatory rules that aims at limiting biopiracy and discouraging the kind of race to the bottom that an unregulated competition among legal systems would trigger. But the application of the protocol is ultimately made dependent on the will of those same players that might take advantage from unregulated competition. Furthermore, excessive regulation through mandatory rules can discourage innovation and the transfer of technology and the Nagoya protocol is a delicate exercise to keep a balance among the values at play.

A strategy of supporting the biotech business vis-à-vis the farmers with the creation of a favorable legal environment (one that allows freedom of contract to the maximum extent and that interprets intellectual property laws as univocally aimed at protecting the right holder) has also negative effects at national level.

Concentration on the supply side is almost inevitable. Because of the capital intensive investments required in the agro-bio industry, there is a natural trend towards concentration and oligopoly, which is a further element of complexity to find an international legal equilibrium. As a matter of fact, the whole agro-bio industry is in the hands of few high-tech, large and organized multinational corporations, which can also exert lobbying power over decision-makers and can easily cope with dispersed and less organized forces.[46]

The extent to which other branches of the legal system can control such powers is unclear. A lenient treatment of contract practices for circulation of proprietary technology clearly goes in the direction of reinforcing the position of the industry. Beyond contract law and intellectual property, competition rules at national level could only be applied in case of restrains on trade or abuses of dominant position (attempt to monopolize the market, in the U.S.), but actions are unlikely. But since

[46]As reported by Center for Food Safety & Save Our Seeds, *Seed Giants vs. Farmers*, cit., 12, three companies (Monsanto, DuPont, and Syngenta) now control 53 % of the global market for seeds, while the top ten companies have a joint market share of 73 % (and many of them are U.S. corporations).

an international regime of antitrust enforcement is missing, the effectiveness of antitrust policy in this respect is doubtful.

It has been also argued that favoring the agro-bio industry and its products (like genetically modified seeds) has effect on the demand side as well. High yield seeds increase productivity, but the higher productivity comes at the cost of margins reduction. Survival then becomes possible only for larger farmers with significant portions of land and financial resources that can rely on large volumes of production. The result is concentration also on the demand side, with the consequence that smaller farmers are marginalized and doomed to disappear. And since biodiversity is strictly dependent on communities of smaller farmers, eventually the risk of dominant varieties becomes actual.

There is evidence of this trend in *Bowman*. One argument raised by the farmer is relevant. Bowman stated that the second sowing is necessary for running its business, but it is riskier (than the first one) and access to less expensive seeds should justify its practice. Bowman's position resembles pretty much like that of many other small farmers worldwide that try to escape or relax the harshness of Monsanto TSA. The argument is not a valid defense against the accusation of patent infringement and provides no excuse from breach of contracts. But it reveals how farmers are exposed to the costs to access seeds and with lower profitability only the large ones have the chance to survive, as long as they concentrate on specialized monoculture, to make sure economies of scale ensure a satisfactory return on their investments.

Last but not least, the intellectual property policy as a means to create incentives for the biotech industry can feed opportunistic behaviors by large corporations with internal research and development capabilities. Systems of *ex post* rewards leave absolute freedom to individuals to pursue their own research agenda. This is one of the undisputable virtues of intellectual property rights, vis-à-vis other more centralized forms of incentives. At the same time, the directions of research could favor varieties that are more resistant to pesticides than to pests, and intellectual property protection would be available for both.[47] The choice about what should be commercialized could be inspired by different motivations and interests. If a corporation is active in sales for pesticides, it is not necessarily motivated to introduce on the markets pest-resistant varieties. It would be too simplistic (and practically unfeasible) to conclude that the way to favor one direction and disfavor the other is to allow protection only in the former case and not in the latter. Intellectual property systems do not discriminate in this regard and it would be a very coarse policy to throw the baby out with the bathwater.

With respect to this latter case, the answer is not necessarily in the intellectual property policy. Many agro-bio products (including seeds) can be subject to regulations and controls and states do have other options to provide signals to the

[47]One often quoted side effect in terms of moral hazard of the massive resort to genetically modified varieties is the increase in the consumption of pesticides/herbicides, which is not necessarily an unwanted consequence from the perspective of the producer of such substances.

industry in terms of what can be more easily commercialized.[48] Incentives to research and development can be left untouched, but more fine-grained regulation downstream can to some extent control opportunistic behavior and make sure that commercial choices are consistent with the public interest and not just with the goal of having short-term financial returns.

But apart from monitoring the market from the easier perspective of regulating products, other problems remain and it should be kept in mind that intellectual property protection on genetically modified seeds has implications that go way beyond the individual rewards for innovative products.

7 Regulation by Technology

The option to dismiss altogether the intellectual property policy in this field would be ineffective, if not ruinous, not just for the potential destruction of individual incentives, but because one alternative for the industry would be to replace exclusive rights with more uncompromising technological solutions.[49]

Of course, in a world of no intellectual property, the industry could raise prices to compensate the loss of business that freedom to reproduce seeds would cause.[50] This strategy would be tantamount to granting absolute protection in terms of discrimination, as only large farming facilities could afford higher prices to access selected seeds. However, the most baleful outcome would be choice to use technology to protect the genetically modified seeds.

Such possibility is open to the industry thanks to so called Genetic Use Restrictions Techniques (GURTs), also referred to as "terminator" technology or "suicide seeds", that is to say genetic modifications that regulate the expression of genes in plants, causing second generation seeds to become sterile.[51] Such technological solutions would remove the self-reproducing traits of genetically modified seeds that justify a different treatment of exhaustions effect. If second generation seeds are sterile, "copies" are technically impossible and downstream control, whether by contract techniques or by property prerogatives, does not make sense.

[48]Many legal systems, including the European Union, have regulated the downstream activities that are required for a genetically modified product to reach the market. Regulation here serves the additional purpose of controlling the impact of the technology on human health and the environment, without discouraging research and development.

[49]Yet, it is an option that someone would pursue firmly; see for instance Boldrin and Levine, *Against intellectual monopoly*, cit., 243 («[P]rogressively but effectively abolishing intellectual property protection is the only socially responsible thing to do»).

[50]See Kesan, *Licensing Restrictions*, cit., 1086, with a further discussion of the complexity of the value chain in the agro-industry.

[51]GURTs are typically split into two categories: those that restrict the use at variety level (V-GURTs) and those that restrict at trait level (T-GURTs). One remarkable case of GURT is one jointly developed by the Delta and Pine Land Company in cooperation with the U.S. Department of Agriculture (USDA). See International Seed Federation, *Genetic Use Restriction Technologies*, Bangalore, 2003 (position paper describing V-GURT development).

GURTs are for genetically modified plant varieties what digital rights management systems (DRMs) are for technological copyright on digital goods; nothing else than a technical response to the threat posed by imitation and reproduction to intangible resources. With one remarkable difference. While legal solutions have national validity and can be enforced at national level, technological solutions, like GURTs and DRMs, do not need enforcement by national authorities and do not suffer from sovereignty limitations. While this feature can be seen as an undisputable advantage, technological self-help comes to the cost of a complete removal of any freedom, including fair uses that legislation might, by time to time, consider in order to balance concurring interests. Technology, in this respect, is much less modular and uncompromising. Above all, technological solutions remove any chance of a regulatory competition and do not favor the emergence of alternative solutions that states can occasionally enact. The mechanics of technological solutions would be even more drastic in terms of consequences.

The topic of GURTs is not the only instance in which the regulatory role of technology is discussed, but the essence of the issue is the same. GURTs imply concentration of power in the hands of technology owners and escape the comprehensive systems of control and limits that are typical of legal regulation in terms of territorial dimension, democratic participation to lawmaking, enforceability before controllable institutions as courts.

There is an ongoing debate about the use of GURTs in the agro-bio industry, and the discussions are not only legal; there are aspects of bio-security and food security that must be dealt with accurately. Moreover, it has to be investigated the impact of GURTs use on biodiversity. If genetically modified seeds are deactivated after the first sowing, the variety has less chance to become dominant. On the other side, the potential decrease of costs of seeds—caused by the reduced vulnerability to copying—could turn into lower prices and easier access for farmers to genetically modified seeds that would eventually become dominant.

Whether regulation by technology is superior to state regulation is open to discussion. For sure, it is not devoid of risks and side effects. Quite paradoxically, regulation by technology can be in need of state laws, as it happens for technological protection measures in copyright. At the other extreme, state regulation could outlaw the use of GURTs, and the relationship between the two techniques of social control could be conflictual.

8 An Alternative Paradigm

The several implications of intellectual property protection applied to genetically modified seeds, and the alternatives available, are evidence of the complexity of a problem, that is the ability of regulation at any level to strike an acceptable balance between innovation, farmers' and communities' rights, the demand to preserve biodiversity and the objective need to limit international negative externalities related to state strategies to attract foreign direct investments or to protect the

national industry at the expenses of other countries (and of the international community at large).

In the field of genetically modified seeds, resort to intellectual property protection is deemed to be cause of multiple side effects, that eat into biodiversity, market concentration and the promotion and protection of other (communitarian) values. In the complexities of regulation, and taking into account all its limitation, one significant support comes from the Nagoya protocol. To the extent plunder of genetic resources (and local varieties among them) is barred, or made more difficult by an international instrument, each country has now more effective means to preserve its genetic diversity and its identity. This is a first small step and there might be technical difficulties in making it work properly, but it is a crucial contribution.

Before a paradigm of regulatory competition, there is sometimes the impression that the race to the bottom is inevitable and independent by states' will.[52] But it is not. At least, lowering the level of protection of non-economic values is not the only available approach if policy makers at state level are willing to pursue alternative models of growth. Diversity in regulation can be instrumental in favoring, at least initially, a strategy of differentiation with respect to other countries without necessarily refusing an intellectual property policy.

Intellectual property rights seem to be supportive of one model of extremely centralized and concentrated agriculture, with low margins for big farmers, based on genetically modified resources, intensive exploitation of large portions of land with monocultures and propagation of market power in other markets (it is not a secret that the largest rights holders on genetically modified seeds also produce herbicides and pesticides). That model is probably responsible for providing resources in bulks, for a fast-growing world, wherever plants can be used for food, energy or raw materials productions. But if a given country does not see fit with that model, other solutions are available.

There can be an alternative model, based on high-quality productions of bio-diverse local varieties (still somehow protected against imitations and, thus, subject to intellectual property rights), cultivated with traditional methods at a very decentralized level by farmers and communities of farmers. The two systems can compete but competition has to be fair and regulation (both at state and international level) is mandated to ensure a level playing field for the two models.

If promoting alternative models of exploitation is the goal, then legal solutions should be consistent. For instance, the answer adopted by the European Directive 98/44 with respect to exhaustion and farmers rights is somehow responsive to the need for farmers to have some limited internal use of second generation seeds. There is an equilibrium in there, but is different from that found by the U.S. courts

[52]States have different options to pursue a strategy of attracting foreign investors. Magic (2003, p. 6), stated that «attracting FDI—and consequently technology transfer—solely by means of strengthening IPR is not a good long term economic strategy for a developing country because it will not do nothing to build a domestic industry of high-tech R&D».

in *Bowman* and it is not said that it is a bad one. After all, the agro-bio industry does business also in Europe.

The case of intellectual property rights on genetically modified seeds is one remarkable example of the direct connection between strategies of growth and regulation, when multiple interests are at play. The seed war is way too often fought in a dismissive way, as a war in favor *or* against intellectual property protection. This attitude might result destructive of incentives for states to experiment background legal conditions for alternative models of agriculture that rely on a more reasonable use of intellectual property rights and a more equitable sharing of resources. The Nagoya Protocol aims at fighting biopiracy by reinstating principles of sovereignty, property and consent. Those same principles are common to intellectual property policy. As the agro-bio industry is able to combine property rights and contractual techniques to serve their purposes, there might be alternative combinations to support an agriculture that is grounded on different values and is more respectful of local communities.

References

Brenchley R et al (2012) Analysis of the bread wheat genome using whole-genome shotgun sequencing. Nature 491:705–710

Altieri MA (2015) The myths of agricultural biotechnology: some ethical questions. http://nature.berkeley.edu/~miguel-alt/the_myths.html. Accessed 9 Feb 2015

Busch L, Lacy WB, Burkhardt J, Lacy L (1990) Plants, power and profit. Basil Blackwell, Oxford

Daniels TP (2003) Keep the license agreements coming: the effects of J.E.M. Ag supply, incorporated v. pioneer hi-bred international, incorporated on universities' use of intellectual property laws to protect their plant genetic research. BYU Educ Law J 2003:771

Demitri C, Scalera F, Madaghiele M, Sannino A, Maffezzoli A (2013) Potential of cellulose-based superabsorbent hydrogels as water reservoir in agriculture. Int J Polym Sci 2013(2013), Article id 435073

Downing-Howk M (2004) The horns of a dilemma: the application of the doctrine of patent exhaustion and licensing of patented seed. San Joaquin Agric Law Rev 14:39

Duffy JF (2010) The federal circuit in the shadow of the solicitor general. George Wash Law Rev 78:518

Ferran S (2014) 'That plant is my ancestor': dilemmas for intellectual property in developing countries, food security and Pacific Island countries. Queen Mary J Intellect Property 4:277

Göbel A (2012) The principle of exhaustion and the resale of downloaded software—the UsedSoft/Oracle case. European law reporter, p 228

Granieri M (2015) Technological Contracts, forthcoming in Monateri PG (ed) Comparative Contract Law, Cheltenham

Johns A (2009) Piracy: the intellectual property wars from Gutenberg to gates. Chicago University Press, Chicago

Leaven TM (2008) The misinterpretation of the patent exhaustion doctrine and the transgenic seed industry in light of quanta v LG electronics. NC J Law Technol 10(119):129

Levidow L, Carr S (1997) How biotechnology regulation sets a risk/ethics boundary. Agric Human Values 14:29–43

Magic P (2003) International technology transfer and intellectual property rights

Nilles AF (2000) Plant patent law: the federal circuit sows the seed to allow agriculture to grow. Land Water Law Rev 35:355

Rives E (2001) Mother nature and the courts: are sexually reproducing plants and their progeny patentable under the utility patent act of 1952? Cumberland Law Rev 32:187

Robin M-M (2015) Le monde selon Monsanto. http://www.arte.tv/fr/le-monde-selon-monsanto/1912682.html. Accessed 2 Feb 2015

Shiva V (2015) Genetically engineered seeds and crops (GMOs) have unleashed seed wars, and knowledge wars. http://www.navdanya.org/news/282-gmos-seed-wars-and-knowledge-wars Accessed 9 Feb 2015

Thompson DC, Wachtell M (2009) An empirical analysis of supreme court certiorari petition procedures: the call for response and the call for the views of the solicitor general. George Mason Law Rev 16:237–302