THE USE OF AGROBIODIVERSITY FOR PLANT IMPROVEMENT AND PROPERTY-PARADIGM BREAKDOWNS:

CAUGHT BETWEEN PATENTS, PLANT VARIETY RIGHTS AND PARTIALLY OPEN INNOVATION SYSTEMS WITHIN THE INTELLECTUAL PROPERTY PARADIGM

Fulya Batur (and Tom Dedeurwaerdere)

TABLE OF CONTENTS

From "a backward repository of unskilled people locked in traditional ways of living" (EVENSON, 2005), agriculture has very quickly metamorphosed into a knowledge-intensive, extremely productive and fast-evolving research-and-development focused industry. Indeed, since the domestication of plants epitomised the dawn of agriculture, it took almost ten thousand years for grain production to reach the impressive one billion tonnes mark in 1960, while the second billion mark was hit merely forty years' later in 2000 (KHUSH, 2001). Such impressive development is not associated with industrialisation, but rather with crop genetic improvement (ANDERSON, et.al., 1988), which still indubitably stands as a sphere where returns on research investment remain "well above the returns attainable from alternative uses of funds" (GARDNER, 2003; EVENSON, 2001). Such controlled plant improvement is pivotal to the achievement of sustainable agriculture and the alleviation of poverty, on account of the impressive results in terms of yield gains and resource management efficiency. Yet this success depends to a great extent upon the effective and equitable use of both wild and improved agricultural biological diversity, which has become an indispensable input to the entire range of modern plant-breeding science. The figures show that, although most breeding programmes remain based on former market successes, with 83 per cent of active selection research being conducted on the basis of standardised and improved varieties, researchers and breeders continue to utilise, and in fact depend upon 'wild germplasm' in order to ensure the long-term sustainability of their studies. Around 6.5 per

cent of their gene pool is continuously maintained with wild species and landraces (SWANSON, 1997). In this regard, both public and private breeders alike rely on traditionally non-proprietary materials that have been, and still may be, accessed through the international agricultural research community under the umbrella of the Consultative Group for International Agricultural Research (CGIAR). It is, for instance, estimated that 75 per cent of all maize sold by private companies in Latin America in 1996 contained germplasm derived from material developed by CIMMYT, the International Maize and Wheat Improvement Centre (MORRIS and LOPEZ-PEREIRA, 1999).

However, plant improvement faces a complex conundrum, due to an essential need to grant artificial lead time for innovations which are easily reverse-engineered, the absence of apparent reward for local actors' efforts to conserve resources upon which innovations are built, and the detrimental effects of increasingly conditional and restrictive re-use possibilities for cultivation or research within the intellectual property (IP) encompassed in the pool of improved varieties in an innovation chain that remains primarily incremental. Follow-on uses of plant material or plant breeding techniques by farmers, breeders and scientists alike, have become remarkably complex on account of the intellectual property rights bestowed upon biological material or breeding techniques, especially following the adoption of the TRIPS Agreement, laying out the foundations of the strong informational property paradigm in its Article 27 §3 b.

At present, the various criticisms of the dominant intellectual property paradigm in plant improvement have not been very effective. Due to their piecemeal nature, critics highlighting genuine insufficiencies related to various areas, such as *in situ* agrobiodiversity, platform technologies and research tools or *ex-situ* pools of improved seed varieties have not yet produced a major shift in the paradigm; nor have the proposed alternative institutional tools been able to impose themselves as valid and viable institutional mechanisms. What is missing in such piecemeal approaches to the institutional effectiveness and/or defects of the protection of agrobiodiversity-related intangibles, in our view, is a systematic analysis of the relationship between institutional paradigms and their context of application.

Our main hypothesis is that, the opposition between the market based and strong intellectual property paradigm in plant improvement, and the public-domain oriented fully-open angle (the main alternative paradigm is too restrictive. We argue that the analysis of the context of application of intellectual property rights can provide better guidance for the future development of appropriate institutional alternatives to face the problems of *in situ* agrobiodiversity conservation and for a more equitable distribution of controlled hybridisation technologies and molecular biology research tools in plant improvement. We also argue that these institutional alternatives can be found within the flexibilities of either the TRIPS Agreement (allowing for effective *sui generis* protection of plant varieties, and loosely setting the contours of compulsory licensing opportunities), or those found within

the intellectual property tools themselves in the form of liability rules, such as farmers', breeders' and research exceptions.

To show the contribution of this analysis, we use the lessons from universally acclaimed research on paradigm breakdowns in science (KUHN, 1962), to investigate whether, in certain areas of plant improvement technologies, a systematic series of breakdown cases have appeared, and, if so, to examine a number of proposed institutional alternatives. To show the contribution of a systematic analysis of the relationship between institutional paradigms and their context of application to the construction of institutional and regulatory alternatives, the analysis in this paper will:

(1) briefly review the shortcomings of the strong intellectual property rights paradigm in relation to certain technological evolutions, assessing the areas where this paradigm clearly contributes to agrobiodiversity innovation, and those areas where systematic or partial breakdowns are observed;

(2) analyse and propose the adjustment of the property paradigm for the systematic breakdown witnessed in mass selection.

1. Shortcomings of the strong intellectual property paradigm as applied to plant improvement based on constant agrobiodiversity input

The design of alternative governance frameworks to promote the successful use of biodiversity in terms of efficiency, distribution and fairness, stems primarily from a single interrogation; that of the adequacy of the currently prevailing IPR paradigm characterised by lenient patent requirements and post 1991 enhanced plant variety rights, *vis-à-vis* all ranges of innovative and sustainable uses of agrobiodiversity. Responding chiefly to the needs of the increasingly intricate, knowledge-intensive, and incrementally cumulative context of agrobiodiversity research and development dominated by molecular plant breeding and DNA recombination, the dominant strong IPR paradigm operates to the detriment of other existing innovation models, be it at community or farmer level, within both the public and private sectors. Our analysis is based on the premise that rules defining the contours of protection and use of plant-related innovations do not adequately correspond to the needs of the entire range of existing agrobiodiversity innovation systems, on account of the characteristics of seeds themselves, but also on account of the specific features defining plant innovation relying on the repeated use of agricultural biodiversity.

1.1. Characteristics of seeds and plant improvement

Seeds embody an inherent duality, as they are not only commercial commodities in their own right, but they also constitute an instrument for technology transfer through their informational public good nature (LOUWAARS, 2002), an informational good that farmers and breeders alike daily seek to improve. Seeds cannot in this regard be merely viewed as inputs for agricultural production, since the genetic resources they encompass also

represent the key input of agricultural research and development activities, as a potential source of innovation. This feature has been enhanced through the infusion of science within the long-established mechanisms of crop improvement based on the observations, instincts and traditions of farmers (or, more generally, mass selection (GEPTS, 2004)). Such scientific input has led to the appearance of methodical and controlled hybridisation, based on empirical trial-and-error techniques, the detection of useful mutations and the 'fixation' of desired characteristics such as disease resistance or flavour enhancement within the deliberate crossings operated by plant breeders (KINGSBURY, 2009).

The rediscovery of Mendelian genetics at the beginning of the 20th century, opening the prospect of unprecedented results in terms of yield, and introducing cultivators to 'hybrid vigour', has spread into the institutional structure of research and development activities themselves (JAFFEE and SRIVASTAVA, 1994). It then broke down once more, with the development of genomics science and our understanding of life at a deeper level, that of the gene (BUTTEL et al., 1985). Even though most of the biotechnological advances witnessed in the early 1980's have supplemented and reinforced the efficiency of conventional selection and hybridisation methods, they have moved the molecular base of new plant breeding forward in an astonishing way (MURPHY, 2007), while genetic modification and DNA recombination techniques have unveiled completely new horizons to the realisation of plant breeding's promises (MOOSE and MUNN, 2008; KLOPPENBURG, 2004). The two revolutions witnessed in relation to plant improvement, pertaining first to our understanding of genetics and rules of heredity, and second to the development of molecular biology and genomics science, have considerably altered the agricultural research paradigm and industry structure (BARTON, 2003). Scientific progress has indeed driven the rise of the private seed sector through the professionalisation of plant breeding, and then created life-science giants through the infusion of molecular capacity into the industry on account of the vertical integration of technology-heavy start-ups.

Agricultural biodiversity-related innovations first and foremost comprise a combination of knowledge disseminated through a wide array of informational tools and products produced by other actors. Crop genetic improvement is essentially a process of derivation, whereby each incremental innovative contribution (realised either through the selection of best performing specimens on farms, through plant-breeding research relying on sexual or asexual crosses, or through various biotechnological instruments and techniques) holds the potential of becoming a commercial product. In this context, follow-on innovations or improvements directly derived from an underlying creation or invention raise, as in all "cumulative innovation chains", critical questions as to their degree of appropriability and control, and thus their optimal treatment (MERGES and NELSON, 1990, LEMLEY, 1997). In the light of a peculiar innovation chain based upon incremental steps, rather than major leaps forward, steadily at the mercy of reverse-engineering, and the intrinsic public good nature of biodiversity's informational component, regulatory intervention is inevitable for fostering investment in plant breeding, while ensuring the conservation of genetic

variability. Such intervention ought therefore to be constructed around a particularly intricate balancing act, having due regard to past contributors to knowledge and biodiversity, as well as to future developers of incremental knowledge and agro-biodiversity, and thereby ensure both the prospects of appropriation and access to innovations. The present dominant intellectual property paradigm, characterised by extended patent protection and stringent plant-variety protection, raises the question as to whether it has successfully achieved such a balancing act in the misunderstood world of agrobiodiversity innovation.

1.2. Plant improvement and IP: Patents or* sui generis *Plant Variety Protection

The recognition of statutory property rights over the informational content of improved plant varieties was operated through the expansion of the scope of traditional IP mechanisms' protection, as well as the enactment of need-specific protection regimes derived from the same premises as the traditional protection regimes. The reality and reach of such proprietary protection climaxed through the adoption of international minimum protection standards in 1994 and Article 27 §3 b of the TRIPS Agreement, which quite uniquely starts with negative obligations, by stating that: *"Members may also exclude from patentability: […] plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."* Acknowledging the controversies surrounding the definition of patentable subject matter with regards to life sciences, the Agreement continues by asserting that: *"Members shall provide for the protection of plant varieties either by patents or by an effective* sui generis *system or by any combination thereof",* thereby setting the foundations of the strong intellectual property paradigm in plant improvement.

By encouraging the inventor to disclose innovative knowledge, while simultaneously holding the rights to protect follow-on uses of inventions, patents avoid underinvestment in costly but socially beneficiary research and development activities, while also preventing the detrimental withholding of knowledge (WENDT and IZQUIERDO, 2001). In so doing they avoid some of the aggravated enclosure-related detrimental effects that might follow from recourse to trade secrecy (EISENBERG, 1997). Within this context, patents, as titles conferring exclusive rights to use, sell and import a novel invention involving an inventive step and susceptible of industrial application, confer rights to exclude others from using the product or process covered by the claim. They can and have been granted intensively on biological material in accordance with the patentability requirements of the national orders where protection is sought, mostly in developed countries and in particular the USA.

The extension of patent claims to the life sciences, mainly attributed to the infamous *Diamond vs. Chakrabarty* ruling of the US Supreme Court, had been regular practice in a number of European countries from the 1930s onwards (STRAUS, 2003; VAN OVERWALLE, 2006). The scope of patentability is today more intricately delineated, especially on the "old continent" (Europe), where plant varieties and essential biological processes are excluded from protection, in accordance with Article 53§a of the European Patent Convention. Even

with the more recent recourse to subject-specific regulatory texts with strong binding potency such as the European Directive 98/44/EC on the legal protection of biotechnological inventions, defining the exact contours of patentability exclusions with regards to biological material has become an increasingly complex task. This complexity derives not only from the growing importance of legal counsel to navigate and enforce protection titles, but also from the remarkable advent of biotechnology and the correlated expansion of innovative breeding processes or tools retaining a biological character yet constituting important technological leaps forward, especially with regard to molecular selection efforts involving a number of highly technical and non-microbiological steps (KOCK, 2007).

A relatively lesser-known intellectual property-rights system (outside those having recourse to its instruments regularly), plant breeders' rights (PBR) or plant variety protection (PVP) has been developed from 1961 onwards, with the enactment of the first Convention under the auspices of the "International Union for the Protection of New Varieties of Plants" (UPOV). The requirement set out in Article 27§3 of the TRIPS Agreement does not make direct reference to the UPOV system, even though today it is considered the only *sui generis* plant variety protection system that is duly implemented and complied with in an *effective* manner (LLEWELYN, 2003). PVP titles, as envisaged within the UPOV system, confer a bundle of rights to a novel *combination* of genes manifested as a distinct, uniform and stable variety, aiming therefore at the phenotype of the variety, rather than its genotype or its isolated biological components.

These titles, offered under national or supranational legislation, require neither proof of an inventive step nor a specific utility, as they are solely based on the evaluation of the variety's value in terms of genetic quality, i.e. uniformity and stability, and on the basis of phenotypic differences *vis-à-vis* "known" varieties. The conditions for protection, formerly found in Article 6 of the 1961 and 1978 Acts with slightly different wordings, now state, in accordance with Article 5 of the 1991 Act, that "t*he breeder's right shall be granted where the variety is new, distinct, uniform and stable*". According to Article 14 of the same instrument, the authorisation of the variety developer should be sought for "*the production, reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing and stocking*" of the propagated material. The exclusive rights granted by such PVP titles are however surrounded by two major counter-conditions, drafted in the shape of liability rules: the breeders' exemption and the farmers' exemption, evidencing the "tailored-for-purpose" nature of this protection mechanism.

The farmers' exemption, allowing farmers to sow seeds for saving, using or exchanging, was in the past implied by the 1961 and 1978 Acts through the scope of protection granted to breeders (since the extent of exclusive rights did not reach acts perpetrated without any commercial purpose by third parties, including unmethodical selectors or farmers) (PIRES DE CARVALHO, 2010). From such an exclusion from the scope of protection, the farmers' exemption has evolved into a formal yet optional exception to the extent of the PVP title that may be granted at the national level for the use of seeds on the farmers' own holdings

and with possible equitable remuneration to the breeder, according to Article 15§2 the 1991 Convention.

The breeders' exemption, granting plant developers the possibility of using protected varieties in their breeding programmes without prior consent from the title holder, had already been formulated in the 1961 text of UPOV. Article 5 stated that the prior authorisation requirement established *"for production, for purposes of commercial marketing, of the reproductive or vegetative propagating material, as such, of the new variety, […] shall not be required either for the utilisation of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such varieties"*, except "*when the repeated use of the new variety is necessary for the commercial production of another variety*"; a wording that remained unchanged in the 1978 Convention. Article 15§1 of the 1991 text now provides for a "*compulsory exception",* whereby the breeders' right does not extend to *"acts done privately and for non-commercial purposes, for experimental purposes, and acts done for the purpose of breeding other varieties".* The UPOV approach, as an instrument specific to the field of incremental plant innovation, thereby takes due account of the characteristics of seed development, and provides for a more adequate institutional fit to the specific features of conventional plant breeding. However, as we will discuss below, both the farmers' and breeders' exemptions have been significantly restricted in the 1991 text, thereby contributing to paradigmatic breakdowns with regards to certain innovation chains, namely mass selection and conventional breeders adrift in legal interpretation of "essential derivation" in variety development.

1.3. Shortcomings of the property paradigm for addressing plant improvement

The inherently incremental nature of controlled plant improvement leads to the assertion that major leaps forward would be much rarer than in other, more classical fields, such as electrical engineering. Except for genetically modified crops (transgenics), leaps achieved in agrobiodiversity innovation chains therefore need to be stretched to effectively qualify as "an inventive step" beyond the existing "prior art", and correlatively open the door for exclusive monopoly under the patent paradigm. The requirement of non-obviousness or of the existence of an inventive step found in all national patent systems, thus theoretically prevents the patentability of plant varieties, unless the criteria for such patentability are revised or re-interpreted with lower standards (BARTON, 2000).

Furthermore, as in synthetic biology, a sphere that draws inspiration from biotechnology, most of the innovations present in the conventional or molecular plant-breeding innovation chains constitute in too many ways a novel recombination of already-existing components or varieties to be effectively protected under the patent paradigm, or to cover the use of a method that has become routine or widely known (RAI and BOYLE, 2007). Even though the obvious character of most plant-related process innovations is frequently highlighted in the protocols, the gene products of such methods may be considered as novel in the patent

paradigm, developed for the purposes of inanimate and chemical rather than self-replicating biological inventions.

This approach creates extensive objections before competent Courts and Patent offices on the damaging spectre of non-novel and broad biotechnology patents (VAN WIJK, 1995). Indeed, while the exclusive monopoly rights awarded to the initial developer by patent protection need to be “commensurate with the contributions to the state of the art” (STRAUS, 2003), such contributions may not be easily determined in those plant improvement models that rely on biological processes. Drawing on the incremental nature of plant innovation, the pivotal notions of prior art and novelty or non-obviousness carry additional cravings for vigilant consideration, as the currently dominant intellectual property paradigm is considered to have enclosed what is by definition not enclosable, while failing to duly recognise past contributions, small or big, of previous germplasm users and conservers, urging calls for caution as to the possible "recycling of public knowledge for private reward" (DRAHOS and BRAITHWAITE, 2002, p.15).

When analysing the magnitude of the rewards that ought to be attained through innovation, especially within a cumulative cycle with few groundbreaking discoveries, it should be remembered that actors possessing restrictive monopoly rights have the ability to "choose the optimal level of output for the intermediate good embodying the patented technology" (GOESCHL, SWANSON, 1999). The proliferation of strong and broad foundational patents designating not only one technological application but encompassing a range of claims, is thought to impede the entire research community's range of action (SALAZAR et al., 2000), thereby potentially threatening an innovators' inherent right to build upon another innovators' creation, and so tampering with the intricate balance of IPR between the appropriation and diffusion of innovations. Fluctuating and fragmented patent landscapes significantly increase the known and unknown costs of research and development, all the while creating “a great deal of uncertainty in making product development and investment decisions, which rely on a realistic ‘freedom to operate’ assessment", both within the private and the public sectors (HENKEL and MAURER, 2009; CHI-HAM, CLARK and BENNETT, 2010).

Furthermore, when competing firms hold patents on different components of a complex technology (thereby creating a phenomenon that has been denoted "a patent thicket"), and decide not to cross-license them, research and development activities can be slowed down or even rendered impossible in an entire industry (SHAPIRO, 2001). Examples regarding delays in attaining research results, or simply conveying the difficulties in gaining access to technologies or a small part of a complex technology are regrettably numerous (KINGSTON, 2001). Within the context of transgenic research, we may cite the setbacks experienced by the relatively large American Cyanamid (since then acquired by BASF) in product development due to the exclusive licensing agreement signed by the "Biolistic Particle Delivery System" gene gun technology developer, Cornell University, towards the university researchers' own start-up company, Biolistics, bought by DuPont. Negotiations between the two companies have failed, partially attributable to their competitor status in a different

product market, and this has caused considerable delays in Cyanamid's alternate product development cycle (PRAY and NASEEM, 2005).

Patents in life sciences have sometimes found themselves used as trading currencies or bargaining chips, as defensive means to prevent lock-outs caused by a competitors' denial of access to its invention, in contrast to simple technologies such as chemicals (MERGES and NELSON, 1990; KINGSTON, 2001). Another infamous example of so-called "blocking patents" on complementary technologies, covering broad market segments and heavily affecting new entrants (MERGES, 1994), relates to the development of pro-vitamin A-enriched 'Golden Rice'. This variety, developed upon a public-domain premise through the initiative of the Rockefeller Foundation, required permission with regard to about 70 patents in the United States, widening concerns *vis-à-vis* the sacrosanct "freedom to operate" in biotechnology-backed plant-breeding activities, even though the patents were seemingly relinquished in favour of the poor in this particular case (KRYDER et al., 2000; HOPE, 2008).

However potent the need for effective protection, faced with the daunting prospect of rapid reverse-engineering may be, the proprietary paradigm that has been established and extended by public authorities to address non-traditional forms of innovation such as those stemming from conventional or molecular plant breeding are a menace to the generalised and pervasive contraction of artificial lead times, thereby straining the regulatory system to its breaking point, and weakening the competitive ethos upon which is continues to be based (REICHMAN, 1994).

2. Institutional alternate tools for Mass Selection Efforts: paradigmatic fit and responses to breakdowns

Acknowledging the shortcomings that emerge from the excessively restrictive and exclusive rights embodied in the strong intellectual property paradigm, the limits around biodiversity use, appropriation, production and re-use need to be clearly re-defined, taking due account of the incorporeal nature of relevant innovations, the ease of reverse engineering, and the colossal investments required for new developments. Systems drawing from completely open-source models or from such understanding would in this regard probably fail to deliver significant portions of socially, agronomically or environmentally meaningful innovations. Far from the lenient pleas that have been associated with equity or piracy discourses, these alternatives shall be developed in view of the importance of the rules of access to innovation which characterise informational property regimes, but also *vis-à-vis* the need to incorporate the contributions of both previous and future stewards and users of agricultural biodiversity. Acknowledging that no perfect trade-off between protection, access and diffusion can exist, the rights, privileges and use conditions inherent in the current patent and PVP approaches may still be adequately distributed in a coherent regulatory framework which would attempt to address the needs of all sub-systems of agrobiodiversity-reliant innovation.

Considering the flexibilities in the TRIPS Agreement, i.e. the principle of an "*effective sui generis plant variety protection system*" mentioned in Article 27§3, the recognition of exceptions from patentability and protection scope in Article 30, and the room provided for

the regulation of licensing protocols, we believe the task at hand hinges on experimenting in a more consistent manner with various models that build partially-open innovation systems based on such flexibilities. In this section, we illustrate a possible way forward for change, by looking in a more consistent way at a set of tools that may address the cases of systematic breakdown (witnessed in mass selection (Section 2.1.)) and partial breakdown (where both institutional approaches may find opportunities, more specifically *vis-à-vis* controlled hybridisation (Section 2.2.) and molecular breeding and research tools (Section 2.3)).

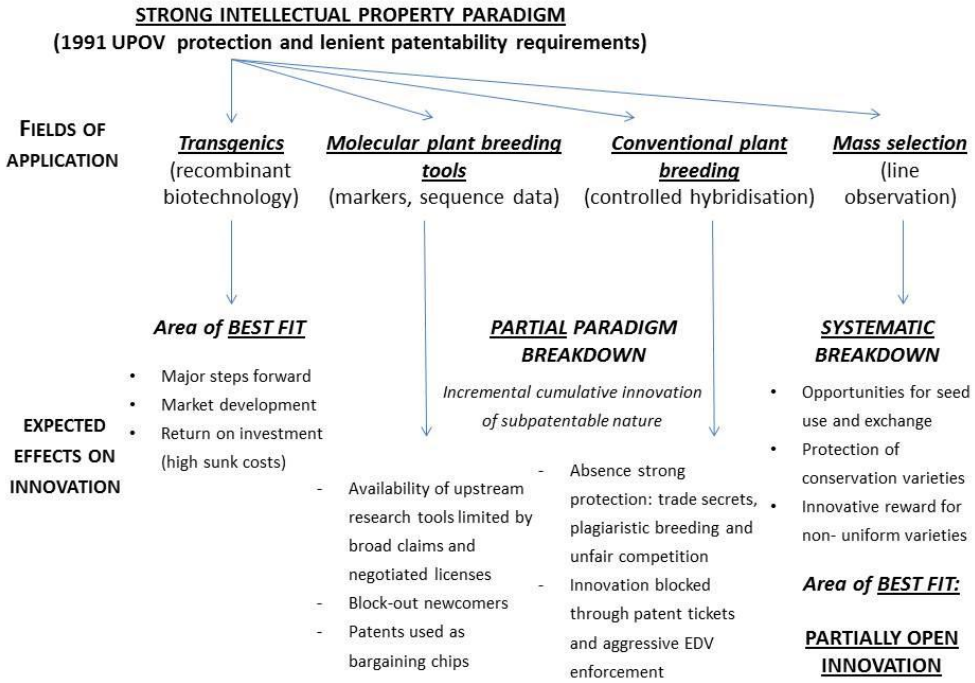

Figure 1: Analysing paradigmatic fit: expected effects of the strong intellectual property paradigm in the main fields of application of plant improvement innovation

2.1. Cultivar selection and exchange on the margin of the strong IP paradigm

In the light of the drastic changes occurring in agricultural production (first through the technological revolutions that have instilled new high-performance inputs on farm, and then through novel regulatory frameworks that have constructed boundaries on the use of such inputs) farmers have been gradually compelled to radically rethink their traditional production chain. Beforehand they had reproduced their own means of production and exchanged selected best-performing or best-fitting varieties with each other. Even today a large proportion of the seed planted worldwide is either saved by farmers or exchanged on a farmer-to-farmer basis. In the mid-1980s farmer-saved seed accounted for an estimated 35 per cent (or $18 billion) of the total estimated value of $50 billion for all agricultural seed

used worldwide, proprietary or not (GROOSMAN et al., 1988). In developing countries, the importance of seed-exchange networks and re-use is seemingly even greater, as an estimated 80 per cent of the seed used in the early 1980s was farmer-saved (PRAY and RAMASWAMI, 1991). While formal seed markets function on the basis of regulation pertaining to approval and promotion, with quality insurance and guarantee as to the identity, purity and performance of purchased seeds, informal exchanges are governed by cultural norms and *ad hoc* rules determined solely by the participants in the exchange, without regulatory intervention (LIPPER et al., 2009).

In addition to the main vertically integrated innovation chain producing improved varieties, mass selection operated on farms by farmers cannot be overlooked as an innovation system contributing to the conservation and sustainable use of agrobiodiversity, whilst also truly ensuring the subsistence of millions of farmers. Mass selection operates on a daily basis, even in developed nations, where a number of noteworthy initiatives have emerged. The French network "*AgroBio Périgord, Maison de la Semence*", for instance, disseminates a technical book on the multiplication and selection of maize and sunflower on farms, based on the principles of mass selection. In order to conserve non-proprietary agricultural biodiversity, this network of 250 growers located in Western France experiments on local populations or 'landraces', selecting those individuals presenting similar characteristics after two or three years of natural local adaptation, without ever falling under a stock of 600 individuals (in order to avoid degeneration and maintain so-called "security stocks" to minimise the risk of losses). Such selection and exchange networks need to re-situate themselves within the technological and regulatory environments that currently surround their activities, sustaining their endeavours without infringing other actors' rights, while protecting tools fostering their own innovation model based on open access.

Commentaire [A1]: Please check that I have understood your meaning correctly here

The possibility of farmers/selectors infringing upon existing patent or plant variety rights remains extremely high, depending on a wide range of circumstances relating to the national legislation in question, as well as to the specific crop or the size of the farming enterprise. These factors influence the recourse and range of the main farmers' exemptions recognised under PVP laws. The shrinking space for manoeuvre left to farmers for seed saving, using and exchanging within the strong IP paradigm, and a seemingly generalised lack of awareness or training in legal issues on the cultivators' side, have led to mounting disagreements between variety developers and sowers, leading to numerous court cases, especially on IP infringement. Litigation has flourished over a range of infringements, from the possession of protected seed in itself, for instance, to its re-use outside the scope of the legislation, without royalty collection or in larger farms than those targeted by applicable legislation.

The recourse to a wide array of enclosing instruments by innovators for a single specific product (such as Round Up Ready canola), simultaneously protected through process and gene patents, plant variety rights, trademarks and the private contract that is the "Technology Use Agreement", has further complicated the delineation of farmers' privilege. This may be overtrumped by patents in countries where plant-breeders' rights recognise

growers' right to save and exchange seeds, as a Canadian court case has quite recently shown (PHILLIPS, 2007, analysing *Monsanto vs. Schmeiser*). Even though the patent-infringing canola farmer could not benefit from the privilege enshrined in PVP legislation to save the seed, monetary compensation deriving from the infringement was overturned on the grounds that no financial or other benefit was generated by the technology. This argument could fuel the debate on the liability thresholds that might be introduced for re-use conditions. With regard to the issue of protection *vis-à-vis* the products of mass selection, namely diverse and unstable yet adapted and local varieties, the dominant paradigm systematically fails to equitably acknowledge mass selection networks, creating unfair competition *vis-à-vis* the methodical plant-breeding innovation chain and pushing selection activities into the realms of compulsory illegality.

The ability of farmers to develop new farmer varieties based on mass selection is still largely ignored by policy-makers, confronted with a regulatory conundrum where protection should not only be granted to the conserved germplasm or created material, but also appreciate the farmers' "dynamic and collective system of technology development and diffusion through every season", based on skill sharing and seed exchange (PELEGRINA and SALAZAR, 2011). Litigation in this regard has prospered (especially in France against the Kokopelli company), over the lack of equivalent certification requirements for the commercialisation of "conservation varieties": the varieties' lack of registration in national catalogues has generally been ruled to be in violation of the seed market rules (*GNIS and FNPSPF vs. Kokopelli*), and has recently been seen as a sign of the existence of unfair competition (Tribunal of Grand Instance of Nancy, *Graines Baumaux vs. Kokopelli*). The institutional characteristics of mass-selection efforts have led to a systematic breakdown of the strong exclusive-appropriation-oriented paradigm with regard to this less technology-driven and more community-oriented innovation system. This continues to remain central to the conservation of agricultural biodiversity, while also constituting the sole livelihood of small-scale farmers.

2.2. Models responding to the paradigm breakdown for mass selection

A. Farmers' exemption and farm-saved seed regulation

Until now, the main approach to allowing mass selection-based innovation to contribute to the sustainable use of biodiversity on farms has been to situate the "traditional practices of farmers as exceptions to the exclusive rights of plant breeders under existing IPR tools". This precludes breeders from demanding payment from farmers who save and plant seeds saved from prior purchases, or informally exchange purchased seeds (HELFER, 2002). The farmers' exception or privilege, allowing farmers to sow seeds for saving, using or exchanging without the authorisation of the variety developer, as it was defined in the first UPOV Conventions, allowed for farmers/selectors to use the diversity created by breeders in their own selection routine.

Although the 1978 Convention, being a minimum standards agreement, granted opportunities for the more precise design of the implicit rights' contours at the national level and thereby more greatly limited non-commercial uses, it should still be noted that under the practice of so-called "brown-bagging" in accordance with this Act, farmers were even allowed to sell limited quantities of protected seeds for reproductive purposes (GHIJSEN, 1998). Today, this privilege, which could either be viewed as an exemption from infringement or as an exception to the variety developer's rights, has become formally conditional to elements related to national circumstances, farm size and the necessity to use the seed on the same farm, and has also been surrounded by licensing obligations (DUTFIELD, 2008). Indeed, the formerly implicit exemption is now enshrined in Article 15§2 of the 1991 UPOV Convention, which states that "*each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, 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*".

The wording clearly shows the shift in this approach to the farmers' exception, which evolved into an *optional exception* to the exclusive rights of breeders, rather than an array of actions considered outside the scope of the IP title in itself. Such restrictive evolution of the exception has been indicated to be the source of the recognition of farmers' rights within the FAO system as a bundle of socio-economic rights including those related to seed as such (as asserted by Article 9 of the International Treaty for Plant Genetic Resources for Food and Agriculture (PELEGRINA and SALAZAR, 2011)). Landmark cases in the USA and Canada have reiterated that the farmers' exception should be interpreted in a narrow fashion *vis-à-vis* the sale of the protected-varieties' progeny (such as the ruling in *Asgrow vs. Winterboer* that identified "brown-bagging" as a marketing practice violating United States' legislation). The European legislation has, in a parallel fashion, dressed the contours of farm-saved seed quite restrictively, and especially conditioned the farmers' privilege to the payment of "an equitable remuneration […] sensibly lower than the amount charged for the licensed production of propagating material" in Article 14 of EC Regulation 2100/94 on Community Plant Variety Rights.

This Article further imposes an information obligation on the farmers and suppliers of processing services *vis-à-vis* farm-saved seed quantities. Both national and European case-law has been built around the interpretation of such terms, balancing the interests of farmers and those of breeders with those human rights to privacy and avoiding an abuse of rights on all accounts. The interlocutory ruling of the Huy, Belgium, tribunal of commerce given on 18 June 2004[1] has, for instance, ruled that the information on farm-saved seed ought to be obtained through or with the consent of the growers. This was in order to protect the farmers' interests at this level from residing in the avoidance of systematic invoicing for seeds that are saved but not used for sowing or multiplication purposes, and

[1] Comm. Huy (réf.) 18 May 2004, I.R.D.I., 2005, liv. 2, p. 163, note VAN OVERWALLE, G., "Over kwekers, boeren en trieerders: driehoeksverhoudingen in het kwekersrecht onder de loep", pp. 168-169.

avoid a potential abuse of rights by avoiding other available remedies for information collection; it was issued without any indication as to the possible infringement of its rights, as asserted by the European Court of Justice in *Schulin vs. Saatgut* (Case C-305/00, 10 April 2003). The French national order has in this regard shown the strictest reaction to the privilege, establishing it solely with regards to wheat through a voluntary compulsory contribution system and considering all other farm-saved seed to be counterfeit, falling within the realm of the strict legislation 2007-1544 dated 30th October 2007.

The inherent concern of the PVP system *vis-à-vis* farmers is not omnipresent within patent laws as such, as these statutes tend to remain abstract in their nature; they are not designed to solely apply to agrobiodiversity-reliant innovations as PVP legislation is, with its inevitable links to the loftier issues of food security or environmental protection. Certain countries have nonetheless equipped themselves with a number of legislative tools in this regard, such as the case of European legal order and its Directive 98/44/EC, making room for a farmers' privilege in domestic patent systems in its rather unusual Article 11§1, allowing farmers to retain material grown on their own farms for subsequent years (NENOW, 2001). Even though this instrument has no direct effect in Member States' national legal orders and allows for restrictions of these rights awarded to farmers, it still acknowledges the specificity of agricultural innovation (as more recent legislative endeavours have in other fora). Even though the so-called "Doha round" and its Ministerial Conventions have seemingly failed to fashion a viable consensus on the terms of a new World Trade order, they have strengthened regulatory determination to include such privilege within domestic patent regulation, leading for instance to the 2007 amendment of the Swiss Federal Patents Act so as to include a farmers' privilege, limited to uses of the patented material within the same farm (PIRES DE CARVALHO, 2010). The relatively rare recourse to the exemption within patent legislation (with the European continent as a notable exception) could be threatened by a specific textual TRIPS interpretation, in accord with which the recognition of such a privilege to farmers might prejudice the legitimate interests of the monopoly holders under Article 27 (WATAL, 2000). The feasibility and conformity of such exceptions in patent legislation has yet to be tested before the judiciary or the WTO dispute-settlement mechanisms, but we believe that the flexibilities inherent in the Agreement and its rationale allow for the recognition of the farmers' exception. Other commentators have in this regard highlighted the possibility that the existence of compensation in return for the right to use, save and exchange the protected material might actually encourage the doctrine of compulsory licensing, viewed as a "statutory license", rather than as a classical exception to IPR protection as grounded in Article 30 of TRIPS (GARRISON, 2006).

B. Reward regime for uncertified seeds and the legal status of exchange platforms

The opportunity of a protection regime for mass selection and landrace revival should be assessed in order to safeguard centuries-long seed-saving and exchange practices, distancing oneself from the reductionist perception that farmers merely manage and cultivate biodiversity. Rather they take active steps for its development, thereby limiting mass

selectors' activities to the realm of exceptions which reduce farmer's privileges to a "basic trickle of rights" (CULLET, 1999). However, amending principles related to protectable subject matter in the current property paradigm would imply radical changes in rationale and attitude, notably because of the inherently variable, non-uniform and collective nature of farmers' varieties (CORREA, 2003, p.369). Indeed, the subject matter requirements of the existing strong-IPR approach relate to new and clearly distinguishable plant varieties, and thus "often cannot accommodate the contributions of individual farmers using more informal methods to select for better crops or sought-after plant characteristics" (HELFER, 2002).

However, within the more general framework of successful agrobiodiversity use, local small-scale innovation and production stemming from mass-selection endeavours comes across as a necessity, just as much as improved varieties stemming from plant breeding efforts. The regulatory framework should therefore reward innovation stemming from mass selection, as a parallel yet different (and not necessarily derogatory) seed-production scheme, raising different predicaments from the dominant vertically integrated molecular breeding innovation, within a dual *sui generis* system taking both modern and farmers' varieties into account. While intended to standardise crop names, protect consumers and foster investment in breeding, existing mainstream certification and informational protection legislation has indeed had "the unintended consequence of drastically reducing the numbers of cultivars grown and impinging on the ability of farmers to grow older varieties or landraces" that do not fit within the formal seed market (VETELAINEN, M., NEGRI, V. and MAXTED, N., 2009).

At this stage, the different options thereby consist of either relaxing the DUS requirements in certified seeds and in the UPOV system to allow for landrace protection and use, or establishing a parallel *ad hoc* regime for local varieties that may create a book log or a flexible national or regional register of *in situ* conservation of uncertified seed. The recognition of biodiversity-related collective intellectual property rights in the hands of local communities has, for instance, been pushed forward within the Indian legal order, within a system where property rights are shared with governmental authorities in an attempt to fill the gap in perception and ensure compliance (CULLET, 1999). In another framework, the International Law Association Committee on the International Law on Biotechnology suggests the creation of mechanisms facilitating access to national or international biological material collections for smallholders. It also suggests "examining whether the UPOV system should be partly adapted and relaxed to allow protection of improved farmers' varieties that result from controlled on-farm breeding processes" (ILA, 2010). If on the other hand, a parallel regime for uncertified farmer seeds is privileged, attention should be given to its contours, especially with regard to equity concerns. Indeed, protection should only concern varieties in themselves, and not extend to their genotype, as it should allow for the acknowledgement of the efforts lying behind mass selection, which are often collective,

while also reflecting on the adequacy of the "exclusivity" approach within such communities, where open licensing and remuneration systems might prove better-fitted (CORREA, 2003).

In Brazil, the recognition of a parallel innovation system operates through amendments of the seed marketing legislation in 2003. Landraces or traditional varieties have found new legroom, notably through the possibility that "family farmers" have been granted to register landraces in the National System of Plants and Seeds. This includes specific criteria that take the cultural and traditional aspects of the varieties into account, without prejudice to the exchange possibilities in the absence of such registration, since an official double exemption from registration was foreseen (SANTILLI, 2012, pp. 50-58).

On the other hand, the establishment of a "light catalogue" has been the way forward in the European legal order, through Directives 2008/62 and 2009/145 on conservation varieties (to the dismay of both commentators (ANVAR, 2008) and those towards whom the provisions are actually directed). The inherent difficulty of uniformly regulating quite diverse farm-innovation systems has led to the funding of several research projects through the FP6 European Research Framework, known as Farm Seed Opportunities (FSO, 2007-2009). This is targeted to support the implementation of seed regulations on conservation varieties but also proposes complementary seed-regulation scenarios, the utility of which should be studied rigorously. To all intents and purposes, opening the Catalogue to conservation varieties remains a means of reducing genetic erosion and preserving varietal heritage, even though critics have argued both ways as to the risk of undermining the main commercial system, and the blockage of open-marketing possibilities for non-industrial models of agriculture such as organic farming or bio-dynamics (BOCCI, 2009). Even though the jurisprudentially evident situation of unfair competition ought to be redressed, a wider regulatory debate is needed about the form of a reward regime which currently satisfies nobody, from mass selectors to methodical breeders.

Kokopelli, whose objective is the revival and commercialisation of conservation varieties, has taken the last unfair competition case brought against it to appeal. The Court of Nancy requested a preliminary ruling before the European Court of Justice in February 2011 (Case C-59/11). Referenced by the national court, the European judiciary now needs to determine whether "the prohibition on marketing seed of varieties which are not demonstrably distinct, stable and sufficiently uniform and, where applicable, of satisfactory value for cultivation and use, is compatible with the higher-ranking rules". In this regard, the Luxembourg-based Court will determine whether seed catalogues violate principles of the *acquis communautaire* related to the liberty of trade, free movement of goods, proportionality, equality and non-discrimination, as well as the Union's obligations under international law, especially with regards to the Convention on Biological Diversity and the FAO International Treaty.

Notwithstanding the impact of the decision to the facts as such, the European high judiciary may shed some light on the difficulties of implementing agrobiodiversity law within national orders. The opinion of Attorney General Kokott, issued on 19th January 2012, seems to

indicate that the International Treaty "*does not include any provisions which are unconditional and sufficiently precise as to challenge the validity of EU legislation on the marketing of seeds*". However, in the light of the proportionality principle*, "the disadvantages of the marketing prohibition, [which include a negative impact on the freedom to conduct a business and agricultural biodiversity] manifestly outweigh its advantages"*, a disadvantage that is not sufficiently attenuated by the derogations carved out by Directive 2009/145. Indeed, the advocate general argues that the conservation varieties Directive, by not giving "*sufficient consideration to the interests of economic operators and consumers"*, does not allow for sufficient scope *vis-à-vis* the use of old varieties and those products of mass selection. It is thus likely that the Court follow his recommendations and pronounce "*the prohibition on the sale of seed of varieties that are not demonstrably distinct, stable and sufficiently uniform […] invalid as it infringes the principle of proportionality, the freedom to conduct a business within the meaning of Article 16 of the Charter of Fundamental Rights of the European Union, the free movement of goods established in Article 34 TFEU [Treaty Founding the European Union] and the principle of equal treatment within the meaning of Article 20 of the Charter*". It thereby seems as though the European take on the protection of conservation varieties needs to be revised and translated into a stronger and less ill-fitted regime.

Ensuring the production of public goods that are the result of mass selection thus entails a comprehensive fine-tuning of dominant intellectual property regulatory tools, reconsidering the existing flexibilities aimed at *in situ* biodiversity conservation within the strong paradigm. The farmers' exception and those regulatory takes on farm-saved seed should be recalibrated in PVP legislation and provided for in patent laws, while, most importantly, a well-suited reward regime should be constructed to free mass selection and exchange practices from the present illegality, thereby ensuring the maintenance and continuous production of biological diversity upon which breeding programmes continue to rely.

3. Conclusion

This paper has explored the effectiveness of the strong intellectual property paradigm to create incentives for innovation in the field of research into food and agriculture, which is based on massive inputs of plant-genetic resources into the research and development cycle. The main lesson is that there is no one regime that fits all contexts best. The strong paradigm has proven very effective in the context of genetic engineering, but faces a systematic paradigm breakdown when it extends its regulatory scope over traditional mass selection operating for example in exchange networks of farmers' landraces, where innovation often has a more collective, community-related nature. In these cases, a different form of intellectual-property protection, based on partially-open innovation systems, has proven more effective. Genetic engineering and mass selection with naturally occurring landraces present two extreme cases.

Perhaps the most important part of modern agricultural research is happening between simple observation and deep molecular introspection. Conventional breeding, characterised by controlled hybridisation, and based upon the methodically-controlled crossing of specific varieties with other plant-genetic material to craft varieties responding to the market's every need, implies the repeated input of vast amounts of plant-genetic material, both from the pool of already domesticated varieties and from wild-plant genetic resources. Similarly, the use of molecular-biology-based gene marker technologies or bio-informatics to empower conventional breeding techniques is built around a process of cumulative incremental innovation, where the outputs of the research are used in turn as the direct inputs for the next innovation cycle. For these intermediary contexts, both overly strong intellectual property rights and the absence of well delineated intellectual-property protection fail to provide incentives for investing in follow-on innovations. In particular, in cases where access to plant-genetic resources is basic to each new product development cycle, overly strong intellectual property rights might hamper or slow down the innovation process due to increased transaction costs generated by the need for complex licensing schemes for the use of these resources. Further, due to the interdependence of developed and developing countries for access to genetic resources for food and agriculture – for example situated in biodiversity hotspots in the South – special attention is required to create investment in genetic resources by countries that are situated far from the innovation frontier and which are less well placed to obtain and enforce strong intellectual property rights.