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Agro-chemical Mega-mergers and Innovation

Between Competition Law, Regulation and IP Rights

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direction of innovation in this industry towards a more agrochem model of agricultural

This study aims to narrate the context that shaped the competition assessment of these mergers. We first focus on the propertization of nature and the shrinking of the public domain, before exploring the important game-changer of the gene-editing revolution, and the way its regulation may kerb the boundaries of the competitive space in which competitive interactions may legitimately occur. Having defined the broader legal and technological context, the next Section focuses on the main trigger for merger assessment, the increasing consolidation of the agrochem industry. This takes various dimensions, although the strict confines of the merger control assessment led competition authorities to ignore some dimensions for which there is still uncertainty as to their welfare effects, in particular in view of the lack of definitive consensus on what is the optimal market structure for innovation. As previously mentioned, in view of their broader socio-economic implications the agrochem mergers raised the thorny issue of integrating in the merger analysis broader concerns than just price effects. Competition authorities were confronted to the choice between, on one side, a more conventional model focusing on consumer welfare, not one limited to price effects but also taking into account other parameters of competition, such as innovation, and, on the other side, that of a model focusing on the broader public policy effects of the merger transactions. Although, competition authorities made the choice of not directly considering public policy concerns, the approach they adopted in assessing innovation effects hints to an effort to surpass the strict boundaries of the relevant market approach.

I. The propertization of nature and the shrinking of the public domain

A. IP regimes in Agricultural Production

The boundaries of these IP rights, with regard to the application of EU competition law, have been broadly interpreted. In *Erawu-Jacquery v La Hesbignonne*, the Court of Justice of the EU(CJEU) held that a prohibition on the sale or export of basic seeds by the IP right holder

In 1930, U.S. Congress established a plant patent regime providing protection over asexually reproducing plants (where each generation is genetically identical to the preceding), with the exclusion of food tubers (such as potato or Jerusalem artichoke, which are considered staple food)[21]. Asexual reproduction is the propagation of a plant without the use of fertilized seeds to assure an exact genetic copy of the plant being reproduced, with the aim to establish the uniformity and stability of the. The grant, which lasts for 20 years from the date of filing the application, protects the patent owner's right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any part thereof, into the United States. The criteria for the patent protection do not include a requirement that plants are useful, but that they are new (non-obvious) and distinct. The plant should be shown to differ from known, related plants by at least one distinguishing characteristic, which is more than a difference caused by growing conditions or fertility levels,. To be patentable, it is also required that the plant was invented or discovered in a cultivated state, and asexually reproduced. Plant patents are mainly used by the horticulture industry.

The development of new traits via biotechnology is a quite costly process, the costs being associated with the discovery, development and authorisation of a new biotechnology derived crop trait being for the 2008-2012 timeframe estimated to $136 million, out of which $31 million are the costs of discovery, $28 million the costs of introgression breeding and wide-area testing and more than $35 million being spent on regulatory science and registration and regulatory affairs[22]. This is quite substantial, although less than the cost of bringing a new conventional chemical crop protection product to the market, which was in the 2005-2008 period $256 million. The mean value of the number of years required from the discovery of the trait to its first commercial sale for all crops is estimated to 13.1 years, this period being 11.7 years for canola, while for soybean this period was in the 2005

In *Diamond vs Chakrabarty*, the US Supreme Court extended patent claims to life sciences, this leading to the emergence of the biotechnology industry[25]. In 1985, the court expanded patent protection to genetically modified plants in *Ex Parte Hibberd*[26]. With a utility patent, patent-holders can sue farmers and rivals for patent infringement and pursue litigation to enforce licensing agreements. These decisions have led the agricultural biotechnology industry to rely heavily on utility patents for intellectual property (IP) protection. Utility patents are thus available for the protection of plant tissue and seeds, as well as for the whole plants. The emergence of IP protection led to a shift of the paradigm from public sector innovation to private sector innovation, particularly in plant technologies and molecular level agricultural biotechnology[27]. It was reported that "the average annual growth rate in utility patents for plant biotechnology was about 20 percent for major field crops, higher than the average rate of growth across all innovation areas"[28].

Patent laws also protect distinct plant varieties that are asexually reproduced. Protection is received by the special Plant Patent Act of 1930 (PPA) which established specific type of patent called 'plant patent'. As opposed to utility patent mentioned above, plant patents do not require utility. Instead, it requires distinctiveness, that the plan be a distinct new variety. According to

double protection under patent law and the *sui generis* plant variety protection resulting from the UPOV (Union for the Protection of New Varieties of Plants) Convention[35].

However, the European Directive 98/44/EC on the legal protection of biotechnological inventions led to the possibility of patenting when the technical feasibility of the invention is not confined to a specific plant variety[36]. In 1999, the Enlarged Board of Appeal of the European Patent Office stated that "(a) patent cannot be granted for a single plant variety but

productivity to the inbred lines. However, this vigor is lost in subsequent generations, making thus necessary for farmers to purchase seeds for every planting season[45]. More recently this "technological protection" has been achieved through cytoplasmic male sterility, one of the

breeders' exemption, which erode the ability of new variety developers to appropriate rent by selling seeds[46]. It was reported that plant variety rights are only associated with low increase in value in comparison to seeds not protected by Plant Variety Rights, and that they are often not litigated, which indicates that they may not be expected to confer substantial market

regulation of access to these resources by scientists for research purposes and eventually farmers. The CBD provided regulations for access to genetic resources and transfer of relevant technologies on Mutually Agreed Terms (MAT) and based on Prior Informed Consent (PIC). The Nagoya Protocol on Access and Benefits Sharing, a 2010 supplement to the 1992 Convention on Biological Diversity, put forward a framework for ensuring that countries where seeds and microbes held in public collections originate, along with the relevant traditional knowledge, share in the profits and other benefits provided from their use. The Nagoya Protocol mainly focused on the creation of a mechanism for bilateral arrangements, but an additional option would have been a multilateral treaty establishing a transnational exchange and remuneration system.

The last option was taken with the PGRFA, with the establishment of public seed banks. The Treaty constitutes the follow up of an International Undertaking on Plant Genetic Resources in 1983[59] The Treaty's aims are the conservation and sustainable use of all plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security [60] Article 9 of the PGRFA provides for farmer's rights, and in particular for "the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture"[61]. The Treaty also puts in place

A key distinction is made between genetically modified organisms (GMOs), where alteration was made "in a way that does not occur naturally by mating and/or natural recombination"[65], requiring the use of techniques listed to Annex I A, part 1 of Directive 2001/18/EC, and food that does not fall within this classification and has not been subject to genetic alteration. In relation to the interpretation of GMO provisions, the techniques used to create GMOs were not exhaustively defined in EU regulations.[66] Although non-GM food and feed is subject to the General Food Law Regulation, which provides general safety standards regulated by the European Food Safety Authority[67], only GMO food and feed is subject to specific regulation in relation to containment and environmental risks[68].

State objects against the assessment report, EFSA will itself undertake a risk assessment. Both cultivation and food and feed authorizations are valid for a maximum of 10 years, and are renewable.[71]

Between 2009 and 2011, the EU legislative framework for GMO regulation was evaluated by two consultancy firms: while the relevant authorities and other stakeholders showed support for the main objectives of the EU's GMO regulation, it was also reported that GMO cultivation would benefit from more flexibility in the authorization process, that the authorization system could be more efficient, and that risk assessment should be more harmonized.[72] Decision-making within the GMO authorization system has indeed been inefficient and ineffective. Shaffer and Pollack described it as "a record of persistent conflict, bargaining from fixed positions, formal votes on nearly every proposed decision, substantial numbers of abstentions (representing a refusal to take a position) and ultimate deadlock".[73] In 2013, the General Court of the European Union forced the European Commission to proceed in the authorization process of maize 1507, an insect-resistant genetically modified maize, after several years of delays, U-turns and inaction since the initial application in 2001.[74]

GMO regulation is broader than just addressing environmental and safety concerns, and relates to the wider economy and governance of agriculture and the control of food production systems. Contrary to the EU regulation of GMOs, the US one does not require the labelling of GM food.

Most recently, “gene-editing” techniques have enabled targeted interventions at the molecular level of DNA or RNA function, thus making it possible to shear DNA with tremendous precision. These New Breeding Techniques (NBT) followed earlier generation genetic engineering techniques that most often involved the transfer of cloned genes from one organism to another in order to produce a transgenic organism. The aim was to use genetic engineering, in order to give rise to a phenotype that may be radically novel in the engineered strain and reproduce this effect in populations. This research came out of dissatisfaction with recombinant DNA technologies that were quite time-consuming, expensive, highly inefficient at times and which required a special skill-set and important investments in specialised personnel and laboratories. NBTs were made possible by advances in genome sequencing and

arise from EU law,[101] the AG argued that it is legitimate for them to legislate with regard to organisms obtained by mutagenesis.

The operation of the precautionary principle may however limit the regulatory autonomy of Member States. This permits different actors (e.g. EU Member States, the Commission or undertakings) to adopt provisional risk management measures,[102] under secondary law provisions, without having to wait until the reality and gravity of the alleged risks become fully apparent provided there is some scientifically-evidenced discernible risk.[103] By virtue of the precautionary principle, the legislator is also obliged to keep its regulation reasonably up to date. However, in his Opinion, the AG argued that, given the absence of conclusive scientific data and surveillance of the novel organisms obtained by mutagenesis, there were not any grounds deriving from the general duty to update legislation (in particular following the application of the precautionary principle) which could affect the validity of the mutagenesis exemption in the GMO Directive[104].

In conclusion, the AG concluded that the effect of Art 3(1) and Annex I B is that the GMO Directive shall not apply to organisms obtained through certain techniques of genetic modification, such as 'mutagenesis', which involves the alternation of the genome of a living species but does not involve the insertion of foreign DNA into a living organism.[105] By also holding that the GMO Directive does not constitute a complete harmonisation measure with regard to organisms obtained by mutagenesis and that Member States are free to regulate, provided they respect the overarching obligations that arise from EU law[106], the AG also embraced some form of regulatory experimentalism in this area.

In a recent judgment, the CJEU agreed with the AG that organisms obtained by means of techniques/methods of mutagenesis constitute GMOs with regard to Art. 2(2) of the GMO Directive[107]. However, it took a different perspective regarding the possibility of excluding organisms obtained by means of techniques/methods of mutagenesis from the scope of the GMO Directive, following the exemption in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto. The AG had argued that such joint interpretation would bring

“[…] the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis. It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that

opportunities for new entry in the seeds/traits/animal genetics markets. Indeed, as a recent Nuffield Council on Bioethics report recognizes, "the potential of genome editing techniques (in terms of decreased cost and technical difficulty, and increased speed) may revive the opportunities for small and medium-sized biotech companies in the agricultural area and unlock development of a wider variety of traits"[113]. These developments may be blocked either by regulatory burdens similar to those imposed to GMOs, or by the business strategies of incumbent agrochem corporations that may try to establish one-shop platforms, combining traits, seeds, pesticides and smart agriculture or digital products in order to erase barriers to the independent entry of small and medium-sized start-ups in the various segments of the value chain, licensing or a merging with the agrochem behemoths being the only options on the table. This leads us to examine the increasing concentration in the agrochem sector and how this may be related to the expansion of IP rights, and merger activity in this sector.

III. Increasing Concentration in the seeds and agrochem sector

The seeds industry constitutes an interesting example of the industries that changed dramatically over the last 50 years the structure of social relations, as agricultural production went from the use of post-harvest seeds savings practice by farmers to them purchasing their seeds from a few global industrial giants. The industry evolved through a number of major biotech advancements and legal enhancements of intellectual property rights (IPRs).

Technology-driven growth has not been the only major transformation of this economic sector. Its consolidation, in particular in the factors of production segment, has been particularly important in recent years. The various segments of the factors of production markets were progressively consolidated in, most frequently, tight global oligopolies (Table 1). The list of the most important companies active in this sector has been remarkably stable the last few decades, indicating a rigid competitive structure controlled by a stable hierarchy with little or no possibilities of market contestability[114].

Table 1: Evolution of the consolidation process in the global seed industry[115].

Year	**1985**	**1996**	**2012**
CR1[116]	4.1%	5%	21.8%
CR2	5.7%	8%	37.3%
CR3	6.8%	10.2%	44.4%
CR4	7.9%	11.7%	48.2%
CR5	8.9%	13%	48.2%
CR6	9.9%	14.1%	54.6%

[113] Nuffield Council on Bioethics, Genome Editing: An Ethical Review (September 2016), 62.
[114] See figure 5 in T.C. Sparks & B.A. Lorsbach, Perspectives on the Agrochemical Industry and agrochemical discovery, (2017) 73 Pest Science Management 672, 675.
[115] See, Figure 6, European Commission, DG for Internal Policies, The EU Seed and Plant Reproductive Material Market in Perspective: A Focus on Companies and Market Shares - Note (2013), 20.
[116] CR1 denotes the market share of the largest in terms of turnover or sales undertaking in the relevant market, CR2 the market share of the two largest in terms of turnover or sales in the relevant market and so on.

players emerged. For instance, before the mid-1980s, Monsanto was primarily active in the production of chemicals and optoelectronics, while Syngenta was created in 1999 as a spin-off, following the merger between the agrochemical business of pharmaceutical corporation AstraZeneca and the seeds and crop protection business of Novartis. The result of this extensive merger activity is that in the number of independent seed companies has passed from 600 in 1996 to 100 in 2009.

The most recent merger wave was initiated in July 2014 when Monsanto made a number of acquisition offers to Syngenta. These offers were rejected, but the Monsanto bid

well as seeds and traits[122]. The remedial package chosen by the European Commission and the US competition authorities aims to transform BASF to the fourth platform in this sector, offering “integrated solutions” for agriculture, the same competitive model than that chosen by the other Big Three. The following Figure provides a picture of the agrochem industry prior and after the mega merger process, without including the changes to be brought after the implementation of the remedial package, as these depend on its approval by various competition authorities around the world (Figure 2). igu( )-1(s)-1: Corld m wpariso(e)nesb341(pa)-(to.84 an

In order to become of interest for competition law intervention, restrictions of vertical innovation competition need to be pervasive and not temporary, and should lead to significant pecuniary externalities, at least in the medium term. There should also be a high likelihood that these could be converted to strong structural positions in other value chains in which the lead firm may be involved, thus renewing the cycle of total surplus value capture. The aim of competition law is not to micro-manage the allocation of profits between the various segments of the value chain but to ensure that the basics of vertical competition are sound, and that there is no entrenched superior bargaining power that may end up misallocating resources, in

been going down recently[142]. Having four instead of six important innovation players in the industry may restrict the possibilities of joint collaboration on R&D, in view of the prevalence of cross-licensing in this sector, thus increasing the risk of tacit collusion, in particular as most stacks are inter-firm stacks. Overlaps in biotech innovation could also lead to size down research capabilities and thus restrict the number of R&D poles. Ø. Solberg & L. Breian (2015) studied five Nordic countries finding that consolidation (from 1950 to the present) has resulted in a decrease in the number of available cultivars, a shift in focus to crops and hybrids more profitable to companies, and termination of breeding programs for regionally relevant crops[143].

Recent research has found that R&D intensity, measured as the share of industry-level R&D expen

trait and roughly USD 136m of R&D costs (excluding failures)[149]. Another study brings this cost to $286 million. The regulatory framework of GM plants is very stringent and typically requires about nine years of regulatory work assuming it is running in parallel to early development stages. A recent report by PricewaterhouseCoopers (2015) indicates that concentration in animal health market has had a negative impact on R&D and that low R&D productivity led to mature portfolios with some of the key drugs on the market present for more than 20 years[150].

Some studies have also found that excessive market power and high concentration in animal genetics industry led to less biodiversity by (i.e., poultry)[151]. Moser and Wong analysed completion dynamics in the US agricultural biotechnology industry before entrance of

The most recent mergers in the agrochem industry were notified to an important number of competition authorities around the world, which approved all of them, in some cases with conditions. As most of these mergers involved horizontal, vertical and conglomerate integration[164]

for vertical and conglomerate mergers[174] and also state that mergers involving innovative companies that are likely to expand significantly in the near future will be extensively investigated even when the post-merger market share is below 30%[175]. The Commission has actively considered innovation effects in the recent agrochem merger cases. It explored the possibility that a horizontal merger may lead to a loss of innovation by eliminating competitors with pipeline products, which would likely have entered existing markets or created entirely new value chains, thus preventing consumers from increased choice and variety[176]. Another concern is for non-horizontal vertical or conglomerate mergers that would have harmed the ability of the merged entity's rivals to innovate[177].

It has been alleged that, in several of these cases, the Commission has proceeded to establish a novel theory of harm, that of a significant impediment to industry innovation (SIII). According to this view, the Commission in these cases has not explored the existence of specific innovation markets that the merger could have affected. It simply relied on several negative views about the merger gathered from third parties, without assessing if the merger would lead to a reduction in the R&D spend/innovation incentives of the merged entity, its rivals and/or the whole industry[178]. For the proponents of this view, the Commission bases its SIII theory on a presumption that regulatory intervention is warranted when a merger removes a “ p

The Commission found that concentration was not also high at the industry level, but also at the level of innovation spaces. The concept of "innovation space" constitutes an intermediate level of consideration of a space where competitive activity takes place, in addition to that of product relevant market downstream, technology market upstream, or at the level of the industry[192]. According to the Commission,

> "(2162) […] (T)he R&D players do not innovate for all the product markets composing When setting up their innovation capabilities and conducting their research, they target specific innovation spaces which are upstream of lucrative product markets and product markets which are of strategic interest for the R&D player in question.1602 In order to assess innovation competition, it is thus important to consider the spaces in which this innovation competition occurs"[193].

The aim here is to delineate spaces where innovation competition takes place and to develop a structured approach that will enable the Commission to assess the existence of competitive constraints to the merging parties. This assessment requires a two-level approach:

> "[…] (F)irst of all the identification of those companies which, at an industry level, have the assets and capabilities to discover and develop new products which, as a result of the R&D effort, can be brought to the market. This analysis would identify the

integrated throughout the entire R&D pipeline[198]. Although the Commission noted the existence of other companies that are active to some extent in R&D, it found that these were not comparable to the five global R&D-integrated players as regards innovation competition[199]

work, less lines of research, less development and registration work and ultimately bringing less innovative Active Ingredients to the market than the merging parties would have done absent the transaction[217]

compatible with the broader aims followed by the EU. Certainly, environmental protection does not constitute an objective of competition law, but to the extent that the text of the EU treaties should be interpreted in its best possible light, the horizontal integration clauses, such as Article 11 TFEU, provide broader hermeneutical instructions to the European Commission when interpreting the provisions of the EU Merger Regulation (hereinafter EUMR). The text of the EU treaties provides a clear idea of the social benefits and costs of the various forms of competitive struggle that competition authorities should be vigilant to preserve.