UCL FACULTY OF LAWS

UCL

Centre for Law, Economics and Society

Research Paper Series: 7/2018

Agro-chemical Mega-mergers and Innovation

Between Competition Law, Regulation and IP Rights

Ioannis Lianos

Centre for Law, Economics and Society

CLES
Faculty of Laws, UCL

Director: Professor Ioannis Lianos

CLES Research Paper Series
7/2018

Agro-chemical Mega-mergers and Innovation

Between Competition Law, Regulation and IP Rights

Ioannis Lianos

September 2018

Centre for Law, Economics and Society (CLES)
Faculty of Laws, UCL London,
WC1H 0EG
The CLES Research Paper Series can be found at
www.ucl.ac.uk/cles/research-papers

Pre-published version of I. Lianos, Agricultural mega-mergers and Innovation – Between Competition Law, Regulation and IP Rights, in G. Muscolo & M. Tavassi (eds.) *The Interplay between Competition Law and IP: An International Perspective* (forth. Kluwer, 2019)

ISBN 978-1-910801-21-5

Centre for Law, Economics and Society
Faculty of Laws, UCL
London, WC1H 0EG
United Kingdom

Agro-chemical mega-mergers and innovation
Between Competition Law, Regulation and IP rights

Ioannis Lianos[*]

Abstract: *This study aims to narrate the context that shaped the competition assessment of the last wave of mega-mergers in the agrochem sector. It first focuses 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 determine the boundaries of possible competition in this sector. 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 (common ownership) 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 concept in analysing the effect of these mergers.*

Keywords*: competition law, GMO regulation, innovation, intellectual property rights, patents, plant variety rights, economic concentration, agriculture, merger control*

JEL Codes: *K21, L4, L66, N50, O13, O30, Q1, Q16, Q18*

[*] Professor of Global Competition Law and Public Policy; Director of the Centre for Law, Economics & Society, UCL Faculty of Laws; Academic Director, BRICS Competition Law & Policy Centre, HSE National Research University. The author has received funding for certain aspects of this research by Friends of the Earth Europe, Food&Water Europe, SumOfUS, and WeMove Europe. The views expressed are, however, strictly those of the author.

Agro-chemical mega-mergers and innovation
Between Competition Law, Regulation and IP rights

Ioannis Lianos*

I. Introduction 5
I. The propertization of nature and the shrinking of the public domain 7
A. IP regimes in Agricultural Production 7
1. Plant variety rights 8
2. Patents 10
3. Beyond IP: technological means of protecting innovation 14
B. The appropriability-commons continuum 15
II. The gene-editing revolution and the changing regulatory framework 19
III. Increasing Concentration in the seeds and agrochem sector 28
IV. The socio-economic effects of the rising levels of concentration in agrochem markets 35
V. Assessing the innovation effects of the agrochem mergers 38
VI. Conclusion 48

I. Introduction

The inputs segment of the food value chain has been the theatre of significant merger activity the last three years led by the top 4 industry leaders. In November 2015, Syngenta accepted the offer of ChemChina (which owns ADAMA, one of the largest agrochemical companies in the world). In December 2015, Dupont and Dow announced their merger. In September 2016, Bayer put forward a merger deal with Monsanto. These merger transactions of a magnitude or around $239 billion were conditionally approved by a number of competition authorities in more than 30 jurisdictions, leading to a transformation of the structure of the industry, now dominated by four integrated platforms of seeds, plant protection agents (e.g. pesticides, insecticides, herbicides) and digital agriculture, namely Bayer/Monsanto, Dow/Dupont, ChemChina/Syngenta and BASF. The assessment of these mergers by the competition authorities around the world was particularly complex. First, they have important social implications, as the mergers affect the livelihood of millions of farmers, and also the

* Professor of Global Competition Law and Public Policy; Director of the Centre for Law, Economics & Society, UCL Faculty of Laws; Academic Director, BRICS Competition Law & Policy Centre, HSE National Research University. The author has received funding for certain aspects of this research by Friends of the Earth Europe, Food&Water Europe, SumOfUS, and WeMove Europe. The views expressed are, however, strictly those of the author.

direction of innovation in this industry towards a more agrochem model of agricultural production, thus also affecting future generations of consumers. Second, the quite dramatic technological changes that have occurred in this industry in recent decades, with the application of biotechnology in agricultural production, have put at the forefront of the competition assessment effects on innovation, rather than the conventional price effects, providing the opportunity to the competition authorities to test new approaches focusing on dynamic, rather than static, competition. Third, the de-nationalisation of food systems and the emergence of an international food order, largely operating on the basis of transnational food value chains, has been an important feature of the evolution of the industry, thus pushing the competition authorities to consider, to a varying extent, the extraterritorial enforcement of their competition law, although the local-nexus played a significant role in delimiting the remedial package. Fourth, the structural transformation of the industry altered to a certain extent the dynamic of merger assessment, requiring from the competition authorities to take a broader, industry-wide perspective, rather than focusing on the effect on specific relevant markets, at least at the level of conceptualising the possible theories of harm.

The way these mergers were reviewed by competition authorities has the potential to transform conventional approaches in envisioning the application of competition law in the food sector. This is particularly significant as this sector has been at the forefront of the development of competition law as a separate field of law. Farmers and their struggle for land re-distribution and economic independence has profoundly influenced the political and economic constitution of modern capitalist societies[1] and, to a large extent, explains the emergence of antitrust law, the last decades of the 20th century[2]. Of particular interest is the increasing role of the broader regulatory and socio-technical context, probably to an extent not previously seen in merger control. Assessing innovation effects led competition authorities to explore the respective role of intellectual property rights, and that of the public domain, in generating innovation. Regulation (for environmental or sustainability concerns) may have also played, and will certainly continue to play, an important role in confining the acceptable directions that this innovation effort may take in the future, thus delineating the competitive space in which the various firms aim to reap various forms of competitive advantage against their competitors. Competition authorities had also to tackle the question of the optimal relation between innovation and market structure, in particular in view of the various forms of consolidation of the agrochem sector. Finally, the focus on innovation raised the challenge of devising the development of new metrics, or methodologies, for assessing innovation effects.

---

[1] K. Polanyi, *The Great Transformation: The political and economic origins of our time* (first published 1944, Beacon press, 2001). According to Polanyi, the disembededness of the market from other spheres of social activity has been achieved only because it has been followed by a counter movement, various social groups (or society) attempting to re-embed market forces in social institutions and thereby to regulate the market mechanism (the so called "double movement"). Social movements, such as those initiated by farmers have played an important role in this respect.

[2] In the US, the so called "Granger movement" was established in 1867 by Oliver Hudson Kelley, with the aim to unite the farmers against the monopolistic practices of railroads and elevators and to institute for themselves cooperative methods of buying and selling: S.J. Buck, *The Granger Movement - A study of agricultural organization and its political, economic, and social manifestations 1870-1880* (Harvard Univ. Press, 1913); T.J. DiLorenzo, The Origins of Antitrust: An Interest Group Perspective (1985) 5 International Review of Law and Economics 73

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 expansion of property rights has been a salient feature of the recent transformation of the economic structure globally as investment in intangibles becomes the core source of value-generation[3]. This process has been particularly significant in agricultural production. Historically, plant and seed material were thought of as communal resources to be freely shared. Farmers were incentivized to save, replant, and resell seeds to other farmers, the dominant paradigm for trait development being farmer sharing[4]. Starting with the mechanization and the use of tractors in the late 19th century and most recently with the granting of the first plant biotechnology patent in 1992, IP rights were used in the agricultural sector in order to stimulate R&D and innovation. They also formed the basis for the emergence of a private seed industry following the Green revolution of the 1960s-1970s.

Initially funded by the public sector, the Green revolution led to an important increase of productivity at a higher cost for the independence of farmers that have until then ensured the effort of innovation in the sector by developing crop diversity (decentralised and highly fragmented innovation environment). Farmers became dependent on external seeds, which led to the emergence of a private seed market. The new varieties introduced by the Green

[3] J. Haskell & S. Westlake, *Capitalism without Capital: The Rise of the Intangible Economy* (Princeton Univ. press, 2017).

[4] M. Llewelyn, The Legal Protection of Biotechnological Inventions: An Alternative Approach, (1997) 19 European Intellectual Property Review 115, 117.

revolution required also sharp increases in the use of fertilisers and pesticides, which added to the dependence of farmers on the private market and increased the need for credit. The development of biotech and genetic engineering in the 1990s had also profound implications on the development of the industry and the process of its privatization. Hybrid crops provide high yields but also lose this advantage the following generation, thus leading farmers to buy new seeds regularly. Genetically modified (GM) seeds are now at the centre of the innovative effort in modern agriculture, the plant science industry being one of the world's most R&D intensive industries[5].

There exist various IP regimes in operation in the food sector, most notably plant variety rights, patents trade secrets and trademarks. The most significant, in terms of guaranteeing a more effective appropriability of innovation, are patents and plant variety rights. There has been a relatively higher increase in the use of utilities patent protection in agriculture filed in the US, in comparison to plant variety protection, although the trend for both has been in the ascendant the last three decades[6]. This may be due to the higher effectiveness of utility patents in ensuring the appropriability of the innovation returns provided by the invention.

1. Plant variety rights

According to the TRIPS agreement, every country must have at least *sui generis* protection for plants. Article 27.3(b) allows WTO members to exclude "plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals other than biological and microbiological processes", provided that they offer patents or establish "an effective sui generis system" of protection for plant varieties. However, the WTO stays short in defining precisely what constitutes an "effective *sui generis* system". Many jurisdictions protect plant varieties through the UPOV (Union for the Protection of New Varieties of Plants) Convention, adopted in 1961, in order to safeguards the interests of farmers and breeders with exemptions permitting farmers to save seed from one growing season to another and allowing breeders to use protected seeds for research purposes[7].

Like patents, plant variety protection provides patent-like rights to plant breeders. These *sui generis* IPRs protect the genetic makeup of a specific plant variety, the criteria for protection being novelty, distinctness, uniformity and stability. PVP confers to the developer of a novel combination of genes manifested as a distinct, uniform and stable variety (the phenotype of the variety) a bundle of rights, without any need to prove an inventive step nor a specific utility, as title is provided solely on the evaluation of the variety's value in terms of genetic quality. Plant variety protection laws can provide exemptions for breeders, allowing them to use protected

[5] See, ETC Group, Who will control the Green Economy? (November 2011), available at http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf

[6] G. Moschini, Competition in the US Seed Industry and the Role of Intellectual Property. (2010) 25(2) *Choices Mag* 1.(providing evidence for the use of Plant Variety Protection rights and utility patents for corn and soybeans and noting that the number of utility patents on varieties exceeded that of PVP rights between 2005-2009); P. Pardey, B. Koo, J. Drew, J. Horwich, C. Nottenburg, The evolving landscape of plant varietal rights in the United States, 1930-2008. (2013) 1(1) *Nature biotechnology* 25

[7] International Convention of the Protection of New Varieties of Plants, Ger.-Neth.-U.K., Dec. 2, 1961, 815 U.N.T.S. 89 (revised Nov. 10, 1972, Oct. 23, 1978 and Mar. 19, 1991).

varieties for further breeding, and for farmers, allowing them to save seeds from their harvest, however these exceptions are provided under highly restricted conditions and these regimes have become more and more similar to the protection provided by patents, in particular since the 1991 UPOV Convention.

Most jurisdictions have pursued a system of concurrent protection of a plant variety through the grant of utility patents, plant patents and plant variety protections (the latter protected in adherence to the UPOV Convention 1991 Act).[8] US Supreme Court decisions in *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred*[9] and more recently in *Bowman v. Monsanto*[10] have emphasized the importance of conceiving these different systems of IP rights (utility patents, plant patent, plant variety protection) as parallel to one another rather than mutually exclusionary. This complementarity is also supported by the lack of wording to the contrary in the relevant legislation (U.S. plant patent legislation, U.S. Plant Variety Protection Act) and the divergence of scope and requirements for each type of IP protection in this area.[11] The plant variety protection is perceived as an encouragement for new varieties of sexually reproduced plants, protecting their breeders and developers. Its scope covers plants that are sexually reproduced, tuber propagated, and F1 hybrids.[12] In addition to compliance with the criteria of "novelty, distinctness, uniformity and stability", the US provisions on plant variety protection require the deposit of propagation material for the purpose of preservation; the material deposited need not be accessible to the public.[13] The issuance of a certificate requires initial fees but no maintenance fees.[14]

A similar overlap of different systems of IP protection in relation to plant varieties also exists in the EU.[15] The Community-wide plant variety protection exists under the Community Plant Variety Rights regime pursuant to Regulation 2100/94 (which rests on the UPOV Convention 1991 Act). The criteria to grant plant variety protection are the same as those identified above in other jurisdictions, including the additional one that the variety under scrutiny must be designated by a denomination in accordance with the provisions of Article 63 of Regulation 2100/94. The Community-wide provisions coexist with national plant variety protection present in twenty-three EU member states.[16] Breeders may choose to rely on a plant variety protection that extends its coverage to the whole EU, or alternatively to a specific number of member states.[17] In order to benefit from the Community-wide plant variety protection, fees have to be paid for registration and on annual basis for each year of protection.

---

[8] On this generally, see also Mark D. Janis, Non-obvious plants, in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar, 2017).
[9] *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124 (2001).
[10] *Bowman v. Monsanto Co.*, 133 S.Ct. 1761, 1767 (2013)
[11] Mark D. Janis, Non-obvious plants, in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar, 2017), pp. 163-164.
[12] http://www.upov.int/edocs/mdocs/upov/en/upov_trainer_en_16/upov_trainer_en_16_05.pdf
[13] Mark D. Janis, Non-obvious plants, in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar, 2017).
[14] http://www.upov.int/edocs/mdocs/upov/en/upov_trainer_en_16/upov_trainer_en_16_05.pdf.
[15] On this, see for example Axel Metzger, Patents on native traits: what scope of protection?' in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar, 2017).
[16] Bart Kiewiet, The Community Plant Variety Protection System, (1 July 2009) CVPO available at: http://cpvo.europa.eu/sites/default/files/documents/articles/2009-07-10_Article_Italy.pdf.
[17] Bart Kiewiet, The Community Plant Variety Protection System, (1 July 2009) CVPO available at: http://cpvo.europa.eu/sites/default/files/documents/articles/2009-07-10_Article_Italy.pdf.

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 was not subject to Article 101 TFEU since considerable investment had been made in developing the basic seed. According to the Court, "a person who has made considerable efforts to develop varieties of basic seed which may be the subject-matter of plant breeders' rights must be allowed to protect himself against any improper handling of those varieties of seed" and "to that end, the breeder must be entitled to restrict propagation to the growers which he has selected as licensees"[18]. In *Bowman v. Monsanto*, the US Supreme Court also held that the sale of one generation of seed does not exhaust rights on later generations: a farmer who purchased seed to grow could not sow a new crop using the seeds produced by the fist crop—as that, the Court held, would constitute *making* the patented product and not *reusing* or s*elling* the seed that had been purchased.

Other countries have taken a cautious approach in implementing plant variety protection, by ensuring that there are provisions protecting farmers' rights. For instance, the India's Protection of Plant Varieties and Farmers' Rights Act, 2001 (PVPFR Act), which became fully operational in 2007, requires that the breeder or any other person entitled to produce, market and sell the seeds of a registered variety must make such seeds or propagating materials available to farmers "in a timely manner" to "satisfy their requirements" and "at a reasonable market price"[19]. A number of provisions in the PVPFR Act directly or indirectly recognize specific rights of, or grant entitlements to, farmers and farming community[20]. Farmers have the right to 'save, use, sow, resow, exchange, share or sell' farm produce including seed of a protected variety in the same manner as they were entitled to prior to the Act, without however that involving the right to sell branded seed of a protected variety. Farmers are also entitled to recognition and reward in cases where the genetic material they preserved and improved is used in developing new varieties. Farmers have the right to claim compensation from the breeder, if the variety they purchased fails to perform as per the disclosure made by the breeder. Finally, they are immune from infringement legal action, if such infringement was innocent. Most importantly, the Authority in charge of the implementation of the Act is empowered to issue compulsory licenses after three years of registration, if the breeder fails to satisfy the reasonable requirements of the public for the seed or other propagating material or that the seed or propagating material has not been made available to the public at a reasonable price. The effects of UPOV protection on the quality or diversity of plant varieties is a matter for investigation, much commercial breeding being directed at cosmetic changes in order to serve market strategies.

2. Patents

---

[18] Case 27/87 *SPRL Louis Erauw-Jacquery v La Hesbignonne SC* [1988] ECR 1919. See also, Case 258/78, *Nungesser v. Commission* [1982] ECR 2015, para. 10

[19] Protection of Plant Varieties and Farmers' Rights Rules, 2003 (as amended in 2012), Rule 36A.

[20] For a description see, Sujith Koonan, India's *sui generis* system of plant variety protection (January 2014), available at http://www.quno.org/sites/default/files/resources/QUNO%20India%20-%20plant%20variety%20protection%20-%202014.pdf

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 is 16.3. years, and for corn 12 years[23]. These considerable investments of resources and time may explain the reason biotechnology-based inventions in agriculture were considered a patentable subject matter.

However, in view of the prevalence of hybridisation and conventional breeding techniques, patents on living organisms were not recognized at least until the early 1980s. The expansion of cellular and molecular biology throughout the 1960s and 1970s, specifically the transplantation of genes between organisms by Cohen and Boyer in 1973, increased the ability of crop scientists to identify and isolate desired traits, modify the relevant genes, and to incorporate these traits into new crop varieties via transplantation with greater precision[24]. These advances had two key implications for agricultural seed manufacturers and plant and animal scientists First, the ability to identify and isolate the relevant genetic traits greatly facilitated the transference of desirable characteristics through selective breeding. Second, the ability to incorporate genetic material from one species into the DNA of another organism allowed for previously infeasible or inconceivable transfers of specific traits.

---

[21] Plant Patent Act 1930, 35 U.S.C. 161.

[22] P. McDougall, The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait, (Phillips McDougall, 2011), 7, available at https://croplife.org/wp-content/uploads/pdf_files/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf .

[23] Ibid., 10.

[24] ISAAA, 2010

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 the Section 161 of the PPA: "whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title."[29]

Sexually reproduced plants, in contrast, are protected by the Plant Variety Protection Act of 1970, which relates to plant variety rights.

Regarding genes, the US Supreme Court held that naturally occurring DNA segment is not patent eligible merely because it has been isolated.[30] According to the US Patent Act and in the light of US Supreme Court's judgment in *Mayo*,[31] laws of nature, natural phenomena, and abstract ideas are not patentable.[32] On the other hand, genes that are not naturally occurring can be patented. In that regard, the court held that synthetically created DNA, that omits portions of the natural DNA, is patent eligible because it is not a product of nature.[33] Therefore, as long as the genes are modified they would be eligible for patent protection in the US.

The scope of patentability is more delineated in Europe, where plant varieties and essential biological processes are excluded from patent protection[34], also in view of the need to avoid a

[25] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[26] 227 U.S.P.Q. 443 (Board of Patent Applications and Interferences, 1985).
[27] Paul W. Heisey, John L. King, and Kelly Day Rubenstein, Patterns of Public-Sector and Private-Sector Patenting in Agricultural Biotechnology, (2005) 8 AGBIOFORUM 73.
[28] Diana L. Moss, Transgenic Seed Platforms: Competition Between a Rock and a Hard Place?, AAI Submission, October 23, 2009, p.25.
[29] 35 U.S.C.A. § 161.
[30] *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2109, 186 L. Ed. 2d 124 (2013)
[31] *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 566 U.S. 66, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012)
[32] 35 U.S.C.A. § 101
[33] *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2109, 186 L. Ed. 2d 124 (2013).
[34] Article 53(b) of the European Patent Convention.

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 can be granted if varieties may fall within the scope of its claims"[37]. Indeed, according to Recital 31 of the Biotechnology Directive, "a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants". Plant varieties may also fall within the scope of patent claims when they are the direct product of a patented non-biological technical process.

The most recent jurisprudence of the Enlarged Board of Appeal (EBA) of the EPO has reduced even further the patentability exception enshrined in Article 53(b) EPC, even for a patent claim for a product that is directly obtained and/or defined by an "essentially biological process". The EBA held that "the fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a patent claim directed to plants or plant material other than a plant variety unallowable".[38] In essence, the EBA found that the patentability exception in Article 53(b) EPC for "essentially biological processes for the production of plants" had to be interpreted narrowly and did not extend beyond the excluded processes in order to cover products defined or obtained by such processes. Hence, a product resulting from an "essentially biological process for the production of plants or animals" may be patented as long as (i) the patentability requirements (novelty, inventive step, industrial application) are satisfied, (ii) the claim defines the product to be covered, either in a product format or in a product-by-process format, and (iii) the patent does not claim a single plant variety, which is something that is explicitly excluded from the scope of patentability under Article 53(b) EPC.

---

[35] International Convention of the Protection of New Varieties of Plants, Ger.-Neth.-U.K., Dec. 2, 1961, 815 U.N.T.S. 89 (revised Nov. 10, 1972, Oct. 23, 1978 and Mar. 19, 1991).

[36] Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ 1998 L 213/13. According to Article 2 of Directive 98/44/EC, "(a) process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection".

[37] Transgenic Plant/NOVARTIS II, G 001/98 [2000] OJ 111.

[38] Enlarged Board of Appeal, EPO, Appeal number T 1242/06, Case G 0002/12, Tomato II (March 25, 2015); Enlarged Board of Appeal, EPO, Appeal number T 0083/05 - 3.3.04, Case G 0002/13, Broccoli II (March 25, 2015). It is noteworthy that the Enlarged Board of Appeal emphasized that "there is no general notion of an obligatorily restrictive construction of exceptions to patentability, for example, such as that adopted by the Court of Justice of the European Union (CJEU) when insisting on a narrow interpretation of exceptions to or derogations from fundamental EC Treaty principles embodied in the four freedoms" (case G002/13, p. 41). Hence, the exclusion of patentability incorporated in Article 53(b) EPC of "essentially biological processes for the production of plants" does not cover any product of such a process, but only excludes biological breeding processes *sensu stricto.*

This is a very favourable position for large agrochemical corporations[39] and contrasts with the more restrictive approach followed by some EU member States' patent legislation, which exclude product claims from patentability where the claimed products have been generated by an essentially biological process for the protection of plants[40]. The position of the EPO, that patents can be granted for plants obtained from essentially biological processes, also contrasts with the position of the European Commission (EC). Namely, the EC issued a Notice where it held that the EU legislator's intention when adopting the Biotechnology Directive was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes. [41] Formally, however, the EPO is not bound by the EU legislation and the European Commission's interpretation. The patentability of plants obtained from essentially biological processes will depend on the future interpretations of this legal framework by the EPO.

Opportunities for access to proprietary knowledge through IP law are generally limited. The EU biotechnology directive includes the possibility of compulsory cross-licensing for non-exclusive use where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, inasmuch as the licence is necessary for the exploitation of the plant variety to be protected. This is subject to payment of an appropriate royalty on reasonable terms[42]. Nevertheless, the conditions to apply for compulsory cross-licensing are quite restrictive, as applicants must show that "(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence; (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety"[43].

3. Beyond IP: technological means of protecting innovation

The seed industry has also put in place biological tools to protect its IP rights by developing hybridization in the 1930s, in particular of corn that strengthened the ability of private actors to appropriate the value of new corn varieties through secrecy[44]. Indeed, corn hybrids rely on cross-polinating two inbred lines in order to generate a hybrid, which displays superior

---

[39] See, the discussion in T. Minssen & A. Nordberg, The Impact of Brocolli II & Tomato II on European patents in conventional vreeding, GMO's and Synthetic Biology: The grand finale of a juicy patents tale?, (2015) 34 (3) Biotechnology Law Report 81-98.

[40] Enlarged Board of Appeal, EPO, Appeal number T 0083/05 - 3.3.04, Case G 0002/13, Broccoli II (March 25, 2015), pp. 64-65 [Part VIII(2)6d] referring to recent amendments to this effect in the German Patent Act of 1936 (as amended in 2013) and in the Dutch Patent Act 1995 (as amended in 2014). However, as the EBA noted, "no such amendments have been made in […] the United Kingdom, […] France […] Austria […] and Switzerland". It remains to be seen if the Court of Justice of the EU will adopt such a narrow interpretation of the exclusion of patentability of products deriving from essentially biological processes, when interpreting the exclusion rule under Article 4(1) of the Biotechnology Directive, the CJEU not being bound by the EBA jurisprudence.

[41] Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, OJ 2016 C 411/03.

[42] Article 12, Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ 1998 L 213/13.

[43] Article 12, Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ 1998 L 213/13.

[44] D.N. Duvick, Biotechnology in the 1930s: the development of hybrid maize, (2001) (2) Nature Reviews Genetics 69.

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 most efficient ways to produce F1 hybrid seeds.

IP right holders may also take measures in order to avoid problems with regard to the implementation of their IP rights, in particular in developing jurisdictions with weak IP enforcement systems. Material Transfer Agreements between the IP right holders and farmers may specify the conditions under which a seed sample will be exchanged. Those holding utility patent rights in seed may sell subject to a contractual provision that bars the farmer from saving seed and using it to grow another generation of crops, thus controlling farmers through purchase agreements. An example is Monsanto's Roundup Ready ® Technology Agreement that usually provides that the farmer cannot save seed or any other part of the crop grown from the Monsanto seed for replanting and that the farmer is prohibited from supplying seed to any other person. Violation of these licenses may be regarded as a breach of contract subject to draconic sanctions, the farmer being obliged to pay 120 times the technology fee plus the legal fee if he/she is caught violating the agreement. Enforcement of these contractual clauses involves the continuous inspection of the farmers' fields by Monsanto staff. Binding arbitration constitutes the default dispute resolution mechanism for these agreements. One may consider these contractual limitations of traditional farmer seed saving and sharing practices as introducing a restriction to research and seed development by farmers and thus a restriction on innovation. Monsanto may advance that such restrictions are necessary in order to protect its own incentives to innovate, in view of its investment on R&D in order to develop the technology and the need to recoup the costs by the appropriation of the profits arising out of the productivity improvements introduced due to its innovative effort.

The seed industry has also put in place biological tools to protect its IP rights through cytoplasmic male sterility, one of the most efficient ways to produce F1 hybrid seeds. The Genetic Use Restriction Technology (GURT) constitutes another form of biological protection, with the development of terminator technologies preventing farmers from saving seeds, since the genetically engineered plants will not germinate in subsequent generations or will not express the specific trait (e.g. herbicide resistance) that is protected by IP rights unless the plant is sprayed with specific chemicals in order to activate the right gene. These biological protection instruments are particularly useful for the private seed industry in jurisdictions with weak enforcement of IPRs. These technologies are protected by patents, a great number of them being held by few global seed companies. This IP-based business environment makes it quite difficult for public institutions to assert themselves in the process of innovation in the seed industry and promote the open access and sharing ethos that was prevalent prior to the expansion of IPRs in this sector of activity.

B. The appropriability-commons continuum

The various IP rights confer different opportunities for appropriating innovation. Appropriability under Plant Variety Protection is limited by the farmer's privilege and the

[45] R. Dixon, Hybrid Corn Revisited, (1980) 48(6) Econometrica 1451.

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 power[47]. There is, however, evidence that Plant Variety Rights stimulate innovation and R&D spending, as their establishment had led in general to an increase in R&D spending for crops eligible for protection[48]. Evidence that their availability as mechanisms to protect plant varieties stimulated the rate of innovation in the industry is more ambiguous[49].

Plant patents do not set limits to appropriability, such as the farmer's privilege or a breeder's exemption, and from this perspective may be considered more valuable than Plant Variety Protection rights[50]. Some studies put the price premium provided to on average a level of 23.5%[51], which declines with the age of the patent and disappears when the plants get of patent, thus showing that the price premium is not merely due to the higher quality of the protected plants[52]. Some other studies indicate that the effect of plant patents on innovation is, similarly to that of plant variety rights, quite limited as there is no evidence that it led to increased commercial breeding, although one might not exclude that the lower impact of plant patents could be explained by other factors, such as widespread breeding by users[53].

---

[46] .S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 16.

[47] W. Lesser, Valuation of Plant Variety Protection Certificates, (1994) 16(2) Rev. Agric. Econ. 231; M.D. Janis & J.P. Kesan, Intellectual Property Protection: Sound and Fury?, (2002) 39 Houston Law Review 727; S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 16-17.

[48] R. Perrin, K. Kunnings, L. Ihnen, Some Effects of the U.S. Plant Variety Protection Act of 1970. *Research Report No. 46, Department of Economics and Business Economics*, (North Carolina State University, Raleigh, 1983); L. Butler & B. Marion, The Impacts of Patent Protection on the U.S. Seed Industry and Public Plant Breeding. *North Central Regional Research Publication* 304 (1985); S. Malla & R. Gra. An Analytical and Empirical Analysis of the Private Biotech R&D Incentives. Selected Paper. *Annual Conference of the Agricultural and Applied Economics Association,* (Tampa, FL, 2000); S. Mall, R. Gray & P. Phillips. Gains to research in the presence of intellectual property rights and research subsidies. (2004) 26(1) *Rev. Agric. Econ.* 63 discussed by S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 16-17.

[49] R. Perrin, K. Kunnings, L. Ihnen, Some Effects of the U.S. Plant Variety Protection Act of 1970. *Research Report No. 46, Department of Economics and Business Economics*, (North Carolina State University, Raleigh, 1983); B. Babcock & W. Foster Measuring the potential contribution of plant breeding to crop yields: flue-cured tobacco, 1954-87. (1991(73 *Amer. J. Agric. Econ.* 850; A. Naseem, J. Oehmke, D. Schimmelpfennig, Does plant variety intellectual property protection improve farm productivity? Evidence from cotton varieties. (2005) 8 *Agbioforum* 100; J. Alston& R.J. Venner, The effects of the US Plant Variety Protection Act on Wheat Genetic Improvement. (2002) 31 *Res. Policy* 527; D.E. Kolady & W. Lesser, But are they Meritorious? Genetic Productivity Gains under Plant Intellectual Property Rights., (2009) 60(1) *J. of Agric. Econ.* 62; R. Thomson. The yield of plant variety protection, (2015) 97(3) *Amer. J. Agric. Econ.* 762, discussed by S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 16-17.

[50] Ibid., 17.

[51] J. Drew C. Yue, N. Anderson & P. Pardey, Premiums and discounts for plant patents and trademarks used on ornamental plant cultivars: a hedonic price analysis, (2015) 50 *HortScience* 879.

[52] S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 17.

[53] See, the work of J. Stallman, *Impacts of the 1930 Plant Patent Act on Private Fruit Breeding Investment*. (Pd.D. Dissertation, Michigan State University, 1986*)* cited by S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 18. See also, P. Moser & P.W. Rhode, Did Plant Patents Create the American Rose?, in J.Lerner & S.Stern (eds.), *The Rate*

Appropriability is quite high for utility patents, and there is evidence that biotechnology patents have one of the largest patent premiums of any industry[54]. This may explain why half of utilities patents on varieties ever issues were granted during the period of 2011-2015 and that during this period there has been a considerable growth of the share of patented private varieties for corn, wheat, cotton and soybeans[55].

The type of IP protection preferred by the firms will not necessarily promote societal welfare if the specific type of innovation could be protected by less restrictive to competition instruments. As it has been shown by some recent research, patents may be best at promoting long-range research programs (such as the introduction of exotic germplasm), while Plant Variety Protection rights promote faster diffusion of genetic improvements across firms, hence, they can be a superior option to patents when the diffusion element of innovation dominates the incentives element[56].

However, not all innovative activity in the food sector has been propertized. There are still some significant pockets of public domain or commons. The fact that successful innovation activity may be organised in the form of "common pool resources" or "knowledge commons" is well-known[57]. Crop genetic resources could be conceptualised as a form of commons, the relative open flows of germplasm making possible collective systems of conservation and innovation, as those self-managed by farmers from the dawn of agriculture[58]. One may cite the example of the collective pooling and management of plant genetic resources for food and agriculture put in place by the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA), adopted by the FAO in 2001 and which entered into force on 29 June 2004. Emergent and developing countries have vigorously campaigned to ensure that genetic material taken from their territories without permission would not be used to generate commercial applications that would benefit from IP rights internationally protected through the TRIPS agreement. By asserting territorial sovereignty over all genetic resources, the Convention on Biological Diversity (CBD) provided the possibility for an international

---

and Direction of Inventive Activity Revisted, (Chicago, IL: University of Chicago Press, 2011) (showing that following the Plant Patent Act 1930 a large commercial breeding sector emerged, but this did not lead to an overall growth of new roses registsred with the American Rose Society, the overall rate falling. S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017), 18, advance that this drop may be explained by the fact that only 16% of the new roses were patented and that there was a widespread breeding of roses by hobbyists.

[54] A. Arora, M. Ceccagnoli & W.M. Cohen, R&D and the Patent Premium. (2008) 26 Int. J. Ind. Organ. 1153; W.M. Cohen Fifty years of empirical studies of innovative activity and performance, in B. Hall & N. Rosenberg (eds.), *Handbook of the Economics of Innovation Volume 1*, (Oxford, UK: Elsevier Publishing, 2010) (finding that utility patents are the most valuable to life science and chemical industries, agricultural biotech presenting many similarities with these sectors).

[55] M.S. Clancy & G. Moschini, Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture, Working Paper 17, WP 572 (January 2017),, 19 , reporting that private corn varieties account for 100% of planted US acres (already since 1980 (this being facilitated by hybrid technology), while for wheat it rose from 5% to 24% between 1980 and the late 1990s, for cotton it rose from 72% to 93% over the same period and for soybeans it rose from 8% to 70-90% over the period.

[56] S.H. Lence, D.J. Hayes, J.M. Alston & J.S. Smith, Intellectual property in plant breeding: comparing different levels and forms of protection, (2016) 43(1) *Eur. Rev. Agric. Econ*. 1.

[57] E. Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action*. (New York: Cambridge University Press, 1990); C. Hess & E. Ostrom, *Understanding Knowledge as Commons* (MIT press, 2006)

[58] M. Halewood, I. López Noriega & S. Louafi (eds.)**, *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance* (Routledge, 2013).**

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 global system for access and benefit sharing in order to provide farmers, plant breeders and scientists with access to plant genetic materials and covering 64 of the most important crops. This easily accessible global pool of genetic resources in various public collections and seed banks is freely available to potential users in the Treaty's ratifying nations for research, breeding and training for food and agriculture. Those who access the materials must be from the Treaty's ratifying nations and they must agree to use the materials totally for research, breeding and training for food and agriculture.

The Treaty prevents the recipients of genetic resources from claiming intellectual property rights over those resources in the form in which they received them, and ensures that access to genetic resources already protected by international property rights is consistent with international and national laws. For those that want to make a commercial use of these resources, the Treaty puts in place a "take and pay" rule. If a plant cultivar put in a public collection is used for commercial purposes, they agree to share any benefits from their use through four benefit-sharing mechanisms established by the Treaty, the exchange of information, access to and transfer of technology and capacity building. They are also required to pay a small percentage of the resulting proceeds, a tithe, back to the Benefit Sharing Fund of the ITPGRFA. Facilitated access to this vast gene pool under the Treaty is provided under the terms and conditions of the Standard Material Transfer Agreement (SMTA). If the recipient commercializes a product (product that is a PGRFA and that incorporates material accessed under SMTA) and where such product is not available without restriction to others, the recipient is required to pay a fixed percentage of the sales of the commercialized product into

[59] Resolution 8/83, see http://www.fao.org/docrep/x5563E/X5563e0a.htm#e.%20plant%20genetic%20resources%20(follow%20up%20of%20conference%20resolution%20681

[60] See, http://www.fao.org/3/a-i0510e.pdf

[61] Art. 9(2)b.

the mechanism. This is specifically 1.1 % of net sales less 30 % or 0.77 % of gross sales. However, if the recipient commercialises a product where product is available without restriction to others, the recipient is encouraged to make voluntary payments into the mechanism. After the expiry or abandonment of the protection period of an IPR on a product, the recipient is encouraged to place a sample of this product into a collection of the multilateral system. In case a recipient obtains IPR on any products developed from the material or its components and assigns such IPR to a third party, the benefit sharing obligations of the agreement is transferred to that third party. The Benefit Sharing Fund invests directly in high-impact projects such as supporting farmers in developing countries who conserve crop diversity in their fields and providing assistance to farmers and breeders who adapt crops to our changing needs and demands. The recent proposals for establishing a commons regime for microbial genetic resources provide another illustration of the international efforts to establish commons[62].

II. The gene-editing revolution and the changing regulatory framework

The adoption of GM seeds and crops raises various ethical and environment-focused concerns, vocally expressed by civil society, which led to the establishment of strict regulatory regimes, eventually also the prohibition of GMOs in a number of jurisdictions. In the EU, regulations have been devised to mandate the assessment of risks to the environmental, human and animal safety arising from GMOs. Genetic engineering technologies were developed from the 1970s onwards but in the last decade, further biotechnologies have been developed. Consequently, many debates have emerged surrounding them. GMOs are regulated in the EU by a comprehensive legal framework, aiming to protect human and animal health and the environment by putting in place procedures for risk assessment, authorisation, labelling and tracing of GMOs when these are placed on the market[63]. In accordance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, the EU legislative framework is based on the precautionary principle. The precautionary principle reflects a risk management strategy whereby the possibility that a given policy or action might cause harm to the public or the environment and the lack of scientific consensus on the issue is sufficient reason for not pursuing the policy or action in question, at least until more scientific knowledge becomes available.[64]

---

[62] P.F. Uhlirch, *Designing the Microbial Research Commons* (National Academies Press, 2011); J. H. Reichman, P. F. Uhlir, & T. Dedeurwaerdere, *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (Cambridge University press, 2016)

[63] Directive 2001/18/EC on the deliberate release of GMOs into the environment; Regulation (EC) 1829/2003 on genetically modified food and feed; Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory; Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms; Directive 2009/41/EC on contained use of genetically modified micro-organisms; Regulation (EC) 1946/2003 on transboundary movements of GMOs.

[64] See Article 191 TFEU. See further Anne I. Myhr, 'The Precautionary Principle in GMO Regulations' in Terje Traavik and Lim Li Ching (eds), *Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Third World Network and GenØk 2009).

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].

The current approval process for GM plants is time-consuming (around 4-6 years) and expensive (around €7-15 million), and does not ensure EU-wide distribution of the approved plant/seed, as the safeguard clause enables Member States to reject already approved GMOs in case of new scientific information about adverse effects. Authorizations for GMOs are available for cultivation and for food and feed purposes under Regulation 1829/2003 (food and feed)[69] and Regulation 2001/18 (cultivation).[70] Applications for authorization for food and feed have to be sent to the relevant national authority, which forwards the application to the European Food Safety Authority (EFSA) for a risk assessment. EFSA evaluates the application based on risks for the environment, human health and animal safety, and may give recommendations on labelling or other conditions. On the basis of EFSA's opinion, the European Commission will advise the Member States to either approve or reject the application. The Member States decide on the application in the Standing Committee on Plants, Animals, Food and Feed by qualified majority. When the Committee fails to reach an approval or rejection decision (because of abstentions), the European Commission can convene an Appeal Committee, which also decides by qualified majority. For authorization applications concerning GMO cultivation, EFSA defers the risk assessment to the relevant national authority of the country where the application is filed. If however at least one other Member

---

[65] Art. 2(2) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, [2001] OJ L 106/1.

[66] Techniques range from nucleases cleaving DNA at specific sites which triggers the cell's repair mechanism, to mutagenesis which involves the cell modifying its own DNA to match the introduced DNA fragments, cell fusion, or other *in vitro* fertilisation techniques, conjugation, transduction, transformation, induction etc.

[67] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] OJ L31/1.

[68] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, [2001] OJ L 106/1, amended by Directive (EU) 2015/412 as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, [2015] OJ L 68/1; and Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, [2003] OJ L 287/1; Regulation (EC) 1829/2003 on genetically modified food and feed, [2003] OJ L 268/1; Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, [2003] OJ L 268/24. On EU Food law, see A. Alemanno & S. Gabbi (eds.), *Foundations of EU Food Law and Policy* (Routledge, 2016); B. Jack, *Agriculture and EU Environmental Law* (Routledge, 2009, paperback ed., 2016); M. Lee, *EU Regulation of GMOs – Law and Decision Making for a New Technology* (Edward Elgar, 2008.

[69] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L268/1.

[70] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L106/1.

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]

The US follows a different regulatory path. A "Coordinated Framework for the Regulation of Biotechnology" was put in place in 1986[75], assigning broad federal jurisdiction over biotechnology products to three federal agencies: the US Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Each of these agencies derives its power to regulate from different legislative frameworks: the USDA relies on the Plant Protection Act[76], the FDA relies on the Federal Food, Drug, and Cosmetic Act, and in particular its provisions on food adulteration and food additives[77], and the EPA mainly on the Federal Insecticide, Fungicide, and Rodenticide Act[78]. Their approach for the regulation of GMOs is products-based, rather than process-based, as it in the EU, as regulation focuses on the *nature* of the products, their characteristics and intended use, rather than on the *process* of their production[79].

An important scientific and social debate is currently ongoing with regard to the regulation of GMOs, in view of some recently published research[80]. Of course, the issue of

---

[71] See, https://ec.europa.eu/food/plant/gmo/authorisation_en.

[72] See, https://ec.europa.eu/food/plant/gmo/authorisation_en.

[73] M. Pollack and G. Shaffer, 'Risk regulation, GMOs, and the limits of deliberation' in D. Naurin and H. Wallace (eds), *Unveiling the Council of the European Union: Games Governments Play in Brussels* (Palgrave MacMillan, 2008), 161.

[74] Case T-164/10, *Pioneer Hi-Bred International, Inc. v European Commission*, EU:T:2013:503.

[75] Coordinated Framework, 51 Fed. Reg. 23,302 (June 26, 1986), available at https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf .

[76] 7 U.S.C. §§ 7701-86 (2012).

[77] 21 U.S.C. § 402 (food adulteration) and § 409 (food additives). Under the FFDCA, substances added to food can be classified either as "food additives," which require approval from the FDA that they are safe before they can be marketed, and substances added to food classified as "generally recognized as safe" (GRAS), as to which preapproval is not needed.

[78] 7 U.S.C. §§ 136-136y (2012).

[79] See, M.T. Roberts, *Food Law in the United States* (Cambridge University Press, 2016); Chris A. Wozniak, Alan McHughen (eds.), *Regulation of Agricultural Biotechnology: The United States and Canada* (Springer, 2012).

[80] See, National Academy of Science and Engineering, and Medicine, Genetically Engineered Crops: Experiences and Prospects (2016); European Commission, A Decade of EU-Funded GMO Research (2001-2010) (European Union, 2010), available at https://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf ; European Academies Science Advisory Council, Planting the future: opportunities

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 DNA assembly, following important progress in connected fields, such as molecular biology, bioinformatics and data technologies[81].

Genome-editing (or 'gene-editing') techniques generally use nucleases which cleave DNA at specific sites and trigger the plant's own repair mechanisms. These NBTs make it possible to introduce changes to the genome without introducing genes or sequences from another species. Oligonucleotide Directed Mutagenesis (ODM or Mutagenesis) is a gene-editing technique, where short DNA (or DNA-RNA) fragments (oligonucleotides) are introduced into cells in order to trigger the cell to modify its own DNA to match the introduced DNA fragments. Alternative gene targeting technologies emerged with genome modification becoming possible via the development of site-directed nucleases (SDN), which operate as molecular scissors. These took first the form of zinc finger nucleases (ZFN) first used in 2005 and the transcription activator-like effector nucleases (TALENs), first used in 2010. They consist in proteins, which are engineered to both recognise specific DNA sequences and to cut DNA in the region of such sequences. They require some considerable effort to produce a pair of proteins for every editing procedure. The Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR/Cas) system, was discovered in 2012. CRISPR is an adaptive immune system that uses complementary single-guide RNA (sgRNA) to recognize and cleave select foreign DNA, neutralising the ability of a pathogen to wreak havoc in the host[82]. It comprises two elements: a clustered regularly interspaced short palindromic repeat (CRISPR) RNA and the CRISPR-associated protein 9 (Cas 9), which is an endonuclease. CRISPR-Cas9 and other gene-editing technologies, such as the "more precise" CRISPR-Cpf1, allow scientists to manipulate the genetic makeup of an organism by de-activating or knocking out a gene function, eventually without the need to introduce genes from other organisms, as this is the case for classical GMO genetic engineering.

---

and challenges for using crop genetic improvement technologies for sustainable agriculture (EASAC Policy Report 21, June 2013), available at http://www.easac.eu/fileadmin/Reports/Planting_the_Future/EASAC_Planting_the_Future_FULL_REPORT.pdf .

[81] Nuffield Council on Bioethics, Genome Editing: An Ethical Review (September 2016), 57.

[82] P. Enriquez, CRISPR GMOs, (2017) 18(4) North Carolina Journal of Law & Technology 432, 509

Genome editing techniques, such as CRISPR, may be used in plant breeding in order to enhance pesticide resistance (e.g. bacterial-blight resistant rice), induce draught tolerance and improve yield or nutritional benefit and appearance[83]. Application of CRISPR technologies for biofuels with the development of plant-based industrial bioproducts may also decrease dependence on oil-based products[84]. In animal genetics, gene-editing technologies "made possible research that had been previously unfeasible"[85], as the technology may apply to animals having long reproduction cycle and CRISPR/Cas9 does not require knowing the entire genetic blueprint of the organism, as it is the case with more "traditional" biotechnology methods.

Compared to the previous technologies of genetic editing technologies, CRISPR is much more efficient ("in terms of successes per attempt"), and cheaper as "the components are trivial to produce", they can be "synthesized with commercially available kits" and the "system functions with a universal Cas9 protein framework that dispenses with the need to design a different protein for each DNA target"[86]. As a Nuffield Council of Bioethics' Report observes, new Breeding Techniques, such as CRISPR, which enable the production of a specific and targeted mutation, "avoid the need to screen hundreds of thousands of crosses […] to identify those with the desired traits", thus significantly reducing "the time and numbers of plants involved in achieving a desired mutation that might otherwise be sought by using methods of random mutation and selection"[87]. To the difference of conventional breeding techniques, gene editing makes it possible to reduce the time needed to generate the desired genetic characteristics in a plant population from 7-25 years to as few as 2-3 years as well as to bypass "the need to go through a number of plant generations to achieve a particular genetic combination"[88]. By enabling multiple editing simultaneously in various parts of DNA able to inactivate up to tens of targets at once[89], CRISPR also allows much faster products development. This complies with the finding of a recent study published by the US National Academy of Sciences that with the CRISPR breakthrough "the scope, scale, complexity, and tempo of biotechnology products are increasing"[90].

Recent USDA regulation suggest that CRISPR modified seeds may not need regulatory approval as GMOs, since in some cases gene manipulations may involve only deletions or modifications with existing DNA[91]. The competitive advantage of such genome-editing technologies, should these not be subject to the existing restrictions of conventional GMO

---

[83] Nuffield Council on Bioethics, Genome Editing: An Ethical Review (September 2016), 61.
[84] Ibid., 61.
[85] Ibid, 62.
[86] Nuffield Council on Bioethics, Genome Editing: An Ethical Review (September 2016), 9.
[87] Ibid., 58.
[88] See, Nuffield Council on Bioethics, Genome Editing: An Ethical Review (September 2016), 56-62.
[89] L. Yang et al. Genome-wide inactivation of porcine endogenous retroviruses (PERVs) //Science. – 2015. – T. 350. – №. 6264. – C. 1101-1104.
[90] National Academy of Sciences, Engineering, and Medicine. Preparing for Future Products of Biotechnology. Washington, DC: The National Academies Press. doi: 10.17226/24605. 2017, p. 53
[91] See, for instance, the recent controversy over the anti-*browning mushroom developed* by plant pathologist Yinong Yang at Pennsylvania State University *using CRISPR-Cas9, which was not considered by the USDA as integrating any introduced genetic material and thus not regulated as a GMO (see* https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf *).*

regulation, in comparison to conventional breeding methods, may significantly alter the market structure and industry dynamics.

Of course, the way GMOs are defined for regulatory purposes is different in Europe, which raises the question whether these techniques of gene-editing, could fall within the scope of the existing EU Regulations on GMOs[92]. In the EU, legal regulation supporting a biotech "process-based approach to GMOs" has been devised in a way that goes beyond merely considering the characteristics of the newly-created GMO. A policy debate emerged. Some contend that GMO regulations should encompass all modern biotechnological processes that directly modify genomes, else the EU would be restricting the choices available to EU consumers. The argument is that a product-based approach, like that used by the US and Canadian regulatory authorities[93] would only focus on the resulting trait but not on the possible long-term health and safety implications[94]. Others put forward the view that a product-based approach would make regulatory decisions more "predictable and efficient",[95] and will reduce regulatory costs[96]. A further argument is that as biotechnologies progress, new methods not listed in the GMO Directive make it increasingly difficult to distinguish GMOs from non-GMOs. These different approaches represent "deep cultural roots relating to different understandings of nature and science in the US and EU" which are at the heart of the controversy.[97]

The question is whether changes introduced through gene-editing should be regarded as constituting a genetic modification. If such do fall under the GMO regulations, these institutions also need to consider the whether any possible exemptions may apply. A recent pending case may provide the opportunity to the CJEU to pronounce itself on this issue. The case was triggered by a Canadian regulatory approval concerning the commercialisation of a GMO developed by Cibus,[98] which used the oligonucleotide direct mutagenesis (henceforth the 'mutagenesis') technique. Following Cibus' request for advice from national regulatory bodies in the EU concerning authorisation procedures, these very institutions have had to determine whether, or which of, the new gene-editing techniques under development would be classified as producing GMOs and so fall under the GMO regulations.

By a request for a preliminary ruling, the French Conseil d'État asked the CJEU to determine whether the GMO is a complete or partial harmonisation measure with regard to organisms obtained by mutagenesis[99]. The purpose was to determine whether Member States

---

[92] *See European Parliament, Briefing, New plant-breeding techniques (May 2016),* http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/582018/EPRS_BRI(2016)582018_EN.pdf *and the expected intervention of the Court of Justice of the EU in pending Case* C-528/16 (judgment expected in 2018)

[93] M. Lusser M. and H. Davies "Comparative Regulatory Approaches for Groups of New Plant Breeding Techniques" (2013) 30 *New Biotechnology*, 437-446.

[94] J. Cotter, D. Zimmerman and H. van Bekken, "Application of the EU and Cartagena Definitions of a GMO to the Classification of Plants Developed by Cisgenesis and Gene-Editing Techniques" (2015) Greenpeace Research Laboratories Technical Report (Review), 12.

[95] Smyth S. and Phillips P., "Risk, Regulation and Biotechnology: The Case of GM Crops" (2014) 5(3) *GM Crops Food*, 170-177;

[96] *Ibid*.

[97] H. Stephan, *Cultural Politics and The Transatlantic Divide over GMOs* (Palgrave Macmillan 2015).

[98] Cibus, Press Release.

[99] Case C-528/16, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, ECLI:EU:C:2018:583.

may either adopt national rules regarding mutagenesis, despite the fact that it is exempt from obligations laid down by the GMO Directive (bar Annex I B), and to determine whether in the process of transposition of the GMO Directive Member States could also apply the obligations set out in the Directive to mutagenesis.

In response to the request from the French Conseil d'État, Advocate General Bobek delivered his opinion on the issues raised in relation to the interpretation of the GMO Directive and its application to mutagenesis. The AG considered that this issue involves two questions. The first concerns the determination of which organisms fall under the definition of a GMO within the meaning of Art. 2(2) GMO Directive.[100] AG Bobek suggested that an organism obtained by mutagenesis can be a GMO under Art. 2(2) if the genetic material has been altered in a way that does not occur naturally. The second question related to the scope of the mutagenesis exemption, as Art 3(1) of the GMO Directive states that it shall not apply to organisms obtained through the techniques listed in Annex I B, one of which is 'mutagenesis'. The issue was if the exemption concerned *all* techniques of mutagenesis or only *some* techniques. There is no clarification in the Directive as to whether the inclusion of the mutagenesis technique in the list provided in Annex I B encompasses all organisms obtained by mutagenesis, including those developed after the adoption of the GMO Directive, or only those that existed prior to the GMO Directive's adoption. Divergent views regarding the scope of the exemption were expressed but the AG, interpreted the provision dynamically, holding that organisms obtained by conventional mutagenesis and by new techniques are exempted from the obligations laid down in the GMO Directive. The important factor for him is whether the specific technique "involves the use of recombinant nucleic acid molecules or GMOs other than those produced by mutagenesis or cell fusion of plant cells of organisms which can exchange genetic material through traditional breeding methods". Essentially, he interpreted the exemption as covering all organisms obtained by any technique of mutagenesis on the condition that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the methods listed in Annex I B.

The AG then examined whether Member States could actually go further than the GMO Directive and decide to subject organisms obtained by mutagenesis either to the obligations laid down by the Directive or to purely national rules. In interpreting the provisions of the GMO Directive, the AG argued that the EU legislature did not make any statement as to the exclusion of all mutagenesis techniques because of safety reasons. There is no trace of any explicit legislative assessment to this effect and it would be wrong to assume that a reasonable legislator such as the EU Parliament would ever wish to state, *en bloc* and for the future, that something is safe to such a degree that it need not be regulated at all on any level (EU or national). Rather, the exclusion simply meant that the EU did not wish to regulate the matter on the EU level. Consequently, provided Member States respect overarching obligations that

[100] Art. 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L 106/1] defines a GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". Annex I A, Part 1 lists techniques through which genetic modification occurs; any techniques listed in Annex I A, Part 2, are not considered to result in genetic modification.

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 *all* types of mutagenesis outside the scope of the GMO Directive, on the basis of the constitutional argument that holding differently would be akin to a judicial redrafting of the GMO Directive, this being instead a task for the legislator[108]. The CJEU disagreed, preferring to put emphasis on the interpretation of the intent of the legislator and of the aims it pursued. It noted that

[101] Compliance with EU law obligations is expected, whether they be rules of primary law (e.g. Arts. 34 and 36 TFEU) or of secondary law origins.
[102] These measures must be non-discriminatory, objective and proportionate to the level of risk involved.
[103] Case C-157/96, The Queen v Ministry of Agriculture, Fisheries and Food [1998] ECR I-02211, para. 63.
[104] The general duty to update legislation may mean that, with the progression of time and greater evidence of independent scientific research, in the future, novel organisms perhaps may not present a level of risk capable of triggering the precautionary principle (i.e. they have proven to be safe) or they may present such a risk.
[105] Opinion of AG Bobek, Case C-528/16, paras 1-3.
[106] Compliance with EU law obligations is expected, whether they be rules of primary law (e.g. Arts. 34 and 36 TFEU) or of secondary law origins.
[107] Case C-528/16, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, ECLI:EU:C:2018:583, paras 30 & 38.
[108] Opinion of AG Bobek, Case C-528/16, para. 105.

> "[…] 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 organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis.
>
> Moreover, as stated in recital 4 of Directive 2001/18, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects of such releases on the environment may be irreversible"[109].

Relying on the precautionary principle[110], the CJEU held that "only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded" from the scope of the GMO Directive, all other organisms obtained by mutagenesis being regulated as GMOs[111]. The CJEU added that the exclusion of organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record cannot be interpreted as preventing Member States from legislating in that area, thus recognising the possibility for Member States to further regulate in this area[112]. This case law will seriously impact the competitive potential of gene-editing techniques, such as CRISPR in Europe, in view of the fact that developing seed varieties on the basis of such technology may be denied or incur significant development and regulatory approval risks and costs.

The impact of these revolutionary technologies on food production is still a matter of speculation. However, the technology trend makes it plausible that the most valuable productive asset in agricultural production will not anymore be the control of genetic material (e.g. seeds) but the control of genetic information (e.g. DNA sequences), the next generation biotech leading to revolutionary changes in bioengineering tools, enabling the systematic design of phenotypes by manipulation of genotypes. The economic actor that will control this strategically essential abstract information, for instance through Intellectual Property (IP) Rights, may finish by controlling physical living DNA designs. This may engender profound structural changes in the industry, as gene-editing technologies may be cheaper and less regulated to develop, therefore leading to lower endogenous sunk costs, which provide more

---

[109] Ibid., paras 48 & 49.
[110] Ibid., para. 50.
[111] Ibid., para. 53. The CJEU arrived to a similar conclusion with regard to the applicability to genetically modified varieties by mutagenesis, with the exception of those obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record, of the conditions of Article 4(4) of Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, [2002] OJ L 193/1]. This provision holds that the "deliberate release into the environment of the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment". See Case C-528/16, paras 67 & 68.
[112] Case C-528/16, paras 81 & 82.

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.

CR7	10.9%	15.1%	57.5%
CR8	11.7%	16%	59.7%
CR9	12.5%	16.8%	60.7

In the seeds sector, a number of merger waves, starting in the 1980s, have led to the emergence of a relatively concentrated market structure of 6 big players thirty years later (Monsanto, Syngenta, DuPont, BASF, Bayer, Dow, the so called 'Big Six'), to be now reduced to the "Mighty Four" (Bayer, Dow/DuPont, ChemChina/Syngenta and BASF).

The first merger wave occurred in the mid-1980s, swiping aside a market structure dominated until then by commercial seed companies that were formed in the 1930s following the introduction of the first hybridized crops. Until then farmers have been cultivating new plant varieties for thousands of years through selective breeding by cross-pollinating two different, but related plants over 6 to 10 plant generations, eventually creating a new plant variety. The introduction of a method of controlled crossing (marker-assisted breeding) that can create these desired traits within just one generation led to the development of a special kind of hybrid crops, the so called F1 hybrid seeds, which combine characteristics of two related plants, thus following the process of cross-pollination. Second generation hybrids do not however 'reproduce true', thus they may not share the desired characteristics as selected in the first generation. A farmer cannot expect the next generation of plants to be identical to the first, which may lead farmers to purchase seeds rather than save the seeds and replant them the next season, as they have done for generations.

Intellectual property protection first permitted small biotech start-ups to receive funding from venture capital and other sources of funding in order to progress in the applied segment of their research, while it also enabled them, at the second stage, to be targeted by a wave of merger and acquisitions with large agro-chemical corporations that started investing in the development and large scale commercialisation of the products emerging out of the research efforts, thus guaranteeing a greater dissemination of these new technologies and products in food production. Already in the 1970s and the development of plant variety protection rights, a number of chemical and pharmaceutical companies had acquired a number of small and medium sized regional seed companies, but a number of larger seed companies (e.g. Pioneer, DeKalb) and smaller regional seed companies remained in the market.

The second wave of M&As occurred in the mid-1990s/early 2000s where a number of seed companies were either acquired or entered into joint ventures with a number of large multinational with investments and research capacity in biotechnology. At the same time, large pharmaceutical companies, such as AstraZeneca, Novartis, and American Home Products, which collectively controlled about 26 percent of the global agricultural market, chose to divest their seed germplasm assets and concentrate on core their pharmaceutical businesses. This led to the re-structuring of the sector with the combination of biotechnology know how, genetic research assets and IP rights with seed germplasm, as this would have facilitated the commercial introduction of new GM or biotech seeds. As agro-chemical firms and other diversified firms vertically integrated into the seed business and seed genetics, new global

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 triggered a number of other M&A transactions that were announced in 2015 and 2016 between the various market leaders in the factors of production segment. In November 2015, Syngenta accepted the offer of ChemChina (which owns ADAMA, one of the largest agrochemical companies in the world). In December 2015, Dupont and Dow announced their merger, which was cleared with conditions by the European Commission in March 2017[117]. In September 2016, Bayer put forward a merger deal with Monsanto, triggering an in-depth investigation[118] by the European Commission due to concerns over reduced competition, especially in the seeds area. One year later, BASF is now set to acquire Bayer's seed business[119] which will result in an even denser market shrinkage. Following the approval of these megamergers, four companies (ChemChina–Syngenta, DuPont–Dow, Bayer–Monsanto, BASF) will own and sell three quarters of the world's patented seeds and pesticides/herbicides, as well as a strategic position in digital agriculture, which will ensure a gatekeeping role for new entrants in all segments of the inputs of production value chains.

The global commercial seed market is valued at around USD 38.5 billion (some estimates putting this at USD 48.5billion)[120], with Monsanto possessing the highest seeds market share of 23%, followed by DuPont at 15%, and Syngenta at 9%. in 2016 [121]**.** Most of the big companies in the sector come from the chemical industry, only Limagrain and KWS being from the agricultural and seed sector. Monsanto and DuPont have a high share of seeds in their total agricultural sales, while Syngenta, Bayer, Dow and BASF mainly sell pesticides, while Limagrain and KWS only focus on seeds. The recent merger consolidation will however establish integrated platforms in both seeds and plant protection agents.

The most recent mergers in the seed and agrochem industry will lead to an even more concentrated structure of the agrochem industry. On the basis of 2015 pro-forma sales, the agrochem industry being valued at approximately 85€bn, Bayer/Monsanto will be the market leader with 23.1€bn, followed by Syntenta/ChemChina Ag with 14.8€bn in the second position, Dow Ag and Dupont Ag with 14.6€bn in the third position, and in fourth position BASF Ag with 5.8€bn. Note that, with the exception of BASF, which, at the time of the merger, was only present in crop protection, all other market leaders were present in crop protection as

[117] European Commission, IP/17/772 (2017), available at http://europa.eu/rapid/press-release_IP-17-772_en.htm

[118] European Commission, IP/17/2762 (2017) available at http://europa.eu/rapid/press-release_IP-17-2762_en.htm

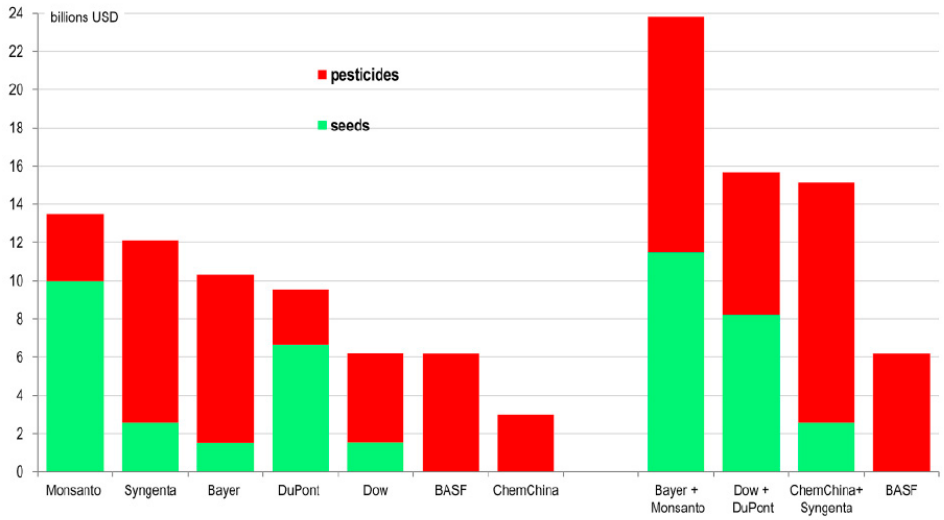
[119] See Financial Times (2017), available at: https://www.ft.com/content/1d5ca16b-412d-3ed2-8899-7185f5308009?mhq5j=e5 .

[120] See the comparative table by S. Bonny, Corporate Concentration and Technological Change in the Global Seed Industry, (2017) 9 Sustainability 1632, Table 1.

[121] Ibid., Figure 3 (noting that "(t)he total size of seed market is not well known due to the difficulty of assessing the value of seeds saved by farmers and the total value of the commercial seed market").

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).

Figure 1: Comparison before and after the most recent mega merger wave in agrochem



(1) Previous situation (2002–2014) with six large groups, "The Big Six": Monsanto, Syngenta, DuPont, Bayer, Dow, and BASF.

(2) Possible situation in 2017, following the 2015–2016 concentrations leading to four main groups, "The Big Four": Bayer + Monsanto, DowDupont, Syngenta + ChemChina, and BASF.

Source: S. Bonny (2017)[123]

Of course, in order to justify competition law intervention, concentration should not be measured at the industry level, but on specific relevant markets to be assessed by competition authorities on a case-by-case basis. Although "conventional seeds" have so far been supplied by a quite competitive market structure, as there are approximately 7500 companies of different sizes present in this segment from around the world, GM seeds have been at the centre of the competitive strategy of big players in this industry, these being usually created by big companies, although smaller companies can also sell GM crops through license agreements on genetic traits. At the same time, farmers' seed systems, which result from the breeding efforts

[122] Bayer, Acquisition of Monsanto to Create a Global Leader in Agriculture, Investor Presentation, June 2016, 13.

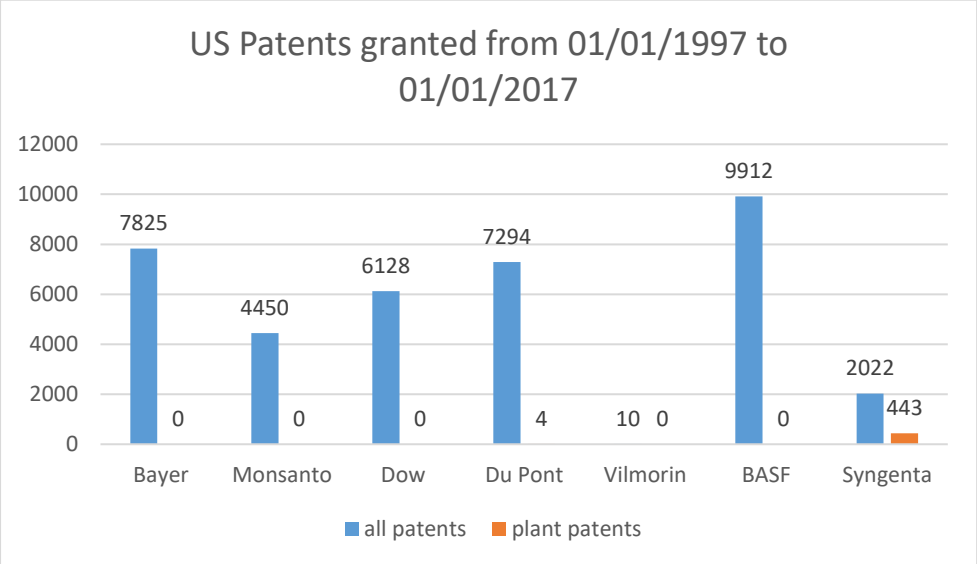
[123] S. Bonny, Corporate Concentration and Technological Change in the Global Seed Industry, (2017) 9 Sustainability 1632, Figure 9. Total sales in seeds and pesticides in 2016 in billion USD. Note that the figure does not take into account the recently announced acquisition of the seeds and non-selective pesticides business of Bayer by BASF.

of farmers in their fields to obtain seeds that they expect to be better suited to their soil, practices, and needs, or seeds *from public research* have seen their importance decline[124].

Genetically modified (GM) seeds' share in the global commerce of seeds has been growing from 9% in 2001 to 33% in 2016. The seed and traits value chain has been primarily guided by the Big Six (Monsanto, Bayer, DuPont, Sygenta, Dow, and BASF), now to become the "Mighty Four", and consists two primary crucial inputs: the germplasm pool and advanced breeding technologies. Plant germplasm refers to the genetic base of a specific crop ranging from the "elite" germplasm of modern plant improvement to more wild plants that can potentially provide useful genes for improvements or for future domestication. As living genetic resources, germplasms are stored in seed banks to be used for plant research, breeding, and preservation and play a critical role in maintain the diversity needed to sustain genetic improvements for polygenic traits like yield, responding to pathogen pressures, and for providing genetic buffering.

Although geographic markets with strict GMO regulation and relying on traditional seeds, like the EU, tend to be less concentrated, GMO-based markets are extremely concentrated. This may be explained by the high concentration of IP protection among the same few players, as the following figure may indicate (Figure 3).

Figure 2: The innovative potential of the large R&D agrichem corporations



Source: Authors's data compilation[125]

Note also that all major companies in the sector invest in "integrated solutions," or combinations of seeds, traits, and crop protection products, all of which digital farming technologies support, thus establishing tight value chains to which farmers may be "locked in" through technological bundling practices or contract farming.

---

[124] S. Bonny, Corporate Concentration and Technological Change in the Global Seed Industry, (2017) 9 Sustainability 1632.

[125] This information of course provides little information as to the quality of these patents. Of course, measure of R&D concentration are issuance of patents.

What is the effect of these increasing levels of concentration on innovation? A classic feature in Schumpeterian approaches to innovation is that market size constitutes a major determinant of innovation incentives and the amount and type of technological change. As Aghion and Howitt put it, when exploring whether market competition is good or bad for growth, "(t)he Schumpeterian answer to this question, appears to be one- sided: to the extent that monopoly rent is what induces firms to innovate and thereby makes the economy grow, product market competition can only be detrimental to growth[126]. However, empirical works by Nickell, Blundell, Griffith & Van Reenen, among others, point to a positive correlation between product market competition (as measured either by the number of competitors in the same industry or by the inverse of a market or profitability index) and productivity growth within a firm or industry[127]. In a competitive environment firms innovate in order to survive (the so called "Darwinian view")[128].

One may further advance that lead firms may undertake strategic investments (in technological innovations such as enhanced traceability, brand building, or product differentiation) to make their products more attractive. If the incentives for these endogenous sunk costs are sufficient, then it is possible that industry structure remains concentrated even in the presence of a substantial increase of demand and output [129]. Hence, high concentration in these markets may persist because of the fact that firms in the industry decide to incur, in addition to the exogenous sunk costs which are costs that any firm will have to incur upon entry into the market, endogenous fixed sunk costs (.e.g. advertising, R&D, process innovations), with the aim to increase their price-cost margin. Sutton shows that the size of these endogenous sunk costs does not depend on the level of output and that as market size grows and demand increases in industries with significant endogenous sunk costs, there will be "a lower bound to industry concentration" and an increase in sales may cause the number of firms to shrink. The reason provided for this is that all firms will invest in endogenous sunk costs and, in the long run, this investment will produce little or no profit in view of the fact that the competitive advantage gained by each firm's investment will be largely ineffective if all other firms may do the same investment. Industry profitability may fall in the long term in such expanding market if the additional profit gained from the increased volume of sales is exceeded by the increase in investment in exogenous sunk costs. Consequently, there will be less entrants in the market and more concentration. Sunk, fixed R&D investments can jointly determine both the levels of concentration and innovation activity.

It is important to analyse whether the consolidation of the inputs of production food sector is consistent with an endogenous sunk costs framework. There have been various studies undertaken within the endogenous sunk costs framework in this sector. Oehmke, Wolf, and Raper show an endogenous, cyclical relationship between industry concentration and R&D

---

[126] P. Aghion Philippe & P. Howitt, *Endogenous Growth Theory* (Cambridge, Mass., MIT Press, 1998), 305.

[127] R. Blundell, R. Griffith & J. Van Reenen, Dynamic Count Data Models of Technological Innovation (1995) 105 (429) Economic Journal 333; S. Nickell, Competition and Corporate Performance, 104(4) Journal of Political Economy 724.

[128] M. Porter *The Competitive Advantage of Nations*, (New York: Free Press, 1990).

[129] J. Sutton, *Sunk Costs and Market Structure: Price Competition, Advertising, and the Evolution of Concentration*, (MIT Press, 1991).

intensity[130]. Magnier, Kalaitzandonakes, and Miller described the decreasing product life cycles associated with increasing innovation in corn seed[131], while Kalaitzandonakes and Bjornson explained the endogenous relationship between firm innovation strategies, including complementary intellectual assets, and industry consolidation characteristics[132]. Fulton and Giannakas[133] claimed that R&D expenses to obtain regulatory approvals should be considered as sunk costs. Sunk costs potentially prevent new entrants to enter a market niche. Taking an endogenous sunk costs approach, Anderson and Sheldon's research supports the hypothesis that the GM corn, cotton, and soybean seed markets are characterized by endogenous fixed costs to R&D with the theoretical lower bounds to R&D concentration ranging from 54.8% for corn, 47.3% for cotton, and 78.6% for soybeans[134]. They find that in the markets for GM corn, cotton, and soybean seeds endogenous R&D investments are mainly responsible for the rising levels of concentration. The authors find little to no evidence that accounting for mergers and acquisitions significantly increases the lower bound to R&D concentration.

However, this research does not account for the possibility that innovation may come from within the various segments of the existing value chain. Lead firms may also behave strategically and block new avenues of innovation challenging their strong structural positioning and the share of the total surplus value they are able to extract from the value chain (vertical innovation competition)[135]. To a certain extent, vertical innovation competition constitutes one of the most frequent ways entrenched dominant positions resulting from the control of general purpose technologies (GPTs) may come to an end[136]. Although there are important benefits in the coordination of innovative activity, it is possible that potential inventors may have different views about the appropriate direction of innovation on the basis of their private information, thus making it worthwhile to enhance vertical competition as a source of innovation variety, in particular if the sector is already highly concentrated. Furthermore, innovation cannot only be evaluated with regard to the possible higher output and lower prices it might bring in the future (benefits or costs that are often discounted as these concern the medium term), but it also constitutes a process, a new technology always calling for another application technology[137].

---

130 J. Oehmke, C. Wolf, & K. Raper, On Cyclical Industry Evolution in Agricultural Biotechnology R&D, (2005) 3(2) Journal of Agricultural and Food Industrial Organization**,** https://doi.org/10.2202/1542-0485.1107 **.**

131 A. Magnier, N. Kalaitzandonakes & D.J. Miller, Product Life Cycles and Innovation in the US Seed Corn Industry, (2010) 13(3) International Food and Agribusiness Management Review, available at http://ageconsearch.umn.edu/bitstream/93557/2/2.pdf .

132 N. Kalaitzandonakes & B. Bjornson 'Vertical and Horizontal Coordination in the Agro-biotechnology Industry: Evidence and Implications', (1997) 29(1) Journal of Agricultural and Applied Economics, 129-39.

133 M. Fulton & K.Giannakas. Agricultural biotechnology and industry structure. *AgBioForum* 4(2), 2001. pp. 137–151.

134 B.C. Anderson & I.M. Sheldon, R&D Concentration under Endogenous Fixed Costs: Evidence from the Agricultural Biotechnology Industry (mimeo, 2015)

135 To a certain extent, these various possibility theorems are common to all forms of vertical integration in the presence of a concentrated market structure: see T. Bresnahan & J. Levin, Vertical Integration and Market Structure, NBER Working Paper No. 17889, available at http://www.nber.org/papers/w17889

136 See, inter alia, the work of See, T. Bresnahan & S. Greenstein, Technological Competition and the Structure of the Computer Industry, Working Paper 1997, available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.598.252&rep=rep1&type=pdf (exploring the end of the hardware manufacturer IBM's dominance of the individual computing industry and its replacement by Microsoft, crucially present in the vertically situated software segment of the individual computing value chain).

137 W. B. Arthur, *The Nature of Technology* (Penguin, 2009).

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 medium and/or long term. The rising levels of concentration may be the triggering factor for competition law scrutiny, but what finally counts is finding the impact of this higher concentration level on consumer welfare and well-being, and in particular innovation.

IV. The socio-economic effects of the rising levels of concentration in agrochem markets

At the more general level of policy design, it is important for policy-makers, and judges/competition authorities implementing this policy framework, to understand the wider context, at the industry level, before focusing on the effects of a merger transaction on specific relevant markets. Recent work has raised questions over the effects of mergers and economic concentration on innovation. The market for agricultural biotechnology research and development is particularly concentrated, with the former "Big Six" (now "the Mighty Four") accounting for a significant number of agricultural bio-technology patents issued in the US, as well as more than 80% of crop field trials for regulatory release in the US[138]. Anticompetitive effects from the rising levels of concentration consist of loss from head-to-head competition, vertical foreclosure, and a material lessening of innovation.

There is empirical evidence of the inverse relationship between firm concentration in corn, cotton and soybean seed markets, and R&D intensity in these markets, research finding that as the number of firms declined following the M&A waves, the intensity of R&D fell[139]. Similar evidence exists for the effect of M&As on innovation in the pharmaceutical industry[140]. Although synergies and efficiencies were often put forward as the main rationale for mergers, the empirical evidence that these are effectively realized remains rather poor[141]. The companies may argue that they will increase spending on R&D. However, there may be doubts on these increases in R&D research materializing, in view of the fact that their R&D expenses have

[138] J.L. King & D. Schimmelpfenig, Mergers, acquisitions, and stocks of agricultural biotechnology intellectual property, (2005) 8(2&3) AgBioForum, 83-88. Available: http://www.agbioforum.org (accessed May 29, 2017).
[139] D. E. Schimmelpfennig et al, The impact of seed industry concentration on innovation: a study of US biotech market leaders, (2004) 30 Agricultural Economics 157–167.
[140] W.S. Comanor & F.M. Scherer, Mergers and innovation in the pharmaceutical industry, (2013) 3291) Journal of Health Economics, 106-113; J. Haucap & J. Stiebale, How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry, DICE DISCUSSION PAPER 218 (2016), available at http://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/218_Haucap_Stiebale.pdf .
[141] For recent empirical evidence: see B.A. Blonigen & J.R. Pierce, 'Evidence for the Effects of Mergers on Market Power and Efficiency' [2016] Finance and Economics Discussion Series 2016-082. Washington: Board of Governors of the Federal Reserve System, available at doi.org/10.17016/FEDS.2016.082.

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 expenditure to sales, increased from 11.0% in 1994 to 15.0% in 2000 before falling back to 10.5% in 2009[144]. There is a significant heterogeneity across firms as they vary by size and innovation strategy with the eight largest seed companies having an average R&D intensity of 15.8% while accounting for 75.6% of the global R&D share. The number of new active ingredients in the R&D pipeline also decreased by 60% between 2000 and 2012, a fact that has been linked to the higher concentration of the industry, as "companies that survived seed industry consolidation appear to be sponsoring less research relative to the size of their individual markets than when more companies were involved"[145]. A recent study on ownership of agriculture seed-related patents concluded that "the restructuring of the crop agriculture industry in the 1980s and 1990s and the strategic use of patent rights enabled some large-scale patent holders to exclude or deter others from using critical research tools and materials", this allowing "a few corporations to influence or control much of global agricultural innovation" [146].

R&D spending of leading agriculture seeds may also constitute a way to assess innovation. The five companies (Monsanto, Syngenta, DuPont Pioneer, BASF and Bayer[147]) had a combined R&D budget accounted for more than $6 billion[148] in 2015. Such concentration of industrial R&D suggests potential barriers to entry for competitors. The industry leaders claim that the process of development of a new biotechnology trait is complex and time consuming. According to Syngenta, it takes about 13 years on average to develop a new GM

---

[142] For instance, Monsanto' expenses for R&D have been going down in recent years: from $1,725 million in 2014 to $1,580 million in 2015 and $1,512 million in 2016: Monsanto 2016 Annual Report, Form 10-K, p. 8. It therefore looks that, as a percentage of sales, R&D spending has actually slumped back down to mid-1990s levels. The level of R&D in this sector (between 8.5-11.4% of sales) [Bayer, Acquisition of Monsanto to Create a Global Leader in Agriculture, Investor Presentation, June 2016, 17] is also much lower than the level of R&D in the pharmaceutical sector (between 16-20% of sales), even if the level of costs of launching an innovative product (including the costs associated to the regulatory approval pipeline) are comparable.

[143] Ø. Solberg & L. Breian, Commercial cultivars and farmer's access to crop diversity: a case study from the Nordic Region, (2015) 24 Agricultural and Food Science 150.

[144] B. Anderson & I. M. Sheldon, R&D concentration under Endogenous Fixed Costs: Evidence from Genetically Modified Corn Seed (2017) 99(5) American Journal of Agricultural Economics 1265.

[145] J. Fernandez-Cornejo & D. Schimmelpfennig, Have Seed Industry Changes Affected Research Effort?, Amber Waves (2004), available at https://www.ers.usda.gov/amber-waves/2004/february/have-seed-industry-changes-affected-research-effort/

[146] A.O. Jefferson, D. Köllhofer, Deniz, T.H. Ehrich & R.A. Jefferson, The ownership question of plant gene and genome intellectual properties. (2015) 33(10) *Nature Biotechnology* 1138-1143.

[147] Source: companies' annual reports. For BASF and Bayer the numbers reflecting agriculture science departments R&D spending were used.

[148] After currency exchange adjustments.

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 Monsanto into this market segment (1996) and after, showing that Monsanto's acquisitions triggered a patent war between Monsanto and Pioneer Hi-Bred, although it also led to important investments in R&D[152].

It is reported that growth of commercial seed industry triggered growth of private R&D spending which increased by 1300 percent (in real terms) between 1960 and 1996 (Fernandez-Cornejo 2004[153]). Since 1984, private research spending has exceeded public spending in seed industry. Rising costs of private R&D spending on seeds by industry leaders were put on farmers: the rise in seed prices outperformed the general index of prices paid by US farmers by nearly 30% over the period of 1994-2008 (since the introduction of the GE seeds in 1996)[154]. For some crops, after adjustments for inflation the price of cotton seeds almost tripled between 1996 and 2007 while growth in price of soybean seed increased by over 60%. Stiegert et al. (2010) claimed that industry concentration can increase seed prices[155]. Schiemmelpfennig et al. (2004) concluded that increase in industry concentration produces negative effect on research intensity of agriculture biotechnology[156]; Industry concentration and market power of leaders in seed industry raise concerns of potential market manipulations from leading companies (i.e. by artificially lowering supply and variability of seeds being produced by the market combined with increased prices). This is important given the fact that farmers need to adapt seeding materials to the specific conditions of local environments[157];

---

[149] Syngenta. Our Industry 2016. http://www4.syngenta.com/~/media/Files/S/Syngenta/our-industry-syngenta.pdf

[150] PWC, Animal health: Strategy Playbook for an Evolving Industry, (August, 2015).

[151] W.M. Muir et al, Genome-wide assessment of worldwide chicken SNP genetic diversity indicates significant absence of rare alleles in commercial breeds, (2008) 105(45) PNAS, 17312-17317.

[152] P. Moser & P.Wong, Competition and Innovation: Did Monsanto's Entry Encourage Innovation in GMO Crops? April 3, 2015.

[153] J. Fernandez-Cornejo, The seed industry in U.S. agriculture: An exploration of data and information on crop seed markets, regulation, industry structure, and research and development. Agriculture Information Bulletin No. 786. U.S. Department of Agriculture–Economic Research Service. Washington, DC. 2004. Available online at http://www.ers.usda.gov/publications/aib786/aib786.pdf

[154] National Research Council. The Impact of Genetically. Engineered Crops on Farm Sustainability in the United States. Washington, DC: National Academies Press. 2010, p. 146, 148

[155] Stiegert, Kyle. W, Guangming Shi, and Jean-Paul Chavas. Innovation, Integration and the Biotechnology Revolution in the US Seed Markets. The Magazine of Food, Farm and Resource Issues. Quarter 2, 25 (2), 2010.

[156] D.E. Schiemmelpfennig, C.A. Pray & M.F. Brennan. The impact of seed industry concentration on innovation: a study of US biotech market leaders. (2004) 30(2) Agricultural Economics 157.

[157] G. Shi & J.-P.Chavas. On pricing and vertical organization of differentiated products. Staff Paper No. 535. University of Wisconsin-Madison. Madison, WI. 2009.Available online at http://www.aae.wisc.edu/pubs/sps/pdf/stpap543.pdf

A number of studies in other factors of production industries (animal health, animal genomics) provided similar conclusions in relation to negative effects of industry concentration. For instance, high concentration in animal genetics industry was found to lead to excessive market power of industry leaders and, more importantly, to restrict biodiversity leading to long-term negative consequences for the industry as a whole. A study conducted by PricewaterhouseCoopers in 2015 focusing on animal health market provided that concentration in animal health market has negative impact on R&D as low R&D productivity lead to mature portfolios with key drugs on the market for more than 20 years[158].

The lack of a widely accepted innovation metric makes also comparisons difficult. Innovation is typically measured by such metrics as R&D expenses, R&D intensity (ratio of R&D expenses to sales), patent counts and patent citations, or field trials. However, none of these indicators treated alone is a useful measure of the true innovation efforts[159]. However, an industry wide context should also be taken into account – i.e., like technology disruption, agriculture commodity price trends, specific policy regulations, etc.

Although it is widely believed that R&D is the main driver of innovation in agricultural biotechnology, some researchers note that R&D is not the only contributor to the innovative products. Some believe that the role of expenditures in improved machinery and capital equipment should not be underestimated[160], while others claim that broader advancements in informatics sciences (bioinformatics), genomics, engineering and other fields of science should be taken into account while as a source of innovation as well[161]. Moreover, agriculture is increasingly prone to potential disruptive shocks. Some studies conclude that both pharmaceutical and agricultural industries are susceptible to technology shocks as new technology discoveries significantly broaden new options for R&D[162], CRISPR/Cas9 being a good example of such technology disruption.

Finally, the potential lobbying power by the seeds and other agriculture input industry leaders requires special attention as it may affect innovation if it leads to barriers to entry for innovative firms in the market. There is evidence that market leaders in agriculture use a sizeable amount of funding for the financing of political campaigns in order to influence public policy processes in their favour[163].

V. Assessing the innovation effects of the agrochem mergers

[158] Animal Health: Strategy Playbook for an Evolving Industry. PWC Report, August 2015. Available at http://www.pwc.com/us/en/health-industries/our-perspective/animal-health-playbook.html

[159] See also, N. Petit, Significant Impediment to Industry Innovation: A Novel Theory of Harm in EU Merger Control? ICLE Antitrust & Consumer Protection Research Program. White Paper, 2017-1, at 8.

[160] R. Piergiovanni & E. Santarelli, The More You Spend, the More You Get? The Effects of R&D and Capital Expenditures on the Patenting Activities of Biotechnology Firms, SCIENTOMETRICS, Volume 94, Issue 2 (2013), pages 497-521.

[161] P. G. Pardey, C. Chan-Kang, J. M. Beddow & S. P. Dehmer, Long-Run and Global R&D Funding Trajectories: The U.S. Farm bill in a Changing Context, (2015) 97(5) American Journal of Agricultural Economics, 1312.

[162] J. Mitra, J. Tait & D. Wield, From Maturity to Value-added Innovation: Lessons from the Pharmaceutical and Agro-biotechnology Industries, (2011) 29(3) Trends in Biotechnology 105.

[163] A. Renwick, M.M. Islam & S.Thompson, Power in Global Agriculture: Economics, Politics, and Natural Resources (2012) 2(1) International Journal of Agricultural Management, 31.

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], the various companies focusing their activities on different segments of the food value chain, and in view of the high level of concentration in some markets, competition authorities focused on the possible effects of these mergers on prices and output, as they do usually for mergers producing horizontal effects to competition. However, and this is a remarkable feature of these cases, many competition authorities focused on the effect of these mergers on innovation, the mergers offering the opportunity to competition authorities to test more dynamic approaches in assessing possible restrictions on innovation competition, going beyond a simple analysis of the effect of the merger on product market competition, technology market competition, or even innovation market competition.

This concern on innovation was not limited in the area of GMOs, but extended to all types of seeds, the competition authorities finding a feedback loop between innovation for GMO seeds and innovation for conventional seeds. The Big Six (now becoming the "Mighty Four") have developed an integrated strategy for R&D for all types of crops, working on "traditional" market-assisted breeding, or the more recent forms of predictive breeding that have become commercially possible with the reduction of the cost of genome sequencing and the use of IT, as well as on genetically engineered seeds. It is clear that the effects of this merger on innovation were not therefore only limited in the genetically engineered traited seeds, but also expanded to conventional seeds. A recent report commissioned by the American Antitrust Institute, the Food&Water Watch and the National Farmers Union indeed found that the agrochem companies cut back their non-biotech offerings, or even altogether dropped them, limiting choice for farmers, following the acquisition by the largest agricultural biotechnology companies of independent conventional and hybrid seed breeders in the last two large merger waves in this sector[165]. One may not also exclude the significant interlinkages between R&D in both bio-tech and conventional plant breeding and the need to ensure that there would be sufficient incentives to innovate in conventional plant breeding, which is still the dominant method of breeding in the EU.

Assessing the possible effects of each merger on innovation was a quite complex exercise, in view of the various perspectives one may take on innovation and its interaction with market structure. Innovation could refer to investment in new technologies, but also on the broader direction of the R&D effort in the industry in the future. Investment in seed saving and seed diversity, rather than standardisation of traits, or in non-agro-chemical pest management approaches constitutes a business model that farmers may be less likely to choose, if they are forced to take their advice from the same agrochem giants. Indeed, one may not exclude the possibility that the latter may have a material bias to promote the type of productive model for farmers, as this would enable them to increase the farmer's technological dependence

[164] A merger is considered as "horizontal" if it involves rivals selling substitutes products, "vertical" if it concerns firms along the supply-chain (eg, input supplier with product manufacturer, and upstream producer with downstream distributor), and "conglomerate" if it involves firms that are involved in totally unrelated business activities.

[165] AAI, Food & Water Watch, National Farmers Union, Proposed Merger of Monsanto and Bayer, (2017, July 26th), 5.

on them and acquire a larger share of the total surplus value produced by the agricultural value chain, in comparison to the conventional breeding model.

Assessing the effects of mergers on innovation has become an important dimension of merger control recently, in particular in the US and the EU. The US DOJ & FTC Horizontal Merger Guidelines of 2010 were the first to include a specific Section on competition harm to innovation and product variety[166]. In analysing effects on innovation, the US competition authorities have often taken an "innovation market" perspective[167], or as this has been reframed in the 2017 update of the US DOJ & FTC Antitrust Guidelines for the Licensing of Intellectual Property, "research and development markets"[168], these consisting "of the assets comprising research and development related to the identification of a commercializable product, or directed to particular new or improved goods or processes, and the close substitutes for that research and development"[169]. The US authorities have employed these concepts in a number of cases[170]. According to this approach, the US Agencies will delineate research and development markets, only when "the capabilities to engage in relevant research and development can be associated with specialized assets or characteristics of specific firms". The authorities seek to identify three key effects: (i) the ability of the merged firm to reduce total market investments in R&D, (ii) the incentive of the merged entity to reduce the innovative effort and (iii) the impact of the merger on the efficiency of the R&D expenditure[171]. This looks like a relatively demanding framework from an evidential perspective. In most recent cases, the US authorities seem to adopt a broader framework and have challenged mergers for diminishing innovation even if the merger would eliminate potential competition from a relative small competitor, in particular when the smaller player has promising pipeline research. The theory of harm in these cases was the "actual potential entrant" theory, a potential entrant merging with an existing competitor and thus leading to lessen future competition.

The effects on innovation also constitute one of the types of effects to be analysed under EU merger control[172]. The innovation potential of the merging firms, in particular if "one or more merging parties are important innovators in ways not reflected in market shares", is taken into account, irrespective of the levels of concentration that are usually considered by the Commission's Horizontal Guidelines as raising competition concerns[173]. Similarly, the EU non-horizontal merger guidelines list the diminishing of innovation as a competition concern

---

[166] USDOJ & FTC, Horizontal Merger Guidelines (2010), p. 2. Emphasis added.

[167] RJ Gilbert and SC Sunshine, 'Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets' [1995] 63 Antitrust Law Journal 569.

[168] US DOJ & FTC Antitrust Guidelines for the Licensing of Intellectual Property, Section 3.2.3. (2017)

[169] Ibid.

[170] The FTC has identified and referred to research and development markets in the following matters: Complaint, Amgen Inc., 134 F.T.C. 333, 337-39 (2002) (identifying a research and development market for inhibitors of cytokines that promote the inflammation of human tissue); Wright Med. Tech., Inc., Proposed Consent Agreement with Analysis to Aid Public Comment, 60 Fed. Reg. 460, 463 (Jan. 4, 1995) (identifying a research and development market for orthopedic implants for use in human hands); Am. Home Prods. Corp., Proposed Consent Agreement with Analysis to Aid Public Comment, 59 Fed. Reg. 60,807, 60,815 (Nov. 28, 1994) (identifying a research and development market for, among other things, rotavirus vaccines).

[171] E. Cefis et al, The Role of Innovation in Merger Policy: Europe's Efficiency Defence versus America's Innovation Markets Approach, Tjalling C. Koopmans Institute, Discussion paper series 07-21.

[172] EU Horizontal Merger Guidelines [2004] OJ C31/5, para 8 (hereinafter EU HMG).

[173] Ibid., para. 20.

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 "parallel path R&D" [179]. In their view, this does not appear in line with the required standard of proof in EU merger control[180].

These criticisms are far-fetched. It is quite difficult to explain why the competition authority should not assess, when examining the merger, what would be the merger's effects on innovation incentives in the industry. This does not necessarily require the definition of a specific "innovation market". Indeed, in the context of the Transfer of Technology Guidelines, the Commission has put in place a filter that confines detailed analysis to cases "that are likely to present real competition concerns", not on the basis of market shares, but referring the existence of "at least four independent technologies that may constitute a commercially viable alternative, in addition to the licensed technology controlled by the parties to the agreement"[181]. According to the Commission, '(i)n assessing whether the technologies are

---

[174] EU Non Horizontal Merger Guidelines [2008] OJ C 265/7, para. 10.
[175] Ibid., para. 26.
[176] COMP/M. 5675 – *Syngenta/Monsanto's Sunflower Seed Business,* Commission decision of 17 November 2010, para. 248 and paras 200 and 207 (finding that farmers would have suffered from reduced choice); COMP/ M.6166 – *Deutsche Börse/NYSE Euronext,* Commission decision of 1 February 2012, section 11.2.1.3.4, confirmed by Case T-175/12, Deutsche Börse AG v Commission, ECLI:EU:T:2015:148; Case No COMP/ M.7326, *Medtronic/Covidien*, Commission decision of 28 November 2014; Case No COMP/M.7275, *Novartis/GlaxoSmithKline's oncology business*, Commission decision of 28 January 2015 ; Case No COMP/ M.7559, *Pfizer/Hospira*, Commission decision of 4 August 2015 Case No COMP/ M.7278, General Electric/Alstom (Thermal Power- Renewable Power & Grid Business), Commission decision of 8 September 2015
[177] Case COMP/ M.5984 – *Intel/McAfee*, Commission decision of 26 January 2011 ; Case COMP/ M.6564 – *ARM/GIESECKE & DEVRIENT/GEMALTO JV*, Commission decision of 6 November 2012; Case No COMP/M.7688 – *Intel/Altera*, Commission decision of 14 October 2015.
[178] N. Petit, Significant Impediment to Industry Innovation: A Novel Theory of Harm in EU Merger Control?, ICLE White paper 2017-1, 22.
[179] Ibid., p. 21.
[180] Ibid., p. 21.
[181] Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements [2014] OJ C 89/3, para. 157.

sufficiently substitutable the relative commercial strength of the technologies in question must be taken into account. The competitive constraint imposed by a technology is limited if it does not constitute a commercially viable alternative to the licensed technology'[182]. Even if an agreement falls outside the safe harbour this does not create a presumption of incompatibility with Article 101 TFEU but simply leads to an individual assessment under the guidelines and Article 101(3) TFEU, the Commission's approach indicates that the main concern is the existence of sufficient choice in terms of independent technologies available in the market. This explains the emphasis put on the existence of various "independent" R&D paths or, more generally, technologies. Limiting the focus on innovation to just adopting the "innovation markets" approach seems reductionist and certainly does not represent the most recent competition law thinking, also of US competition agencies. It is also important to take into account the patent portfolio strength of the merging parties, as well as the existence of licensing and cross-licensing agreements and internal strategy documents in order to assess the possible effects of a specific merger on innovation.

The assessment of innovation effects by the Commission in the *Dow/Dupont* merger may provide an interesting case study illustrating the approach followed[183]. The Commission found that the merger may have reduced **innovation competition** *for pesticides by looking to the* ability and the incentive of the parties to innovate. *The* Commission focused its assessment both on innovation competition at the level of *innovation spaces* within the crop protection industry and on innovation competition at the *industry level*. In particular, the Commission looked

> '(1) At the level of innovation spaces, the overlaps between the Parties' lines of research and early pipeline products as well as between lines of research and early pipeline products of a Party that will compete in a market where the other Party is an existing or potential supplier; and
>
> (2) At the industry level, the overlap between the Parties' respective global R&D organisations, that is the resources, personnel, facilities, and other tangible and intangible assets dedicated to research, development and registration of new active ingredients (including lines of research, field testing facilities, registration capabilities)'[184].

Showing its concern with the whole *process of innovation*, rather than with specific innovation outputs, the Commission explored the innovation effects of the merger by looking to

(i) *lines of research,* which comprise the set of scientists, patents, assets, equipment and chemical class(es) which are dedicated to a given discovery target whose final output are successive pipeline AIs targeting a given innovation space,

(ii) (*early pipeline products,* that is, products which are intermediate results of lines of research, which have already been selected among leads, but with a lower

[182] *Ibid.*

[183] European Commission, Case M.7932 *Dow/Dupont* (2017). The Commission also looked to effects on innovation in the context of its analysis of the *Bayer/Monsanto* merger: Commission, Press Release IP/18/2282.

[184] Case M.7932 *Dow/Dupont* (2017), para. 1957.

likelihood of success than development products and still in the discovery or predevelopment stage and

(iii) *pipeline products* in the development stage whose likelihood of being successfully launched is between 80 to 90%[185].

The Commission dedicated several hundred pages of its lengthy decision on innovation competition. Referring to paragraphs 8, 24 and 38 of the EU Horizontal Merger Guidelines (HMG), the Commission held that "(i)nnovation is an important criterion relevant in order to conduct the appraisal (of a merger)"[186]. The Commission derived from this focus on innovation competition that the framework in the HMG dealing with the non-coordinated (unilateral) effects of mergers could also apply in order to assess mergers affecting other parameters of competition than price, such as innovation competition[187]. In this case, the Commission needs to assess whether the transaction reduces important constraints on one or more sellers and significantly impede effective innovation competition, considering both the loss of competition between the merging firms, and the reduction of competitive pressure on other non-merging firms. According to the Commission, "(o)verall, the loss of product variety brought about by less innovation harms consumers by depriving them of choice, and reducing competition on rival products".[188]

This innovation-focused framework is also manifest in the theories of harm put forward by the Commission, in particular the harm to innovation. The Commission linked the existence of rivalry/competition with the promotion of innovation, finding that "[…] the market features of the crop protection industry suggest that rivalry (or competition) is likely an important factor driving innovation, and that a merger between important rival innovators is likely to lead to a reduction in innovation"[189]. Many reasons were given for this prior belief or Commission's starting point in this case:

> '(i) individual crop protection product markets are contestable on the basis of innovation; (ii) given the strong Intellectual Property Rights (IPRs) in the crop protection industry, the original innovator can be expected to reap the benefits from its innovation, by preventing rivals from imitating the successful innovation (that is, appropriability is high); (iii) innovation is mostly based on product innovation; (iv) consolidation between rival innovators is unlikely to be associated with efficiencies ([…]); and (v) the fear of cannibalisation of own existing products is a disincentive to innovate which is likely to be reinforced by a merger between rival innovators'[190].

The Commission also relied on a body of theoretical and empirical economic literature that raised doubts over the Schumpeterian linkage between monopolistic profits and innovation, and empirical evidence that "in the past, concentration in the industry was accompanied by a decrease in innovation"[191].

---

[185] Ibid., paras 1958-1960.
[186] Ibid., paras 1989-1990.
[187] Ibid., para. 1994.
[188] Ibid., para. 1998.
[189] Ibid., para. 2000.
[190] Ibid., para. 2001.
[191] Ibid., para 2003. See also 2157-2158 and the discussion in Section 8.5. of the Commission's decision.

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 industry players who are capable to bring innovation to the crop protection markets overall. Against this background, it is possible to assess whether, through increased concentration and in light of high barriers to entry, the Transaction would be likely to reduce innovation output in the crop protection industry overall.
>
> Secondly, and at another level, however, it is also relevant to identify and analyse those spaces in which innovation competition occurs in the crop protection industry, so as to assess whether the Transaction would significantly impede innovation competition in such spaces"[194].

These "innovation spaces" are getting smaller in the crop protection industry, in view of the increasing regulatory hurdles, which require crop protection products to be ever more selective, compared to the past[195]. Noting that the early leads pursued do not indicate clearly what specific type of downstream product will materialise with the final Active Ingredient, the Commission rejected the view of the parties that the choice was either to focus on the effect of the merger on specific relevant markets, such as upstream technology market and the relevant product markets, or on the assessment of innovation in the industry in general. For the Commission, it was necessary to assess innovation competition in innovation spaces, these corresponding to small groupings of crop/pest combinations[196]. The tight oligopolistic structure of the industry dominated by four integrated crop protection R&D players, following the unprecedented wave of consolidation in the industry since the mid-1990s, makes somehow this assessment easier[197]. In contrast to other industry players, these players have scale, assets, capabilities, disposing the possibility to access to markets to pursue R&D globally and are

---

[192] Ibid., paras 2159-2162.
[193] Ibid., para 2162.
[194] Ibid., paras 2163-2164.
[195] Ibid., para 2166.
[196] Ibid., paras 2171 & 2191
[197] Section 8.6.2. of the Commission's Dow/DuPont decision.

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].The fact that for some of these companies their revenues relied on "decades old innovation" was also to be taken into account[200]. Quantitative metrics on the basis of patent applications confirmed that these global R&D-integrated players play a predominant role in crop protection innovation[201].

Moving beyond the industry level, the Commission noted that concentration of R&D-integrated players at specific innovation spaces is even higher leading to tighter oligopolistic markets. Indeed, not all the R&D integrated companies are present in each innovation space and are present in all the downstream markets for formulated products. Despite being active at an industry level, each R&D player only competes in some markets for formulated products and therefore develops innovation efforts aiming at introducing new products in downstream markets for formulated products in *some* innovation spaces, but not all. As the Commission notes, "(o)therwise, they would be present with a product in all the downstream markets"[202]. This implies that at each innovation space level concentration may likely be higher than the overall industry level[203]. The Commission further observed that the merging parties are important innovators in the crop protection industry with ambitious targets in terms the number and quality of new AIs and that their shares of patents (including citations of patents, which was thought as the most relevant criterion to assess the quality of patents) and new active ingredients shares (based on turnover on downstream markets), at industry level are higher than their downstream shares and their R&D expenditure shares suggest[204]. Their closeness as competitors in several innovation spaces was also found to be significant[205].

After identifying the structure of competition in the industry and in specific innovation spaces, the Commission proceeded by exploring if the merged entity would have incentives to reduce innovation efforts on overlapping lines of research and early pipeline products on the innovation spaces where the merging parties currently compete[206]. In order to assess these incentives the Commission referred to economic theory suggesting that a merger bringing together two competing early pipeline products (or lines of research) or an early pipeline product positioned to compete with an existing product may lead to a reduction on the efforts to continue with those overlapping early pipeline products (or lines of research). This possible harm could occur if the early pipeline product (or line of research) of one of the merging

[198] Ibid., paras 2205 & 2209.
[199] Ibid., para. 2228.
[200] Ibid., para. 2232. The Commission noted, for instance, that Monsanto was not a strong player in the crop protection industry as its most significant activity as regards crop protection innovation has been the introduction of one extremely successful AI (Glyphosate) more than thirty years ago, and its patent share in the market has been insignificant since.
[201] Section 8.6.3.5. of the Commission's Dow/DuPont decision.
[202] Ibid., para. 2363.
[203] The Commission explains this higher degree of concentration in innovation spaces for various reasons detailed in paras 2365-2393.
[204] Sections 8.7.1. & 8.7.2. of the Commission's Dow/DuPont decision.
[205] Ibid., para. 2601.
[206] Section 8.9 of the Dow/DuPont decision.

parties was likely to capture significant revenues from the competing product[207] of the other merging party, each company's research posing an externality to the other's[208]. According to the Commission, '(t)his adverse externality is internalized post-merger – from the perspective of each innovator, the expected loss of profits on the products of the other merging firm adds to the opportunity cost of innovating –, making it more likely that an early pipeline product (or line of research) is suppressed, deferred or re directed (particularly in the presence of significant development and commercialisation costs)'[209]. Similar cannibalisation concerns could also arise if a merging party's early pipeline product overlaps with an early pipeline product of the other merging party[210]. In these cases, consumers may be harmed "by both the loss of product variety, and the reduced intensity of future product market competition in the markets where the discontinued/deferred/redirected early pipeline product would have been introduced but for the merger"[211].

Although the Commission was not be able to identify precisely which early pipeline products or lines of research the merging parties would likely discontinue, defer or re-direct, it considered probable that the early pipeline products and lines of research where the parties were close innovation competitors would be the those for which the merging parties would have less incentive to innovate[212]. The Commission also noted that "discontinuation of an early pipeline product or line of research is more likely to occur the higher the expected sales which that early pipeline product from the merged entity would capture (if launched) from another existing or future product of the merged entity"[213].

In the same vein, the Commission noted that the merged entity would have lower incentives to achieve the same overall level of innovation as the merging parties pre-merger, in view of the fact that "rivalry at the innovation stage is a crucial driver of the incentives to innovate"[214]. This is particularly the case "[…] on highly concentrated innovation driven industries with very high barriers to entry such as the crop protection industry", where "the internalisation of the effects of innovation competition between the parties of a merger between important innovators would likely lead to noticeable reductions in the innovation efforts of the parties in relation to any future products that would otherwise be introduced in the absence of the transaction"[215].

This theory of harm goes beyond the "short-term" harm to innovation competition that would likely come with the discontinuation of overlapping lines of research and early pipeline products targeting the same innovation spaces[216]. It consists in a medium and long-term theory of harm that results from the lower overall incentives of the merged entity to innovate as compared to the merging parties separately before the transaction. What is take into account here is the "structural effect of the transaction", the merged entity pursuing less discovery

[207] This could refer to another early pipeline product – or line of research - or products currently marketed.
[208] Ibid., paras 3017-3018.
[209] Ibid., paras 3018 & 3024.
[210] Ibid., para. 3022.
[211] Ibid., para. 3019.
[212] Ibid., para. 3025
[213] Ibid. & 3053.
[214] Ibid., para. 3054.
[215] Ibid., para. 3055.
[216] Ibid., para. 3056.

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]. To the extent that "lowered innovation incentives can manifest themselves in (i) lower innovation efforts reflected for example in less financial resources, less scientists, less physical assets devoted to innovation, and (ii) lower internal innovation output targets", the Commission explored the parties' post-integration planning documents and the synergies put forward by the merging parties which were set from the beginning to be more focused on cost cutting than on creating value (as more than 70% of the announced synergies were cost-based)[218].

The Commission also found unlikely a sufficiently strong countervailing reaction of innovation competitors as the combination of efforts of players with discovery capabilities and of players with R&D capability would not offset the reduction of output resulting from the transaction[219]. It was not also to be expected that third-party R&D-integrated players would increase their R&D expenditure and R&D targets following a concentration, in particular in view of the finding that the past consolidation of the industry seems to have harmed innovation competition in the crop protection industry[220].

In conclusion, the Commission found that he harm to innovation would be significant to the extent that unilateral (non-coordinated) effects are expected to be more pronounced if the merger brings together "two out of a limited number of large, qualitatively and highly effective R&D-integrated players", the effects on innovation being stronger if the merging parties are close competitors in terms of their likely innovation trajectories or in the product markets targeted with their innovation[221].

One of the lessons of the agrochem cases is that innovation cannot only be evaluated with regard to the possible higher output and lower prices it might bring in the future (benefits or costs that are often discounted as these concern the medium term), but it also constitutes a process, a new technology always calling for another application technology[222]. But should we also move further and consider the *direction* of innovation, in particular when this is *socially valuable*? How can we define what is *socially valuable*?

A possible approach is to claim that the role of competition law is not only to promote innovation competition in the abstract, but competition in quality and innovation for more environmentally-friendly and sustainable methods of agricultural production. Following the Treaty of Lisbon, which stipulates, among the aims of the EU, the objective to develop a "highly competitive *social* market economy[223]", and the inclusion of horizontal clauses mandating the integration of environmental protection requirements into the definition and implementation of the Union's policies and activities[224], as well as the quite important regulation of the sector, in particular with regard to GMOs, one may argue that the Commission should take care to protect and to promote the type of competition that would be

[217] Ibid., para. 3057.
[218] Ibid., para. 3071.
[219] Section 8.10.6 of the Dow/DuPont decision.
[220] Ibid., para. 3242.
[221] Ibid., para. 3287.
[222] W. B. Arthur, *The Nature of Technology* (Penguin, 2009).
[223] Article 3(3) TEU.
[224] Article 11 TFEU.

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.

The *Dow/Dupont* merger decision of the Commission may be instructive on the approach to follow. As it focused on the non-price parameter of innovation, the Commission made efforts to explain why innovation in crop protection is of crucial importance 'both from the perspective of farmers and growers", the consumers affected by the merger, but also "from a public policy perspective", in view of the increased effectiveness of crop protection and its positive impact to food safety, environmental safety and human health[225]. The Commission did not explain under which legal basis these public policy concerns were integrated in the competition law analysis. Oddly enough, it did not refer to the horizontal integration clauses in the EU Treaties, such as Article 11 TFEU, that impose duties to the Commission, as to all other EU Institutions, to 'integrate' environmental protection requirements, 'into the definition of the Union's policies and activities', such as competition law. However, one may imagine that the presence of such clauses surely has influenced the Commission's view on the desirable direction of innovation. This did not result from some contingent valuation analysis performed with regard to the value attached by consumers on environmentally friendly innovation. Instead, the Commissions seems, at least implicitly, to have relied on the choice formulated by the EU Treaties for a competition law and policy that integrates these concerns. Although these may not balance restrictions of competition, as public interest concerns do not form part of the EU merger assessment, they can certainly provide broader interpretative principles in order to provide meaning to the fuzzy concepts of quality and innovation, which are the parameters of competition public authorities seem to have wanted to promote in these cases.

VI. Conclusion

It remains to be seen how this new competitive environment emerging out of the most recent mega-merger agrochem wave will evolve at a global and regional level, now that most jurisdictions have taken position on the existence of a restriction of competition, the expansion of the propertisation logic that is deemed desirable, the space for competition left by environmental and GMO regulation, and the development of specific doctrines and approaches in assessing innovation. Despite the global organisation of the industry in global food value chains, and the international architecture put in place by the TRIPS agreement for the protection of IP rights, this emerging landscape is characterised by regulatory fragmentation, some jurisdictions applying to gene-editing GMO regulation, while others take a more "liberal" approach. Similarly, jurisdictions take different approaches on the respective role of patents and that of the public domain, applying different logics of propertisation of innovation in the

[225] Commission Decision, Case *M.7932 – Dow/DuPont* (2017), paras 1977, 1979 & 1980.

food sector. There are also considerable differences in the way innovation effects are examined, and on the possibility for broader socio-economic effects to influence the competition assessment of these mergers. Hence, the food sector mergers become an interesting case study of the gradual transformation of competition law from a monocentric focus on price effects to a more polycentric model, directly and indirectly engaging with the broader social costs of merger activity, and the development of a dynamic and, to a certain extent, reflexive equilibrium between competition law, IP law and regulation[226].

[226] I. Lianos, Polycentric Competition Law, (forth.) (2018) Current Legal Problems; also available as a CLES Research Paper 4/2018.