Discussion

# Is Intellectual Property Right Legislation Constraining the Agrifood Biotechnology Sector in the European Union?

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In this paper, we discuss the implications of the recent Intellectual Property Right (IPR) enforcement in the European Union (EU) as a potential factor affecting agrifood biotechnology industry stagnation. After presenting a theoretical framework justifying patents, we describe some controversial questions in the European patent protection related to: a) the distinction between discovery and invention and; b) the morality and *ordre public* exception to the patentability. Although we provide some evidence about the reduction in importance of agrifood activities compared to that of pharmaceutical areas of application, we conclude that differences between EU and other developed countries IPR legislations are not the principal regulatory controversial factor affecting activities in the agrifood biotechnology sector.

*Keywords*: agricultural biotechnology, IPR legislation, European Union

In the European Union (EU), during the past four years, 39% of agrifood biotechnology centres have cancelled at least one research project, with private sector frequency higher (61%) than public (23%). One of the main factors for cancellation argued by centres was the existence of an unclear regulatory framework. Recently, a survey conducted by the *European Science and Technology Observatory* revealed that both public and private biotechnology research centres find it difficult to commercialise their inventions (Lhereux *et al.*, 2003). In addition, recent mergers between European agrochemical firms, like Aventis CropScience and Bayer, have been attributed to new environmental standards and pesticides residue regulation – entailing high expenditure on R&D – increased risk of liability suits and consumers' reluctance towards Genetically

Modified Organisms (GMOs) (Régibeau and Rockett, 2001).

Without trying to cover everything, the agrifood biotechnology sector is affected by different regulations: Intellectual Property Rights (IPR), International trade rules, Environmental regulations, and mandatory labelling and traceability. Public intervention in the agrifood biotechnology sector attempts to stimulate the development of the new GMO sector, but also to protect health and the environment. The actors involved in the agrifood biotechnology chain – biotechnology enterprises, public and private institutes and universities responsible for the generation of knowledge, seed companies, manufacturers and consumers – are affected by these regulations. In this sense, government regulatory actions at each stage – which continue to develop along with advances in biotechnology in the EU – play an important role in allocating costs and benefits of biotechnology innovations among agents. Each of those agents advocates their own interests in order to not be worse off by regulation.

This paper will focus on the Intellectual Property regulation affecting the agrifood biotechnology sector in the EU. The main goal is to clarify if differences in regulations, compared to other developed countries, could be constraining the evolution of agrifood biotechnology industry. The first section describes the theoretical justification for IPR and the European regulation of IPR. The second section refers to controversial questions relating to patent protection and finally, the third section summarises some potential effects of these regulations on the European agrifood biotechnology sector.

## Theoretical and Legal Framework of European Innovation in the Agrifood Biotechnology Sector

Genetic material is increasing in both economic and intellectual value to the industries that use it for research. In this sense, both international and national regulations have established some property rights over inventions – Intellectual Property Rights (IPR) – particularly the patent system. The international framework on IPR is integrated by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. There are two economic justifications for patents: a) as an incentive for investment in inventive activities; and b) as way to enhance technology transfer. We briefly describe these theoretical aims.

Agrifood biotechnology inventions have been considered basic knowledge, and as such, a public good – *non-rivalrous* consumption and *non excludability* – (Huffman and Evenson, 1993). The first one means that the research is available to everybody at zero marginal cost. The second one, *non excludability*, implies the infeasibility, or high cost, of denying use to those who do not pay for it so that a "free rider" problem is present. Private sector enterprises are not interested in producing goods that are *non-rival* or *nonexcludable* because they would be unable to capture benefits to cover the costs resulting from their research activities. As a result, private industry may invest too little in scientific research. Prior to the IPR legislation, the discovery, evaluation and storage of germplasm and plant breeding were carried out in the public sector because of "market failure" attributable to the absence of effective property rights. Private

companies have historically found it unprofitable to invest in R&D for open pollinated crops because of farmers' ability to save and replant their own seed. Hence, given the difficulty of capturing benefits from a crop with no plant variety protection, private firms alone produced sub-optimal quantities of varieties.

Thus, the characteristic of *non-rivalness* in agricultural research encourages the market mechanism to fail, or the attainment of an inefficient outcome in the market, providing a justification for government regulation. *Free-rider* problems emerge unless there are clearly defined property rights. This provides a theoretical justification for IPR. Patents could be economically justified as an incentive for investment in inventive activities. In that sense, IPR serves as a mechanism to transform non-exclusionary knowledge into private property (Maclup, 1958). Consequently, the expansion of IPR mitigate this market failure and would provide some form of "right to exclude" others from using genetic resources and stimulate more private sector breeding activity.

Public intervention through regulation could be considered justified when these legal instruments contribute to increases in social efficiency, although allocation of benefits will necessarily occur. The existence of patents confers temporary monopoly rights to the discoverer, and this market power influences the prices that can be charged for innovated inputs. The pricing of innovations in turn affects its adoption by farmers and could reduce consumer gains (Moschini, 2001).

A second aim of IPR is to enhance technology transfer (Lesser, 2000). The complexity of agrobiotechnology innovation might require inventors to focus on their scientific and technological expertise rather than on commercial skills. In this respect, the biotechnological industry performs a crucial role of transforming fundamental scientific knowledge into technological and commercially valued knowledge. IPR provide inventors a negotiating tool with which to license or sell an invention. Through the possible appropriation and transfer of knowledge, specific genes become a product market and this market cannot exist without IPR. As a result, the "synergy" between IPR and the biotechnology sector is strong (Santianello, 2000).

Nevertheless, in Europe universities and public research centres continue to play an important role in the generation of new products (curtivars) and processes (methods) in European biotechnology (European Commission, 2001). In that sense, problems of technology transfer from public centres and universities to the industry could emerge, unless collaboration between public and private sector continue to be promoted. IPR also may play a key role in favouring this rapid transference of public scientific research into private industrial R&D.

Most of the economic studies related to the impact of IPR on economic activity have been focused on property rights and regulations for transgenic crops in North America (Carlston and Marra, 2000), as patent data evidence from the USA biotechnology inventions show higher development in this country. Nevertheless, IPR are not uniformly enforced throughout all the countries. Less attention has been paid to EU legislation. Among others, Santianello (2000)

revised the Protection of Plant Varieties and the Future Development of a European Gene Market. According to those substantial differences between European and other developed countries biotechnology legislations, we will contrast the hypothesis that if those disparities could be affecting European biotechnology sector evolution.

In this respect, regulation of IPR in the agrifood sector is contained in two different legislative instruments. First, for plant varieties, Europe follows the *sui generis* systems stated by the International Convention for the Protection of New Varieties of Plants which established an International Union for the Protection of New Varieties of Plants (UPOV). This Convention was revised on March 19, 1991, in order to reflect technological developments in plant breeding and experience acquired with the application of the UPOV Convention. This system recognised the "breeders' right" over the variety bred or discovered. The Community plant variety was enacted in Europe in 1994 giving breeders the following rights: production or reproduction (multiplication); (b) conditioning for the purpose of propagation; (c) offering for sale; (d) selling or other marketing; (e) exporting from the Community; (f) importing to the Community; (g) stocking for any of the purposes mentioned in (a) to (f) (European Council, 1994).

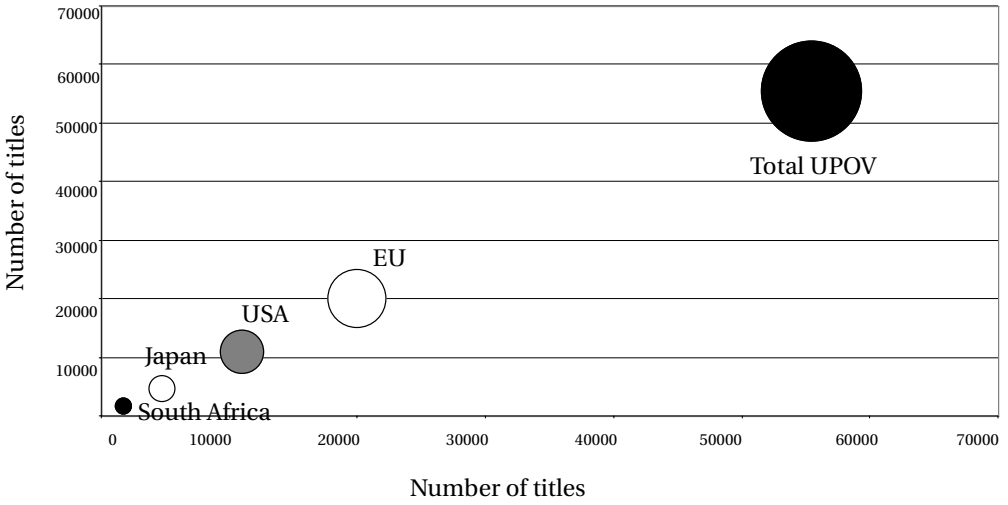
Evidence from Plant Variety Protection (PVP) statistics suggests that the EU has the advantage in the intensification of innovative activities in this field. Figure 1 shows that the EU almost doubles other countries' number of titles in force, like the US, at the end of 2001. Thus, the PVP system could have contributed to improving European potential of innovative activities. This favourable proportion in number of European innovations does not explain lagged evolution of the European firms behind the US biotechnology sector.

Second, patents protect biotechnological inventions in the agrifood sector - with the exception of plant or animal varieties or essentially biological processes for the production of plants or animals. The two ways for obtaining patents in Europe are based on the European Patent Convention (EPC) of October 5th 1973 and the national legislations. European decision makers have established a regulatory framework on the legal protection of biotechnological inventions (European Parliament and Council of 6, 1998).

This Directive provides certain important principles, in particular, to determine the difference between inventions and discoveries, the scope of protection conferred by a patent on a biotechnological invention, the right to use a deposit mechanism in addition to a written description and, lastly, the option of obtaining non exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely.

Patent data provide relevant information about the geographical distribution of biotechnology research across regions and so the location of the innovative activities. The available empirical evidence (European Commission, 2001) shows that the US is the most important innovator in biotechnology and that they continue to increase their relevant importance. From 1990 to 2000 the US share of all biotechnology patents granted by the United States Patent and Trademark Of-

*Figure 1. Plant Variety Protection Statistics. Titles in force at the end of 2001*




Source: UPOV

fice (USPTO) increased by 9 percent. Considering patent citations, as a measure of economic value of the innovative activities, eleven of the twenty top institutions in terms of patent citations are American, in the period 1978-1995. The rest of the institutions are German, British, Japanese, Swiss, French and Danish (European Commission, 2001). But if we consider the presence of centres in Europe of absolute excellence, scientific quantity and quality research seems to lag behind the US. It has been considered as the European paradox and could be related to some institutional factors that constrain the innovative activities, e.g. financial constraints, the structure of the research system, the relationship between universities and industry, and the regulation of IPR in biotechnology. The following section presents these controversial factors related to the regulation of IPR, in order to clarify the role of constraints on the innovative agrifood biotechnology sector in Europe.

## Controversial Questions Related to Patent Protection

The patentability of biotechnological inventions emerged in Europe to develop this sector and to stimulate innovation, following US legal positions. In the US, the biotechnological industry began to develop seriously after a Supreme Court decision of 1980, the landmark *Diamond v. Charkrabarty*, which stated that a live, human–made microorganism is patentable. In this respect, European regulations of biotechnological inventions would also improve the biotechnological industry in Europe.

Nevertheless, it was not clear that biotechnological inventions were subject patent matter under European regulations. Neither the European Patent Convention (EPC, 1973), nor the national patent systems consider living material as patentable invention because it is a discovery rather than an invention and, on the other hand, it was considered that granting a patent for a human gene offends morality or *ordre public*. In the following paragraphs we present these two issues.

First, a long-standing practice in European patent law considers that only inventions are patentable. The question posed is how to distinguish discovery from invention in the biotechnology field. Discovery can be defined as everything that exists in nature; in this sense the mere sequencing of a genome belongs to the area of discovery.

Article 3.2 of the EU Directive 98/44/EC (European Parliament and Council of 6, 1998) provides that: "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature". So, genes in their naturally existing form were unpatentable as discoveries, but they can be described and claimed in a form that is different from the naturally existing form, and then they will be patentable. In the same way, and in order to comply with the industrial application criterion, it is necessary, in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which is produced or what function it performs (Recital 22 to 24). Also a patent may be granted for any new application of a patented product (Recital 28). In other words, a sequence or partial sequence must be disclosed in patent application as filed and the mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. So, the traditional exclusion of discoveries as patentable subject does not constraint the effectiveness of granting patents in the biotechnological sector, despite it being admitted that biological material isolated from its natural environment is subject to patent protection. However, some difficulties arise from describing function.

Second, the morality and *ordre public* exception to the patentability is recognised by Article 53 EPC (European Patent Organisation, 1973) which states that: "European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to *ordre public* or morality". In the same way Article 6 of the Directive (Directive, 1998), excludes the patentability of inventions whose commercial exploitation would be contrary to *ordre public* or morality. Those provisions allow the administrative authorities and Courts - European Patent Convention and Member States institutions - a wide scope for manoeuvre in applying this exclusion. This scope for manoeuvre is not discretionary, since the European Patent Convention and the Directive, (Directive,1998) limit these concepts: *ordre public* or morality, both by stating that commercial exploitation is not to be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation, and by giving examples of processes or uses which are not patentable.

The Directive (European Parliament

and Council of 6, 1998) gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents: Article 6 cites as contrary to *ordre public* and morality and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes.

In the agrifood sector, the protection of environment and the regional and worldwide genetic resources must be included in the *ordre public* and morality terms.

The World Trade Organization Trade-Related Aspects of International Property Rights (WTO-TRIPs) agreement recognises, in the context of *ordre public* and morality, the grounds of protection of human, animal or plant life or health and the avoidance of serious damage to the environment. If we apply this concept to European positions, we will have to consider that, for the purpose of Article 6 (1), a serious harm to the environment, or the risk thereof, may fall within the concept of *ordre public* (Jacobs, 2001).

The Parliamentary Assembly of the Council of Europe (Council of Europe, 1999) considers that the "monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of traditional knowledge in those countries that provide access to these resources" (nº 9) and that "neither plant-, animal- nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be subject to monopolies granted by patents" (nº 12). This position has not been adopted by compulsory rules in Europe but we think it could be met in place under the concept of "order public" established by Court decisions.

As far as the controversy posed by the undetermined concepts of order public and morality is concerned, some legal instrument must be consulted to solve questions concerning these subjects, but it will be Tribunals and Ethical Committees who play an important role in this respect. Tribunals and Court decisions will decide the scope of these open concepts. In the European Patent Convention context there is the Plant cells/Plant Genetic Systems case (European Patent Office, 1995) where it was argued that inventions, the exploitation of which is likely to seriously prejudice the environment, are to be excluded from patentability as being contrary to *ordre public*. The decision states that:

"Inventions, the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to [the culture inherent in European society and civilization] are to be excluded from patentability as being contrary to morality" (European Patent Office, 1995).

Furthermore, if other European regulations take into account the potential risks arising from the deliberate release of GMOs into the environment, such as Directive 2001/18/EC (European Parliament and the Council of 12, 2001) on the deliberate release into the environment of genetically modified organisms which repealed Council Directive 90/220/EEC, it would be incoherent to grant a patent over products or procedures which seriously damage the environment.

Nevertheless, although the "moral question" in European IPR could be invoked in certain cases in the agrifood

sector, this exception affects overall the biotechnological sector – human, animal and agricultural applications- and does not constraint, in particular, the effectiveness of granting patents in the agrifood sector.

## Possible Effects of IPR Legislation on the Agrifood Biotechnological Sector

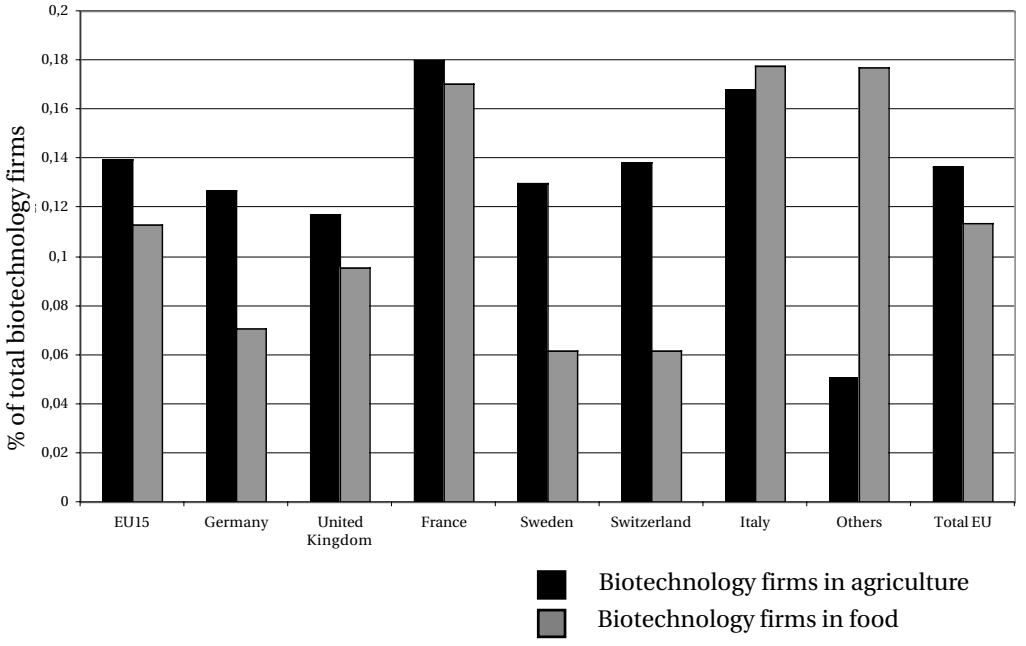
Considering that various interest groups are affected differently by government intervention through IPR legislation, in this section we describe two main actors involved in the innovation process: industry and farmers.

*Industry*

The EU enforced IPR legislation in order to mitigate the market failure inherent to the public good nature of innovation and to provide incentives to innovation. Nevertheless, the impact on the private biotechnology sector, nowadays measured by patent citations, appears to be minor, as it was described in the previous sections. In addition, because IPR prevent the entry of imitators and competitors, they may result in concentrated, protected market.

In Europe, agriculture and food areas of activity in biotechnology comprise less than 14% and 12 %, respectively, of

*Figure 2. Biotechnology specialization in Agriculture and Food*




Source: European Commission, 2001

the number of total European biotechnology firms. Figure 2 shows, by country, the relevance of agriculture and food specialization. France and Italy maintain the higher proportion, with more than 15% of the biotechnology firms in agriculture and food sectors.

The relative importance of agrifood activity compared to that of pharmaceutical areas of application has changed in the EU. Thus, the proportion of new firms that entered agrifood industries declined from 1995, from about 15% to less than 5% in the year 2000 in the EU (European Commission, 2001). The number of biopharmaceutical companies, on the other hand, rose from 35% to over 50% of the total number of new firms.

This stagnation in agrifood biotechnology industry could be causing consolidation in the seed industry. Two factors may have accounted for this consolidation in the European seed industry: a) the combination of R&D in novel biotechnology techniques in agricultural applications by firms with prior experience in industrial chemicals; and b) acquisitions representing efficient instruments for obtaining intellectual property and know-how of smaller firms, rather than replication. Although this concentration in agrifood biotechnology does not mean lack of competition, the resulting industry might not operate efficiently due to price distortions.

In conclusion, the European IPR legislation could have changed in the short term the structure of the agrifood biotechnology industry encouraging inventors to exert market power. However, this concentration movement is also observed in the US agricultural input sector (King, 2001). Although the impact of IPR on the provision of incentives for innovation has not been realized yet in the European industry, one could expect in the long term, gains in the European firms' productivity to compensate for those short-term welfare losses.

Nevertheless, the impact of biotechnology on economic growth does not only depend on the innovation and competitiveness within the industrial sector, it also depends on the transmission process, which includes the adoption of those GM products (cultivars) by farmers.

*Farmers*

Recent evidence shows a high rate of adoption, especially in countries like the US, Canada and Argentina, which reflects growing acceptance of transgenic crops by farmers using the new technology. 6 million farmers in 16 countries around the world plant genetically modified varieties. During the period from 1996 to 2002, the global area of transgenic crops increased 35 fold, from 1.7 million hectares in 1996 to 58.7 million hectares in 2002 (ISAAA, 2003). By type of crops, industrial crops are relatively more important, so GM maize, cotton, soya and colza increased the arable area in 2002. In fact, GM soya represents 50% of soya arable land in the world.

In the EU the diffusion of the GM crops depends on several factors. Firstly, the agricultural landscape, that has rapidly been changing towards industrial crops, and that potentially benefit GM farmer adoption. In the EU there has been a rise of conventional industrial crops that grew by a factor of nearly five between 1975 and 1997. It has increased by a factor of 12 in the United Kingdom

and by 10 in Italy. It has changed the agricultural landscape, and fibre crops like cotton, and also oleaginous crops like soya and colza quite literally gained most ground. However, of the 15 Member States, industrial crops have become the most important in Greece, where they occupied 24% of the countries' arable land in 1997; followed by France (11.1%), Spain (9.5%) and Germany (9.1%). These four countries' final agricultural production amounted to approximately 56% of all EU Member State production in final agricultural production in 1999 (Eurostat, 2003).

Secondly, the farmers' decision as to whether to adopt GM crops, depends on the costs and benefits. European farmers will be induced to use GMOs if there is a change in the marginal cost of producing the crop between using GMOs and using existing technology. Possibly, in other countries, the lack of strong intellectual property protection results in considerable benefits for farmers through adopting GMOs, by a reduction in price for seed and then a profit advantage. But, in the EU, with effective property rights, as describe below, the owner of the GMO is a monopolist and the gross margin using existing technology would be higher than the farmers' gross margin using GMO technology. Previous studies reveal significant differences in magnitude and distribution of the benefits of GMOs between enterprises suppliers of technology and farmers depending on effectiveness of the property rights over GMOs (Godden, 2000). Thus, the farmers would rationally remain with the old technology and the diffusion and adoption of GM technology would be minor.

Thirdly, the political and regulatory conditions of international trade could affect adoption by European farmers. Thus, the EU has net importer position on some of these GM industrial crops, like corn. Nowadays, there are fourteen GM plants produced by different companies that have been approved for commercialisation so far. Under Council Directive 90/220/EEC (Council of the European Communities, 1990) several GMOs were approved for launching on the market, but after 1999 no authorisation has been given, either pursuant to the previous Directive 90/220/EEC, or to the present Directive 2001/18/EC (European Parliament and the Council of 12, 2001).

## Conclusion

This paper underlines the importance of regulation as an institutional factor to play in the development of the European agrifood biotechnology market. According with the theoretical justification about government intervention related to Intellectual Property Rights - the effects on stimulating innovations and transferring knowledge - European legislation has been reinforced in the last few years.

Although European policy pretends to follow the development of this agro-biotechnology sector in other developed countries (US) and has accepted the regulation and recognition of biotechnological inventions as patentable, some differences attributed to the unpatentability of discoveries and the order public and morality exceptions have been maintained. This implies that the scope of patent protection on biotechnological inventions in Europe is more restricted than in other developed coun-

tries.

With reference to the first question, the EU Directive 98/44/CE established a system which permit that patents could be granted over living material, when the natural element is isolated and the function of the invention is performed. So the difficulty came from the way this function is described.

With reference to the second question, although in the European IPR legislation, "moral question" could be invoked as an exception to the patentability of biotechnological inventions also in the agrifood sector, this exception affects overall the human and animal biotechnological sector.

Despite maintaining these exceptions, current European legal practice – in the European and national patent systems- shows that there is no substantial conflict with the purposes of stimulating innovations and transferring knowledge in the agrifood biotechnology sector in Europe. Nevertheless, further clarification of these concepts could be necessary in order to assure uniform application by national legislations in the European Union.

Finally, there is no clear evidence that these differences between European and other developed countries' Intellectual Property Rights legislations become the principal regulatory controversial factor affecting activities in the agrifood biotechnology sector. In that sense, further research needs to be carried out in order to clarify European agrifood biotechnology stagnation.

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