

BIOTECHNOLOGY PATENTS USE AND RIGHT TO FOOD

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The authors summarize how biotechnology patents may be strategically used to control access to food (point 1). This strategy is illustrated by the Argentinean soybean case (point 2). Some recommendations are made in order to avoid the abusive use of biotechnology patents (point 3).

1. Strategic use of biotechnology patents

Patent law is concerned by the right to food insofar as (i) some elements of plants and animals which constitute food are patentable subject matter and insofar as (ii) patents create strong exclusive rights allowing the development of monopolies and the implementation of commercial strategies likely to restrict access to food.

Such commercial strategies begin with the creation of a genetically modified organism (hereafter GMO), vegetal or animal, and with the patent protection of (i) the genetic modification introduced into the organism (product patent) and/or (ii) the creation-process of the genetic modification or the process for inserting the genetic modification into the organism (process patent).

On the periphery of these stages, the creation of *de facto* monopolies on traditional seeds has been observed as a consequence of the acquisitions, since the year 1990, of a large number of traditional seed companies by a small number of large multinationals which « create » the GMO's.

The second stage focuses on the commercialisation of the patented GMO. The purpose of this stage is « to convert » the relevant GMO, either the entire cultivation or breeding activities or just one sector of these activities. The conversion needs investments and strategic changes from farmers or breeders.

Once the conversion is achieved, it becomes very difficult for the converted sector to be moved backwards. A new situation is created that is characterized by a *de facto* dependence to GMO and by the patent owner's exclusive right on the GMO itself and its corollary, the right to prohibit the non-authorized use of the GMO. The combination of this *de facto* dependence and exclusive right confers a very strong market power to the patent owner, even an excessive one.

The third stage of the strategy consists in using patent rights not only to control the primary market (the genetic modification of the plant or of the animal) but also the derivatives. The abusive use of administrative and legal procedures related to the respect of intellectual property rights offers the opportunity to compel extra-judicial recognition of inexistent rights in favour of the patent holders by creating such a large financial pressure on the market players that these latter are forced to sign non-fair license « agreements » with the right holders.

2. Illustration of the strategy: the Argentinean soybean case

The Argentinean soybean case illustrates the strategic use of biotechnology patents. In 1991, a transgenic soybean was invented. The inventions are (i) a DNA sequence whose function is to make the soybean plant resistant to a total herbicide and (ii) the process allowing the introduction of this artificial DNA sequence into the soybean genetic code. The total herbicide destroys all vegetal life; not only the weeds but also the crop cultivation. By making the soybean plant artificially resistant to the herbicide, the invention allows using the total herbicide for the cultivation of soybean plants: so they won't be destroyed by the herbicide.

The inventor asserts that this invention involves a cost reduction because one herbicide is used instead of several and because of time and energy saved as a result of a decrease in the times and amounts of watering needed. The GMO seller also asserts that the transgenic soybean fields would be more productive.

The transgenic soybean's inventor also "invented" the total herbicide; both elements are covered by patents. The inventor sells – and owns exclusive rights on - a « technology package » comprising the transgenic soybean and the herbicide. Every transgenic soybean buyer of necessity also buys the total herbicide.

In 1996, the Argentinean Government authorized the cultivation of transgenic soybean. In order to "convert" farmers to its technology, the inventor transferred the soybean technology at low cost and under favourable terms to the local seed companies while keeping the herbicide technology for himself. In particular, she authorized the local seed companies to create their own transgenic soybean variety. In a few years, approximately 170 transgenic soybean varieties were recorded in Argentine. The inventor's strategy was crystal clear: to promote the use of the transgenic soybean to sell a maximum quantity of « her » own total herbicide.

In less than ten years, the surface devoted to the GMO soybean in Argentine has increased by 115%. Nowadays, 98% of the Argentinean soybean is transgenic. The cultivation of soybean replaced livestock and forest activities. A new industrial sector for the transformation of soybeans into derivatives (flour, oil and flakes) was created; roads, bridges, export facilities, etc. were built. International trade of soybean derivatives was developed in particular with Europe. Soybean derivatives are the top export products of the country before traditional products like meat, corn, etc.

The conversion of Argentina to transgenic soybean cultivation allowed the inventor to sell enormous quantities of his patented herbicide. In 2005, the estimated volume of this herbicide business amounted to 160 millions litres for the Argentinean territory.

Under these conditions, it became almost impossible for the Argentinean soybean sector to move backwards and to stop the cultivation of the GMO. Most notably, the use of the total herbicide impoverishes soils and it would have been impossible to cultivate something else other than transgenic soybean on the same soil in the short term.

One of the main buyers of Argentinean soybean derivatives is the European livestock industry. This industry uses soybean derivatives as cattle food. The European Union imports 14.000.000 tons of Argentinean soybean flour each year (2006 statistics from the Argentine

government) and these imports represent more than half of the annual Argentinean production and more than two-thirds of European Union's annual need for soybean flour (20.000.000 tons).

The inventor was always kept informed of the Argentinean production level, which obviously exceeded the interior consumption needs. The inventor also knew that a large amount of derivatives were exported to European Union. During a ten-year period, the inventor did not oppose, neither the large scale cultivation of the transgenic soybean in Argentine nor the importation of soybean derivatives into the European Union.

Besides its Argentinean patent, the inventor also owned European patents on the transgenic soybean technology. In 2005, for the first time in ten years, the inventor pretended that his European patents covered transgenic soybean derivatives and that the European importers had to pay a royalty of 15 USD per ton of soybean derivative imported into the European Union.

The inventor's legal reasoning was the following. He owns a patent on the artificial DNA sequence which confers a resistance to the total herbicide on the soybean plant. This patent relates to a product: the DNA sequence. A product patent allows the blocking of any commercial use of the patented product such as a non-authorized importation of the patented product. The inventor asserts that the patented DNA sequence is present in the imported soybean flour. Therefore, he considers that he has the right to block every importation of Argentinean soybean flour into the European Union.

Regarding the right to food, this reasoning is important. Biotechnology patents relates to living matter and thus (i) raw materials which will be transformed into the end-products of food manufacture and (ii) reproducible or self reproducible materials (capable of being reproduced or to reproduce themselves without any human intervention).

If we follow the inventor's reasoning in the soybean case, it must be considered that a DNA sequence patent covers any material in which it is possible to find a trace of the patented DNA sequence: the seed, the plant, the fruit of the plant, and the food products manufactured with the plant's fruit (in this case the soy flour). The chain probably does not stop there: it is maybe possible to find a trace of the DNA sequence in the stomach of the cattle which eat

soybean flour and into the meat, the milk, etc. produced by the cattle (but it is evident that the DNA sequence does not perform its function – making soybean resistant to the total herbicide – in these situations).

The inventor's reasoning in the soybean case implies that a patent related to a DNA sequence would grant the inventor a monopoly on the entire production of food products. From a legal point of view, this reasoning makes sense on the basis of the traditional patent law: usually a product patent confers an exclusive right to control any commercial use of the patented product as such, or in combination with other products. But traditional patent law also implies that biotechnology inventions are mere discoveries that should not be patentable.

Under European law, this reasoning does not have a legal base. Indeed, European Union has adapted traditional patent law to biotechnology with the Directive 8/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions¹. This Directive limits the scope of the rights conferred by biotechnology patents, precisely in order to avoid situations such as those that occurred in the soybean case.

Article 9 of the Directive mentions that: "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material (...), in which the product is incorporated and in which the genetic information is contained and performs its function".

In the soybean case, the function of the patented DNA sequence was to make the soybean plant resistant to the total herbicide. Obviously, this function is fulfilled only during the cultivation of the plant and not in its derivatives. Besides, European importers demonstrated that the DNA sequence did not perform its function in the soybean flour because soy flour is a "dead" material in which only fragments of the DNA sequence were present while a DNA sequence must be complete and intact in a living organism to perform its function. Under European law, soybean flour does not infringe the patent on the DNA sequence.

¹ *O. J.*, L. 213, July 30, 1998, p. 13-21.

It should be noted that the interpretation of article 9 of the Directive 98/44 is the subject of a prejudicial question actually pending before the European Court of Justice. The Court decision, expected in 2010, will have a decisive impact on the scope of biotechnology patent rights in the European Union.

In the soybean case, the inventor has abusively used administrative and judicial procedures existing in European law. In particular the border seizure established by the Council Regulation (EC) N° 1383/2003 of July 2003 concerning customs' action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods was found to have infringed such rights².

This Regulation allows customs agents to seize any goods which is at the border of the European Union and which is suspected of infringing an intellectual property right existing in a Member State of the European Union. In this case, the inventor asked the customs' administrations to seize every import of Argentinean soy flour.

Notwithstanding the obvious limitations to her rights, the inventor has asserted that his product patent on the DNA sequence covered the imported Argentinean soybean flour. On the sole basis of the unilateral claim presented by the inventor, the customs agents of different Member State have seized every import of Argentinean soybean flour. It will be noted that customs agents are not tribunals; they do not offer any guarantee of independence and impartiality and they are not able to establish whether the patents which are the basis for the seizure seem valid, nor whether the patented DNA sequence is effectively present in the soy flour (which is a condition imposed by the Directive for the patent covering soy flour).

The abusive seizures made at the request of the inventor, have had catastrophic consequences for European soy flour importers and, in repercussion, for the Argentinean producers and for the European users as well. Indeed, when customs agents seize soy flour, this mean that the flour has to stay in the containers of the companies responsible for operation at the duty on imported goods.

² *O.J.*, L 196, August 2, 2003, p. 7-14.

Soy flour is imported in very large quantity (tens of thousands of tons per importation) and it needs a large place to store. The cost generated by the seizure amounts to several thousand Euros per day. At least during the ten first days following the seizure (and in practice for a longer period), the storage costs must be paid by the importer to the company in charge of the operation at the duty. Of course, these costs can be recovered later by the importer from the claimant but this will only happen at the end of the legal proceedings and if and when it is demonstrated that soy flour is not covered by the patent. These proceedings take several years.

During these years, the seizure costs have to be borne by the importer: they have to be able to block for years, several thousands of Euros that they will only get back at the end of the proceeding. Moreover, if the importer wants to obtain the release of the goods, he has to provide a security which amount is sufficient to protect the interests of the right holder. For example, Belgian law provides that the security must be at least equal to three times the value of seized goods.

The cost of the security is added to the cost of the goods' storage. In total the average cost of a seizure on soy flour imported amounts to several hundreds of thousands Euros. Moreover, as long as any judicial decision has not been taken to confirm the non-counterfeiting character of the Argentinean soy flour, every import may be seized. In these circumstances, several importers have declared they were financially capable to support the cost of one or two seizures, not more.

In parallel to the seizures, the inventor "proposed" the importers sign a "royalty payment agreement". This "agreement" would offer the importers legal certainty and the guarantee not being subjected to other seizures. Moreover, the inventor offered the reimbursement of all expenses caused by the seizures to importers who agreed to sign the agreement.

In exchange, the importers had to acknowledge that Argentinean soy flour was covered by the patent on the DNA sequence and had to commit themselves to pay royalties to the inventor for each import. Of course by acknowledging that soy flour was covered by the

patent, the importers accepted the recognition of a principle which gave the inventor the right to control soy flour importation into the European Union.

The inventor has abusively used the custom seizure procedure to force extrajudicial recognition, by “agreements”, of inexistent rights. In the soybean case, the Argentinean Government and the importers have informed the European Commission of the abusive use of the custom seizure procedure by the inventor. These contacts have led to an opinion issued by the European Commission explaining that the customs’ seizures should no longer be applied to soy flour imports. To date, the soybean case has led to three judgments in three different Member States; all have confirmed that soy flour is not covered by the patent on the DNA sequence.

3. Recommendations

It should not be inferred from the soybean case that biotechnology patents restrict access to food, but this case highlights:

- the necessity to develop clear and precise legal limitations on the scope of rights conferred by biotechnology patents; which seems to be the case in European Union and it would be necessary to prevent the adoption of legislation that might extend the scope of biotechnology patent rights;

- the importance to exclude the patentability of genetic information “as such” and always to bind the existence and the scope of patent rights on genetic information to the sole function of the genetic information as described in the patent;

- the necessity to take serious measures to prevent abusive uses of the procedure related to the respect of intellectual property rights; in particular, any administrative or judicial decision taken within the framework of an unilateral procedure, that might be prejudicial to a third person, should be immediately revisable and under similar conditions as those resulting in the revisable decision (i.e. if it is only necessary to demonstrate the

appearance of an infringement to obtain a seizure order, the release of the seized goods should also be based on the apparent lack of infringement);

- the possibility to impose the local exploitation of the patented invention as a condition of the validity of the patent in the field of biotechnology patents on agricultural or livestock activities, since such an obligation seems to correspond to the fair limits of the rights conferred by such patents (i.e. the scope of the rights should be limited to the performance of the function of the patented DNA); - this recommendation would be difficult to impose since it would require a modification of Article 5, a of the Paris Convention -;

- the relevance of an analysis of an international exhaustion rule in the field of biotechnology patents related to agricultural and livestock activities in the interest of reaching an improved consistency between the scope of the rights and their existence (limitation of the scope of the rights to the function).
