

# RESEARCH ACTIVITY AND THE PRINCIPLE OF SOLIDARITY IN THE EU LEGAL FRAMEWORK FOR BIODIVERSITY<sup>1</sup>

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## ARTICLE INFO

### ABSTRACT

The paper aims to analyse how Reg. EU n. 511/2014 links the principle of solidarity to one of the most visible areas of intersection between EU law and ethical choice, particularly in the field of research activity: the implementation of the Nagoya Protocol in the EU legal framework. A broad range of users and suppliers in the Union, including academic, university and non-commercial researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes. Some also use traditional knowledge associated with genetic resources [see point 3 Reg (EU) 2014/511]. Thus, all research activities involving germplasm, genetic resources, and traditional knowledge related to genetic resources are currently subject to Article 15, point 6, of the Convention on Biodiversity, and they also must observe the fundamental principle (established by Article 19 of the Convention and EU legal sources) of benefiting the countries involved in the research and development actions. The mutually agreed terms and the contracts mandated by art. 3 reg. EU n. 511/2014 are correlated with distributive justice and the principle of solidarity, which underpin the entire EU legal system.

### KEYWORDS

Research Activity. Principe of solidarity. European Union legal framework. Biodiversity.

## 1. A BRIEF INTRODUCTION

In 2011, the European Commission (EC) adopted an EU biodiversity strategy extending to the year 2020 aimed at halting the loss of biodiversity and ecosystem services by 2020. This document is an integral part of the Europe 2020 strategy and the 7th Environmental Action Programme. It implements the EU's commitments under the Convention on Biological Diversity (CBD). Further, Reg. EU n. 511/2014 - on compliance measures for users under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (ABS) arising from their Utilization in the Union - is correlated with distributive justice and the principle of solidarity, which underpin the entire EU legal system as general principles of EU law.

In the European Union legal system, matters relating to seeds are governed by various directives: Council Directive 2002/55/EC of 13 June 2002; Commission Directive 2009/145/EC of 26 November 2009; Commission Directive 2003/91/EC of 6 October 2003; Council Directive 2002/53/EC of 13 June 2002; and Council Directive 98/95/EC of 14 December 1998.

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In its decision of 24 February 2004, the Council of the European Union approved the conclusion of the International Treaty on Plant Genetic Resources for Food and Agriculture.

However, it was only during 2014 that the European Union ruled on measures for users under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from the Utilization in the European Union (Reg. EU n. 511/2014). Further, it was only in the second part of 2015 that articles 4, 7 and 9 of Reg. EU n. 511/2014 entered into force. The abovementioned articles respectively address the “Obligations of Users”, “Monitoring user compliance” and checking user compliance. By “users”, Reg. EU n. 511/2014 means the natural/legal persons that utilise genetic resources or the traditional knowledge associated with genetic resources.

The biodiversity guarantee is expected to have many legal consequences in the EU legal system: i.e. on contracts for the transfer of knowledge and/or germplasm; on the circulation of the results of research activities and germplasm; on bioethics; on EU funding; on EU patents; on access and benefit sharing, etc.

More generally, the activities of modern factories, laboratories, universities and research centres have produced a great deal of valuable information based on genetic resources and traditional knowledge. They have generated income through the free access to this kind of knowledge, non-protected information and genetic resources with the aim of developing their business (POSEY, 1993: 287). Multinational enterprises have trademarked the full use of traditional knowledge, although the local communities, farmers and indigenous persons that provided it have not provided conscientious assent or received adequate remuneration from the multinational beneficiaries of their knowledge (DUTFIELD, 2005: 513).

As a matter of fact, this iniquitous approach stems from the abusive exploitation of traditional knowledge, which has occurred based on corruption and is not politically or ethically acceptable. The abovementioned iniquitous approach is amplified by the common behaviours of multinational firms, which are able to obtain (including in the EU legal system) patent protection or other forms of intellectual property rights (trademarks, utility models, short-term patents, plant variety rights) based on traditional knowledge or genetic sources.

The above-mentioned legal framework must comply with the EU jurisprudential approach to the biodiversity guarantee. In fact, on the 12th of July 2012, the European Court of Justice, in the case Case C-59/11 (*Association Kokopelli v. Graines Baumaux SAS*), confirmed that “old varieties” could be traded if they are listed in the official catalogues of one or more of the Member States and if they comply with the requirements of Directive 2002/55/EC. That directive allows for the trading of certain “conservation varieties” and “varieties developed for growing under particular conditions”. The European Court of Justice reconfirmed that only seeds of registered varieties may be traded within the EU.

The European Union seems to have a two-faced approach to biodiversity. One approach is to support the defence of biodiversity through the EU’s political positions, and now, through EU law having a direct effect, i.e. Regulation n. 511/2014. On the other side, the limitation on the certification and marketing of vegetable seeds was affirmed by the EU Court of Justice in Case C-59/11.

The paper aims to analyse how Reg. EU n. 511/2014 links the principle of solidarity to one of the most visible areas of intersection between EU law and ethical choice: the

implementation of the Nagoya Protocol in the EU legal framework. This meanwhile presupposes that EU institutions must “align” their two-faced approach to biodiversity in the legal system.

To achieve these goals, in section 2, the paper analyses the function of contracts and mutually agreed terms for the fair and equitable sharing of benefits, and section 3 evaluates whether or not the obligations of Article 3 reg. EU n. 511/2014 constitute a general principle of EU law. Next, the paper investigates the nature of the invalidity of contracts and mutually agreed terms if specific provisions for the fair and equitable sharing of the benefits arising from the utilisation of genetic resources or the traditional knowledge associated with genetic resources are missing. Thus, in light of the legal framework described in the previous sections, section 5 examines how to apply for a vegetable patent in light of the aims of reg. EU n. 511/2014 despite the absence of any apt coordination between the Regulation itself and the system for the protection of plant variety rights established by European Union legislation. The same section briefly considers art. 2 Prot. 1 ECHR as an underpinning support for the biodiversity guarantee in the EU legal system. Section 6 is the concluding discussion on contractual liability, actions for damages and the nullity of contracts as measures that safeguard the EU economic order.

## **2. CONTRACTS FOR THE FAIR AND EQUITABLE SHARING OF BENEFITS**

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Reg. EU n. 511/2014 identifies a set of criteria that should be applied in the identification of the areas (country, region, etc.) from which the genetic material used for developing new varieties comes. These criteria reflect the enforcement of legal rights, the rate of entrepreneurship, the structure of the higher education system, etc. of the partner countries of the Nagoya Treaty. First, they should guarantee the effectiveness of legal contracts and technology transfer agreements following the completion of the biotech research activity.

Second, they must contribute to developing the potential market value of new crop varieties. Thus, the measurement of returns - mainly monetary - for the commercialisation of innovations will be crucial in identifying fair prices for which the new varieties could be sold, with particular attention to the local communities.

One of the criterion is a provision in the contract for benefit sharing with the provider of the genetic resources or the traditional knowledge arising from their utilisation, subsequent application and commercialisation.

The competent authorities of the Member States should verify whether users are complying with their obligations (see point 29, reg. EU n. 511/2014). In addition, the competent authorities could refer to the judges of national and European Union courts. It is possible to fulfil the goal of reg. EU n. 511/2014 through the jurisdictional control of contracts for the utilisation, subsequent application and commercialisation of genetic resources and the traditional knowledge linked with them; in the European Union’s internal market, this mandates the fair and equitable sharing of the benefits arising from the utilisation of genetic resources and traditional knowledge.

Reg. EU n. 511/2014 requires mutually agreed terms and contracts including prior informed consent and establishing the terms for benefit sharing with the provider of the genetic resources or the traditional knowledge associated with genetic resources.

These kinds of contracts must set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or the traditional

knowledge associated with genetic resources. According to article 3 reg. EU n. 511/2014, they must also include further conditions and terms for such utilisation, as well as subsequent applications and commercialisation.

For such cases, and to gain a better understanding of the kinds of juridical control there could be over these contracts and mutually agreed terms, it is relevant to determine the nature of their invalidity. This situation is complicated and takes on different contours depending on the nature of the interests to be protected.

It is relevant to understand whether or not the obligations of Article 3 reg. EU n. 511/2014 express general principles of EU law.

Starting at this point, the following paragraph considers the nature of the invalidity of the relevant contracts and mutually agreed terms in the absence of specific provisions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or the traditional knowledge associated with genetic resources.

### **3. MUTUALLY AGREED TERMS AND THE EU PRINCIPLE OF SOLIDARITY**

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It is true that, more often than not, the general principles of EU law were not developed or based on a thorough textbook style of analysis. However, this does not make an examination of the interaction of EU law and comparative law in this particular field less interesting.

Reg. EU n. 511/2014 links the “general principles of law” to one of the most visible areas of intersection between EU law and ethical choice in light of maintaining the EU legal system. The mutually agreed terms and contracts covered by art. 3 reg. EU n. 511/2014 are correlated with distributive justice and the principle of solidarity, which underpin the entire EU legal system.

As a matter of fact, the legal traditions of some of the EU Member States (formerly planned economies) have had an impact on the European Union’s legal system in dealing with distributive aims and approaches.

Studies have demonstrated a variety of institutional settings observed across the EU (AMABLE, 2003). They are deeply rooted in historical and cultural factors, which have decisively shaped its social structures and distribution of power, and the resulting juridical settings and evolution (ACEMOGLU, 2010).

The institutionalisation of the legal concept of solidarity in Europe has been a long journey (STJERNØ, 2004), starting with the *Summa Theologiae*, in which the Catholic ideas of solidarity are expressed, moving to the Age of Enlightenment, and continuing into the formation of the welfare states (BOURGEOIS, 1906: 10). However, at the beginning of the 21<sup>st</sup> century, doubt continued to persist about whether or not the provisions of the constitutions regarding solidarity, as a general principle, could be directly applied (CIPPITANI, 2011). With the post-World War II constitutions, the principle of solidarity began to shape the institutional and juridical settings of the European States. It was only after the adoption of the international treaties of human rights and the “second generation” of constitutions that was possible to refer to the principle of solidarity in explicit terms. In second half of the 20<sup>th</sup> century, an exploration began of the idea that people could make claims to the public authorities in order to obtain social benefits, as explained by Thomas H. Marshall, who recognised a new political notion of citizenship (MARSHALL, 2002: 48). Thus, it has only been in the most recent times that the provision of the proper conditions to guarantee equal opportunities

and substantial equality before the law has been recognised as a State responsibility (MEZZADRA, 1995: 81; MORTATI, 1946: 49). This was a time during which European democratic institutions were gaining increasing strength. The most recent developments in the literature now recognise a horizontal effect on constitutional norms: The interpretation of constitutional rules in the European States is increasingly related to the concept of individualisation (ARNOLD, 2003). Individualisation is an anthropocentric approach based on the full respect for human dignity as a precondition for the protection of fundamental rights, which must occur to the largest extent possible and must be functionally efficient.

According to this approach, a modern constitution should be able in itself to guarantee the complete protection of the individual, even against new and emerging threats. The role of the judge is, therefore, crucial in interpreting and implementing general constitutional principles and translating them into binding protective measures.

At the same time, it is up to the constitutional courts to provide interpretations of laws that ensure the complete protection of the individual (ARNOLD, 2013: 563).

In the European multilevel juridical approach, this role is also assigned to the EU Court of Justice and the European Court of Human Rights. As matter of fact, after a long process of institutionalisation, the legal concept of solidarity is now part of all EU constitutions, as a spill-over effect of the European legal tradition, the jurisprudence of the ECHR and EU adhesion (MONATERI, 2003: 575).

In more recent years, the process has been completed and reinforced by the adoption (in 2001) of the Charter of Fundamental Rights of the European Union. Specifically, the principle of solidarity has been translated into concrete provisions by the States (Article 36 of the Charter of Fundamental Rights), such as social security and welfare services.

Those working together in elaborating the general principles of EU law tend to be responsive to input from national laws, and the laws of the Member States have no choice but to be responsive to the general principles developed at the EU level (COLCELLI, 2015).

The presence of the principle of solidarity, which underpins the EU legal system - which requires access to essential services by EU citizens in destination Member States - may be better explained by this spill-over effect. This is because the status of citizenship also incorporates the right of free circulation, which is interconnected with distributive justice through the possibility of acceding essential services and benefits in the destination Member States [COM(2002)694]. In addition, based on the principle of solidarity, no limitations on the free circulation of EU citizens are recognised.

The principle of solidarity, which also supports reg. EU n. 511/2014, could be defined as a general principle common to the laws of the Member States [Art. 340(2) TFEU] (CIPPITANI, 2011).

#### **4. THE NULLITY OF MUTUALLY AGREED TERMS AND PROTECTION OF THE COMPENSATION OF PROVIDERS**

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Starting with the above conclusion, based on reg. EU n. 511/2014 and art. 191, 192(1) and art. 340(2) TFEU, it is possible to say that in the field of biodiversity, the EU framework aims at structuring and safeguarding the EU internal market as a market that avoids bio-piracy.

The nature of the general principles of law described, which are aimed at maintaining the EU legal system and are carried out by individuals against other individuals, requires that the *effet utile* of EU rights be ensured<sup>3</sup>. In this situation, as in other similar situations, the EU legal system assigns to contracts the role not only of self-regulating the private interests directly involved in them, but also of preserving the economic order sought by the European Union.

A comparison of the term “nature” in reg. EU n. 511/2014 with that provided in art. 101 TFEU is helpful in providing a better understanding of the above consideration.

Based on Art. 101, paragraph 1, TFEU (Art. 81 of the EC Treaty) (conferring rights on individuals), persons can assert claims for damages caused by actions or contracts which may restrict or distort the competitive process.

It is well known that the full effectiveness of such a disposition - and specifically, the effectiveness of the prohibition established in paragraph 1 Art. 101 TFEU - may be jeopardised if the domestic legal system renders the exercise of the rights conferred by European Union law either practically impossible or excessively difficult (the principle of effectiveness) because of a distortion of competition<sup>4</sup>. In the *Manfredi* judgements, which confirm the Court of Justice’s reading of *Courage v. Crehan*, the Court pointed out that Art. 101, paragraph 1, TFEU has a direct effect on horizontal relationships and confers rights on individuals which the national courts must protect.

In protecting the economic order of the European Union, Art. 101 TFEU legitimises the public reliance on the invalidity of competition-restricting agreements, and therefore, enables anyone to seek the remedy of damages suffered if a causal link can be established between the aforementioned agreements or practices and the damages claimed.

Anyone (not only businesses, but also consumers) who suffers damages because of competition-restricting agreements can claim for damages<sup>5</sup>. The case law of the Court of Justice on the infringement of Arts. 101, 102 et seq. TFEU (old Arts. 81 and 82 of the EC Treaty), which are aimed at structuring and safeguarding the EU’s internal market, often combines claims for damages with those for the absolute or relative nullity of the competition-restricting contracts (SCAGLIONE, 2008).

Like Art. 101 TFEU, the general principles underlying reg. EU n. 511/2014 and the nature of reg. EU n. 511/2014, which confers rights on individuals, work within the EU legal system to maintain the economic order of the EU. It legitimises anyone’s reliance on the invalidity of mutual agreements lacking specific conditions for the fair and equitable sharing of the benefits arising from the utilisation of genetic resources or the traditional knowledge associated with genetic resources, and therefore, their ability to seek damages suffered if a causal link can be established between the agreements or practice and the damage suffered.

More specifically, the local community, the native populations and everyone involved in conserving the biodiversity and traditional knowledge associated with genetic resources, as weaker parties, can legitimately rely on the invalidity of mutual agreements lacking the specific conditions mentioned above. Thus, the infringement of EU rules through the failure to set out the specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or the traditional

<sup>3</sup> Corte giust., sent. 20-9-2001 c-453/99, *Courage/Crehan*.

<sup>4</sup> Corte giust., *Courage/Crehan*, cit.

<sup>5</sup> Corte di Cassazione, 2-2-2007 n. 2305/07.

knowledge associated with genetic resources in a contract results in the nullity of that contract.

In the case law of the EU Court of Justice regarding the infringement of arts. 101, 102 et seq. TFEU (old Arts. 81 and 82 of the EC Treaty), claims for damages are often combined with those for the absolute or relative nullity of a competition-restricting contract. Specifically, the principles of equivalence and effectiveness are the basis of the most recent intervention by the Court of Justice for damages regarding the breach of European Community competition law in the important judgement of the 13th of July 2006 (the *Manfredi* case)<sup>6</sup>.

The principle of equivalence requires the Member States of the European Union to ensure that the protection of EU civil rights is at least as effective as the national rights.

The principle of effectiveness requires the Member States of the European Union to adopt a national framework that will ensure the practice and the exercise of rights.

On the basis of the complex and substantial framework for antitrust used in this comparative analysis, it is now possible to make a few observations on the actual application of the remedial system of private law to the market.

Just as the civil protection of the weaker party in a contract to supply a monopoly is expected, according to the jurisdictional rule, the protection of the local community and the indigenous population protecting biodiversity can also be expected.

The invalidity of the contract and damages are, in fact, intertwined and take on different contours depending on the nature of the interests to be protected. This can be found only through a proper investigation of the systematic and conceptual synthesis of the doctrine.

We will start with the recognition of the essential unity of the subject, especially with regard to the execution of contracts that are prohibited on the basis that they will result in the abuse of a dominant position.

In both cases, the remedial situations to be contemplated are identical, and they should be distinguished on the basis of the interest claimed in court.

That said, the fundamental interests of the weaker party that may be asserted before the civil courts are twofold and coincide with those already examined in respect of contracts regarding competitive bidding:

a) The interest in the elimination of an unfairly unbalanced contract and b) the interest in the preservation of the contract through the balancing of the contracts' terms.

However, there may be an assumption that a) the most appropriate remedy is that of relative nullity, accompanied by an action for damages, and that b) an award of damages should open the gate to begin the rebalancing of the relationship.

The determination of a "*quantum*" of damages may not be reinstated according to unfair decisions based on the willingness of the contracting parties. It must be determined through the use of objective guidelines based on the comparison of the terms offered to the competitive structure of the market. It must be executed in this way because the weaker party is unable to assess the economic viability of the matter for the purposes of making a free and informed choice regarding the contractual conditions most favourable to him. He has nothing to compare with the terms of the offer. He is

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<sup>6</sup> Corte giust., sent. 16-07-2006 c-295-298/04, *Manfredi*.

only able to appreciate the prejudice that arises as a result of the absence of bargaining power.

In light of what has been mentioned here, it is easy to see that a nullity that is imposed making the contract null and void is essentially a sanction. The shared interests of the undertakings participating in the cartel, outside of cases of exemption, relentlessly clash with the public's interest in the efficiency of the EU market.

If the heart of the legal problem of contracts that pursue prohibited agreements is neglected, this will result in the violation the public policy of economic protection, which prohibits the freedom of contract of the weaker party from being hindered.

As a result, unlike the nullity of the agreement (which is absolute), the nullity of the contract is valid and important, because this sanction has been put in place to protect the harassed or weaker party.

The same reasoning can be used in cases involving the abuse of a dominant position through imbalanced or unfair contracts. Thus, the possibility of invalidity based on relative nullity arises as a general remedy for an imbalance of economic power, and thus, is contractual.

In order to protect compensation, it may be in the weaker party's fundamental interests to preserve the contract if the terms of the contract are revised as a compensatory measure.

Thus, on the one hand, if a weaker party has suffered damages because of an unfair or unbalanced contract, the fundamental interests of that party concerning the contract may produce a desire not to maintain the contract. In such a case, the remedy that is likely to coincide with the weaker party's interest is a nullity action related to an action for damages within the bounds of the negative interest. Conversely, the weaker party may envisage maintaining a contract that infringed competition rules. Thus, the remaining terms of the contract are safeguarded by an action for damages based on a violation of the rules intended to safeguard the internal market. In such cases, the protection of compensation is not connected to a nullity action.

## 5. RECONSIDERING THE EU APPROACH TO BIODIVERSITY

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In light of the above-mentioned legal framework, it is possible to critically analyse the EU's two-faced approach to biodiversity which proposes legal transfer models based on "benefit sharing" to the local community in order to avoid a multinational bio-raid.

When art. 4 reg. EU n. 511/2014 entered into force, problems arose regarding the correct interpretation of documents requesting patents for vegetables. In settling the different approaches that apparently exist between the jurisprudential defence of patents (Corte giust., sent. 12-07-2012 c-59/11, *Association Kokopelli v Graines Baumaux SAS*) and the EU law on the defence of biodiversity, particular attention should be paid to the use of benefit-sharing tools with regard to new varieties that are derived from traditional plant material with a view to increasing the benefits to the local communities that have traditionally maintained the selection.

Users [art. 3, point 4), reg. EU n. 511/2014] must exercise due diligence to ascertain the genetic resources. The due diligence obligation should apply to all users, regardless of their size (including micro, small and medium-sized firms) [point 23, reg. EU n. 511/2014]. Art. 4 reg. EU n. 511/2014 explains what users must do in order to comply with the "due diligence" requirement in their own activities linked with ascertaining



genetic resources: The transfer and keeping of genetic resources, including food and agriculture not listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), require the presence of an internationally-recognised certificate of compliance.

Point 21 of reg. EU n. 511/2014 requires that “genetic resources have been accessed by applicable legal or regulatory requirements and to ensure that, where relevant, benefits are fairly and equitably shared”. In that context, it is relevant that the user has obtained “internationally-recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein” (point 21), and that the national authorities have evaluated them.

Where no international certificate exists, the documents and information must be verified by the users (reg. EU n. 511/2014). Also, the regulation states that users must declare and provide evidence that they have exercised due diligence when requested.

Due diligence and an internationally-recognised certificate of compliance, as well as full information on the genetic material and resources, give attention to and address how to apply for a vegetable patent pursuant to the aims of reg. EU n. 511/2014.

It is relevant to underline point 25 of reg. EU n. 511/2014, which affirms that suitable points for such a declaration are when research funds are received, as well as at the final stage of utilisation, i.e., the stage of the final development of a product, before a request for market approval for a product developed *via* the utilisation of genetic resources or the traditional knowledge associated with such resources, or if market approval is not required, at the stage of the final development of a product before it is first placed on the Union market.

Also, in accordance with Article 291(2) TFEU, the aforementioned point 25 underlines the need for the implementing power of the EU Commission to determine the stage of final development of a product, in accordance with the Nagoya Protocol, which is the system for the protection of plant variety: See Reg. EC n. 2100/94 of 27 July 1994 on Community plant variety rights, reg. EC n. 1238/95 of 31 May 1995, which establishes rules for the application of the fees payable to the Community Plant Variety, and Reg. EC n. 1768/95 of 24 July 1995, for the implementation of the rules on the agricultural exemption set forth the system for the protection of plant variety rights established by the European Union. The abovementioned legislative framework allows intellectual property rights, which are valid throughout the EU, to be granted for plant varieties.

Even without waiting for the implementing power of the Commission, a method for applying for vegetable patents in light of the aims of reg. EU n. 511/2014 could be realised. The quickest solution could be to refuse to grant vegetable patents if the relevant documents do not indicate that due diligence has been exercised and would likely result in the nullity of a bad patent if granted. Also, in accordance with the nature of the juridical goods protected by art. 2 Prot. 1 ECHR, and allowing the direct effect of reg. EC n. 2100/94, each Member State of the ECHR could assert claims before the European Court of Human Rights in order to evaluate the legitimacy of vegetable patents granted which were initiated based on genetic resources and traditional knowledge, seeking their rejection if they do not comply with the Nagoya Protocol.

This hypothesis is strengthened by art. 2 Prot. 1 ECHR, as well as scholars’ studies (VEZZANI, 2007: 305-342) on the nature of genetic resources and traditional knowledge

as juridical goods protected by the ECHR. Genetic resources and traditional knowledge could be qualified as “goods” protected by Article 1 of the First Additional Protocol of the European Convention on Human Rights. It is clear, therefore, that the scope of the cited article is quite extensive and includes any measure that involves a legal situation regarding goods (COLCELLI, 2012). Genetic resources and traditional knowledge represent a mixture of private and public characteristics. Thus, they could be treated as impure public goods.

According to the case law of the European Court of Human Rights, the notion of goods protected by the law has a broad meaning. It is not limited to the ownership of material goods, and it not only covers private ownership rights, but extends to public benefits<sup>7</sup> and entitlements such as genetic resources and traditional knowledge.

The nature of the goods and the increasing complexity of resources, as well as the changing roles for the State, are analysed frequently because of the challenges in understanding the introduction of adaptive ecosystem governance (SANDBERG, 2007).

## 6. CONCLUSION

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The nature of reg. EU n. 511/2014 is correlated with distributive justice and the principle of solidarity, which underpin the entire EU legal system as general principles of EU law; consequently, the infringement of EU rules regarding the specific conditions for the fair and equitable sharing of the benefits arising from the utilisation of genetic resources or the traditional knowledge associated with genetic resources in a contract results in the nullity of the same contract/mutually agreed terms (which is absolute) or in the revision of the contract in order to guarantee the protection of compensation if it would be in the fundamental interests of the weaker party to preserve it. Local communities and native populations that conserve biodiversity and the traditional knowledge associated with genetic resources, as the weaker parties, can legitimately rely on the invalidity of mutual agreements that fail to include the specific conditions for the fair and equitable sharing of benefits. Actions for damages claimed by the weaker party to an unfair contract are also expected.

Reg. EU n. 511/2014 also provides for the nullity of bad patents in the absence of due diligence, internationally-recognised certificates of compliance, and full information on genetic material and resources to apply for a vegetable patent, which are the aims of reg. EU n. 511/2014. As a matter of fact, art. 2 Prot. 1 ECHR lays down a jurisprudential path for the protection of genetic material and resources in order to fully implement the spirit of the Nagoya Protocol. This is based upon the nature of the genetic resources and traditional knowledge as juridical goods and allows the direct effect of reg. EC n. 2100/94. This means that each ECHR State member can assert claims before the European Court of Human Rights to evaluate the legitimacy of the vegetable patents granted in the EU legal system to determine whether they comply with the Nagoya Protocol.

These conclusions confirm the trend in the EU legal system toward using new complementary/alternative ways to govern its market integration<sup>8</sup>, including familiar private law instruments (COLCELLI, 2013). Thus, tort or contract law are now only a

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<sup>7</sup> ECHR, *Woonbron Volkshuisvestingsgroep & Others v the Netherlands*, 47122/99/18-6-2002.

<sup>8</sup> Le Livre blanc sur la gouvernance européenne COM 428 (2001) final and Suivi du Livre blanc sur la gouvernance européenne - Pour un usage mieux adapté des instruments, COM 278 (2002) final, 5 June 2002, Recours encadré à un mécanisme de corégulation.

small part of many possible tools that can be utilised with the aim of obtaining allocative efficiency or distributive justice, which are synthetically described as correcting market failures (e.g. legal rules applicable to contracts for services, EC environmental law, environmental liability, product safety, product liability, etc.). Additionally, private law assumes the effects of the externalities suffered by third parties (see e.g. liability that may also provide ex post situational remedies in cases in which one party has been seriously underprivileged) (AMUNDSEN, BALDURSSON & MORTENSEN, 2003). In this situation, in the EU legal system, contracts are assigned not only the role of the self-regulation of the interests of the individuals directly involved in them, but also the function of maintaining the economic order of the EU (CAFAGGI & WATT, 2008), which has been described by scholars as the “social” regulation of private law (JOERGES & PETERSMANN, 2006).

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