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Theorizing an enhancement of the protection and of the justiciability of biorights in the European Union

UNA TEORIZACIÓN DE LA PROTECCIÓN Y DE LA JUSTICIABILIDAD DE LOS BIODERECHOS EN EL MARCO DE LA UNIÓN EUROPEA

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ABSTRACT

The attention given to bioethics and biolaw has grown throughout the decades in the framework of the European Union, since the first steps were taken in the field of medical products, with the adoption of Council Directive 65/65/EEC. Moving from the EU Treaties, which provide the legal bases for bioethics and biorights as well as for some potentially competing principles and interests, as the four freedoms, this study adopts a human rights-based approach to biolaw and assesses the jurisprudence of the Court of Justice of the European Union and the role of the Charter of Fundamental Rights of the European Union (CFR) from this viewpoint. Comparison is made with the jurisprudence of the European Court of Human Rights, for analysing viable paths of judicial dialogue and cross-fertilization as a response to the challenges posed by biolaw, in line with Article 52(3) of the CFR.

KEYWORDS

Court of Justice of the European Union
European Court of Human Rights
Biorights
Human embryo research
Surrogacy
Abortion
Cross-fertilization

RESUMEN

A lo largo de las décadas, la Unión Europea ha dedicado una creciente atención a la bioética y al bioderecho a partir de la adopción de la Directiva 65/65/CEE sobre las especialidades farmacéuticas. A partir del análisis de los Tratados UE y de sus disposiciones capaces de justificar la incorporación de un enfoque bioético y biojurídico, y buscando un equilibrio entre los principios e intereses contrapuestos, el presente estudio aborda la jurisprudencia del Tribunal de Justicia de la Unión Europea y el papel desempeñado por la Carta de los Derechos Fundamentales de la Unión Europea (CDFUE). Mediante la comparación con la jurisprudencia del Tribunal Europeo de Derechos Humanos, se pretende elaborar unas soluciones viables basadas en los derechos humanos para enfrentar los desafíos que plantean la bioética y el bioderecho, haciendo hincapié en la técnica de la fertilización cruzada jurisprudencial y de conformidad con el Artículo 52(3) de la CDFUE.

PALABRAS CLAVE

Tribunal de Justicia de la Unión Europea
Tribunal Europeo de Derechos Humanos
Bioderechos
Investigación con embriones humanos
Maternidad subrogada
Fertilización cruzada jurisprudencial

I. Introduction

The attention given to bioethics and biolaw has progressively grown throughout the decades in the framework of the European Union (EU). The first steps were taken in the field of medical products in 1965, with the adoption of Council Directive 65/65/EEC and, since then, the EU has addressed many areas, including data protection and the right to privacy, clinical trials on medicinal products for human use, legal protection of biotechnological inventions and the standards of quality and safety concerning several practices related to human tissues and cells. This is a growing trend, which has also led to the adoption of the ground-breaking Regulation (EU) No. 2016/679 and of Regulation No. 2017/746.

Relentless scientific progress constantly poses new challenges, and the European Union cannot overlook them; indeed, it is necessary that the EU addresses such an important field, consistently with its crucial supranational, institutional, and political role. In this sense, the EU should provide guidance to Member States, keeping in mind that the promotion of harmonization is not always neither an easy task nor a viable option when the peculiar fields of bioethics and the protection of human rights are at stake.

The purpose of this paper is to assess the responses that the European Union has aimed to provide in the field of bioethics and biolaw. To this end, firstly, an introductive analysis of the EU normative framework is made, focusing on the EU Treaties, which provide the legal bases for bioethical issues and biorights as well as for some potentially competing principles and interests as, for instance, the four freedoms. Subsequently, this study focuses on the analysis of a human rights-based approach to biolaw in the legislation of the European Union and on the role of the Charter of Fundamental Rights of the European Union (CFR) as an instrument of protection, having regard to both its potential and practical use.

In particular, the relevant case law of the European Court of Justice is taken into consideration, for assessing the strengths and the weaknesses of the Court's approach, in order to finally suggest some viable ways for developing a robust human rights-based approach to biolaw in the European Union.

To this end, comparison is made with the jurisprudence of the European Court of Human Rights, in order to evaluate whether and to which extent some guidance and inspiration may be provided by a human rights system that has proven capable of offering evolutionary and interesting responses to the challenges posed by biolaw, in line with Article 52(3) of the CFR.

II. The purposeful approach of the European Union to biolaw

The results currently achieved by the European Union in the area of biolaw are the outcome of decades-long efforts. As anticipated above, the EU made its first steps in this field in the mid-1960s, when it adopted Council Directive 65/65/EEC, that addressed the approximation of national regulatory frameworks on medical products for human use. Since then, the EU has expanded its engagement with biolegal issues to various fields. In the late 1990s, it addressed the legal protection of biotechnological inventions and *in*

IUS ET SCIENTIA • 2021
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vitro diagnostic medical devices, by adopting Directive 98/44/EC and Directive 98/79/EC. These instruments marked the beginning of an important process that is still ongoing, and that is characterized by an interesting interaction between ethics, morality, public order, at the intersection between the protection of the human beings, the interests of research and significant economic implications. In particular, it is not easy to strike the balance between the protection of human beings - and their fundamental rights – and the need to keep pace with relentless scientific progress; the tension between these different dimensions underlies the instruments adopted by the EU over the decades. In this respect, it is indicative that the EU had to update its approach in the field of medical products several times: in fact, Council Directive 65/65/EEC was repealed by Directive 2001/83/EC, which, again, was amended on several occasions. In addition, some other instruments had to be adopted for tackling the challenges related to medical products and public health, as Regulation (EC) No. 726/2004 and Regulation (EC) No. 1394/2007. As new substances, technologies and techniques spread, legal rules needed to be adjusted, also for preserving patients, consumers, and medical professionals' confidence in medical devices as well as in diagnostic and therapeutic tools. Last year, two new Regulations, namely Regulation (EU) 2017/745 and Regulation (EU) 2017/746, were adopted for the purpose of filling some of the gaps of the legal framework on medical devices. In particular, for instance, a stricter *ex-ante* control for high-risk devices was defined and post-market surveillance requirements for manufacturers were strengthened; again, a new risk classification system for *in vitro* diagnostic medical devices was provided, also in order to improve transparency.

Many other instruments can be recalled as paradigmatic examples of EU's approach to the field of bioethics and biolaw, which also includes such issues as clinical trials, the protection of informed consent and confidentiality of the participants in the experimentation, as well as the definition of oversight mechanisms headed by the European Medicines Agency. In this regard, Directive 2001/20/EC addressed the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. This instrument, now, has been repealed by Regulation (EU) No. 536/2014, that has significantly changed EU's previous approach to research, which had raised some criticism for being too strict and for having caused, in practice, a decrease in clinical trials (Daniels, 2004; Hemminki *et al*., 2006; StatBite, 2010; Frewer *et al*., 2011; Hartmann, 2012). By adopting Directive 2004/23/EC, Directive 2006/17/EC and Directive 2006/86/EC, the EU tackled another challenging field and engaged with setting common standards of quality and safety for human tissues and cells in Europe. The scope of application of these instruments is comprehensive, with the exception of blood and blood products (other than haematopoietic progenitor cells), human organs and tissues of animal origin, and tissues and cells to be used as an autologous graft within the same surgical procedure and without undergoing any banking process. The articulated normative framework that the EU has developed throughout the years is complemented by the protection ensured to personal data by Regulation (EU) 2016/679, the so called "General Data Protection Regulation", which repealed Directive 95/46/EC and addressed the processing and the free movement of personal data concerning natural persons, and

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

by Directive (EU) 2016/680 (García San José, 2018; Hoofnagle *et al*., 2019; Van Der Sloot y Zuiderveen Borgesius, forthcoming), which has repealed Council Framework Decision 2008/977/JHA and addresses the processing - and free movement - of personal data concerning natural persons by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties.

The ability of the European Union to address biolaw is all the more remarkable, when it is considered that this kind of issues do not expressly fall within its purview. Nevertheless, EU Treaties offer some suitable legal bases, which have made possible the adoption of the above-mentioned legal framework, in particular: Article 114 of the Treaty on the Functioning of the European Union (TFEU) on internal market (former Article 95 of the EC Treaty), on which the adoption of such tools as Directive 98/44/EC and Regulation (EU) 1394/2007 is based; Article 168 of the TFEU on public health (former Article 152 of the EC Treaty), with reference to Directive 2004/23 /EC and Regulation (EU) No. 726/2004; Articles 179 and the following provisions of Title XIX, Part III of the TFEU on Research and technological development (former Article 163 ff. of the EC Treaty), which provide the legal bases for several initiatives intended to support research and also mobilize funding. In practice, in this respect, significant examples can be observed in the adoption of an interinstitutional multiannual framework programme and, from 2007 to 2013, the Programme for Research and ad Technological Development. Finally, another suitable legal basis offered by the architecture of EU Treaties is Article 208 of the TFEU on development cooperation (former Article 177 ff. of the EC Treaty), which concerns Union's external action and has led to a number of initiatives aimed at promoting sustainable development and fighting poverty, as Regulation (EC) No. 1567/2003 on aid for policies and actions on reproductive and sexual health and rights in developing countries, and Regulation (EC) No. 1905/2006, establishing a financial instrument for developing countries. The possibility and the ability to rely on the available legal bases to tackle biolegal issues have resulted to be a key element for the European Union. In fact, the EU cannot overlook the challenges posed by biolaw, for a number of reasons. Firstly, because relentless scientific progress requires adequate supranational responses, largely due to the increase in the transboundary involvement of private investors in such sectors as health and research, especially when biotechnological progress is at stake. The Union had already a clear perception of the need to take action, when, in the late 1990s, adopted Directive 98/44/EC, also for the purpose, among the various aims, of attracting investments (European Commission). In that case, EU's response consisted in the definition of an accurately conceived patent regime. However, also other initiatives are necessary in this regard, especially in the framework of decision-making, and the adoption of effective regulatory instruments is of basic importance. Indeed, it is essential to ensure appropriate protection at the social level, and the protection of fundamental rights, in such a sensitive filed as biolaw, is crucial (Rogers, 2008). The connection between science and democracy is acknowledged in the framework of the European Union, that has made significant efforts to enhance public trust in "the institutional use of science" and to "increase public knowledge ad transparency about institutional procedures and

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

decision-making". That being said, EU's approach to the biolegal field is characterized, at the same time, by the promotion of the harmonization and the approximation between Member States' legal orders, and by the respect and the valorisation of the peculiarities of the different domestic realities, in light with the variety of views that inherently characterizes biolaw. In this regard the EU has aimed at striking the balance between the competing economic interests - which ontologically relate to its origins as an economic organization – and the protection of human rights, while also aiming at reconciling the divergent moral and legal views that often exist in the field of biolaw. This process is conveyed by the above-mentioned secondary sources of EU law.

From closer analysis of these tools, it can be observed that human rights were not overlooked; otherwise, several eloquent references can be found. What is more, it seems relevant to recall that the protection of human rights is of basic importance in the framework of the EU, since they consist in founding values and objectives of the Union, consistently with Articles 2 and 3 of the Treaty on the European Union. Moreover, the Charter of Fundamental Right of the European Union (CFR) is a primary source of EU law in the post-Lisbon framework, which marks the culmination of a process that started in the late 1960s, when the Court of Justice began to recognize and protect human rights as general principles of EU law (*Erich Stauder v City of Ulm - Sozialamt*, 1969; *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel*, 1970; *J. Nold, Kohlen- und Baustoffgroßhandlung v Commission of the European Communities* , 1974).

What is more, as this paper discusses more in-depth in the following paragraph, EU's approach to human rights is also defined by the close connection between the CFR and the system of the European Convention on Human Rights (ECHR). In fact, not only the rights enshrined in the ECHR "shall constitute" general principles of EU law, pursuant to Article 6(3) of the TEU as amended by the Treaty of Lisbon but, moreover, Article 52(3) of the CFR provides that the minimum scope and meaning of the human rights enshrined in the Charter is identified by making reference to the ECHR, as interpreted by the ECtHR. Incorporation of human rights in the legislation of the EU addressing bioethics and biolaw is essential for setting common standards of protection between Member States, for suiting a twofold purpose: firstly, for ensuring adequate protection to human beings in a field where scientific progress is both a means of improvement of health and well-being and, at the same time, a potential threat to human dignity and integrity. Secondly, it is essential for promoting the necessary harmonization between different national legal landscape, as far as it is possible. The latter goal cannot prescind from the pluralism of views inherent to bioethics and biolaw and, in this regard, human rights are capable of offering a least common denominator to reconcile moral divergencies, that are often likely to lead to ethical relativism (Andorno, 2002; Nickel y Reidy, 2007; Spaak, 2007; García San José, 2010; Aparisi Miralles, 2013; Donnelly, 1984). Human rights, indeed, embody shared, universal values and help to tackle the peculiarities that characterize domestic frameworks. Against this backdrop, The European Court of Justice has played a crucial role, for promoting harmonization and for enhancing the definition of a coherent and shared human rights-based approach in the context of the EU.

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

III. The elaboration of a human rights-based approach to bioethics and biolaw in the jurisprudence of the European Court of Justice

As anticipated above, some provisions enshrined in the EU Treaties provide the suitable legal bases for addressing biolegal issues. In this sense, relevant changes were introduced by the Lisbon Treaty, that not only has redefined some basic aspects related to EU's institutional framework and linked to the Union-Member States relationship but has also introduced some major changes with respect to the protection of human rights, by including the CFR among the primary sources of EU law and making it legally binding. As a result, it can be observed how human rights permeate the whole legal system of the EU and how this results in an enhancement of their role in the case law of the ECJ. In this regard, it cannot be overlooked that the Court of Justice of the European Union was not originally established as a human rights body, as it was the case for the European Court of Human Rights, instead. Nevertheless, despite in the past the Court's approach to human rights was defined "an offshoot of the EU's more central, market-led functions", it is undeniable that the ECJ has historically played a basic role in the affirmation and in the evolution of the protection of human rights since the late 1960s, when it affirmed their nature of general principles of EU law. The judgments of the ECJ in the *Stauder* case, in the *Nold* case and in the *Internationale Handelsgesellschaft* case are paradigmatic examples in this sense (*Erich Stauder v City of Ulm - Sozialamt*, 1969; *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel*, 1970; *J. Nold, Kohlen- und Baustoffgroßhandlung v Commission of the European Communities*, 1974).

Against this backdrop, since relentless scientific progress has a growing impact on life and on law and requires the rethinking of some legal approaches and categories which affect individual rights (Ienca y Andorno, 2017), it has become a crucial task for the ECJ to provide adequate human rights-consistent responses, especially by providing guidance to Member States in such an ethically and legally pluralistic field as biolaw – especially in the case of a reference for a preliminary ruling. Its case law provides various interesting examples of how the Court has addressed this challenge, which has often been intertwined with important issues related to the market and to labour law.

In this sense, the early steps were made in the early 1990s, when the ECJ was called on to decide on an Irish injunction banning the advertisement of abortion services provided by British clinics in the *Grogan* case (*The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others* 1991). Under the specific circumstances, the focus was put on the free movement of services, and the Court was called on to deal with the issues related to the freedom of expression of an Irish students' association engaged in the dissemination of information to university students on the abortion services offered in the United Kingdom. In fact, this activity was illegal in Ireland since, in those times, there was a constitutional ban on abortion, which was also provided as a crime under Sections 58 and 59 of the *Offences against the Person Act*. In particular, the Irish Constitution, at Article 40.3.3, acknowledges the right to life of the unborn "with

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

due regard to the equal right to life of the mother", prohibiting any interference and imposing on the State a positive obligation to "defend and vindicate" it. Under those circumstances, the Society for the Protection of the Unborn Children (SPUC) had filed a lawsuit before the competent domestic Court, for obtaining a restrictive injunction against the students' association in order to prevent it from continuing to disseminate information about British clinics' abortion services. Against this background and in relation to the request for a preliminary ruling of the Irish High Court, the Court of Justice was called on to address three questions: firstly, whether abortion fell within the notion of 'service' contemplated by EU law; secondly, whether the restrictive injunction granted by the Irish Court was an invalid restriction on the freedom of services under EU law; thirdly, whether the restriction amounted to a violation of human rights, with regard to the freedom of expression and to impart and receive information of the students' association.

The view adopted by the Court's ruling on the *Grogan* case is noteworthy, since it elaborated the so called "Grogan template" (Nicola y Davies, 2017), which can be found also as a characteristic of the approach of the Court of Justice in its subsequent case law, including when biolegal issues were at stake. In particular, consistently with its competence, the Court relied on legal definitions based on EU law and destined to be applied within the scope of Union law; by so doing, it did not engage with the ethical issues related to the case, which helped the ECJ to develop a legal reasoning that went beyond the peculiar domestic ethics (Nicola y Davies, 2017).

As a result, the Court came to the conclusion that the termination of pregnancy fell within the notion of "service" contemplated by EU law, since it was provided for remuneration and consisted in a professional activity, as the then-Article 60 of the EC Treaty required. Consistently with this statement, the Court rejected the SPUC's moral view that "abortion […] is grossly immoral and involves the destruction of the life of a human being, namely the unborn" (*The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others* 1991, para. 19). In fact, the ECJ clarified that "[w]hatever the merits of those arguments on the moral plane, they cannot influence the answer to the national court's first question. It is not for the Court to substitute its assessment for that of the legislature in those Member States where the activities in question are practised legally" (*The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others* 1991, para. 19). Consequently, when dealing with the other two questions referred by the High Irish Court, the Court of Justice explained that the restrictive injunction of the domestic Irish Court did not address the British Clinics that provided abortion services but, otherwise, the students' association and their activity of dissemination of information, which lacked any connection with the UK clinics as well as the "economic" characterization that would have made it relevant for EU law. Therefore, the Irish Court's restrictive injunction fell outside the scope of EU law; therefore, since the restrictive injunction was considered by the students' association the "cause" of the violation of their freedom of expression and to receive and impart information, protected under Article 10(1) of the European Convention on Human Rights (that the students' association had expressly invoked), the Court of Justice could not address the human

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

rights issues at stake in the case. Nonetheless, the judgment is not any less interesting from a biolegal viewpoint: in fact, it allowed the Court of Justice to provide some indirect protection to abortion rights and to the freedom to provide and receive information in relation to abortion services. In the *Grogan* case, the Court considered that the free movement of services could not be restrained on the grounds of an adverse domestic ethical view, even though highly sensitive and political issues were at stake. The kind of assessment that the ECJ made, including its "detachment" from moral implications in the elaboration of the EU definitional categories (Nicola y Davies, 2017), has helped the Court's jurisprudence to provide guidance and to harmonize some standards to ensure adequate levels of protection, while also avoiding to frustrate the exigencies related to research and the market. However, varying results can be observed in the subsequent Court's case law: the responses given when human rights, and especially biorights, were at stake, sometimes were satisfactory whilst, on other occasions, raised a great debate and some disappointment.

Over the following years, the jurisprudence of the ECJ had the chance to deal with biorights in other two fields, namely, on the one hand, maternity rights at workplace and non-discrimination and, on the other hand, research on human embryos and patentability under the Biotechnology Directive 98/44/EC.

Before delving into the reflection on these issues, it seems relevant to say that the Court, in the majority of cases, has succeeded to provide a quite satisfactory response to the questions related to human rights, but without making any express reference to the Charter, even when it might have been reasonably expected in light of the approach of the ECJ had adopted in other cases, under comparable circumstances.

A significant example can be found, as far as it concerns the Court's jurisprudence on maternity rights at workplace, in the *Mayr* case (*Sabine Mayr v Bäckerei und Konditorei Gerhard Flöckner OHG*, 2008), where the ECJ was called on, by the Austrian Court making the reference for a preliminary ruling, to provide interpretive guidance on the Directive 92/85/EEC, in particular on whether the guarantees it provides to women workers from dismissal in case of pregnancy also applied to employees undergoing IVF treatment before the implantation of embryos. The approach adopted by the Court echoes the "*Grogan* template": primarily, it detached from any moral implication of the case concerning IVF techniques, by clarifying that "although […] artificial fertilisation and viable cells treatment is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of Directive 92/85 taking account of the wording, the broad logic and the objectives of that directive". Subsequently, the ECJ excluded that the case fell within the scope of application of the "Pregnancy Directive", since Ms. Mayr had not undergone embryo implantation yet. Nonetheless, the Court ensured some protection by recalling *motu proprio* Directive 76/207/EEC, on equal treatment of workers regardless of their sex, now repealed by Directive 2006/54/EC: since IVF treatment can affect only women, any dismissal related to that circumstance amounts to direct gender discrimination (Nicola y Davies, 2017; Wright, 2015). It is interesting

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

to stress that the Court came to these conclusions without even recalling the Charter, which could have helped to enhance the view expressed from the perspective of human rights. In particular, the ECJ might have recalled or used in its legal reasoning Articles 21 and 23 of the CFR, respectively on non-discrimination and on equality between women and men. This might have been helpful, especially in relation to Article 21 of the Charter; in fact, that provision expressly prohibits discrimination on the grounds of gender, since it has horizontal effects, which means it applies also in disputes between individuals. In this regard, the view that the principle of non-discrimination has horizontal effects was expressed by the ECJ in the *Mangold* case (*Werner Mangold v Rüdiger Helm*, 2005, paras. 75 ff.) by recalling it as a general principle of EU law, in the pre-Lisbon framework, and was reaffirmed in the *Kücükdeveci* judgment (*Seda Kücükdeveci v Swedex GmbH & Co. KG*, 2010, paras. 21 ff.) in 2010. It seems interesting to stress that both cases dealt with discrimination on the grounds of age at workplace. A similar perspective might have been helpfully adopted in the *Mayr* ruling. Nor any reference to the Charter, in particular to Article 21, can be found when the analysis of the jurisprudence of the ECJ is extended to the case law related to the protection of women workers against discrimination on the grounds of sex in cases falling within the scope of Directive 2006/54/EC. For example, in the *Napoli* judgment (*Loredana Napoli v Ministero della Giustizia - Dipartimento dell'Amministrazione penitenziaria*, 2014) the Court made no reference to the CFR where, pursuant to several provisions including Recital 23 and Articles 1 and 14 of Directive 2006/54/EC, it found that an Italian civil servant had been discriminated on the grounds of sex. In fact, because of the fact that she had enjoyed compulsory maternity leave, she had been prevented from accessing to a vocational course, that would have given her the chance to be promoted to a higher grade and receive the corresponding better remuneration treatment (Storey y Turner, 2014).

Again, in the field of maternity rights, the ECJ had the chance to tackle one of the most controversial issues of the international legal scenario: surrogacy. This question has raised global concerns and has split the international legal, scientific and, last but not least, ethical debate; in this sense, surrogacy provides an interesting example of the pluralism of views and approaches that characterizes biolaw. In some countries, as Russia and in several States of the United States of America (like Arkansas, California, Idaho and New Hampshire. Gerber y O'Byrne, 2015), both gainful and altruistic forms of surrogacy are allowed. In Europe, the situation is varied; however, surrogacy is prevalently banned by domestic legal orders, as in Austria, France, Germany, Italy, Norway and Spain. The rejection of surrogacy as a form of exploitation of the human beings can be found also at the regional level in Europe, in the framework of both the EU and the Council of Europe (Fafce, 2017; European Parliament, 2014), according to which surrogacy violates the human dignity of the woman and causes a commercialization and an annihilation of the surrogate mother, besides being at odds with child's best interest and fundamental rights, as respect for his or her private and family life (Hrafn y Salvör, 2015).

When the ECJ was called on to express its view on maternity rights at workplace in relation to surrogacy in the *Z.* and in the *C.D.* cases (*Z v A Government Department, The Board of Management of a Community School*, 2014; *C. D. v S. T.*, 2014; Peers, 2014; Finck,

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

2014), it primarily clarified that surrogacy falls outside the scope of application of EU law, as it is not contemplated in the "Pregnancy Directive" 92/85/EEC, that pursues the objective "to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or who are breastfeeding". In a similar fashion, adoption does not fall within the scope of application of EU law either. However, it seems interesting to assess whether the Court might have sought to provide a different response to these issues, possibly by making reference to the CFR.

A brief comparison between the two cases can help to explain why a human rights-based approach was a viable option in the in the *C.D.* case, while it was not feasible in the *Z.* case. In fact, the *Z.* case patently fell outside the scope of EU law, especially of the "Pregnancy Directive", as well as of EU legislation on non-discrimination. In particular, Ms. Z. and her partner were commissioning and genetic parents of a baby; Ms. Z. had applied for the grant of the paid leave equivalent to a maternity leave or to an adoption leave, but it was denied. She argued that the refusal amounted to a discrimination on grounds of sex according to Directive 2006/54/EC with regard to the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation, and additionally alleged that she had been discriminated on grounds of disability in relation to Directive 2000/78/EC.

The Court dismissed both allegations, by clarifying that the refusal to provide a maternity leave amounts to a direct discrimination on grounds of sex only if it applies exclusively to one gender. This is not what had happened under the circumstances of the *Z.* case; in fact, a commissioning father, having his baby through surrogacy, would have equally been denied access to paid leaves, which were provided on the basis of a different condition them, that is, the previous state of pregnancy. Again, adoption leaves are an issue that was left to the free assessment and decision of Member States; therefore, they fell outside the scope of Directive 2006/54/EC and were beyond the purview of the Court. Similarly, the allegations of discrimination on the grounds of disability had to be dismissed: a woman's inability of carrying her own baby cannot be intended as a disability preventing her to exercise her professional activity, according to the definition provided by Directive 2000/78/EC and as clarified by the well-established jurisprudence of the ECJ, since the early Nineties, as it was the case for *Webb* and *HK Denmark* rulings (*Carole Louise Webb v EMO Air Cargo (UK) Ltd.*, 1994; *HK Danmark, acting on behalf of Jette Ring v Dansk almennyttigt Boligselskab(C-335/11) and HK Danmark, acting on behalf of Lone Skouboe Werge v Dansk Arbejdsgiverforening, acting on behalf of Pro Display A/S (C-337/11)*, 2013). Therefore, in this regard, the Court did not - reasonably – engage in any human rights assessment under the United Nations Convention on the Rights of Persons with Disabilities, since the case fell outside the scope of this instrument, to which the EU is Party. In *Z.* ruling, since the case fell outside the scope of Union's law, the Charter was not applicable pursuant to Article 51(1) thereof, therefore the ECJ did not engage in a human rights assessment of the case on the grounds of Articles 21, 23, 33 and 34 of the Charter, which were recalled by the Equality Court referring the case to the ECJ for a preliminary ruling.

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

The facts in the *C.D.* case were similar to those of the *Z.* ruling: Ms. D. was the commissioning mother of a baby who was genetically fathered by her husband and who was carried by a surrogate mother, and her request for a paid leave equivalent to a maternity or an adoption leave was rejected. The ECJ took up the view set out in the *Mayr* judgment in order to clarify that the condition for the enjoyment of the protection provided by Directive 92/85/EEC is the state of pregnancy, and that the refusal to grant her a maternity leave did not amount to a direct discrimination on grounds of sex under Directive 2006/54/EC, since the same treatment is provided for both commissioning mothers and fathers.

However, the particular circumstances in the *C.D.* case might have led the Court to different conclusions and, especially, the ECJ might have engaged in a human rights-based assessment due to a specific fact: Ms. D was breastfeeding the baby. The possibility to adopt a human rights-based approach and, in particular, to rely on the Charter, was suggested by Advocate General Kokott in her Opinion, where she said that "Directive 92/85, and in particular the maternity leave for which it provides, is not intended solely to protect workers. Maternity leave is also intended to protect the special relationship between a woman and her child over the period which follows pregnancy and childbirth, a position which is also consistent with Articles 24(3) and 7 of the Charter of Fundamental Rights of the European Union. In the initial stage this relationship should not suffer from the mother simultaneously pursuing employment". Advocate General Kokott came to this conclusion by adopting a "functional" instead of a "monistic" reading of the "Definitions" regarding the personal scope of application of the "Pregnancy Directive", provided by Article 2 thereof. By so doing, from that perspective, the intended mother could be compared to and be treated in the same way as the biological mother, consistently with "the basic idea expressed in Article 24 of the Charter of Fundamental Rights of the European Union, under which in all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration" (Opinion of the Advocate General Kokott, 2013, paras. 60, 52). According to Advocate General Kokott, the comparison between an intended and a biological mother was justified by "[the] 'special relationship between a woman and her child over the period which follows pregnancy and childbirth' [which] warrants protection in the case of an intended mother in the same way as it does in the case of a biological mother". The delicate early relationship between the mother and the child should be protected, according to Advocate General Kokott, because this is consistent with the Directive's proclaimed objectives; what is more, protection should be ensured even regardless of breastfeeding. However, the Advocate General did not overlook to also emphasise that "the situation of breastfeeding intended mothers is entirely comparable with that of breastfeeding biological mothers. In both cases there are health risks, for example in the case of occupational exposure to chemicals or under certain working conditions" (Opinion of the Advocate General Kokott, 2013, para. 44). It could be argued that this interpretation of Directive 92/85/EEC would have allowed to ensure more significant protection to reproductive rights, in a fashion that is consistent with the Court's approach in the *Mayr* case. In particular, by relying on the Charter, as

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

Advocate General Kokott had suggested, the Court might have framed the discourse on maternity rights in human rights terms. More specifically, this might have helped to promote and to valorise the protection of the parental relationship and of the best interest of the child, by adopting a human rights-based interpretation of EU law definitions and rules. This is particularly true for the concept of "breastfeeding" under the circumstances of the *C.D.* case.

However, the possible explanation of the Court's different approach in the *Mayr* judgment and in the *C.D.* ruling may be sought in the different ethical regional view respectively on IVF and surrogacy. Indeed, ARTs and IVF have raised some criticism and domestic approaches are varied in Europe; however, differently from surrogacy, they were not as harshly criticized and ethically rejected for being considered an exploitation of the human being and a violation of human dignity, as it happened with surrogacy instead. In this respect, it seems significant to recall the Resolution of the European Parliament dating to back to January 2016, where this EU Institution expressly "[c]ondemn[ed] the practice of surrogacy, which undermines the human dignity of the woman since her body and its reproductive functions are used as a commodity", and "reproductive exploitation and use of the human body for financial or other gain" to which women in poor countries are particularly exposed due to their vulnerable conditions, "shall be prohibited and treated as a matter of urgency in human rights instruments" (European Parliament, 2015, para. 115). Nevertheless, some time later, a more open view was expressed by the European Parliament, when, in its Briefing "Regulating international surrogacy arrangements. State of Play" (European Parliament, 2016), suggested that cross-border recognition of domestic cases and the enhanced cooperation at the EU level in such sensitive family law issues may be a viable approach for addressing surrogacy. Possibly, this view might be taken into consideration by the ECJ in its future case law.

Focusing on ARTs and IVF, consistently with the less hostile European ethical and legal landscape, the ECJ adopted a proactive approach in the *Mayr* case and found that Ms. Mayr's dismissal was discriminatory on the grounds of sex and, thus, unlawful. The Court adopted an 'ethically neutral' approach and said that it did not mean "to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions". This kind of approach may be seen as a helpful way for tackling such highly sensitive and political issues as biolaw, for the purpose of ensuring effective protection, consistently with the purposes of EU law and, at the same time, of the pluralism of the national legal views.

That being said, in its ruling, when the Court made reference to the *Mayr* case (*C. D. v S. T.*, 2014, paras. 37-39), it did it for the purpose of relying on a 'strict' conception of 'pregnancy'; as a result, the ECJ excluded that Article 8 of the "Pregnancy Directive" applied to surrogacy, "even in circumstances where she may breastfeed the baby following the birth or where she does breastfeed the baby [thus] Member States are not required to grant such a worker a right to maternity leave pursuant to that article". Nor any protection could be sought on the grounds of gender discrimination by invoking EU Directive 2006/54/EC, whose applicability was excluded, similarly to the *Z.* judgment

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

(*C. D. v S. T.*, 2014, paras. 46-50). As a result, no protection could be sought under EU law and the Charter in the *C.D.* case, as it fell outside their scope of application.

Adopting a "morally neutral" approach was harder for the ECJ when it was called on to address the concept of human embryo with respect to patentability, in relation to the Biotechnology Directive 98/44/EC. The approach of the Court in the *Brüstle* and the *International Stem Cell* cases raised some criticism, due to the legal and practical impact that those decisions had. Those cases, related to two requests for a preliminary ruling, gave the ECJ the opportunity to assess whether the Biotechnology Directive's provisions were consistent with human dignity and with human rights. This challenge was not new to the Court, since it had already tackled these issues in the *Netherlands v. European Parliament and Council* case, in the context of an annulment proceeding.

Delving into the analysis of the *Brüstle* and the *International Stem Cell* cases, the ECJ had to deal with the ethical pluralism that characterizes Member States' different approaches to some highly sensitive issues of biomedical research. In this regard, the 'Biotechnology Directive' contains a relevant provision, which aims at preserving the specific domestic ethical and legal approach adopted by each Member States, namely Article 6(1), which allows that, at the national level, specific prohibitions on patentability are introduced in case they are justified on the grounds of morality and public order. In this sense, Article 6(2) explicitly provides several possible examples of some practices that "shall be considered unpatentable", namely: the processes for cloning human beings; the processes for modifying the germ line of humans and, specifically, their genetic identity; using human embryos for industrial or commercial purposes; the processes for modifying the genetic identity of animals, which may likely cause them suffering without any substantial medical benefit to man or to animal, and also animals resulting from such processes. However, as the ECJ has clarified, an exception to the prohibition is allowed when uses and inventions for therapeutic and diagnostic purposes are applied to the benefit of the embryo.

The 'Biotechnology Directive' conveys EU's efforts to define a comprehensive legal framework, for the purpose of addressing, at the same time, the protection of the human being, the interests of research, and the financial interests of the investors. The flexible regime provided by Article 6(1) is of crucial importance in this sense, because it helps to reconcile the different interests at stake and to respect the domestic ethical and legal views, on the grounds of morality and *ordre public* exclusion, also helping to ensure, at the same time, the effectiveness of the rules enshrined in the 'Biotechnology Directive'. This approach seems particularly interesting when one considers the heterogeneous European legal landscape with regard to research on human embryos. Indeed, as authoritatively said in scholarship, the pluralism of approaches in this field, at the regional level, can be defined as "variable geometry" (García San José, 2013), that ranges from permissive approaches to restrictive regulation, while sometimes legislation completely lacks.

The important role of the provision enshrined in Article 6(1) was clarified by the ECJ few years after the adoption of the Biotechnology Directive, in the case *Kingdom of the Netherlands v. European Parliament and Council* (*Kingdom of the Netherlands v Europe-*

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

an Parliament and Council of the European Union, 2001). In particular, the Netherlands argued that Article 5(2) of the Directive, which allows the patentability of an "element isolated from the human body or otherwise produced by means of a technical process" was at odds with human dignity, human rights and integrity.

Moreover, the Dutch Government maintained that the Directive "fail[ed] to provide [adequate guarantees] for the respect of donors' right of control over donated matter and of medical patients' right of consent to treatment".

Advocate General Jacobs, in his Opinion (Opinion of Mr Advocate General Jacobs, 2001), recalled the Charter in his legal reasoning, and the Court, at least in part, supported his view in its judgment. In particular, the Advocate General suggested an interesting approach to the Biotechnology Directive, which aimed at addressing the view expressed by the Dutch Government through a human rights-based approach. Firstly, Advocate General Jacobs stressed the importance of the right to human dignity, which is "perhaps the most fundamental right of all", and is protected under Article 1 of the Charter. Subsequently, the Opinion recalled the right to free and informed consent of both donors of elements of the human body and of recipients of a medical treatment based on a material which has been processed or obtained by biotechnological means, that can be "regarded as fundamental", and is protected under Article 3(2) of the Charter" and under the Convention on Human Rights and Biomedicine of the Council of Europe. However, Advocate General Jacobs excluded that Directive 98/44/EC violates human dignity or the right to informed consent, and set out the reasons for that. In particular, this is so because the Directive does not allow patentability of "the human body, at the various stages of its formation and development", a practice that is expressly prohibited by the Directive. Although it cannot be excluded that, in the future, scientific progress might raise some concerns about human dignity and its respect, the morality and *ordre public* exclusion should grant States a 'margin of manoeuvre' wide enough to adopt appropriate responses and, if necessary, to provide adequate prohibitions (Opinion of Mr Advocate General Jacobs, 2001, paras. 199-204). Advocate General Jacobs considered the Directive did not violate the right informed consent either: indeed, the Biotechnology Directive aims at defining a common European regime of patentability but, at the same time, some issues are more properly tackled at the domestic level (Opinion of Mr Advocate General Jacobs, 2001, paras. 212-213). Therefore, it is a task entrusted to Member States to define, more specifically, how the right to informed consent is protected in relation to the field of patent law (Opinion of Mr Advocate General Jacobs, 2001, para 210). In this sense, this is consistent with Recital 26 of the Directive, which provides that the donor of the biomaterial "must have had an opportunity of expressing free and informed consent thereto, in accordance with national law" (Opinion of Mr Advocate General Jacobs, 2001, para. 207). In this respect, Advocate General Jacobs tackled these issues from a wider and thorough perspective, and also explained the lack of any express reference, in the Biotechnology Directive, to the right to informed consent of the recipients of a medical treatment based on a material which has been processed or obtained by biotechnological means, as the Dutch Government had stressed. Certainly, as the European Convention on Human Rights and Biomedi-

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

cine (also known as the 'Oviedo Convention') provides, "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it" (Convention for the Protection of Human Rights and of the Human Being with regard to the Application of Biology and Medicine, Art. 5). Nevertheless, the Advocate General clarified that the Directive was not "the proper place for rules governing the consent of the donor or of the recipient of elements of human origin", since these issues "are not to be resolved by patent law, and in particular by patent law as it applies in th[e] specific sector" (Opinion of Mr Advocate General Jacobs, 2001, para 213) addressed by the Directive. With particular reference to the recipients, Advocate General Jacobs also stressed that "The conditions of exploitation or use of patented inventions are, as discussed above, outside the scope of patent legislation, falling to be controlled by other means", consistently with Recital 14 of the Directive.

The ECJ supported the view expressed by Advocate General Jacobs in his Opinion, clarifying that the Directive does not reduce living human matter to a means to an end, since not the human body but "[a]n element isolated from [it] or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention" (Article 5(2) of the Biotechnology Directive) (*Kingdom of the Netherlands v European Parliament and Council of the European Union*, 2001, para. 74). Therefore, the 'innovation' is a necessary component for identifying a 'patentable invention'. What is more, as both the Advocate General Jacobs and the ECJ have stressed, the Directive excludes the patentability of the human body at the various stages of its formation and development, which ensures the due protection to human dignity and to integrity.

When dealing with "the fundamental right to human dignity and integrity", the Court stated that it is entrusted with ensuring their protection "in its review of the compatibility of acts of the institutions with the general principles of Community law", therefore, with human rights, as they were defined as general principles in the pre-Lisbon system of the EU law sources (*Kingdom of the Netherlands v European Parliament and Council of the European Union*, 2001, para. 70).

However, similarly to Advocate General Jacobs in his Opinion, the ECJ clarified that the protection of the right to integrity, encompassing the right to free and informed consent, is beyond the scope of the Directive. Indeed, it is "clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products".

It can be observed that the Court incorporated the human rights discourse in its legal reasoning; nevertheless, no reference was made to the Nice Charter, which may be possibly explained by the fact that, in the pre-Lisbon framework, it did not have the same prominence as today (Fact Sheets on the European Union, 2020). What is more, it was not a binding instrument. Despite this, some reference to the Charter might have been helpful, also in light of the fact that it contains – and, back then, contained – a specific provision on the right to integrity, and that it expressly addresses the "fields of medicine and biology", by also contemplating "the prohibition on making the human

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

body and its parts as such a source of financial gain" (Art. 3(2) CFR, former Art. 3(2) of Charter of Nice). The Oviedo Convention is not mentioned either; reference to this instrument might have helped the Court to provide a stronger foundation to its legal reasoning, consistently with Article 31(3)(c) of the Vienna Convention on the Law of the Treaties.

Reference to the Nice Charter and to the Oviedo Convention might have helped the ECJ to better elucidate Member States' obligations with respect to the protection of human rights when implementing the Biotechnology Directive.

However, drawing some conclusions, it seems interesting to stress that, in the *Netherlands v. European Parliament and Council* judgment, the Court adopted a human right-based approach when dealing with one of the most ethically discussed EU acts, for the purpose of affirming its validity. It appears noteworthy.

The decision rendered in 2001, in the *Netherlands v. European Parliament and Council* case, was the interesting first step taken by the ECJ with regard to the Biotechnology Directive and the protection of human dignity and human integrity in the dimension of science and its relentless progress. It took ten years before the Court was called on to deal again with these issues, and the controversial *Brüstle* case (*Oliver Brüstle v Greenpeace eV.*, 2011) gave the ECJ the chance to do this. The case was referred to the ECJ under the preliminary reference procedure by the German *Bundesgerichtshof*, namely, the Federal Court of Justice: in particular, Greenpeace had requested the annulment of the patent held in Germany by Mr. Oliver Brüstle, a German neurobiologist who claimed to have developed a promising method for the treatment of neurological disease through the production of neural precursor cells from human embryonic stem cells. Therefore, the ECJ was called on to provide its interpretive guidance with regard to several issues, namely: on the definition of the scope of the cases of non-patentability under Article 6(2)(c) of the Directive, especially on whether patentability was excluded in those cases where the patent concerned a product whose production necessitated the prior destruction of human embryos, as it was the case for Mr. Brüstle's patented process; on the definition of human embryo; on whether the expression "for industrial or commercial purposes" encompassed scientific research.

Providing a definition of 'human embryo' was clearly a highly sensitive task and, in this sense, the Court had to provide a conceptualization under EU law, specifically, under the Biotechnology Directive (Nicola y Davies, 2017). Consistently with the view expressed by Advocate General Bot in his Opinion, the Court stressed, in this respect, it was called on to address a question that was "exclusively legal in nature", as a 'neutral' approach was required by the peculiar sensitivity of the issues involved, that are particularly influenced by the national ethics.

Echoing the *Mayr* case (*Sabine Mayr v Bäckerei und Konditorei Gerhard Flöckner OHG*, 2008, para. 38), the ECJ clarified that it was not called on by the Federal Court of Justice "to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive" (*Oliver Brüstle v Greenpeace eV.*, 2011, para. 30). Under this premise, and after clarifying that "the meaning and scope of terms for which European Union law provides no definition must be determined by

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

considering, *inter alia*, the context in which they occur and the purposes of the rules of which they form part", the Court tackled the definition of human embryo by relying on the dignity of the person, seeking for some guidance in Recital 16 of the Biotechnology Directive, which "emphasises […] that 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person'" (*Oliver Brüstle v Greenpeace eV.*, 2011, para. 32). It followed that patentability had to be excluded when it was capable of violating human dignity, as it was the case for the exclusion from patentability of the human body pursuant to Article 5(1) of the Biotechnology Directive. Moreover, as the Court stressed, "[a]dditional security [was] offered by Article 6 of the Directive, which lists as contrary to *ordre public* or 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. [Moreover,] Recital 38 in the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offends against human dignity are also excluded from patentability" (*Oliver Brüstle v Greenpeace eV.*, 2011, para. 33).

As a result, the ECJ stated that the "concept of 'human embryo' within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense" and, therefore, it provided a broad definition.

In this sense, the notion of human embryo relevant under Article 6(2)(c) of Directive 98/44/EC was interpreted by the ECJ as including "any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo'", due to their capacity of "commencing the process of development of a human being" (*Oliver Brüstle v Greenpeace eV.*, 2011, paras. 36, 37).

The view taken by the Court has some important consequences, as it narrows the possibilities of scientific research: in this sense, it has an important impact on the interpretation of the Directive's purpose "to encourage industrial research and development in the field of genetic engineering" by helping the "smooth functioning of the market" through the harmonization of the national rules aimed at protecting biotechnological inventions. In this regard, the ECJ clearly prioritizes the protection of human dignity, and it can be observed that the Court ensures a wide protection not only to the integrity of the human being, but also to life. In this sense, making reference to embryo's capacity of "commencing the process of development of a human being", the ECJ has protected its 'potential' of life, despite it is not expressly said or recalled in the ruling.

In this regard, therefore, when addressing the Federal Court of Justice's preliminary question on whether scientific research fell within the expression "for industrial or commercial purposes", the ECJ said that the exclusion from patentability "covers the use of human embryos for purposes of scientific research", since "only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable". What is more, consistently with the broad conception of human embryo adopted, the Court excluded the patentability of an invention "where

IUS ET SCIENTIA • 2021
Vol. 7 • Nº 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos". In this sense, the ECJ seemed to have aligned with the regional view that can be observed also in the Oviedo Convention, for instance, which prohibits the creation of embryos for research purposes at Article 18.

In this respect, it cannot be overlooked that a common view on the definition of human embryo, for the purposes of and with respect to the scope of application of Directive 98/44/EC, can be helpful for preventing some dangerous practices as "patentability tourism" and its negative impact on the functioning of the market.

Nevertheless, it can be observed how the view taken by the Court was capable of restraining science from advancing in the fields where using embryos may be helpful; for example, one can think of the use of embryonic stem cells.

The *Brüstle* judgment raised wide criticism for its restrictive impact on scientific research, and so did also the Court's subsequent *International Stem Cell* judgment (*International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, 2014), although for different reasons. In this case, again, the ECJ was called on to provide interpretive guidance on the scope of application of Article 6(2) of the Biotechnology Directive but gave a broader reading of the concept of 'human embryo' with respect to the notion of 'parthenote'. Supporting the view taken by Advocate General Cruz Villalón in his Opinion, the ECJ clarified that, in order to be classified as a 'human embryo', an unfertilised human *ovum* whose division and further development have been stimulated by parthenogenesis – that is, a parthenote - must necessarily have "in itself" the 'inherent capacity of developing into a human being' (Opinion of the Advocate General Cruz Villalón, 2014, para. 69). In this respect, therefore, the Court put emphasis on a more specific and indicative element than the mere capacity "of commencing the process of development of a human being". This change of perspective depended on the specific scientific information provided by the referring Court in its written information, which defined a different framework than in the *Brüstle* case (Dannreuther, 2014; Bonadio y Rovati, 2015; Penasa, 2013). It followed that parthenotes fell outside the scope of the prohibition set by Article 6(2) of the Directive 98/44/EC, therefore, as a result, fertilization was irrelevant as a standard for defining an organism as a human embryo. The decision left a wider 'margin of manoeuvre' to research than the *Brüstle* judgment, which is to be welcomed from a scientific perspective, since "[s]tem cells have the potential to revolutionise the treatment of human disease because of their capacity to differentiate into almost any type of adult cell", as Henry Carr QC, a Deputy Judge of the High Court referring the question for a preliminary ruling, had stressed. This also seems in line with the purposes of the Biotechnology Directive, which highlights the need to strike the balance between the competing interests involved, namely, on the one hand, to encourage biotechnological development through an appropriate patent system and, on the other hand, to en-

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

sure adequate protection to 'the fundamental principles safeguarding human dignity and integrity" (Directive 98/44/EC, Recital 16).

However, at the same time, the ECJ failed to provide some further useful guidance, especially in relation to the stage of development at which the parthenote develops into a human being and, thus, is excluded from the notion of human embryo. This is a tricky point. In fact, on the one hand, the valorisation of the role and of the margin of appreciation of the Courts that, at either the international or the domestic level, tackle this issue, may help to keep pace with scientific progress and to provide more satisfying practical solutions. However, on the other hand, this may raise some uncertainties and cause gaps between Member States with regard to patentability (Dannreuther, 2014). Indeed, in light of the Court's view in *International Stem Cell* judgment, the exclusion of parthenotes from patentability is still a viable 'option' for Member States on the grounds of *ordre public* or morality pursuant to Article 6(1) of the Biotechnology Directive; this might pose some threats of 'patent tourism'. In this sense, an interesting example related to potential 'patent tourism' is represented by the genetic manipulation of parthenotes and their patentability, as some scholars have suggested.

The Court has not provided any further guidance from the perspective of human rights either: in this regard, the Court recalled the principle of human dignity and made reference to the *Brüstle* judgment for clarifying that its respect is a condition for patentability. However, the issues raised by the referring Court would have allowed wider analysis from this viewpoint, especially where the British High Court recalled that "[t]he Biotech Directive is to be interpreted in a way that balances these competing policy considerations", that is to promote a "research-friendly" patent regime and the protection of human dignity.

Some remarks can be made in light of the analysis of the approach of the ECJ in the *Brüstle* and *International Stem Cell* judgments. The Court's efforts to provide a definition of human embryo under the Biotechnology Directive which was "exclusively legal in nature" had a negative impact on research in Member States. In fact, despite the Court's efforts to provide a 'morally neutral' definition, the limitations on patentability that it implied were hard to reconcile with the ethical "variable geography" (García San José, 2013) that characterizes Member States' different approaches. Indeed, such a narrow reading of the concept of 'human embryo' and, in turn, of patentability under Directive 98/44/EC, appeared to be at odds with a market-led perspective, besides limiting the possibilities of research.

Again, the ECJ does not seem to have properly considered the importance of scientific research for human health, which can be of crucial relevance. This seems to be inconsistent with the Court's view that allows the "use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable". In this sense, consistently with the principle of beneficence, it could be recalled, again, how research on stem cells is resulting to be promising for treating many diseases (Mayo Clinic. 2019; Redi, 2011), and embryonic stem cells can be particularly helpful thanks to their totipotent nature (García San José, 2012; De Miguel Beriain, 2008; Penasa, 2015).

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

Both in the *Brüstle* judgment and in the *International Stem Cell* ruling, the Court has stressed the fundamental importance of the protection of human dignity and integrity. Therefore, some remarks should be made more specifically in this respect, in order to clarify the concept of human dignity under EU law. In particular, EU law conceives human dignity as an indivisible, universal and founding value of the European Union. However, consistently with the ontological flexibility of the concept (Durand, 2011; García San José, 2010; Nuevo López, 2012), the ECJ has usually entrusted Member States with identifying the specific content of human dignity, after clarifying in the *Omega* case (*Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn*, 2004; Nuevo López, 2012; García San José, 2012) that the EU protects human dignity as a general principle of law ((*Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn*, 2004, para. 34). Title I of the Charter of Fundamental Rights of the EU is dedicated to human dignity and, at Article 1, affirms its inviolability. In scholarship, different views were authoritatively advanced. On the one hand, it was advanced that the expression "human dignity" enshrined in the Charter addresses the human being and the mankind as a species and not only any born person (Nuevo López, 2012). On the other hand, in scholarship it was advanced an interesting reading of the concept of human dignity with respect to Title I of the Charter, that can have a very important impact on scientific research and, in the future, this view may help the ECJ when dealing, again, with the Biotechnology Directive. In this sense, it was suggested that the conception of human dignity enshrined in the Charter refers to the born person, not to pre-natal life. This can be inferred from the fact that the Charter provides the prohibition on human cloning at Article 3, on the right to integrity, and not at Article 2, on the right to life, which is a very eloquent choice in this respect (García San José, 2013, 2012). Had the ECJ valorised this latter conception of human dignity according to the Charter, possibly it might have adopted a more flexible view, especially considering that, in the *Brüstle* judgment, the Court had explained the reasons for the adoption of a broad concept of 'human embryo' under Article 6(2)(c) of the Biotechnology Directive by saying that "[t]he context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected" (*Oliver Brüstle v Greenpeace eV.*, 2011, para. 34). This seems all the more true when one considers that the ECJ has made reference to the commencement of the process of development of a human being as a standard for excluding patentability of the human embryo, and not such standards as the beginning of life, on which no regional consensus exists (*Oliver Brüstle v Greenpeace eV.*, 2011, para. 35).

Similar remarks could be made with respect to *International Stem Cell* judgment (Rigby, 2014; García San José, 2013; Plomer *et al*., 2008; the case could be interestingly compared with *Use of embryos/WARF*, 2008).

Some remarks can be made, conclusively, with regard to the case law of the ECJ that was analysed above. First of all, it may be argued that, when dealing with biolegal issues, the Court has achieved interesting results. In some cases, its approach was proactive,

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

and the *Mayr* judgment is evidence for that, since a purposeful paradigm of protection was adopted. Nevertheless, the Court has not adopted a human rights-based approach as much as it was possible, which is particularly true for the Charter in the post-Lisbon framework. As stated above, wider reference to human rights might have helped the ECJ to enhance the protection granted and to provide a stronger foundation to its legal reasoning. This would have been a viable and helpful way for promoting the protection of biorights in the context of the EU, which may also help to promote a shared ethical view and the harmonization of the domestic standards of protection in relation to such highly sensitive and political issues. At the same time, as mentioned above, the fact that the ECJ has advanced purposeful responses to challenging biolegal questions is praiseworthy.

Therefore, it seems interesting to question whether and how the ECJ might improve its approach and if, to this end, it might benefit from reference to the experience of the European Court of Human Rights and its wide and well-established jurisprudence in the field of biolaw. In fact, judicial dialogue and cross-fertilization between the jurisprudence of the two Courts would be consistent with the relationship that exists between the Charter and the European Convention on Human Rights on the grounds of the provision enshrined in Articles 52(3) of the Charter, which provides that the minimum scope and meaning of the human rights enshrined in the Charter is identified by making reference to the ECHR, as interpreted by the ECtHR. In this respect, further guidance is provided by the Explanations relating to the Charter, that clarify the scope of Article 52(3) by specifying that "the meaning and the scope of the guaranteed rights are determined" also by reference to the case law of the ECJ and of the ECtHR. Furthermore, it should be recalled that Article 53 of the Charter provides a non-regression clause according to which the Charter must not to be interpreted as "restricting or adversely affecting" the human rights to whose protection the Union, the Community and Member States are duty bound under international law, including the ECHR. What is more, the relationship between the EU and the European Convention on Human Rights is defined, importantly, also by Article 6(1)(3) of the Treaty on the European Union (TEU), which provides that "[f]undamental rights, as guaranteed by the European Convention […] shall constitute general principles of the Union's law".

That being said, judicial dialogue and cross-fertilization between the two Courts would also help to prevent fragmentation, which could affect the respective case law of the two major European Courts in case they did not 'communicate' with each other. Indeed, without overlooking that a different number of European States are respectively Members of the COE and of the EU,this seems particularly important for promoting a common, coherent regional ethical and legal approach in such a highly sensitive field as biolaw. In this sense, the ECJ may particularly benefit from reference to the jurisprudence of a judicial body that is specifically tasked with the protection of human rights.

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

IV. The jurisprudence of the European Court of Human Rights and the possibilities of judicial dialogue and cross-fertilization with the case law of the European Court of Justice

The European Court of Human Rights (hereinafter, the 'ECtHR' or the 'Strasbourg Court') has developed an advanced approach in the field of biolaw and a wide and well-established case law, which is unique in the international legal landscape. In this sense, this jurisprudence is evidence of the capacity of ECtHR to provide an evolutive interpretation of the ECHR as a 'living instrument' (*Tyrer v United Kingdom*, 1978; *Goodwin v United Kingdom*, 2002, para. 74; *Demir and Baykara v Turkey*, 2008, paras. 68, 146; *Vo. v. France*, 2004, para. 82 and the Dissenting Opinion of Judge Mularoni, Joined by Judge Strážnická; Letsas, 2010), and to make the 'requirements [of the Convention] practical and effective' (*Airey v. Ireland*, 1979, para. 26; Gerards, 2019).

The Strasbourg Court's approach has been crucial for facing the challenges posed by biolaw, especially for tackling the ethical pluralism that characterizes domestic legal orders; in this respect, also the theory of the margin of appreciation has played a very important role (Legg., 2012). Indeed, the task of the ECtHR was – and, of course, still is – quite complex: it has to ensure a consistent protection of human rights in Europe, preventing lacks or gaps of protection and providing guidance; at the same time, it has to respect regional ethical pluralism.

Over the years, the Strasbourg Court has been called on to express its view on many highly sensitive issues, such as research on human embryos and patentability, ARTs and surrogacy, dealing with illustrative examples of the "variable geometry" in these fields (García San José, 2013).

Our analysis of the relevant case law of the Strasbourg Court starts with an illustrative decision that the Court adopted in the early Nineties, only one year after the *Grogan* ruling was handed down by the ECJ: the *Open Door* judgment. The two cases show some similarities and both of them, importantly, concern abortion rights. However, the approach of the two Courts was different and, interestingly enough, in scholarship it was observed that the "ECJ continuously affirms the mechanical applicability of EU law categories to those matters, whereas the ECtHR [and the Commission in the *Open Door* case] consistently defers back to the States, therefore limiting the relevance of the ECHR law" (Nicola y Davies, 2017). Therefore, it was suggested that, in those days, the paradigm adopted by the ECJ in the *Grogan* ruling "did more" than the approach adopted by the ECommHR (Council of Europe, European Commission of Human Rights, 1991) and the ECtHR in the *Open Door* case (*Open Door and Dublin Well Woman v. Ireland*, 1992), for the protection of abortion rights (Nicola y Davies, 2017). Some closer analysis is necessary for making a more precise comparison. In the *Open Door* ruling, the ECtHR found a breach of Article 10 of the ECHR insofar as the injunction issued by Irish Supreme Court prevented counselling agencies from providing information about the possibility to access to abortion abroad to Irish women. The circumstances of the case were particularly dramatic, as they concerned a young girl who had been victim to a rape and threatened

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

to suicide in case she was unable to abort. Irish public opinion, in the early Nineties, was particularly sensitive to abortion issues, due to the increasing number of babies who were abandoned by their mothers right after birth and, in turn, often died. In this sense, it should be recalled that, back then, abortion was prohibited by the Irish Constitution; what is more, it is significant to remind that in 2013 the Irish Protection of Life During Pregnancy Act had been voted into law. It took many years before the situation changed when, in 2018, with a referendum, the Irish people voted to legalise abortion (McDonald y Graham-Harrison, 2018).

The ECtHR took carefully into account the domestic framework and said that the protection of morals, "of which the protection in Ireland of the right to life of the unborn is one aspect", represented a legitimate aim, pursued by the restrictions imposed by Irish law (*Open Door and Dublin Well Woman v. Ireland*, 1992, para. 63). In this sense, the Court supported the view that had been previously taken by the European Commission on Human Rights (ECommHR), which had said that "the protection afforded under Irish law to the right to life of the unborn is based on profound moral values". This approach is different from the 'morally detached' view adopted by the ECJ in the *Grogan* case, and the Strasbourg Court "acknowledge[d] that the national authorities enjoy[ed] a wide margin of appreciation in matters of morals, particularly in an area such as the present which touches on matters of belief concerning the nature of human life" (*Open Door and Dublin Well Woman v. Ireland*, 1992, para. 68), even if in Europe existed a shared consensus on the admissibility of abortion.

This is an unusual application of the doctrine of the margin of appreciation, which in general allows the Strasbourg Court to exert a more pervasive scrutiny when regional consensus on a given issue exists.

Nevertheless, the approach to abortion rights that the ECtHR adopted in the *Open Door* case was reaffirmed almost two decades later in the *A, B and C* judgment (*A, B and C v. Ireland*, 2010) when, again, the domestic morals was considered to prevail over regional consensus. Again, the Court was called on to assess whether Article 8 of the ECHR, in the right to private life, had been breached. The decision raised some debate, and the dissenting opinions of some judges of the ECtHR seem to highlight some weaknesses in the Court's reasoning. In particular, the view expressed by the Court did not seem convincing where, similarly to the *Open Door* case, a wide margin of appreciation was granted to Ireland due to the strong domestic view on abortion, despite the regional consensus favourable to abortion rights. In particular, some criticism was raised by the Court's statement that the Irish prohibition on abortion did not exceed the margin of appreciation because "the impugned restrictions […] were based on profound moral values concerning the nature of life which were reflected in the stance of the majority of the Irish people against abortion during the 1983 referendum and which have not been demonstrated to have changed significantly since then". This statement may be criticized for various reasons, firstly in light of the data - that the applicants had reported – emerging from a survey carried out in 2003 on a significant sample of population, that demonstrated that the public opinion on abortion had changed in Ireland, and was not the same as in the 1980s. Secondly, the legal reasoning of the Court did not seem very

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

convincing where it made reference to its judgement in the case of *Vo v. France* as of "central importance" for defining the width of the margin of appreciation in the *A, B and C v Ireland* ruling. In this respect, given the interconnection between abortion rights and the definition of the beginning of life, the ECtHR reminded that "it was impossible to answer the question whether the unborn was a person to be protected for the purposes of Article 2. Since the rights claimed on behalf of the foetus and those of the mother are inextricably interconnected […] the margin of appreciation accorded to a State's protection of the unborn necessarily translates into a margin of appreciation for that State as to how it balances the conflicting rights of the mother". Therefore, the Court concluded that the existence of European consensus on abortion rights could not represent a "decisive factor" when striking the balance between the competing interests at stake, and did not find a violation of the right to private life of the first and the second applicants. The ECtHR came to different conclusions with regard to the complaints of the third applicant under Article 8 of the ECHR because a risk for her life existed and, under those circumstances, Irish law allowed abortion.

In this respect, the Court, in line with its view on abortion rights and their protection under the procedural limb of Article 8 of the ECHR, found that a violation had occurred basically because Ireland had failed to adopt the legislation aimed at implementing Article 41(3)(3) of the Constitution, that contemplated the prohibition on abortion. In particular, Ireland had failed to introduce a procedure by which it could be established whether a woman qualified for a lawful abortion in the country on grounds of the risk to her life of her pregnancy. This had generated a situation of uncertainty, that was also caused "more particularly by the lack of effective and accessible procedures to establish a right to an abortion under that provision [that had generated an uncertainty resulting] in a striking discordance between the theoretical right to a lawful abortion in Ireland on the ground of a relevant risk to a woman's life [like the third applicant, who was affected by a rare form of cancer] and the reality of its practical implementation" (*A, B and C v. Ireland*, 2010, para. 264, where the Court held that "once the legislature decides to allow abortion, it must not structure its legal framework in a way which would limit real possibilities to obtain it"; *Tysiac v. Poland*, 2007, para. 116).

The view that States, in relation to the right to respect for private life, have some procedural obligations to ensure access to abortion if legislation allows it, is well-established in the jurisprudence of the ECtHR. In this sense, an illustrative example, to be recalled briefly here, is offered by the case of *Tysiac v. Poland* (*Tysiac v. Poland*, 2007, para. 116), where the Court clarified that "once the legislature decides to allow abortion, it must not structure its legal framework in a way which would limit real possibilities to obtain it." Again, in the *R.R. v. Poland* judgment, the ECtHR also specified that "[w]hile a broad margin of appreciation is accorded to the State as regards the circumstances in which an abortion will be permitted in a State, once that decision is taken the legal framework devised for this purpose should be "shaped in a coherent manner which allows the different legitimate interests involved to be taken into account adequately and in accordance with the obligations deriving from the Convention"" (*R.R. v. Poland*, 2011, para. 137).

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

Coming back to the *A, B and C* judgment, it is interesting to highlight that the ECtHR considered the possibility to access to cross-border healthcare and abortion services in another European country as a way to respect domestic moral view and ethical pluralism while, at the same time, ensuring the enjoyment of the applicant's rights. The *A, B and C* ruling is not the only example of this view, which can be found also in the *S.H. and Others v Austria* judgment with regard to *in vitro* fertilization. This decision is an illustrative example too: when called on to take into consideration the restrictive Austrian regulation on artificial reproductive techniques (ARTs), the Grand Chamber, reversing the Chamber judgment (Timmer, 2011), granted to the respondent State a wide margin of appreciation since "emerging consensus [about sperm and ova donation for the purposes of *in vitro* fertilization] is not, however, based on settled and long-standing principles established in the law of the member States but rather reflects a stage of development within a particularly dynamic field of law and does not decisively narrow the margin of appreciation of the State" (*S.H. and Others v. Austria*, 2011, para. 96; Fleig-Goldstein, 2017). Therefore, no violation of Article 8 of the ECHR was found. It is interesting to remark that, in the *S.H. and others v Austria* decision, the Strasbourg Court found no breach of Article 8 of the ECHR due to the accessibility in other countries to several types of ARTs that were prohibited in Austria.

What is more, the view of the ECtHR on the existence of a regional consensus on ARTs is questionable, as Judges Tulkens, Hivelä, Lazarova Trajkovska and Tsotsoria stressed in their Dissenting Opinion, where they said that "[t]he Court thus takes the unprecedented step of conferring a new dimension on the European consensus and applies a particularly low threshold to it, thus potentially extending the States' margin of appreciation beyond limits". However, they also added that, possibly, "[t]he current climate", namely the criticism that some States have expressed towards the Court "is probably conducive to such a backward step" (see, e.g.: *Hirst v. the United Kingdom (2)*, 2005; *Konstantin Markin v. Russia*, 2012. With regard to Article 46 of the ECHR, it is interesting to consider *Ilgar Mammadov v. Azerbaijan*, 2014, and *Ilgar Mammadov v. Azerbaijan*, 2019). Therefore, the Court's approach might be interpreted as a response to States' criticism; in this sense, it might be seen as a sort of conciliatory approach in relation to national ethics, especially in light of the important moral issues at stake in the case of *S.H. and Others v. Austria*, in such an ethically and politically sensitive field as ARTs, where important moral implications are at stake. In fact, in this sense, the Dissenting Opinion stressed that "[t]he current climate is probably conducive to such a backward step"; however, Judges Tulkens, Hivelä, Lazarova Trajkovska and Tsotsoria also observed that "[t]he differences in the Court's approach to the determinative value of the European consensus and a somewhat lax approach to the objective indicia used to determine consensus are pushed to their limit here, engendering great legal uncertainty" (*S.H. and Others v. Austria*, 2011, Dissenting Opinion of Judges Tulkens, Hivelä, Lazarova Trajkovska and Tsotsoria, para. 8. See: Rodotà, 2012).

Wider analysis of the Strasbourg jurisprudence shows how the Strasbourg Court has been exposed to States' attempts to put pressure on it: in the last years, some States, have specifically tried to influence the Court, for example by refusing or being reluctant

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

to execute the judgments of the ECtHR. The approach adopted by the Russian Constitutional Court is one of the most illustrative examples, as it refused to execute the decision of the ECtHR in the *Yukos* case (*Oao Neftyanaya Kompaniya Yukos V. Russia*, 2011) claiming that it was at odds with the Russian Constitution.

From this perspective, without forgetting the different nature of the two Courts' competence, the 'morally detached' approach of the ECJ may be helpful to handle domestic ethical implications, as well as to deal with States' pressure. As a result, it may benefit the consistency of the case law.

It is not reasonable to suggest that the ECtHR might adopt a similar approach as the ECJ; however, what appears to be desirable is that the Court gives more consideration to the evolution of the domestic moral scenario, which would have been helpful in relation to abortion rights and the change in Irish public opinion's view, for example (a comparison could be made with the relevant case law of the Inter-American Court of Human Rights, in particular: *Artavia Murillo v. Costa Rica*, 2012; *Matter of B.*, 2013. See: Chia y Contreras, 2014; Ruiz Miguel, 2014; Arango Olaya, 2014). This seems a fundamental step to promote an appropriate application of the doctrine of the margin of appreciation, and for preventing it from being misled by possible States' pressure.

That being said, it could be assessed whether the ECJ might benefit from reference to the Strasbourg case law on abortion rights, with special reference to the protection granted under the procedural limb of Article 8 of the ECHR. Before delving into these issues, it should be recalled and stressed that abortion falls outside the scope of EU law; however, the procedural guarantees ensured by the Strasbourg Court may help when tackling healthcare services in case a State allows abortion, especially for better elucidating their features. In this regard, for example, this may help to better elucidate the scope of Article 35 of the CFR on health care, which is a programmatic provision that would be benefit from the definition of some minimum basic human-rights standards of implementation. Moreover, it can be argued that, possibly, reference to the Strasbourg Court's approach under consideration may be helpful also with regard to a human rights-based reading of secondary EU law, for example, Directive 2011/24/EU, renowned as EU Patients' Rights Directive. That Directive, in fact, is a significant example of the promotion of patient mobility and access to cross-border safe and high-quality health care in the EU (Baeten, 2014), and of the cooperation between Member States. According to the Directive, patients are entitled to several rights, primarily the reimbursement of the actual costs faced. Again, the right to accountability and the right to transparency characterize the protection ensured by the Directive which, in this sense, goes beyond the view affirmed in the case law of the European Court of Justice (ECJ) that had encouraged the adoption of this act, from *Kohll* to *Watts* case (*Raymond Kohll v Union des caisses de maladie*, 1998; *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 2006). It is noteworthy that the Directive applies to all types of curative health care, including those provided privately, outside of public health system.

In the field of reproductive rights, both the ECJ and the Strasbourg Court have been called on to deal with issues related to surrogacy, a particularly highly sensitive field

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

on which, so far, neither global nor regional consensus exists. In Europe, the scenario is quite fragmented: such countries as Greece and the United Kingdom (that, as we know, is no more an EU Member State) allow altruistic surrogacy. The situation in Portugal is very interesting: in 2019, the Constitutional Court – with its decision n. 465/2019, has declared that some basic provisions of the domestic legislation on surrogacy are unconstitutional (Raposo, 2020). Russian legislation allowed both altruistic and commercial surrogacy almost thirty years ago, in 1993, but now in the country – that is a member of the COE but not of the EU – there is an important debate on the issue (The Economist, 2021). Similarly, Ukrainian legislation allowed surrogacy in 2002. On the contrary, other countries, as Finland, France, Italy and Spain expressly prohibit surrogacy. In other cases, domestic law does not regulate surrogacy as, for example, Czech Republic: in this country, due to the legislative gap, altruistic surrogacy is allowed in practice. That being said, in general, surrogacy is considered to be at odds with human dignity and is not considered morally acceptable; therefore, surrogacy is pre-eminently prohibited in Europe.

The ECtHR was called on to deal with surrogacy on various occasions. With regard to the intended parents' position, the *fil rouge* among the ECtHR decisions concerning surrogacy issues is the valorisation of States' margin of appreciation in a field where ethical as well as legal implications are highly sensitive. In practice, surrogacy is often considered at odds with overriding public interests inherent to founding values of the domestic society.

The case of *D. and Others v Belgium* (D. and Others v. Belgium, 2014) is an illustrative example in this sense. Belgium had initially refused to authorise the arrival on its national territory of a child who had been born in Ukraine from a surrogate pregnancy. The Court considered that the situation complained of fell within the scope of Article 8 of the ECHR. However, the ECtHR held that the State enjoyed a wide margin of appreciation and that it pursued a legitimate objective, namely, the prevention of crime, with particular reference to the trafficking in human beings.

Again, in the *Mennesson* (*Mennesson v. France*, 2014), *Labasee* (*Labassee v. France*, 2014), and *Foulon* and *Bouvet* rulings (*Foulon et Bouvet v. France*, 2016), the Court found that the intended parents' right to private and family life under Article 8 of the ECHR had not been violated, because the measures adopted by France did not exceed the margin of appreciation since they pursued public policy or public order, being irrelevant in this regard the existence of a genetic link between one of the intended parents and the child. Otherwise, a different consideration was given to the position of the child. Children are the most vulnerable subjects involved in this context, and they risk being affected by the adverse consequences of the prohibition of surrogacy or by the lack of national regulation, generally related to the impossibility of recognizing legal affiliation. The protection of the best interest of the child is of crucial importance when minors are involved, and it has played a fundamental role in the Court's assessment when striking the balance between the private and the public interests at stake, in relation to Article 8 of the ECHR. The ECtHR recognized that no consensus on the legality of surrogacy

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

agreements existed in Europe, but at the same time it held that State's margin of appreciation had to be considered narrow since "an essential aspect of the identity of individuals" (*Mennesson v. France*, 2014, para. 80; *Labassee v. France*, 2014, para. 79) was at stake, namely biological parenthood. Moreover, as the refusal to recognize biological parenthood would have made uncertain the granting of French nationality, it would have also affected children's identity in the French society (*Labassee v. France*, 2014, para. 76; *Mennesson v. France*, 2014, para. 100), as well as their possibility to become full members of it, and their inheritance rights. It followed that "preventing both the recognition and the establishment under domestic law of their legal relationship with their biological father, the respondent State overstepped the permissible limits of its margin of appreciation" (*Mennesson v. France*, 2014, para. 100), and that "it cannot be said to be in the interests of the child to deprive him or her of a legal relationship of this nature where the biological reality of that relationship has been established and the child and parent concerned demand full recognition thereof" (*Mennesson v. France*, 2014, para. 100).

However, recently the Grand Chamber has overturned the Chamber's judgment (that had ensured some protection to the intended parents' right to private life even if a biological link lacked between them and the child. *Paradiso and Campanelli v. Italy*, 2015, para. 69) in the case of *Paradiso and Campanelli* (*Paradiso and Campanelli v. Italy*, 2017); it provided a narrower reading of the concept of *de facto* family life (Poli, 2017) when ascertaining its existence, and adopted an interpretation prevalently focused on the element of the duration of the cohabitation rather than its 'quality'. As a result, the Court found that the best interest of the child had not been disregarded due to the separation of the child from his intended parents and by the fact that he was subsequently placed in foster care (*Paradiso and Campanelli v. Italy*, 2017, paras. 208-214).

The Grand Chamber found that State's interference was lawful since it pursued a legitimate aim, namely the prevention of disorder, and that the measure adopted was proportionate, as the applicants had - willingly - acted at odds with Italian legislation on the prohibition of heterologous fecundation and on adoption, causing the unlawful situation under consideration. It is significant to stress that Judge Dedov alone and together with Judges De Gaetano, Pinto De Albuquerque, Wojtyczek, in their Concurring Opinions, remarked the risks of human trafficking related to surrogacy and how this practice can pose high threats of commodification of the surrogate mothers as well as of the children (*Paradiso and Campanelli v. Italy*, 2017, Concurring Opinion of Judge Dedov, para. 6, and Joint Concurring Opinion of Judges De Gaetano, Pinto De Albuquerque, Wojtyczek, and Dedov).

That being said, reluctancy against surrogacy is a common trait of the approach of both the ECtHR and the ECJ. However, despite surrogacy falls outside the scope of EU law and it is not reasonable to expect EU legislation to address this field, in practice it cannot be excluded that issues of surrogacy may be involved in the fields that are covered by EU law and, thus, the ECJ may be called on to take a decision in this respect. It might happen in different ways: for example, in a similar fashion as in the *Z.* and *C.D.* cases, because maternity rights are invoked by women workers. Or otherwise, because the ECJ may be called on to take into consideration surrogacy as a "service" under EU

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

law, in relation to the freedom to provide services, as it was the case for abortion in the *Grogan* case. This possibility does not look unreasonable when one recalls that some EU Member States allow surrogacy.

In this respect, according to the '*Grogan* template', if a "service" under EU law is characterized by the fact that it is provided for remuneration and as a legally recognized professional activity, thus, surrogacy might fall within this definition. This is a possible route also because of the 'morally detached' approach of the ECJ; in this sense, it is significant to recall that the Court, in the *Grogan* case, held that "[w]hatever the merits of those arguments on the moral plane, they cannot influence the answer to [whether medical termination of pregnancy, performed in accordance with the law of the State where it is carried out, constitutes a service within the meaning of Article 60 of the EEC Treaty] [as indeed] [i]t is not for the Court to substitute its assessment for that of the legislature in those Member States where the activities in question are practised legally" (*The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others*, 1991, paras. 20, 21).

It may be argued that, consistently with this kind of approach, the ECJ might deal with surrogacy as a cross-border medical service among Member States, and it might adopt a human rights-based approach, especially the best interest of the child and the protection of vulnerable minors require it, regardless of the existence of a genetic link with the intended parents (García San José, 2017). For example, it may be made in the same fashion as Advocate General Kokott suggested in her Opinion in the *C.D.* case, through reference to Articles 24(3) and 7 of the CFR, which would help to define a family dimension consistent with the best interest of the child, that would possibly help social inclusion.

In this sense, the view expressed by the Strasbourg Court in its case law on surrogacy in the *Mennesson*, *Labasee,* and *Foulon* style, could be helpful for the ECJ, and could provide the suitable reference for the definition of a minimum threshold of protection according to Article 52(3) of the CFR.

This would be a proactive way for developing the judicial dialogue and the cross-fertilization between the two major European Courts' jurisprudence, and this would be desirable. In fact, providing some responses is necessary given the important impact of surrogacy on the lives of Europeans – and, it cannot be overlooked, of all people at the global level – and requires that at least such fundamental issues as the *status* of the children born from surrogacy and their relationship with the intended parents be addressed. These issues have to be dealt with either a genetic link with the intended parents exists or not, and regardless of the 'geographical' implications, since in many cases the questions of surrogacy go well beyond the European borders.

Importantly, both the EU and the COE, especially the ECtHR, seem to have made some interesting steps towards a more open approach, that appears to be in line with this idea.

The ECtHR, indeed, in 2019, has expressed a very interesting view in its Advisory Opinion on the request made by the French *Cour de Cassation* – the first one received by the Court since the entry into force of Protocol No. 16. In particular, in case of gestational surrogacy arrangement, the Court has held that "the child's right to respect

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

for private life within the meaning of Article 8 of the Convention requires that domestic law provide a possibility of recognition of a legal parent-child relationship with the intended mother, designated in the birth certificate legally established abroad as the "legal mother" (*Advisory opinion concerning the recognition in domestic law of a legal parent-child relationship between a child born through a gestational surrogacy arrangement abroad and the intended mother, Requested by the French Court of Cassation*, 2019, para. 1), for example, through adoption. In this sense, therefore, it may not be unreasonable to expect the Strasbourg Court to reconsider the Grand Chamber's view in the *Paradiso and Campanelli* judgment.

In this sense, it may be suggested that the regional perspective on surrogacy might be changing in Europe, at the EU and the COE level; indeed, it should be recalled that also the EU adopted a more open view in the above-mentioned European Parliament's Briefing "Regulating international surrogacy arrangements. State of Play" (European Parliament, 2016).

Certainly, surrogacy remains a highly sensitive issue, but the two major European organizations seem to have captured the importance to define some basic regional common standards for the protection of the children, their fundamental rights and their and their best interest.

Similarly to surrogacy, the definition of the *status* of the human embryo is a sensitive issue and has been challenging for the ECJ to tackle it in its judgments in the *Brüstle* case and in the *International Stem Cell* case. This question deserves some further remarks from the perspective of the judicial dialogue and the cross-fertilization between the jurisprudence of the ECtHR and the ECJ. Striking the balance between the different and often divergent interests at stake is a complex task in this context; however, research on human embryos has a huge potential, and the reflection on how to frame this issue in ethical and legal terms cannot be delayed. In this respect, it would be helpful that both Courts took into account the important and beneficial results that scientific progress and research on human embryos may offer. In this sense, it seems interesting to recall what Judge András Sajó stressed in his Dissenting Opinion in the judgment issued by the ECtHR in the *Parrillo v. Italy* case, "the important third-party interest in the health benefits arising from scientific discovery" should be taken into account (*Parrillo v. Italy*, 2015, Dissenting Opinion of Judge Sajó, para 18; Poli, 2015). This case is particularly interesting because the Strasbourg Court was called on to consider whether the prohibition on the donation of embryos for research purposes set by the Italian legislation amounted to a violation of the right to private life under Article 8 of the ECHR. A prohibition which, according to the applicant, appeared quite inconsistent when considering that Italy allows the use of cell lines obtained from human embryos destroyed abroad at an earlier stage. However, the Court recognized that, in such a delicate ethical field, States enjoy a wide margin of appreciation and, as usual, did not engage in the definition of the beginning of life (see, e.g., *Evans v. the United Kingdom*, 2007). What is more, it rejected the applicant's argument by adopting a "*gradation dans le processus de procreation*" (Poli, 2015), as it was highlighted in scholarship. This is particularly interesting from two viewpoints: firstly, because it helps to clarify that even if the ECJ had made

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

reference to the jurisprudence of the Strasbourg Court, it is not likely that it would have come to different conclusions with regard to the assessment of the stages of development of human embryo for the purposes of patentability under the 'Biotechnology Directive'. Secondly, because the 'potential of life' of the embryo, on which the ECtHR puts emphasis, precludes any possible property claim over it. The Court had focused on the peculiar link between the embryos – that had been cryopreserved (Hoffman *et al*., 2003; Toner *et al*., 2016) - and the applicant, who was the mother, whilst the father had lost his life years before in the tragic attack to the Italian base in Nasiriya, Iraq. Therefore, it had held that "the embryos contain the genetic material of the person in question and accordingly represent a constituent part of that person's genetic material and biological identity". Nevertheless, in a way that may seem inconsistent, it had come to the conclusion that "the right invoked by the applicant to donate embryos to scientific research is not one of the core rights attracting the protection of Article 8 of the Convention as it does not concern a particularly important aspect of the applicant's existence and identity" (*Parrillo v. Italy*, 2015, para. 174). Nor it would have been reasonable to expect the Strasbourg Court to address human embryos from the perspective of the right to property and, thus define them as 'possessions' under Article 1 of Protocol No. 1 to the ECHR, to be given to research through a deed of donation.

The case of *Parrillo v. Italy* is one of the most illustrative examples of how research needs to be addressed and of how crucial it is to give careful consideration to its exigencies, its benefits and its potential, and to reconcile them with the human rights discourse. In this sense, in fact, law lags behind scientific progress (García San José, 2010), whilst it would be important to give adequate attention to how promising genetic research is, and how it could help to change the lives of those patients who suffer from a genetic disease, who hope for an effective medical treatment. In this regard, it seems significant to recall how such advanced techniques as the CRISPR-Cas9 have marked the beginning of a new era, by improving targeted genome editing and the feasibility of human germline alterations. In 2015, some Chinese scientists have relied on the CRISPR/Cas9 technique in order to realize the first genetically modified human embryos by taking "human tripronuclear embryos" and alter[ing] mutant DNA that causes the human disease β-thalassemia" (Cyranoski y Reardon, 2005; Brown, 2017; Cyranoski, 2017) which caused great concern in the international community, from the perspective of ethics and safety. The point is that, however, this kind of research might help to tackle many serious diseases as, for example, cystic fibrosis, Huntington's disease and even to intervene on the BRCA mutation to which the increased risks of ovary and breast cancer is related. Scientific progress keeps evolving relentlessly: over the last years, some American researchers created the first genetically modified human embryo in the United States of America, by using the CRISPR system in a way that helped them to avoid the Congress' ban on clinical trials involving the genetic modification of human embryos (García San José, 2012; Gómez-Salvago Sánchez, 2012; Connor, 2017; Orcut, 2016); moreover, in late 2017 the news circulated that a Chinese scientist had developed a method for fixing the genetic mutation linked to β-thalassaemia in cloned human embryos (Cyranoski, 2017). Again, in late 2018, the scientific community strongly criticized the fact that the Chinese

IUS ET SCIENTIA • 2021
Vol. 7 • Nº 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

researcher He Jiankui, of the Southern University of Science and Technology in Shenzhea, claimed to have edited the genes of two baby twins to make their cells resistant to HIV infection using CRISPR-Cas9 technology (Staff and Agencies, 2018; Kuo, 2018). Important examples of advanced scientific practices can be found also within European borders: some years ago, in fact, the United Kingdom approved the UK 2015 Regulations, that allows a new form of *in vitro* fertilization that provides the replacement of mitochondrial DNA with that from a healthy donor woman, which combines with the DNA of the parents for preventing destructive cell mutations (Castro, 2016; Di Salvo, 2014).

These techniques are promising but their potential still has to be fully explored and understood since, as the scientific review "Nature" has stressed, "[t]he precise effects of genetic modification to an embryo may be impossible to know until after birth" (Lanphier *et al*., 2015). A cautious approach is necessary and human rights may offer a suitable response for reconciling the promises of scientific progress and the hope it gives to patients and the threats of risky or even unregulated research. It is necessary to adopt an internationally concerted response and to ensure appropriate judicial review, especially using the human rights language, which can help to support ethics as well as a consistent political and democratic approach.

In this regard, human dignity can play a crucial role, as it is the ultimate founding value that can help to define an ethical and human rights-consistent approach to science, in order to help scientific progress to meet patients' expectations of a dignified life.

The ECtHR and the ECJ could help to promote this kind of approach to scientific progress in their case law. In particular, they could frame science in human rights terms, and, to this end, they could use several helpful human rights instruments as a support to their interpretive efforts. Again, the results achieved may be shared and enhanced through judicial dialogue and cross-fertilization. From this viewpoint, several provisions may play an important role, especially those that contemplate the right to science or the right to enjoy the benefits of scientific progress, as Article 27 of the Universal Declaration of Human Rights (UDHR) and Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which could be used as a support to interpretation of the ECHR and the CFR, consistently with Article 31(3)(c) of the Vienna Convention on the Law of the Treaties. For example, focusing on the ECtHR, it could promote this kind of approach in its jurisprudence for elucidating States' duties under the ECHR, in particular under Articles 2, 3 and 8. It seems a viable approach in practice; in this sense, for instance, the Strasbourg Court might incorporate this view for the protection of the right to health and of human dignity, consistently with its well-established interpretation of Article 3 of the ECHR. From this viewpoint, the right to health may be read in such a way as to include some advanced scientific and therapeutic practices, especially those that can help to ensure patients a dignified life and to give them relief from the suffering that diseases cause. Again, in this way, the doctrine of the margin of appreciation should be wisely used by the ECtHR, in order to avoid unnecessary self-restraint while also respecting regional ethical pluralism on the most sensitive issues (*Costa and Pavan v. Italy*, 2012; Di Stefano, 2012, 2013; Penasa, 2012).

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

Moreover, therapeutic choices could be considered as an element of private life under Article 8 of the ECHR, as the Strasbourg Court, in its well-established case law, has interpreted the notion of private life not only as covering the right to the protection of physical, moral and psychological integrity, but also as covering the right to choose or to exercise one's personal autonomy, which also encompasses, for example, the right to refuse medical treatment or to request a particular form of medical treatment (Council of Europe, European Court of Human Rights, 2015; *Glass v. the United Kingdom*, 2004, paras. 70 ff., 74-83; *Pretty v. the United Kingdom*, 2002, paras. 61, 63).

Last but not least, it seems interesting to suggest that it would be helpful if the Strasbourg Court provided an interpretation of the freedom of expression, protected under Article 10 of the ECHR, that included not only "the right vesting in the operators in the field, namely, researchers and other scientists" (*Parrillo v. Italy*, 2013, "The Law", para. 2) to provide information, but also a patients' right to receive information about the advanced medical treatments available in case they wanted to access such therapeutic opportunities. This kind of interpretation may draw inspiration from the view expressed in the case of *Open Door*.

The kind of approach suggested for the ECtHR, with appropriate contextualization, may be helpful for the ECJ as well, not only when issues of cross-border healthcare or the freedoms of movement are at stake (see, for example, Regulation (EU) No 536/2014), but every time it is called on to deal with healthcare services. In this regard, it is significant to recall also the above-mentioned conception of human dignity as referred only to born subjects that, as authoritatively elucidated in scholarship, the CFR contemplates (García San José, 2013, 2012). In this way, the CFR might be used as a powerful tool for the promotion of a human right-consistent conception of scientific progress under EU law. This seems particularly true when one considers the scope of Article 3 of the Charter, on the right to integrity of the person, which explicitly addresses such advanced scientific issues as eugenic practices and reproductive human cloning.

V. Conclusions

Analysis of the jurisprudence of the two major European Courts has shown strengths and weaknesses in the approach that the ECJ and the ECtHR have developed when tackling such a delicate and sensitive field as biolaw. It was not an easy task for the Courts, since the issues at stake are highly sensitive and their nature is complex, as it entails, mainly but not exclusively, legal, ethical, biological, and political questions. What is more, regional views are still pluralistic in many fields, and this requires important judicial efforts for the ECtHR and the ECJ, especially when dealing with such questions as research on human embryos and surrogacy.

As observed above, judicial dialogue between the two Courts and the cross-fertilization of their respective case law may be a viable and helpful way for the definition of common, human rights-consistent standards of protection in the field of bioethics, pursuant to Article 52(3) of the CFR. This would be an opportunity to prevent fragmentation and

IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

to promote the creation of regional bioethics. Furthermore, that would help the EU to enhance its engagement in the protection of human rights as global leader, demonstrating its capacity to overcome its original economic nature, including when such sensitive issues are at stake.

Dealing with biolaw is particularly challenging: the pluralism of views is still strong in some fields and scientific progress is relentless, therefore law often "lags behind science" (García San José, 2010). Rethinking legal approaches and instruments is necessary and, as late Professor Rodotà said in *Il diritto di avere diritti*, sometimes law has to define the legal rule so that it replaces those natural rules that science has 'disrupted'. This makes it even more important for the two major European Courts to define a shared approach.

This paper has aimed at suggesting a viable path to develop this view, namely through the valorisation of a human rights-based approach. Human rights may help to define common shared standards of protection as they have proven capable of representing the minimum common denominator of the international discourse. Indeed, they represent a global *koiné*, despite some scholars have addressed them as a "cultural product" (Herrera Flores, 2005). The need to use a common language when biolaw is addressed is particularly strong at the moment, considering the challenges that scientific progress poses. The need to develop this approach transcends European borders, especially since biolegal issues, as surrogacy and research on human embryos, for instance, are global and have a cross-border impact.

Fruitful cross-fertilization and judicial dialogue aimed at the constant improvement of an equitable enjoyment of biorights in Europe is arguably one of the most interesting contributions that our Continent can offer to the creation of cosmopolitan solidarity as a response to the global ethical and scientific challenges that mankind has to face.

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ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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Vol. 7 • Nº 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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Vol. 7 • Nº 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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IUS ET SCIENTIA • 2021
Vol. 7 • N° 1 • pp. 204 - 249
ISSN 2444-8478 • http://doi.org/10.12795/IESTSCIENTIA.2021.i01.13

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