The Patentability of Human Embryonic Stem Cell-Based Inventions in the European Union

Is the current treatment of such inventions under article 6 of Directive 98/44/EC on the legal protection of biotechnological inventions consistent with European human rights laws? Does the interpretation of the morally problematic legal terms therein come under the ambit of patent law?

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Abstract

The Court of Justice of the European Union (CJEU) cases Brüstle v Greenpeace and International Stem Cell Corporation have led to many human embryonic stem cell (hESC)-based inventions becoming unpatentable under Directive 98/44/EC art 6 due to the ‘dignity’ of the ‘human embryo’. This article highlights these cases’ failure to consult external authorities when defining ‘human embryo’ and assessing its enjoyment of ‘human dignity’, despite the terms’ roots in human rights law. It notes that European patent law and human rights instruments closely linked to EU law including the European Convention on Human Rights have long accommodated European moral pluralism, arguing this has led certain EU Member States to accept the commercialisation of hESC-based inventions. This suggests the CJEU’s decisions may disproportionately interfere with competing human rights interests including those to health (due to the medical potential of hESC therapies) and to property. Equally it suggests that these decisions attempt to regulate the development of hESC-based inventions, which is problematic because in isolation patent law cannot inhibit their commercialisation. Accordingly, the article concludes that although morality plays an important role in patent law, interpreting morally problematic terms such as ‘human embryo’ and the ‘human dignity’ it enjoys falls outside its ambit.

Keywords: Embryonic stem cell, patent, human dignity

1. Introduction

The patentability of inventions based on uses of human embryonic stem cells (hESCs) is a highly controversial area, which in addition to challenges for technical reasons is open to attack on grounds of morality. This is particularly true in Europe, where the European Patent Convention (EPC)¹ art 53(a) and EU Directive 98/44/EC

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3 'Public policy'.

4 Granting Body created by EPC (n 1) ch III. A successful application to the EPO grants a ‘bundle’ of individual patents in each EPC Contracting State named by the applicant, rather than a single, unitary patent across EPO territory. This avoids the need to submit multiple applications. See EPC (n 1) art 64(1)-(2).

5 WARF/Stem Cells (G2/06) [2009] EPOR 15.

6 This article shall use the abbreviations ‘CJEU’ and ‘ECJ’ interchangeably depending on whether the Court was sitting in the post-Lisbon era or in its previous guise as the European Court of Justice.

7 Case C-34/10, Brüstle v Greenpeace eV [2011] ECR I-9821.

8 Brüstle (n 7) paras 38, 46, 52.


10 Shawn Harmon, Graeme Laurie and Aidan Courtney ‘Dignity, Plurality and Patentability: The Unfinished Story of Brüstle v Greenpeace (Case Comment)’ (2013) 38(1) EL Rev 92, 97-98.

11 Brüstle (n 7) para 26.


(‘the Biotechnology Directive’)2 art 6(1) exclude patents if commercially exploiting the underlying invention would violate ‘ordre public’3 or morality. The Biotechnology Directive art 6(2) goes on to provide a non-exhaustive list of inventions automatically falling foul of this provision, with art 6(2)(c) encompassing ‘uses of human embryos for industrial or commercial purposes’.

The Biotechnology Directive was adopted shortly before the first successful isolation of hESCs, and so makes no mention of inventions involving them. This has caused inevitable difficulties, particularly regarding the interpretation of ‘human embryo’ under art 6(2)(c). The European Patent Office (EPO)4 has adopted a broad definition of this term in an effort to safeguard the ‘human dignity’ attaching to embryos,5 which was confirmed by the Court of Justice of the European Union (CJEU)6 in Brüstle v Greenpeace.7 Here, the inviolability of ‘human dignity’ was held to necessitate the refusal of patents over hESC-based inventions involving the destruction or use as a base material of what it defined as a ‘human embryo’ – regardless of when in the development process this took place or the reason for which it occurred.8 The International Stem Cell Corporation (ISCC) judgment then clarified this by excluding inventions requiring uses of cells possessing the ‘inherent capacity’ to develop into a human being.9

However, in deciding these cases the CJEU did not consider the wealth of relevant European human rights authorities on matters including the rights of the unborn child, the needs of competing stakeholders, and the content of ‘human dignity’.10 Instead, it defined the ‘human embryo’ and its protection ‘autonomously’ for the purposes of EU law.11 Yet patents are inherently commercial in nature, and depriving inventors and investors in innovative projects of property rights over their inventions may deter them from commencing that work.12 If this occurs, the potential medical benefits of hESCs – the early application of which points to a future
revolution in numerous medical treatments\textsuperscript{13} – may be slowed within Europe to the
detriment of present and future patients.\textsuperscript{14}  

This suggests that the dignity of the human embryo was not the only relevant
consideration at stake in the CJEU decisions. Therefore, this article will firstly outline
the interaction of morality with European patent law and how it has influenced the
current approach to hESC-based inventions under the Biotechnology Directive art
6.\textsuperscript{15} Next it shall be argued that sufficient links exist between these cases and the
human rights regime to merit closer consideration of the latter's authorities on
human dignity and the status of the human embryo.\textsuperscript{16} It will be investigated
whether, due to the potential benefits for the right to health of allowing their
commercialisation and the scope to claim a disproportionate deprivation of the right
to property, the post-ISCC treatment of hESC-based inventions under the
Biotechnology Directive art 6 presents inconsistencies with European human rights
laws.\textsuperscript{17} Finally, as the CJEU ‘autonomously’ defined the ‘human embryo’ purely to
apply the Biotechnology Directive art 6, it shall be asked whether the interpretation
of such morally problematic terms falls under the ambit of patent law and what
implications this isolated approach may have.\textsuperscript{18}

2. Morality in European Patent Law

A. Background

It has long been accepted that to receive a patent, applicants must demonstrate that
their inventions are novel, implement an inventive step, are industrially applicable,
and fall outside the exceptions to patentability.\textsuperscript{19} These criteria have become uniform
standards within Europe by means of the EPC, which has been transposed into the
national legislation of all signatory states\textsuperscript{20} and so influences the grant of both
‘bundle’ EPO patents and those in individual states.\textsuperscript{21} Paten
tees receive a negative
right to prevent others from infringing upon\textsuperscript{22} their invention – which, following the
Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS

\textsuperscript{13} Scott Parker and Paul England, ‘Where Now for Stems Cell Patents?’ (2012) 7(10) JIPLP 738, 738;
\textsuperscript{15} Harmon, Laurie and Courtney (n 10) 97.
\textsuperscript{16} Part 2.
\textsuperscript{17} Part 3.
\textsuperscript{18} Part 4.
\textsuperscript{19} Part 5.
\textsuperscript{20} EPC (n 1) art 52; Patents Act 1977, s 1.
\textsuperscript{21} There are currently 38 signatory states. See EPO, ‘Member States of the European Patent
February 2015.
\textsuperscript{22} Each EPO (and therefore EU) Member State continues to grant national patents in accordance with
the EPC alongside the ‘bundle’ European patents – see Charlotte Waelde and others, Contemporary
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Agreement), lasts for at least twenty years\textsuperscript{23} – and in this sense gain a limited monopoly over its use in return for releasing its innovative details into the public domain. Thus, as noted in the introduction, refusals of patentability can have adverse commercial consequences.\textsuperscript{24}

Such exclusions have always been a part of the patent regime,\textsuperscript{25} as have revocations of protection after grant,\textsuperscript{26} however EPC art 53(a)’s ‘ordre public’ and ‘morality’ exception received little attention until recent advances in biotechnology.\textsuperscript{27} Biotechnological inventions challenge the patent system in general due to the complexity of ascertaining their inventive qualities,\textsuperscript{28} but this is especially true where the morality exception is engaged. This was illustrated by the EPO’s difficulties in balancing the suffering of genetically-engineered mice with the benefits of advancing mankind’s understanding of cancer in \textit{HARVARD/Oncomouse}.\textsuperscript{29} Similar difficulties were experienced at a national level which was problematic for the EU\textsuperscript{30} as the lack of a common policy towards biotechnological inventions led to an increasingly fragmented legal landscape within its territory.

B. The Biotechnology Directive

Therefore, the European Commission drafted the Biotechnology Directive\textsuperscript{31} in an effort to harmonise the treatment of biotechnological inventions by the EU Member States’ patent regimes,\textsuperscript{32} with corresponding Regulations being incorporated into the EPC.\textsuperscript{33} This clarified that biological material isolated from its natural environment constitutes an invention rather than a discovery\textsuperscript{34} provided it satisfies the patentability criteria.

However, the ethical controversy surrounding biotechnology caused the Directive’s initial rejection\textsuperscript{35} and the adoption of a revised version in 1998 which pays

\begin{footnotesize}
\textsuperscript{23} Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C (TRIPS) art 33, annexed to the Agreement Establishing the World Trade Organisation arising from the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and administered by the World Trade Organisation - Waelde and others (n 21) para 10.42.

\textsuperscript{24} Biotechnology Directive (n 2) Recital 14; Howard Florey/Relaxin T74/91 [1995] EPOR 541 (Op Div), para 6.3.3.

\textsuperscript{25} EPC (n 1) art 53.

\textsuperscript{26} ibid art 138.

\textsuperscript{27} Waelde and others (n 21) para 11.51.

\textsuperscript{28} See, for example, the UK case \textit{Asahi Kasei Kogyo} [1991] RPC 485, where a genetically engineered protein was deemed novel despite a reference to its natural existence in an earlier patent.

\textsuperscript{29} \textit{HARVARD/Oncomouse} (T19/90) [1991] EPOR 525.

\textsuperscript{30} All EU Member States are also EPC Contracting States.

\textsuperscript{31} Originally proposed in 1988.


\textsuperscript{33} Implementing Regulations to the Convention on the Grant of European Patents, Part II, Ch V (as amended 2012).

\textsuperscript{34} Biotechnology Directive (n 2) art 3(1); Aurora Plomer (Project Coordinator), ‘Stem Cell Patents: European Patent Law and Ethics Report’ (Nottingham, 2006) 18-20

\texttt{<www.nottingham.ac.uk/~llzwvw/StemCellProject/project.report.pdf>} accessed 4 March 2015.

\textsuperscript{35} Biotechnology Directive (n 2) art 3(1).

\textsuperscript{36} Porter (n 32) 13.
\end{footnotesize}
greater attention to moral sensitivities. Principally this includes the aforementioned denial of patentability where commercial exploitation contravenes ‘ordre public’ or morality, and art 6(2)’s list of examples of such inventions. Art 5 also precludes the human body from patentability at any stage of development, but under art 3(2) an element isolated from it by means of a technical process is patentable. This is reinforced by Recitals 16 and 38, which state that such inventions must not be contrary to ‘human dignity’.

Thus it appears that the protection of this fundamental principle was always envisaged in part through art 6’s ‘ordre public’ and morality exception, which provides a check on the Biotechnology Directive’s conflicting but related aim of promoting patentability and innovation. This is supported by the ECJ decision Kingdom of the Netherlands v European Parliament, which stated that in addition to art 5, art 6(2)’s exemplary list of unpatentable inventions helps ensure the safeguarding of human dignity.

It is this complex legislative framework that was applied by the CJEU in the hESC-based inventions cases Brüstle and ISCC. Yet in so doing, despite basing its definition of ‘human embryo’ on the somewhat indeterminate principle of ‘human dignity’, little consideration was given to what this value actually encompasses. As it is rooted in human rights law and theory, it appears that authorities from this area would have provided a useful insight into the assessment of hESC-based inventions. However, this has occurred in neither the main cases on the ‘ordre public’ and ‘morality’ exceptions, nor the hESC-based inventions decisions.

C. ‘Ordre public’ and ‘Morality’

These terms have long been associated with intellectual property regimes, as illustrated by the EPO case Plant Genetic Systems (PGS), decided before the adoption of the Biotechnology Directive. Here ‘ordre public’ was stated to encompass matters including the protection of the physical integrity of individuals, whilst ‘morality’ concerned ‘the belief that some behaviour is right and acceptable whereas other behaviour is wrong (…) rooted in a particular culture’. For the EPO, the relevant culture was that of European society as a whole. Yet the exact content of such standards remained unclear, meaning that despite consensus on issues such as the

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37 Biotechnology Directive (n 2) art 6(1).
38 ibid art 6(2).
39 ibid art 5(1).
40 ibid art 5(2).
41 Brabin (n 13) 690.
44 Netherlands (n 43) paras 76-77.
45 Harmon, Laurie and Courtney (n 10) 96-97; elaborated upon in Part 3.
46 Paris Convention for the Protection of Industrial Property, as amended (20 March 1883) art 6 B(3) concerning Trade Marks.
48 PGS (n 47) 366.
immorality of human cloning, the acceptability of hESC research gave rise to a plurality of views between states. This led the EPO to repeatedly to interpret art 53(a)’s provisions narrowly.

European value pluralism was also reflected at EU level by the Netherlands decision. In addition to the safeguarding of human dignity mentioned above, it was observed that ‘ordre public’ was well-recognised in Community law, and that when applying morality exceptions to movement of goods provisions Member States could refer to their ‘own scale of values’. Therefore, a ‘wide scope of manoeuvre’ for Member States in the application of art 6(1) was acknowledged as a means of respecting cultural sensitivities, though it also noted that art 6(2)’s list of immoral inventions prevented the provision becoming discretionary.

This was supported by Commission v Italy, which considered art 6(2) to allow Member States no discretion in transposition as its purpose is ‘to give definition to the exclusion laid down in art 6(1)’. The provision was therefore argued to be definitional rather than moral in nature, meaning that under art 6(2)(c) only industrial or commercial uses of human embryos, rather than of hESCs, should be excluded as any wider definition would ignore the moral pluralism surrounding such inventions.

Thus it appeared that art 6 was to be interpreted narrowly, and any extended application to hESC-based inventions seemingly had to be justified with reference to fundamental European values such as ‘human dignity’. Once again, therefore, it is clear how regard to the human rights regime could be useful in the application of the ‘ordre public’ and morality exception.

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49 Acknowledged in Biotechnology Directive (n 2) Recital 40 and unpatentable under art 6(2)(a).
50 See Part 4.
54 Case 34/79 Henn and Darby [1979] ECR 3795, para 15.
55 Netherlands (n 43) para 38.
56 ibid para 39.
57 Case C-456/03 Commission of the European Communities v Italian Republic ECR 1-5335.
58 ibid para 78.
60 Plomer, ‘Stem Cell Patents’ (n 34) 71-73; Pierre Triechel, ‘Case Comment: G2/06 and the Verdict of Immorality’ (2009) 40(4) IIC 450, 465-466.
62 Harmon, Laurie and Courtney (n 10) 95-98.
D. hESC-Based Inventions

As noted above, however, the Directive makes no mention of hESC-related inventions. Thus, the extent to which patents involving methods of extracting hESCs necessitating the destruction of human embryos engaged art 6(2)(c)63 was uncertain.

The issue was first addressed by the EPO in the Edinburgh patent64 case. Here, the definition of ‘morality’ enunciated in PGS was repeated, but as no ‘uniform’ European approach to hESCs could be ascertained,65 a broad construction of EPC Rule 28(c) was adopted where an invention isolating ‘animal’ transgenic stem cells also encompassed hESCs. This was justified on the basis that a narrow protection of embryos ‘as such’ was already provided by Rule 23d(e),66 and that Biotechnology Directive Recital 16’s reference to respect for dignity and integrity of the person necessitated the preclusion of hESCs from patentability due to their destructive origins.67

This approach was followed in WARF/Primate ESCs, which declared an invention enabling the production of hESCs unpatentable.68 Indeed, its scope was extended to preclude inventions requiring uses of destructive methods even where they were not mentioned in the claims,69 though it also left open a ‘deposit loophole’ whereby patents would be granted if performing the invention required no further destruction.70

These cases prompted fears in some quarters that future hESC research would be overly restricted,71 whilst elsewhere the EPO’s wider conception of ‘human embryo’ that considered stakeholders other than the patentee was praised. Yet, Harmon notes that they remained lacking in meaningful engagement with the balancing of these issues, and were decided in isolation of overarching principles from relevant legal regimes such as the European Convention on Human Rights (ECHR).72

WARF’s approach was then built upon at EU level by the CJEU’s preliminary ruling in Brüstle v Greenpeace. After the German Bundesgerichtshof (Federal Court of Justice, BGH) asked it to define the term ‘human embryo’ under art 6(2)(c), the court gave a wide, ‘autonomous’ interpretation to be applied solely for the purposes of EU

63 Together with its EPC (n 1) counterpart, Rule 28(c) (former Rule 23d(c)).
65 Edinburgh at [2.5.3], as cited by Harmon (n 64) 396.
66 Biotechnology Directive (n 2) art 5(1) equivalent.
67 Harmon (n 64) 396-397.
68 WARF (n 5).
69 Waelde and others (n 21) para 12.60.
71 Harmon, Laurie and Courtney (n 10) 100-101.
72 Convention for the Protection of Human Rights and Fundamental Freedoms 1950 (European Convention on Human Rights, as amended) (ECHR); Harmon (n 64) 399-403.
law in order to avoid divergence in the patentability criteria of Member States. This definition encompassed:

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.

As such cells were considered capable of commencing ‘the process of development of a human being’, respect for ‘human dignity’ was held to necessitate their unpatability, although Member States were permitted to determine whether hESCs obtained from human blastocysts also fell under the term.

Yet, this definition was formulated with minimal consideration of both the term ‘human dignity’ and European moral pluralism on the status of the human embryo. The CJEU claimed it was adjudicating on a purely legal – as opposed to medical or ethical – issue, but neglected to consider the numerous legal authorities in this area – particularly from the European human rights regime. These were dismissed by Advocate-General Bot as irrelevant because they related to subjects outside the EU’s competence including abortion. However, the Biotechnology Directive itself specifically recalls the authority of fundamental freedoms enshrined in the ECHR – which, following the Treaty of Lisbon, are even more closely integrated into the EU legal order. This has also raised arguments that the decision is inconsistent with the Directive’s Recital 8, as the ‘autonomous’ definition effectively constitutes a legal term entirely separate from its understanding in national patent laws.

On the basis of this wide definition, the CJEU responded to the BGH’s second question by declaring inventions involving uses of embryos for scientific purposes unpatabile due to the commercial and industrial interests inherent to applying for patents over such products. This is again problematic as it causes extended interferences with private property rights. Furthermore, the need to protect the dignity of human embryos as defined in this case was held to necessitate the

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73 Brüstle (n 7) paras 26-28.
74 ibid para 38.
75 ibid paras 34-36, 38.
76 ibid para 30; this contention is also debatable as suggested by the activity in this area by Ethics Committees such as the European Commission’s European Group on Ethics in Science and New Technologies; to which Recital 44 of the Biotechnology Directive specifically refers: ‘Whereas the Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles’.
77 Harmon, Laurie and Courtney (n 10) 96.
78 Brüstle (n 7) Opinion of AG Bot para 49.
79 Biotechnology Directive (n 2) Recital 43; all EU Member States are also High Contracting Parties to the ECHR.
80 Harmon, Laurie and Courtney (n 10) 95-99; see also Part 3 section C.
81 Harmon, Laurie and Courtney (n 10) 97; Plomer, ‘After Brüstle’ (n 61) 125; see also Part 5.
82 Brüstle (n 7) para 41.
83 Plomer, ‘After Brüstle’ (n 61) 130-135.
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unpatentability of inventions requiring their destruction or use as a base material at any point in the development process. This closed WARF’s ‘deposit loophole’.  

Brüstle was therefore criticised due to concerns the ‘immoral’ origins of hESC-based inventions would render them largely unpatentable, despite their moral acceptability in certain Member States. Given the innately commercial nature of patents, concerns also arose that – to the detriment of healthcare patients – investment in European stem cell research would decline. These were compounded when TECHNION/Culturing Stem Cells incorporated Brüstle into EPO jurisprudence, extending the ruling’s scope outside EU territory.

However, the recent CJEU case ISCC clarified a limitation to Brüstle in the light of clearer scientific evidence. Brüstle’s inclusion of human ova stimulated by parthenogenesis under the term ‘human embryo’ caused confusion as they are unable to form extra-embryonic tissue needed to develop to term. Indeed, similar cases led the BGH to permit the Brüstle patent where its claims explicitly excluded uses of destructive methods after the CJEU’s ruling – though this has been criticised for equating ‘destruction’ to ‘uses’ of the human embryo for industrial or commercial purposes. It was held in ISCC that such cells were not human embryos as they lacked the ‘inherent capacity’ to develop into a human being, subject to Advocate-General Villalón’s caveat that later genetic manipulations restoring that capacity would render them again unpatentable. Thus, this case allows patents over hESC-based inventions in certain circumstances. However, Plomer argues the ‘inherent capacities’ test promotes uncertainty as it leaves Brüstle’s extensive definition of ‘human embryo’ intact and raises questions over how particular types of embryo – such as those left over from in vitro fertilisation (IVF) treatment – are capable of developing to term. Furthermore, it still neglects to consider human rights authorities on human dignity and the human embryo, or to balance these concerns with competing interests.

84 Brüstle (n 7) para 52.
87 Harmon, Laurie and Courtney (n 10) 100-101.
88 T2221/10 [2014] EPOR, 23.
89 Mahaalatchimy and others (n 85).
90 ISCC (n 9) para 38.
91 O’Sullivan (n 42) 162.
92 ISCC (n 9) para 38.
E. Summation

Part 2 has sought to demonstrate that the EU and EPO patent regimes have always recognised the overarching need to respect fundamental values such as human dignity. However, this principle’s grounding in human rights philosophies means it has interacted through its influence on human rights laws with other moral issues seen in the hESC-based inventions cases – including the nature and status of the human embryo. This also encompasses the protection of ‘ordre public’ to the extent that it addresses respect for physical integrity. Yet the CJEU made no link between the two in Brüstle, which has resulted in the wide, ‘autonomous’ post-ISCC approach seen today. Therefore, Part 3 will expand upon the intersection between the Biotechnology Directive and human rights laws.

3. The Intersection with Human Rights

A. Morality, Human Rights and Biotechnology

The relationship between morality and the law in general has long been a source of legal and philosophical debate. This is no different in the field of human rights law, with commentators arguing that it draws upon and gives legal force to ‘moral’ values. Indeed, early legal instruments incorporating elements of such rights reflect the teachings of natural law; whereby legal rules were thought to arise from the individual’s inherent ability to naturally know right from wrong. In Locke’s view this drove human beings to form political orders respecting everybody’s fundamental rights; including those to life, liberty and property.

Following World War II, modern forms of human rights philosophies have come to the fore; largely centring on Kant’s view of ‘personhood’, whereby all individuals enjoy a minimum level of protection simply due to their membership of the human race. For example, this concept can be seen underlying Dworkin’s argument that human rights are based on affording privileged status to basic values

95 PGS (n 47) 366.
99 Shestack (n 98) 42-44.
that ensure the equal treatment of all. This led him to reject an entirely utilitarian consideration of what constitutes a societal benefit.\textsuperscript{100}

It is submitted that this core value of respect for the individual, arising purely out of their being, encompasses the concept of ‘human dignity’. This is reflected by the Universal Declaration of Human Rights (UDHR),\textsuperscript{101} which recalls the ‘inherent dignity’ and ‘equal and inalienable rights of all members of the human family’, arising solely from the fact of being born.\textsuperscript{102} Furthermore, though the UDHR itself is not legally enforceable, it is expanded upon by the International Covenants on Civil and Political Rights (ICCPR)\textsuperscript{103} and Economic, Social and Cultural Rights (ICESCR);\textsuperscript{104} both of which are overseen by compliance Committees.\textsuperscript{105} The Preambles of these Covenants retain references to the ‘dignity’ of every ‘human person’, and state that all rights found therein arise from this principle.\textsuperscript{106}

It can therefore be argued that these provisions reflect a conception of ‘human dignity as empowerment’, where it is the overarching principle giving validity to the other rights recognised by the universal human rights regime.\textsuperscript{107} However, those rights inevitably come into conflict with one another - particularly where biotechnology is concerned. Indeed, the acceptance that biotechnological progress requires balancing with fundamental rights\textsuperscript{108} has prompted the adoption of non-binding documents including the Universal Declaration on the Human Genome (UDHG).\textsuperscript{109} Whilst art 1 of this Declaration reiterates the need to recognise the ‘inherent dignity’ of the human family, new considerations including the principle of non-commercialisation of the human body and its parts\textsuperscript{110} are also present. Many writers suggest this reflects the operation of ‘dignity as constraint’ on biotechnological development.\textsuperscript{111} In this way, the principle encourages innovation on a ‘responsible moral basis’ whereby such work is not entirely prohibited but acknowledges the rights of others whose dignity may be compromised.\textsuperscript{112}

\begin{thebibliography}{99}
\bibitem{100} ibid 55.
\bibitem{101} Universal Declaration of Human Rights (10 December 1948) UNGA Res 217 A(III) (UDHR).
\bibitem{102} UDHR (n 101) Preamble, arts 1-2.
\bibitem{103} International Covenant on Civil and Political Rights (signed 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR).
\bibitem{106} ICCPR (n 103) Preamble; ICESCR (n 104) Preamble.
\bibitem{109} Universal Declaration on the Human Genome and Human Rights (11 November 1997) UNGC 29 C/Res 16.
\bibitem{110} ibid art 4; later seen in Biotechnology Directive (n 2) art 5.
\bibitem{111} Beyleved (n 107) 40-43; Francioni (n 108) 20.
\end{thebibliography}
Thus it is clear that morality and human rights laws are inherently inter-related, with the latter attempting in part to provide minimum levels of respect for the moral value of ‘human dignity’ inherent to all individuals. Part 2 noted that the hESC-based inventions cases refer to the immorality of violating the ‘human dignity’ of human embryos. This implicitly (under the post-JSCC regime) assumes that any cell possessing the ‘inherent capacity’ to develop into a human being is subjected to the operation of ‘human dignity’, either ‘as constraint’ on the actions of others or ‘as empowerment’ so that other rights attach to it and prevent its use. Therefore it is possible to suggest that human rights authorities on the right to life of the unborn child and other issues concerning dignity and the human embryo should be considered.

These will now be discussed within the European human rights framework.

B. The Council of Europe

The Council of Europe’s principal human rights mechanism is the ECHR; which, as noted in Part 2, is specifically referred to as authoritative by the Biotechnology Directive.113 In contrast to the universal human rights regime, this Convention initially made no mention of the term ‘human dignity’, though it is now cited to justify abolishing the death penalty.114 However, the concept’s importance as a ‘fundamental objective of the Convention’ has long been recognised by the European Court of Human Rights (ECtHR).115

The ECHR’s sole reference to ‘human dignity’ is recalled alongside the ‘basic value’ of the right to life.116 Art 2 guarantees this right to ‘everyone’, but gives no indication of when it begins. This has prompted litigation on the status of the human embryo. For example, in Vo v France117 it was alleged that by declining criminally prosecute a doctor whose negligence caused a patient to miscarry, France failed to protect the foetus’ right to life under art 2. In response, the ECtHR consulted numerous ethical and legal authorities and found that there was no consensus in France or Europe regarding the nature and rights of the unborn child. Accordingly it applied a margin of appreciation, affording France a scope of manoeuvre to decide on such issues at national level.120

This was reinforced by Evans v UK,121 in which the margin of appreciation was relied upon when refusing to consider the right to life of human embryos frozen for the purposes of IVF treatment. As the would-be father withdrew his consent to their

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113 Biotechnology Directive (n 2) Recital 43.
114 ECHR (n 72) Protocol 13 Preamble.
115 S.W. v UK App No 20166/92 (ECtHR, 22 November 1995) para 44.
118 Vo (n 117) 277-280.
119 ibid 274-277.
120 ibid 296-298.
121 Evans v UK App no 6339/05 (ECtHR, 10 April 2007).
implantation, it was held that his right to choose not to become a father outweighed any right the embryo may have enjoyed.

Thus it appears there is nothing to suggest any European consensus on when ‘human dignity’ takes hold of the human embryo. This is supported by the rejection of numerous opportunities to protect the unborn child from conception under the universal human rights regime. Indeed, as Vo and Evans illustrate, whilst it accepted that the embryo belongs to the human race, the ECtHR has recognised that precisely because of the disharmony over the level of protection it requires, High Contracting Parties are entitled to approach the issue individually, each according to the moral views of their people.

With regard to hESC-based inventions, therefore, it may be argued that European human rights laws do not regard ‘human dignity’ as providing the human embryo with a right to life from conception. Thus, to declare such inventions unpatentable across all Member States, their commercial exploitation would have to run contrary to this principle.

This may be possible under the Oviedo Convention, a Council of Europe mechanism which attempts to incorporate human rights into the growing field of biomedicine and prohibits all uses of the human body, as such, for financial gain. Thus, whilst this seemingly reflects the Biotechnology Directive in allowing commercialisation where isolated elements are used, if read in conjunction with art 18(1)’s requirement that the human embryo in vitro enjoy ‘adequate protection’ when involved in research, it may be argued that commercially exploiting methods that entail the embryo’s destruction or use as a base material – as a stage of the body’s development – is unacceptable. This is based on the recognition of the ‘dignity’ of ‘everyone’, though Vo noted that the plurality of European views concerning when life begins led the Convention’s framers to leave the term ‘everyone’ undefined so signatory states could approach it individually. It is therefore clear that ‘human

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122 ECHR art 8 enshrines the right to respect for private and family life.
123 Evans (n 121) paras 83-92.
125 Vo (n 117) 295.
129 Plomer, ‘Stem Cell Patents’ (n 34) 60.
130 Oviedo Convention (n 128) art 1.
131 Millns (n 108) 77.
132 Vo (n 117) 275-276; Council of Europe, ‘Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on
dignity’ justifies constrained actions in this area, and that despite the lack of a uniformly accepted stage at which this principle attaches to human embryos they are owed a minimum level of protection of the kind enunciated in human rights philosophies.

Furthermore, although some EU Member States including the UK and Germany are yet to sign Oviedo, the ECtHR has relied on its provisions in cases under the ECHR. This has prompted some to argue that, together with Brüstle, a European consensus on the moral abhorrence of commercial activities relating to the human embryo is beginning to emerge, though as noted above the ECtHR also cited the Convention as evidence of moral pluralism in Vo.

C. EU Fundamental Rights

Having been incorporated into the EU legal order by the Treaty of Lisbon, the EU Charter of Fundamental Rights (EU Charter) now binds the Union and all Member States. Its first chapter is dedicated to the protection of ‘dignity’, with art 1 stating that ‘human dignity is inviolable. It must be respected and protected’. This is supplemented by rights to life and physical and mental integrity – including a prohibition on uses of the human body and its parts for financial purposes.

In the interpretation of ‘human dignity’ the CJEU has been receptive to the concurrent right found in the German Grundgesetz (Basic Law) art 1, which often constrains actions that disregard the value of human beings as individuals. This was illustrated by Omega Spielhallen, where the principle justified a German

133 Beyleveld (n 107) 40-43.
135 See Part 2 section A.
137 Glass v UK App No 61827/00 (ECtHR, 9 March 2004).
141 EU Charter, art 2.
142 ibid art 3.
143 Art 1 I Grundgesetz (German Basic Law); O’Neill (n 138).
144 N Foster and S Satish, German Legal System and Laws (3rd edn, OUP 2002) 214-216.
restriction on the import of laser guns from within the EU to the detriment of free movement of goods.\textsuperscript{146} However, as this interpretation was particular to Germany, the restriction’s application was not required of all Member States. This has prompted claims that pluralism regarding the scope of ‘human dignity’ necessitates the determination of such limitations at national rather than EU level, with the CJEU assessing only their necessity and proportionality to the protection of this value.\textsuperscript{147} It appears that the pre-EU Charter approach,\textsuperscript{148} when the common constitutional traditions of Member States were recognised as a source of the fundamental rights\textsuperscript{149} ‘enshrined in the general principles of Community law and protected by the Court’,\textsuperscript{150} supports this as the German view of human dignity clearly was not a ‘common constitutional tradition’.

\textit{Omega} also seemingly reflects the \textit{Netherlands} ruling, which in Part 2 was shown to recognise the margin of manoeuvre states enjoy in applying the art 6(1) morality provision whilst at the same time using art 6(2) to avoid creating uncertainty. It seems strange, therefore, that when adopting \textit{Brüstle}'s expansive definition of ‘human embryo’ when protecting ‘human dignity’, no attempt was made to find a consensus on this value between Member States. Indeed, if the CJEU had done so it would have observed that moral pluralism surrounding the embryo’s legal status has led the ECtHR to apply a margin of appreciation in \textit{Vo and Evans}. Thus it is clear that the adoption of an ‘autonomous’ definition in \textit{Brüstle} with no reference to authorities from human rights law is problematic.\textsuperscript{151}

This is further supported by the emphasis in the Biotechnology Directive, the Charter,\textsuperscript{152} the Treaty on European Union art 6(3) and CJEU jurisprudence\textsuperscript{153} of the authority of fundamental rights guaranteed by the ECHR. Indeed, even in the pre-EU Charter era \textit{Nold v Commission} stated that international human rights treaties to which Member States were signatories supplied ‘guidelines’ for Community law.\textsuperscript{154} In addition, since 2009 the EU Treaties have provided that the Union shall accede to the ECHR.\textsuperscript{155} Although recent developments have led to uncertainty concerning the

\textsuperscript{146} Omega (n 145) paras 34-35.
\textsuperscript{147} Thomas Ackermann, ‘Case C-36/02 Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundeshauptstadt Bonn’ (2005) 42(4) CMLR 1107, 1116-1117.
\textsuperscript{150} Case 29/69 Stauder v City of Ulm [1969] ECR 419, para 7.
\textsuperscript{151} Plomer, ‘After \textit{Brüstle}’ (n 61) 125; Harmon, Laurie and Courtney (n 10) 100.
\textsuperscript{152} EU Charter (n 139) Preamble.
\textsuperscript{154} Nold v Commission (n 149) para 13.
\textsuperscript{155} Treaty on European Union (n 139) art 6(2); Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47, Protocol (No 8).
terms and timescale of this process, this reinforces the claim that ECtHR case law should be considered when interpreting morally sensitive issues.

D. Summation

This discussion has sought to illustrate that the hESC-based inventions cases under the Biotechnology Directive are based on the inconsistent application of a uniform standard. Although the CJEU recognised moral pluralism between EU Member States in Brüstle, it proceeded to define the status of the human embryo according to a conception of human dignity that had no basis in the legal documents from which these principles originate: namely international and European human rights laws. Furthermore it was observed that numerous EU authorities recognise the value of the ECHR – indeed there is an ongoing accession process between the two. This suggests they should be interpreted harmoniously.

4. Is the Current Treatment of hESC-based Inventions Consistent with European Human Rights Laws?

The discussion in Part 3 illustrates that there is reason to question whether the current treatment of hESC-based inventions is consistent with European human rights laws. This will now be considered by assessing the interpretation of art 6(2)(c) under the post-ISCC regime, with close reference to the realities of commercialising inventions relating to the human embryo and the conflicts that may arise due to competing human rights interests.

A. ‘Human Dignity’, the Human Embryo and the post-ISCC Framework

The CJEU held in ISCC that the human embryo’s ‘dignity’ is violated where a patent is sought over an invention involving the use of cells possessing the ‘inherent capacity’ to develop into a human being. This was argued by Advocate-General Villalón to form a ‘no-go zone’ common to all Member States. Thus, when read together with Brüstle, the current position on the treatment of hESC-based inventions is that any work requiring the destruction or use as a base material of such cells, regardless of the stage in the development process at which this occurred or whether they were originally used for scientific purposes, will be unpatentable.

In order to demonstrate the full implications of this, the properties of different types of hESC will now be briefly outlined. Broadly, they are split into two main categories: totipotent and pluripotent cells. It is widely accepted that as totipotent
cells can become fully-formed human beings, they constitute a ‘stage of human development’ and are therefore unpatentable. 161 This is in keeping with the post-ISCC framework and reflects national definitions of the ‘human embryo’ such as that of the UK Human Fertilisation and Embryology Act (HFEA). 162 On the other hand, as noted in Part 2, 163 pluripotent cells cannot develop to term. 164 This characteristic led the CJEU to accept parthenotes – a form of pluripotent hESC – as morally acceptable under art 6(2)(c) in ISCC, though, as these cells arise from unfertilised human ova, they also avoid Brüstle’s exclusion of patents using ‘human embryos’ as defined in that case.

It is therefore clear that the exclusion from patentability of inventions based on pluripotent hESCs takes hold only where they were derived from ‘human embryos’ as defined in Brüstle. Yet, Part 3 illustrates that there is no European consensus on the ‘human embryo’ and its status with regard to ‘human dignity’. Indeed, a brief examination of hESC research regulation in Member States shows a plurality of approaches, 165 ranging from the UK’s issue of licences to perform research on leftover human embryos 166 from IVF which would otherwise be destroyed, 167 or even those made purely for research purposes, 168 to Ireland’s complete lack of regulation due to its recognition of the unborn child’s right to life from conception. 169 Furthermore, Spain adopts a somewhat intermediate approach in allowing research on supernumerary IVF embryos in the ‘pre-embryo’ stage, which it defines as prior to the 14th day after fertilisation,170 whilst other states require that only non-viable embryos – for example with chromosomal abnormalities precluding life – be used in research.171

161 Brüstle (n 7) Opinion of AG Bot paras 84-85; Plomer, ‘Stem Cell Patents’ (n 34) 66-69; Schuster (n 12) 631-633.
162 Human Fertilisation and Embryology Act 1990 (HFEA) s 1(1)(b) of which states that the human embryo includes ‘an egg (…) undergoing any (…) process capable of resulting in an embryo’.
163 See Part 2 section D.
166 HFEA (n 162) sch 2, para 3.
167 ibid sch 3, para 6.
168 ibid sch 2, para 3(1), this is prohibited under Oviedo Convention (n 128) art 18(2) in EU Member States that have ratified it.
169 Constitution of Ireland art 40(3).
171 Isasi and Knoppers (n 170) 48.
This plurality is also recognised within the EU legal order by the Human Tissues and Cells Directive (HTCD),\(^\text{172}\) which was adopted to harmonise the approach to ‘health threats’ within EU territory following increased research on the human body. As the EU’s competence in this area does not encompass the integration of moral views\(^\text{173}\) however, the HTCD is stated to apply to hESC research in those Member States where it is permitted.\(^\text{174}\) Furthermore, ‘the legal term “person” or “individual”’ was left to be defined by individual states.\(^\text{175}\)

This illustrates the necessity of the margin of appreciation applied in Vo. Yet, in neglecting to consider this authority, Brüstle stated that respect for the dignity and integrity of the person required that ‘any human ovum must, as soon as fertilised, be regarded as a “human embryo”’ under art 6(2)(c), ‘since that fertilisation is such as to commence the process of development of a human being’.\(^\text{176}\) This ignored certain Member States’ acceptance of using non-viable and supernumerary IVF embryos in hESC research, despite the latter’s potential to develop into a human being if implanted into a woman’s uterus. It is also inconsistent with Evans’ statement that the right to life of the frozen IVF embryo is to be determined by individual states.\(^\text{177}\)

However, it must be remembered that art 6(2)(c) is an example of commercial exploitation that would be contrary to ‘ordre public’ or morality. Thus far the legitimacy of hESC research itself under human rights laws has been considered, though it is now established that ‘human dignity as empowerment’ does not recognise a right to life of human embryos from conception. However, this does not equate to issues where dignity acts as a ‘constraint’, as occurs when commercially exploiting uses of the embryo is prohibited. In this regard it is noteworthy that some Member States that have ratified the Oviedo Convention – which as noted in Part 3 requires an ‘adequate level of protection’ for the embryo and prohibits uses of the human body as such for financial gain – continue to allow uses of non-viable and supernumerary IVF embryos\(^\text{178}\) and allude to upstream commercialisation in hESC research legislation.\(^\text{178}\) Moreover, other Member States are yet to sign or ratify this Convention, and prior to Brüstle had granted patents over hESC-related inventions.\(^\text{179}\) Thus, it is submitted that nothing in the European human rights regime suggests ‘human dignity’ necessitates the prohibition of commercialising


\(^{173}\) Plomer ‘Towards Systemic Legal Conflict’ (n 59) 181-182.

\(^{174}\) HTCD (n 172) Recital 7.

\(^{175}\) ibid 12.

\(^{176}\) Brüstle (n 7) para 35 (emphasis added).

\(^{177}\) Plomer, ‘After Brüstle’ (n 61) 132-134; Plomer, ‘Human Dignity, Human Rights, and Article 6(1)’ (n 134) 213; Isasi and Knoppers (n 170) 42; Spranger (n 126) 1207.

\(^{178}\) Ley 14/2007 (Spanish Law No 14/2007) (n 170).

pluripotent hESCs derived from uses of supernumerary IVF and non-viable embryos.

This is lent further credence by the EU Advanced Therapies and Medicinal Products Regulation (ATMPR), which was adopted shortly after the HTCD and aims to facilitate the market entry of products of human origin ‘prepared industrially or manufactured by a method involving an industrial process’ within EU territory. Like the HTCD, it applies equally to advanced therapies involving uses of hESCs where Member States permit their ‘sale, supply or use’. Thus, the ATMPR seemingly recognises the moral pluralism between European states regarding the commercialisation – as well as the acceptability – of hESC-based inventions. Indeed, commentators have observed that by allowing data exclusivity over therapeutic cell lines permitting up to 11 years of uninterrupted use of the experimental data behind the product, the ATMPR itself creates a right facilitating commercialisation that delays the appearance of generic competition on the market. Furthermore, the difficulties and costs involved in creating generic references of large products such as entire cells mean there is little incentive for generics companies to invest in developing rival products – so in fact there may be almost unlimited rights to exploit the advanced therapy.

In all, therefore, the post-ISCC treatment of hESC-based inventions is clearly problematic from a human rights perspective. However, it is equally apparent that the CJEU’s jurisprudence does not violate human rights laws with regard to the right to life of the human embryo. Rather, it imposes a greater level of protection than the ECHR requires. This is permitted by the EU Fundamental Charter and the ECtHR. However, if such provisions encroach on other rights, the European human rights regime would oblige them to pursue a legitimate aim and be proportionate to that aim – as demonstrated by the CJEU in Omega and the

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181 ATMPR (n 180) Recital 6.
182 ibid.
184 Daniel Acquah, ‘Extending the Limits of Protection of Pharmaceutical Patents and Date outside the EU – Is there a Need to Rebalance?’ (2014) 45(3) IIC 256, 265.
187 Hitchcock (n 185) 395-396.
188 EU Charter (n 139) art 52(3).
The Patentability of Human Embryonic Stem Cell-Based Inventions in the European Union

Netherlands case.\textsuperscript{191} This points to the necessity of considering competing human rights interests.

B. Competing Human Rights Interests

\textit{i. The Right to Health}

The post-ISCC approach to the patentability of hESC-based inventions is likely to encourage at least some diversion of investment and development away from inventions the CJEU considers to be morally unacceptable.\textsuperscript{192} In EPO practice it appears this will result in those patented between the first derivation of hESCs in 1998 and the first recognised derivation of hESCs from non-destructive sources in early 2008\textsuperscript{193} being unenforceable. The effect on future research may be minimal, as stem cell lines from such origins have been publicly available since this date and so inventions completed after it did not necessitate the use of destructive methods.\textsuperscript{194} It is unclear whether this would be the case if the issue came before the CJEU however, as, whilst supported by the German BGH’s grant of the Brüstle patent in an amended form that excluded destructive uses of human embryos, O’Sullivan argues that this appears to disregard the CJEU’s prohibition of uses ‘as a base material’ under art 6(2)(c).\textsuperscript{195}

The issue here is that the development of hESC-based therapies is likely to take decades,\textsuperscript{196} and there is a chance that denying patentability to and so reducing the prospects of commercialising inventions created during this initial ten-year period may delay the appearance on the market (at least from within the EU) of such therapies. This would equally delay the unlocking of their potential benefits to health.

This raises the question whether ‘human dignity’ also requires respect for the right to health.\textsuperscript{197} Thus far, this article has illustrated the lack of European consensus on when ‘human dignity’ attaches to the human embryo.\textsuperscript{198} However, the very reason for this principle and related rights including the right to life is that they...

\textsuperscript{191} Also before the ECtHR in \textit{A, B and C v Ireland} (n 189).
\textsuperscript{192} Harmon, Laurie and Courtney (n 10) 97.
\textsuperscript{193} ASTERIAS/Embryonic stem cells, disclaimer (T1441/13) [2015] EPOR 9, para 35; George Schlich and David Eyre, ‘Morally Acceptable Sources of Human Embryonic Stem Cells (hESCs): Embryos that Never Were, or Never Could Be’ (September 2014) <www.schlich.co.uk/latest_stem_cell_patenting.php> accessed 14 March 2015; Barbara Rigby ‘EPO Shies Away from Taking a Stand on Human Embryonic Stem Cells’<www.dehns.com/site/information/industry_news_and_articles/epo_shies_away_from_hum an_embryonic_stem_cells.html> accessed 14 March 2015.
\textsuperscript{194} George Schlich and David Eyre, ‘The First Glimmers of Hope After the Doom of the Brüstle Decision’ (October 2012) <www.schlich.co.uk/latest_first_glimmers_after_the_doom.php> accessed 24 February 2015.
\textsuperscript{195} Brüstle (n 7) para 52; O’Sullivan (n 42) 162.
\textsuperscript{197} Ohly (n 190) 158-160; Harmon, Laurie and Courtney (n 10) 97.
\textsuperscript{198} For example, the EU Charter art 1 (n 139) states that ‘Human dignity is inviolable’, but it has been shown that there is no way of definitively deeming it to attach to anything capable of developing into a human being from the moment of fertilisation (or stimulation).
‘empower’ human beings already alive.\textsuperscript{199} This may result in certain states regarding the restriction of activities that could lead to cures for patients as morally unacceptable and, by extension, contrary to ‘human dignity’.\textsuperscript{200} This is supported by Member State legislation on hESC research, which often justifies these activities with reference to their prospective benefits for human beings suffering today.\textsuperscript{201} The rationale was also behind the HTCD and ATMPR, whilst the Biotechnology Directive itself recalls the medical progress attributable to biotechnological advances.\textsuperscript{202}

Yet, the hESC-based inventions cases argue that restricting patents over such works is necessary to maintain respect for ‘human dignity’ when harmonising Member State patent laws on biotechnological inventions. As noted above, affording the embryo greater protection than European human rights laws require is permitted, and it is difficult to see any issue with the harmonisation of patent systems to promote biotechnological innovation.\textsuperscript{203} Therefore, the cases shall be assumed to pursue a legitimate aim.\textsuperscript{204} However, the right to healthcare is specifically recalled by EU Charter art 35,\textsuperscript{205} and although not present in the ECHR is outlined in ECtHR jurisprudence.\textsuperscript{206} Moreover, following \textit{Nold} from the pre-EU Charter era\textsuperscript{207} it may be argued that other Council of Europe instruments including the European Social Charter (EuSC)\textsuperscript{208} and the Oviedo Convention\textsuperscript{209} incorporate this right into EU law, particularly as those Member States applying the EU Charter’s Protocol – which invalidates art 35 insofar as it is not provided by national law\textsuperscript{210} – have also signed and ratified the EuSC.\textsuperscript{211}

\textsuperscript{199} See, for example, ECHR (n 72) art 2; EU Charter (n 139) arts 1-2; ICCPR (n 103) art 6.


\textsuperscript{201} Isasi and Knoppers (n 170) 43.

\textsuperscript{202} Biotechnology Directive (n 2) Recital 17; Advocate-General Bot also makes reference to those with health problems – see Brüstle (n 7) Opinion of AG Bot, para 43.

\textsuperscript{203} Indeed, the Netherlands case appears to support this notion in recognising the margin of manoeuvre for Member States under art 6(1).


\textsuperscript{205} EU Charter (n 139) art 35.


\textsuperscript{207} \textit{Nold v Commission} (n 149) para 13.

\textsuperscript{208} European Social Charter (concluded 18 October 1961, entered into force 26 February 1965) ETS No 035, as amended 1996 (EuSC) art 11; whilst this Charter is non-binding, all EU Member States have ratified it.

\textsuperscript{209} Oviedo Convention (n 128) art 3.

\textsuperscript{210} Treaty on the Functioning of the European Union (n 155) Protocol (No 30) art 1(2).

\textsuperscript{211} The signatories of Protocol (No 30) are Poland and the UK, as stated by Treaty on the Functioning of the European Union (n 155) Protocol (No 30), both of which have ratified the EuSC: Council of Europe, ‘Signatures and Ratifications of the European Social Charter, its Protocols and the European Social Charter (Revised)’ (26 March 2013) <www.coe.int/t/dghl/monitoring/socialcharter/Presentation/SignaturesRatificationsMarch2013_en.pdf> accessed 10 September 2015.
The EuSC recognises ‘effective access to healthcare for all (...) as a basic human right’, whilst Oviedo requires this access to keep pace with scientific developments. Therefore, as the right can be linked to respect for the ‘human dignity’ of patients requiring medical treatment today, the post-ISCC regime’s proportionality may be questioned. Furthermore, though it is unclear whether the right to health extends to the development of new, innovative methods of healthcare, as Oviedo specifically addresses biomedicine, it seems that if therapies arising from hESC-related inventions are accepted within a signatory state, the right to health would apply pressure for it to be used. Thus, when read together with the EU Charter’s right to freedom of scientific research, there is scope to argue that the European human rights regime favours measures facilitating the development of hESC therapies.

This could be countered with reference to human rights-related claims raised concerning the effects of intellectual property on the right to health. The grant of a limited monopoly in this vital sector is controversial, as evidenced by the work of the UN Special Rapporteur on Health and Intellectual Property and the adoption of the Doha Declaration on TRIPS and Public Health, which highlight the danger of intellectual property rights being used to restrict access to healthcare. Similarly, the limitations imposed (albeit between private entities) upon European patent law by ‘Bolar’ exemptions allow greater freedom to use patented drugs when seeking regulatory approval for generic or new products. As pharmaceutical companies continue to develop medicines despite the likelihood of future reduced prices due to competition appearing on the market sooner than it would in the absence of such exemptions, and the encouragement of developing countries to enact similar flexibilities, these examples suggest that limiting patent rights does not necessarily deter innovative activity.

Furthermore, patents over parthenotes and inventions not necessitating the use of destructive methods are currently accepted, meaning that if inventors engage in what the CJEU considers morally acceptable activities they can seek protection.
The underlying hESC research equally avoids prohibition. Thus there is a case in favour of the post-ISCC regime’s proportionality with regard to the right to health. Nevertheless, this discussion illustrates that the right to health may justify the grant of patents over hESC-based inventions in states considering their commercialisation to be compatible with ‘human dignity’. It is also noteworthy that, in the complete absence of patent rights, the alternative methods of commercialising such therapies elaborated in Part 5 may be of greater detriment to the right to health.

ii. The Right to Property

Another human rights concern engaged by the post-Brüstle and ISCC framework is the right to property. ISCC retained Brüstle’s interpretation of art 6(2)(c) as precluding patentability where the ‘embryo’ – including cells capable of developing to term – is used or destroyed at any time during the development of or scientific research leading to the invention. This was deemed necessary because where an invention is patented and the limited monopoly takes hold, it cannot be considered in isolation of the research that led to its creation. Yet it clearly interferes with the private property rights of patentees.

Part 3 noted that Locke considered the right to property to be a fundamental right that all individuals possess: a significance reflected by its presence in universal human rights authorities. It is also included in ECHR Protocol 1 art 1 (P1A1), which protects the ‘peaceful enjoyment’ of property for ‘every natural and legal person’, whilst the EU Charter art 17(2) explicitly extends this right to include intellectual property. Furthermore, the ECtHR has protected patents under P1A1 in Smith Kline and French Laboratories v Netherlands, and although American Tobacco notes that no violation occurs where a patent application is validly rejected by the appropriate authority, the right arguably encompasses such applications in limited circumstances.

Together, these provisions suggest that authors of innovative works become endowed with a human right to property of which they should not be arbitrarily dispossessed. Thus although the desirability of granting such rights to legal persons – which allows corporate investors behind inventions to claim interferences

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221 See Part 5 section B.
222 Brüstle (n 7) para 43.
223 Harmon, Laurie and Courtney (n 10) 98-99.
224 Shestack (n 98) 37.
225 UDHR (n 101) art 17; ICESCR (n 104) art 15(1)(c).
226 EU Charter (n 139) art 17.
227 No 12633/87, Commission decision of 4 October 1990, Decisions and Reports 66, 70.
230 UDHR (n 101) art 17(2).
with their human rights – has been questioned,\textsuperscript{231} patentees clearly require at least some level of protection.

However, the right to property may be restricted in certain situations. Under the universal human rights regime ICESCR art 15(1)(c)’s protection of innovative works arises out of the ‘inherent dignity’ of all human beings,\textsuperscript{232} and so only ensures that creators are treated fairly once their work is publicly disclosed rather than providing a basis for the potential accumulation of substantial profits.\textsuperscript{233} In this way it is not equal to the rights conferred by patent regimes. The European framework reflects these concerns; with the ECHR\textsuperscript{234} and EU Charter\textsuperscript{235} allowing states to deprive individuals of their property in the ‘public interest’ and to control uses of that property in the ‘general interest’. Both the ECtHR\textsuperscript{236} and CJEU\textsuperscript{237} recognise a wide margin of appreciation for states applying such restrictions, provided they pursue a legitimate aim and fulfil the proportionality principle.\textsuperscript{238} This suggests a need to balance the right to property with other considerations, particularly other human rights under the European framework.\textsuperscript{239}

However, assuming once again that the hESC-based inventions cases pursue a legitimate aim,\textsuperscript{240} it remains valid to argue that achieving harmonisation by applying a broad definition of ‘human embryo’ to protect a conception of ‘human dignity’ that fails to acknowledge European moral pluralism contravenes the proportionality principle.\textsuperscript{241} Furthermore, excluding inventions involving the destruction or use as a base product of an embryo even where this occurred for scientific purposes arguably extends the definition of ‘industrial and commercial purposes’ in a manner that was never intended. Indeed, Porter notes that the Biotechnology Directive’s framers inserted this wording to narrow the previous exclusion’s scope from ‘methods in which human embryos are used’.\textsuperscript{242} When read together with the Italy case\textsuperscript{243}, this suggests that art 6(2)’s non-discretionary nature requires the terms ‘industrial’ and ‘commercial’, as well as ‘human embryo’, to be given their natural meaning.\textsuperscript{244} Applying this literal approach, patents over works relating to pluripotent hESCs

\begin{footnotesize}
\begin{enumerate}
\item ibid 716.
\item ibid 716-717.
\item ECHR (n 72) Protocol 1 art 1.
\item EU Charter (n 139) art 17(1).
\item American Tobacco (n 228).
\item Case C-275/06 Productores de Musica de Espana (Promusicae) v Telefonica de Espana SAU [2008] ECR I-271, paras 67-71.
\item EU Charter (n 139) art 51(1); L.B. v Italy App No 3254/96 (Judgment of the First Section, 15 November 2002) paras 23-25.
\item See section B(i).
\item Plomer, ‘After Brüstle’ (n 61) 131.
\item Porter (n 32) 20-21; Plomer, ‘After Brüstle’ (n 61) 123, 131-135; Harmon, Laurie and Courtney (n 10) 98-100.
\item Commission v Italy (n 57) para 78; Part 2 section C.
\item Plomer, ‘After Brüstle’ (n 61) 123.
\end{enumerate}
\end{footnotesize}
derived from supernumerary IVF and non-viable embryos in jurisdictions where such actions are morally acceptable would not run contrary to art 6(2)(c).\textsuperscript{245} 

At the most it could be claimed that declaring such hESC-based inventions unpatentable is proportionate in EU Member States that prohibit hESC research or the commercialisation of products arising from them on grounds of morality and the protection of ‘human dignity’.\textsuperscript{246} Yet this cannot be said for states that allow such practices.

In return it could be argued that ISCC has improved the treatment of hESC-based inventions under the Biotechnology Directive. The case has certainly returned an amount of proportionality to the restriction on the right to property\textsuperscript{247} for post-2008 works, but will do little to mitigate the losses of those registered prior to this date. The extension of ‘industrial and commercial purposes’ to scientific purposes also raises the question of whether an invention involving research performed before this date – when no non-destructive methods of deriving hESCs were available – will also be caught by art 6(2)(c).\textsuperscript{248} Such works may still be commercialised for example through the ATMPR or robust trade secrets laws; however, as shall be discussed in Part 5, these may be more harmful to the right to health than the patent regime.\textsuperscript{249}

Therefore, it is submitted that the current regime arguably represents a disproportionate denial of the human right to property for patentees whose rights are now unenforceable due to the ‘moral impermissibility’ of their invention, despite its grant in a Member State that regards it as morally acceptable.\textsuperscript{250}

C. Summation

This discussion has sought to dissect the post-ISCC interpretation of the art 6(2)(c) provision ‘uses of human embryos for industrial or commercial purposes’ as an example of a commercial exploitation contrary to ‘ordre public’ or ‘morality’ under art 6(1), with close reference to its consistency with European human rights laws. Having established the pluralism surrounding the term ‘human dignity’ and the status of the human embryo in Part 3, section A showed that the ‘human embryo’ is defined differently by EU Member States, and that uses – whether destructive or as a base material – of pluripotent hESCs derived from sources such as supernumerary IVF and non-viable embryos are not universally regarded as morally abhorrent. It was then demonstrated that the same is true of the commercial exploitation of such materials; before the proportionality of this finding’s impact on the right to health was considered – though this author notes there are strong cases on both sides of this debate. Finally it was observed that the extension of ‘industrial or commercial purposes’ to include uses of human embryos for scientific purposes, as a result of European moral pluralism, may constitute a disproportionate interference with the right to property where it renders patents unenforceable in states considering

\textsuperscript{245} Harmon, Laurie and Courtney (n 10) 98-99; Plomer, ‘After Brüstle’ (n 61) 130-131.
\textsuperscript{246} Plomer, ‘After Brüstle’ (n 61) 130-135.
\textsuperscript{247} Hayes (n 220) 952.
\textsuperscript{248} O’Sullivan (n 42) 162.
\textsuperscript{249} Harmon, Laurie and Courtney (n 10) 104-105; see discussion in Part 5.
\textsuperscript{250} Plomer, ‘Inherently Uncertain?’ (n 94).
inventions involving such activities to be morally acceptable. It may therefore be argued that the current treatment of hESC-based inventions under art 6 is inconsistent with European human rights laws.

5. Does the Interpretation of the Morally Problematic Terms in Article 6 Come Under the Ambit of Patent Law?

Thus far this article has suggested that the CJEU should have taken European human rights authorities into consideration when adjudicating on the patentability of hESC-based inventions. It has demonstrated that there are arguably inconsistencies with these provisions, particularly regarding the rights to health and property. Furthermore the protection of an extended definition of the human embryo – the ‘human dignity’ of which accords it a status universally recognised by neither Member States nor the European human rights regime – seemingly disregards the Biotechnology Directive Recital 8’s rejection of creating a ‘separate body of law in place of the rules of national patent law’. Yet, the current approach was also shown to go further than human rights laws require in protecting the status of the human embryo, and this may not violate the right to health because of the post-ISCC possibility to gain patents over inventions involving non-destructive methods. Is this an unacceptable legal position? Part 3 recalled that some commentators argue the judgment could be construed as the origin of European consensus on the embryo. This raises the question whether the interpretation of the morally problematic term ‘human embryo’ and related issues such as the extent to which it enjoys ‘human dignity’ as seen in Biotechnology Directive art 6 comes under the ambit of patent law. In order to address this issue, the rationales of patent law itself shall be outlined, before the other methods of protecting and exploiting unpatentable inventions are considered. After illustrating that moral pluralism over such works not only prevents their being outlawed but potentially pushes them towards more monopolistic protection, it will be asked whether it is viable for patent law to operate in isolation of external legal regimes.

A. Rationales of Patent Law

Perhaps the most commonly cited justification for the grant of patents and the limited, negative monopoly accompanying them is the incentive-disclosure rationale. This is often likened to a ‘social contract’, whereby in return for publishing details of the innovative activity behind their invention, inventors are rewarded with a property right allowing them to benefit from it for a period of time. It is claimed that this encourages would-be inventors to invent and contribute to advancing human knowledge and deters engagement in ‘free-riding’ activities.

251 O’Neill (n 138).
253 It has also been suggested that the reward itself is a justification of patents; however this is now seen as a weak argument due to the availability of other forms of prize – see Fisher (n 252) 11.
that will stagnate development. This is equally true of investors in innovation, whose financial contributions are as important as the inventor’s actions to innovative projects. Indeed, modern justifications of patent law have centred on the investor due to this reality. For example, it has been noted that inventors who obtain patents over their inventions when looking to commercialise them are more likely to attract the necessary investors because the patent functions as a ‘signal’ of financial viability. The influence of these justifications can clearly be observed in the hESC-based inventions cases, as illustrated by the post-Brüstle claims that the ruling would cause a future lack of investment in European hESC research.

An earlier rationale of relevance to the present discussion is that inventors enjoy a ‘natural right’ of property over the fruits of their innovative efforts, though the incentive-disclosure rationale has taken precedence over this because it is undermined by the temporally-limited nature of patents. However, Part 4 illustrates that the European human rights framework protects intellectual property, and that any interference with this right must be legitimate and proportionate.

On the other hand, where these limitations are justified, it has been observed that patents may be used to regulate particular activities. This effect can be seen in the hESC-based inventions cases, as it appears that the protection afforded to the human embryo in the name of ‘human dignity’ – though intended to enable the application of a uniform interpretation of art 6(2)(c) – has a regulatory function by encouraging future investment in hESC-related activities that the CJEU considers morally acceptable. Indeed, the inclusion of morality and ‘ordre public’ provisions in European patent laws implies the system has always been capable of playing such a role.

Thus, it is submitted that the discussion regarding patents over hESC-based inventions in this article has reflected all the aforementioned rationales. In particular the CJEU judgments’ regulatory effect seems to have influenced the other justifications’ operation in a manner that merits further investigation. Therefore, their practical implications – especially the widely claimed assertion that Brüstle would inhibit European hESC research, and its continued veracity after ISCC – will now be discussed.

257 Waelde and others (n 21) para 10.18.
258 Harmon, Laurie and Courtney (n 10) 100-101.
259 Fisher (n 252) 6.
260 ibid 7-8.
261 Waelde and others (n 21) para 10.20; Bently (n 243) 340-341.
262 Plomer, ‘After Brüstle’ (n 61) 130-135; see also Part 4 section B(ii) on right to property.
263 Schuster (n 12) 638-639.
264 Derclaye (n 52) 258-259.
B. Inhibiting Commercialisation?

The post-ISCC regime will undoubtedly have some effect as a regulatory measure whereby inventors and investors are encouraged to engage in developing hESC-based inventions that do not involve embryos possessing the ‘inherent capacity’ to become a human being at any stage. This will be facilitated by the rapid development of non-destructive methods of obtaining hESCs, particularly parthenogenesis following ISCC, which was ongoing at the time of the Brüstle judgment.265 On the other hand, Parts 3-4 illustrated that the current treatment of hESC-based patents under the Biotechnology Directive art 6 in fact relies on an interpretation of human dignity that has no basis in human rights law, and that, as a result, inventions involving work on supernumerary IVF and non-viable embryos are now considered unpatentable despite them being morally acceptable in certain Member States.

Yet, the Biotechnology Directive is incapable of preventing the commercialisation of these uses by other means and other bodies. For example, the EPO still allows patents with post-2008 priority dates266 over ‘immoral’ hESC-based inventions as the destruction of hESCs was unnecessary after this date – even though this seemingly contradicts the CJEU’s reference to uses ‘as a base material’ in Brüstle.267 This suggests that the ‘natural rights’ justification is protected, as a right to property still arises out of the inventor’s innovative activity.

Moreover, even if in future litigation the CJEU were to reject EPO practice – as it did in closing the ‘deposit loophole’ after WARF – Member States still wishing to encourage the continued development of unpatentable works in the pipeline could provide tax incentives or ensure robust protection from trade secrets laws.268 For example, they may strictly enforce non-disclosure agreements and restrictive covenants against those dealing with inventors, and more generally may protect confidential information in a manner similar to that offered by the UK’s common law doctrine breach of confidence.269 Indeed, Bently suggests that although not being a full property right, the protection of such information is often considered to be an intellectual property right,270 as supported by the English Court of Appeal.271 In addition the ATMPR permits temporary data exclusivity over hESC-based therapies, which, as noted in Part 4, is likely to have a chilling effect on the market, particularly for generic competition.272


266 ASTERIAS (n 193) para 35.

267 O’Sullivan (n 42) 162.

268 Harm, Laurie and Courtney (n 10) 104-105.


271 Vestergaard Frandsen S/A and Ors v Bestnet Europe Ltd [2011] EWCA Civ 424 [56].

272 Part 4 section A.
Accordingly, it is clear that those whose patents are rendered unenforceable or inventions unpatentable by the current regime may rely on other legal mechanisms to develop a monopoly in the absence of a patent. Although there would always be a risk of the disclosure of a trade secret to the public\textsuperscript{273} and without further EU clarification the laws protecting them would be likely to vary between Member States,\textsuperscript{274} the costs involved in reaching the market and complexity of ‘reverse-engineering’ cell-based products is likely to deter competition.\textsuperscript{275} Thus, even after data exclusivity ends, such products may effectively be subjected to an unlimited monopoly.\textsuperscript{276} This suggests that denying patentability does not necessarily remove the commercial incentive to work such inventions; rather, it removes the signal of viability to potential investors. Provided such investors understand the risks of these alternative methods of commercialisation, they may still wish to invest. Moreover, if the ‘fixing’ of patent claims is indeed contrary to \textit{Brüstle}, creators of such works that have not already been disclosed in newly unenforceable patents may combine data exclusivity and trade secrets to gain market exclusivity without publicly detailing their inventive work. Given the potential medical benefits of hESC-based therapies, this would certainly be less socially desirable than allowing the grant of a patent and could have greater adverse effects on the right to health,\textsuperscript{277} as if managed correctly the invention could be kept secret and monopolised.

Therefore, it appears that the post-ISCC treatment of hESC-based inventions does not prevent all commercialisation of violations of the human embryo’s dignity (as conceived by the CJEU) before the EPO, in Member States and even under the EU legal framework. Thus it is questionable whether the ‘autonomous’ definition of ‘human embryo’ is capable of having a truly regulatory effect on hESC-based inventions. Indeed, as non-destructive methods of deriving hESCs were first disclosed in 2008 – perhaps earlier\textsuperscript{278} – it can hardly be said that the patent system has been used to regulate innovation towards the development of such methods. Rather, following ISCC, the CJEU is encouraging the creation of inventions using what it considers to be the most morally desirable methods available today. Yet, the underlying ‘immoral’ research activities themselves remain permissible. It was even suggested they could be increased and patents sought outside Europe following \textit{Brüstle},\textsuperscript{279} though it now appears that a combination of EPO practice and the ISCC ‘inherent capacities’ test, which seems much more focused on balancing scientific advances and the attendant medical potential, property rights, and respect for ‘human dignity’,\textsuperscript{280} have reduced this possibility.

\begin{footnotes}
\item[274] Concerning the scope for Directive 2004/48/EC on the enforcement of intellectual Property rights to encompass confidential information, see Bently (n 270) 73; WIPO (n 273). This contention is supported by TRIPS (n 23) art 39 and Paris Convention (n 46) art 10bis.
\item[275] Parker (n 13) 746; WIPO (n 273).
\item[276] Hitchcock (n 185) 395-396.
\item[278] Schlich (n 265).
\item[279] Harmon, Laurie and Courtney (n 10) 105-106.
\item[280] Hayes (n 220) 952.
\end{footnotes}
This again supports the contention that consultation of relevant human rights law authorities would have highlighted European moral pluralism and competing interests such as the rights to property and health. The patent regime alone is incapable of determining when life begins, and in this respect its isolation from other legal authorities weakens the power of the regulatory function, which, as noted above, appears to be the prominent concern of art 6’s morality exclusion.

C. Isolated Patent Law?

This finding seemingly reflects a criticism that has previously been levelled at the patent regime in a different respect. In 1995 Bently and Sherman observed that historically patent law has always been considered separately to ‘matters cultural, political and ethical’.281 This characteristic has also caused difficulties in the USA, where the assessment of moral issues is tied to the doctrine of ‘utility’: a concept akin to European ‘industrial applicability’. 282 Biotechnological advances in this jurisdiction have led to the rejection of patents over ‘human organisms’283 but many such inventions escape scrutiny on moral grounds.284 Yet, ethics committees such as the European Group on Ethics in Science and New Technologies have suggested that, provided activities proceed on a responsible basis, the patentability of certain hESC-based inventions, due to the medical advances they could help contribute to, is acceptable.285 Although non-binding, such committees have a strong influence due to their expert composition.286

Thus, there is evidently a need to consider morally problematic issues within patent law. However, as shown in the previous section, when considered only in the context of the patent regime, their effects are equally isolated, as the grant of a patent does not equate to a right to commercialise. Indeed, as a patent only allows its holder to prevent others from commercially exploiting the invention, that holder is not necessarily able to bring her/his invention to the market in any case, and instead may be subjected to regulatory measures from outside the patent regime.287

D. Summation

Patents are primarily intended to incentivise engagement in innovation and the subsequent public disclosure of the advances that such work provides. They are also the result of deploying this incentive to regulate development in certain contexts.

283 Burke (n 200) 348-349.
284 Mills (n 282) 49-50.
287 As illustrated by European states’ pluralistic approach to hESC research.
However where this occurs on grounds of morality, at least in the context of a supranational organisation such as the EU, those moral values must be universal or they will fail in their regulatory objectives. The alternative methods of commercialising ‘immoral’ inventions remain, and may be more harmful to human rights concerns than the patent system. It is therefore clear that treating the human embryo as it is recognised under the European human rights regime would ensure that patent law is more integrated with other legal policies in its approach to hESC-related inventions, as well as maintaining consistency within the internal EU legal order under the HTCD and ATMPR. Thus it is submitted that whilst moral considerations certainly come under the ambit of patent law, the interpretation of morally problematic terms such as ‘human embryo’ and its right to ‘human dignity’ does not – as implied by Biotechnology Directive Recital 8.

6. Conclusion

In closing, it is submitted that the references to ‘human dignity’ in applying the Biotechnology Directive’s art 6 morality exception to hESC-based inventions suggests a clear link between the patent and human rights regimes. The failure to consider this in CJEU cases has resulted in an approach to such inventions that is inconsistent with European human rights laws. Whilst the interpretation of ‘human embryo’ and the dignity attached to it in fact provides greater protection than the human rights regime requires, it is undermined by its lack of a basis in European moral consensus. This creates potential conflicts with the rights to health and property, and pushes the commercial exploitation of ‘immoral’ inventions towards other legal regimes – which raises questions regarding the legitimacy of the Court’s ‘autonomous’ definition of ‘human embryo’.

Whilst Brüstle used ‘human dignity’ to justify a wide, constraining interpretation of this term, ISCC seems to limit it by considering competing concerns to a greater extent. Nevertheless, patent law cannot operate in isolation of outside regimes. Issues of morality and ‘ordre public’ are essential to the responsible management of patents over hESC-based inventions, but alone are vulnerable to ineffectiveness in the achievement of their aims. Therefore it appears that the interpretation of the morally problematic term ‘human embryo’ in art 6(2)(c), together with the attendant issues relating to its status and attachment to ‘human dignity’, does not come under the ambit of patent law. Rather, a much more harmonious position could be achieved if it were applied as approached under European human rights laws.

288 Plomer (n 59); Hitchcock (n 185) 395-396.