ARTICLES

Embryonic Stem Cell Research according to German and European Law

By Christian Starck[*]

A. Background Situation and the Issue under Discussion

I. Research and Therapy with Embryo Stem Cells

For some years now, reproductive medicine has been capable of performing the act of human procreation *in vitro*, fusing the female ovum and the male semen outside of the human body. The embryo created by this process is then "implanted" into the uterus of the woman who had previously provided the ovum. This technique serves to overcome certain physical defects – such as a malfunction of the fallopian tubes – of a couple that wants to have children.

In vitro fertilisation, meanwhile, has not only allowed doctors to control the procreative act and its immediate result, it also provides scientists with the opportunity to use the embryos from the *in vitro* fertilization process as "material" for research. Six years ago the American scientist James Thomson was the first to extract stem cells from embryos in a blastocyst stadium (on Day 5 or 6 after their procreation) which were no longer intended for use for reproductive purposes. Stem cells can be copied at will (without any limitation in numbers) and differentiated into a wide range of tissue types such as myocardial tissue, bone marrow etc. For the creation of stem cells, embryos are "consumed".

This means that embryos serve a second purpose. Apart from serving its inherent purpose of developing as a human being in a woman's uterus in order to be born, the embryo is ascribed extrinsic purposes: (1) as a source of knowledge about the development of human beings, (2) as a raw material for the therapy of human beings, and (3) as an instrument for medical diagnoses. The second of these

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purposes is the objective of the so-called therapeutic cloning, which has not yet advanced beyond the arena of scientific research.[1]

During the medical process of therapeutic cloning, the nucleus of one of the patient's cells is transplanted into a woman's (extracted) unfertilized ovum – out of which the nucleus has been previously removed – in the metaphase of the second meiosis. This means that the ovum, which is ready to be fertilized, has reached the status with external polocytes and a chromosome pattern in the metaphase plate. Provided that the membranes of the donor cell and the recipient stimulation cell are close and provide sufficient contact areas, the application of electric pulses can achieve a locally confined fusion of the two membranes. This means that the donor cell is integrated into the cytoplasm of the recipient cell.[2] A non-sexual procreation takes place. A totipotent cell will develop in analogy to a sexually fertilized ovum, *i.e.* an embryo will start to develop. This development will then be interrupted in order to provide embryonic stem cells with the genetic material of the cell donor. This process would allow researchers to develop tissue and organs with characteristics identical to those of the patient, quite possibly eliminating the risk of rejection by the body's immune system. Nevertheless, no technique has yet been developed for using embryonic stem cells for therapeutic purposes. We are equally unsure about the effects of these stem cells in the patients' bodies. From experiments with mice we know that side effects – such as cancer – are possible. This may be the reason why the *Deutsche Forschungsgemeinschaft* (DFG – German Federation for Research) has rejected therapeutic cloning.[3]

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[1] For a summary of the existing scientific-technological difficulties, *see* Ralf Müller-Terpitz, *Die neuen Empfehlungen der DFG zur Forschung mit menschlichen Stammzellen,* 34 WISSENSCHAFTSRECHT (WissR) 271, 273 (2001); Ernst-Ludwig Winnacker, *Human Cloning from a Scientific Perspective, in* HUMAN DIGNITY AND HUMAN CLONING 55 (Silja Vöneky & Rüdiger Wolfram eds., 2004).

[2] The description of this process has been taken from the report that dealt with the question of whether there was a need for the legislature to amend the Embryo Protection Act in the wake of the – present and foreseeable future – developments in animal cloning and the techniques used. BTDrucks 13/1/263 at 8. See also the description in the DFG statement about "Human Embryo Stem Cells", *available at* www.dfg.de/aktuell/stellungnahmen/lebenswissenschaften/ eszeit_d_99.html, at p.2. *See also* Jan Schindehütte &Peter Gruß, *Die molekulare Basis für regenerative Medizin, in* WISSENSCHAFTEN 2001 – DIAGNOSEN UND PROGNOSEN 224 (Akademie der Wissenschaften zu Göttingen ed., 2001).

[3] *See* recommendations from 3 May 2001. *See also* Ralf Müller-Terpitz, *Die neuen Empfehlungen der DFG zur Forschung mitmenschlichen Stammzellen*, 34 WISSENSCHAFTSRECHT (WissR) 271 (2001).

II. The Issue Under Discussion

Embryo research or embryo stem cell research causes the consumption, *i.e.* the destruction of embryos, whether it is undertaken for the purpose of acquiring knowledge about the development of human beings, developing new therapeutic techniques, or for diagnostic purposes. Before we can establish whether or not the European Union is legally entitled to fund or subsidize embryo stem cell research, we must first examine whether such consumptive embryo research complies with existing European Law. Even though the issue of the legality of financial support is to be determined on a European level, German Law is also relevant for the following reason: If it turns out that embryo research violates existing German Law, we would have to establish whether the EU is entitled to support and subsidize activities which violate the laws of one of its member states. This question is independent of the issue whether such activities are compatible with European Law or not.

We must begin by establishing whether the European Union is at all responsible for providing support for such research activities (B.), and by examining – if the answer to the first question is "yes" – to which limitations consumptive embryo research is subjected by Community Law (C.).

B. Competences of the European Union for Research Funding and its Framework Research Programmes

Articles 163 to 173 of the EC Treaty [hereinafter "EC"][4] determine the competences and objectives of the EU in the area of research. Since the Community itself does not conduct research, its competence consists of encouragement, coordination and funding. The stated objective is the creation of a "European Research Area." Several communications of the Commission have indicated that the intention is to utilize the existing resources and infrastructural provisions to their full capacity on a European level, to apply public funds with the greatest possible coherence, to encourage the mobility of the researchers and to simultaneously implement common values as the foundation and framework for a European research policy.[5]

[4] Treaty Establishing the European Community, Nov. 10, 1997, 1997 O.J. (C 340) Part 3, Title XVIII .

[5] *See* Hans-Heinrich Trute, *EC Treaty art. 163, in* EUV/EGV KOMMENTAR margin note 7, 10 (Rudolf Streinz ed., 2003); on the occasion of the *Annual Report of the Commission 2001*, at 8, COM (2001), 756 final.(Dec. 12, 2001).

The common values expressed in the constitutions of the individual Member States have manifested themselves in the Charter of Fundamental Rights. Provisions with a concrete relevance for research include the guarantee of human dignity (Article 1), the right to the physical integrity of the person (Article 3 Clause 1), the limitations of medicine and biology (Article 3 Clause 2) and the freedom of scientific research (Article 13). This shows that the science and technology policies of the European Union have been embedded in an environment of ethics.[6]

This is concretely manifested in the diverse Framework Research Programmes (FRPs) of the European Union (Article 166 EC). Article 7 of the 5th FRP provides that "all research activities… shall be carried out in compliance with fundamental ethical principles."[7] Under the heading "Scientific and Technological Objectives," Appendix II demands that – in view of genetic research and development efforts – issues of biomedical ethics and biological ethics should be resolved by taking into account fundamental human values. This is further elaborated in a footnote:

> Taking account of the declaration of the European Council of Amsterdam and the European Parliament resolution on the banning of human cloning (OJ C 115, 14 April 1997, p. 92) and of relevant Community legislation,…no research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such alteration heritable will be carried out under the present framework programme. In the same way, no research activity, understood in the sense of the term "cloning," will be conducted with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a late stage of development to the human embryo. [8]

The wording of this passage clearly indicates that the earliest form of human development immediately after the fusion of the cell nuclei is already considered to be an embryo and that all forms of cloning are banned.

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[6] Trute, *EC Treaty art. 163*, *id.* at margin note 13.

[7] Resolution of the European Parliament and Council (EG) No. 182/1999 of 22 December 1998, 1999 O.J. (L 26) 6.

[8] Trute, *EC Treaty art. 163*, *supra* note 5, at margin note 13.

The European Parliament has banned support for cloning and cloning experiments on several occasions.[9] Since the act of therapeutic cloning involves the non-sexual creation of a totipotent cell, *i.e.* an embryo, it, too, falls under the ban on cloning. Even if we were not ready to concede that the ban on cloning includes cloning for therapeutic purposes, such a ban on therapeutic cloning would follow from the following consideration: In the footnote quoted above, the 5th FRP explicitly outlaws "research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development." Since the act of therapeutic cloning involves the modification of the ovum's genome through the removal of the nucleus, and since this modification is then transmitted to a totipotent cell, this process – a necessary intermediate stage on the way to the creation of embryo stem cells – is based on an unlawful alteration of the germ track.[10]

The 6th FRP from 27 June 2002[11] also points out (in Consideration 17 and Article 3) that the conduct of research activities will need to comply with ethical principles including those from Article 6 of the EU Treaty [hereinafter "EU"] and the Charter of Fundamental Rights. The ethical requirements are specified in Appendix I to the Parliament's and Council's Resolution, "Scientific and Technological Objectives, Broad Lines of the Activities and Priorities." This text describes the binding ethical principles as follows: "These include, *inter alia*, principles reflected in the Charter of Fundamental Rights of the European Union, protection of human dignity and human life." References are made to the European Convention on Human Rights and Biomedicine of the European Council (Oviedo, 4 April 1997) and the Additional Protocol about the Ban on Human Cloning (Paris, 12 January 1998). We also must point out the Council Decision from 30 September 2002 adopting a specific programme for research, technological development and demonstration "structuring the European Research Area" (2002 – 2006).[12] Consideration 6 in this Council Decision demands compliance with fundamental ethical principles including those from the Charter of Fundamental Rights of the European Union.

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[9] *See also* JENS KERSTEN, DAS KLONEN VON MENSCHEN 201 (2004).

[10] *See also id* at 202.

[11] Resolution of the European Parliament and Council (EC) No. 1513/2002, 2002 O.J. (L 232) 2.

[12] Resolution of the European Parliament and Council (EC) No. 2002/835, 2002 O.J. (L 294) 4. *See* The Inter-institutional File 2001/0122 (CNS), Brussels, 9 August 2002, 11385/02, p. 7 ("During the implementation of this programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include the principles reflected in the Charter of Fundamental Rights of the EU, including the following: protection of human dignity and human life ... in accordance with Community Law and relevant international conventions and codes of conduct ...").

Furthermore, Article 3 Appendix I categorically states that "research activity aiming at human cloning for reproductive purposes or to create human embryos for the purpose of stem cell procurement including by means of somatic cell nuclear transfer will not be financed."[13]

C. Freedom of Research and its Limitations under European Law

Stem cell research – which is the focus of this paper – including the process of therapeutic cloning (which is based on stem cell research) qualify as scientific research. Such research is protected by German constitutional law (Article 5 Clause 3 of the *Grundgesetz* [GG – Basic Law or Constituiton]) and equally by the primary law of the European Union, manifested in Article 6 Clause 2 EU,[14] and more clearly demonstrated by Article 13 of the Charter of Fundamental Rights (Article II-73, Constitutional Treaty for Europe [hereinafter "CTE"]).[15]

The freedom of scientific research is not unlimited. Scientific research is obliged to respect human dignity and the life, physical integrity and freedom of the person. The government is obliged to protect its citizens them from the researchers.[16] The same applies to European Law, based on the existing jurisprudence of the European Court of Justice,[17] which is reflected by Article 52 of the Charter of Fundamental Rights (Article II-112 CTE). The Charter also provides normative provisions for the protection of human dignity (Article 1 is the equivalent of Article II-61 CTE) and the right to life (Article 2 Clause 1 is the equivalent of Article II-62 Clause 1 CTE).

As far as the protection of fundamental rights is concerned, the European Court of Justice ruled, as early as 1974, that

> As the Court has already stated, fundamental rights form an integral part of the General Principles of Law, the observance of which it ensures. In

[13] Corresponding passages can be found on page 8 of the Inter-institutional Memorandum. *See id*.

[14] *See* THOMAS GROß, DIE AUTONOMIE DER WISSENSCHAFT IM EUROPÄISCHEN RECHTSVERGLEICH 142 (1992).

[15] Like in the Preamble for the Charter of Fundamental Rights.

[16] Christian Starck, *Artikel 5*, *in* 1 GRUNDGESETZ KOMMENTAR margin note 418 (Hermann von Mangoldt, Friedrich Klein and Christian Starck eds., 5th ed. 2005).

[17] *See* Jürgen Kühling, *Grundrechte, in* EUROPÄISCHES VERFASSUNGSRECHT 583, 616- 624 (Bogdandy ed., 2003).

> safeguarding these rights, the Court is bound to draw inspiration from constitutional traditions common to the member states, and it cannot therefore uphold measures which are incompatible with fundamental rights recognized and protected by the constitutions of those states. Similarly, international treaties for the protection of human rights on which the member states have collaborated or of which they are signatories, can supply guidelines which should be followed within the framework of Community Law.[18]

This statement is reflected by Article I-9 Clause 3 of the Constitutional Treaty for Europe, which states: "Fundamental rights as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union's Law."

In the following, we shall therefore begin by outlining the norms of the European Convention on Human Rights and of other international agreements including their additional protocols promulgated by the Council of Europe, which are legally binding for the European Union and continue by applying them to the issue under review (I). Subsequently, we shall establish the extent to which Community Law has served to provide more specific instructions for the protection of human dignity in respect of embryos (II).

I. The European Convention on Human Rights and Similar International Agreements Including their Additional Protocols

Article 2 Clause 1 of the European Convention on Human Rights [hereinafter "ECHR"] protects the right to life without explicitly mentioning unborn human life. The European Court for Human Rights has not yet ruled whether this right also applies to embryos. The (former) European Commission for Human Rights had deliberately left this question open when confronted with abortion cases.[19]

The Federal Republic of Germany has (so far) failed to ratify the "Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to

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[18] Case 4/73, Nold v. Commission, 1974 E.C.R. 491, margin note 13.

[19] Jochen Abr. Frowein, *Article 2*, *in* EUROPÄISCHE MENSCHENRECHTSKONVENTION – EMRK KOMMENTAR margin note 3 (Jochen Abr. Frowein & Wolfgang Peukert eds., 2nd ed. 1996).

the Application of Biology and Medicine on the Prohibition of Cloning Human Beings" from April 4, 1997.[20] The convention came into force on 1 December 1999 for the first five countries having ratified the treaty.[21] Germany has objected that the Convention provides insufficient protection for the embryo. Article 1 Clause 1 of the treaty begins by stating that the dignity and identity of human beings are protected. According to Article 2, the interests and the welfare of the human being shall prevail over the sole interest of society or science. Article 18 states:[22]

> (1) Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
>
> (2) The creation of human embryos for research purposes is prohibited.

The aforementioned Convention about human rights and biomedicine interprets Article 2 ECHR to be binding in such a way that the protection of life guaranteed by said Article 2 includes human embryos, *in utero* as well as *in vitro*. This is clearly demonstrated by the heading and by Article 18 Clause 2, which can only be interpreted to prohibit the *in vitro* fertilization of a human ovum for research purposes.

The "Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings" from 12 January 1998[23] contains the consideration that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine.[24] Article 1 of the Additional Protocol therefore states:[25]

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[20] Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, April 4, 1997, Europ. T.S. No. 164.

[21] These are Denmark, Greece, San Marino, Slovakia and Slovenia. In the meantime, more countries have ratified the Convention, by the end of September 2005, 18 countries had done so.

[22] The English version is legally binding.

[23] Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, January 12, 1998, Europ. T.S. No. 168.

[24] Direct quote from the English text.

[25] The English version is legally binding.

> (1) Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
>
> (2) For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.

With the Convention from 4 April 1997 and the Additional Protocol from 12 January 1998, the European Council has expressly extended the ECHR's guarantee for the protection of human life to embryos, taking into view and consideration medical techniques that were unknown in 1950.[26]

This interpretation is not generally accepted, as evidenced by the refusal of the German Federal Government to sign the Convention for the Protection of Human Rights with Regard to the Application of Biomedicine and the Additional Protocol on the Prohibition of Human Cloning, arguing that it fails to provide a sufficient level of protection for the embryo. There are also attempts to interpret the ban on the creation of human embryos in such a way that research for therapeutic purposes is not affected by the ban and that, accordingly, Article 18 Clause 2 of the Convention does not apply.[27] Additionally, the British Parliament has permitted researchers to create (cloned) embryos for the provision of stem cells until the 14th day after the fertilization. In the UK, at least, this Parliamentary decision is apparently not seen to constitute a breach of the Convention for the Protection of Human Rights with Regard to the Application of Biomedicine and the Additional Protocol on the Prohibition of Human Cloning.

The effort required to develop a well-reasoned, independent approach for the purpose of interpreting the Convention would seem to be disproportionate to the relevance of the Convention, which comes across as a rather hastily and poorly

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[26] Switzerland, for instance, a member of the Council of Europe, embodied embryo protection in its constitution in an amendment from 18 December 1998. "All types of cloning and interventions in the genetic heritage of human germ cells and embryos are prohibited." Clause 2c ends: "... only the number of human ova may be developed into embryos outside the woman's body as can be immediately implanted into her." Bundesverfassung der Schweizerischen Eidgenoosnschaft [BV] / Constitution federal de law Conféderation Suisse [Cst] [Constitution], December 18, 1998, SR 101, art. 119 section 2 lit. a (Switz).

[27] For a detailed explanation *see* KERSTEN, *supra* note 9, at 83.

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constructed piece of legislation and which has been signed by only a few member states of the Council of Europe.

II. European Community Law

1. The Charter of Fundamental Rights

The Charter of Fundamental Rights, solemnly proclaimed on the occasion of the Intergovernmental Conference at Nice in December 2000, but not subsequently enacted, casts the long shadow of a "pre-emptive normative effect"[28] that is further reinforced by its integration into the Constitutional Treaty for Europe. The CTE was signed on the occasion of the Intergovernmental Conference on 29 October 2004 in Rome and has been subjected to the ratification processes in a number of individual member states, most notoriously in losing votes in France and Holland.

Article 1 of the Charter of Fundamental Rights (Article II-61 of the CTE) declares that human dignity is inviolable and requires both respect and protection. Article 1 would seem to allow an interpretation along the lines of the interpretations for the identically worded Article 1 GG. We shall return to this later in greater detail. Article 3 Clause 2 lit. d (Article II-63 Clause 2 lit. d of the CTE) prohibits reproductive cloning of human beings. This qualification could seem to imply that cloning for therapeutic or diagnostic purposes is not subject to the ban.[29] The non-binding motivation of the Presidium of the Convent explains that Article 3 was worded in such a way that it would not contradict the Convention for the Protection of Human Rights with Regard to the Application of Biomedicine and the Additional Protocol on the Prohibition of Human Cloning. Therefore, only reproductive cloning was prohibited. The Charter neither permitted nor prohibited other forms of cloning. Legislators would be free to extend the ban to all forms of cloning.[30] The explanations of the President provide no other reason for the prohibition of human cloning and in particular lack any reference to the guarantee for human dignity.

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[28] *See* Rudolf Streinz, *Charta der Grundrechte der Europäische Union*, *in* EUV/EGV KOMMENTAR 2573 (Rudolf Streinz ed., 2003).

[29] So far this is the prevailing opinion. For additional information, *see* Thomas Schmitz, *Die EU-Grundrechtecharta aus grundrechtsdogmatischer und grundrechtstheoretischer Sicht,* 56 JURISTENZEITUNG (JZ) 833 (2001); Kyrill-Alexander Schwarz, *Therapeutisches Klonen,* 89 KRITISCHE VIERTELJAHRESSCHRIFT FÜR GESETZGEBUNG UND RECHTWISSENSCHAFT (KritV) 182, 192 (2001); Rudolf Streinz, *Article 3 Charter of Fundamental Rights*, *in* EUV/EGV KOMMENTAR margin note 2, 5 (Rudolf Streinz ed., 2003); Matthias Pechstein, *Article 6 EUV*, *in* EUV/EGV KOMMENTAR margin note 17 (Rudolf Streinz ed., 2003).

[30] Presidium of the Convent, CHARTE 4473/00, CONVENT 49, p. 5.

2. Resolutions by the European Parliament

The European Parliament has dedicated three remarkable resolutions to the issue of human cloning which we shall subject to closer scrutiny. Resolutions of the European Parliament constitute legal acts that are not provided for under Article 249 EC. This is why such resolutions are, strictly speaking, not legally binding. They are "declarations of legal policy" and represent as such "soft law" inasmuch as they have been published in the Official Journal.[31] Resolutions are particularly useful as interpretation guides and are therefore relevant for the issue under review.

The resolution of cloning from 12 March 1997 states:

> In the clear conviction that the cloning of human beings, whether experimentally, in the context of fertility treatment, preimplantation diagnosis, tissue transplantation or for any other purpose whatsoever, cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans.[32]

The list of possible cloning purposes makes clear that the ban is intended to cover therapeutic cloning, too.

The resolution from 15 January 1998 was passed with an awareness of the Convention for the Protection of Human Rights with Regard to the Application of Biomedicine from 4 April 1997 and the Additional Protocol on the Prohibition of Human Cloning from 12 January 1998. In essence, the 1998 resolution repeats the crucial points of the 1997 resolution and calls upon the Council of Europe member states to ratify both the Convention and the Additional Protocol. After these preliminary matters, the 1998 resolution amends the 1997 resolution as follows: "Whereas human cloning is defined as the creation of human embryos having the

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[31] *See* THOMAS OPPERMANN, EUROPARECHT margin note 586 (2nd ed., 1999); Werner Schroeder, *Article 249 EGV*, *in* EUV/EGV KOMMENTAR margin note 32 (Rudolf Streinz ed., 2003).

[32] 1997 O.J. (C 115) 14, 4 Consideration B. The awkward wording suggesting that human experiments are "required" is common to the German, English and French versions.

same genetic make-up as another human being, dead or alive, at any stage of its development from the moment of fertilization, without any possible distinction as regards the method used."[33]

This statement reflects the acknowledgement that the human person is created by the fusion of the cell nuclei and that this person's human dignity is entitled to protection from this moment in time.

The resolution from 7 September 2000 represents a reaction to a proposal for the legalization of therapeutic cloning, submitted by the British Government. The European Parliament objected to any such attempt to distinguish between therapeutic and reproductive cloning and thereby to any liberalization of the ban on cloning, defining "... human cloning as the creation of human embryos having the same genetic make-up as another human being dead or alive, at any stage of their development, without any possible distinction as regards the method used." [34]

The resolution from 10 March 2005 about the market for human ova – which has not yet been published in the Official Journal – represented a reaction to media reports which alleged the existence of a clinic in Romania where EU (mainly UK) citizens were provided with donor ova for a price of € 1000.[35] Consideration H no. 14 welcomes the resolution of the 6th Commission of the United Nations from 18 February 2005 and calls upon the European Commission to exclude human cloning research from funding under the 7th FRP. No. 15 reminds the Commission of the subsidiarity principle and demands that other forms of embryo research and embryo stem cell research in those member states where such research is lawful must be exclusively funded from the respective national budgets. The Consideration continues with the suggestion "that EU funding should concentrate on alternatives like somatic stem cell and umbilical cord stem cell research, which are accepted in all Member States and have already led to the successful treatment of patients."

The four resolutions of the European Parliament represent an attempt to provide a more precise definition of the ban on cloning contained in European primary law by legal policy statements on the level of secondary Community Law.[36]

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[33] 1998 O.J. (C 34) 164 Consideration B.

[34] Not published in the Official Journal. *See* www.euro-parl.eu.inter.

[35] *See* http://www2.europarleu.int/omk/sipa-de2.

[36] Similarly, KERSTEN, *supra* note 9, at 119.

Consideration 40 of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions issued by the European Parliament and the European Council on July 6 1998 states: "Whereas there is a consensus in the Community that interventions in the human germ line and the cloning of human beings offends against public order and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes of cloning human beings."[37] The subsequent consideration provides a definition for the "process of cloning human beings," prohibiting any process – including techniques of embryo splitting – that intends to create a human being whose cell nuclei contain the same genetic information as another human being, dead or alive.

Following Article 6 of the Directive, no patent application can be filed for the following processes, due to their incompatibility with public order or public morality: a) processes for cloning human beings; and b) processes for modifying the germ line genetic identity of human beings.

Plenty of good evidence seems to support the assumption that this patentability ban is based on the view that all cloning techniques and purposes offend against public order and morality.[38] This Directive must be seen in a close chronological context with the aforementioned resolutions of the European Parliament, which have categorically outlawed ("... for any other purpose whatsoever"[39]) all cloning purposes.

3. Interpretation of the Human Dignity Guarantee in the Charter of Fundamental Rights

We have already discussed the importance of the human dignity guarantee that received a most prominent position when it was integrated into Article 1 of the Charter of Fundamental Rights (Article II-61 CTE).[40] The Charter of Fundamental Rights is not yet legally binding, but the European Parliament, the Commission and the Council of the European Union committed themselves to following its provisions immediately after it was proclaimed. In the long term, the European Court of Justice may find it difficult to ignore the Charter and may have to consider it, if need be *via* the bridge provided by Article 6 Clause 2 EU.[41]

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[37] 1998 O.J. (L 213) 13.

[38] *See* KERSTEN *supra* note 9, at 120 – 193.

[39] Resolution from March 12, 1997.

[40] *See* Schmitz, *supra* note 29, at 836.

[41] *See* KERSTEN *supra* note 9, at 88.

Meanwhile, Article 1 of the Charter of Fundamental Rights (Article II-61 CTE) has been subjected to its first interpretation. Borowsky predicts in Jürgen Meyer's commentary that an interpretation of the phrase "human dignity" along the lines provided by Kant – prohibiting any treatment of human beings as mere objects or things – would we widely approved throughout Europe. Borowsky also sees the Charter as a potential instrument to improve the legal protection for embryos which – on a European level – (he argues) has so far not been particularly strong.[42]

We are still a long way away from an established legal doctrine of human dignity on a European level. Much can be said in favour of interpreting Article 1 of the Charter of Fundamental Rights (Article II-61 CTE) in the same way as Article 1 Clause 1 GG.[43] The text is a straight borrowing from German Constitutional Law, and one may assume that this borrowing was made in full awareness of the prevailing German interpretation. As we shall demonstrate shortly in greater detail (E.I.), all living beings that are the product of human procreation are entitled to the protection of human dignity, whether the act of procreation was performed naturally or extracorporeally with human (germ line) cells.[44] As soon as the cell nuclei have been fused or a totipotent cell has been created (using non-sexual techniques of procreation), this cell enjoys the protection of human dignity. The process of embryo splitting artificially creates a pair of identical twins: both of them have a human dignity. The transfer of a cell nucleus into an ovum whose nucleus has been removed also creates a totipotent cell capable of developing as an embryo and therefore equipped with human dignity that requires protection. The use of totipotent cells for extraneous ends – other than as an end in themselves – violates human dignity. On this basis, the corresponding processes can be neither patented nor lawfully funded. There is currently no such support from the European Union.

4. Existing Uncertainties and a Proposal for their Resolution

The dispute about the UN Convention against Human Cloning – which aroused a certain amount of media interest towards the end of 2004 – demonstrated that there was a fairly sizeable contingent of EU Member States reluctant to ban therapeutic

[42] Borowsky, *Artikel 1*, *in* KOMMENTAR ZUR CHARTA DER GRUNDRECHTE DER EUROPÄISCHEN UNION 45 (Jürgen Meyer ed., 2003).

[43] Rudolf Streinz, *Article 1 of the Charter of Fundamental Rights*, *in* EUV/EGV KOMMENTAR margin note 1, 2581 (Rudolf Streinz ed., 2003).

[44] *See* the detailed explanation in KERSTEN, *supra* note 9, at 403, 554.

cloning (performed by a transfer of cell nuclei) alongside reproductive cloning.[45] This contingent includes Belgium, Sweden and the UK, supporters of therapeutic cloning with public subsidies. In discussions about therapeutic cloning, the human dignity aspect is frequently side-stepped, not least by an act of semantic reassurance, labelling the totipotent cell – which is fully equipped to develop as an embryo and therefore is an embryo – the "cell nucleus transfer product."

The behaviour of many EU Member States during the deliberations of the UN Cloning Convention has demonstrated that the European Union is still undecided whether or not to extend the ban on reproductive cloning (Article 3 Clause 2 lit. d of the Charter of Fundamental Rights is the equivalent of Article II-63 Clause 2 lit. d of the CTE) on other forms of cloning.

Jens Kersten who has provided the most thoroughly researched inquiry into the importance of human cloning in Constitutional, European and International Law,[46] has submitted the following proposal for an amendment to every future Framework Research Programme of the European Union:[47]

> The basic ethical principles ... include the principles of the Charter of Fundamental Rights of the European Union, the protection of human dignity and human life, the protection of personal data and privacy as well as the protection of the environment in compliance with Community Law, the relevant international treaties and the Helsinki Declaration in its most recent version, the Convention of the European Council about Human Rights and Biomedicine signed in Oviedo on April 4, 1997 and the Additional Protocol about the ban on human cloning signed in Paris on January 12 1998, the UN Convention on Children's Rights, the General Declaration about the Human Genome and Human Rights by UNESCO, the relevant resolutions of the World Health Organisation (WHO) as well as the

[45] According to the report by Christian Schwägerl in the *Frankfurter Allgemeine Zeitung* there are eleven states. Christian Schwägerl, FRANKFURTER ALLGEMEINE ZEITUNG (FAZ), November 27, 2004, at 12. *See also* CSL, FRANKFURTER ALLGEMEINE ZEITUNG (FAZ), November 20, 2004, at 6.

[46] *See* KERSTEN, *supra* note 9.

[47] *Id.* at 584.

> laws and regulations valid in the countries where the research projects in question are conducted.
>
> This is why no research activities will be conducted within this Framework Research Programme which have the objective of human cloning (Article 3 Clause 2 lines 1-4 of the Charter of Fundamental Rights of the European Union in conjunction with Article 1 of the Additional Protocol of the Biomedicine Convention about the ban on human cloning). Embryos, once they have begun their development as totipotent cells, must be considered as human beings. This specifically rules out the provision of any form of support for embryo splitting and the transfer of cell nuclei.
>
> Neither shall research projects qualify for support which aim to alter the genetic heritage of human beings in order to make such alterations heritable.

If Kersten's proposal, which neatly summarizes the point of view taken so far by the European Parliament, should fail to find favour when future Framework Research Programmes are devised, the problem would arise that the European Union funds research projects which are illegal under German Law. Not only would this create a regrettable conflict with some basic values of the European Union's Member States, it would also mean that the German tax payer – Germany, after all, is a net contributor to the EU budget – would be funding activities that are prohibited in Germany because they violate human dignity, a value the German government is required to protect in compliance with Article 1 GG.

In the following, we shall therefore submit the legal situation in Germany (D.) and its constitutional foundation (E.) to a closer analysis.

D. The German Embryo Protection Act and the Stem Cell Act

The Embryo Protection Act,[48] which came into force on 1 January 1991, contains the following punishable acts in connection with embryo stem cell research:

- The *in vitro* fertilization of a woman who has donated an ovum for any other purpose but to induce a pregnancy (§ 1 Clause 1 no. 2). It is equally prohibited to fertilize ova which are not intended for implantation within one cycle (§ 1 Clause 1 no. 5).

- The artificial transfer of genetic information (cloning) of a human being, a dead human being, a foetus or an embryo to an(other) embryo (§ 6 Clause 1).

In § 8, the Act defines an embryo as "the fertilized human ovum which is capable of development after the nuclei have merged, also any totipotent cell extracted from an embryo capable – under the right circumstances – of dividing and developing into an individual."[49]

Under these provisions, any type of stem cell research is prohibited because you always need to consume an embryo in order to create such stem cells. The same applies to the creation of tissue through therapeutic cloning.

The Embryo Protection Act is clearly based on the value judgment that an embryo, which has been created *in vitro,* must be consumed neither for research nor for therapeutic purposes, but must – in line with its natural "telos" – be given the chance instead of developing into a human being and of being born.[50] This value judgment also has the consequence that the import of embryo stem cells is always illegal, whether or not the consumption of embryos for research purposes is lawful in the stem cells' country of origin. Since the Embryo Protection Act is a criminal law and as such subject to strict conditions – for every punishable act the elements of the offence must be clearly established (Article 103 Clause 2 GG: *nullum crimen*

[48] Embryonenschutzgesetz (ESchG- Embryo Protection Act), December 13, 1990, BGBl. I at 2747.

[49] This definition is, in essence, repeated by § 3 no. 4 of the Stem Cell Act.

[50] ROLF KELLER, ET AL., KOMMENTAR ZUM EMBRYONENSCHUTZGESETZ § 1, margin note 4 (1992). The same judgment of value provides the basis for Article 119 no. 2 lit. a and c of the Swiss Federal Constitution, which prohibits all types of cloning and limits the amount of embryos created during the act of *in vitro* fertilization to the number of embryos which can be immediately implanted into the woman.

sine lege) – it was disputed whether stem cells created abroad could be imported for research purposes to Germany, because the import of such stem cells was not explicitly banned.

The "Act to ensure embryo protection with regard to the import and use of human embryo stem cells" (the "Stem Cell Act") from 28 June 2002,[51] resolved such questions by prohibiting the import and use of embryo stem cells (§ 4 Clause 1). In qualification of this, § 4 Clause 2 permits the import and use of embryo stem cells for research purposes, provided the conditions of § 6 have been met, if:

> 1. the authority responsible for issuing the permit has established to its own satisfaction that
>
> a. the embryo stem cells have been created in compliance with the laws of the country of origin before 1 January 2002 and that they have been kept in a culture or have subsequently been stored in cryopreservation (embryo stem cell line).
>
> b. the embryos from which the stem cells were extracted have been created by means of a medically supported extracorporal fertilization with the purpose of inducing a pregnancy, that they shall definitely and irrevocably no longer be used for this purpose and that there is no indication to support the assumption that this turn of events had anything to do with the embryos themselves.
>
> c. the procurement of the embryos for the creation of stem cells was not connected in any way with the payment of monies, the exchange of equivalent benefits or any promise thereof.
>
> 2. no other laws or regulations – specifically the provisions of the Embryo Protection Act – prevent the import or use of the embryo stem cells.

[51] Stammzellgesetz (StZG- Stem Cell Act), June 28, 2002, BGBl. I at 2277.

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The exception has been justified by pointing out that embryo stem cells were produced in many countries in compliance with national laws before the cutoff date. The exception nevertheless will only apply inasmuch as the stem cells are coming from embryos that were created *in vitro* for the purpose of inducing a pregnancy.

The purposes and techniques of research for which embryo stem cells may be imported are restricted as follows:

> § 5 Embryo stem cell research
>
> Embryo stem cell research must only be conducted if it can be scientifically reasoned that
>
> 1. such projects would serve high-ranking research objectives to provide new knowledge in the area of basic research or the extension of medical knowledge with a view to developing diagnostic, preventive or therapeutic techniques for the benefit of human beings,
>
> 2. considering the current level of scientific and technological knowledge,
>
> a. the questions addressed by the research project have already, to the furthest possible extent, been examined by *in vitro* models using animal cells or animal experiments,
>
> b. the new scientific knowledge the acquisition of which is the purpose of the project can presumably only be gained by using embryo stem cells.

The conditions for the approval of the research project have been defined as follows:

> § 6 Permission
>
> (1) Any import and any form of use of embryo stem cells requires permission from the responsible authority.

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(2) Any application for such a permission needs to be filed in writing. The applicant will have to provide the following information:

1. the name and the office address of the person responsible for the research project in question,

2. a description of the research project including a scientifically founded representation that the project complies with the requirements of § 5,

3. a documentation of the stem cells about to be imported or used, demonstrating that the requirements of § 4 Clause 2 no. 1 have been met. Such a documentation will need to provide evidence that

a. the embryo stem cells about to be imported or used are identical with those which have been entered in a scientifically recognized and publicly accessible register office which is run either by the government itself or by organisations which have been duly authorized by the government,

b. such registration demonstrates that the requirements of § 4 Clause 2 no. 1 have been met.

(3) Upon the arrival of the application and attached documents, the responsible authority shall provide the applicant immediately with a written confirmation of receipt. At the same time, it shall procure the opinion of the Central Commission for Ethics in Stem Cell Research. After the opinion has been provided, the authority shall inform the applicant of its content and of the date set for a decision by the Central Commission for Ethics in Stem Cell Research.

(4) Approval shall be given, if:

1. the conditions of § 4 Clause 2 have been met,

2. the conditions of § 5 have been met and the research project can be ethically justified in compliance with the provisions therein,

3. the Central Commission for Ethics in Stem Cell Research has provided an opinion at the request of the responsible authority.

(5) After the application with all required attachments and the opinion from the Central Commission for Ethics in Stem Cell Research have arrived, the authority will have two months in which to prepare a written decision. In this, the authority will have to consider the opinion of the Central Commission for Ethics in Stem Cell Research. In the event that the authority were to arrive at a decision which went against the opinion of the Central Commission for Ethics in Stem Cell Research, it would need to provide the reasons for this in writing.

(6) Any approval may be linked to certain conditions and added requirements or may be issued for a limited period only, insofar as this is required to meet the permit conditions of paragraph 4 either now or on an ongoing basis in the future. If, after the permit has been issued, new factual constellations occur which violate the conditions under which said permit has been provided, the permit can be partially or entirely withdrawn with effect for the future or may be linked to certain conditions and added requirements or may be issued for a limited period only, insofar as this is required to meet the permit conditions of paragraph 4 either now or on an ongoing basis in the future. Objection and action for avoidance against the cancellation or withdrawal of the permission have no suspensive effect. Violations of § 6 are punishable (§ 13) or subject to a fine (§ 14). The Stem Cell Act does not affect the ban on therapeutic cloning. The embryo stem cells required for such activities would

> need to be procured for each individual therapeutic case.

The legal extent of embryo protection described herein is questioned by some authors who base their argument on the freedom of research (Article 5 Clause 3 GG) and, connected with this, on the right to life of people with an illness for whom embryo research would seem to offer a chance for a therapy.[52]

The decision of the British Parliament from September 2000 to allow the creation of cloned embryos with a view to procuring stem cells until the 14th day after the fertilization of the ovum in particular has led to renewed calls in Germany for an amendment of the Embryo Protection Act that would enable research into new therapies and their subsequent application. This is in accord with the recommendation of the *Deutsche Forschungsgemeinschaft* about embryo stem cell research from 3 May 2001.[53] Demands to reduce the level of embryo protection or to withdraw any such protection from embryos that were fertilized *in vitro* are substantiated by the claim that the *Grundgesetz* (GG – Basic Law or Constitution) did not demand the type of regulation contained in the Embryo Protection Act.

Before we can assess these demands, we need to clarify the constitutional status of the embryo.

E. The Constitutional Foundation of Embryo Protection

I. The Onset of Dignity Protection

Article 1 Clause 1 of the *Grundgesetz* (GG – Basic Law or Constitution) declares human dignity "inviolable." The normative character of the human dignity guarantee is stated unambiguously by the second sentence of the Article, which compels the government and all of its agents to "respect and to protect" human dignity.[54] All living beings that are the product of human procreation possess and are imbued with human dignity, even after their deaths. This most inclusive and

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[52] Jörn Ipsen, *Der "verfassungsrechtliche Status" des Embryos in vitro*, 56 JURISTENZEITUNG (JZ) 989, 995 (2001); Michael Kloepfer, *Humangenetik als Verfassungsfrage*, 57 JURISTENZEITUNG (JZ) 417, 425, 427 (2002); Werner Heun, *Embryonenforschung und Verfassung – Lebensrecht und Menschenwürde des Embryos*, 57 JURISTENZEITUNG (JZ) 517, 523 (2002).

[53] Deutsche Forschungsgemeinschaft, *Recommended Amendment to the Embryo Protection Act*, 34 WISSENSCHAFSRECHT (WissR) 287 (2001).

[54] Christian Starck, *Article 1*, *in* 1 GRUNDGESETZ KOMMENTAR margin note 14 (Hermann von Mangoldt, Friedrich Klein and Christian Starck eds., 5th ed. 2005).

farthest-reaching of all possible definitions of possession of dignity is no biological-naturalistic fallacy,[55] but a value judgment that is based on a vitally important self-restraint of human beings. Any limitation would create a situation where the person who interprets the constitution "grants" or "denies" dignity. The protection of dignity cannot be conditioned upon the "possession awareness" or any conscious experience of self, reason, or the capacity for self-determination.[56] Birth, too, is an arbitrary point of reference, because human beings are capable of determining the moment of birth towards the end of a pregnancy. How can it be reasoned that an unborn foetus in his or her mother's womb does not enjoy any right for the protection of his or her dignity, in contrast to the prematurely born child of the same age?

All other attempts to define cutoff lines in order to separate those with from those without a right to the protection of their human dignity are similarly afflicted by a pronounced arbitrariness: the capacity of the foetus to survive, the end of the third month of pregnancy, the beginning of the development of the brain, nidation. The arbitrary character of selecting nidation as the point where human dignity deserves protection has been contested because – it is argued – only the mother's control apparatus gives the "embryogenesis commands."[57] The arbitrariness is, however, demonstrated by the simple fact that – during *in vitro* fertilization processes – it would fall to human beings (by selecting the time of embryo implantation) to determine where and when the right to the protection of human dignity begins. People who use this very fact – that the implantation is subject to human decisions – as an argument in favour of setting the respective cut-off date[58] ignore the existence of a strict and constitutionally established coherent relationship between the *in vitro* fertilization and the implantation of the embryo into the womb of the woman whose ovum is being fertilized. This means that the "lack of accommodation" for the unsettled embryo cannot be used as an argument to question its capacity for development with a view to surrendering it as raw material for research.

II. The Human Embryo is a Subject, not an Object

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[55] Horst Dreier's wording. *See* Horst Dreier, *Article 1*, *in* 1 GG KOMMENTAR margin note 66 (Horst Dreier ed., 2nd ed. 2004).

[56] According to Dreier. *See id.* at margin note 64.

[57] Jochen Taupitz, *Der rechtliche Rahmen des Klonens zu therapeutischen Zwecken*, 54 NEUE JURISTISCHE WOCHENSCHRIFT (NJW) 3433, 3438 (2001). On the basis of a speech by Johannes Huber. *See* Johannes Huber, Address: Möglichkeiten und Grenzen der Embryonenforschung aus der Sicht der Medizin.

[58] Rüdiger Wolfram, 27 AUS POLITIK UND ZEITGESCHICHTE 4 (2001); *see also* Taupitz, *supra* note 57, at 3438.

The process of *in vitro* fertilization has created the impression that the procreative cells extracted from man and woman – the semen and the ovum – are objects which, once they have been fused in the test tube, do not lose this essential quality and become, if anything new at all, a new kind of object. The language used to discuss and describe *in vitro* fertilized eggs demonstrates this clearly: "lumps of cells in a petri dish;"[59] "cell walls with a size of a few millimeters;"[60] or, soberly and scientifically emphasizing the 93:7 ratio between trophoblast cells and embryoblast cells.[61] From such an angle it is easy to overlook the fact that the procreation of a human being is based upon an act. If you remove this process from the female body into a test tube in order to overcome certain physical restrictions of those willing to reproduce, the ingredients may have been separated from the acting and procreating persons, but the quality of the act remains the same. It remains an act of procreation. Any other interpretation of the act of *in vitro* fertilization generates unsolvable problems. If you deny the fertilized egg the status of a person and the right to human dignity, regarding it as an object, it would be necessary to explain how such an object can ever become a person. This does not seem possible within the framework of either philosophical or legal theory.[62]

Some authors have tried to question the legal personality of the fertilized ovum by contesting – following some Anglo-Saxon legal theorists[63] – that the fact of the embryo's membership of the human species, the continuity of its development, its potential to develop as a human being and the identical character of the genetic programs of embryo and post-birth human being alone do not provide sufficient ground for extending the human dignity protection to embryos.

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[59] Stephen Jay Gould, *Baers Gesetz*, FRANKFURTER ALLGEMEINE ZEITUNG (FAZ), August 30, 2001, at 32.

[60] Nida-Rümelin, SÜDDEUTSCHE ZEITUNG, February 3/4, 2001.

[61] Heun, *supra* note 52, at 519.

[62] For a detailed view on this, *see* Christian Starck, *Verfassungsrechtliche Grenzen der Biowissenschaft und Fortpflanzungsmedizin*, 57 JURISTENZEITUNG (JZ) 1065 (2002); *see also* Christian Starck, *Der kleinste Weltbürger – Person, nicht Sache: Der Embryo,* 96 FRANKFURTER ALLGEMEINE ZEITUNG (FAZ), April 25, 2002, at 50; Josef Isensee, *Der grundrechtliche Status des Embryos - Menschenwürde und Recht auf Leben als Determinanten der Gentechnik*, *in* GENTECHNIK UND MENSCHENWÜRDE 37, 52 (Otfried Höffe, eds., 2002); E-W. Böckenförde, *Menschenwürde als normatives Prinzip,* 58 JURISTENZEITUNG (JZ) 808, 811 (2003) (who, however, does not use the personality argument, though he arrives at the same conclusion); KERSTEN *supra* note 9, at 411, 419; Wolfgang Graf Vitzthum, *Back to Kant! An Interjection in the Debate on Cloning and Human Dignity, in* HUMAN DIGNITY AND HUMAN CLONING 87, 101 (Silja Vöneky & Rüdiger Wolfram eds., 2004).

[63] Selected examples are presented by Heun, *supra* note 52, at 519.

The *species argument* is countered by pointing out that embryos are incapable of acting morally. Since, however, the same could be said about small children – whose dignity is unquestionably under protection –, this does not refute the species argument. The crucial point is the embryo's capacity for development as a human being. This is equally true for embryos that have been created non-sexually through cell nuclear transfer or embryo splitting.

Attempts to refute the *continuity argument* are based on the fact that trophoblast cells outnumber embryoblast cells and on the assertion that continuities exist both before the fusion of the cell nucleus and after the birth of human beings whose lives are quite often – and with full legal force – sub-divided by arbitrarily drawn cutoff lines (for instance, attaining full age). Insofar as these reasons are not overly far-fetched, one may state that life in general is a continuum. For the purpose of our review, however, we are exclusively interested in the question at what point new individual human life begins. The fusion of the pronuclei from ovum and semen that "leads to the creation of a new cellular structure, the so-called zygote"[64] is the crucial point. The potential for individual development is only inherent in the fused cell, not in the ovum and not in the semen cell. It is only after the semen has entered the ovum that it is decided which of the two maternal sets of chromosomes will be passed on to the new life. The development of the *in vitro* embryo is not any less continuous because the embryo still needs to be implanted into the womb of the woman whose ovum was (extracorporeally) fertilized.[65]

The *potentiality argument* is closely related to the continuity argument. In an attempt to refute it, the argument has been advanced – in a *reductio ad absurdum* – that the interest of "the individual not to let contraceptives intervene in his or her creation" was equivalent to the interest of the embryo as the possessor of later basic rights not to be killed in a prenatal stage. This deliberately ignores that the aforementioned "individual" has not yet reached the state of "a new cellular structure, the so-called zygote" which is the basic condition on which the right is founded and to which it is attached. The potentiality of the embryo is an active potentiality with a complete programme, not one with a programme in need of completion during a later stage (nidation). Already in his or her earliest stages, the embryo is equipped with instruments capable of correcting the length of chromosomes that may have been shortened in the process of cell division.[66]

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[64] *Id*.

[65] The issue of the "non-accommodated" embryo that has not yet been implanted is discussed in section E.I. of this text. *See also* KERSTEN, *supra* note 9, at 550.

[66] Josef Wisser, *Einzartig und komplett. Der Embryo aus biologischer Sicht,* FRANKFURTER ALLGEMEINE ZEITUNG , July 20, 2001, at 44.

The *identity argument* is countered with the assertion that genetic identity alone is insufficient to define a human being and that the embryo does not yet meet the description of a human being because it lacks required elements such as a developed brain. This argument ignores the fact that every embryo has carried a programme for such brain development since the moment of his creation. It is equally inappropriate to deny the existence of a genetic identity by pointing out the occurrence of genetically identical twins, because in such an event two people with identical genetic make-ups will need to be protected[67] who will grow up to be separate and independent individuals in possession of their fundamental rights.

III. The Connection between the Protection of Life and the Protection of Dignity

Another attempt to withdraw the protective cover of the human dignity guarantee from the human embryo is based on the decoupling of the protection of life from the protection of dignity. The fertilized egg is "granted" a right to the protection of life, but not to the protection of dignity.[68] This construction serves to by-pass the absolute legal position of the human dignity guarantee that cannot be restricted or made conditional in any way. The protection of life, on the other hand, guaranteed by Article 2 Clause 2 GG can be restricted and qualified by other laws (Article 2 Clause 2 sentence 3 GG). Even at first sight, such decoupling attempts seem entirely futile. By granting the fertilized egg the right to a protection for life, after all, it is implied that it represents human life. The legislature will find no compulsory reasons to intervene in the life of fertilized eggs – such interventions in human life are only allowed if this life threatens the life of another human being and if this threat can only be averted by killing. The ovum that has been fertilized *in vitro* does not pose a threat to anyone. This qualification only applies if the unborn child threatens the life of his mother – in which case an abortion may be performed on the basis of a medical indication. Not even the highest-ranking objectives of medical research (developing therapies for grave illnesses, prolonging human lives) can justify the consumption of human life. Even if the embryo were denied any protection of human dignity, consumptive embryo research would still be illegal because embryos – as human life – would still be entitled to the protection of life.

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[67] For a line similar to the one taken here, *see also* KERSTEN *supra* note 9, at 552.

[68] Adalbert Podlech, *Article 1 Clause 1,* ALTERNATIVKOMMENTAR ZUM GRUNDGESETZ margin note 58 (1989); Hasso Hofmann, *Die versprochene Menschenwürde,* 118 ARCHIV DES ÖFFENTLICHEN RECHTS (AöR) 353, 376 (1993); Horst Dreier, *Article 1, in* 1 GRUNDGESETZ KOMMENTAR margin note 67 (Horst Dreier ed., 2nd ed., 2004); Matthias Herdegen, *Article 1 Clause 1, in* GRUNDGESETZ KOMMENTAR margin notes 57-60 (2003); Edzard Schmidt-Jorzig, *Systematische Bedingungen der Garantie des unbedingten Schutzes der Menschenwürde in Art. 1 GG,* 54 DIE ÖFFENTLICHE VERWALTUNG (DÖV) 925, 928 (2001); Ipsen, *supra* note 52, at 989, 994; Hans Georg Dederer, *Menschenwürde des Embryo in vitro?* 127 ARCHIV DES ÖFFENTLICHEN RECHTS (AöR) 1, 18 (2002).

IV. Interim Conclusions

The fertilized human egg (embryo) is a person and belongs to the human species as soon as the cell nuclei have merged. The embryo's genetic programme provides the potentiality for the development as a human being that occurs continuously and not in discernible stages with clearly marked cutoff lines, beginnings or ends. The identity between embryo and newborn child is a genetic identity. This is all we need to establish since the later development of the human being is subject to a wide range of influences that can – and, of course, do – lead to continuous changes in the fully-fledged identities of individuals. Since the fertilized egg represents individual human life, it is fully entitled to the constitutional protection of life and dignity.

V. Contradiction Between Embryo Protection and Abortion Laws?

Some people have asserted that the constitutional protection for embryos has already been derogated by the abortion legislation and the corresponding jurisprudence of the *Bundesverfassungsgericht* (BVerfG – Federal Constitutional Court).[69] Ordinary legislation is incapable of derogating Constitutional Law because the latter enjoys a higher legal rank. The *Bundesverfassungsgericht* has ruled – in 1975 and 1993 – that any abortion not performed under medical conditions is unlawful and must be prohibited[70] because the dignity of unborn life was also in need of protection. Since both rulings addressed the termination of pregnancies, only the period between the "accommodation" (*i.e.* the start of the pregnancy) and the birth (*i.e.* the end of the pregnancy) was under review. Nevertheless, the Court's opinion – which has served as the foundation for the establishment of the constitutional status of the embryo – is equally relevant for the embryo outside the womb and *in vitro*. The *Bundesverfassungsgericht* ruled:

> *At any rate* during the thus determined term of pregnancy, the unborn child represents an individual and indivisible human being with a fixed genetic identity, unique and distinct from everybody else, who will grow, mature and develop not into a human being, but as a human being.[71]

[69] *See* Reinhard Merkel, *Embryonenschutz, Grundgesetz und Ethik*, 80 DEUTSCHE RICHTERZEITUNG (DRiZ) 184, 190 (2002).

[70] BVerfGE 39, 1 (44); BVerfGE 88, 203 (255).

[71] BVerfGE 88, 203 (251) (with reference to BVerfGE 39, 1 (37)) (emphasis added).

The Court emphasized that the unborn child's right to life must not be subjected to the free and unconstrained decision of a third person, not even a decision of his or her mother.[72]

Nevertheless, the Court accepted the principle and concept of the *Schwangerschaftskonfliktberatung* (compulsory counselling for women with unwanted pregnancies). The Court specified the minimum requirements for this counselling service and its framework conditions.[73] Unfortunately, the Federal Legislation has failed to comply with these requirements,[74] and when the *Land* Bavaria tried to implement these requirements by way of its own legislation in the field of professional medical practice (over which, pursuant to Article 74 Clause 1 no. 19 GG, the Federation has no competing legislative competence), the First Senate of the *Bundesverfassungsgericht* used novel and less than totally convincing arguments to declare this legislation null and void as an alleged transgression of the *Land's* competences.[75]

Without a doubt, the decisions of the *Bundesverfassungsgericht* and, even more so, the abortion laws promulgated in their wake, have weakened the protection of unborn human life. It must nevertheless be considered that the problem in abortion cases is posed by the refusal of the pregnant woman to accept her pregnancy. The case of *in vitro* fertilizations is a different one,[76] and even more radically different conditions apply to therapeutic cloning: here, human embryos are created with the objective of consuming them for extraneous purposes.

No fundamental contradiction exists between existing abortion laws and the legal protection for extracorporeally created embryos.[77] Legislative failings and practical

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[72] BVerfGE 88, 203 (252).

[73] BVerfGE 88, 203 (270).

[74] *See* Christian Starck, *Verfassungsrechtliche Probleme der deutschen Abtreibungsgesetzgebung*, *in* FESTSCHRIFT FÜR OTFRIED H. SCHIEDERMEIER 377, 382 (2001).

[75] BVerfGE 98, 265 (312). For a critical assessment, *see* Christian Starck, Neues *zur Gesetzgebungskompetenz des Bundes kraft Sachzusammenhangs, in* FESTSCHRIFT FÜR MAURER 281, 289 (2001).

[76] *See* Claus Dieter Classen, *Die Forschung mit embryonalen Stammzellen im Spiegel der Grundrechte*, 117 DEUTSCHES VERWALTUNGSBLATT (DVBl.) 141, 143 (2002); KERSTEN, *supra* note 9, at 570 note 110.

[77] Regine Kollek, *Schutz des Embryos, Freiheit der Forscher,* 1 GEGENWERT, ZEITSCHRIFT FÜR DEN DISPUT ÜBER WISSEN 52, 54 (1998); Josef Isensee, *Der grundrechtliche Status des Embryos - Menschenwürde und Recht auf Leben als Determinanten der Gentechnik, in* GENTECHNIK UND MENSCHENWÜRDE 37, 52 (Höffe, et al., eds., 2002). For another opinion, *see* Ipsen, *supra* note 52, at 991.

difficulties in the attempt to protect unborn life in the mother's womb cannot compromise the duty to protect *in vitro* fertilized ova.

All of this clearly shows that the constitutional protection for human embryos has not been derogated.[78] The protection for embryos provided by the existing laws cannot be withdrawn without violating the *Grundgesetz* (GG – Basic Law or Constitution).

VI. Summary of the Embryo Protection Provided by German Law

The strict protection of embryos under German law prohibits the consumptive research with embryos and the cloning of embryos for diagnostic, therapeutic and reproductive purposes. Corresponding legislation is demanded by the *Grundgesetz* (GG – Basic Law or *Constitution*).[79] Since the protection of human dignity is at risk, Article 1 Clause 1 GG applies. This leads us to the final question: does the provision of financial support from the European Union for research projects that contravene human dignity exceed the frontiers of integration for Germany (F.)?

F. Limitations of Research Funding for the European Union

I. The Importance of Article 23 para. 1 sentences 1 and 3 GG

Article 23 para. 1 *Grundgesetz* (GG – Basic Law or Constitution) identifies the national purpose of the Federal Republic: to participate in the development of the European Union in order to create a unified Europe, "which is committed to the democratic, social and federal principles and the rule of law as well as the principle of subsidiarity and which provides the fundamental human rights with a level of protection which can be essentially compared to the level of protection provided by the *Grundgesetz*." This fundamental rights clause owes its existence to the *Bundesverfassungsgericht*, which ruled that any transfer of competencies to a supranational community would need to be accompanied by a protection guarantee for fundamental human rights, ensuring that such rights would enjoy the same level of protection as they did under the national jurisdiction.[80] Since the human dignity guarantee provides the foundation for those basic rights that do not only require the respect but also the active protection of the government, human dignity is a primary constituent in need of respect and support from the Union in

[78] KERSTEN, *supra* note 9, at 110.

[79] Classen, *supra* note 76, at 145.

[80] BVerfGE 37, 271 (280); BVerfGE 58, 1 (30); BVerfGE 73, 339 (376); BVerfGE 89, 155 (174).

the form of normative regulations and action. This is also stated by Article 23 Clause 1 Sentence 3 GG, which refers to Article 79 Clause 3 and thereby to Article 1 GG, demanding protection for human dignity. What is required is an effective protection of fundamental rights. This does not have to be exactly identical in each and every respect to the protection offered under German law[81] as long as the fundamental rights under protection are not questioned in principle. This would be the case if the European Union provided financial funding for research projects that treat embryos – which enjoy human dignity protection under German law – like raw materials, *i.e.* as objects rather than subjects.

II. The Principle of Loyal Cooperation and the Luxembourg Compromise

The heretofore described conflict can only be resolved by not allowing the European Union to fund consumptive embryo research. The reasons for this are as follows.

The objective expressed in Article 163 EC of strengthening the scientific and technological foundation of the Community's manufacturing industry, of supporting its efforts to increase its international competitiveness and of funding research projects that are deemed necessary on the basis of other chapters of the same agreement as well as the coordination tasks described by Article 165 EC cannot provide a basis for the harmonization and indirect mutual assimilation of the law in sensitive areas where the human dignity guarantee is involved and concerned. This is justified by the European Parliament in Consideration H no. 15 of its aforementioned resolution from 10 March 2005, operating in conjunction with the subsidiarity principle.

The provision of funds for research projects which, for constitutional reasons, are unlawful in one of the Member States based on a majority decision in compliance with Article 165 Clause 1 in conjunction with Articles 251, 205 EC would violate the principle of loyal cooperation. This would particularly apply to the constellation under review, *i.e.* a violation of the human dignity guarantee that is provided by the *Grundgesetz* (GG – Basic Law or Constitution) in an unalterable form. The principle of loyal cooperation within the EU[82] has been developed in an analogy to the principle of loyal cooperation within the Federal Republic inasmuch as it

[81] Claus-Dieter Classen, *Article 23, in* 2 GRUNDGESETZ KOMMENTAR margin note 49, 51 (Hermann von Mangoldt, Friedrich Klein and Christian Starck eds., 5th ed. 2005).

[82] Case 804/79, Commission v. United Kingdom, 1981 E.C.R. 1045; OLE DUE, DER GRUNDSATZ DER GEMEINSCHAFTSTREUE (1992); Peter Unruh, *Die Unionstreue – Anmerkungen zu einem Rechtsgrundsatz der Europäischen Union*, 37 EUROPARECHT 41, 45 (2002).

commits the Member States as well as the bodies, organs and institutions of the Community.[83] If one of the Member States were to announce that a particular policy of the Union was potentially violative its constitutional integration norms, the principle of loyal cooperation would compel the Community to desist.[84]

The principle of loyal cooperation has been expressed in the Luxembourg Compromise from 29 January 1966,[85] which ended the French "policy of the empty chair." In its most important passage, the document explains:[86] If issues which are decided by majority voting on the recommendation of the Commission involve the vital interests of one or several partners, the members of the Council shall attempt within an appropriate period of time to arrive at solutions acceptable to all Council members, allowing their mutual interests and the interests of the Community to be preserved in compliance with Article 2 of the Treaty.

In its reply to a written query, the Council announced on 27 September 2001 that the Luxembourg Compromise would preserve its status also after the Treaty of Nice has come into force.[87] It will be possible to assert vital interests in any case when these can be derived from the constitutional structure of the Member State in question and the constitutionally established integration limits.[88]

G. Results

After the fusion of the cell nuclei, embryos, whether *in utero* or *in vitro*, have legal personality. Therefore they enjoy the right to protection of their human dignity, guaranteed by German Constitutional Law and the primary law of the European Union. The use and – even more so – the creation of embryos for purposes of scientific research, diagnosis or the development or application of medical therapies disregards the moral principle that human beings are ends in themselves

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[83] Albert Bleckmann, *Art. 5 EWG-Vertrag und die Gemeinschaftstreue*, 91 DEUTSCHES VERWALTUNGSBLATT (DVBl.) 483, 487 (1976); OPPERMANN, *supra* note 31, at margin note 486.

[84] It is not enough, as stated in the inter-institutional memorandum quoted *supra* at note 12, that research banned under the law of one Member State is only excluded from receiving funding in this particular state.

[85] Waldemar Hummer & Walter Obwexer, *Article 205 EGV, in* EUV/EGV KOMMENTAR margin note 45 (Rudolf Streinz ed., 2003).

[86] Bulletin of the European Economic Community, year 9, no. 3 (March 1966), p. 9

[87] 2001 O.J. (C 364) 48. For the legal character of the Luxembourg Compromise, *see* Hummer & Obwexer, *supra* note 85, at margin note 42.

[88] Hummer & Obwexer, *supra* note 85, at note 45.

and thus violates human dignity. The German Embryo Protection Act complies with the human dignity guarantee, but the secondary law of the European Union does not seem to provide a similarly firm commitment. The European Union is only allowed to fund research which complies with human rights and – particularly – human dignity.

In the face of this complex of issues, Germany is entitled to prevent the use of EU funds from being used to support research projects that entail the destruction of embryos. Such a German veto is supported by the principle of loyal cooperation as expressed in the Luxembourg Compromise from 1966.