MELITA THEOLOGICA
Journal of the Faculty of Theology
University of Malta
62 (2012) 23-54

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Human Dignity in European Public Policy on Biotechnology

Since the discovery of the structure of the 'DNA' (or deoxyribonucleic acid) in the 1950's by Watson and Crick, modern biotechnology has made a quantum leap in its field of application in the areas of the life sciences, chemistry, agriculture, environmental science, medicine, veterinary medicine, engineering, and computer science.[1] Although biotechnology in the broadest sense is not new, what is new now, however, is the level of complexity and precision involved in scientists' current ability to manipulate living organisms, making such manipulation predictable, precise, and controlled.

To date the greatest and most notable impact of biotechnology has been in the medical and pharmaceutical arena. It is by no means an exaggeration to conclude that the application of biotechnological techniques in the field of health and life sciences has brought a revolution rather than an evolution in medicine. This biotechnological advancement in healthcare has brought great hopes and expectations of improvement in the human condition of both current and future generations. In fact, advances in genetics, regenerative medicine, pharmacology, neurosciences, assisted reproduction, embryo manipulation and transfer, reproductive and therapeutic cloning, genetic engineering, pre-implantation genetic diagnosis, enhancement techniques and the use of nanotechnology promise cures for dreaded diseases, relief from terrible suffering and alterations of the human body and psyche.

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[1] Martina Newell-McGloughlin, Edward Re, *The Evolution of Biotechnology: From Natufians to Nanotechnology* (Dordrecht, 2006), vii.

According to Leon Kass, the underlying force of today's biotechnology is shaking our perception on life in general and human life in particular.[2] Today's 'reductionist' and 'objectified' approach to human life has enhanced the scientific power over human nature and at the same time blurred all ethical standards to guide the application of biotechnology. Modern biology is projecting a vision of the human body not as something animated, purposive and striving, but as an inanimate organism. As a result, our self-understanding as creatures of dignity has been challenged. Biotechnology is in urgent need of a richer, more natural biology and anthropology in order to do justice to the holistic vision of the human person from conception to natural death.[3] What is needed is to go back to the pre-modern philosophical sources to perceive the human person not as a ghost in a machine but as a union of soul and body. Epistemological and scientific hubris need to be tamed by the rediscovery of a sense of wonder and mystery about the world, a reverential contemplative attitude that is itself an expression of human dignity.[4]

With the advance of medical technologies and their increasing power over life and death, discussions on 'human dignity' have begun to take a more central role in bioethics. But what exactly is human dignity? Is dignity an arbitrary cultural construction conditioned by the times and pragmatically tied to preferences for this or that agenda? Is human dignity an intrinsic value or a relative value particularly associated with the notion of 'quality of life' or 'sanctity of life'? How should we view this dignity discourse? Is Kass' claim true, namely, that the concept of human dignity is a very "useful tool for thinking about what sort of changes we should be willing to introduce and which we should avoid?"[5] Or, is it instead an abstract concept prone to misuse or a camouflage for unconvincing arguments and unarticulated biases? In other words, is human dignity an adequate moral guide to policy making in today's biotechnological era?[6]

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[2] Leon Kass, *Life, Liberty and the Defense of Dignity: The Challenge for Bioethics* (San Francisco, 2002), 7.

[3] Ibid., 20.

[4] Ibid., 24.

[5] Matthew C. Jordan, "Bioethics and 'Human Dignity'," *Journal of Medicine and Philosophy* 35 (2010): 191.

[6] Caulfield Timothy, Roger Brownsword, "Human Dignity: A Guide to Policy Making in the Biotechnological Era?," *Nature Reviews Genetics* 7/1 (2006): 72-76.

This paper is an attempt to answer these thorny issues. First, the leading philosophical arguments for and against the concept of human dignity shall be analysed. Secondly, the emergence of the concept of human dignity as a key point of reference for the regulation of modern science and technology in the European Union shall be evaluated. The main contribution of this paper is to prove that in EU Directives and Recommendations, human dignity is not an elusive concept but rather a regulatory restraint in European public policies on biotechnology, particularly through the influence of the *European Group of Ethics in Science and New Technologies* (EGE), of which I have been a member since 2005. Several of the European Commission's decisions are consistent with EGE recommendations. Although one cannot claim that the Commission took these decisions because they were recommended by the EGE, however it is evident that these decisions are in line with the EGE's ethical perspective.

The Disputed Concept of Human Dignity

One of the central terms or concepts regularly used in popular bioethics is that of human dignity.[7] However, it is rarely scrutinized so as to qualify what it really refers to. This popular vagueness is further compounded by the fact that many speak of dignity as also being predicable to animals and plants! These ambiguities explain why many remain in the dark on how to interpret the notion of "human dignity." Both religious and secular nonreligious people invoke it to support their arguments. Respect for human dignity is, paradoxically, an ethical mandate to which both sides of many ethical debates appeal.[8] For example, arguments both for and against the morality of euthanasia invoke the word 'dignity'. Many defend human dignity because they claim that this concept provides a secularly accessible language on which a pluralistic society can find common moral ground. In spite of these ambiguities, many assume, through immediate intuition, that we do have something that differentiates us from the rest of creation, an intrinsic dignity. Roberto Adorno called this intuition the "Standard Attitude".[9]

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[7] The various approaches to human dignity have been developed by John F. Kilner, "Human Dignity," in *Encyclopaedia of Bioethics*, ed. Warren Thomas Reich (New York, 2004), 1193-1200.

[8] Mitchell C. Ben et al., "Biotechnology and Human Dignity," in *Biotechnology and Human Good*, ed. Mitchell C. Ben et al., (Washington, D.C., 2007), 58.

[9] Roberto Andorno, "The Paradoxical Notion of Human Dignity," cited in Dan Egonsson, *Dimensions*

Though it is a moral standard to which most people refer to justify their claim, understanding what people mean by human dignity is one of the greatest challenges and opportunities in our biotechnological era. Particularly in the face of today's emerging biotechnologies, an adequate anthropology is needed to support the concept of human dignity. As Gabriel Marcel wrote, "The problem in question is that of understanding what happens to human dignity in the process of technicalization to which man today is delivered."[10] Gabriel Marcel wrote these words in 1963 when biotechnology was a set of optimistic promises, and bioethics had yet to be born.

Current literature shows that scholars are divided into four distinct groups with regard to the meaning of human dignity. One group regards all "dignity-talk" as incoherent and at best unhelpful, at worst misleading.[11] Another group finds dignity-talk illuminating in some respects, but strictly reducible to autonomy as extended to cover some marginal cases.[12] The third group considers dignity to be a concept in a family of concepts about capabilities, functionings, and social interactions.[13] The final group considers dignity as a metaphysical property possessed by all human beings, and which serves as a foundation for moral philosophy and human rights.[14]

The notion of human dignity is under attack primarily from those who are prejudiced against its religious connotations. Some philosophers contend that the contested concept of human dignity should be discarded since it is a vague concept which is open to many interpretations. For this reason there is little clarity about its real meaning, except that it is based on the religious concept of the sanctity of human life. However,

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of Dignity - The Moral Importance of Being Human (Dordrecht, 1998), 34.

[10] Gabriel Marcel, *The Existential Background of Human Dignity* (Cambridge-Massachusetts, 1963), 158.

[11] Ruth Macklin, "Dignity is a Useless Concept," *British Medical Journal* 327 (2003): 1419-1420.

[12] Roger Brownsword, "Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'," *Notre Dame Journal of Law, Ethics and Public Policy* 17 (2003): 15-51.

[13] Michael G. Marmot, "Dignity and Inequality," *Lancet* 364 (2004): 1019-1020; Richard Horton, "Rediscovering Human Dignity," *Lancet* 364 (2004): 1081-1085.

[14] President's Council on Bioethics, *Human Cloning and Human Dignity* (Washington, D.C., 2002); Kass, *Life, Liberty and the Defense of Dignity*; Lennart Nordenfelt, "Dignity and Care of the Elderly," *Medicine, Health Care and Philosophy* 6 (2003): 103-110; Daniel P. Sulmasy, "Dignity and Bioethics: History, Theory, and Selected Applications," *Human Dignity and Bioethics*: *Essays Commissioned by the President's Council on Bioethics*, ed. The President's Council on Bioethics (Washington, D.C., 2008), 469-501.

this religious source cannot explain how and why dignity has crept into the secular moral reasoning in bioethics.

Among the leading critics of human dignity we find Ruth Macklin, Peter Singer, John Harris, Julian Savulescu and Steven Pinker who all claim that appeals to dignity are either vague restatements or mere slogans. Ruth Macklin argues that dignity is a rhetoric slogan imported from religion and for this reason it is a useless concept in medical ethics.[15] She firmly believes that this concept can be eliminated without any loss of content. Moreover, she claims that 'dignity' seems to have no meaning at all beyond the concept of respect for autonomy or the capacity for rational thought. This explains, Macklin contends, how bioethics has done just fine with the principle of personal autonomy, namely the idea that, because all humans have the same minimum capacity to suffer, prosper, reason, and choose, no human has the right to impinge on the life, body, or freedom of another. Similarly, John Harris and John Sulston argue that dignity can be reduced to a Benthamite belief in human equity, namely, "the idea that each is entitled to the same concern, respect, and protection as is accorded to any other."[16]

In a utilitarian perspective, dignity derives mainly from sentience and one's utility. It is not the sanctity-of-life, but rather the quality-of-life which is the ultimate measure of human dignity according to utilitarianism.[17] Peter Singer,[18] who is the most famous exponent of this philosophical approach regards this principle as empty rhetoric and questions what it adds to other principles.[19] Thus, in accordance with his rigorous utilitarian principles, Singer proposes that infanticide should be admissible within the person's first two years of life. In the same vein of thought, John Harris and Julian Savulescu believe that the inappropriate use of this concept can be an oppressive force, silencing open and transparent debate in biotechnology.

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[15] Macklin, "Dignity is a Useless Concept," 1419-1420.

[16] John Harris, John Sulston, "Genetic Equity," *Nature Reviews Genetics* 5 (2004): 796–800.

[17] Marie-Jo Thiel, "Human Dignity: Intrinsic or Relative Value?," *Journal international de bioéthique* 21/3 (2010): 55-58.

[18] Miguel A. Guanipa, "Peter Singer and Human Dignity," [Accessed November 25, 2011], available at http://www.canadafreepress.com/index.php/article/3304.

[19] John Harris, "Cloning and Human Dignity," *Cambridge Quarterly of Healthcare Ethics* 7 (1998): 163-167. See Macklin, "Dignity is a Useless Concept," 1419-1420.

This pragmatic approach provoked a debate to which, in March 2008, the American President's Council for Bioethics responded with an anthology of essays which defend the notion of human dignity. And this in turn provoked Steven Pinker to rebut it in the most influential opinion journal in the US, *The New Republic*, under the provocative headline, "The Stupidity of Dignity".[20] Pinckers claims that the concept of dignity remains a mess since this concept has three features that undermine any possibility of using it as a foundation for bioethics: first, dignity is relative; secondly, dignity is fungible; and thirdly dignity can be harmful. However, he claims that dignity is almost a useless concept. The word does have an identifiable sense, which gives it a claim, though a limited one, on our moral consideration. Dignity is a phenomenon of human perception. Certain signals from the world trigger an attribution in the mind of a perceiver. The perception of dignity in turn elicits a response in the perceiver. Just as the smell of baking bread triggers a desire to eat it, and the sight of a baby's face triggers a desire to protect it, the appearance of dignity triggers a desire to esteem and respect the dignified person. This explains why dignity is morally significant: we should not ignore a phenomenon that causes one person to respect the rights and interests of another. But it also explains why dignity is relative, fungible, and often harmful. He concludes that dignity is skin-deep.

In spite of this strong criticism by some philosophers, many others have taken a defensive approach to the concept of human dignity. Among these, William P. Cheshire remarked that

> Now that society has approached the brink of human cloning, the need for a valid understanding of human dignity is unprecedented. It is also urgent. Biotechnology has already begun to supply the tools capable of altering the basic genetic structure and familial relationships of human beings. If human dignity is to be preserved, we must hold fast also to the language of human dignity.[21]

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[20] Steven Pinker, "The Stupidity of Dignity," *The New Republic*, May 28, 2008, [Accessed November 25, 2011], available at http://www.tnr.com/article/the-stupidity-dignity.

[21] William P. Cheshire, "Toward a Common Language on Human Dignity," *Ethics and Medicine: An International Journal of Bioethics* 18/2 (2002), [Accessed November 25, 2011], available at http://www.ethicsandmedicine.com/archive/18/summer02_commentary1.php.

At stake in defending and defining human dignity is not the question of when a human being acquires dignity but whether human beings have at all intrinsic dignity. Many authors claim that a frequent mistake is to equate dignity with certain functional capacities such as intelligence, abstract reason, language, creativity, ability to feel pain, empathy and awareness of personal biography over time, health, or beauty. In contrast to abstract dignity these capacities at first glance seem clearer in that they are visible, tangible, and measurable. This position has been defended by Daniel Sulmasy on the basis of the theory of natural kinds,[22] by Patrick Lee and Robert P. George on the basis of natural law,[23] and by Gilbert Meilaender on the basis of man's special relation with his Creator.[24] Each of these authors makes a clear distinction between 'intrinsic human dignity' and 'attributed or imputed human dignity'. From their viewpoint, intrinsic human dignity is founded on the inherent worth present in all humans simply by virtue of being human beings. Intrinsic dignity cannot be gained or lost, expanded or diminished. It is independent of human opinions about a person's worth. It is the inherent grounding for the moral entitlements of every human to respect for one's person, one's rights, and one's equal treatment under the law in a just political order.

Leon Kass is one of the leading contemporary bioethicists who have taken a strong position in defence of human dignity. His argument is based on the distinction between "the basic dignity of human *being*" and "the full dignity of being (flourishingly) *human*."[25] These two views of human dignity have different supporters and they often clash in the field of bioethics. Kass' principal sympathies and focal point lie with "the full dignity of being (flourishingly) *human,*" for it is the area to which he dedicates most of his energies, yet, tends to be critical of the general notion of a blanket human dignity, in which everyone is lumped on the same level in the name of some egalitarian principle. In his debate between the two views of dignity, Kass is quite conciliatory and sees no reason why all those who cherish human dignity should not defend it in all its forms.

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[22] Sulmasy, "Dignity and Bioethics: History, Theory, and Selected Applications," 470-474.

[23] Ibid.

[24] Gilbert Meilaender, "Human Dignity: Exploring and Explaining the Council's Vision," in *Human Dignity and Bioethics*, ed. The President's Council on Bioethics, 253-275.

[25] Leon R. Kass, "Defending Human Dignity," in *Human Dignity and Bioethics*, ed. The President's Council on Bioethics, 304.

Kass also makes an effort to show that, when accurately understood, "the two notions are much more intertwined than they are opposed."[26]

Thus, Kass opts for a concept of human dignity that embraces the worthiness of embodied human life and life as it is ordinarily lived: "The account of human dignity we seek goes beyond the said dignity [of rationality] to reflect and embrace the worthiness of embodied human life, and therewith of our natural desires and passions, our loves and longings."[27] Subsequently, Kass does not believe in a universalised basic human dignity, that is, a universal dignity shared equally by all. Rather, he believes that human dignity is always found and shown in different degrees in different people. He maintains that the limitation of Kant's theory is that it is too lofty and it denies the importance of life's concrete particularity, which is always limited to a particular body and a particular place and time. Kant's personhood is very different from our daily lives, which are embodied and connected both by blood ties and friendly relationships. Kass believes a "...rational choice pays no respect to all the dignity we have through our loves and longings... Not all of human dignity consists in reason and freedom."[28] Consequently, he concludes that Kant's notion offers no protection from the brave new world! It is clear that Kass here presumes an anthropology that takes into account man's biological rootedness, his upward spiralling civilization and the inbuilt limitations (the finitude) of his life.

Robert Andorno's perspective of human dignity is very much in line with Kass' ideas. He distinguished the 'basic meaning' from the 'extended meaning' of human dignity. Whereas the latter corresponds to a more abstract notion, which relates to the value of humanity *as a whole*, including future generations, the former refers to the intrinsic worthiness of human beings, irrespective of age, sex, physical or mental ability, religion, ethnic or social origin. The word 'intrinsic' is used to indicate that such a dignity does not rely on a particular feature or capacity of persons but only on their *human condition*. This is why dignity cannot be gained or lost, and it does not admit of any degrees. In other words, the idea of dignity refers "to the intrinsic importance of human life" and

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[26] Kass, "Defending Human Dignity," 306.
[27] Kass, *Life, Liberty and the Defence of Dignity*, 117-118.
[28] Ibid., 313.

requires that "people *never* be treated in a way that denies the distinct importance of their own lives."[29]

Extrinsic or imputed dignity, on the other hand, is the assessment of the worth or status humans assign to each other or to themselves. It is based on external measures of worth or value as perceived in a person's behaviour, social status, appearance, etc. It sums up certain perceived attributes judged admirable or condemnable by other persons, by culture, by political or social criteria, by fashion, or by membership in certain groups. Imputed dignity can be gained or lost simply by one's own self-judgement or by the judgement of others. It can be taken away or granted by law or social convention or by one's opinion of one's own worth in comparison with others.

Human Dignity as an Emerging European Fundamental Value

In May 2007, on the occasion of the 50th anniversary of the Treaty of Rome, the Heads of State and Government of the European Union re-launched the European political project by adopting the *Berlin Declaration* which, instead of advocating socio-economic goals, pointed to the need for establishing a new dimension in the EU that is based on shared values. The Declaration states that "in the European Union we realise our common ideals: for us the individual is central. His dignity is inviolable. His rights are inalienable."

The concept of respect for human dignity is endorsed in the two most important institutional instruments of the European Union: the Charter of Fundamental Rights and the *Lisbon Treaty*. The very first article of the Charter of Fundamental Rights of the European Union is entitled 'Human Dignity' and reads as follows: "Human dignity is inviolable. It must be respected and protected." Human dignity is also referred to in the Charter's Preamble. The Note from the *Praesidium* explains this article as follows:

> The dignity of the human person is not only a fundamental right in itself but constitutes the real basis of fundamental rights... it results that none of the rights laid down in this Charter may be used to harm the dignity

[29] Roberto Andorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics," *Journal of Medicine and Philosophy* (2009): 223-240, [Accessed November 25, 2011], available at http://www.unesco.org.uy/shs/red-bioetica/uploads/media/dignidad_Andorno.pdf

> of another person, and that the dignity of the human person is part of the substance of the rights laid down in this Charter. It must therefore be respected, even when a right is restricted.[30]

The Charter starts from the concept of human dignity and places the human person at the centre of the Union's action. Derych Beyleveld and Roger Brownsword claim that human dignity is a value that gives a community its particular identity. Seen from a communitarian perspective, human dignity speaks less to what is special about human beings *qua* human beings and more to what is special about a particular community's idea of civilized life and the concomitant commitments of its members. The new bioethics aspires to represent Europe as a community that stands for a certain vision of human dignity; and, what is more, it is this particular vision of human dignity that identifies Europe as the particular community that it is. In principle, a particular community might conceive of human dignity in terms that give priority to the exercise of free choice, such that individual autonomy is seen as the highest expression of human dignity. However, the European project takes a different turn by conceiving of human dignity as setting limits to individual autonomy.[31]

The Treaty on the European Union, which aims to provide the Union with a legal framework and the tools necessary to meet future challenges, introduces the notion of a Europe of rights and values: human dignity, freedom, democracy, equity, the rule of law and respect for human rights. It recognises this right of human dignity enunciated in Article 2 of the EU Constitution which states that the Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights. Now that the Lisbon Treaty is in force, the Charter of Fundamental Rights has achieved a legally binding status. So not only is human dignity elevated into a legally enforceable fundamental right but, within the Lisbon Treaty's hierarchy of rights, it is superior to human rights and fundamental freedoms which owe their origin and existence to the dignity of the human person.

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[30] "Explanations (*) Relating to the Charter of Fundamental Rights (2007/C 303/02)," *Official Journal of the European Union C 303/1* 50 (14 Dec 2007): 17.

[31] Derych Beyleveld, Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford, 2001), 65.

The adoption of the Charter and of the Lisbon Treaty therefore launched the integration of EU fundamental values into the core political design of the EU. This notion has been advocated by, respectively, the first European Council President, Mr Van Rompuy, the President of the Commission, Mr Barroso, and the President of the European Parliament, Mr Jerzy Buzek. In his first speech after his nomination on 19 November 2009, Council President Van Rompuy advocated "Europe is a community of values"; and Commission President Barroso indicated to the European Parliament: "our union is founded on values: respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights." (President Barroso, "Speaking with one voice: defining and defending the European interest", European Parliament Plenary: vote on new College, Strasbourg, 9 February 2010).[32] European Parliament President Jerzy Buzek on the European Day against the Death Penalty (10 October 2009) said: "The European Day against the death penalty is the day on which we recall that the defence of human rights and a justice system based on the full respect of human dignity is a key part of our shared European values."[33]

The bioscientific and biotechnological revolution has provoked in all European institutions a demand for human dignity to be respected. The concept of human dignity is visible also in the instruments on bioethical issues adopted during the last decades by intergovernmental bodies, such as UNESCO and the Council of Europe. Those instruments confer on the notion of human dignity the status of an 'overarching principle', that is, of an ultimate and general standard that is called to provide an ultimate foundation to the norms governing the whole biomedical field, in particular those relating to the requirements of informed consent, the ban on genetic discrimination, the confidentiality of personal health information, and the protection of organ donors, among others.[34]

As Philippe Séguin, president of the National French Assembly of the French Republic, remarked in the mid-1990s, not only is there a trend towards the enactment

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[32] See http://ec.europa.eu/commission_2010-2014/president/index_en.htm.

[33] *General Report on the Activities of the European Group on Ethics (EGE) in Science and New Technologies to the European Commission: 2005-2010* (Brussels, 2010), 19.

[34] Andorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics," 223-240, [Accessed November 25, 2011], available at http://www.unesco.org.uy/shs/red-bioetica/uploads/media/dignidad_Andorno.pdf

of bioethics law, but this trend illustrates a growing awareness around the world that legislators must, despite the difficulties, act to ensure that science develops with respect for human dignity and fundamental rights.[35] This trend is further illustrated by, for example, the Preamble to the Council of Europe's Convention for the Protection of Human Rights and Human Dignity with Regard to the Application of Biology and Medicine, which requires its signatories to resolve "to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine." And in Article 1, it states that the purpose of the Convention is to "protect the dignity and identity of all human beings and guarantees everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."

Similarly, the Preamble to UNESCO's *Universal Declaration on the Human Genome and Human Rights*, whilst recognising "that research on the human genome and the resulting application open up vast prospects for progress", emphasises "that such research should fully respect human dignity and individual rights"; and Article 5 underlines the legitimate limits of such research by providing that "[n]o research application should be allowed to prevail over the respect for human dignity and human rights, in particular in the fields of biology and genetics." Moreover, article 3 of UNESCO's Universal Declaration on Bioethics and Human Rights lists human dignity and human rights as the fundamental principles to be respected in medicine, life sciences and associated technologies.

The discourse on human rights and human dignity in bioscience and biotechnology is being interpreted as a new horizon of human rights in Europe. The 'first generation' of human rights – political freedom and civil liberties – are reaching the whole of the European people for the first time in history. 'Second generation' rights – the social charter – are still awaiting general recognition. The 'third generation' or 'solidarity rights' are accepted in principle by all European countries. But now, the institutions of the EU and the Council of Europe are rightly leading the way toward the 'fourth generation of human rights' or 'bio-rights' that imply a universal protection of the human person

[35] Beyleveld, Brownsword, *Human Dignity in Bioethics and Biolaw*, 9.

with intrinsic value as an end-in-itself. This 'new generation of human rights' is accepted internationally as an adequate development that is urgently needed to guide today's accelerated progress in life sciences and biotechnologies.

Noëlle Lenoir, former President of the European Group of Ethics in Science and New Technologies, observes that the principle of human dignity is stronger in Europe than the principle of unrestrained freedom of research.[36] Recognition of the dignity of every human being gives rise to a number of criteria – often also referred to as principles – essentially concerned with care and protection of human beings on the one hand, and respect for human freedom on the other. Both sets of criteria (protection and respect) equally have their origin in human dignity.[37]

Thus, lively debates have been held over which should be more respected: freedom of research or human dignity? The European Union is committed to becoming a more competitive player in the global economy. A central plank of its Lisbon strategy towards this end is to increase and improve investment in research and development, to facilitate innovation, and to contribute to a strong European industrial base.[38] Among these, biotechnology is the key for the European Union's future competitive development.[39]

Yet, as recognised by the European Commission since at least the early 1990s,[40] many biotechnologies central to this vision of economic growth are ethically contentious amongst the populations of the Member States of the European Union. In such circumstances, granting regulatory powers to the EU Commission is politically controversial. Moreover, the Commission lacks both the resources and the expertise

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[36] Noëll Lenoir, "Europe Confronts the Embryonic Stem Cell Research Challenge," [Accessed November 25, 2011], available at http://www.genethik.de/stem_cells/stem_cells6.htm.

[37] Günter Virt, "Unity and Diversity of Ethical Principles: Human Dignity Endangered," in *General Report on the Activities of the European Group in Science and New Technologies to the European Commission, 2000-2005* (Brussels, 2005), 59.

[38] Communication on Working Together for Growth and Jobs - A New Start for the Lisbon Strategy COM (2005) 24 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0024:FIN:en:PDF

[39] Communication on Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology Within the Community SEC (91) 629 final, available at http://aei.pitt.edu/5970/

[40] See Communication on Promoting the Competitive Environment, 1–2, where the Commission emphasised the need for ethical discussions on the development of biotechnology: "it is imperative that problems of public acceptability, and ethical questions raised, be recognised and dealt with. It is suggested that there should be advice available to the Commission in the area of ethics in biotechnology." http://aei.pitt.edu/5970/

to take detailed regulatory and administrative decisions in technical fields such as biotechnology. At the same time, however, the benefits of European integration, and thus the prize of global competitiveness, cannot be readily achieved without EU-level regulatory standards and administrative procedures.[41]

One of the contentious ethical issues raised by biotechnology is the moral status of nascent human life. Even if positions differ on the status of the human embryo and human embryonic research, there is however in Europe a general agreement on the need for some level of protection based on the argument of human dignity. The tendency, however, goes towards consensus on the lowest common denominator. This explains why there is a general ban at the European level on reproductive cloning and on human germline modifications, both in the EU directive on the Legal Protection of Biotechnological Inventions and in the decision of the EU to refuse funding for such research.

In the Directive on the Legal Protection of Biotechnological Inventions (98/44/EC), the need for patent law to respect dignity is emphasised. Recital 16, for example, proclaims that "patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person." The Directive also stipulates that "processes for cloning human beings" and "uses of human embryos for industrial or commercial purposes... shall be considered unpatentable." Article 6 of this directive prohibits from patentability inventions when their commercial exploitation would be contrary to *ordre public* or morality.

The same article refers to the following process as unpatentable:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes.

Recital 38 of the EU biopatenting directive excludes from patentability processes, the use of which offends human dignity, such as those to produce chimeras from germ cells or totipotent cells of humans and animals. Such processes are considered to be against *ordre public* and morality. This is in line with Article 5 which states that the

[41] Helen Busby, Tamara Hervey, Alison Mohr, "Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies," *European Law Review* 33/6 (2008): 804.

"human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."

Moreover, the European legislation does not permit human embryonic research without any limit or restrictions. The Charter of Fundamental Rights of the European Union prohibits different kinds of practices possibly related to embryo research, namely "eugenic practices, in particular those aiming at the selection of persons" and "the reproductive cloning of human beings." Where EU funding of research involving human embryos is concerned, the following activities are categorically excluded under the current Seventh Research Framework Programme (2007-2013):

a) research activity on human cloning for reproductive purposes (reproductive cloning);
b) research activities intended to modify the genetic heritage of human beings which could make such changes heritable (germline gene therapy);
c) and research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement.

Furthermore, in the Council of Europe, provisions do exist for specific issues, such as prohibition against producing human embryos solely for research purposes (Oviedo Convention art. 18) and against any commercial exploitation, and the forbidding of reproductive cloning and of modifications of the human germline cells. The Preamble to the Protocol to the Convention dealing with the cloning of human beings states that the Protocol is guided by 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."

The EGE's Role in the Embedment of Human Dignity in EU Policies on Biotechnology

In the European Union, ethics has been institutionalized by the setting up of the European Group of Ethics in Science and New Technologies (EGE) which is significantly influential in bolstering the acceptance of emerging biotechnologies. The EGE's remit is to prepare Opinions with authoritative normative statements. One

observes that these Opinions have exerted a considerable amount of influence on the legislation and administrative activity that supports the activities of market actors within the biotechnology industry.[42] The EGE's remit needs to be understood within the EU's political decision to reconcile and balance scientific and technological innovation as a necessary impetus for European advancement with the safeguarding of the manifold values upon which European identity has been built.[43] Before focusing on the EGE's crucial role in embedding the normative concept of human dignity in EU public polices on biotechnology, the origin and remit of the EGE shall be elaborated further.

In November 1991, the European Commission decided to incorporate ethics into the decision-making process for Community research and technological development policies by the setting up of the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). The Commission's Communication, which specifically refers to the need for expert advice in biotechnology, indicates that the rationale for establishing the GAEIB was to support the regulatory process of biotechnology.[44] Moreover, this rationale is evident in the Communication on promoting the competitive environment for industrial activities based on biotechnology within the Community.[45] The Communication states that

> It is desirable that the Community has an advisory structure on ethics and biotechnology which is capable of dealing with ethical issues where they

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[42] Helen Busby, Tamara Hervey and Alison Mohr, "Ethical EU Law?," 803-842.

[43] *General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 1998-2000*, (Brussels, 2000), 9, [Accessed October 1, 2008], available at http://ec.europa.eu/european group ethics/archive/1998 2000/activities en.htm; see also Herméren, "Value Conflicts and the Integration of Europe," in *General Report on the Activities of the European Group in Science and New Technologies to the European Commission, 2000-2005*, [Accessed October 1, 2008], available at http://ec.europa.eu/european-group-ethics/docs/publications/genactrep05txt_en.pdf [Accessed 22 November 2012].

[44] "Biotechnology is not only a vital sector of European research and industry. It is inevitably a source of large amounts of legislation: directives on the use of genetically modified organisms, proposed directives on the legal protection of biotechnological inventions, etc. This legislation cannot ignore the ethical dimension. This was what prompted the European Commission on 20 November 1991 to set up a group of advisers on the ethical implications of biotechnology." See the EGE website at http://ec.europa.eu/european group ethics/archive/1991 1997/index en.htm, [Accessed October 1, 2008].

[45] See Communication on Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community SEC (91) 629 final, http://aei.pitt.edu/5970/

> arise in the course of Community activities . . . The Commission considers that through addressing explicitly the ethical challenges, it is helping to improve the climate of public understanding and opinion concerning the responsible development of biotechnology; hence facilitating the acceptance of its benefits, and ensuring a single market for its products.[46]

Eventually, the Commission decided on 16 December 1997 to replace the GAEIB by the European Group on Ethics in Science and New Technologies (EGE), extending the Group's mandate to cover all areas of the application of science and technology. The EGE issues its Opinions following a series of meetings, hearings with external experts, and public round tables with relevant stakeholders. It has grown incrementally in both size and scope, to include wider expertise and more established members. With six members at its inception, the GAEIB expanded to nine in 1994. The EGE, which had 12 members when it was established, has now increased to 15 in 2005.

The remit and responsibilities of the EGE have developed with each successive mandate. According to the current EGE remit, the role of the EGE is to provide the Commission with high quality and independent advice on ethical aspects of science and new technologies to help prepare and implement EU legislation and policies. The EGE, which is an independent, pluralist and multidisciplinary body, provides its advice either at the request of the European Commission or on its own initiative. The Parliament and the Council of Ministers were also given power to request Opinions. The mutual independence of the two bodies is the key element that characterises the rationale and working link between the EGE and the EU institutions.

The EGE's advice to the Commission, Parliament and Council takes the form of written Opinions.[47] The EGE/GAEIB has issued some 26 Opinions, at the rate of one or two each year. These include Opinions on EU agriculture[48] and food law, animal cloning

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[46] Communication on Promoting the Competitive Environment for Industrial Activities Based on Biotechnology within the Community SEC (91) 629 final, p.16.

[47] For the full text of all the Opinions, see EGE [Accessed October 1, 2008] website at http://ec.europa.eu/european group ethics/avis/index en.html.

[48] EGE, *Ethics of Modern Developments in Agricultural Technologies,* Opinion n° 24 (December 17, 2008), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion24_en.pdf.

for food supply,[49] and on the labelling of the food derived from modern biotechnology.[50] They include Opinions on biomedical matters, such as on gene therapy,[51] prenatal diagnosis,[52] human tissue banking,[53] umbilical cord blood banking,[54] nanomedicine,[55] synthetic biology,[56] and on matters relating to biotechnological research that might have medical applications in the future, such as on genetic modification of animals,[57] cloning techniques,[58] on human stem cell research and use[59] and on intellectual property rights in biotechnological invention.[60] Three Opinions concern the European Union's "Framework" research funding programmes[61] and one covers clinical research

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[49] EGE, *Ethical Aspects of Animal Cloning for Food Supply,* Opinion n° 23 (2008), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf.

[50] EGE, *Ethical Aspects of the Labeling of the Food Derived from Modern Biotechnology,* Opinion n° 5 (May 5, 1995), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion5_en.pdf.

[51] EGE, *The Ethical Implications of Gene Therapy*, Opinion n° 4 (December 13, 1994), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion4_en.pdf.

[52] EGE, *Ethical Aspects of Prenatal Diagnosis,* Opinion n° 6 (February 20, 1996), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion6_en.pdf.

[53] EGE, *Ethical Aspects of Human Tissue Banking,* Opinion n° 11 (July 21, 1998), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis11_en.pdf.

[54] EGE, *Ethical Aspects of Umbilical Cord Blood Banking,* Opinion n° 19 (March 16, 2004), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis19_en.pdf.

[55] EGE, *Ethical Aspects of Nanomedicine,*: Opinion n° 21 (January 17, 2007), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_21_nano_en.pdf.

[56] EGE, *Ethics of Synthetic Biology*, Opinion n° 25 (January 17, 2007), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion25_en.pdf.

[57] EGE, *Ethical Aspects of Animal Cloning for Food Supply,* Opinion n° 23 (January 16, 2008), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion23_en.pdf.

[58] EGE, *Ethical Aspects of Cloning Techniques,* Opinion n° 9, (May 28, 1997), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion9_en.pdf.

[59] EGE, *The Ethics Review of hESC FP7 Research Projects,* Opinion n° 22 (July 13, 2007), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf.

[60] EGE, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Opinion 16, available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_en.pdf.

[61] EGE, *The Ethics Review of hESC FP7 Research Projects,* Opinion n° 22 (July 13, 2007), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf; *Ethical Aspects of Human Stem Cell Research*

in developing countries.[62] There is also an Opinion on doping in sport,[63] and one on "healthcare in the information society."[64] The EGE's Opinions cover the main areas in the field of bioethics.[65]

In one of its general reports (2005-2010) on its activities, the EGE declares that the fundamental principle of European ethics is, ultimately, the principle of human dignity.[66] The EGE has endorsed this principle in its various opinions, giving further clarification to this debated principle by quoting W. Cheshire who defines human dignity as

> the exalted moral status which every being of human origin uniquely possesses. Human dignity is ... not contingent upon any functional capacities which vary in degree. ... The possession of human dignity carries certain immutable moral obligations. These include, concerning the treatment of all other human beings, the duty to preserve life, liberty, and the security of persons, and concerning animals and nature, responsibilities of stewardship.[67]

Two particular issues shall be elaborated to illustrate EGE's influence on EU law and policy-making processes by imploring the fundamental principle of human dignity: firstly, intellectual property in biotechnological inventions, and secondly the funding of research proposals involving the use of human embryonic stem cells. These two issues are

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and Use, Opinion 15, available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis15_en.pdf; and *Ethical Aspects of the 5th Research Framework Programme*, Opinion 10, available at http://ec.europa.eu/bepa/european-group-ethics/docs/opinion10_en.pdf.

62 EGE, *Ethical Aspects of Clinical Research in Developing Countries,* Opinion n° 17 (February 2, 2003), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf.

63 EGE, *Ethical Aspects Arising from Doping in Sport,* Opinion n° 14 (November 14, 1999), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis14_en.pdf.

64 EGE, *Ethical Issues of Healthcare in the Information Society,* Opinion n° 13 (July 30, 1999), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis13_en.pdf.

65 Fronçois D. Lafond, "Towards a European Bioethics Policy? Institutional Structuring and Political Responses," in *Health Governance in Europe: Issues, Challenges and Theories*, ed. Monica Steffen (London-New York, 2005).

66 *General Report on Activities of the European Group of Ethics in Science and New Technologies to the European Commission* (Brussels, 2010), 17.

67 William P. Cheshire, "Toward a Common Language on Human Dignity," *Ethics and Medicine: An International Journal of Bioethics* 18/2 (2002), quoted in EGE Opinion 20, 5.1.

clear evidence that the principle of human dignity is not an empty concept but rather a normative guideline that is shaping European policies on biotechnology.

The Interpretation of the "Morality Clause" of Directive 98/44 on the Legal Protection of Biotechnological Inventions

The first draft of Directive 98/4452 on the legal protection of biotechnological inventions, originally proposed in 1988, was essentially technical and legal in nature. It was adopted 10 years later, largely because of the highly controversial ethical debates surrounding the Directive, concerning not only patent law, but also biotechnology in general. The Commission's original Proposal was explicitly related to the European Union's need to keep pace with the United States and Japan which were dominating the world market in biotechnology.[68] However, concerns that the Commission was paying insufficient attention to the ethical implications of its proposal were raised,[69] in particular by the European Parliament.[70] The original proposal was rejected by Parliament in 1995, due mainly to conflicting interpretations of the 'ethical problems' at hand, in particular those relating to the patentability and genetic manipulation of various elements of the human body.

Patenting, the core of the Biotechnology Directive, was the first biotechnological issue to be addressed in legislation by the European Union. Partly in response to the ethical debate surrounding the Directive, the EU set up in 1991 a Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) which adopted two Opinions that have actually influenced the development of the Directive and the terms on which it was eventually adopted. These were Opinion N° 3 on the 'Ethical Questions arising from the

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[68] "Directive 98/44 on the Legal Protection of Biotechnological Inventions," *Official Journal of the European Union* L 213/13 (1998).

[69] See, for example, "Opinion of the Economic and Social Committee on the Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions," *Official Journal of the European Union* C159/10 (1989). The Economic and Social Committee in 1989 criticised the Proposal as too legal and technical without enough consideration of ethical questions. The report criticised the Commission saying it did not "face up to all the issues" and that they regretted that "human beings per se are not expressly mentioned in the Directive as not being patentable."

[70] The main issues of debate revolved particularly around the question of the patentability of parts of the human body and the genetic manipulation of the human body. The Parliament was reacting to what it saw as the public's concerns in the area of biotechnology.

Commission Proposal for a Council Directive for Legal Protection of Biotechnological Inventions'[71] and Opinion N° 8 on the 'Ethical Aspects of Patenting Inventions involving Elements of Human Origin.'[72]

The Directive (98/44/EC) on the legal protection of biotechnological inventions, finally adopted by the European Parliament and the Council in 6th July 1998, raises important moral issues concerning the patenting of living human material. In fact, certain moral exclusions that are contrary to 'ordre public' or 'morality' are endorsed under Article 6 of the European Biopatenting Directive as follows:

1. Inventions shall be considered unpatentable where their commercial exploitation should be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
   (a) processes for cloning human beings;
   (b) processes for modifying the germ line genetic identity of human beings;
   (c) the use of human embryos for industrial or commercial purposes;
   (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. [73]

Since controversies and uncertainties persisted on the precise interpretation of this article after the adoption of the Directive, particularly the questions of the patentability of parts of the human body and the genetic manipulation of the human body, in October 2000, the EU President, Romano Prodi, requested the EGE, which eventually replaced the GAEIB, to prepare an opinion document on the ethical aspects of patenting inventions involving human stem cells. Opinion N° 16 on 'The Ethical Aspects of Patenting Inventions involving Human Stem Cells'[74] contains

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[71] http://ec.europa.eu/bepa/european-group-ethics/docs/opinion3_en.pdf, [Accessed November 25, 2011].

[72] http://ec.europa.eu/bepa/european-group-ethics/docs/opinion8_en.pdf, [Accessed November 25, 2011].

[73] Astrid Burhöi, "Moral Exclusions in European Biotechnology Patent Law," [Accessed November 25, 2011], available at http://biblioteket.ehl.lu.se/olle/papers/0002294.pdf

[74] http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_en.pdf, [Accessed November 25, 2011].

the EGE's interpretation of the morality clause as well as its recommended ethical restrictions.

In Opinion N° 16, published in May 2002, the Group considered that only human stem cells lines which have been modified by an inventive process to get new characteristics for specific industrial application are patentable:

> The Group considers that patenting of inventions allowing the transformation of unmodified stem cells from human embryonic origin into genetically modified stem cell lines or specific differentiated stem cell lines for specific therapeutic or other uses, is ethically acceptable, as long as the inventions fulfil the criteria of patentability, and in respect of the above-mentioned ethical principles.[75]

However, the Group recommended that stem cells which have been isolated and cultured but which have not been modified should not be considered as patentable inventions:

> Isolated stem cells which have not been modified do not, as product, fulfil the legal requirements, especially with regards to industrial applications, to be seen as patentable. In addition, such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body.
>
> When unmodified stem cell lines are established, they can hardly be considered as a patentable product. Such unmodified stem cell lines do not have indeed a specific use but a very large range of potential undescribed uses. Therefore, to patent such unmodified stem cell lines would also lead to too broad patents.
>
> Therefore only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application, fulfil the legal requirements for patentability.
>
> As to the patentability of processes involving human stem cells, whatever their source, there is no specific ethical obstacle, in so far as they fulfil the requirements of patentability (novelty, inventive step and industrial application)[76]

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[75] Opinion n°16, par. 2.3.
[76] Ibid., section 2.3.

As already stressed by the Group in the Opinion N° 15 of November 2000 on the ethical aspects of human stem cell research, there are strong ethical concerns about the use of human embryos and for this reason this requires specific caution. These concerns are reflected in the 1998 EU Directive which states that processes which would lead to uses of human embryos for industrial or commercial purposes are contrary to "*ordre public*" and morality and are not patentable. The Group sticks to the strict application of the principle of non-commercialisation of human embryos, which is in line with the principle of non-commercialisation of the human body.[77]

The Group also decided that, as mentioned in its Opinion N° 15 of November 2000 on research on human stem cells, there are strong ethical concerns to be taken into account about cloning for stem cells. Therefore, in view of the risk of instrumentalisation and commercialisation of the human embryo,[78] the Group calls for a cautious approach, excluding the patentability of the process of creation of a human embryo by cloning for stem cells.[79]

Concerning the patentability of stem cells from human embryonic origin, one member of the Group, Professor Günter Virt, submitted a dissenting view maintaining that the patentability of inventions involving embryonic stem cells is ethically unacceptable since the obtaining of these cells require the destruction of human embryo. This technique contradicts the principle of human dignity due to the fact that the human embryo is a human being. Whereas the majority opinion is based on the interpretation of article 6 (2) c in the light of art. 5 (2) of the Directive, Prof. Virt's dissenting opinion is based on the interpretation of article 6 (2) c in the light of art. 5 (3):

> Human embryonic stem cells and also embryonic stem cell lines are excluded from patentability because we cannot get embryonic stem cell lines without destroying an embryo and that means without use of embryos. This use as material contradicts the dignity of an embryo as a human being with the derived right to life. If the condition for patentability is the industrial

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[77] Ibid., section 2.4.

[78] This ethical controversy on the issue of commercialisation involved in the granting of patenting brings into sharp contrast the difference between the European and the US patenting systems. In the US one may patent any invention even without commercial use and also against morality; in Europe one can patent only when the commercial use is clearly spelled out.

[79] Ibid., section 2.5.

> and commercial use and if the use of human embryos for industrial and commercial purposes is not patentable, then every exception, which cannot exclude industrial and commercial purposes, is against the ethical sense of the directive. Patenting is an incentive. Patentability of human embryonic stem cells and stem cell lines would push research towards embryonic stem cells and thus undermine the priority of research using non embryonic stem cells. Despite the relatively clear regulations in the directive this incentive for research will lead to forms of 'bypasses' which makes it impossible to guarantee an ethically tolerable situation in the field of patentability.[80]

The moral reasoning underpinning Prof. Virt's dissenting view runs as follows: those who argue in support of patenting hESC justify their position by the patentability of an isolated part (not an embryo) of the human body as endorsed in art. 5 (2). However, those who disagree with the patenting of hESC claim that art. 6 (2) c, which prohibits the use of human embryos for commercial use, should be interpreted in the light of art. 5(3) which specifically endorses a provision of commercial use as a *sine qua non* condition for patentability. It follows that if patenting for stem cell lines would be granted, then this authorisation would always involve a commercial interest which is an affront against human dignity. If the patenting of hESC always involves a commercial use, then it is evident that in accordance with 6(2)c, the use of human embryos for commercial use should be excluded from patenting. Art. 5 refers to the patenting of genes since at the time when the Directive was approved in 1998, no hESC was scientifically available. But Prof. Virt's interpretation rests on an analogy between genes and the other parts of the human body, including hESC. It is interesting to observe that the European Patent Office (EPO) and the European Court of Justice (ECJ) followed Virt's line of moral reasoning.

The debatable and thorny issue concerning the interpretation of the morality clause of the Directive is primarily due to its lack of clarity and guidance on how to interpret '*ordre public* and morality'. Article 6 (2b) prohibits processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; and uses of human embryos for industrial or commercial purposes. However, no definition of 'human embryo' is provided in the Directive. In fact, the directive literally does not speak of embryonic stem cells and cells of it, as this technology did not yet exist when

[80] Ibid., par. 2.10.

the directive was discussed. To clarify this ambiguity the European Parliament adopted in 2005 a resolution to make this case clear. Therein it "insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive."[81]

Moreover, the Biotech directive states in article 5(2) that an element isolated from the human body or otherwise produced by means of a technical process can be patented, provided that the regular patentability requirements are met, even if the structure of that element is identical to that of a natural product. Furthermore, it is said in article 5, paragraph 1 that "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."

The crux of the problem is the interpretation of these articles. Are embryonic stem cells derived from an embryo analogous to elements isolated from the human body produced by means of a technical process? Is it analogous to the sequence or partial sequence of a gene, and thus constitutes a patentable invention, even if the structure of that element is identical to that of a natural element? Does the principle of human dignity play any role in this debate? Should the patenting of human embryonic stem cells lines be prohibited on the basis of the argument of human dignity?

These questions received a definitive answer by the EPO and the ECJ in two landmark decisions. The first was the important decision taken by the Enlarged Board of Appeal (EBoA) of the EPO in December 2008. It refused in last instance an application for a patent from the Wisconsin Alumni Research Foundation for a method of deriving stem cells from human embryos. Although the US Patent and Trademark Office granted the patent, the EPO has rejected it on the basis that commercial exploitation of the patent would be "contrary to public order or morality" and hence not permissible according to their own Convention. Had the patent been upheld, however, it would potentially have covered virtually any application relating to the use of human embryonic stem cells, so that any company or hospital using such applications in Europe could have been compelled to pay licensing fees.

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[81] *Official Journal of the European Union* C272E/ 440.

What is interesting in the decision of the EBoA is its unequivocal interpretation of article 6 of the Biopatent Directive which in fact follows Prof Virt's dissenting opinion rather than the position taken by the majority of the Group. This landmark decision has vindicated the principle of human dignity!

Another example which proves that the principle of human dignity is not a useless and rhetoric concept on the European level but rather a guiding ethical norm in the interpretation of the article 6 of the Biopatent Directive is the Brüstle case. The case stems from a German patent filed by Oliver Brüstle who invented a method for converting human embryonic stem cells into nerve cells. Greenpeace first challenged Brüstle's patent in 1997. A German court ruled the patent invalid, and, upon appeal by Brüstle, the German Federal Court of Justice referred the case to the ECJ. The Bundesgerichtshof (the German Federal Court of Justice) requested clarification of the following issues related to the EU Biotechnology: a) what is a 'human embryo' for purposes of the EU Biotechnology Directive?, and b) what are 'industrial or commercial purposes'?

In its ruling on 18th October 2011, the ECJ gave a clear legal definition of the concept of 'human embryo', thus closing any loophole in the interpretation of the 'morality clause' (Article 6) of the 1998 EU Patent Directive (98/44/EU). Any human ovum must, as soon as fertilised, be regarded as a 'human embryo' if that fertilisation is such as to commence the process of development of a human being. A non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted (somatic-cell nuclear transfer - SCNT) and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis must also be classified as a 'human embryo'.[82]

The ruling came as no surprise in the light of the Opinion of the Advocate General of the European Court of Justice, M. Yves Bot, released on 10 March 2011.[83] Though not binding on the Court of Justice, the Advocate General indicated the legal and moral solution of the Brüstle case by stating unequivocally that totipotent cells carrying within

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[82] http://curia.europa.eu/jcms/upload/docs/application/pdf/2011-10/cp110112en.pdf, [Accessed November 25, 2011].

[83] Opinion of the Advocate General in Case C-34/10 Brüstle v Greenpeace eV (Luxembourg March 10, 2010), [Accessed November 25, 2011], available at http://europa.eu/rapid/pressReleasesAction.do?reference=CJE/11/18&format=HTML&aged=1&language=EN&guiLanguage=en

them the capacity to evolve into a complete human being must be legally classified as human embryos and must therefore be excluded from patentability. Nor can a procedure using other embryonic stem cells, known as pluripotent cells, be patented where it first requires the destruction or modification of the embryo.

The decision of the European Court, though, very minimal, vindicates once more the principle of human dignity and the dissenting view of Opinion N° 16. It does not prevent human embryos from being destroyed. It does not stop scientists from using human embryos in research. But it does make it more difficult for European commercial companies to profit from this destruction. It is to be hoped that this decision will act as a 'nudge' encouraging scientists to turn away from embryonic stem cells and towards ethical and more effective alternative forms of stem cell research such as iPS (induced pluripotent stem cells). Till now these have remained in the shadow of research on human embryonic stem cells. The use of adult stem cells, stem cells derived from umbilical cord blood and others offer, in some cases already, significant possibilities for regenerative medicine. These methods enjoy wide acceptance both on scientific and ethical grounds.

The Use of Human Embryonic Stem Cell in FP 7

The EGE's influence on the refinement of the ethical review processes for the selection of protocols involving human embryonic stem cells research under EU funding is another example which proves how important the concept of human dignity is in EU policies. The EGE prepared three Opinions[84] on this contentious ethical issue among EU Member States. However, only Opinion N° 16, which was prepared in 2007 by the EGE in connection with the Seventh Framework Programme for Research and Technological Development (FP7), shall be discussed to articulate how the

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[84] *EGE*, *Ethical Aspects of Research Involving the Use of Human Embryo in the Context of the 5th Framework Programme*, Opinion n° 12 (November 23, 1998), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis12_en.pdf.
EGE, *Ethical Aspects of Human Stem Cell Research and Use*, Opinion n° 15 (November 14, 2000), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis15_en.pdf.
EGE, *The Ethics Review of hESC FP7 Research Project,* Opinion n°22 (July 13, 2007), [Accessed November 25, 2011], available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf

ethical principle of human dignity is unequivocally accountable for additional ethical restrictions to FP7, in comparison to FP6, in its ethical review policy on the funding of research protocols involving human embryonic stem cells.

The objective of the ethical review is to ensure that the European Union does not support research that would not comply with fundamental ethical principles[85] and to examine whether the ethical rules set out in FP7 are met. In fact, Opinion N° 22 explicitly states that "Ethically responsible research involving human embryonic stem cells must comply with fundamental ethical principles and human rights in the European Union, from the procurement of stem cells to clinical research based on hESCs."[86] However, the crucial issue is how the fundamental ethical principle of human dignity, which is the basis of human rights, is to be interpreted and applied.

According to EU policy, each proposal to use human embryonic stem cells must successfully pass a scientific evaluation. Proposals which successfully pass this scientific evaluation are then subject to a stringent ethical review organised by the European Commission.

The EU ethics review panel, for which Opinion N° 22 was prepared as a guidance, is a transnational body composed of experts from different disciplines. This ethical review is based on ethical rules embodied in the European Charter of Fundamental Rights and, as President Barroso himself stated, takes into account the Opinions of the EGE.[87] In the ethical review report, the panel lists the different ethical issues, describes the way these issues were handled by applicants and gives recommendations on how to resolve these issues. After having successfully passed both the scientific and ethics review, proposals for the funding of hESC projects are then handed over to a Regulatory Committee composed of EU Member States representatives, which decides upon the projects on a case-by-case basis.[88]

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[85] Seventh Framework Programme (Decision No 1982/2006/EC), Article 6(1): "All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles." Rules for Participation, Article 10: "A proposal [...] which contravenes fundamental ethical principles [...] shall not be selected. Such a proposal may be excluded from the evaluation and selection procedures at any time."

[86] Opinion n° 22, par. 4.2.1.

[87] Letter sent by President Barroso to the EGE on November 22, 2006.

[88] Opinion n° 22, par. 4.2.

In November 2006, Commission President Barroso requested the EGE for an Opinion on implementing measures required during the ethics review of research projects involving human embryonic stem cells. President Barroso's letter to the EGE states explicitly that his request is to "assure that the ethical rules and requirements are fully met. Such an Opinion would provide guidance (in relation to the values and principles to apply) for the European Review within the frame of the Programme approved by the Council and the European Parliament."[89]

The EGE's Recommendations in Opinion N° 22 acknowledge at their outset the political co-decision taken by the European Commission, the European Parliament and the Council of Ministers regarding the approval of funding of protocols involving human embryonic stem cells. Yet, the Group emphasizes at the outset that "the ethical dilemma regarding the moral status of the human embryo and its use in research still persists. The EGE therefore stresses that the ethical differences of Opinion concerning human embryonic stem cell research have not been resolved."[90]

Moreover, the Group recognises that it has neither the mandate nor the power to change the political co-decision already taken by the EU on the funding of research projects involving human embryonic stem cells. Furthermore, the Group admits that it is divided on this issue:

> As is the case in the European Union, there are divergent views within the EGE on the moral legitimacy of research on human embryos and hESCs, ranging from objection to research involving the destruction of human embryos (which makes the full respect of dignity of the human embryo impossible), to a position allowing hESC research under certain conditions or on a broader basis.[91]

This unequivocal statement has been endorsed in Opinion N° 22 since some members of the Group declared at the outset of the discussions that they have fundamental ethical objections to the use of embryonic stem cells in scientific research. They also underlined that they are not ready to make any *ethical* compromise on this issue because any use of human embryonic stem cells in medical research involves the destruction of human life

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[89] Letter sent by President Barroso to the EGE on November 22, 2006.
[90] Opinion No. 22, par. 4.1.
[91] Ibid., par. 4.1.

and accordingly is against the ethical principles of the human dignity and inviolability of a human being who must be respected and protected in all stages of its development.

Though in Opinion N° 22 members of the EGE did not have the mandate, due to political reasons, to change the EU co-decision on the funding of research involving human embryonic stem cells, however it is quite clear that, in comparison to FP6, stricter rules of selection procedure were introduced as a result of the arguments based on human dignity presented by some members in the Group's discussions and deliberations. This strategy was achieved by articulating convincing scientific, legal and ethical arguments in support of the dignity and integrity of every human being from fertilisation. As a result, higher scientific and ethical standards were endorsed in Opinion N° 22 so as to make it more and more stringent for research protocols to be accepted for funding under FP7 by the scientific and ethical review boards.

The import attributed to the normative principle of human dignity in Opinion N° 22 is evidenced by some examples. The Group pleads for the reduction of the use of human embryos to generate stem cells by calling on the European Union to develop appropriate systems to minimise the use of human embryos to cases for which no alternatives exist.[92]

Moreover, the Group endorses in Opinion N° 22 the same specific restrictions and conditions for the eligibility of funding of research activities as in FP6:

- research activity aiming at human cloning for reproductive purposes (reproductive cloning),
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable (germline gene therapy),
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer (commonly referred to as therapeutic cloning).

In addition to these former restrictions, in Opinion N° 22, the EGE recommends the following considerations:

- FP7 hESC lines have to result from non-implanted IVF embryos; [93]

[92] Ibid., par. 4.3.
[93] Ibid., par.4.2.2.

- hESC lines banked in the European Registry should be used where possible; [94]
- both the positive and negative results of the research performed with/on the hESC lines should be published by researchers.[95]
- if alternatives to hESC with the same scientific potential as embryo-derived stem cells are found in the future, their use should be maximised; [96]
- donors' rights (in terms of health [risk by excessive ovarian stimulation], free and informed consent, data protection and free donation without undue pressure) are paramount and accordingly have to be protected and safeguarded. Moreover, no financial incentives are to be offered to donate embryos for research; [97]
- action to stimulate public debate on this research area is needed at EU level.

Moreover, in addition to the ethical review, the EGE recommends in Opinion N° 22 that the scientific review should address issues such as whether the research objectives could be achieved with alternatives to human embryonic stem cells and whether the applicants can demonstrate that their research is aimed at improving human health or boosting biomedical knowledge.[98] Furthermore, the scientific panel should "ensure that researchers of human embryonic stem cell FP7 projects collaborate nationally and internationally in order to minimise the use of human embryonic stem cells within FP7 funded projects and to achieve complementary synergy rather than competition."[99]

Finally, the Group addressed the wider ethical aspects of research using human embryonic stem cells. As the ethical conflicts concerning these cells have not been resolved either academically or politically, the EGE recommends that, under FP7, "funding should be provided in order to foster further collaborative and multidisciplinary international research on the ethical implications of human embryonic stem cell research and the pertinent surrounding issues, as well as to encourage informed public debate."[100]

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[94] Ibid., par.4.2.4.
[95] Ibid., par. 4.2.4.
[96] Ibid., par. 4.2.3.1.
[97] Ibid., par. 4.2.3.2.
[98] Ibid., par. 4.2.1.
[99] Ibid., par. 4.2.1.
[100] Ibid., par. 4.3.

Thus, researchers who receive funding for human embryonic stem cell research under FP7 should also be encouraged to engage in social, political and ethical debates.[101]

In conclusion, it is evident that the EGE plays an important role in bolstering the acceptance of emerging biotechnologies in EU policies by supplying ethical Opinions which contain authoritative normative guidelines which do not only support the activities of market actors within the biotechnology industry but also ensure that fundamental moral principles are not compromised. One of these moral principles is that of human dignity which, as has been argued in this article, is central to the EGE's ethical discussions and deliberations. This study has shown that human dignity is not a useless or rhetorical concept, as some mistakenly argue, but rather a universal overarching ethical principle which is shaping EU policies on biotechnology.[102]

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[101] Ibid., par. 4.2.4.

[102] The original version of this paper was first submitted and accepted for publication to the *Human Reproduction and Genetic Ethics Journal* under the title *Human Dignity and Biotechnology: A European Perspective.*