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Patentability of Human Enhancements

Maurice Schellekens and Petroula Vantsiouri*

I. INTRODUCTION

The patent system is dynamic. Its limits are redefined as industries evolve and explore new technologies. History has shown that campaigners for novel patents are likely to succeed, except where they meet persistent opposition from other interests groups.¹ Human enhancing technologies may very well be the next field where the battle of patentability is fought.

We define human enhancement as a modification aimed at improving individual human performance and brought about by science-based or technology-based interventions in the human body.² Hence, in our analysis we use a broad concept of human enhancement, which may involve aspects of healing. This is the case, for example, where the healing of a condition yields a result that in some respects constitutes an enhancement compared to the situation that existed before the ailment set in. But purely restorative healing is not included in our definition of human enhancement. On top of that, we concentrate on human enhancements that rely on nanotechnology, biotechnology, information technology and cognitive science (NBIC) technologies. Thus, more traditional forms of human enhancement such as glasses, certain nutrients, learning and training fall outside our conception of human enhancement. Examples of human enhancement technologies include the following: implants and organ transplants ('medical'), robotic arms and powered exoskeletons ('mechanical'), drugs and doping ('medicinal'), and neurostimulation and brain-computer interfaces ('neural').

As human enhancement is increasingly becoming a reality, developers of human enhancements seek patent protection for their technologies. However, strong opposition to their patentability may be anticipated, based on a wide range of ethical issues. Therefore, this article focuses on the patentability of human enhancements. It addresses the question of whether patent protection is and should be available for human enhancement technologies, in view of the fact that the products of these

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¹ Indicatively, see patenting practices in the industries of agriculture, horticulture, animal production, microbiology and biotechnology.

² Christopher Coenen *et al*, Human Enhancement Study (IP/A/STOA/FWC/2005-28/SC35, 41 & 45), May 2009, p 22, [www.europarl.europa.eu/RegData/etudes/etudes/join/2009/417483/IPOL-JOIN_ET\(2009\)417483_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2009/417483/IPOL-JOIN_ET(2009)417483_EN.pdf).

³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴ ~~Conductively on the Granting of European Patents for Inventions in the Field of Biotechnology, by the EPO, 1997, 39 *Intellectual Property Quarterly* 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1174, 1175, 1176, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1192, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1213, 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technologies become part of our bodies and are strongly linked to our identities. To answer this question, the article examines whether human enhancement technology may be patented even though its products become part of our bodies and whether human enhancement technology should be patented in view of its possible moral implications.

In the US, such questions are of a simply theoretical nature as ‘anything under the sun made by man’, apart from a human being, is regarded as patentable.³ In Europe, though, the European Patent Convention (EPC)⁴ and the Biotechnology Directive⁵ have established a particularly complex set of rules to address the advancement of patent frontiers in new technological developments closely related to living matter and especially humans.⁶ Therefore, it is worth examining whether we can and should use the commercial stimulus of an exclusive property right to encourage human enhancement.

Of course patent law in Europe should respect the obligations that the EU and all its Member States have undertaken as signatories to the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement). In particular, Article 27 of TRIPs introduces a principle of non-discrimination and requires patent protection for products and processes in all areas of technology, thus reinforcing the neutrality of the patent regime and the idea that technical invention is itself intrinsically uncontroversial.⁷ Therefore, an absolute ban on patenting any human enhancement would contravene the international obligations that Europe has undertaken.⁸ Nonetheless, WTO members ‘may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality’.⁹

³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴ Convention on the Grant of European Patents of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act Revising the EPC of 29 November 2000 (EPC).

⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 , 30/07/1998, pp 13–21 (Biotechnology Directive). The Directive has been adopted into the EPC by Implementing Regulation r 23d: [1999] OJ EPO 434.

⁶ The EU unitary patent system is drawn into the analysis, to the extent that the authors deem that it impacts on the issues discussed therein.

⁷ Art 27(1) TRIPs requires that patents ‘shall be available for inventions, whether products or processes, in all fields of technology ... patents should be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported, or locally produced.’ Likewise, Art 52(1) EPC provides that European patents shall be granted for any inventions in all fields of technology, provided they are novel, non-obvious and susceptible of industrial application.

⁸ Indeed, despite widespread protests against genetic engineering and biotechnology, Art 1(1) of the Biotechnology Directive requires Member States to protect biotechnological inventions under national patent law.

⁹ Art 27(2) TRIPs. WTO members may also exclude from patentability ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’ (Art 27(3)(a) TRIPs), as well as ‘plants and animals and other

Accordingly, the Biotechnology Directive and Article 53(a) of the EPC introduce exceptions to patentability that may raise ethical concerns.

In that respect, this article identifies novel ethical concerns that may arise with regard to human enhancements, and examines whether such concerns could lead to an exclusion of patentability based on Article 6 of the Biotechnology Directive and Article 53(a) of the EPC. This examination is based on an assessment and comparison of the concerns that have been expressed with regard to the patentability of biotechnology and the ways in which the European Patent Office (EPO) and Court of Justice of the European Union (CJEU) have addressed them. The article concludes that the uncertainty as to the role that ethical concerns should play within the patent system does not allow for definite answers and demonstrates how this can be problematic for the evolution of new technologies, such as human enhancements.

II. PATENTING PART OF THE BODY

The techniques of human enhancement are often applied to specific parts of the human body. In certain circumstances, the Biotechnology Directive prohibits the patenting of parts of a human body. How does this affect opportunities to patent certain applications of human enhancements? The Biotechnology Directive states in Article 5(1) and (2):

1. The 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.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

In its sixteenth recital the directive indicates the rationale behind these provisions:

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

micro-organisms, and essential biological processes for the production of plants or animals, other than non-biological and microbiological processes' (Art 27(3)(b) TRIPs).

The rules and recital above mention the concepts of ‘discovery’, ‘human dignity’, ‘integrity of the person’ and ‘element of the human body’. These concepts will now be clarified for the purpose of this article.

(a) Discovery

The mention of ‘discovery’ in the sixteenth recital is a reminder and clarification of the rule that discoveries as such cannot be patented.¹⁰ It is a reminder in that the mere discovery of a human body or one of its elements cannot constitute a patentable invention. In the context of the EPC, this already follows from Article 52(2) and (3) EPC. It is a clarification in that it removes any doubt that an element isolated from the body or otherwise produced is not necessarily a discovery even if the structure of that element is identical to that of a natural element.

The chances that a human enhancement is not patentable as a discovery are not particularly great. The concept of human enhancement implies that some technical steps are taken to improve the human condition. These steps preclude that a human enhancement is qualified as a mere discovery.¹¹

(b) Human Dignity

Dignity is a concept that is difficult to capture and may to some extent be considered indeterminate. For an approximation of its meaning, we turn to the EU Charter of Fundamental Rights (‘the Charter’). In his commentary on Article 1 of the Charter, Olivetti describes dignity as the ‘idea that the “intrinsic value” of the human being is evoked as unique, capable of self-determination, and holding a value which transcends every situation and condition in which a person might find himself, even going beyond the existence of the person himself’.¹² He discerns human beings becoming mere objects in medical or biological practices as an example of an affront to dignity.¹³

¹⁰ See the last sentence of recital 16 of Directive 98/44/EC: ‘whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented’. Also, Art 5(1) Directive 98/44/EC explicitly mentions ‘discovery’.

¹¹ Compare Case C-377/98, *Kingdom of the Netherlands v European Parliament and the Council of the European Union* [2001] ECR I-7079. Nor are elements of the human body patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent.

¹² Marco Olivetti, ‘Article 1: Dignity’ in William Mock and Gianmario Demuro (eds), *Human Rights in Europe: Commentary on the Charter of Fundamental Rights of the European Union* (Carolina Academic Press, 2010) 7.

¹³ *Ibid*, 9.

Brownsword—not specifically referring to EU law—distinguishes two approaches to dignity.¹⁴ He describes the first approach to human dignity as empowerment:¹⁵

If we accept that human dignity (qua the capacity to make choices) is worthy of respect, the following triple demand is invited: that one's capacity for making one's own choices should be recognized; that, other things being equal, the choices one freely makes should be respected; and that the need for a supportive context for autonomous decision-making should be appreciated and acted upon.

The other approach noted by Brownsword is human dignity as a constraint. This approach teaches that modern developments, for example in science, should respect human dignity. It is the latter approach that lies at the basis of dignity as intended in the directive.¹⁶ Patents on the elements of a human body may encourage its commoditisation and commercialisation.¹⁷

How does human enhancement relate to human dignity? Human dignity may be implicated in many ways by human enhancements. It may for example be feared that human enhancement contributes to a view of human beings as entities whose value depends on their physical or mental abilities, and this detracts from and affects their dignity. Or it may be feared the human enhancements will be applied in circumstances where the persons involved have not given their true and informed consent. Specifically with a view to patentability of parts of the human body the following can be argued: non-isolated parts of the human body cannot be patented. Here, patent law helps to uphold respect for human dignity.¹⁸ Patents on non-isolated body parts could presumably have contributed to an instrumental view of human life. However, isolated parts of the human body can be patented. This does not in itself mean that there can be no dignity-based objections to human enhancements involving isolated body parts. A possible lack of respect for dignity should be addressed outside patent law. Possible affronts to dignity include lack of consent (eg to the act of isolation) and commoditisation or even commercialisation of isolated body parts. These possible affronts are not unique to human enhancement, but may become

¹⁴ Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford University Press, 2008) 41–47.

¹⁵ *Ibid*, 42.

¹⁶ See Case 377/98 (n 11) 77: 'It is clear from those provisions that, as regards living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.'

¹⁷ See also Art 21 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4.IV.1997 (ETS No 164) (Convention on Human Rights and Biomedicine).

¹⁸ Case 377/98 (n 11) 71–73.

more acute as a consequence of the opportunities that human enhancement offers. Below in section (e), different types of human enhancements involving body parts are described.

(c) Integrity of the Person

In its third article, the EU Charter of Fundamental Rights protects the right to respect for a person's physical and mental integrity.¹⁹ The concept of physical and psychic integrity has been characterised as an expression of 'the elements forming the identity of the human being and hence the human personality. The subject protected by article 3(1) coincides with the right to identity of every individual, or rather the claim of every individual, to express his or her own different unique identity without harm to others.'²⁰

Concrete examples of legal claims that may be based on the first section of Article 3 in the field of medicine and biology are mentioned in the second section. It states:

2. In the fields of medicine and biology, the following must be respected in particular:
 - (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
 - (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
 - (c) the prohibition on making the human body and its parts as such a source of financial gain;
 - (d) the prohibition of the reproductive cloning of human beings.

These examples are conceivably relevant for human enhancements.

Human enhancements may involve third parties who apply the human enhancement to the subject. An example is surgery to insert or remove an element of a human body. For such acts informed consent is required in much the same way that consent is required for medical acts for healing purposes. In other relations, consent may also be required. Such situations could include employers requesting that employees enhance themselves in some way or another. Consent also needs to be obtained where elements of a body are taken and an enhancement is developed on the basis of the materials taken. For example, cells that have a remarkable property may form the basis for research²¹ into future enhancements. Presently, the patent system does not play an active role in ensuring that consent is obtained.²² As the CJEU pointed out in Case C-377/98 on the validity of the Directive on Biotechnological Inventions, 'the purpose of the Directive is not to replace the restrictive provisions

¹⁹ Compare Art 3 Charter of Fundamental Rights of the European Union, OJ C83/389.

²⁰ Raffaele Bifulco, 'Article 3: Right to the Integrity of the Person' in Mock and Demuro (n 12) 19.

²¹ For example, the HeLa cell line.

²² In literature, this is subject to discussion. See eg Laurie G Patents, 'Patients and Consent: Exploring the Interface between Regulation and Innovation Regimes' in Hans Somsen (ed), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar, 2007) 214.

which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent'.²³ The first responsibility for regulating consent lies with regulation of research, not so much with patent law.

The prohibition on eugenic practices may be relevant if an enhancement is genetically passed on to the descendants of the enhanced person and the person to be enhanced is selected on the basis of untoward criteria. As far as patentability is concerned, selection on the basis of untoward criteria could be a circumstance that depends only on how the patented enhancement is used. In that case, the mere possibility of misuse of the patented invention is not a reason to deny a patent.²⁴ However, if the patent directly or indirectly invites eugenic practices—for example if eugenic considerations are part of the specification or the claims of a patent cannot reasonably be read as not having eugenic effects—an issue of patentability arises. This is an issue that may not be adequately discussed under Article 5 of Directive 98/44/EC because the link with isolation of elements of the human body may be weak or even absent. It is probably more appropriately dealt with under the morality clause.

As far as the third example is concerned, parts of a human body may have a financial value for enhancement purposes. For example, because of natural diversity, some persons may have organs that have advantageous characteristics for certain applications. These organs may have a financial value, since they may be transplanted or otherwise be the input material for enhancements. The prohibition on making such elements a source of financial gain clearly shows the link with human dignity.

According to Nowak, the right to integrity of the person includes a number of rights that were traditionally protected under the right to privacy.²⁵ These include the right to bodily integrity. Bodily integrity relates not only to acts that affect the health or functionality of a person's body; it also concerns any act the body is subjected to even if it does not do physical harm to the body itself, such as taking a saliva swab for DNA testing purposes. As far as human enhancements are concerned, acts affecting bodily integrity will mostly be covered by informed consent. For human enhancements, the relevant question is whether there are breaches of the right to bodily integrity that cannot be justified by informed consent. This may be the case in labour relations or in a military context where consent may not be given completely of one's free will. As we saw above, the CJEU does not place the first responsibility for autonomy with patent law.

²³ Case 377/98 (n 11) 80.

²⁴ T 0866/01 (Euthanasia Compositions/MICHIGAN STATE UNIV) of 11.5.2005, at 5.8.

²⁵ Manfred Nowak, 'Article 3: Right to the Integrity of the Person' in EU Network of Independent Experts on Fundamental Rights, *Commentary of the Charter of Fundamental Rights of the European Union* (June 2006), 36.

An expansive definition of human enhancement may include human cloning. Having oneself cloned or perhaps being a clone may strengthen one's identity.²⁶ This type of enhancement will not be dealt with further in this article.

(d) Element of the Human Body

What are elements of the human body? This concept clearly includes elements that are naturally part of a human body. It also includes elements in the previous sense that have been isolated from the human body. Does it also include elements that are not naturally part of a human body, but have been artificially brought into or attached to the human body or are being produced with the aim of insertion in a human body? The rationale of Article 5 EPC denies such an extension of the concept.

An important element of human dignity and integrity of the person is that parts of the body should not be commoditised and commercialised. This is clearly not an issue for parts that do not originate in the human body. A patent on an artificial hip is not an affront to the dignity or integrity of the person. There is not a natural part of the body that is being commoditised or commercialised. The integrity of the person is not affected.

A theoretical counterargument could be that 'element of the body' has a functional rather than a literal or 'natural' meaning, ie that patenting a human heart is not allowed, regardless of whether it is a natural or an artificial one. However, patents on artificial elements of a body are regularly granted.²⁷

(e) Patenting of Human Enhancements

Human enhancements come in many shapes and sizes. In order to structure the treatment of different technologies in relation to Article 5 of Directive 98/44/EC, we conceptualise here four different types of human enhancement techniques: (i) Materials taken from a human body, enhanced and then placed back into the same body; (ii) An element produced outside the body and attached to the body; (iii) An element produced outside the body and placed inside the body; and (iv) elements that the body is in some way induced to grow itself.

Analysing the four concepts of human enhancement gives rise to the following picture:

(i) Materials taken from the body, enhanced and placed back

²⁶ Bert-Jaap Koops, 'A Unique Copy: The Life and Identity of Clones in Literary Fiction' in Bert-Jaap Koops *et al* (eds), *Engineering the Human: Human Enhancement between Fiction and Fascination* (Springer, 2013) 129, 135, 146.

²⁷ Examples of patents on artificial heart valves (to name just one element of the human body) include: patent EP1251803 (B1) of Robert Snyders in 2005, patent EP0632711 (B1) of John Fisher in 1997, and patent EP0318351 (B1) of Jean-Paul Couetil in 1992. 'Element of the body' can therefore safely be assumed to have a literal meaning.

In the German literature, attention is drawn to the situation where an element of the body is only temporarily isolated from the body.²⁸ An example is blood that is taken from the body, is subjected to dialyses and then fed back into the body. The stance of the German authors is that elements that are only temporarily isolated from the body should not be patentable. Assuming that the person whose bodily elements are taken away is most probably relying on the quick and safe return of those elements, the bodily integrity of the person indeed provides a strong argument in favour of non-patentability. This could be a situation that gains in importance for human enhancement. Human enhancement by treating blood could become an important technique. Other parts than blood seem to be less suitable for a temporary excursion outside the body.

(ii) An element produced outside the body and attached to the body

The situation described here concerns an element that need not surgically be brought into the body. It can casually be attached to the body. An example is a (powered) exoskeleton. It is clear that such an object is not an element of the human body. As has been explained above, ‘element of the body’ does not have a functional meaning, but rather a literal one. Such an element is clearly patentable subject matter.

(iii) An element produced outside the body and placed inside the body

This concerns both situations where a clearly artificial element such as a pacemaker is introduced into the body as well as those where an organ is placed in the body that is indistinguishable from a human original. Neither situation concerns elements of the human body, for the same reason as indicated above. They are not natural elements in the literal sense of the word. If an element isolated from the human body can be patented even though it is structurally similar to a natural element, then certainly an element that has never been a natural element can be patented. Even if some elements of a body were used, the conclusion would be no different. This could be the situation where some DNA sequences of the eventual recipient of a synthetically produced organ have been introduced into that organ, eg to diminish the chance of repulsion of the organ by the body’s immune system.

(iv) Elements that the body is induced to grow itself

Bodies have some self-healing characteristics. A small cut on your finger will stop bleeding by itself and after some time the skin will grow together again, possibly forming scar tissue. Some animals, such as salamanders, are able to grow complete limbs after they have been severed. The application of these mechanisms in humans is part of the field of regenerative medicine and some considerable

²⁸ Roth Schulte and Rainer Moufang, *Patentgesetz mit EPU* (Heymanns, 2004) para 1a, rdn 21; Georg Benkard, Klaus Bacher and Klaus Jurgen Melullis, *Benkard Patentgesetz Gebrauchsmustergesetz* (CH Beck, 2006) 137.

progress has reputedly been made.²⁹ It is not completely unimaginable that at some point the technology involved will be used to induce bodies to enhance themselves in some way or another. If this technique leads to a body growing an organ itself then Article 5(1) seems to be applicable: it is a part of a human body and it is not isolated.

Looking at the rationale behind Article 5 of Directive 98/44/EC, this conclusion is less self-evident. On the one hand, the organ is not a discovery and its genesis requires a technical process. On the other hand, dignity may be implicated because the element is not isolated and patenting the organ would imply that it is produced for an industrial application.

This is so much a future technology that it is hard to pinpoint its implications. Much depends on the context in which the technology is used. A categorical statement about its patentability now would be premature. For example: If it were possible that somebody could grow a kidney, would the commercial offering of this kidney for transplant be an affront to dignity, because we do not want trafficking in human organs?³⁰ Should the affront to dignity be a reason not to allow a patent on the kidney? Or should we think about it differently since a transplant of a kidney has less serious effects for the donor? After all, he can grow a new one, so the risk of having to live with a single or no kidney is seriously reduced. This may not take away concerns related to dignity, but would disallowing a patent still be a necessary consequence? Even though there is doubt about the patentability of the 'human' elements that are grown, substances that are used to induce the body to grow an organ can be patented. At least, they do not raise issues under Article 5 of Directive 98/44/EC.

(f) Conclusion

In general, Article 5 of the Directive does not block human enhancement technologies that involve elements or parts of the human body. The rationale for limiting the patentability of parts of the human body is twofold. On the one hand, discoveries should not be patentable. This is clearly not an issue with human enhancement technologies, since they always involve some technical teaching. On the other hand, dignity and the integrity of the person require a certain respect and reticence in the patenting of elements of the human body. However, this respect and reticence extends to parts that are naturally in the body and not to parts that are developed outside the body and then placed inside or attached to the body. This gives considerable room for the patenting of the results of human enhancement technologies. There are, however, some areas where patenting is not allowed or the issue of patentability is in discussion. The former concerns elements that are only temporarily removed from a body. The second involves parts of the body that the body is induced to grow itself. Here, it is

²⁹ Tanya Brown, 'Remodeling the Human Body with Regenerative Medicine and Tissue Engineering', Purdue Alumni Association, Inc (November/December 2010), www.mcgowan.pitt.edu/news/article.asp?qEmpID=597.

³⁰ We assume that transplants would still be needed if the technology to grow a new kidney would not work for everybody.

unclear what the demands of human dignity and the integrity of the person will be and whether patents will be allowed.

III. MORALITY AND *ORDRE PUBLIC*

Another hurdle to the patentability of human enhancing technologies is the risk that their commercial exploitation could endanger the *ordre public* or morality within Europe.³¹ The concepts of *ordre public* and morality differ semantically.³² *Ordre public* is an evolutionary concept that concerns the fundamentals from which there can be no derogation by the institutions of a given society.³³ The term expresses concerns about ‘matters threatening the social structures that tie a society together, i.e. matters that threaten the structure of civil society as such’.³⁴ Morality, on the other hand, can be defined as ‘the degree of conformity to moral principles’,³⁵ corresponding to the French concept of *bonnes mœurs*.³⁶ The EPO Board of Appeal defined it as being

related to the belief that some behaviour [is] right and acceptable whereas other behaviour [is] wrong, this belief being founded on the totality of the accepted norms which [are] deeply rooted in a particular culture. For the purposes of the EPC, the culture in question [is] defined as the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which [is] not in conformity with the conventionally accepted standards of conduct pertaining to this culture [are] to be excluded from patentability as being contrary to morality.³⁷

Although the aforementioned definitions appear to be expansive, the two notions have been interpreted quite restrictively with regard to Article 53(a) EPC. The provision was long thought of as being of marginal relevance, but in the tide of concern over the inherent desirability of biotechnological

³¹ Art 53(a) EPC. The present wording of the EPC derives from Art 27(1) TRIPs, which names as grounds for the exception the need ‘to protect human, animal or plant life or health, or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by ... law’.

³² See *Harvard/Transgenic Animals*, T315/03 (2006) OJ EPO 15 (TBA), where the EPO’s Board of Appeal held that *ordre public* and morality may form the basis of separate objections.

³³ Daniel Gervais, *The TRIPs Agreement: Drafting History and Analysis* (Sweet & Maxwell, 2008) 343.

³⁴ *Ibid*, with further reference to Pedro Roffe *et al*, ‘Resource Book on TRIPs and Development: An Authoritative and Practical Guide to the TRIPs Agreement’, INCTAD-ICTSD Capacity – Building Project on IPRs, www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

³⁵ Philipp W Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (Oxford University Press, 4th edn 2004).

³⁶ Gervais (n 33) 345.

³⁷ T 356/93, OJ 1995, 545.

inventions and their potential dangers to humans and the environment it suddenly became the focus of a heated debate. Indeed, there has been a shift from a restrictive interpretation of the provision in the early case law of the EPO to the establishment of a more expansive exclusion from patentability. This dynamic evolution of the concepts is interesting to the extent that it may signal further expansion of the exclusion to include certain human enhancing inventions.

(a) Morality and *Ordre Public* in the Case Law of the EPO and the CJEU

Until recently, ethical considerations were rarely taken into consideration within patent law, as it was considered to operate in an apolitical way to reward and stimulate scientific progress, without discrimination or prejudice.³⁸ It was only after developments in biotechnology and the related attempts to patent the products of that research that ethical considerations began to play a more prominent role in patent law.³⁹ Thus, it is only logical to reflect upon the way in which ethical concerns have been addressed by the European legislature and in the case law of the EPO in the field of biotechnology, and to try to anticipate how ethical concerns related to human enhancement may be addressed within the European patent system.

In the first case where the meaning of the morality exclusion was considered, the 1989 *Onco-mouse/Harvard* case, the Examining Division refused to consider the application of Article 53(a) EPC, stating that it was inappropriate for examiners qualified as technicians to consider such an issue.⁴⁰ The Technical Board of Appeal took a different view in its 1990 decision, and introduced a utilitarian balancing test, as it explained that the application of Article 53(a) EPC ‘would seem to depend mainly on a careful weighing-up of the suffering of animals and possible risks to the environment on the one hand, and the invention’s usefulness to mankind on the other’.⁴¹

The utilitarian balancing test was reconfirmed in the latest instalment of the Onco-mouse saga, the 2003 *Transgenic Animals* decision.⁴² The Technical Board of Appeal reiterated that the test allowed a

³⁸ Lionel Bentley and Brad Sherman, ‘The Ethics of Patenting: Towards a Transgenic Patent System’ (1995) 3 *Medical Law Review* 275.

³⁹ See Arts 4–6 Biotechnology Directive and the EPO case law on the morality clause (below).

⁴⁰ *Harvard/Onco-mouse*, [1989] OJ EPO 451 (Exam). The case concerned the patentability of mice that had been genetically modified so that they would develop cancer, to be used in cancer research.

⁴¹ *Harvard/Onco-mouse*, T19/90 [1990] OJ EPO 490 (TBA). For an analysis of the case see Rebecca Dresser, ‘Ethical and Legal Issues in Patenting New Animal Life’ (1998) 28(4) *Jurimetrics Journal* 399; Ulrich Schatz, ‘Patentability of Genetic Engineering Invention’ (1998) 29 *IIC International Review of Intellectual Property and Competition Law* 2; Volker Vossius, ‘Patent Protection for Animals’ [1990] *European Intellectual Property Review* 250.

⁴² *Harvard/Transgenic Animals*, T315/03 (2006) OJ EPO 15, 54. The utilitarian balancing test had been applied in 1991 when the EPO warned that it would not accept an application to patent a transgenic mouse used to cure

range of factors to be taken into account, including harm to the environment, possible use of alternatives, possible threats to human evolution and so on. The Board stressed that Article 53(a) EPC was only concerned with the morality of the publication or exploitation of an invention, and not with the morality of the invention as such.⁴³

The utilitarian balancing test was rejected by the Opposition Division of the EPO in *Plant Genetic Systems* (1993), with the reasoning that they were not competent or qualified to decide ethical issues and that the patent system should take into consideration such concerns only where the invention would be universally regarded as outrageous and where there is an overwhelming consensus that no patent should be granted.⁴⁴ Following this reasoning, it was only necessary to consider ethical questions once a certain ethical threshold had been crossed. Proving this, though, would not be easy. The Opposition Division rejected opinion poll evidence, it was unable to quantify the objections raised against the patent, and it refused to evaluate the claims based on their personal philosophy or conviction on the basis that it would produce ‘individualistic’ or ‘arbitrary’ decisions.

On appeal, the Technical Board of Appeal suggested that the morality provision is to be construed narrowly but should not be disregarded. It opined that the concept of morality under the EPC was built upon a belief rooted in European society and civilisation that some behaviour is right and acceptable, and other behaviour is wrong.⁴⁵ Noting that patent offices exist ‘at the crossroads between science and public policy’, the Board of Appeal held that *ordre public* covers the protection of public security, the physical integrity of individuals as part of society, and protection of the environment. It stated that where the exploitation of an invention was likely to breach public peace or social order or seriously prejudice the environment, the invention would be excluded from patentability under Article 53(a) EPC. Such harms, though, could not be proven by opinion poll evidence, nor by the fact that certain behaviour was prohibited in some or all contracting states.⁴⁶ With regard to the utilitarian balancing test, without rejecting it, it held that it was not the only method of assessing patentability, although it was useful where actual damage and/or disadvantage existed.

hair loss. See Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 3rd edn 2009) 456.

⁴³ *Harvard/Transgenic Animals* (n 42) 29. It should be noted that the EPC does not refer to the publication of the invention after its 2000 amendment, instead it is limited to the commercial exploitation of the invention in line with Art 27(2) TRIPs and the Biotechnology Directive.

⁴⁴ *Plant Genetic Systems* (1993) 24 *IIC International Review of Intellectual Property and Competition Law* 618. In this case, Greenpeace objected to a patent for a genetically engineered plant on the grounds that it was inherently immoral and that it created risks for the environment.

⁴⁵ *Plant Genetic Systems* (1995) OJ EPO 545.

⁴⁶ See also Art 27(2) TRIPs, which requires that exclusions from patentability should not be made merely because the exploitation is prohibited by national law.

This line of interpretation was followed in the subsequent case of *Howard Florey* (1995), where the EPO's Opposition Division interpreted the exclusion of Article 53(a) EPC as existing merely to ensure 'that patents ... [are] not granted for inventions which would universally be regarded as outrageous', such as a letter bomb, or an invention based on the use of detached body parts without informed consent.⁴⁷ Addressing the opponent's claim that patenting of a DNA sequence resulted in slavery, the Opposition Division noted that such an assertion misunderstood the nature of a patent, as a patent does not give the proprietor any rights over a human being, but rather provides a right to prevent someone from practising the same invention.

A review of the early EPO case law on Article 53(a) EPC reveals a tension between the interpretation of the provision by the Opposition Division and that by the Technical Board of Appeal. On the one hand, the Opposition Division repeatedly tried to avoid taking into consideration fundamental ethical concerns, on the basis that the members of the EPO are not qualified to address such concerns, and that patent law is not the appropriate forum for ethical assessments.⁴⁸ On the other hand, the EPO's Technical Board of Appeal remained closer to the wording of the EPC and rejected the Opposition Division's interpretation, still, though, arguing in favour of a restrictive interpretation of the exception to patentability on morality and *ordre public* grounds.⁴⁹ This tendency was also followed by the CJEU in its decision on the validity of the Biotechnology Directive, as the Court rejected the relevance of the right to bodily integrity to issues of patentability, holding that such a right 'is clearly misplaced as against a directive whose scope does not extend to activities before and after grant, whether they involve research or the use of the patented product'.⁵⁰

Thus, in the early case law of the EPO the question of immorality of an invention was essentially a technical inquiry, where considerations of ethics had no role beyond ensuring that the grant of a patent would not be universally regarded as outrageous. Early EPO case law left the door open for the

⁴⁷ *Howard Florey/Relaxin*, T74/91, [1995] EPOR 541 (Op Div). The case concerned an opposition of the Green Party to a patent for the DNA sequences of a naturally occurring substance that relaxes the uterus during childbirth, which is obtained from the human ovary, on the grounds that the use of pregnancy for profit was offensive to human dignity, that the applicant was patenting life, and that this patenting was equivalent to slavery.

⁴⁸ Cf William Cornish and David Llewellyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (Thomson Sweet & Maxwell, 6th edn 2007) 881–2, noting that EPC decisions are open to wide-scale review before and after grant by the EPO.

⁴⁹ Indeed, there have been voices that viewed with scepticism the treatment of the patent system as a neutral form of state aid and the disclaimer of responsibility by the state for the inventions for which it grants protection. See Deryck Beyleveld and Roger Brownsword, *Mice, Morality and Patents* (Common Law Institute of Intellectual Property, 1993).

⁵⁰ Case C-377/98, *Kingdom of the Netherlands v European Parliament and Council of the European Union* [2001] ECR I-7079.

assessment of ethical objections to new technologies, such as human enhancing ones, without, though, leaving significant leeway. Recently, however, the EPO and the CJEU pushed the door further, in their decisions in *WARF/Stem Cells*⁵¹ and *Brüstle v Greenpeace*⁵², where the morality exception was construed expansively with a view to achieving one of its motivating purposes of preventing the commodification of human embryos.

In *WARF/Stem Cell* the patentability of a cell structure comprising primate embryonic stem cells capable of in vitro fertilisation was questioned. The patent was refused by EPO's Examining Division on the grounds that the invention concerned the use of human embryos for industrial or commercial purposes, while the applicant denied that the use of human embryos to make the claimed human embryonic stem cell cultures is a use for industrial or commercial purposes. The Enlarged Board of Appeal of the EPO held that:

Making the claimed product remains commercial or industrial exploitation of the invention *even where there is an intention to use that product for further research*. On the facts, which the Board must assume in answering the referred question, making the claimed product involves the destruction of human embryos. This use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) EPC. (emphasis added)

In *Brüstle v Greenpeace* the CJEU went a step further. *Brüstle's* patent concerned the use of a cell structure, rather than the cell structure as such, for treating Parkinson's disease, and it did not require the use of embryonic stem cells, as in *WARF*, but the use of neural precursor cells, namely pluripotent stem cells of human origin, which are removed at an early stage of the development of the result of the fertilisation of an ovum by a sperm. The case was referred to the CJEU, which followed an expansive interpretation of the term 'human embryo', on the grounds that in the context of the Biotechnology Directive 'the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected'. The CJEU held that the concept 'human embryo' included non-fertilised human ova into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.

WARF and *Brüstle* raise the spectre of further restrictions on patentability with reference to the history of an invention and European conceptions of morality and *ordre public*. Now patentability must take full account of human dignity as one of the values underpinning European law and culture, and thus

⁵¹ G_2/06 *WARF/Stem Cells* [2009] EPQR 15 (eba).

⁵² Case C-34/10 *Olivier Brüstle v Greenpeace Ev* [2011] ECR I-09821.

recent jurisprudence has called for a re-evaluation of the relationship between human rights and values and patentability of inventions in Europe.

Human enhancement can be expected to revive the debate on the role that moral and public policy concerns and human rights should play in the grant of patents and the relationship between human rights and the patent system. And this time the implications of a positive or negative answer may be even greater, in view of the implementation of the unitary patent system that has been agreed among 25 of the 27 EU Member states.⁵³ In particular, under the existing system the EPO grants national patents, whose validity after grant and infringement are decided on a national level. Accordingly, a Member State retains the power to reject the consequent national patent on morality and *ordre public* grounds—including religious or cultural ones—that seem sufficient within its own territory. The unitary patent protection package changes that to the extent that the validity of EU patents with a unitary effect will be decided at a European level, thus showing less flexibility to accommodate particular ethical and moral concerns that may arise within one of the 25 countries participating in the enhanced cooperation procedure that establishes the unitary patent system. As a result the EU, as a granting authority, bears even greater responsibility for the inventions for which it grants protection.

In this light the substantive morality and *ordre public* concerns that may arise with regard to human enhancements will be reviewed. To do so, though, we must first revisit the approach established so far by the EPO and the CJEU case law to address them and its suitability to address ethical concerns that arise with regard to human enhancement.

(b) The Model for Assessment of Moral and *Ordre Public* Concerns

The case law of the CJEU and of the EPO left unanswered the question of how to evaluate ethical concerns and subsequently translate them into the language of patent law. EPO case law has rejected the assessment of ethical oppositions based on personal philosophy and conviction and the quantification of ethical objections through opinion polling. Indeed it would be wrong to decide upon the immorality of objections based on personal views. Still, continental legal systems that contain the *ordre public* and morality as principles in their civil laws have long applied those principles in private matters, not based on private convictions of the judge, but based on the way that the judge understands

⁵³ In late 2012 and early 2013, 25 out of 27 EU Member States adopted two new regulations establishing the EU Patent with Unitary Effect (Regulation 1257/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1 and Regulation 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L361/89) and concluded an international agreement that establishes a single patent litigation system, through the establishment of the Unified Patent Court (Agreement on a Unified Patent Court, Council of the European Union, Brussels, 11 January 2013 (OR.en), Document no 16351/12, PI 148 COUR 77). The single patent litigation system is currently expected to commence in January 2015.

the convictions of society. Therefore, such an approach should not be excluded from the outset, if the proper conditions for its application are set.

Based on the case law of the EPO, the immorality of an invention can be assessed using a *utilitarian balancing test*, especially where actual damage and disadvantage exist, such as animal suffering. In the case of human enhancement, one could imagine that the intrusion of robotic technologies into the human body, and the monitoring of the actions of the human, can be considered as such harm. Of course, the free and informed consent of the person, provided for example by a patient before an operation, will bring the discussion to an end.⁵⁴ However, in other fields where human enhancements are expected to be utilised, such as in the military or in the workplace, it is rather questionable whether subjects can provide their consent freely. In such cases, where humans will undeniably suffer harm, it is worth rethinking whether the utilitarian test used so far by the EPO is the appropriate means to decide on the morality of human enhancing technologies, or whether the line of reasoning of the CJEU in *Brüstle*, where the Court held that ‘the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected’ is more appropriate. Of course the utilitarian test has so far been applied by the EPO in cases of animal, rather than human, suffering; nonetheless, arguments weighing national sovereignty, the fight against terrorism or boosting a state’s commercial competitive advantage against an intrusion into an individual’s personal sphere are not unthinkable. After all, the balancing of conflicting fundamental rights is not foreign to many constitutional orders. Still, we need to think through how and whether this weighing exercise can take place for the entire European territory, especially since the EU is not a political union, but rather an economic one.

There may also be cases where no such harm exists, such as the question of whether overcoming the limitations of the human body through technical means to create super-humans is desirable. In such cases it is clear from previous EPO case law that the balancing exercise cannot be applied. This is rather a question of accommodating ethical considerations, on which different people may have diverse, albeit strong, opinions. It remains to be seen how such conflicts can be accommodated. If the concept of morality under the EPC is actually built upon a belief rooted in European society and civilisation that some behaviour is right and acceptable, whereas other behaviour is wrong,⁵⁵ the right

⁵⁴ See *Relaxin*, where the EPO held that patenting of DNA sequences obtained from the human ovary was not immoral, as the human tissue used in research was donated by the women, who provided their informed consent. On the other hand, supporters of stronger limits to technological development may view such cases as *dignity-compromising procedures as such*. For those who want stronger limits, human dignity is non-negotiable and thus consent to a dignity-compromising procedure can be deemed irrelevant. For further analysis see Roger Brownsword, ‘Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the “Dignitarian Alliance”’ (2003) 17 *University of Notre Dame Journal of Law, Ethics and Public Policy* 15; Roger Brownsword, ‘Stem Cells and Cloning: Where the Regulatory Consensus Fails’ (2005) 39 *New England Law Review* 535.

⁵⁵ *Plant Genetic Systems* (1995) OJ EPO 545.

or wrong could be decided based on the European polity and in particular by first consulting the European Charter of Human Rights.

In short, the EPO and the CJEU have left many questions unanswered with regard to the role that moral and *ordre public* concerns play in the patent system. With this in mind, we discuss below the substantive ethical concerns that human enhancement technologies may raise.

(c) Substantive Moral and *Ordre Public* Concerns

The EPO understands *ordre public* to cover the protection of public security, the physical integrity of individuals as part of society, and protection of the environment,⁵⁶ while it is clear that this is not an exhaustive list. Factors that were considered by the EPO as indicators of immorality include harm to the environment, existence of less harmful measures (ie proportionality of the measure), possible threats to human evolution and so on.⁵⁷ The decision of the CJEU in *Brüstle* signalled that patentability may need to take full account of human rights and values underpinning the European order, rather than restricting the application of Article 53(a) EPC to what is considered as universally outrageous. Therefore, although the role that human rights and values play within the patent system is far from clear, the rights enshrined in the EU Charter of Fundamental Rights can form the basis of the analysis of the ethical concerns that human enhancement may raise. Of course there are significant differences between the fields of biotechnology, which has triggered the application of the morality clause so far, and human enhancement. Those differences should be taken into consideration when examining the patentability of human enhancing technologies.

In both industries the cost of R&D is very large, while the odds on striking a truly valuable product are long. So, the need to induce private parties to engage in costly speculative research is significant in both fields. One of the major differences between the two industries, though, is that human enhancing technologies also extend to strictly technical inventions that do not entail life-forms. On a first reading, this would make the grant of patents for human enhancing technologies less controversial. A closer look, though, reveals that the fact that human enhancing technologies may not constitute life-forms as such signifies that the limitations to the patentability of life-forms also do not apply, although human enhanced parts may have the same ‘look and feel’ and, more importantly, the same function as ‘living’ subject matter.

As explained above, European patent systems have dealt with patentability of living matter with great reluctance. This is reflected in the exclusions from patentable subject matter in the EPC and the Biotechnology Directive. On top of those exclusions, though, ethical and utilitarian concerns have

⁵⁶ *Ibid.*

⁵⁷ *Harvard/Transgenic Animals* T315/03 (2006) OJ EPO 15.

been addressed via the application of the ‘invention-discovery’ dichotomy.⁵⁸ The requirements of novelty and inventive step also limit the availability of body part patents to newly isolated parts such as gene sequences, stem cells and other biological material. Moreover, the requirement that an invention be susceptible of industrial application necessitates showing how the isolated part may benefit the industry.⁵⁹ In contrast, all those requirements are fulfilled easily by human enhancing technologies.⁶⁰

As a result, human enhancement enables for the first time the patenting of what will later constitute body parts, thus raising the debate on the exclusions to patentability to a whole new level. The idea that substantial space must be left for basic discoveries because they need to be shared at once by all who contribute to the corpus of knowledge⁶¹ resurfaces, and so do ethical, theological and environmental concerns with regard to human intervention in nature. Human enhancement achieved by strictly technological means could raise the same dislike for treating humans and their body parts as the subject of property rights.⁶²

Based on the early EPO and CJEU case law, such concerns would not be likely to lead to an exclusion of patentability of human enhancing technologies, as it is almost impossible for them to be quantified and taken into consideration in a balancing exercise or even as an expression of human rights violation. Moreover, although *WARF* and *Brüstle* may lower the threshold for the application of Article 53(a) EPC, they do not automatically signify that human enhancing technologies will be excluded from patentability based on the aforementioned concerns. On the contrary, the issue of quantification of such concerns still exists, thus leaving open the question of how those concerns can be accommodated within the patent system.

Some of the ethical concerns with regard to human enhancement may arise in the future, as they are dependent upon the widespread use of the invention. For example, if human enhancement becomes

⁵⁸ Patent laws protect ‘inventions’, as distinct from ‘discovery, scientific theory or mathematical method’. See Art 53(2) EPC, Art 27 TRIPs Agreement; Art 3(1) and (2) Biotechnology Directive. See also section II(a).

⁵⁹ Justine Pila, ‘Intellectual Property Rights and Detached Human Body Parts’ (2012) 10 *Journal of Medical Ethics* 1136.

⁶⁰ See above, section II(e).

⁶¹ This idea has been expressed with regard to the Human Genome project. Indicatively see John Sulston and Georgina Ferry, *The Common Thread* (Corgi Books, 2002).

⁶² For an overview of ethical concerns expressed with regard to genetic engineering of humans as an interference with the sacred, God-given human form, as raising the spectre of eugenics and leading to a re-emergence of slavery, see Dan L Burk, ‘Patenting Transgenic Human Embryos: A Nonuse Cost Perspective’ (1993) 30 *Houston Law Review* 1597, 1664 ff; Rachel E Fishman, ‘Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?’ 15 *American Journal of Law and Medicine* 461, 468–9; Rachel E Fishman, ‘Patenting Human Beings’ (1990) *Trial* 54, 60; G Kenneth Smith and Denise M Kettelberger, ‘Patents and the Human Genome Project’ (1994) 24 *American Intellectual Property Law Association* 27.

widespread and has many practical applications, the granting of patents over it may furnish commercial monopolies of excessive compass, conferring the power to control other people's activities and to extract financial returns on a disproportionate scale.⁶³ This development could undermine the right of access to health. Indeed, the right to human dignity encompasses the right to health care services, which in turn requires that patents are not used to deny citizens access to health on reasonable terms.

Currently it is unlikely that human enhancement will constitute an infringement of the right of access to health, as such a violation is contingent upon the future widespread adoption of the technology. It would not be wise, nor is it likely, to decline patentability of human enhancement based on hypothetical concerns.

In addition, human enhancement may raise further ethical concerns, especially when not used for therapeutic purposes, but as a means to overcome the limitations of the human body. For example, human enhancement may raise concerns as to possible inequality among individuals, if only part of a community can be subjected to human enhancement, due to financial or health related reasons, thus gaining an advantage over the rest of their community. Of course, an infringement of equality depends mainly on the conditions on which human enhancement will be made available.

Indeed, it is not only the nature of the patented technology that should be considered in an ethical assessment of the invention, but also the way in which it is expected that the invention will be applied. When we think of biotechnological inventions we may think of transgenic mice suitable for cancer research, or human stem cells used to treat Parkinson's disease, or modified genes making plants resistant to herbicides. In other words, biotechnological inventions are patented to fulfil a specific purpose and may be applied to humans, animals or plants. In contrast, human enhancing technologies are applied by definition to humans, in order to overcome certain limitations of the human body. This significant difference in the application of such inventions bears further consequences for the assessment of the ethical concerns that arise.

Due to the omnipresent intervention of the human factor in the application of human enhancing technologies, it is impossible to evaluate *in abstracto* such enhancement from a moral, ethical or political perspective. This is so because the consequences of enhancement are always context specific and depend on the way the human enhanced individual chooses to act at each and every moment. To give an example, the ethical concerns that arise when a blade runner competes in a running contest, such as equality amongst athletes or undermining the athletic spirit, do not arise when a blade runner runs to catch a bus. Different ethical concerns arise when a blade runner escapes police arrest due to her ultra-human ability to run fast, or when she saves a child from a fire. The uncertainty that envelops

⁶³ Note, though, that the CJEU mitigated fears about the far-reaching monopolising effect of patent law in its decision in Case C-428/08, *Monsanto Technology v Cefetra* [2010] ECR I-6765. The Court held that gene patents only protect the gene when able to perform the specific function for which it was patented.

the ways in which enhanced abilities will be put to use raises questions as to the suitability of the patent system to address them.

One may argue that a level of uncertainty exists with regard to all new inventions, as any invention may have additional uses, capabilities or attributes that the inventor was not aware of at the time of the filing of the patent application. In contrast, even if the function of a human enhancing technology is known from the outset, namely to overcome a particular physical human limitation, there is still uncertainty as to the way in which the conferred ability will be put to use. Moreover, this uncertainty and context dependency of the ethical evaluation of human enhancements should be contrasted with the uncertainty that exists with regard to biotechnological inventions as to the moral acceptance of inventions, which is dependent upon the political, religious and moral views of different communities and the ways in which they alter over time.

Nevertheless, the uncertainty surrounding human enhancement does not call for the application of the precautionary principle.⁶⁴ This uncertainty should not be perceived as an obstacle to the development of human enhancements, as immoral applications of the technology can be confronted via regulation of human behaviour. Indeed, human societies have long had complex rules to regulate human behaviour that adapt to new developments and that are appropriate to address the ethical concerns that may arise from the use of human enhancements. In contrast, the introduction into the environment of a genetically modified plant, for example, may have irreversible consequences.

Nonetheless, there may be instances where a patent application is filed with regard to the use of human enhancement within a particular environment, such as the workplace or the battlefield. In such cases the technology can be considered impermissibly intrusive, as it is questionable whether the individuals that will be subjected to human enhancement, and in particular workers and soldiers, can provide their consent freely. Indeed, the EPO rejected the finding that patenting Relaxin would infringe on women's bodily integrity, as the substance was provided after informed consent was obtained, thus leaving open the door to questions about whether the absence of informed consent would qualify the invention as outrageous and thus unpatentable. Human enhancement is unquestionably more intrusive than the use of a naturally occurring substance and therefore it is expected to raise serious ethical concerns that could justifiably lead to an exclusion of patentability. Of course, even if human enhancements used in the workplace or on the battlefield can be patented, human rights violations may restrict the enforceability of patents for human enhancing technologies. Nonetheless, this does not undermine the responsibility of states as granting authorities for the inventions for which they grant protection.

⁶⁴ The precautionary principle is a principle of public decision making that requires decision makers in cases where there are 'threats' of environmental or health harm not to use 'lack of full scientific certainty' as a reason for not taking measures to prevent human harm. See Elizabeth Fisher, Judith Jones and Rene von Schomberg, 'Implementing the Precautionary Principle: Perspectives and Prospects' in Elizabeth Fisher, Judith Jones and Rene von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Edward Elgar, 2006) 2.

The technologies of human enhancement may be patented while some applications of the very same technology are morally objectionable and even forbidden in law. This may call into question regulatory coherence. Regulatory coherence can be understood as the demand that the provisions of a regulatory regime should not be contradictory.⁶⁵

A first defence against such a claim resides in a correct understanding of what a patent is and what it is not. A patent is an exclusive right to forbid, but it does not give a positive right to use or market an invention. This can clearly be seen in the pharmaceutical industry, where patents on effective substances are usually obtained long before market approval for the medicines based on these substances is obtained. So, a pharmaceutical company will own a patent but it is not allowed to market the patented substance; that is, as long as it has not obtained approval to market the substance. Such approval may not be forthcoming at all if clinical trials show that the medicine has very serious and deleterious side effects. Such a negative outcome, however, would not invalidate the pertinent patent. In conclusion, if you purely look at the legal effect of a patent—it gives a right to refuse, not to use—there is no incoherence.

However, apart from a strict legal effect, patent law aims for behavioural effects. In particular, a patent is an encouragement to develop and market a technology. So the claim of regulatory incoherence can better be phrased as: are human enhancements encouraged and forbidden at the same time? The answer lies in the object of the encouragement and prohibition. The encouragement concerns a technology, eg a human enhancement, whereas the prohibition relates to a specific application of the technology, eg using enhanced vision to invade privacy. They relate to different things. In a formal sense, there is no incoherence. However, while from a substantive perspective a technology and its applications are not identical, they are also not unconnected. With knowledge of a technology, some uses—good and bad—may be foreseeable. Encouraging a technology with foreseeable bad and prohibited uses can be viewed as a form of regulatory incoherence. This incoherence stems from the fact that different regulations have different perspectives and different definitions of their objects. The object of a patent (a technology) is hopelessly broad if viewed from another perspective such as that of direct regulation of bad uses of a technology. In this sense, there is regulatory incoherence, and if aligning the objects and perspectives of different regulations is impossible—which may very well be the case—there is also an unavoidable regulatory incoherence. Nevertheless, this form of regulatory incoherence need not be unacceptable if we can find a way of dealing with multiple use technologies, ie technologies that have ‘good’ and ‘bad’ uses. The difficulty is to decide whether the bad applications of a technology are so relevant that they should lead to a prohibition, perhaps a precautionary prohibition of the technology or the denial of patents, or conversely one could ask

⁶⁵ R Brownsword, ‘Human Dignity, Human Rights, and Simply Trying to Do the Right Thing’ in Christopher McCrudden (ed), *Understanding Human Dignity* (Proceedings of the British Academy and Oxford University Press, 2013) 470.

whether the bad uses are so minor that precautionary exclusion of or denial of patents for the entire technology would be disproportionate.⁶⁶ As argued above, patents for human enhancements need not be denied simply because they relate to a human enhancement. However, some patents, especially if they relate to ‘narrower’ and ‘more objectionable’ uses of human enhancements, may very well find themselves in the danger zone.

A follow-up question is this: what happens in cases where a technology is permitted by law, but is not deemed patentable based on morality reasons? For example, a critique against the *Brüstle* judgment is that it lacks regulatory coherence, in the sense that the legal framework permits *Brüstle* to carry out research that uses materials derived from human embryos and yet the Court decided to deny the grant of a patent on the products of that research. Indeed, it has been argued that it is incoherent to decline to encourage a research activity that is permitted.⁶⁷ A counterargument to such claims is that ‘it is coherent to gloss a permission with a lack of encouragement’.⁶⁸ This would be a way of signalling that a transaction is permitted but not encouraged. For example, obligations arising out of certain transactions, such as gambling, are not enforceable, although they are permitted.⁶⁹

IV. THE EXCLUSION FOR THERAPEUTIC TREATMENT

Article 53(c) EPC excludes the following subject matter from patentability:

methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

At first sight, this provision does not pose a barrier to the patenting of methods of enhancing humans. Therapy is not enhancement, as has been confirmed in case law of the Technical Board of Appeal and can be deduced from case law of the Enlarged Board of Appeal.⁷⁰ Nevertheless, as has been mentioned

⁶⁶ Theoretically many circumstances could be relevant when addressing the patentability of multiple use technologies, such as the intended use of the invention as apparent from the patent specification, the expected uses of the technology, the benefits of good uses, the seriousness of the implications of ‘bad’ uses and the adequacy of other regulations targeting ‘bad uses’. See also Roger Brownsword, ‘Regulating Human Enhancement: Things Can Only Get Better?’ (2009) 1 *Law, Innovation and Technology*, 125, 141–3.

⁶⁷ See the range of criticisms of the Wisconsin Alumni Research Foundation case in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents* (Oxford University Press, 2009).

⁶⁸ Brownsword (n 65).

⁶⁹ *Ibid.*

⁷⁰ See eg decision T 774/89: ‘the purpose of therapy was invariably to restore the organism from a pathological to its original condition, or to prevent pathology in the first place whereas a non-therapeutic improvement of performance took as its starting point a normal state (to be defined)’. In G 0001/04 (Diagnostic methods) of

above, the distinction between curing and enhancement is not clear-cut. Is, for example, a prosthesis an enhancement if it is in some respects superior to a natural limb, but in others not? Is a prosthetic hand that is stronger but less precisely controllable than a natural hand restorative or enhancing? When patenting a method for attaching such a prosthetic, a patent attorney may try to present the claim as relating to enhancement, in order to evade the exclusion of Article 53(c) EPC. However, there are limits to how inventions can be presented. It must not become too artificial. Sometimes industry makes life hard for itself, such as where it engages in so-called disease mongering. ‘Inconvenient’ conditions such as male baldness are being presented as pathological. This may be done in order to stimulate ‘patients’ to address the condition or to try to get the condition recognised as a pathology that health insurance will cover. From the perspective of IP protection, this approach may backfire. Where the general view of the condition becomes that of a pathology, patenting of the ‘method’ may get excluded as therapy. From a patent perspective, a pharmaceutical company striving for and succeeding too well in depicting an inconvenient condition as a pathology may shoot itself in the foot. Sometimes things are simpler, for example if a method can be used in a therapeutic and an enhancement context where those contexts are clearly separable. In such cases, the method can be claimed for the enhancement purposes only.

V. CONCLUSIONS

There is a hot debate as to the morality of human enhancement as such, as well as the ethical implications of the utilisation of human enhancement in a number of fields. This article tested whether and how such concerns can be accommodated within the patent system.

Article 5 and 6 of the Biotechnology Directive are unlikely to block the patenting of human enhancement technologies, with the exception of body parts that the body is induced to grow itself, while the answer to the question of whether morality and *ordre public* concerns may raise barriers to the patentability of human enhancing is not particularly clear.

The recent case law of the CJEU and the EPO signals that the patent system in Europe is no longer conceived of as some morally neutral form of state aid. However, what is not clear is how to decide whether a particular idea is inherently too repellent or dangerous to deserve the incentive granted by patent law. Of course, the power to refuse a patent on grounds of morality or *ordre public* should be used cautiously, where the threats of inventions such as human enhancement are present and real and not future or hypothetical. The application of Article 53 EPC is an appropriate step only where all significant uses of the invention are objectionable, and not where there is uncertainty as to the possible

16.12.2005, the Enlarged Board of Appeal of the EPO clarified the meaning of ‘diagnostic methods’ which is mentioned next to therapy in the text of Art 53(c) EPC. It held that the relevant claim should include features relating to, *inter alia*, the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise. If the purpose of diagnosis is to be curative *stricto sensu*, then it is probable that this will also hold for therapy.

uses of an invention. But if real ethical concerns exist, the objection should be applied and should not be interpreted out of existence. For example, the use of human enhancements in the military or the workplace should be heavily scrutinised before a patent is granted. If the current legal framework cannot address such real ethical concerns, it is worth considering whether, *de lege ferenda*, it would be sensible to introduce a specific exception to patentability for human enhancing technologies.