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Morality in Intellectual Property Law: A Concept-Theoretic Framework

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Abstract

This paper presents a 'concept-theoretic' position on the relationship between law and morality in any legal system that includes respect for human rights as a fundamental principle of the legal validity of its rules. With European Union law (EU law) as its central focus, this concept-theoretic position is premised upon the adoption by the EU of fundamental principles, which include human rights. Therefore, given the current status of human rights within the EU, the jurisprudence of the Court of Justice of the European Union (CJEU), and, indeed, any EU law hence any EU Intellectual Property law (IP law)must be consistent with what follows logically and conceptually from the concept of a human right given by the UDHR. The paper will first present the conceptttheoretic framework with reference to EU patent law arguing that some requirements need to be read into EU patent law even when not expressly stated. Furthermore, with reference to Article 6 of Directive 1998/44/EC we argue that this provision must be interpreted broadly to give full effect to human rights and human dignity. The second part of the paper looks at the CJEU ruling in Brüstle v Greenpeace (Case C-34/10 2011) as viewed from the concept-theoretic position. We argue that the CJEU reasoning is substantially sound on the requirements of the Directive and the CJEU had no option but to make the rulings it did. The third part of the paper looks at several objections raised by scientist and lawyers regarding the CJEU decision in Brüstle from the concept-theoretic position. We conclude that the CJEU has not misinterpreted the law. Finally, we conclude that the law governing the grant of patents must be read in line with the concept of human rights and human dignity.

Keywords: Intellectual property law; Concept-theoretic position; Human rights; Patents; Brüstle v Greenpeace

Introduction

This paper presents a 'concept-theoretic' position on the relationship between law and morality in any legal system that includes respect for human rights as a fundamental principle of the legal validity of its rules. With European Union law (EU law) as its central focus, this concept-theoretic position is premised upon the adoption by the EU and its member states of fundamental principles, which include human rights under the concept of a human right contained within the Universal Declaration of Human Rights 1948 (UDHR) and the human rights conventions and other instruments that give effect to the latter, and elicits what follows logically and conceptually from this adoption. The concept-theoretic position is, thus, tied to the positive law of the EU and its member states in so far as it reasons from the status given to human rights by the legislative bodies and courts of and within the EU. However, it is not tied completely to this positive law. It retains an independent critical edge in that it does not take the jurisprudence of the relevant courts to be definitive as to the principles that follow logically from the adoption of human rights principles by the EU. Its guiding assumption is that, given the current status of human rights within the EU, the jurisprudence of the Court of Justice of the European Union (CJEU), and, indeed, any EU law–hence any EU Intellectual Property law (IP law)–must (in order to be valid) be consistent with what follows logically and conceptually from the concept of a human right given by the UDHR.

This Paper has Three Parts

In Part One, we present the concept-theoretic framework, primarily, but not exclusively, with reference to EU Patent law as an exemplar. Operating with the idea that moral requirements are, by definition, requirements on action governed by a categorically binding impartial principle [1], we argue first that human rights, as conceived in international human rights instruments that are intended to implement the UDHR, are moral rights. Such rights have, for some time, been recognized by the CJEU as fundamental principles of EU Law [2], and this status has recently been formalized by the incorporation of the EU's Charter of Fundamental Rights and Freedoms into the Constitution of the EU [3]. Secondly, we argue that this entails that any instrument of EU law that does not protect human rights in relation to its remit, or which is contrary to human dignity (which the preamble to the UDHR proclaims to be the foundation of fundamental rights and freedoms) is void (which is just the position that the CJEU has consistently adopted) [4]. In short, no EU law may validly prescribe or permit activities that it regulates that violate human rights or human dignity. Since human rights are moral rights, it follows that EU law may not grant any IP right if to do so would be contrary to human rights or human dignity. So, for example, under Directive 1998/44/EC on the Legal Protection of Biotechnological Inventions, inventions must be considered patentable on the ground of immorality if to grant a patent would be contrary to human rights or human dignity, even though this is not expressly stated in the Directive [5]. While human rights requirements are clearly moral requirements (as we have defined them), moral requirements are not necessarily human rights requirements–which raises the question, 'What moral requirements other than those connected to human dignity and human rights must patentable inventions meet?' The answer provided by Directive 1998/44/EC is any such requirements listed in Article 6(2) as well as 'ethical or moral principles recognized in a Member State' (recital 39). Putting this together, we argue thirdly

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that (i) there are some requirements that are readable into (indeed, would need to be read into EU patent law, even if Article 6 had never been enacted) [6]; (ii) some moral conditions of patentability are not open to the discretion of member states, whereas other are; (iii) given that Article 6(1) of the Directive specifies that patents may not be granted for inventions the commercial exploitation of which is contrary to ordre public or morality, the conditions under which the commercial exploitation of the invention is contrary to morality cannot be the only immorality conditions under which a patent may not be granted, or else these conditions must, for the purposes of the Directive, be identical to those under which the grant of a patent is contrary to morality; (iv) there is a definite sense in which exclusions under Article 6 must be interpreted broadly, not narrowly–contrary to the manner in which general exclusions under patent law are customarily interpreted. Fourthly, we argue that extra flesh can be put on the content of the morality that must be consistent with human rights and human dignity, on the basis of a principle that any system of rules must recognize on pain of having no coherent application to actions, viz., the Principle of Hypothetical Imperatives (also known as the Principle of Instrumental Reason) (PHI), If doing X or having Y is necessary for an agent (A) to do E, then A must do X or act to secure possession of Y, or give up pursuit of E. When the PHI is coupled with the idea that there are conditions ('generic conditions of agency') (GCAs) that are necessary for all action or successful action, regardless of the purposes involved (i.e., regardless of what E is or might be) [7], it follows that no system of rules can have any coherent application to agents [8] unless it is consistent with the principle A ought to act to defend A's possession of the GCAs unless A is willing to suffer generic damage to A's ability to act. From this, we argue that it follows that any requirements for morality recognized by EU law must be consistent with (though not necessarily exhausted by) the principle, A ought to act to defend any other agent's (B's) possession of the GCAs unless B is willing to suffer generic damage to B's ability to act. Putting these two principles together entails that all EU law must recognize that all agents have rights to the GCAs, which is to say that it must be consistent with Principle of Generic Consistency (PGC) of the American philosopher Alan Gewirth: Act in accord with the generic rights of all agents [9]. In Part Two, we provide a detailed illustration of the application of this framework by commenting on the CJEU's controversial reasoning in the Brüstle Case [10], and provide a qualified defence of the CJEU's position. The main thrust of our argument is that the CJEU's judgment is substantially correct on the basis of Directive 1998/44/EC. While the provisions of the Directive that compel the judgments of the CJEU are not necessitated by the PGC, unless it is clearly the case that they are in violation of the PGC, then the CJEU had no option but to apply these provisions. We contend that the Directive's provisions are sufficiently consistent with the PGC to have left the CJEU no option but to apply them. To conclude Part Two, we consider some miscellaneous general objections to the Directive as well as some specific objections to the CJEU's reasoning in Brüstle.

In Part Three, we argue that the connection that the concept-theoretic position forges between IP law, while making immorality a barrier to the grant of IP rights, also makes morality a reason for granting IP rights.

Part one: Principles for the interpretation of immorality exclusions

Human rights as moral rights: Moral obligations and rights, as traditionally understood in European philosophy are requirements laid down by a categorically binding impartial principle. Being requirements of a categorically binding principle, they override all other kinds of obligations and rights. Since the principle is impartial, and some would argue that this impartiality follows simply from the idea of a categorically binding principle [11], all those who have moral obligations and rights have them equally to the extent that they are capable of discharging or exercising them. Now, as Kant claims, if there is a categorical imperative then it must be connected entirely a priori with the concept of being an agent, a being who does things voluntarily for reasons [12]. From this it follows that moral rights and duties (if they exist) are rights and duties that agents must accept that they have inalienably, simply by virtue of comprehending the idea that they are agents. If there are any moral rights that non-agents can have, then they have these inalienably too, because agents who have correlative obligations to respect these rights cannot alienate themselves from categorically binding duties.Now, according to the Preamble of the UDHR, all 'members of the human family', all 'human beings', and all 'human persons' are equal in inherent dignity and inalienable rights, and Article 1 UDHR proclaims, All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood, and Article 2 UDHR states, Everyone is entitled to all the rights and freedoms … [of the UDHR] … without distinction of any kind.

If all human beings are equal in dignity and rights then whether or not the UDHR intends what the second sentence of Article 1 seems to imply (that all human beings are agents), it certainly entails that all human agents categorically ought to be treated as equal in dignity and rights.

Although the UDHR is not itself a legally binding instrument, legally binding instruments such as the International Covenant on Civil and Political Rights (ICCPR) and the European Convention on Human Rights (ECHR) make it quite clear in their preambles that they exist to give effect (at least in part) to the rights of the UDHR. They can only do so on the understanding that it is the rights proclaimed by the UDHR as conceived by the UDHR that they are giving effect to. It follows that human rights in the current human rights system organised around the UDHR are, in conception, moral rights. The preamble of the International Covenant on Civil and Political Rights (ICCPR) adds to our understanding by declaring that the rights of the UDHR 'derive from the inherent dignity of the human person'. So referred to, human dignity is not itself a human right but the property all human beings inherently have (by their mere nature as human beings) by virtue of which they possess inalienable rights.

The concept of a moral right used here is not unproblematic. Indeed, there are some who not only find the claim that there are moral rights (and obligations), so conceived, to be rationally unjustifiable, but even consider it to be unintelligible [13]. We disagree [14]. But, in any event, exactly the same claims can be and have been made about human rights. Be that as it may, short of such unintelligibility being conclusively demonstrated, it follows that all those legal systems that recognize human rights (and all the rights they recognize and duties they impose) must be consistent with anything that follows logically from their acceptance of the idea that there are human rights under the UDHR conception, on pain of repudiating their acceptance of such human rights. Equally, it follows that all the actions they permit must be consistent with the human rights and duties that are so compliant and with the principle that all human beings possess inherent dignity as the basis of their human rights.

Immorality exclusions as fundamental principles of EU law: The

CJEU has, from very early on in its history, consistently held that the fundamental rights and freedoms enshrined in the ECHR (and other international human rights instruments, like the ICCPR, to which all the EU's member states are party) form part of the legal order of the Community [15]. Indeed, the CJEU has held that at least secondary instruments (directives, regulations, etc.) of the EU must comply with these fundamental principles on pain of being void, and that the CJEU has the power to declare them void on such a basis [16].

Later on, the status of these rights was explicitly acknowledged in the EC Treaty and the Treaty of European Union (TEU). For example, Article 6 TEU declares that

1. The Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law, principles which are common to the Member States.

2. The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law. …

Most recently, the Lisbon Treaty has incorporated the European Charter of Fundamental Rights and Freedoms into the Constitution of the EU, and requires the EU to become a formal member of the ECHR (which requires the CJEU not only to attend to the principles contained in the ECHR, which it has already done, but to view the EU, effectively, as a state party to the ECHR). However, since applicable EU law takes precedence over the domestic law of the EU states, differences between EU law and domestic law cannot stand in exactly the same relation to the ECHR as do differences between the domestic laws of parties).

Our submission is that this position is straightforwardly a logical and conceptual implication of the concept of a human right as a moral right, with the implication that failure to give human rights this status in EU law is to repudiate acceptance of human rights per the UDHR (and consequently per the ECHR).

Implications: This has a number of specific implications for the interpretation of immorality exclusions in EU patent law (and EU IP law generally).

Ineradicable status of immorality exclusions: The first implication is that there are some requirements that are readable into (indeed, would need to be read into) EU patent law, even if Article 6 had never been enacted. These requirements are, at the very least, constituted by the requirement to act in compliance with human rights in relation to the activities that are regulated by Directive 98/44/EC. There is nothing special about patent law in this regard. Given the EU's recognition of human rights, all activities regulated by EU law must, by virtue of the concept of human rights recognized, comply with human rights, and the provisions that regulate them must be equally compliant, which they can only be if they prohibit activities within their scope that are in violation of human rights. Patent law can only be an exception to this if it is not part of the EU legal order [17]. Consequently, only if the EU abrogates the idea that there are human rights under the current conception of them can this position be altered, and it cannot do this while its Member States remain party to the current international human rights instruments. So, we can say, with equal validity that there are immorality exclusions that must be read into any EU IP laws, even though they are not expressly articulated: viz., that these laws must be applied consistent with compliance with human rights.

Necessary vs discretionary immorality exclusions: Exclusions required to act in conformity with the recognition of human rights are necessary exclusions. This fact does not entail that no other exclusions may be enacted on moral grounds (i.e., which are to be treated as having the same status as an appeal to human rights). The only exclusions that may not be so enacted are ones that are incompatible with human rights. While the exclusions of Article 6(2)(a)-(d) of the Directive are arguably necessary exclusions, it is also arguable that they are discretionary. Discretionary exclusions still, however, need a justification with reference to human rights as the duties that they impose on agents can, in principle, conflict with the human rights of agents. Thus, for example, freedom of research may be viewed as falling under the human right to freedom of expression, and (so viewed) recognition of moral rights of animals (implied by Article 6(2)(d)) might impose a restriction on the exercise of the right to freedom of expression (though not a denial of the existence of this right, which must be viewed as inalienable). To justify this, the reason for recognizing a moral right of animals must be to protect human rights of agents. Such justification is not impossible. It is arguable that lack of certainty that animals are not agents requires agents to act in a precautionary manner in relation to animals in order not to violate their possible agency rights (i.e., the rights they must be accorded if they are in fact, though unknowably, agents) (agency being the basis of human agents' human rights) [18]. If so, the exclusion is arguably a necessary one. Alternatively (or additionally) it is arguable, e.g., that the contingent sensitivity of some humans to the suffering of animals, can entail that not to recognize moral rights of animals is to threaten the rights of some human agents [19]. Because the latter argument rests on contingencies, it is not necessary and its justification must lie in the human rights considerations that must be held to justify democratic decision making in a society that recognizes human rights [20].

The proper focus for immorality exclusions: patent grant or commercial exploitation of the invention?: A patent confers a right on the patent-holder to prevent others from using the invention without the consent of the patent-holder. The patent does not confer a right on the patent-holder to exploit the invention. Furthermore, Directive 98/44/EC regulates the grant of patents for biotechnological inventions. It does not regulate research that leads to an invention [21] or the exploitation of the invention by the patent-holder, which is to say that it neither determines the lawfulness of the activities that lead to an invention nor the lawfulness of exploitation of the invention by the patent-holder. It does, however, affect the lawfulness of exploitation by a third party of the invention, insofar as it provides the patent-holder with a cause of action for unconsented exploitation of the patented invention. It follows from this that the proper focus for immorality exclusions is the morality of granting the monopoly that the patent confers. That the Directive does not say so explicitly is beside the point. The Directive is to be declared void if it does not prohibit conferring this monopoly when to do so would be contrary to human rights, for it is this activity that alone falls directly within its scope. But there is no serious problem here. True, the explicit focus of the Directive makes the morality of commercial exploitation a necessary condition for patentability. But what are the conditions under which commercial exploitation would be contrary to morality (or ordre public)? For the purposes of the Directive, the conceptually compelled answer is any circumstances in which the grant of the monopoly right would be contrary to morality (or ordre public), including those when commercial exploitation of the invention would independently of considerations of patenting be contrary to morality (or ordre public). This, however, only applies for the purposes of the Directive. It does not imply, e.g., that the conditions of morality of commercial exploitation

for the purpose of regulating research that might lead to an invention or for the purpose of regulating commercial exploitation of the invention per se must be regarded as identical to those under which it is moral to grant the patent monopoly [22].

Again, should the point really need restating, the proper focus for immorality exclusions in any EU IP law is on the morality of granting the IP right, rather than anything else.

Broad not narrow immorality exclusions: Because morality refers to values thought of as categorical (i.e., part of a categorically binding system) [23], there is a sense in which exclusions on the ground of immorality are necessarily to be operated broadly. If A categorically ought to do X, then A categorically cannot risk not doing X or doing not X if it is possible for A to avoid this risk. In a nutshell, this means that if there is doubt about the application of, e.g., a human right, then subject to it being possible to act in conformity with what protection of the right requires, the onus is on those who wish to dispute the application of the right to make their case rather than the other way around. Put another way, if a case can plausibly be made for considering that an immorality exclusion applies, then the exclusion is to apply unless it can be shown that the case has, in fact, no plausibility. Now, the general practice and policy of patent offices and courts is to apply exclusions to patentability narrowly, in the sense of applying the least restrictive interpretation when different interpretations present themselves. This might be fine when fundamental rights and values are not at stake, but it certainly isn't when they are [24].

Putting extra flesh on the necessary immorality exclusions: As linked to human rights provisions, immorality exclusions are rich in content. However, there are a number of interpretive lacunae that need to be filled for these provisions to be capable of uniform interpretation and application to a significant degree. For example, the relevant human rights instruments provide no comprehensive principle for prioritizing one right over another when the right of one person conflicts with the right of another [25]; it is unclear to what extent having a human right includes the right-holder having a right to release others from the duties they have correlative to the right; it is unclear to what extent human rights are positive (rights to assistance to secure the object of the right) as well as merely negative (merely rights to non-interference with possession of the object of the right); and it is also unclear to what extent, if any, duties not to harm animals and unborn humans are to be viewed as functions of human rights or as independent of them. In this sub-part, we suggest that there is a principle implicit in the recognition of human rights that provides at least the outline of an answer to all of these questions.

Human rights are correlative to obligations of others in relation to the object of the right. If person B has a right to privacy then at least some other person A has a duty to protect, or at least not to interfere with, B's privacy. But to say that A has a duty to do something E, is to say that there is a reason (indeed, a sufficient reason) why A ought to do E. Further, to say that A ought to do E is to imply that A has the capacity to choose whether or not to do E. In other words, rules prescribing duties can apply only to agents, those who are capable of doing something (X) voluntarily in order to achieve purposes or ends (E) they have chosen.

Now, if doing X is necessary for A to do E, then A has as much reason to do X as to do E. So, if A is unwilling to do X then A ought to be unwilling to do E. In other words, A ought to do X or give up trying to achieve E. This means that A must, on pain of failing to understand what it is to be an agent, accept the Principle of Hypothetical Imperatives (PHI); viz:- If doing X (or having Y) is necessary for A to do E, then A must do X (or act to secure possession of Y) or give up pursuit of E.

The implication of this is that any system prescribing duties may only make rules that are consistent with the PHI. Any rules that are inconsistent with the PHI cannot coherently be accepted by any agent (hence cannot be coherently prescribed to an agent).

The PHI, however, is empty of content. But, suppose that there are generic conditions of agency (GCAs), conditions the possession of which are necessary for A to pursue or achieve E, whatever E is or might be (which might also be called categorically instrumental conditions of agency). If A is unwilling to defend his possession of the GCAs, then A must accept that A cannot pursue or achieve E, regardless of what E is or might be. It follows that A must, on pain of failing to understand what it is to be an agent, accept, A ought to defend his possession of the GCAs, unless he is willing to accept generic damage to his ability to act. So, any human agent must on pain of failure to understand what it is to be a human agent also accept this principle, which is to say that any other agent B must, on pain of failing to understand what it is to be an agent, accept B ought to defend her possession of the GCAs, unless she is willing to accept generic damage to her ability to act.

While we consider that it follows logically from this that A must, similarly accept that A ought to defend B's possession of the GCAs, unless B is willing to accept generic damage to her ability to act, which requires A to accept that B has a right to the GCAs, and by implication that he has the same right, so that A (and logically also B) must accept the PGC, Act in accord with the generic rights of all agents, this is highly contentious [26].

In the present context, however, it is not necessary to engage in a debate about this. According to Article 1 UDHR, all human beings are equal in dignity and rights. It follows that all human agents are equal in dignity and rights. But because the GCAs are generic conditions of agency they are also generic conditions of the ability to do anything required to exercise a right or defend a right, and no grant of an inalienable right can be sincere if it precludes the right to defend the right. It follows that any grant of human rights to human agents must include the grant of human rights to the GCAs. Furthermore, since this grant must be consistent with the PHI, it follows that all human rights must be interpreted so as to be consistent with the PGC [27].

Now, since the PGC is the universal form of the PHI provided with content by the GCAs, it permits agents to release other agents from their duties in relation to the generic rights on condition that the rights-holder is willing to suffer generic damage to the rights-holder's ability to act. This entitlement is subject only to such release not disproportionately damaging possession of the GCAs of other agents against their will. This has obvious consequences for cases like that of Pretty v the UK [28]. Furthermore, since some GCAs cannot be removed without necessarily removing others, but not vice versa (e.g., to remove one's life is to remove all other GCAs, whereas to be provided with false information is not to necessarily remove one's life), the PHI implies that the GCAs and, hence the generic rights, are ranked hierarchically according to the degree to which their absence has a generic impact on the ability to act. In cases of conflict between the right of one agent to a GCA with the right of another agent to another GCA, the 'more needful' GCA takes precedence. In principle, all human rights granted to agents must be viewed as rights to agents' possession of the GCAs in line with the PGC, and so no exceptions to these rights can be granted except to defend the generic rights of other agents. Since agents need assistance to secure their possession of the GCAs when they cannot

do so by their own unaided efforts, all generic rights are positive as well as negative. However, because agents cannot, in many cases, act positively to secure the GCAs of others without disproportionate risk to their own possession of the GCAs, protection of positive generic is, in practice, the responsibility of collectivities rather than individuals, beyond the responsibilities individuals can be assigned to set up the necessary collectivities [29].

What then of human non-agents? Well, on the basis of the reasoning presented here, human non-agents and other non-agents cannot be granted the generic rights, because the generic rights are by their nature rights to assistance/non-interference in accordance with the right holder's will, and only agents have a will. But this does not mean that agents do not have or may not be charged with duties to protect interests of humans and non-humans who do not display the capacities of agency. Such duties may be imposed on at least two different grounds. The first ground is that a democratic legislative decision has imposed such duties, which at least in the case of human beings can be made correlative to a human right, provided only that this grant does not interfere disproportionately with the generic rights of agents. The second ground rests on arguing that because we do not know that various living creatures lack the capacities of agency just because they are unable to display the capacities of agency, there is always a risk that, in acting against interests that living creatures have that they would have rights to if they are agents, we violate their rights. In order to guard against this, one of us has argued elsewhere that we have duties to unborn humans and non-human animals in proportion to the degree to which they approach apparent agency [30]. Strictly speaking, in this way of thinking, even adult human beings are not to be thought of as agents but as apparent agents. However, the precautionary reasoning involved categorically requires agents to treat apparent agents as agents [31].

Part two: Brüstle

Brüstle as viewed from the concept-theoretic position: In Brüstle, the Grand Chamber of the CJEU gave a preliminary ruling under Article 267 TFEU on a reference from the Bundesgerichtshof (Germany) that, with reference to Article 6(2)(c) of Directive 1998/44/EC, a 'human embryo' refers to any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis … [but that] it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a human embryo [para 38] [32] . The CJEU essentially provides two arguments. The first runs as follows.

1. Any provision of EU law that 'makes no express reference to the law of the Member States for the purpose of determining its meaning and scope [which is the case with the term 'human embryo' in Directive 1998/44/EC (see para 26)] must normally be given an independent and uniform interpretation throughout the European Union' [para 25], which is certainly the case where the express object of the Directive is to harmonise rules for the legal protection of biotechnological inventions (see recitals, 3, and 5 to 7) [see para 27].

2. Without a uniform definition, inventors would be tempted to apply for patents in countries with the least restrictive definition ('narrowest' in the CJEU's terminology), and this would 'adversely affect the smooth functioning of the internal market which is the aim of the Directive' [para 28] [33].

3. Therefore, 'human embryo' must mean any structure totipotent to develop into a born human being [34].

This argument cannot stand by itself. Suppose an embryo were defined as only coming into existence at the blastocyst stage. With nothing more to add, a just fertilized egg would not be an embryo. Consequently, to use it commercially would not be excluded by Article 6(2)(c). Authors could, therefore, obtain patents on cell stems produced by destroying pre-blastocyt humans in countries that define an embryo as a blastocyst or post-blastocyst human. Certainly, this would mean that patent practice would not be uniform, but it would not mean that patent law was not harmonized with respect to the protection required by the law. To think otherwise is to presuppose that the aim of the law is to render commercial uses of pre-blastocyst embryos unpatentable, when this is just what the argument is supposed to show.

However, the CJEU presents a second argument that runs, in essence, as follows.

a. The preamble to the Directive provides that 'use of biotechnological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person. Recital 16, in particular, emphasizes that "patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person"' [para 32].

b. According to Article 5(1) of the Directive, the human body at the various stages of its formation and development cannot constitute a patentable invention.

c. Recital 38 of the Directive makes it clear that the list of exclusions of Article 6(2) is not exhaustive 'and that all processes the use of which offends against human dignity are also excluded from patentability' (referring to Netherlands v Parliament and Council para 71 and 76) [35].

d Hence, the concept of human embryo must be understood in a wide sense, so as to exclude 'any possibility of patentability where respect for human dignity could thereby be effected' (para 34). Hence, 'human embryo ' must cover any process that begins the process of development of a human being' (para 35) (see paras 35-37), in relation to which it is for Member States to decide whether a cell taken from a human embryo at the blastocyst stage is, in the light of scientific developments, a human embryo (i.e., totipotent) [36].

We submit that this second argument is sound, provided that one supposes that a totipotent cell is a stage in the development of the human body and not merely a stage towards the development of the human body. Although the CJEU does not say so, this supposition is justified because recital 16 further specifies that 'the human body, at any stage in its formation or development, including germ cells [our emphasis]' is unpatentable. If even germ cells are to be regarded as a stage in the human body's development then so too must totipotent cells. We submit, therefore, that with this being understood, as it must, this argument is a correct reading of the Directive, with one proviso. That proviso is that an embryo should be defined as a fertilized egg or an egg in the process of fertilization as the UK law does [37].In other words, the Directive actually requires an even narrower definition of a human embryo than the CJEU contends [38].

This position is further supported in International Stem Cell Corporation (ISCC) [39]. In the appeal by ISCC over the rejection by the UKIPO of a patent application concerning methods of producing pluripotent human stem cell lines from parthenogenetically-activate oocytes [40], the UK court sought clarification as to the meaning of human embryo by referring the case to the CJEU. The CJEU was asked

to consider the question: 'Are unfertilized human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilized ova, contain only pluripotent cells and are incapable of developing into human beings included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions?' [41]. The CJEU ruled [42] that Article 6(2)(c) Biotech Directive must be interpreted in the sense that "an unfertilized human ovum whose division and further development have been stimulated by parthenogenesis does not constitutes a 'human embryo'" under the condition that "it does not, in itself, have the inherent capacity of developing into a human being" (Paragraph 28). The CJEU further clarifies Brüstle, by stating that the "the mere fact that an organism commences the process of development is not sufficient for it to be regarded as a 'human embryo'" (Paragraph 23-29). Therefore, parthenotes should not fall under the exclusion as they are considered not capable of developing into a 'human being'. In order to be classified as a human embryo, a non-fertilized human ovum must have the inherent capacity of developing into a human being.

The decision is clearly in line with the second CJEU argument in Brustle which should be read as the exclusion covering the development of the human body and not applying merely a stage towards the development of the human body, or, as asked by the High Court, the commencement of a process of development, even though the process cannot be completed, so that it is incapable of leading to a human being [body].

Does the use by the CJEU in ISCC of the term 'inherent capacity' actually distinguish ISCC from the decision in Brustle? [43] No, all that the CJEU is doing is recognizing that it had relied on incorrect scientific data concerning parthenotes. We further submit that, with the proviso just made, with the second argument supposed, the CJEU's first argument serves to emphasize the importance of the narrowest definition of 'human embryo' for the purposes of the Directive. The CJEU also ruled that uses of human embryos for scientific research are additionally excluded from patentability as falling under the industrial and commercial uses of embryos. This is because, while 'the aim of scientific research must be distinguished from industrial or commercial purposes', when the use of human embryos for research is the subject matter of a patent application, that use is ipso facto for a commercial purpose (patenting), and recital 42 of the Directive makes it clear that only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it is patentable [see paras 43,44]. In this the CJEU claimed [see para 45] to be providing an identical interpretation to the Enlarged Board of Appeal of the EPO regarding its decision of 25 November 2008, G/206, Official Journal EPO, May 2009, p.306, paras 25-27 Decision [44]. This reasoning is logically sound.

Finally, the CJEU ruled that an invention is excluded from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

The key issue here is whether if a human embryo is used to produce something else, and this something else is then used as base material for an invention, then use of this base material for a commercial purpose (which it is) constitutes use of a human embryo for a commercial purpose. The CJEU answers in the affirmative. The reason it gives is that if this answer is not given then the intention of the legislator would be evaded by skilful drafting of the claim (which was also the reasoning of the Enlarged Board in WARF, point 22). Intuitively, this must be so, and would be accepted without question in in any area other than patent law. If James steals Martha's car and uses its material to make a metal sculpture, which he then sells for profit, can he claim that he has not used Martha's car to make this profit? Why is it different here? Surely, it is different only if we suppose that we must interpret exclusions narrowly, not even neutrally, let alone broadly. Under a broad interpretation, which the concept theoretic position requires when conformity with fundamental principles of EU law is stake, the matter is clear.

We submit, therefore, that with the provisos made, the CJEU's judgment is substantially sound on the requirements of the Directive. This, however, cannot be the end of the story from within the concept-theoretic position. This is because this position (as does the CJEU's own jurisprudence) requires the Directive itself to be in conformity with human rights. Now, the position on the moral status of the human embryo that the concept- theoretic position requires is that the human embryo is to be accorded only some intrinsic moral status, which increases as it develops, and that it is not to be accorded full intrinsic moral status until the development of the capacities of agency (beyond birth in fact). This does not mean that the human embryo may not be assigned a full moral status by democratic legislative decision at an earlier stage in its development. But if it is to be assigned such a status then the reasons for doing so must be compatible with the full intrinsic moral status that human agents must be assigned. In other words, it needs to be argued that taking all human rights considerations into account, as required by the concept-theoretic position; the Directive is not clearly in contravention of human rights. Now, claims are regularly made that, e.g., rendering stem cells that are derived by destroying totipotent human cells unpatentable are violations of academic freedom (the right to freedom of expression of agents), and, indeed, violations of the right to life and dignity of agents because this will prevent the development of treatments for fatal or debilitating diseases and conditions that have at least a strong likelihood of development if these stem cells are patentable.

If this is, indeed, clearly the case, and there are no further human rights considerations to take into account, then our concept-theoretic position requires the CJEU, to have declared the Directive (or at least the offending provisions of it) to be void because they are in contravention of fundamental principles of EU law. However, as will shortly be seen, it is not clearly the case. With this in mind, we submit that the matter is, at the very least, not sufficiently clear for the EU to have annulled the Directive, and failing being in a position to do so the CJEU had no option but to make the rulings it did (subject to the relatively minor proviso that we have mentioned).

Objections to Brüstle: The CJEU's decision was met with outrage by many stem cell scientists seeking patents and by many lawyers as well. Criticism may be grouped into a number of different categories, some of which were raised during the course of the Brüstle and WARF cases. For example,

A Claims that the CJEU has acted ultra vires in some way.

B Claims that the CJEU has not acted ultra vires, but has misinterpreted the law or interpreted it inconsistently with previous decisions.

C Claims that while the CJEU might have interpreted the law correctly, the law is at fault and ought to be changed. There are two subcategories here

(i) Claims that, while it is fine to have immorality exclusions in

patent law, the law enshrines the wrong way of operating them.

(i) Claims that immorality exclusion have, in principle, no place in patent law

We will not consider every objection that has been raised, but we will comment on these categories as such and what strike us as some of the most important examples of them. Throughout, our intention is to apply the concept-theoretic position we have outlined to the issues, and not to consider objections on their own terms.

A The CJEU acted ultra vires

Objection: It is not the role of the courts to make their own moral judgments. That is the role of legislation. But the narrow interpretation of 'human embryo' involves the court making a moral value judgment, which a broad interpretation would not do [45].

Reply: If adopting a narrow interpretation (a definition that implies a broad exclusion) involves a court in making a moral value judgment then so does adopting a broad interpretation. Adopting a broad interpretation would not exclude inventions involving the destruction of fertilized eggs, whereas adopting the narrow interpretation does. But to permit patenting of the morally controversial use of fertilized eggs is just as much to make a moral judgment as to exclude the patenting of such use. However, it is, in any event, not true that when the CJEU (or other court) interprets legislation it is necessarily making a de novo moral value judgment as against judging what moral judgment is implicit in the legislation (which is there, implicitly, and unavoidably once the issue is morally controversial).

Objection: The specific exclusions of Article 6(2) are with reference to Article 6(1), so must be interpreted in line with Article 6(1), which, by the jurisprudence of the, requires subsidiarity. So, unless Member States share their moral beliefs, definitions of 'a human embryo', etc., the CJEU may not interpret Article 6(2) so as to impose a uniform moral exclusion, definition, etc. [46].

Reply: It simply does not follow from the fact that Article 6(2) is an interpretation of Article 6(1) that it cannot impose a uniform definition, etc., just because, standing alone, Article 6(1) allows a margin of discretion to Member States. An interpreting sub-article can impose a uniform definition if it imposes it explicitly (not the case here) or if a uniform definition is implicit in what has been legislated elsewhere in provisions applicable to the interpretation of the sub-article. The CJEU has argued cogently that such a uniform definition is implicit in the provisions of the Directive.

Objection: Given accession of the EU to the ECHR, the CJEU will be bound by the ECtHR's jurisprudence, which grants a margin of appreciation to Member States on contested issues re application of the ECHR (e.g., whether or not the pre-born is a human for the purposes of the ECHR). To take this away from the Member States is to act unconstitutionally in the new arrangement [47].

Reply: Even supposing that the terms of the EU's accession to the ECHR involve it being bound by the ECtHr's jurisprudence on human rights, this does not follow. The ECtHR does indeed operate a doctrine that accords Member States a degree of discretion in the interpretation of unclear and hotly contested moral matters between States. But this is not a doctrine that States are required to mirror. For them to do so would mean that they could not adopt any views on moral matters at all in their legislation (which is impossible when the activities raise moral issues), for the ECtHR's doctrine presupposes that States do and may adopt different specific moral positions in their law. In short, the question of a margin or appreciation can only arise if the member States have different positions. And, surely, if the EU as such accedes to the ECHR then it must be regarded by the ECtHR as a Member State of the Council of Europe. But in being a Member State of the Council of Europe it will not be like the Member States of the EU in that it operates with, and the EU States have acceded to, the doctrine of the supremacy of EU law. Ergo, if it is possible for the EU to accede to the ECHR then it follows that the ECtHR cannot treat views that Member States have that are in contravention of EU law as laws to which it needs to grant a margin of appreciation [48].

B The CJEU has misinterpreted the law

Objection: Patent law requires morality exclusions to be interpreted narrowly not broadly [49].

Reply: In response to this objection, the EPO's Board of Appeal in WARF (point 33, T 1374/04) stated that in decision G 1/04 (point 6 of the reasons) the Enlarged Board of Appeal held that the frequently cited principle according to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, did not apply without exception (point 33, T 1374/04). Provisions must be considered in the light of their wording, the object and purpose of the provision, the interests involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty. This is required by our concept-theoretic position, in relation to which there is a presumption that moral exclusions are to be interpreted broadly because of the categorical importance of complying with morality.

Objection: Patent law requires terms to be given their ordinary scientific meanings [50], which (by medical practice) means that an embryo does not exist until 14 days after fertilization [51].

Reply: As we have argued elsewhere [52], the meanings to be given to terms in a legal statute depend on the purposes of the statute. Thus, for example, the UK Human Embryo and Fertilization Act 1990 was clearly designed to provide a proportional degree of protection to 'embryos' [53]. While it defined an 'embryo' as 'a fertilized egg or an egg in the process of fertilization', it was also clear that its concern was with structures that could develop into born human beings. The Pro-life Alliance, which brought the case, claimed that the Act did not cover the latter structures if these were produced by inserting an adult somatic cell into a enucleated ovum because this was not a process of fertilization (and so the structures were not embryos). However, the UK House of Lords ruled that the purpose of the Act was primary and on this basis the latter structures were embryos, and that the 'definition' was not a definition, but merely an indication of the stage of development at which protection began. We argued that the House of Lords would have done better to claim that, for the purposes of the Act, the provisions constituted a definition but that the process was, in legal fact, a process of fertilization, and that the enucleated ovum and somatic nucleus were, in the context of being used to produce an organism capable of development into a born human being, gametes. The ruling of the CJEU, in effect, follows just such a path.

There is nothing in the least odd about this. The now replaced UK Act did not, and the Directive does not, exist to regulate the use of terms for scientific or medical purposes, and their definitions have no bearing on or implications for the latter. Their definitions must serve the normative purposes of their legislation and nothing else.

Objection: The CJEU in Brüstle falsely claims the authority of Italy and The Netherlands [54].According to Italy and The Netherlands, under Article 6(1) Member States have discretion, while under Article

6(2) they do not. So, since embryonic stem cells are not embryos, they do not fall under Article 6(2), merely under Article 6(1), and so Member States must have discretion to decide what counts as a human embryo [55].

Reply: Article 6(1) and Article 6(2) cannot be separated in this way. Article 6(2) is a list of what under Article 6(1) is excluded, and it is clearly stated that what is excluded under Article 6(2) (i.e., without a margin of appreciation for Member States) is not exhaustive. So, it must be possible for some exclusions to exist under Article 6(1) (i.e., ones not specifically listed under Article 6(2)) over which there is no margin of appreciation. These are those that are excluded because of violation of fundamental principles of EU law or by explicit EU legislation elsewhere, with those over which there is a margin of appreciation being those that are excluded for reasons of domestically restricted moral objection. When Italy and The Netherlands states that there is discretion under Article 6(1) this cannot be taken to mean that there is a universal margin of appreciation under Article 6(1). It must be taken to mean that, absent exclusion under Article 6(2), Member States are presented with having to make the decision (it not having been made for them already) about its status vis a vis Article 6(1). In doing so, they must reason according to the criteria laid down by the Directive, which are, broadly, fundamental principles and/or existing co-ordinate EU legislation vs domestic principles. If the exclusion falls under fundamental principles or co-ordinate EU legislation, there is no margin of appreciation (i.e., the discretion that Member States have cannot be exercised to defend a margin of appreciation). If it falls under the latter then there is. What the CJEU argues in Brüstle, is consistent with this: its claim is that the exclusion of embryonic stem cells is due to what is legislated, inter alia, in Article 5 of the Directive.

C The law ought to be changed

(i) The wrong morality test is enshrined [56].

Reply: We will not go into what the test is that objectors think should be employed. Rather we will concentrate on the test that the concept-theoretic position requires.

First of all, it holds that it is not rationally required to grant the human embryo full moral status. Under precaution, the human embryo is to be granted some status, which is to increase as the embryo develops. Precisely how much status, however, is not something that it holds can be determined directly. Consequently, only in limited circumstances does it dictate directly and unequivocally how conflicts between the interests of the embryo and (apparent) [57] agents are to be dealt with. These are circumstances in which there is a clear one variable conflict between identifiable interests of the embryo (e.g., its life) and the corresponding right of an agent. In this example, the right of a mother to life will override the interest in life of her unborn embryo in utero when the continued existence of the embryo threatens the life of the mother simply because the mother is more probably an agent than the embryo. But things are different if we must weigh the life of the embryo against a lesser right of the mother. When these complexities are introduced, the concept-theoretic position requires decisions to be made by delegating decisions to the democratic legislature (which might delegate them to courts or other bodies). Such delegation is not unlimited, however. It is subject to constraints that derive directly from the PGC.

The issue with regard to patenting is essentially this. If granting patents for stem cell research on embryos (even where the destruction of embryos is involved) is necessary for lifesaving treatment to be developed then the concept-theoretic position will, with nothing more to be said, allow such patenting. The problem is that it is far from clear that granting patents on products and procedure that involve the destruction of embryos is necessary for lifesaving treatments to be developed. This is not only because of the possible use of stem cells derived from adult cells, but because of the use of pluripotent cells taken from blastocysts that do not involve the destruction of embryos. To this must be added the fact that there are other means by which researchers can protect their investments in stem cell research [58], and, indeed, that prohibiting patents on products and processes involving the destruction of embryos might even be an incentive to research [59].

According to the concept-theoretic position, it is necessary, in principle, to allow for the weighing of the rights-corresponding interests of the embryo against the rights of agents on the premise that the embryo has only a minimal moral status to begin with that develops as it develops to agency, and if the Directive were to disproportionately to endanger the rights of agents then the offending provisions should be declared void. It is, however, wholly unclear that this is the case and we do not see how the CJEU could have declared this to be the case.

But might it not be said that the problem is that the Directive does not recognize that the human embryo is only to be granted a proportionate status, and so does not allow for any circumstance in which a patent could be allowed on processes or products developed by destroying an embryo?

Now, if it were clear that the Directive was legislated on the presumption that the embryo has full moral status, this would create a problem. But this is not clear. So, provided that the fact that the legislation does not permit circumstances in which commercial uses of embryos may be patented is compatible with the embryo having only a proportionate status, then the problem evaporates. However, for attribution of a proportionate moral status of the human embryo to conflict with the provisions of the Directive it is necessary that the satisfaction of human rights of born humans requires research to be done that involves the destruction of totipotent cells and that such research will not be done unless patents are granted for the products and processes of such research. But the first condition is not satisfied because stem cells developed from single merely pluripotent human blastocyst cells (which do not require the destruction of human embryos) are as efficacious as those produced from totipotent cells. And, even if the first condition were satisfied, the second condition is not satisfied because there are ways in which investment can be protected other than by the grant of patents [60], and (as we have already said) it is even arguable that not granting patents is likely to stimulate rather than inhibit research [61]. Consequently there is no basis for holding that the Directive relies on a position incompatible with our concept-theoretic position.

(ii) Immorality exclusions have no place in patent law

Objection: Law and morality are conceptually distinct [62].

Reply: That law and morality are conceptually distinct is a contested thesis about the sources of obligation in law. But even if it is true (which one of us, at least, does not accept) [63], this thesis does not entail that law may not or cannot incorporate morality clauses. The thrust of the legal positivism that the objection appeals to is that the validity of a law depends on nothing other than its source in positive enactment. But that positive enactment, as the source of legal authority, can and may lay down moral rules for the validity of laws and actions, because the authority of morality so laid down is a function of the fact of the enactment. In this perspective, positive EU law can make conformity with human rights (as we have argued it does) a condition of legality.

Legal Positivism differs from the opposed legal idealist (or natural law) perspective in that the latter requires positive law to lay down such requirements in order to be valid. If human rights can be justified as categorically binding requirements on action, then it follows that no rules can be binding that are not in conformity with human rights. But we have not assumed or argued that this is the case here. All we have assumed is that when the law enshrines human rights then it is bound to give these a fundamental status on pain of abrogating its acceptance of human rights. That is both possible and coherent.

Objection: Moral considerations render the law uncertain [64].

Reply: Moral considerations are often complex and moral criteria are disputed. This is not something that is unique to morality, however. Many legal cases are deeply contested and disputed without involving moral clauses, and not merely because of their factual complexity. A key to legal certainty is clear definitions and rules of interpretation. These can be absent when moral clauses are not involved. But clear rules and definitions are no more (or less) problematic when immorality exclusion clauses are not involved than when they are.

Objection: Patent examiners/judges/lawyers have no competence to deal with moral questions.

Reply: The reply to this can be very short. Any examiner/judge/lawyer operating within the patent system who claims this should be dismissed (or should be regarded as having resigned). If the law requires moral questions to be assessed then those required by law to assess them must obtain and gain the necessary expertise. But, as we have indicated, previously, judges and others considering morality provisions in the law are interpreting it not making de novo judgments.

Objection: Moral concerns about research activities and their consequences are not the concern of patent law and should be dealt with entirely by the law outside of patent law.

Reply: It is not the concern of patent law to regulate anything other than the grant of a patent. The fact that the law requires it to consider the morality of commercial exploitation of an invention in doing so, alters this not one jot. Requiring commercial exploitation not to be contrary to morality does not render commercial exploitation unlawful. Of course, denying patents on particular grounds might make it unprofitable for would be inventors to engage in those activities. So, such a prohibition might assist with the aim of regulation of these activities. If so, those wishing to prohibit certain activities would be wise to render the products of these activities or the activities themselves unpatentable. But in no way does this imply that patent law is to replace direct regulation of these activities.

Part three: Morality as a basis for IP rights: The prevailing attitude of those seeking IP rights (particularly patents) is to view attention to moral considerations in the law as an obstacle to the grant of these rights. This is despite the fact that IP rights are traditionally referred to as moral rights. To be sure, this reference does not carry the same meaning (categorically binding impartial requirements) that out use of the term primarily carries in this paper. Rather it refers to the idea that IP rights are to be granted as owed to the inventiveness of the author. However, the two ideas are not wholly disconnected.

It is not our intention, in this concluding Part, to provide and justify a full-scale view on how our concept-theoretic position justifies IP rights in terms of human rights. We will, however, sketch such an account, in full appreciation that what we will say is highly contentious and requires a great deal of elaboration and fuller justification.

So how might our concept-theoretic position justify IP rights in terms of human rights? One of us has argued elsewhere [65] that a property right is best understood as a 'rule-preclusionary right', which is to say that what characterizes a claim to a right as a property right is not centrally the claim to have some specific bundle of powers to control an object, though the power to use and to prevent others' use of the object of the right is essentially involved. Rather, it is the claim that if X is A's property then A does not, as a presumptive rule, need to justify A's power to use and to prevent others from using the object of the right even when A does not need to use it and others do. Premised on this, it was argued that there is only one object that A clearly has a right to in these terms. This is A's body as an instantiation or vehicle of A's person. The reason for this is that A's body is so related to A's existence as a person that for A to have to justify A's control over A's body on a case by case basis before the power's A claims over it can be exercised would disproportionately threaten A's very existence. This does not mean that A's claim can never be overridden. The central point is that the default position must always be that, failing the case being made by others for the moral rights of others conflicting with and overriding (in PGC terms) A's right to control A's body, A must be granted, without having to justify this, the essential powers of control over A's body. So (and contrary to much received bioethical wisdom) unless one can own one's body, one cannot own anything. In these terms, a claim to have some object as one's property that is not physically part of one's body, is the claim that it is normatively to be regarded as part of one's body (i.e., as having the same normative significance it would have if it were physically part of one's body).

Now, things that A has created, whether they be works of art, or inventions, are naturally viewed as expressions, indeed, as instantiations of A's person; the further thought being that, as such, to use such instantiations, especially for another's personal profit, without A's consent is to use A's person to A's (at least putative) detriment. As such, rights to control such works have the hallmarks that would enable them to be assimilated under what in German jurisprudence are thought of as personality rights (to be distinguished from, though related to, such rights in IP law) [66]. Here it is to be observed that the jurisprudence of the ECtHR has been in the direction of construing the right to private life under Article 8 ECHR as just such a right [67]. Hence, our suggestion is that IP rights be viewed as falling under the Article 8 right to private life, which in turn is to be analyzed as a property right in rule preclusionary terms. The significance of such an account is that if IP rights are grounded in human rights (moral rights in our primary sense) (specifically the right to private life) then there is a ++ balance to be drawn between the PGC's protection of an IP right and PGC driven exclusions to the grant of the right in particular circumstances. If the reason for granting the right is exclusively to protect investment of the would-be IP right holder, without this being justified by human rights considerations, then any conflict with PGC driven reasons not to grant the right must automatically preclude the right. In these terms, moral considerations in IP law are as much friend as foe to authors' IP rights.

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29. Gewirth A (1996) The Community of Rights (1st Edn) Chicago: University Of Chicago Press, USA 59.
30. Pattinson, Shaun D, Beyleveld D (2000) 'Precautionary reason as a link to moral action', in Medical ethics. Upp er Saddle River, New Jersey: Pearson, 39-53.
31. Beyleveld D (2011) 'The Principle of Generic Consistency as the Supreme Principle of Human Rights' Human Rights Review 13: 1-18.
32. In deciding that Rule 28d(c) applies, the Enlarged Board of the EPO had decided that 'human embryo' is not to be given a restrictive interpretation (as referring only to 'embryos of 14 days or older, in accordance with usage in the medical field') [para 19 of the Reasons for the Decision]. The CJEU ruling goes further than the EPO that the fertilized human ovum counts and, although it mentions only two other cases, by implication, any human ovum treated so as to be able to start the path to potential development into a born human being, from the moment of that treatment producing a diploid 'zygote' or its functional equivalent.
33. At paragraph 29, the CJEU claims that (by its case law, specifically Commission v Italy paras 78 and 79) Article 6(1) gives a wide degree of discretion to member States to determine what it excludes, but that Article 6(2), by specifying examples of what is in particular excluded by Article 6(1), gives Member States no discretion, and that this supports this premise.
34. This is not stated explicitly, but it is implied.
35. The CJEU does not say this explicitly, but the clear implication is that those exclusions of Article 6(2) that refer to uses of human material are excluded because the legislature judged these uses to offend human dignity.
36. Oliver B , Greenpeace V (2011) Opinion of Advocate General Bot delivered on 10 March (1) Case C 34/10: 138.
37. Human Fertilisation and Embryology Act (1990) S1(2)(b). As amended 2008
38. Beyleveld D, Pattinson S (2001) 'Possibilities for European Regulation of Research on Human Embryos'. In M. Friele and B. Bad-Neuenahr-Ahrweiler.: Embryo Experimentation in Europe: Biomedical, Legal, and Philosophical Aspects. European Academy of Science 58-72.
39. Case C-364/13, International Stem Cell Corporation v Comptroller General of Patents, EU:C:2014: 2451.
40. International Stem Cell Corporation (2013) EWHC 807 (Ch).
41. Reference for a preliminary ruling from High Court of Justice (Chancery Division) (United Kingdom) made (2013) - International Stem Cell Corporation v Comptroller General of Patents (Case C-364/13): 59.
42. Case C-364/13, International Stem Cell Corporation v Comptroller General of Patents, EU:C:2014: 2451.
43. Any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo'" (Paragraph 38).
44. According to the Enlarged Board, because a product must be made before it can be used, and such making is the ordinary way commercially to exploit the claimed invention and falls within the monopoly granted … [m]aking the claimed product remains commercial or industrial application of the invention even where there is an intention to use that product for further research [point 25 of the Decision].

45. WARF (2008) Reported as made by the applicant in the Appeal against the decision of the Examining Division of the EPO in the Decision of the Board of Appeal T 1374/04, 3.

46. Plomer, Torremans P (2009) Embryonic Stem Cell Patents: European Law and Ethics (eds.), (Oxford: Oxford University Press, India.

47. Plomer (2012) 'After Brüstle: EU Accession to the ECHR and the Future of European Patent Law' Queen Mary Journal of Intellectual Property, 2: 110-135.

48. Lewis J, Fenwick H, Phillipson G, Masterman R (2007) 'The European Ceiling on Rights' Public Law 720; and R. Masterman, 'Aspiration or Foundation? The Status of the Strasbourg Jurisprudence and the 'Convention Rights' in Domestic Law' in (eds), Judicial Reasoning under the UK Human Rights Act (Cambridge: Cambridge University Press, UK.

49. Shum J (2012) 'Moral Disharmony: Human Embryonic Stem Cell Patent Laws, Warf, and Public Policy' (2010) Boston College International and Comparative Law Review, 33: 8.

50. Adcock MD, Lewelyn M (2001) TRIPs and the Patentability of Micro-Organisms. Bio-Science Law Review 4: 91-101.

51. Human Fertilization and Embryology Act (1990) Section 3(4), London.

52. Adcock M, Beyleveld D (2007) 'Purposive Interpretation and the Regulation of Technology: Legal Constructs, Legal Fictions, and the Rule of Law' Medical Law International 8: 305-324.

53. The Human Fertilization and Embryology Act (1990) were amended in 2008.

54. Commission of the European Communities v Italian Republic Case C-456/03 and Kingdom of the Netherlands v European Parliament and Council of the European Union. Case C-377/98.

55. Plomer A (2012) 'After Brüstle: EU Accession to the ECHR and the Future of European Patent Law' Queen Mary Journal of Intellectual Property, 2: 110-135.

56. Reported as made by the applicant WARF in the Appeal against the decision of the Examining Division of the EPO in the Decision of the Board of Appeal T 1374/04, 3 March 2008.

57. We will not repeat this qualification, which is to be taken as implicit.

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60. Cohen WM, Walsh JP (2008) 'Real impediments to biomedical research' Innovation Policy and the Economy 8: 1-30.

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62. Gummer T (2013) 'Rethinking Morality: Human Embryonic Stem Cell Innovation, to patent or not to patent?' 3 The Student Journal Part 2.

63. Beyleveld D, Brownsword R (1986) Law as a Moral Judgment. London: Sweet and Maxwell, 52: 139-142.

64. Stephen CR (1997) 'Biotechnology patents and morality' Trends in Biotechnology, 15: 123-129.

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66. The general right of personality is constitutionally guaranteed by Articles 1 and 2 of the German Basic Law. It is held against 'the entire world' and guarantees protection of human dignity and the right to free development of the personality.

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