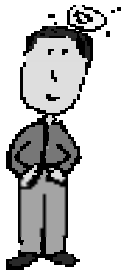
BEAUTY & THE BEAST:

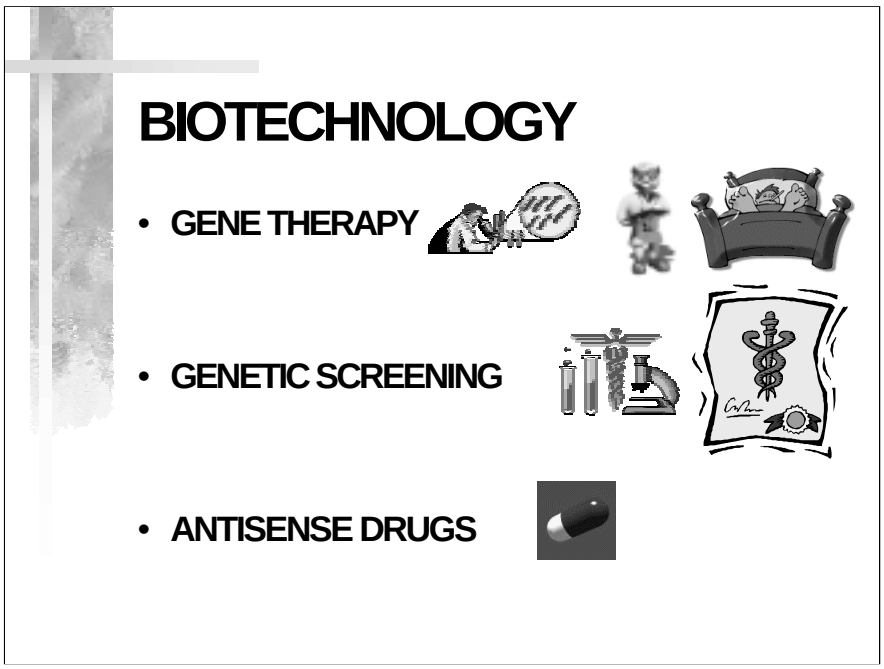
A MORAL TALE OF HUMAN BIOTECH



The patent law 'morality' criterion has become the focus of much attention and speculation since the advent of modern biotechnology. This is principally because it has formed the only means by which NGOs[1] can gain direct access to the regulatory system[2] in order to participate in the direction of social development. However, as is often the case with general legal provisions which are designed to have the greatest possible relevance in future application, detailed scrutiny has merely raised a range of potential interpretations. This seminar assesses those interpretations and re-centres the debate upon the fundamental purpose of the patent system in order to suggest a resolution.

[1] Non-Governmental Organisations, such as Greenpeace, Friends of the Earth, etc.

[2] in its widest sense, as incorporating the patent system within what is more traditionally considered to be the framework of regulation consisting of Local Research Ethics Committees (LRECs)/Multi-Research Ethics Committees (MRECs); Funding Councils; as well as market authorisation bodies such as the Human Fertilsiation and Embryology Authority (HFEA), the Medicines Council, etc.

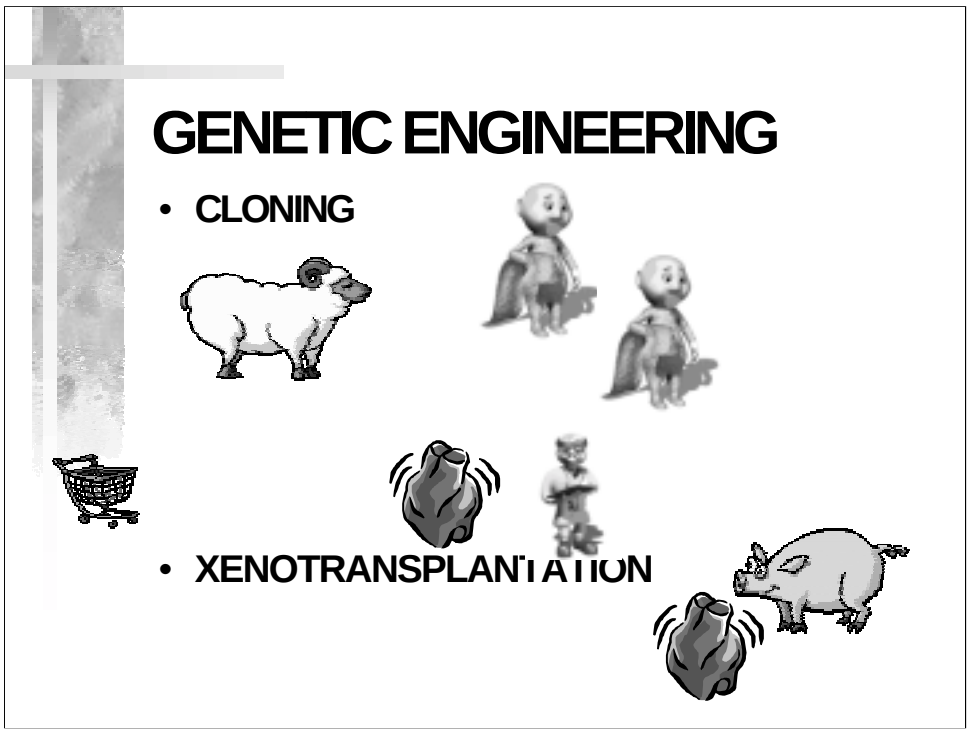


The starting point for the analysis therefore is to have a clear understanding of what is meant by modern human biotechnology and why it has formed such a point of contention. Some of the main applications of human biotechnology are listed in this slide and the next.

Gene therapy provides potential for remedial and curative treatments for humans by altering the DNA within the nucleus of cells (DNA is what chromosomes are made up of). Gene therapy is generally divided into two main categories: (1) *somatic cell gene therapy* in which the treatment administered to the patient will affect only their individual health; and (2) *germ-line gene therapy* in which the treatment is administered to inheritable cells, which means that the treatment will affect not only the individual but also future generations.

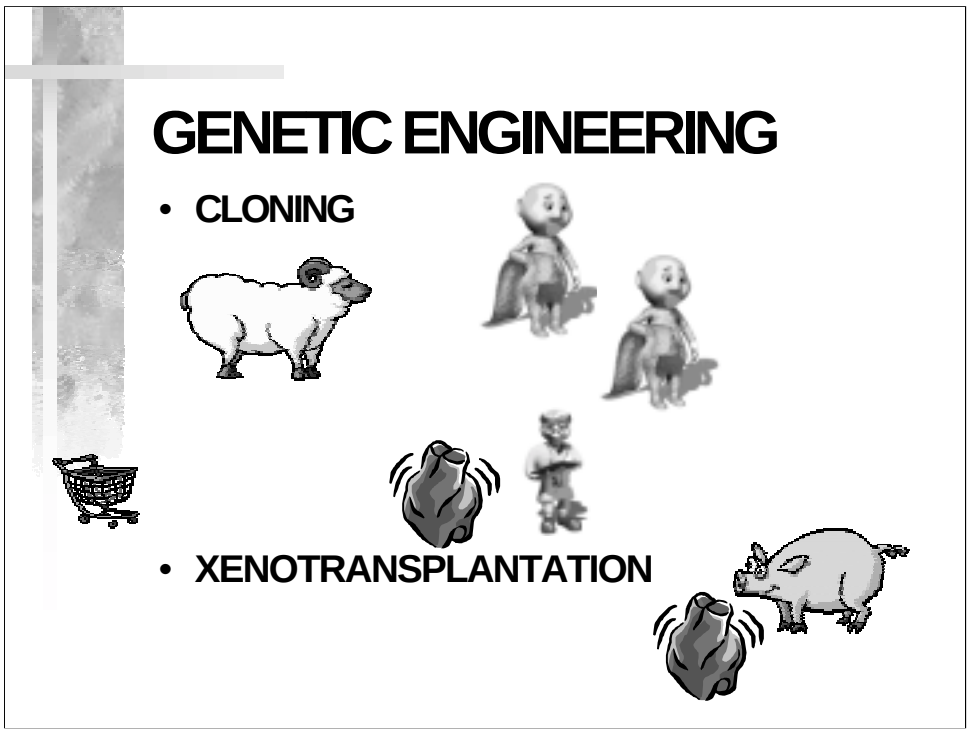
Genetic Screening is no less contentious for the fact that it simply provides information regarding the genetic make-up of an individual. Under current practice, it is utilised to identify the genetic components of diseases, which indicate that the individual has either a propensity or a certainty of developing a specific medical condition.

Antisense Drugs conversely have raised no controversy, but are included for comparative purposes as an application of human biotech. In common with gene therapy, Antisense Drugs are used to treat human diseases. However, unlike gene therapy, the treatment is not administered to the DNA within the individual s genome (all of the DNA in the nucleus), but is used to prevent the production of proteins which have adverse effects upon the body.



Human cloning should, from all the media coverage over the past six years, be a concept which is reasonably familiar to you. To expand upon this, cloning is a development which was pioneered for use on animals. A natural consequence of this innovation is that it provides the possibility of cloning human cells. This then enables *Human Reproductive Cloning* in which the cloned embryo develops to full term, but it also leads to the production of *Embryonic Stem Cells (ESCs)*. These are sometimes referred to as master cells, because they have the capacity to become any type of cell (liver, lung, blood, etc.) and consequently they can be utilised as a form of treatment. At present within the UK, human reproductive cloning is criminalised by the Human Reproductive Cloning Act 2000 and the production/utilisation of ESCs for organ/tissue transplantation or therapeutic treatment (*embryonic stem cell therapy)* for Alzheimer s or Parkinson s Diseases, for example, cannot be licensed. Conversely, the utilisation of human stem cells for research and in testing drugs/treatments (*therapeutic* cloning) can and is licensed.

Finally, **Xenotransplantation** is included here although strictly speaking it is not a form of human biotechnology, but of animal biotechnology. However, it is of interest in this context comparatively with embryonic stem cell therapy as a means of producing replacement organs for the purposes of transplantation. One of the central difficulties created by the ability to push back the boundaries of medical care is that there is now such a huge demand and potential for transplantation that the frequency of human organs becoming available as replacements cannot keep pace. This leaves the situation in which transplants must be found from other sources. Embryonic stem cell therapy cannot form an alternative as yet, because it cannot be licensed. However, xenotransplantation is already licensed and this involves the humanisation on a genetic level of animal organs, which can then be transplanted into humans. As the slide indicates, the preferred animals being utilised as organ donors at present are pigs.



So why are these applications of biotechnology contentious?

Well, each innovation has created possibilities for how our society may develop and they each represent various activities which must be assessed on the basis of whether they represent beauty (in other words, morally permissible forms of conduct which will enhance our society) or the beast (morally impermissible activities which should not become social realities). However, this is a far from straightforward analysis. For example, as will be discussed shortly, it has become generally accepted that germ-line gene therapy is immoral principally because it could have an adverse effect upon our gene pool . In other words, it could negatively impact upon future generations. So, for example the gene responsible for sickle cell anaemia causes a terrible disease which is transmitted to offspring. It could be thought, therefore, that this would be a good thing to get rid of in those carrying the disease and to remove that genetic code from the inheritable cells so that future children will not suffer the disease. However, the same gene also provides protection against malaria. Therefore, if there were a pandemic, the only survivors could be those carrying this gene. Conversely, if we eradicated the gene with germ-line gene therapy, it is argued that this may result in wiping out mankind.

So with some idea of the science behind this issue, it now becomes possible to assess patent law and the place to begin is with an overview of what the law currently prescribes.

THE CORE PROVISION

ART 53(a): EPC 1973 (as amended)

- *"inventions the commercial exploitation of which would be contrary to "ordre public" or morality, provided that such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;"*

Given that the case law which has arisen on this issue has come before the European Patent Courts, it is appropriate to discuss this issue in terms of the provisions under the European Patent Convention (EPC) 1973 (as it was amended in 2000). Since the UK Patents Act 1977 (as amended) must be read as being in conformity with the EPC 1973, there is no need to consider it individually as providing for a divergent standard. However, it is worth noting at this juncture that the UK provision refers to ***public policy*** and not ***ordre public*** . Profs Armitage and Davis indicated that the term *ordre public* was intended to represent a concept between 'public order' and 'public policy', which aligned more closely with the latter[3]. Since it is somewhat inconceivable that any court would refuse to consider an objection on the grounds that it fell outside of the definition of ***ordre public or morality*** , this becomes something of a moot point.

What becomes clear from the provision, however, is that there are three main elements to it:

(1) That the aspect of the invention which is being assessed is its ***commercial exploitation*** ;

(2) That the invention is assessed to ensure that it does not conflict with principles of ***ordre public or morality*** ; and

(3) That when the assessment is carried out, it must not be governed solely by legislation/regulation.

[3] E Armitage and I Davis: *Patents and Morality in Perspective* : 1994: Common Law Institute of Intellectual Property, London: p18

SPECIFIC MORAL EXCLUSIONS

Sched A2, para 3: UK PA 1977 (as amended)

BIOTECH DIRECTIVE: 98/44/EC: Art 6(2)

- **PROCESSES FOR CLONING HUMAN BEINGS**
- **PROCESSES FOR MODIFYING THE GERM LINE GENETIC IDENTITY OF HUMAN BEINGS**
- **USES OF HUMAN EMBRYOS FOR INDUSTRIAL OR COMMERCIAL PURPOSES**
- **PROCESSES FOR MODIFYING THE GENETIC IDENTITY OF ANIMALS/THE ANIMALS WHICH RESULT FROM SUCH PROCESSES (PRODUCT)**
  - ***LIKELY TO CAUSE SUFFERING; &***
  - ***WITHOUT ANY MEDICAL BENEFIT TO MAN/ANIMALS***

In addition to the central moral provision which applies to all types of invention, the Biotech Directive has added moral exclusions which are specific to biotechnology and these have been adopted into the UK Patents Act by Schedule A2. Of these, we are really concerned in the context of human biotech with the first three exclusions.

What is being excluded, therefore, should be very clear where these provisions are specific to biotechnology and, in comparison with the general provisions contained within the patent legislation which must be flexible in order to have the widest possible application, this would certainly seem to be the case. Consequently, human reproductive cloning, germ-line gene therapy and the commodification of human embryos are all precluded from patent protection. Whether or not these provisions are in fact this determinative is an issue which will be returned to at the end.

In the meantime, with a general overview of the relevant provisions to the issue of human biotech, it becomes necessary to focus upon the core provision for a more definitive understanding of it.

THE CORE PROVISION

ART 53(a): EPC 1973 (as amended)

- **COMMERCIAL EXPLOITATION**
- ***ORDRE PUBLIC OR MORALITY***
- ***THE PROVISO***

While the specific exclusions for human biotech are very insightful, they are not comprehensive. This means that any inventions which circumvent these specific exclusions may still be deemed to be unpatentable on the basis of the core morality provision. So far we ve managed to establish that the core provision is comprised of three main elements:

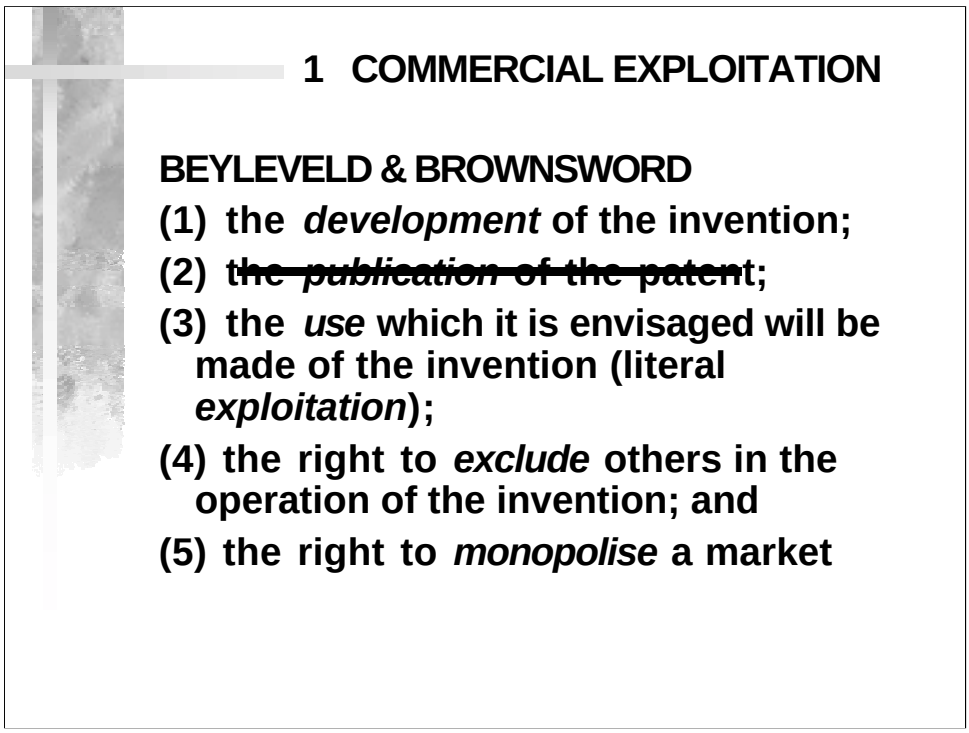
(1) That the aspect of the invention which is being assessed is its ***commercial exploitation*** . This part of the provision not only identifies what it is about the invention which is being morally assessed, but in doing so it also prescribes at what point in the patent examination procedure that the assessment is made;

(2) That the invention is assessed to ensure that it does not conflict with principles of ***ordre public or morality*** . For an effective form of assessment, this must at least prescribe a standard of morality and a source from which that standard derives; and

(3) That when the assessment is carried out, it must not be governed solely by legislation/regulation. This is generally referred to as the proviso and is a limiting parameter upon the source of the morality being utilised under the assessment.

So what is required is a clear understanding of each of these aspects.

[3] E Armitage and I Davis: *Patents and Morality in Perspective* : 1994: Common Law Institute of Intellectual Property, London: p18



Profs Beyleveld and Brownsword are generally regarded as having produced the seminal work on this issue [4]. However, their assessment pre-dates the change in wording and, under the former wording of the provision, it was the ***publication and exploitation*** of the invention which was required to be assessed. On their analysis the provision means that there are five aspects of the invention which are morally assessed:

(1) How it was developed;

(2) Putting it into the public domain in a published form;

(3) How it is used in a commercial setting;

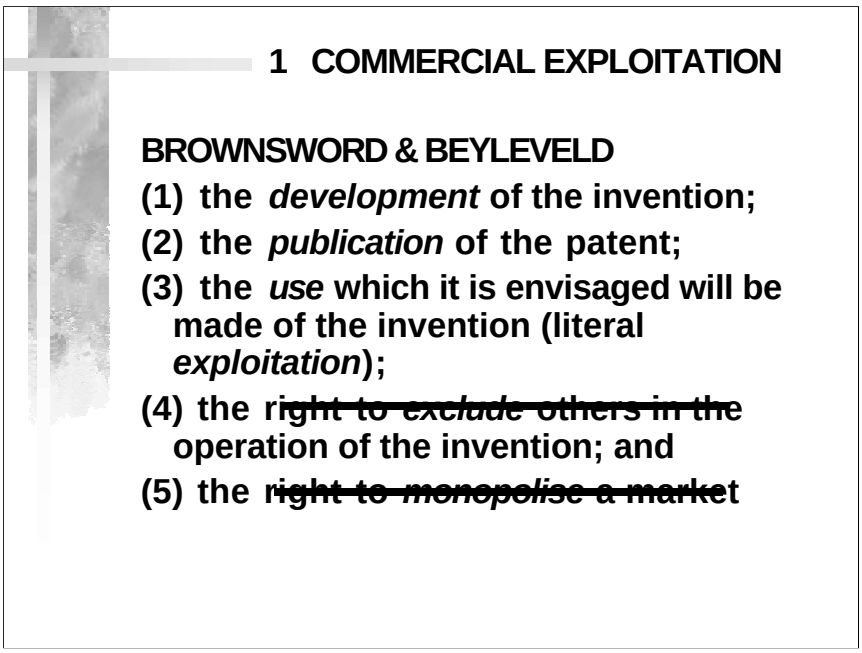
(4) The exclusivity which prevents third parties from utilising the invention; and

(5) The invention s monopolisation of a specific market sector.

However, under the change in wording, it could be thought that publishing details of the invention is no longer required to be morally scrutinized and some commentators have construed it as having an even greater impact upon the assessment process [5]. Nevertheless, all of the evidence suggests that the removal of *publication* represents merely the discarding of a superfluous term and this is further supported by EPO practice, which still requires their Receiving Section to make an initial moral assessment of inventions prior to publication.

[4] D Beyleveld and R Brownsword: *Mice, Morality and Patents* : 1993: Common Law Institute of Intellectual Property, London

[5] R Ford: *"The Morality of Biotech Patents: Differing Legal Obligations in Europe?"*: [1997] 6 European Intellectual Property Review 315; and O Mills: *"Biotechnology and the Ethical Moral Concerns of European Patent Law"*: [2000] 6(1) Bar Review 46-51



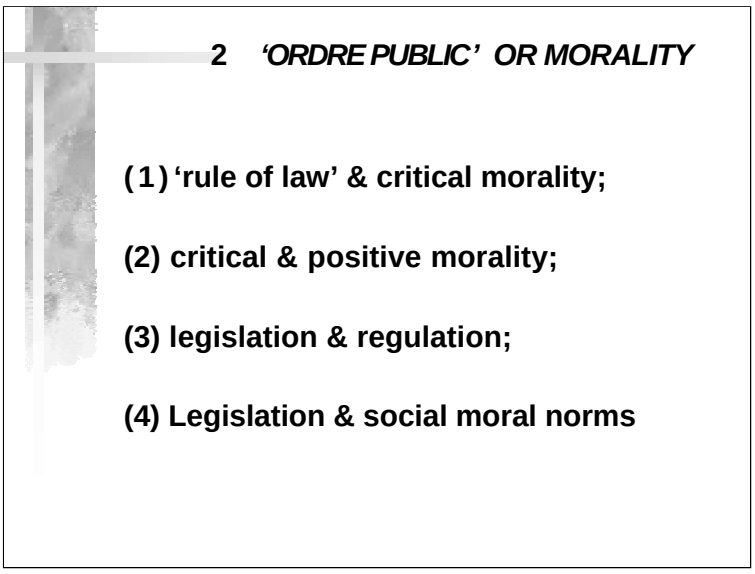
In assessing the approach of the European Patent Courts on this issue, both before and after the change in wording, what becomes clear is that they are only prepared to assess inventions from the first three aspects: its development; its publication; and its eventual use. Conversely, the courts tend to utilise exclusivity and monopoly as being devices to reject overly broad objections. Indeed, the closest that the courts have come to actually addressing such issues arose in the Leland Standford case [6] (which concerned a chimera [7] designed to further AIDS research). One of the objections raised was that the exclusivity granted by the patent would inhibit future research. In response, the Opposition Division stated that ***"...the EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly."[8]***

Furthermore, sanctioning the immoral development of an invention by refusing to grant patent protection poses problems. This is because the consequence is that any number of third parties can simply pick up the details of the invention which have already been published by the time the decision to refuse is made, and then seek market authorisation. Where the immorality only arises in the initial development of the invention, there are then no means for the regulatory body to identify the immorality. The result could be the implementation of an invention which has its roots in an immoral act. Conversely, granting protection would at least enable the regulatory body to back track and identify the initial immorality.

[6] [2002] EPOR 2 ˚

[7] a chimera is produced by combining cells from different sub-species/species and in this instance a genetically altered mouse had been combined with human cells, forming a hybrid.

[8] Supra 6: at point 49



Now we can turn our attention to the second aspect of the provision, what it meant by ***ordre public or morality*** . While it has already been indicated that this is something of a moot point where no court would consider an objection as falling outside of its boundaries, it does bear some analysis to see if it is at least a generally understood concept.

Quite the contrary, the commentators have posited four contenders as to what is intended by these terms:

(1) Profs Beyleveld and Brownsword [9] view it as being governed by tenets comprised within both rule of law and critical morality. This means that inventions must comply with justice, fairness, etc. under the rule of law and with fundamental freedoms and rights, such as freedom from slavery and the right to family life, under a ***critical cultural morality*** ;

(2) Prof Straus [10] perceived that the moral assessment is undertaken on the basis of broad principles of law which cannot be derogated from and which are inherently contained within subject-specific legislation (such as ***"the inviolability of human dignity and the right to life, physical integrity and personal freedom"***) and principles which are overtly apparent in subject-specific legislation (for example prohibitions on: germ-line gene therapy; human cloning; and the commercialisation of human embryos);

(3) Prof Schatz [11] considered that the assessment fixes upon basic values of society which are discernable from legislation, as well as a morality which is determinable from non-legal sources such as regulation, codes of practice, etc.; and

(4) Dr Moufang [12] believed that the assessment requires that inventions comply with moral principles contained within legislation and which are generally socially accepted.

In order to concur with any of these perceptions, it is necessary to have in mind the third aspect of the morality provision, which is the proviso .

[9] Supra 4

[10] J Straus: *"Patenting Human Genes in Europe - Past Developments and Prospect for the Future"*: [1995] 26(6) IIC 920

[11] U Schatz: "Patents and Morality" in *"Biotechnology, Patents and Morality"*: S Sterckx (Ed): 1997: Ashgate Publishing Ltd, Aldershot: at p161

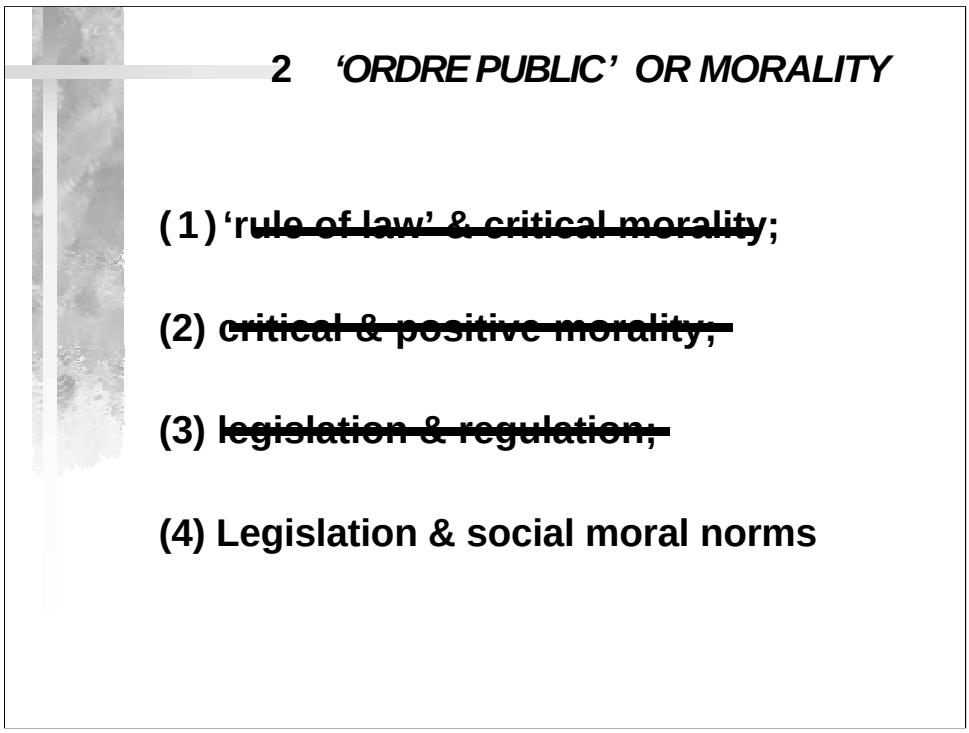
[12] R Moufang: *"Patenting of Human Genes, Cells and Parts of the Body? - The Ethical Dimensions of Patent Law"*: [1994] 25(4) IIC 487

3 THE PROVISO

ART 53(a): EPC 1973 (as amended)

- *"provided that such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;"*
- MEANS THAT LEGISLATION/REGULATION CAN ONLY BE A PART OF THE DECISION TO FIND A PATENT 'CONTRARY TO MORALITY'

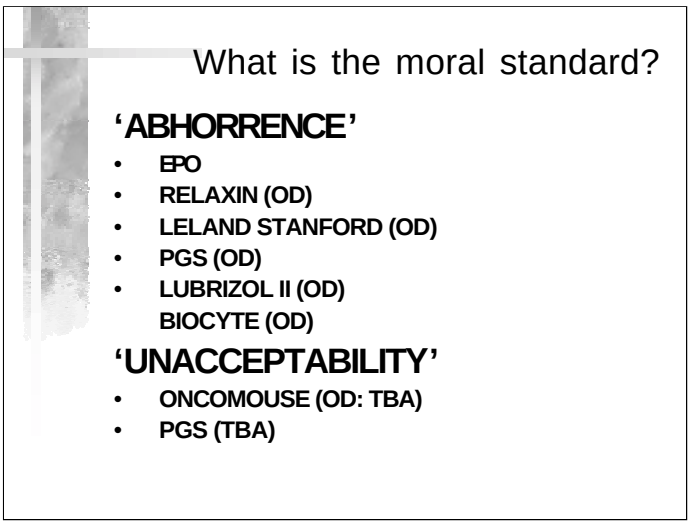
The proviso basically means that, in conducting the moral assessment required by the legislation, recourse must be had to more than simply legislation or regulation. Consequently, this provides a limiting parameter against which the commentator s theories may be measured.



In respect of Profs Beyleveld and Brownsword s theory, this does not accord with a literal interpretation of the proviso . Indeed, they indicated that this aspect of the provision could be read non-literally as meaning that the assessment could be confined to legislation/regulation provided that it does not concern every aspect of it, ie the positive morality clear on the face of the provision being considered. However, this lacks complete cogency where critical morality coincides with positive morality, as in the case of the Human Rights Act 1998 for example.

Furthermore, the theories of both Profs Straus and Schatz similarly must be doubted in enabling the assessment to focus solely upon law and regulation.

Consequently, this leaves Dr Moufang s approach as leaving scope for recourse to other evidence in determining whether an invention is immoral. This is then further supported by the EPO Guidelines, which indicate that the moral assessment rests upon a public standard. However, this makes it clear that in assessing the core morality provision, no particular standard of morality is inherently conveyed and this strikes at the heart of the ambiguity with this provision.



This ambiguity can be more clearly seen from an analysis of the approach of the EPO and the attitudes of the European Patent Courts through the applicable decisions. In this context, it is not possible to go through every case in detail and so the citations are listed below.

Two separate standards have emerged from the patent system, which cannot be attributed to either the level of the court making the decision or the form of biotechnology under consideration. These standards are abhorrence , which indicates that an invention is deemed immoral only where its use cannot be countenanced by right-thinking members of the public and unacceptability , which indicates that inventions be deemed immoral on a majority preference.

It must be noted that the Biocyte case, which concerned a patent application on human blood stem cells in combination with a cryopreservative was not a biotech case, but is included comparatively as being the only other recent case in which the courts considered the morality provision.

From this it could be thought that the correct standard to adopt would be the most prescriptive, the standard which filters out inventions to the highest moral standard and this would suggest the adoption of unacceptability . However, in deciding which standard to adopt, it must be borne in mind the context in which the decision is made: the patent system.

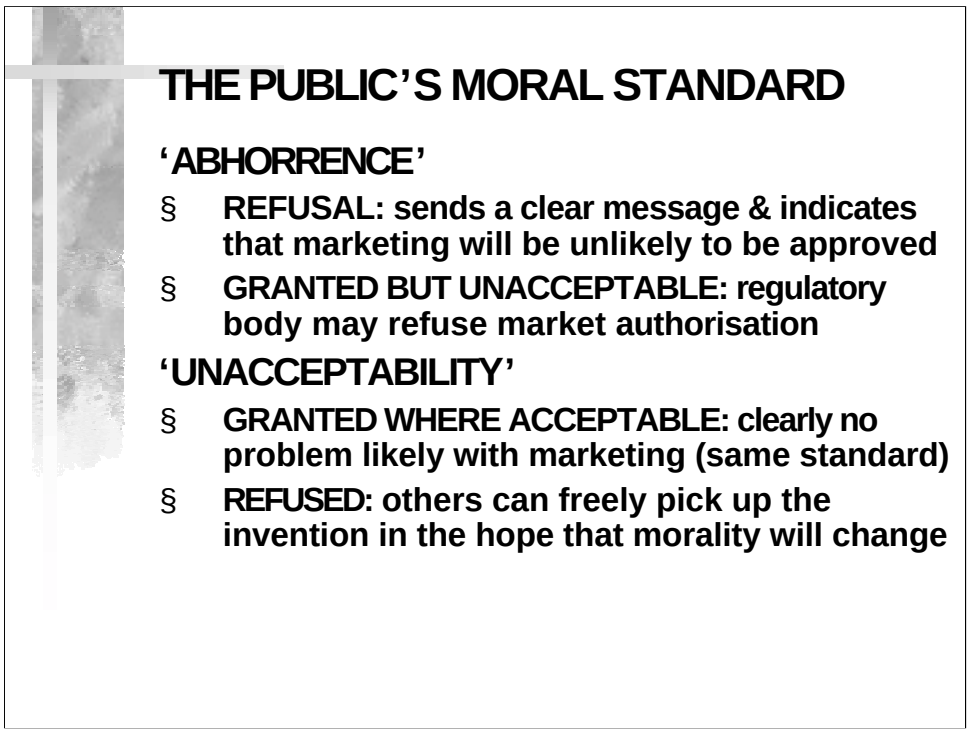
[13] RELAXIN/Howard Florey Institute *[1995] 6 OJ EPO 388*

[14] Supra 6

[15] Plant Cells/PLANT GENETIC SYSTEMS *[1992] 24 IIC 618 (Opposition Division); [1995] 8 OJ EPO 545 (TBA)*

[16] Lubrizol II case ([1992] EP-B1-122 791 (Opposition Division): (unreported): H-R Jaenichen H-R and Schrell, A: "The European Patent Office's Recent Decisions on Patenting Plants": [1993] 12 *European Intellectual Property Review* 466-469

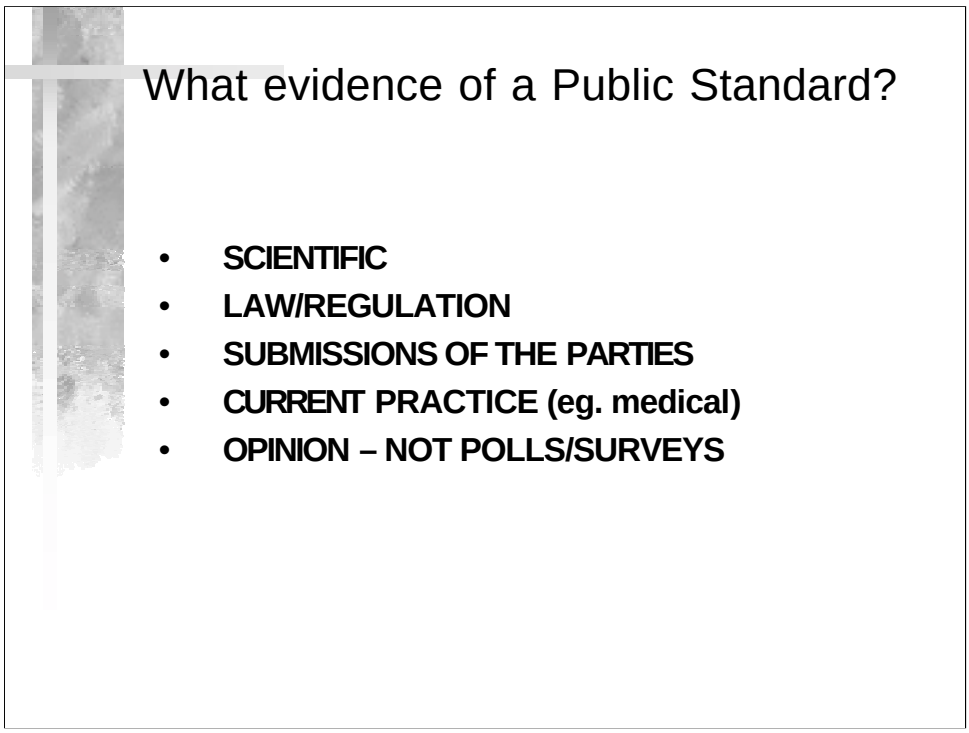
[17] Oncomouse/HARVARD T19/90 *[1990] 12 OJ EPO 476: (TBA); [1992] 10 OJ EPO 588: remitted to Opposition Division*



This reveals a peculiarity about the patent system. This is that, while it can have an economic impact, it does not guarantee marketing. This means that the effect of refusing patent protection where the invention is abhorrent is that, where it is a well understood standard, it sends a clear message to interested third parties indicating that there is no purpose to picking up the innovation, because it will not receive market authorisation. Although an abhorrence standard then enables inventions which are either acceptable/unacceptable to gain protection, those which are unacceptable would be filtered out at the regulatory stage. It is then up to the patentholder to decide whether to pay his fees to keep up his patent in the hope that the regulatory body will change its decision in the future or to give it up.

Conversely, where the patent morality standard is set at the level of unacceptability granting protection may accord with the assessment taken later by the applicable marketing authority, but it represents a doubling up of consideration and leaves scope for disparities which cannot be easily accounted for. Similarly, where patent protection is refused on the basis of unacceptability it means that others are free to pick it up in the hope that the regulatory body may decide that it is an acceptable social development in the near future. Given that social morality can change quite quickly, especially in the context of biotechnology, this strips the inventor/owner of his benefit without justification. For example, in 1997 the knee-jerk reaction to the prospect of human cloning was that it needed to be banned in entirety, but already regulation permits therapeutic cloning.

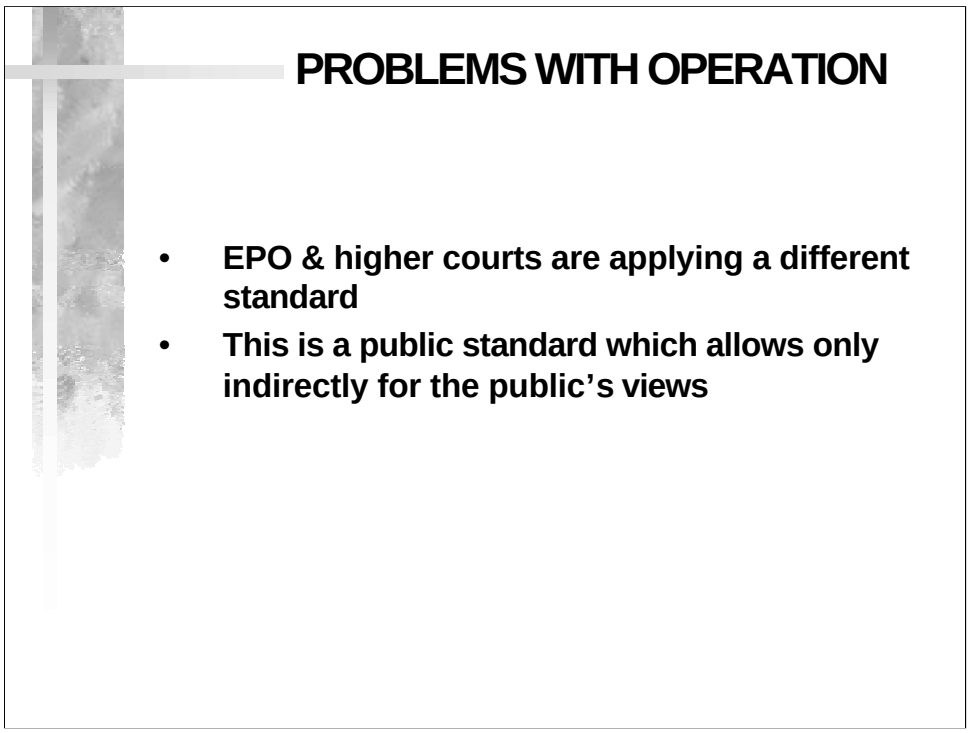
Even where a standard of morality can be agreed, it must be questioned as to whose morality this standard rests upon. So far, this aspect has been related to its being a public standard, but what does that actually mean?



The European Patent Courts have shown themselves very willing to consider a whole range of evidence in determining the question of morality. Scientific evidence is generally accepted within patent law examinations, but the courts have had recourse principally to Law/regulation, the submissions of the parties and current practice by way of comparison. On this latter point, the ethos being that, if the invention is a close comparator of an existing medical practice, this suggests its moral permissibility.

However, in both cases in which evidence of public opinion by polls/survey were in point, the court refused to accept is as appropriate. The Opposition Division in the Relaxin case were prepared to accept evidence of public opinion where it reached ***"overwhelming consensus*** and the Technical Board of Appeal in the PGS case allowed that empirical data could be utilised ***"if the surveys and opinion polls....***[are undertaken] ***ad hoc on the basis of specific questions in relation to the particular subject-matter claimed", they felt that practicality precluded this*** . So, although the courts have not rejected direct evidence of public opinion *per se,* they have laid down a set of guidance for its acceptability which in terms of practicality and cost, prohibit it as a possibility.

This means that the patent law morality provision is perceived as being a public standard which relies upon an intuitive understanding of common morality as construed by Patent Office Examiners and the European Patent Courts. In as much as everyone can be said to have an intuitive understanding of what a particular society considers to be abhorrent , this lends weight to this standard of morality. However, it therefore becomes unjustifiable to adopt an unacceptability standard where applying it to particular inventions relies upon an individual determining what the majority would/would not find appropriate.



What becomes clear from this analysis of the core morality provision, therefore, is that there are two fundamental problems with the way in which it is being comprehended and operated.

The first is that two standards of morality have emerged, which are in conflict with each other. This is because, where the EPO adopt a standard of abhorrence and some of the court decisions have been determined by unacceptability , there is no clear way of predicting whether a particular invention will be granted. This is because an invention which is unacceptable, but not abhorrent would be granted by the EPO, but whether it is eventually invalidated by the courts could rely upon whether grant is opposed and which court makes the decision. No patent system should be operated with this type of uncertainty.

Secondly, the only means of justifiably operating the core morality provision where it rests upon individual decision-making which does not have direct recourse to public attitudes is where those attitudes are inherent. This argues that the patent system must consider inclusion of public opinion polls/surveys for the sake of validity and without the current limiting parameters, unless it can be said that they are intuitively known to everyone.

In addition, there are further potential problem with this area of law which emanate from the specific moral exclusions.

4 MORAL EXCLUSIONS

Sched A2: para 3: UK PA 1977 (as amended)

BIOTECH DIRECTIVE: 98/44/EC: Art 6(2)

- **PROCESSES FOR CLONING HUMAN BEINGS**
- **PROCESSES FOR MODIFYING THE GERM LINE GENETIC IDENTITY OF HUMAN BEINGS**
- **USES OF HUMAN EMBRYOS FOR INDUSTRIAL OR COMMERCIAL PURPOSES**

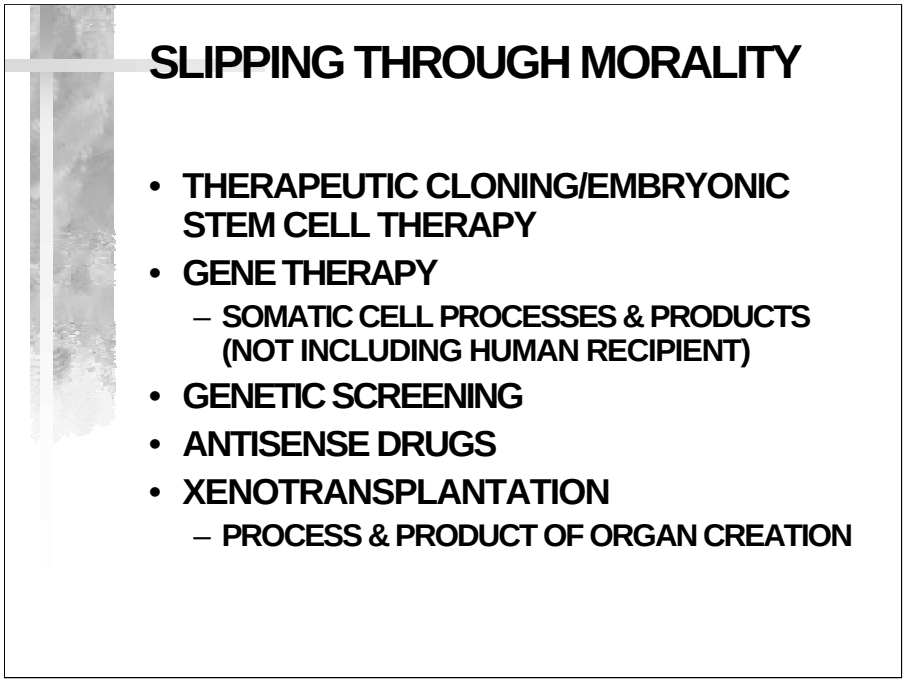
The exclusions which have already been introduced by the Biotech Directive were put forward as being a non-exhaustive list, to which Member States would add developments which they found immoral as they arose. The basic premise was that this list represents clear cases of immorality and that the European Patent Office would be able to utilise the experience of Member States in order to operate the core morality provision effectively, to add to these prescribed instances.

However, there are two fundamental flaws in this approach:

(1) All of the inventions which have raised the morality provision have come before the EPO, so Member States are not providing any additional or refining moral tenets to this list; and

(2) The list does not in fact provide a clear statement regarding current developments.

This latter point requires elucidation.



The first exclusion is directed toward the process of creating a human clone and this does not cover the clone itself. Nevertheless, both the Biotech Directive and Schedule A2 of the UK Patents Act collaterally state that ***the human body, at the various stages of its formation and development*** cannot be patented and this closes this loophole. So while it is clear that human reproductive cloning cannot attract patent protection, the situation with therapeutic cloning (for research and testing drugs/treatments) and embryonic stem cell therapy (for actual treatment or organ/tissue transplantation) is ambiguous. This is because therapeutic cloning, which is presently licensed in the UK, may be viewed as falling outside of this moral prohibition because it does not give rise to a human being and, on the basis of the Human Fertilisation and Embryology Act 1990, the pre-14 day old embryo is not accorded human status legally. Furthermore, embryonic stem cell therapy would fall within the same argument and additionally could become patentable once the stem cells have differentiated into particular cells: so liver cells created by the artificial production of ESCs would be patentable, for example.

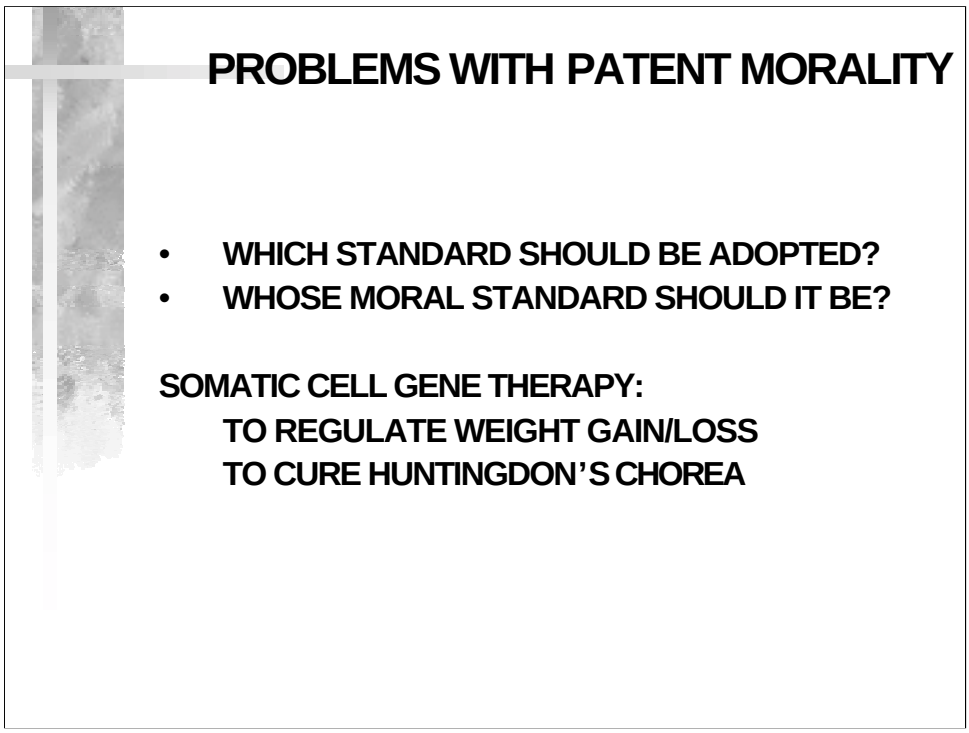
Processes for modifying the germ-line of humans is prohibited, but this permits processes involving somatic cell gene therapy to be patented, as well as the genetic/cellular products associated with either somatic or germ-line gene therapy. Although in terms of the latter, only where they can be deemed as having an independent existence.

SLIPPING THROUGH MORALITY

- **THERAPEUTIC CLONING/EMBRYONIC STEM CELL THERAPY**
- **GENE THERAPY**
  - **SOMATIC CELL PROCESSES & PRODUCTS (NOT INCLUDING HUMAN RECIPIENT)**
- **GENETIC SCREENING**
- **ANTISENSE DRUGS**
- **XENOTRANSPLANTATION**
  - **PROCESS & PRODUCT OF ORGAN CREATION**

Uses of human embryos for industrial or commercial purposes, are derogated from in Recital 42 which states that the prohibition ***"does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it .*** Therapeutic cloning to acquire information may be considered a research purpose, taking it outside of this prohibition. However, therapeutic cloning for the purposes of testing drugs/treatments where those drugs/treatments are later sold would arguably bring it within this exemption. This would mean that no patents could attach where it is unlikely that the drugs/treatments could be perceived as falling within the derogation on the grounds that it was useful to the embryo (cloned or otherwise), given that the embryo is terminated after 14 days. This reasoning would therefore mean that the differentiated products of embryonic stem cell therapy would similarly be prohibited from gaining patent protection under this ground of objection. This is because such organ/tissue products would be required to be 'capable of industrial application' under the main legal criterion, but be construed as not being industrial or commercial for the purposes of the moral prohibition. Quite clearly the derogation was designed to save applications such as somatic cell gene therapy which may be practiced on a post-differentiated embryo in order to correct genetic defects and the main prohibition is more likely to be construed as preventing commercialisation of the human embryo itself, rather than as extending this meaning to experimental utilisation where subsequent commercialisation occurs.

Consequently, this leaves it open for debate that all of the innovations listed in the slide could be patentable, because they arguably do not fall within the specific exclusions. This means that the only moral guard against their patentability comes down to the core morality provision.



So this brings us back to the central difficulty with this area of law. Legal certainty and commercial expediency require that this issue needs to be resolved. Human biotechnology represents an advancement with the potential to change our society forever, but it is both beauty and the beast and the point is to establish a legal framework which ensures that we only encourage the one that benefits us all.

So this is the main crux for you to think about. What standard of morality do you think that patent law should adopt and how would you utilise an appropriate source in order to ensure its validity? When you have reached your own conclusions, test your convictions by considering the inventions listed in blue on the slide.