NEWS LEXTTER

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HEALTHCARE & LIFE SCIENCES

RECENT DEVELOPMENTS IN HEALTHCARE AND LIFE SCIENCES

COURT OF JUSTICE OF THE EU BANS PATENTING OF HUMAN EMBRYONIC STEM CELLS [1, 2]

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«Case C-34/10 Oliver Brüstle v. Greenpeace e. V. (18 October 2011).[1] [2]

A process wich involves removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo, cannot be patented.

The use of human embryos for therapeutic or diagnostic purposes which are applied to the human embryo and are use ful to it is patentable, but their use for purposes of scientific research is not patentable.»

For some time now we have been expecting to see case law on the interpretation to be given to Directive 98/44/EC[3] (article 6 (2) (c)) which provides that "uses of human embryos for industrial or commercial purposes" may not be patented, when their commercial exploitation would be contrary to public order or morality.

With the growing interest in research into human stem cells – which was barely even being talked of (let alone researched) when that directive was approved – questions were soon raised as to what the concept of "human embryo" for the purposes of interpretation of that provision of the directive would be.

Now, with the decision of 18 October 2011, the Court of Justice of the European Union (CJEU) has passed its first judgment on this controversial issue of the interpretation to be given to article 6 (2) (c) of the said directive.

Far from putting an end to the discussion which is over a decade old, the CJEU was not, as it made very clear, called upon to broach questions the status of the embryo from a medical or ethical perspective, but rather to consider the issue from a "strictly legal" point of view. This approach was taken in a decision will very probably come to influence European research strategy in this area and its future development within the European Union.

[1] The full text of the judgment can be read at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CJ0034:EN:HTML

[2] The press release can be read at http://europa.eu/rapid/pressReleasesAction.do?reference=CJE/11/112&format=HTML&aged=0&language=PT&guiLanguage=en

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All this came about because Oliver Brüstle had held a patent since 1997 relating to isolated and purified neural precursor cells produced from human embryonic stem cells used to treat neurological diseases.[4]

At the request of Greenpeace e. V, the Bundespatentgericht (German Federal Patent Court) ruled that Brüstle's patent was invalid insofar as it covers processes for obtaining precursor cells from human embryonic stem cells.
At the appeal brought by Brüstle, the Bundesgerichtshof (German Federal Court of Justice) decided to refer questions to the CJEU on the interpretation of, in particular, the concept of the 'human embryo' which is not defined in Directive 98/44/EC on the legal protection of biotechnological inventions. The question was whether the exclusion from patentability of the human embryo covers all stages of life from fertilisation of the ovum, or whether other conditions must be met, for example that a certain stage of development be reached.

To decide whether or not the German legal provision that transposes the said directive had been infringed the CJEU had to interpret the provisions of article 6 (2) (c) and answer the question of whether human embryonic stem cells used as base material for patented processes are "embryos" for the purposes of that provision and whether the organisms a from which they are obtained are "human embryos" for the purposes of the same directive.[5]

What is the meaning of "human embryos" in the context of the Directive?

What is the meaning of the expression "uses of human embryos for industrial and commercial purposes"?

First of all, we must consider, in the context of the directive, whether the question is only relevant to assessing whether or not the patent is admissible. And we must naturally bear in mind that the patenting implies, in principle, to its industrial or commercial application. Indeed, the decision itself emphasises that the objective of the Directive is limited to biotechnological patents and is not intended to regulate the use of embryos in the context of scientific research.

The fact that there is no uniform definition of the human embryo - it is rarely defined in national legislations and always generates great ethical controversy - contributes to the complexity of the assessment.

In the interpretation made by that Court, its starting point was the principle that with the said provision, the Directive intended to exclude the possibility of patenting whenever there was a violation of the principle of human dignity.

The Court held that the concept of "human embryo" must be considered in a broad sense and, this being the case, the concept applies to the human ovum as soon as it is fertilised, as long as that fertilisation begins a process of development of a human being. The case at hand involved the stem cell, at the blastocyst stage, before being implanted.

In this context, the Court also analysed the question of the destruction of human embryos when the patent relates to a product obtained through a prior destruction of those embryos or a process that requires a base material obtained from the destruction of human embryos.

To conclude, the Court holds that an invention is excluded from patentability where the implementation of the technical process requires either the prior destruction of human embryos or their prior use as base material, even if, at the time of the patent application, the description of that process, as in this case, does not mention the use of human embryos.
In the context of awarding patents it is certain that the requirements of not being contrary to public order or morals contained in article 53 of the European Patent Convention have, for a long time, given rise to renowned and naturally controversial decisions (see the cases OncoMouse[6], Relaxin[7] and Plant Genetic Systems [8], among others), decided by the European Patent Office and even on the patenting of stem cells, the question has been analysed in the well-known case of the University of Edinburgh patent[9]. However, the CJEU had never gone so far as to provide such a broad interpretation of the concept of the embryo, even though it did so only for the purposes of interpretation of the Directive.

It is an undisputed fact that all cases directly or indirectly touching on the human embryo are controversial involving, as they do, a discussion on the ethical and legal status of the embryo and on the beginning of human life and the protection that should be given to it at its different stages of development. Even among those who consider it ethically acceptable to carry out research on human embryos, there are many who feel reluctant to patent the result of the inventions.

The consequences of this decision may, in fact, be very important for a number of reasons. On the one hand, in the direction of the case law on the concept of the embryo and its consequences for future patent applications where human embryonic stem cells are used and, on the other hand, in reigniting the ongoing debate on the status of the human embryo, even outside the scope of the discussion on patentability. Finally, it will probably act as a disincentive to some European research into inventions that it was intended to protect through the award of a patent. Even if the research in itself is not prohibited (this is not even what was analysed in this case), the truth is that, in preventing the patentability of the result of this research, this could, in many cases, come to be a disincentive as it makes it unviable for the investor to be able to receive the revenue that the patent confers. The consequence of this is that research in this area will be concentrated in countries or continents where more permissive legislation rewards investment.

[3] Of 6 July on the legal protection of biotechnological inventions.
[4] According to information provided by Brüstle, there are already clinical applications, particularly for patients suffering from Parkinson's disease.
[5] See, for example, opinion no. 16 "Ethical Aspects of patenting Inventions involving Human Stem Cells", European Group on Ethics in Science and New Technologies of the European Commission at http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_en.pdf http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_en.pdf : this article leaves open the question of patentability of cells obtained from donated embryos, nor does it state precisely which embryos are subjected to this exclusion.

[6] Harvard/Onco-mouse, T 19/90, 1990.
[7] Relaxin / Howard Florey Institute, T 0272/95.
[8] Plant Genetic Systems N. V. - T 0356/93.
[9] EP 0695351.

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PRESCRIPTION BY INTERNATIONAL NON-PROPRIETARY NAME (INN)

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The Portuguese Parliament has approved legislation which alters the rules on prescription of medicines for human use and provides for the new rules to come into force on 1 January 2012.

The fundamental objective of this legislative change is to promote the prescription and dispensation of generic medicines as a way of promoting savings on the part of citizens in buying medicines and, at the same time, as a means of reducing public spending on healthcare.

In fact, prescribing by the international non-proprietary name of the active substance (INN) disassociates the brands of medicines from the pathologies, leaving users free (although with some reservations) to acquire the medicine they need for the lowest price.
This way of prescribing is not new in the Portuguese legal system as it is already provided for in Law 14/2000 of 8 August.

However, the fact that the prescribing doctor is, freely and without any reason, able to oppose the dispensation of the generic medicine has greatly limited the practical application of this rule and has made it necessary to specify the cases in which the doctor can restrict the choice of the user to the generic medicine.

Against this background a new law was approved that alters Decree-Law 176/2006 of 30 August and Law 14/2000 of 8 August and concretely defines the rules for prescription and dispensation that will come into force.

The prescription of medicines will, therefore, have to include the international non-proprietary name of the active substance, the pharmaceutical form, the dosage, the posology and it may also include (exceptionally, in the case of medicines subsidised by the National Health Service), a commercial brand name or an indication of the name of the holder of the marketing authorisation.

However, for the prescribing doctor to be able to oppose the substitution of the medicine prescribed with a brand name, he or she must provide an express, clear and adequate indication of one of the following grounds:

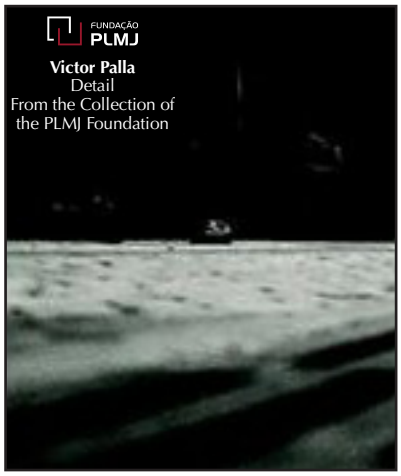
a) Prescription of a medicine with a narrow therapeutic margin or index, in accordance with information provided by INFARMED, I.P.

b) A well-founded suspicion, previously reported to INFARMED, I.P., of an intolerance or adverse reaction to a medicine with the same active substance, but identified by another brand.

c) Prescription of a medicine aimed at ensuring the continuity of a treatment with an estimated duration of more than 28 days.

d) Prescription of a medicine with an active substance for which there is no subsidised generic medicine or for which only the original brand and licences exist.

Furthermore, upon dispensing the medicine, the pharmacist must inform the patient of the existence of medicines available in the pharmacy with the same active substance, pharmaceutical form, presentation and dosage as the medicine prescribed. The pharmacist



must also inform the patient about those which are subsidised by the National Health Service and which have that lowest price that is available on the market. At the same time, pharmacies are under an obligation to always have available for sale at least three medicines with the same active substance, pharmaceutical form and dosage, from among the medicines that correspond to the five lowest prices for each homogenous group.

This means that, with the prescription and the information provided by the pharmacy, the user will have the right to choose any medicine that contains the same international non-proprietary name of the active substance, pharmaceutical form and dosage of the medicine appearing in the medical prescription, except in cases where one of the situations described in paragraphs a), b) and d) above exists.

This is because in the situation described in paragraph c) above – the case in which the prescribing doctor opposes the substitution of the medicine prescribed with a commercial brand on the basis of the fact that the medicine is intended to ensure the continuity of a course of treatment with an estimated duration of more than 28 days – the patient may, even so, opt for the generic medicine as long as the medicine prescribed by the doctor has a price greater than the reference and the user signs the prescription.

It is clear then that, on the one hand, this legislation limits the power of doctors to choose brand medicines (except when there are technical grounds to justify otherwise) and, on the other hand it gives greater freedom and responsibility to patients in their choice of the medicines they take. This means it is to be expected that patients will choose the cheaper generic medicines and this approach will increase savings on medicines for

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REGULATION OF NON-CONVENTIONAL THERAPIES

Non-conventional therapies, commonly known as 'alternative medicines', were the subject of specific regulation under Law 45/2003 of 22 August (The Base Framework Law for Non-conventional Therapies).

This law laid down the general basis for the framework for the activity and practice of professionals working with these therapies. In particular, non-conventional therapies were defined as those that come from a philosophical basis that are distinct from conventional medicine and apply specific processes for diagnosis as well as its own therapies, such as acupuncture, homeopathy, osteopathy, naturopathy, herbal medicine and chiropody.

The law referred to above established the following general guidelines:

(i) Guiding principles for non-conventional therapies: the individual right to choose the therapeutic method based on informed choice over the safety, quality, effectiveness and possible risks of the same; the defence of public health, with respect to the individual right to protection of health; the defence of users and the consequent duty of care, diligence and competence, based on the professional qualification of those who exercise the profession and their respective qualifications; the defence of the well-being of the user, which includes complementing the work of other health professionals; the promotion of scientific research in the different areas of non-conventional therapies;

(ii) Rules relating to qualifications and professional status, in particular, the creation of an advisory technical committee with the objective of studying and proposing general parameters for the regulation of the exercise of non-conventional therapies, specifically in relation to accreditation, training and certification of the respective professionals and assessment of equivalences;

(iii) Users' rights, specifically the right to choose, the right to information, consent, confidentiality and the right to make a complaint.

For the purposes of its practical application, the Law established the requirement for regulations to be put into place within 180 days of the Law's entry into force.

The Law also provides that the advisory technical committee referred to in point ii) above must implement the procedure for accreditation, training and certification of non-conventional therapy professionals before the end of 2005.

None of the above deadlines were met and, to date, none of the measures to which they relate have been implemented or adopted.

The summary of the requirements and questions answered after the deadline or not answered by 30 April 2011, published in *Diário da República*[1] (the official gazette) , reveal a number of initiatives in relation to this topic, although none led to any results. Eight years after coming info force, Law 45/2003 is still awaiting regulation.

The lack of regulation is particularly serious in relation to the rule that establishes that non-conventional therapies can only be practiced by professionals who have the qualifications that are legally required and duly

[1] In *Diário da República*, II Series B – Number 172, 6 May 2011.

accredited for the said practice. As the requirements, legal processes and general procedure for accreditation, training and certification for the activity of non-conventional therapies have not yet been defined, this material is in a legislative void, which creates potential harm for both users and professionals.

This legislative vacuum also has consequences in terms of taxes since, as long as there is no regulation of Law 45/2003, non-conventional therapy professionals remain subject to VAT at the normal rate and this is not the case for the provision of services by other healthcare professionals who are exempt from VAT.
It should be emphasised that the Ministry of Finance and Public Administration has already made an announcement on this issue in response to Question 3401/XI/1.ª: "As Law45/2003 of 22 August has not been regulated, the said activities remain outside the field of application of that VAT exemption [article 9 (1) of the VAT Code - CIVA]".

The most recent initiative on this matter, which took place on 29 July 2011[2], was the draft resolution presented by the parliamentary group Bloco de Esquerda to the Government, by which it recommends the urgent adoption of the measures necessary to re-start the works on the regulation of Law 45/2003, specifically, the definition of a new deadline for the implementation of the process for accreditation training and certification of professionals working in non-conventional therapies.

On 21 October 2011 the Portuguese Parliament approved the draft resolution and, on 9 November, the resolution of the Parliament was published in the official gazette, *Diário da República*. This resolution recommends that the government should proceed with the regulation of Law 45/2003.

In this scenario, it only remains to await the response to the said resolution.

[2] Resolution of the parliament 146/2011, in *Diário da República*, I Series — No. 215, 9 November 2011.

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