Stem Cell Research and Patenting

WORKSHOP

EN 2012
Abstract

This report summarises the presentations and discussions at the Workshop on Stem Cell Research and Patenting, held at the European Parliament in Brussels, on Monday 19 March 2012. The aim of the workshop was to better understand the scientific and legal issues surrounding stem cell research and patenting, in particular to improve awareness about the recent judgement of the Court of Justice of the European Union. The workshop was co-chaired by MEPs Glenis WILLMOTT and Alojz PETERLE.
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The video recording of this workshop is available at:

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<tr>
<td><strong>DG RTD</strong></td>
<td>Directorate General for Research and Innovation, EC</td>
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<td><strong>ECJ</strong></td>
<td>European Court of Justice</td>
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<td>European Science Foundation</td>
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<td><strong>EMRC</strong></td>
<td>European Medical Research Council</td>
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<td><strong>ENVI</strong></td>
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<td><strong>EPO</strong></td>
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<td><strong>FP 6</strong></td>
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<td><strong>GMP</strong></td>
<td>Good Manufacturing Practice</td>
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<td><strong>hESC</strong></td>
<td>Human Embryonic Stem Cell</td>
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<td><strong>IPO</strong></td>
<td>Intellectual Property Office, UK</td>
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<td><strong>iPSC</strong></td>
<td>Induced Pluripotent Stem Cells</td>
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<td><strong>SCNT</strong></td>
<td>Somatic Cell Nuclear Transfer</td>
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EXECUTIVE SUMMARY

On the 19 March 2012, the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament organised a workshop on ‘Stem Cell Research and Patenting’, hosted by Ms WILLMOTT (MEP) and Mr PETERLE (MEP), Co-chairs of the Health Working Group. The aim of the workshop was to increase understanding amongst participants of the scientific and legal issues surrounding stem cell research and patenting in Europe, as well as to improve awareness regarding the recent judgement of the Court of Justice of the European Union.

Technologies involving stem cells have the potential to alleviate and cure human medical problems, including neurological disorders such as Parkinson’s disease and Alzheimer’s disease, degenerating eyesight, organ failure and birth defects to name but a few. However, the possibility of using stem cells for therapeutic purposes raises serious ethical, legal and health issues. As Mr PETERLE pointed out in his opening statement at the workshop, the use of stem cells demands a distinction between ‘what is allowed’ and ‘what is possible’. Further clarity could be provided by legislation and by the interpretation provided by the Court of Justice of the European Union.

The European Union already supported stem cell research under both the Sixth and the Seventh Framework Programmes. The new research framework programme, the so-called Horizon 2020, is now under consideration. In this respect, Ms WILLMOTT stressed that the EU should address the issue of research incentives if it wants to maintain Europe’s leadership position in this area. Ms Willmott also emphasized the importance of better understanding the impacts of the Court’s judgement on this research area.

The first panel consisted of two speakers who provided presentations on the recent ruling of the Court of Justice of the European Union and its practical implications.

Mr Martin MACLEAN, European Patent Attorney, Chartered Patent Attorney and Member of the Life Science Committee for the UK Chartered Institute of Patent Attorneys addressed the fundamentals of the ruling. With regard to the Brüstle v. Greenpeace case, he noted that one of its most important resulting impacts is that stem cell based patent claims are now prohibited if patent ‘embraces’ human embryonic stem cells.

Ms Heli PIHLAJAMAA, Director of the Directorate Patent Law, European Patent Office, spoke about the patentability of stem cells. With regard to stem cell-derived patent applications, she noted that the European Patent Office does not grant European patents for biotechnological inventions that involve the uses of human embryos for industrial or commercial purposes.

The second part of the workshop focused on the present and future clinical applications of stem cells and included presentations from four panellists.

Dr Vanessa CAMPO-RUIZ, Science Officer to the Chief Executive of the European Science Foundation highlighted differences in legislation across Europe, with some countries having strict legislation on stem cell research while others have none. According to Dr CAMPO-RUIZ this discrepancy could result in healthcare tourism.
Recommendations were made regarding flagship principles, such as accurate scientific information, respect for universal human rights, recognition of intellectual property and also the promotion of integrity in healthcare practice.

Dr Anna VEIGA, Scientific Director of the Reproductive Medicine Service of the Barcelona Stem Cell Bank, described how the different sources of stem cells have important implications for legislation, and further highlighted the need to have scientifically-informed definitions to be taken into account by policy-makers.

Professor Petr DVORAK, Head of the Department of Biology at the Faculty of Medicine at Masaryk University, spoke on the subject of human pluripotent stem cells for disease modelling and cell replacement therapy. He addressed safety issues concerned with stem cell-derived therapies, such as immunological compatibility and the potential for tumour formation. He concluded by providing examples of on-going stem cell research, including efforts to address spinal cord injuries, Stargardt macular dystrophy and age-related macular degeneration.

Ms Heather CLARKE, Political Affairs Officer of the European Parkinson’s Disease Association delivered the final presentation of the workshop, which focused on the human dimension of stem cell research. She stressed the hope that the regulation of stem cell research would not impede research in the future and that it would continue to realise its promise.

In her concluding remarks, Ms WILLMOTT expressed her hope that stem cell research will continue in Europe and highlighted the opportunities that may arise from stem cell therapies. Mr PETERLE agreed with Ms WILLMOTT, but at the same time acknowledged that stem cell research raises serious ethical issues, in particular with regard to the destruction of embryos. Mr PETERLE advocated conducting more research and collecting more evidence in order to be sure that new therapies are beneficial for patients.
1. LEGAL AND POLICY BACKGROUND

Stem cells are cells with the ability to develop into different cell types of the body. Although this capability was discovered in the mid-1800s, stem cell research emerged only in the 1990s and has been rapidly developing ever since. Medical applications based on human stem cells have the potential to treat serious and disabling diseases and disorders by replacing and regenerating lost or damaged cells. Human stem cells may come from three main sources: adult cells (typically from the bone marrow), umbilical cord blood cells and embryonic cells. It should be noted that human embryonic stem-cells (i.e. stem cells from a recently fertilized egg) are the only cells that can evolve into the complete range of cells in the human body (totipotent stem cells).

The European Union has provided support for stem cell research in the framework of the Sixth Framework Programme (FP6). About 104 projects were financed by the European Union under FP6, with a total budget of approximately EUR 500 million. Of these 104 projects, 18 involved research on human embryonic stem cell. Stem cell research that involves human embryonic stem cells raises serious ethical issues. As the European Parliament pointed out in its Resolution in 2005, ‘the creation of human embryonic stem cells implied the destruction of human embryos and […] therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation […]’ of applicable EU legislation. This understanding was reflected under FP6 and was also followed under the current Seventh Framework Programme (FP7), in that under both research programmes EU funds cannot be granted to projects in the following research areas: reproductive human cloning; research aiming to alter human genetic stock, such as that modifications become heritable; and research aiming to create human embryos solely for research purposes or for stem cell procurement. While negotiations on the new research framework programme (FP8) are on-going, a recent Communication of the European Commission suggests that the Horizon 2020 programme will follow the same path and will not allow the financing of ‘research activities intended to create human embryos solely for the purpose of research and stem cell procurement, including by means of somatic cell nuclear transfer.’ It is likely that the recent ruling of the Court of Justice of the European Union (CJEU) on the patentability of inventions related to stem cells will impact the outcome of the legislative process.

The landmark decision of the CJEU in the Brüstle versus Greenpeace case clarified that research involving the destruction of embryos cannot be patented. The case was referred before the Court in the framework of a preliminary ruling procedure, on the legal grounds provided under Article 267 of the Treaty of the Functioning of the European Union (TFEU). The procedure concerned the interpretation of Article 6(2)(c) of Directive 98/44/EC of the Biotech Directive, which was adopted with the aim of harmonising the laws of Member States regarding the patentability of biological inventions. Article 6(2) of the Directive lists examples of biological inventions that cannot be granted a patent. One of the examples included in Article 6(2)(c) of the Directive states that in particular the ‘uses of human embryos for industrial or commercial purposes’ are excluded from patentability.

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1 Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation
2 Judgement of the Court of 18 October 2011, Oliver Brüstle v. Greenpeace, Case 34/10.
The Directive fails to define precisely what the terms ‘human embryos’ and ‘industrial or commercial purposes’ cover, which resulted in different legal solutions and practices across the EU. For example, the UK interpreted the provision in a flexible manner and provided about 100 patents on hESC-based invention (Human Embryonic Stem Cell research based invention), whereas Germany followed a more restrictive approach. In its decision the Court declared that ‘any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ if that fertilisation is such as to commence the process of development of a human being.’ The Court also ruled that any investment in the field of biotechnology must respect fundamental rights and in particular, the dignity of person. This judgement and its legal implications are described in more detail under Section 2.1.

As referred to above, the main piece of EU legislation regulating the patentability of stem cells is the Biotech Directive (Directive 98/44/EC). In addition to this Directive, the EU has also adopted Directive 2004/23/EC on human tissues and cells. Directive 2004/23/EC applies to the donation, procurement, testing, preservation, storage and distribution of human tissues and cells intended for human use, including stem cells. The recent Court decision makes it questionable, whether stem cells and tissue-specific cells obtained from a human embryo can at all be used for treatment purposes, due to moral considerations.

The Court judgement may also affect the practices followed by the European Patent Office (EPO). The European Patent Office is the executive body of the European Patent Organisation, which is an international intergovernmental organisation, created under the European Patent Convention, to which all EU Member States are signatories. EPO may grant patent protection for inventions under a centralised application and examination procedure. After being granted, European patents are designated according to the individual Member States. Consequently, cases on the validation and infringement of patents are dealt by with the national competent authorities. EPO, as the executive body of a separate international intergovernmental organisation (i.e. European Patent Organisation), is not bound by EU acquis and is not obliged to follow the rulings of the CJEU. In practice, however, EPO follows a similar pathway to the European Union. As an example, Article 6(2) of the Biotech Directive is almost verbatim reproduced in the Implementing Regulations of EPO. Moreover, EPO tends to interpret patent laws in a manner similar to the CJEU. It remains to be seen how closely EPO will follow the ruling of the Court provided in the Brüstle v. Greenpeace case. EPO has already touched upon the same issues as the Court in its WARF decision, in which the Enlarged Board of Appeal ruled that all inventions are excluded from patentability if their exploitation involved destruction of a human embryo.

The Workshop was organised against this background, and presentations touched upon the legal issues related to stem cell research and patenting, as well as the clinical implications of stem cell research.

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2. PROCEEDINGS OF THE WORKSHOP

2.1. Part I: On the ECJ ruling on patenting research for embryonic stem cells


In her opening remarks, Ms Willmott explained that the catalyst behind the organisation of the workshop was the recent ruling of the Court of Justice of the European Union (CJEU), which made it clear that patents cannot be granted to techniques that are based on the use of human embryonic stem cells. The recent ruling affects many people, including both researchers and patients. Among the other impacts, Ms Willmott said that consequently there is no longer an incentive for conducting further research within the EU and identified the risk that research might move outside Europe. She stressed that Europe must maintain its leadership, especially now during the global economic crisis, and should not lose highly qualified workforce.

Ms Willmott also briefly identified the key issues that the workshop would address, namely the legal framework and related ethical issues, as well as the clinical application of stem cells, and introduced the two representatives of the European Commission, Stefaan van der Spiegel (DG SANCO) and Charles Kessler (DG RTD).

Mr Peterle explained that the expectations and hopes are high regarding stem cell research. At the same time, he noted that stem cell research raises important ethical, legal, economic and health-related questions. The recent judgement of the CJEU needs to be assessed in order to better understand what it means for researchers and patients, as well as other members of the society.

2.1.2. Introduction to the ECJ Ruling - Martin MACLEAN (United Kingdom)


Mr MacLean’s presentation aimed at providing an introduction to the recent CJEU ruling on the patentability of inventions using stem cells, as well as describing the legal and historical background which led to the Court decision.

The Biotech Directive 98/44/EC is the main piece of EU legislation that effects the patentability of stem cells inventions, in particular its Article 6(1) and (2)(c). Article 6(1) of the Directive provides a rather general statement, according to which ‘inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality’. Pursuant to Article 6(2)(c), unpatentable inventions include the ‘uses of human embryos for industrial or commercial purposes.’ The Directive does not define the term ‘human embryo’, which has given rise to confusion and resulted in differentiated practices among national patent authorities.
The Directive has also been implemented by the European Patent Office (EPO), which in principle is not bound by EU legislation given that it is the executive body of the European Patent Organisation, which is a separate international intergovernmental organisation. Article 6(2)(c) of the Directive has been reproduced almost verbatim by Rule 28(c) of Implementing Rules 26-29 EPC.\(^6\)

In line with Rule 28(c), the EPO Enlarged Board of Appeal ruled in its WARF Decision that claims are not permitted to inventions that at the time of filing the application require the destruction of human embryos. The decision also touches upon the question of disclosing information, notably how detailed the application should be in order to allow specialists to take well-informed decisions. Mr MacLean also explained that since 2003, stem cell lines have been commercially available. Therefore, for applications filed after 2003 it can be more easily proven that a product of the patent claim used stem cell lines and did not destroy a human embryo. The assessment of whether a patent can be granted is thereby facilitated. Subsequent applications now include reference to the filing date and use language that explicitly states that no human embryonic stem cells (hESC) were used.

The second half of Mr MacLean’s presentation focused on the recent judgement of the CJEU. In the Brüstle v. Greenpeace case, Mr Brüstle was the holder of a patent, granted in 1997, which involved the use of isolated and purified neural precursor cells, produced from hESC, to treat neurological diseases. Greenpeace brought a revocation case before the German Court on the legal ground that the precursor cell was derived from hECS and thus violated Article 6(2)(c) of Directive 98/44/EC.

The Court, in its judgement, first defined the meaning of ‘human embryo’ and ruled that it covers any human ovum post-fertilisation that ‘is capable of commencing the process of development of a human being.’ According to Mr MacLean, with this definition the Court implicitly differentiates between totipotent and pluripotent stem cells. Moreover in point 49 of the decision, the Court ruled that patents cannot be provided to inventions that have involved the destruction of embryos, even if this destruction took place long before the implementation of the invention. As an example, the Court referred to the production of ‘embryonic stem cells from a lineage of stem cells, the mere production of which implied the destruction of human embryos […]’. In other words, the Court does not allow for patents to be granted to inventions that rely on stem cell lines. As such, it goes beyond the interpretation provided in the WARF Decision by EPO.

Preliminary ruling decisions of the Court are directly binding on national authorities, and thus the decision impacts on patent claims involving stem cells. The judgement may suggest to national patent authorities that they must ban all patent claims embracing hESC, which according to Mr MacLean is a broad interpretation. Mr MacLean also highlighted the unclear character of the term ‘use as base materials’ referred to in point 52 of the Court decision. As the concept of ‘base material’ is not defined in the ruling, national authorities may interpret it in a way that it concerns all products obtained from stem cells. There is no up-to-date guidance available from the EPO, or from national patent authorities such as the UK Intellectual Property Office (IPO), that could serve to elucidate these points.

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2.1.3. The patentability of stem cells- Heli Pihlajamaa (EPO)

_Heli Pihlajamaa: Director of Directorate Patent Law, European Patent Office_

In her presentation, Ms Pihlajamaa described the patentability of inventions related to stem cells and the practice followed by European Patent Office when granting European patents.

The European Patent Office (EPO) is the executive body of European Patent Organisation. The European Patent Organisation became operational after the ratification of the European Patent Convention by its signatories. As of today, 38 countries have become signatories to the Convention, and the scope of application of European patents granted can be extended to two other European countries.

European patents are granted through a single procedure, but following their validation, European patents fall into the bundle of national patents. EPO receives over 250,000 applications each year, out of which 5% concern the patentability of biotech applications. Patent applications are examined and decisions taken by an Examination Division, which consists of three highly qualified specialists (also called as patent examiners). First instance decisions can be appealed before the Board of Appeal and in more complicated cases before the Enlarged Board of Appeal. The European Patent Office has over 4,000 qualified patent examiners, whose work is supported by specialised lawyers. Using statistical data, Ms Pihlajamaa described how out of all biotech applications only 28% lead to patents, demonstrating how carefully EPO examines patent applications. Sensitive cases, such as cases that concern hESC are dealt by with specialist panels.

Ms Pihlajamaa then explained how patents can be granted to inventions that use new techniques, than can be industrially applicable and that involve at least one inventive step. With regard to biotech applications, specific requirements and prohibitions are applied. According to one of the prohibitions, European patents cannot be granted to inventions, the commercial exploitation of which would be contrary to _ordre public_ or morality. Article 6(2)(c) of Directive 98/44/EC have also been reproduced under the European Patent Convention (in 1999) and in its Implementing Rules.

The third part of Ms Pihlajamaa’s presentation focused on the ruling of the CJEU and its implications to EPO practices. As a bottom line, she explained that the practices and decisions of the European Patent Office are in line with the Court judgement, which in the EPO’s point of view is a far-reaching decision, since it defines the terms ‘human embryo’ and ‘industrial and commercial use’.

Ms Pihlajamaa then compared the WARF case with the CJEU ruling and reached a number of conclusions. Firstly, the WARF decision does not define the meaning of embryo, thus the facts are interpreted on case-by-case basis upon examination of all aspects of an application. However, in practice European Patent Office specialists apply a common approach (i.e. technically feasible concept of embryo) which corresponds with the term provided by the Court ruling. Secondly, the CJEU case explicitly excludes from patentability the use of embryos for not only industrial and commercial, but also scientific purposes. Scientific purposes are not reflected in the WARF decisions, as in the view of EPO it is the very nature of invention patents that they are granted for industrial and commercial purposes. Thirdly, Ms Pihlajamaa explained that the views of the CJEU and the EPO are similar with regard to the use of embryos as base materials.
In other words, when the destruction of an embryo is required in order to permit the invention for which a patent is claimed, then the application is prohibited as it falls under exclusion for patentability.

Finally, Ms Pihlajamaa referred to the guidelines prepared by EPO on examination practices. The next edition of these guidelines will enter into force in June 2012, and will introduce a minor change to patentability practices. The draft version of these guidelines was due for publication at the end of March 2012.

2.1.4. First Rounds of Questions and Answers

After the first part of the workshops, Ms WILLMOTT opened the floor for questions.

The first question was asked by Dr VEIGA and related to the definition of embryo. This question looked into the meaning of the term, and in particular aimed to clarify whether the term covers also parthenogenetic embryos. In Dr VEIGA’s view parthenogenesis never leads to a birth of a human being, and thus it cannot be considered as something that generates an embryo.

Ms PIHLAJAMAA explained that according to EPO practices, parthenogenesis is considered as a theoretical mean that may lead to the development of a human being, thus no patents can be provided to inventions making use of parthenogenesis.

The second question was rather hypothetical and concerned the potential patentability of a non-compound that was developed by using a human embryonic stem-line as a base-material. In this hypothetical example, the patent application related to the use of the non-compound for differentiating an embryonic stem cell to a neurogenic cell. It was also specified that this non-compound could apply not only to embryonic stem cells, but also to adult cells and induced pluripotent stem cells. In other words, the question touched upon the issue of what EPO considers as a base material.

In Mr MACLEAN’s view, the patent application in such cases should contain a disclaimer that the subject of the claim does not read into effects involving hESC. Ms PIHLAJAMAA presented the EPO’s point of view by saying that EPO takes decisions on a case-by-case basis after taking into consideration all the technical features of the application. In line with the recent Court decision, EPO would most probably refuse such patent application.

The third question concerned the potential impacts of the recent Court judgement on research activities in the EU. In his answer, Mr KESSLER from DG RTD referred to the European Commission’s Communication of 31 November 2011 on the new Horizon 2020 research framework programme, which contains reference to stem cells and also to hESCs. The Communication follows the same approach as the previous Sixth and Seventh Framework Programmes, namely it excludes certain hESC related research from EU funding.

The last question was posed by Mr PETERLE and also concerned the upcoming Horizon 2020 Programme. In his question, he asked whether the Court judgement has had any impacts whatsoever on the policy process for the Horizon 2020 proposal.

Mr KESSLER in his answer emphasized that the proposal aims to follow the approach developed by previous framework programmes. He said that the Court judgement was only the first step on a long road, noting that it is too early to judge how the industry will develop and what types of patent applications will appear in the future. Emerging economic and patent models might shape both the applicable legal framework and research programmes.
2.2. **Part II: Present and future clinical applications of stem cell research**

2.2.1. **Human Stem Cell Research and Regenerative Medicine: an EMRC perspective - Dr Vanessa Campo-Ruiz (ESF)**

*Dr Vanessa Campo-Ruiz: Science Officer to the Chief Executive, European Science Foundation*

Dr Campo-Ruiz addressed the topic of human stem cell research and regenerative medicine from the European Medical Research Council’s point of view. The European Medical Research Council (EMRC) works under the European Science Foundation (ESF), and has the remit of promoting innovative medical research and its clinical application in order to achieve improved human health. The EMRC also advocates on behalf of the biomedical community, provides expert advice on research management and ethics, and disseminates knowledge with the aim of promoting biomedical research to the society. EMRC’s remit covers all aspects of biomedical research, including both basic and clinical research. The European Science Foundation counts 72 member organisations, including research funding organisations, research performing organisations and academies and learned societies from 30 European countries.

After the short introduction on EMRC and ESF, Dr Campo-Ruiz referred to the joint reports of the two organisations that are published in forms of ‘Science Policy Briefings’, and that address key science policy issues relevant to member organisations and the scientific community. These reports are aimed at providing evidence-based strategy recommendations to policy makers and leaders.

Among the ‘Science Policy Briefings’, two concern stem cell research, the first of which was published in 2002 and the second in 2010. The latest report, called ‘Human Stem Cell Research and regenerative Medicine: A European perspective on Scientific, Ethical and Legal Issues’⁹ formed the focus of Dr Campo-Ruiz’s presentation. The report includes the following five chapters: sources of stem cells; clinical applications in regenerative medicine and regulations; ethical and legal issues; legislation across Europe; and access to therapies.

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⁹ The report is available under the following web link: [http://www.esf.org/publications/science-policy-briefings.html](http://www.esf.org/publications/science-policy-briefings.html).
Among the five chapters, Dr Campo-Ruiz described in more details the second one on clinical applications. The first point she touched upon was the applicable regulatory framework, which includes the Tissues and Cells Directive,\textsuperscript{10} the Clinical Trials Directive on Medicinal Products,\textsuperscript{11} as well as the Transplants and Advanced Therapy Medicinal Products Regulation.\textsuperscript{12}

The ESF has published reports on clinical trials, that include a report from 2009 on 'Investigator Driven Clinic Trials',\textsuperscript{13} the main findings of which have been fed into a 2011 ESF-EMRC position paper looking at the possibilities for revising Directive 2001/20/EC.\textsuperscript{14} This chapter of the report also describes the choice between treatment strategies and touches upon the role of safety studies, in particular of animal studies.

Dr Campo-Ruiz also summarized the main ethical concerns that may arise from stem cell research, including: dilemmas related to the sources of stem cells (i.e. tissue banks, surplus tissue); controversy concerning consent forms from patients and the early animal hybrids that have been created; and most recently concerns regarding induced pluripotent stem cells. The report also refers to the role of private companies and personal stem cells, in the context of guaranteeing the quality of stem cells and at the same time ensuring social justice.

In terms of applicable legislation, Dr Campo-Ruiz highlighted existing differences across European countries. As of 2010, 25 European countries prohibited reproductive cloning and seven countries had laws on hESC research and the derivation of new cell lines, whereas the remaining countries neither prohibited nor allowed such practices. Three countries allowed for the creation of embryos for research purposes under strict conditions, 17 had laws on the procurement of stem cells from supernumerary embryos and six had no legislation whatsoever on stem cell research. Existing differences in legislation put researchers, innovators and entrepreneurs conducting cross- and multi-country research projects into a difficult situation. Moreover patients’ access to treatment varies. Dr Campo-Ruiz explained that such differences may lead to ‘healthcare tourism’ and potentially to ‘ethical inequalities in society’. She suggested that the European legislators look into these issues.


\textsuperscript{13} The report is available under the following web link: \url{http://www.esf.org/fileadmin/links/EMRC/FL_IDCT.pdf}.

\textsuperscript{14} The position paper is available under the following web link: \url{http://www.esf.org/publications/science-position-papers.html}.\n

In her concluding remarks, Dr Campo-Ruiz described the main controversy surrounding stem cell research, namely the challenge of addressing new social dilemmas versus the opportunities presented by stem cell research for revolutionary therapies. In the view of ESF and EMRC, these challenges can be met by respecting the following five principles:

1. building on accurate scientific information;
2. building on diverse ethical principles across nations;
3. respecting universal human rights;
4. recognising and fostering intellectual property; and
5. ensuring the integrity in healthcare practice.

Finally, Dr Campo-Ruiz drew the audience's attention to a recent ESF-EMRC White Paper on ‘Stronger Biomedical Research for a Better European Future’.¹⁵

2.2.2. New Sources and Heterogeneity of Pluripotent Stem Cells - Dr Anna Veiga (Spain)

Dr Anna Veiga: Scientific director of the Stem Cell Bank at the Centre of Regenerative Medicine and director of the Reproductive Medicine Service Biomedical Research Park, University Institute Dexeus, Barcelona

Dr Anna Veiga explained that it is very important, especially for policy makers, to understand exactly what stem cells are and the ways in which they can be used. The significant differences in the developmental potential of stem cells from different sources were highlighted, including totipotent, pluripotent, multipotent and unipotent stem cells. Particular emphasis was put on the fact that only totipotent cells have the potential to give rise to a human being, whereas pluripotent cells cannot. Pluripotent stem cells may be obtained from cells located in the inner cell mass of blastocysts, such as from an embryo, or via nuclear reprogramming. While there are two processes whereby pluripotent stem cells can be reprogrammed by nuclear means, the method of Somatic Cell Nuclear Transfer (SCNT) has been largely abandoned and replaced by the technique Induced Pluripotent Stem Cells (iPSC). Human stem cells necessitate the destruction of an embryo in order to create a hESC line. Although it has been claimed that it is possible to obtain hESC from a single blastomere, these reports are considered to be of a marginal methodology.

Induced Pluripotent Stem Cells may be induced to differentiate to an embryonic-state via the introduction of highly-defined transcription factors that are introduced into somatic cells, which are then cultured under embryonic conditions. The choice of transcription factors has grown immensely since the initial publications of Yamanaka in 2006 and 2007. Importantly, utilising this technique does not require the destruction of a human embryo. There are various ways in which these transcription factors may be introduced to the somatic cell, although it is usually via a virus vector. There are inherent problems when using different somatic cells from which to begin the process. For example, the use of keratinocytes is possible, but requires far greater effort than with, for example, cord blood cells, to achieve pluripotency. The closer the somatic cell is to a pluripotent state, the easier it is to convert into embryonic-like stem cells.

¹⁵ The White Paper is available under the following web link: www.esf.org/index.php?...European%20Science%20Funding%20of%20Research%20Brussels.
Further, Dr Veiga explained that although iPSC may be very similar to embryonic stem cells, they do in fact differ. Heterogeneity in stem cell populations provide for problematic outcomes such as chromosomal abnormalities and oncogene activation. There is also the matter of epigenetic memory, whereby DNA methylation signatures characteristic of the cells’ origin may exist. Skin cells may remember they were skin cells, for example, thereby leading to restricted alternative cell differentiation. The use of human iPSC provides far more opportunity for aberrations in differentiation than hESC. This increased heterogeneity has been demonstrated in many published scientific papers.

Finally, Dr Veiga briefly explained some of the challenges for this potential new cell therapy, such as immunologic rejection, the possibility of tumour formation, differential efficiency in cell populations, and GMP (Good Manufacturing Practice) in production.

### 2.2.3. Stem Cell Therapy - Prof. Petr Dvorak (Czech Republic) and Heather Clarke (EPDA)

**Prof. Petr Dvorak: Department of Molecular Embryology, Masaryk University, Prague**

Prof. Dvorak stated that the two important features of stem cells are that they have the capacity to copy themselves, either by symmetric or asymmetric division, and that they can differentiate into different types of cells. In addition, the possibility to expand embryonic stem cells in culture to an unlimited quantity confers a huge advantage over the more mature adult stem cells. The origin of adult stem cells is still not fully understood and they are far more problematic to work with.

Prof. Dvorak explained some of the main medical applications that may be possible using stem cells, pointing out the opportunities to provide great scientific insight. The use of human pluripotent stem cells in disease modelling was elaborated. Through generating mutant pluripotent stem cells for studying disease and drug development, there is a vast wealth of scientific information that may be uncovered and harnessed.

There are now 45 human diseases that have been modelled using iPSC, and 13 of these diseases show very similar phenotypes to actual human diseases, while five show a partial phenotype. This makes it possible to test new drugs and new modes of treatment on these cell lines.

The potential of stem cells in the treatment of human diseases, such as the ex-vivo repair of genetic mutations, provides a vision of the future where patients could use their own somatic cells to generate individual iPSC, which were then transplanted back to the patient. This would, for example, avoid any immunologic compatibility problems for the patient. Lastly, another potential use of these differentiated cell progeny is in replacing damaged or missing cell types in a person.

There are still many scientific barriers to fully realising this potential. Further insight is needed into such issues as optimal culturing conditions, the mechanisms of self-renewal and cellular differentiation. There are also safety issues concerned with stem cell-derived therapies, including immunological compatibility and the population diversity of pluripotent stem cell lines. However, advances are being made to address these problems. Echoing Dr Veiga, Prof. Dvorak pointed to greater concerns with the use of pluripotent stem cells as opposed to embryonic stem cells, in that there is greater genetic instability and heterogeneity, along with possibilities such as oncogene activation.
At the same time, it must be remembered that both iPSC and embryonic stem cells harbour the same genes necessary for tumour formation. Mention was made of the ethical and legal barriers and obstructions to stem cell research.

Prof. Dvorak concluded with an outline of some promising stem cell research currently underway, such as efforts to address spinal cord injuries, Stargardt macular dystrophy and age-related macular degeneration.

**Heather Clarke: Policy Officer, European Parkinson’s Disease Association**

Ms Clarke spoke on behalf of the European Parkinson’s Disease Association, an umbrella organisation with 45 member organisations that represents the interests of people living with the disease and of their family members.

Ms Clarke presented the question of stem cell research and patenting from the patients’ point of view - in particular from the point of view of those suffering from Parkinson’s disease, a degenerative disorder of the central nervous system. Parkinson’s disease results from the death of neurons in the brain. These neurons produce dopamine, which is a chemical messenger responsible for transmitting signals between the nerve cells that allow for the coordination of movements. Parkinson’s is a chronic disease which affects every aspect of the patient’s daily life, and produces well-known symptoms such as tremor, and other less commonly known symptoms such as rigidity, pain and depression. After Alzheimer’s disease, Parkinson’s is the most common neurological disease, affecting about 1.2 million people in Europe. By 2030 this number is forecasted to double, because of the ageing population. The disease has economic impacts, especially at the latest stage of the disease. Ms Clarke explained that Parkinson’s disease costs society around 13.9 billion Euros annually.

Current treatments do not offer adequate symptom management options for patients, and they may cause major side-effects. Ms Clarke then presented the symptoms (e.g. loss of control over movements, hallucinations, behaviour change, and aggressiveness) and their severity through the real story of a friend of hers who suffers from the disease. The stigmatism of patients with Parkinson’s disease was also reflected upon.

People with Parkinson’s disease need new treatments and therapies. In this context Ms Clarke explained the role played by the European Parkinson’s Disease Association, namely that it supports innovative research aimed at understanding the causes and preventing the disease. Stopping the progression, reversing brain damage and ultimately curing Parkinson’s disease also constitute objectives of the Association.

Today, there exist innovative research programmes that may eventually lead to improvements in the lives of people with Parkinson’s disease, which include promising research on embryonic stem cells. Stem cells, because of their high biological flexibility, may have the potential to replace damaged neuron cells in the brain and reverse the effects of Parkinson’s disease. Ms Clarke said that the main advantages of stem cells are that they are expandable and renewable sources, which may positively affect the standardisation of treatment, a hurdle in obtaining successful outcomes from transplantations. However, research has proved that stem cells may result in uncontrolled growth of cells and may lead to other chronic diseases such as cancer. Ms Clarke therefore concluded that ‘more research must be done in order to understand the way these cells work and in order to ensure that safe treatments are developed.’
While it was acknowledged that in the future other cells or therapies might be developed with positive results, for the time-being embryonic stem-cell research is one of the most interesting sources of new therapies for Parkinsons’ disease. Finally, Ms Clarke welcomed the Horizon 2020 proposal of the European Commission and encouraged the European Parliament to endorse it.

2.2.4. Second Round of Questions and Answers

Before opening the second rounds of questions, Mr PETERLE said that the European Parliament wishes to be informed about stem cell research and new therapies, stating that the workshop has played a particularly important role in this respect. He explained that stem cell research raises the big dilemma of ‘what is possible’ and ‘what is allowed’, and noted that legislation constitutes part of the answer to these contradictory questions.

In responding to this point, Dr VEIGA provided a description of the use of iPSC in stem cell research. Human embryos do not need to be destroyed for that type of research. Despite all the results achieved by iPSC research, there is still a need to conduct research on human embryonic stem cells, as it is important to compare the results of research on hESCs and iPSCs. Dr Veiga then continued that most probably there is no need to derive new hESCs, but rather there is a need to use those that already exist.

Karen BUCKER asked Dr Veiga whether it is possible to obtain totipotent stem cells from sources other than the human embryo. Dr VEIGA explained that the only source of totipotent stem cell is the human zygote. Totipotent cells can be developed into the foetus, as well as into any type of extra-embryonic cells.

The third question concerned the clinical applications of stem cells in the light of the recent Court judgement. It was explained that in his view the Court judgment leaves it up to the Member States to judge if cells taken at the blastocyst stage can be considered as totipotent stem cells. Dr VEIGA was asked to share her views on this issue as a scientist. She highlighted the differences between the cell of an embryo and the embryo, as well as between hESC and an embryo. She explained that not only a totipotent cell can be developed to a human being, but an iPSC cell can also be induced to develop into a human embryo (this latter would be called as a chimera). She explained that this latter practice is not legally and scientifically feasible.

Following this explanation, the question was reformulated in such a way to focus only on cells obtained from the morula. Dr VEIGA explained that scientifically there is no added value in obtaining a cell from the morula, which is totipotent, in order to develop an embryonic stem cell line from it. Mr MACLEAN responded to the question from a patent attorney’s perspective, by saying that the cell obtained from the morula would most probably be considered as a base material and consequently the application would fail.

The fourth question was addressed to the European Commission and concerned the potential impacts of the Court Decision on Regulation (EC) No 1394/2007. Mr VAN DER SPIEGEL said that it is too early to give a well-established opinion on this, as research involving hESC is still relatively new. He explained that there is a possibility that the Court decision will affect the Regulation, as market authorisation processes and patents might no longer give exclusivity.
Dr CAMPO-RUIZ pointed out that researchers are incentivized by the possibility of their product being granted by a patent. Mr VAN DER SPIEGEL, in his response, differentiated between the role of patents that incentivise researchers at the beginning of projects and market authorisation that may be granted at the end of the process, i.e. once the product has been developed.

The fifth question enquired whether it is possible to amend existing legislation in such a way to allows for research on embryonic stem cells. In his answer, Mr VAN DER SPIEGEL referred to the existing mandate of the European Union, which allows the EU to legislate in order to ensure ‘safety and quality’. This mandate gives enough room for incentivising research and address current safety and quality challenges.

With regard to this point, Mr MACLEAN said that in his view the mandate of the EU, i.e. regulating in order to ensure ‘safety and quality’, is self-limiting. According to Mr MACLEAN, patenting gives more flexibility to those who seek to carry out further research on hESC, assuming that researchers respect the applicable technological requirements.

The next question asked for clarification with regard to the conditional market authorisation requirements. Mr VAN DER SPIEGEL explained that conditional market authorisation only applies to new marketing authorisation applications and can be granted to certain medicinal products, such as medicinal products for rare diseases, orphan medicinal products, or medicinal products to be used in emergency situations.

**2.2.5. Conclusions: Glenis WILLMOTT (MEP), Alojz PETERLE (MEP)**

In her concluding remarks, Ms Willmott referred to the fact that there are still some issues to be clarified following the judgement of the CJEU. In particular, it is important to clarify intellectual property rights. She acknowledged the opportunities that arise from stem cell therapies, but warned that there are still many challenges to address. Ms Willmott also expressed her wish to ensure that research stays in Europe, which in her point of view would be beneficial for both researchers and patients.

Mr Peterle followed the same path as Ms Willmott. While highlighting that stem cell research may lead to new therapies, he also warned that such therapies may give rise to serious ethical and legal issues. Among the ethical issues, the destruction of embryos was mentioned. The Court has made it clear in its judgement that embryos are to be considered as human beings from the moment of fertilisation.

Mr Peterle advocated conducting more research and collecting more evidence in order to be sure that new therapies are beneficial for patients. With regard to the commercial use of hECS, Mr Peterle stated that the EU should ensure that legal frameworks developed and applied by Member States are similar and that there is no room for ‘health tourism’ and business speculation. He also encouraged to European Union to play a bigger role at the international level.
ANNEX 1: AGENDA

WORKSHOP ON
'STEM CELL RESEARCH AND PATENTING'

Monday, 19 March 2012 from 16.00 to 18.00
European Parliament, Room ASP A5G-2, Brussels

Organised by Policy Department A - Economic & Scientific Policy
for the Committee on the Environment, Public Health and Food Safety (ENVI)

AGENDA

16:00 - 16:05  Welcome and opening by Co-chairs of the Health Working Group
Glenis WILLMOTT and Alojz PETERLE, MEPs

European Commission: Stefaan Van Der Spiegel, from the Directorate D- Health Systems
and Products, Unit D4 - Substances of Human Origin and Tobacco Control (DG SANCO),
and Charles Kessler from the Directorate Health, Unit F4 - Advance Therapies and Systems
Medicine (DG RTD) will attend the meeting and participate in the debates.

Part 1: On the ECJ ruling on patenting research for embryonic stem cells

16:05 - 16:15  Introduction to the ECJ ruling
and biotechnology specialist. Member of the Life Sciences Committee for the UK Chartered
Institute of Patent Attorneys (CIPA) (UK).

16:15 - 16:25  The patentability of stem cells
Heli Pihlajamaa, Director of Directorate Patent Law, European Patent Office (EPO)

16:25 - 16:45  Question time
Part 2: Present and future clinical applications of stem cell research

16:45 - 16:55  Human Stem Cell Research and Regenerative Medicine: an EMRC perspective
Dr Vanessa Campo Ruiz, Science Officer to the Chief Executive, European Science Foundation.

16:55 - 17:05  New Sources and Heterogeneity of Pluripotent Stem Cells
Dr Anna Veiga, Scientific director of the Stem Cell Bank, Center of Regenerative Medicine in Barcelona. Reproductive Medicine Service Biomedical Research Park, University Institute Dexeus. European Society of Human reproduction and embryology (ES)

17:05 - 17:20  Stem Cell Therapy
Prof. Petr Dvorak, Department of Molecular Embryology, Masaryk University, Prague (CZ)
Heather Clarke, European Parkinson's Disease Association.

17:20 - 17:55  Question time

17:55 - 18:00  CONCLUSIONS

18:00  CLOSING
Annex 2: SHORT BIOGRAPHIES OF THE EXPERTS

**Martin MACLEAN**

Mr MacLean is a Chartered Patent Attorney and European Patent Attorney. He qualified as a patent attorney in 1999, and became a partner of the firm Mathys & Squire in 2004. Martin has a first degree in microbial technology and a PhD in biochemistry (both from Warwick University). He also has a Masters degree in Intellectual Property (IP) from London University.

Martin specializes in IP relating to technologies such as toxin-based therapeutics, vaccines, stem cells, and siRNA, and represents clients ranging from government departments and blue chip biotech companies, through to spin-outs and start-ups. Martin’s principal practice areas include patent drafting and prosecution, together with patent defence and opposition proceedings, and his experience includes over 100 Hearings before the European Patent Office. Chambers (2011; and 2012) ranks Martin as a ‘Key Individual’ for biochemistry and biotechnology patents and praises him for being “diligent and proactive, and provides excellent strategic advice” (2011) and "relaxed, personable and approachable" (2012). Martin also comes highly recommended by Legal 500 (2012). Martin is a member of the Life Sciences Committee for the UK Chartered Institute of Patent Attorneys (CIPA), and acts as a tutor for the UK and European Qualifying Examinations. He also serves as a lecturer and clinician for CIPA.

**Heli PIHLAJAMAA**

Ms Heli Pihlajamaa studied Law at the University of Helsinki, Finland and completed her postgraduate studies at the Max Planck Institute for Intellectual Property, Competition and Tax Law. She worked for the Finnish Patent and Registration Office and for a patent attorney’s office in Helsinki before moving to Munich in 1996 to take up a post as lawyer in Directorate Patent Law at the European Patent Office. For several years Ms Pihlajamaa taught Industrial Property Law at the Technical University of Helsinki, Finland. She has published books and newspaper articles on patent law in Finnish. In January 2011 she became Director of the Patent Law department.

**Dr Vanessa CAMPO-RUIZ**

Vanessa Campo-Ruiz serves as the Science Officer to the CEO of the European Science Foundation (ESF). Her work focuses on advising on international science policy developments and corporate intelligence issues, identifying opportunities, building alliances with international organizations, and managing overarching science policy initiatives in domains such as international collaborations, research integrity, research careers, gender balance, education, science policy management, or biomedical research policy. Dr Campo-Ruiz is also an elected member of the Governing Board of Euroscience. Vanessa Campo-Ruiz received her MD PhD from Complutense University in Madrid, Spain, with a summa cum laude and a Special Award in Medicine. She also trained in business management at IESE Business School, and in European Affairs at Spain’s School of Diplomacy. She has work experience across Europe and in the USA, and speaks Spanish, English, French, German, and Italian.
Dr Anna VEIGA

Dr Veiga holds a PhD in Biological Sciences from the Autonomous University of Barcelona. Between 1982 and 2004 she was the head of in vitro fertilization laboratory at the Dexeus Institute’s Department of Reproductive Medicine. She is currently the Scientific Director of the Reproductive Medicine Service, the Director of the Stem-Cell Bank at the Centre of Regenerative Medicine of Barcelona and acts as an associate professor at the Department of Reproductive Medicine at the Dexeus University Institute. Dr Veiga is the member of the International Centre for Scientific Debate Scientific Committee. Since the early times of in vitro fertilisation, Dr Veiga has been highly involved in the development of Reproductive Technologies (ART) and has published many related articles in both national and international journals. Her main areas of interests are fertility and assisted reproduction, genetics and reproduction, embryonic development and pre-implantation genetic diagnosis, as well as embryonic and pluripotent stem cell research.

Prof. Petr DVORAK

Petr Dvorak is a Professor of Molecular Biology and Genetics at Masaryk University, Brno, Czech Republic. He is the head of Department of Biology, one of the key research departments of the Faculty of Medicine. Since 2011, he has also been serving as the vice-rector for research. He has been involved in the Czech dialogue on embryonic stem cell policy since 2003, when his group derived several lines of human embryonic stem cells. Petr Dvorak is interested in fibroblast growth factor signalling in human embryonic as well as in induced pluripotent stem cells and several specific topics related to their differentiation, genomic stability, and use for drug development. He has published many research articles and reviews in the biology of embryonic stem cells and he has worked on several national and European projects focused on the development of tools for medical application of stem cell research and contextual regulatory issues (e.g. ESTOOLS, European Human Embryonic Stem Cell Registry).

Heather CLARKE

Heather Clarke worked in the European Parliament for many years as an assistant to four parliamentarians. From 2006 - 2010 she worked for the International AIDS Vaccine Initiative [IAVI].She joined the European Parkinson's Disease Association [EPDA] team as the European Political Officer in 2011. Her daily work is motivated by a friend who has Parkinson’s. “The impact the illness has on him and his family drives me.” EPDA is 20 years old this year. The EPDA is the only European umbrella organisation for Parkinson’s disease and represents 45 member organisations advocating for the rights and needs of more than 1.2 million people with Parkinson’s and their families. EPDA’s vision is to enable all people with Parkinson’s in Europe to live a full life while supporting the search for better treatment and ultimately a cure.
ANNEX 3: PRESENTATIONS

Presentation by Martin MacLean

Introduction to the ECJ ruling

The Biotech Directive

- EU Directive 98/44/EC (binding on EU Member States)
  - Article 6(1): excludes from patentability inventions whose commercial exploitation would be contrary to *ordre public* or *morality*
  - Article 6(2)(c): explicitly excludes “uses of human embryos for industrial or commercial purposes”

- Implemented via national law
  - e.g. in the UK by Patents Regulations 2000 (SI 2000/2037)

- EPO is not an EU Member State
  - The EPO implemented the Biotech Directive (via Rules 26-29 EPC), notably via Rule 28(c) EPC for ‘stem cell’ inventions
‘WARF’ – EPO EBoA Decision G2/06

- The EPO Enlarged Board of Appeal (EBoA) held that Rule 28(c) EPC prevents grant a patent claim directed to a product which [could only be prepared] by a method that necessarily involved the destruction of a human embryo

- The following questions were not answered by the EBoA
  - Q3. If Rule 28(c) EPC does not prevent the grant of such a patent claim, does the wider scope of Article 53(a) EPC prevent grant of such a patent claim?
  - Q4. Does it make a difference if, after the filing date, the product of the patent claim could be obtained without the need to destroy an embryo (ps. human embryonic stem cell lines became commercially available in May 2003)

Practical effect post-‘WARF’ (G2/06)

1) EPO
   - Followed G2/06 and thus continued to refuse patent claims directed to products which could only be prepared by a method that necessarily involved the destruction of a human embryo
   - Allowed corresponding patent claims in applications having a filing date after May 2003
   - Possibly an additional EPO requirement that patent claims must explicitly include language that explicitly excludes “human embryonic stem cells” – this additional requirement has not been rigorously applied by the EPO

2) UK IPO
   - Patent claims for processes of obtaining stem cells from human embryos are not allowed (even if the embryo is not destroyed). Patent claims for pluripotent (though not totipotent) human embryonic stem cells are allowed.
   - see UKIPO Practice Notes issued April ’03 & 3 Feb ’09
   - Approved G2/06
   - see UKIPO Practice Note issued 3 Feb ’09
CJEU Case C-34/10 – Oliver Brüstle v Greenpeace eV

Background

- O. Brüstle is the proprietor of a German patent which concerns isolated and purified neural precursor cells, processes for their production from embryonic stem cells, and the use of neural precursor cells for the treatment of neural defects.

- Clinical applications in e.g. the treatment of Parkinson’s disease.

- Greenpeace eV brought a revocation action (in the German Federal Court) on the grounds that the neural precursor cells are derived from human embryonic stem cells in violation of Article 6(2)(c).

CJEU Case C-34/10 Cont’d...

The Decision

- The CJEU Decision goes much further than G2/06 ‘WARF’. In particular, the CJEU held that:

  - the term “human embryo” covers any human ovum after fertilisation (whether by artificial or natural means) that “is capable of commencing the process of development of a human being” [Point 37]

  - “the fact that destruction may occur at a stage long before the implementation of the invention….is... irrelevant” [Point 49]

  - “Article 6(2)(c) of the Directive excludes an invention from patentability… [if] the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place” [Point 52]
The Impact of CJEU Case C-34/10

- All patent claims embracing human embryonic stem cells are prohibited
  - This prohibition impacts on patent claims directed to stem cells (or the use thereof) where said patent claim embraces human embryonic stem cells (even when said stem cells could be obtained from a publicly available stem cell line)
  - The prohibition would appear to extend to patent claims directed to products obtained from said stem cells (e.g., where the stem cells are used as "base material"—[Point 52])
- To-date, no updated 'guidance notes' have been issued by the EPO or the UKIPO in response to CJEU Case C-34/10

Questions?

- Martin MacLean
  BSc PhD MSc CPA EPA
  PARTNER

MATHYS & SQUIRE
INTELLECTUAL PROPERTY

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Presentation by Heli Pihlajamaa

EPO Practice under A53(a) and R28(c) EPC and CJEU Decision C-34/10

Heli Pihlajamaa
Director
Patent Law (5.2.1)  
Brussels 19 March, 2012

The European Patent Office

The executive body of the European Patent Organisation, an intergovernmental organisation grounded by the European Patent Convention (signed 1973)

Our mission:
As the patent office for Europe, we support innovation, competitiveness and economic growth across Europe through a commitment to high quality and efficient services delivered under the European Patent Convention
Biotech patent applications at the EPO

- The EPO received almost 250,000 patent applications in 2011
  - less than 5% of all applications in biotech

Very strict quality standards
- the EPO is ranked n°1 in the world for the quality of patents
- average grant rate for all technical fields is around 45%
- only about 28% of biotech applications lead to a patent
- high examiner awareness for "sensitive cases"

Exceptions to Patentability

European patents shall not be granted in respect of:
(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; […]

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
[…]  
(c) uses of human embryos for industrial or commercial purposes;

Ruling C-34/10 of the CJEU and EPO Practice

CJEU Ruling C-34/10 main conclusions concern:
- definition of embryo
- scientific research as industrial and commercial use
- technical teaching

⇒ The practice and earlier case law at the EPO are already in line.

Definition of "embryo"

I. CJEU Decision C-34/10 (Bristle, 18.10.2011, reasons 35-36 and holding 1):
The concept of 'human embryo' within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense, namely to cover any organism capable of commencing the process of development into a human being.

"Article 6(2)(c) of the Biotech-Directive must be interpreted as meaning that:
- any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo';
- it is for the referring court to ascertain, in the light of scientific developments, whether a stemcell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within this meaning."

II. Compare EBA Decision G2/06 (Use of embryos/WARF, 25.11.2008, reason 20):
The term "embryo" in Rule 28(c) EPC is not to be given any restrictive meaning; what is an "embryo" is a question of fact in the context of any particular patent application.
Scientific Use

I. CJEU Decision C-34/10 (Brügge, 18.10.2011, holding 2):
"The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of the Directive also covers use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable."

"Making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research [...] only inventions for therapeutic or diagnostic purposes applied to the human embryo and useful to it [are] not excluded from patentability."

Use Required But Not Claimed

I. CJEU Decision C-34/10 (Brügge, 18.10.2011, holding 3):
"Article 6(2)(c) of the Directive excludes an invention 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."

II. Compare EBA Decision G2/06 (Use of embryos/WARF, 25.11.2008, reasons 22 and 24):
"What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since [...] the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) [...] EPC [...]"
"[...] it is of no relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos."
Presentation by Dr Vanessa Campo Ruiz

Human Stem Cell Research and Regenerative Medicine: an EMRC perspective

Workshop on Stem Cell Research and Patenting

European Parliament, Brussels, 19 March 2012

Vanessa Campo-Ruiz, MD PhD
Science Officer to the Chief Executive
European Science Foundation (ESF)

The European Science Foundation and EMRC

ESF: 72 Member Organisations
- research funding organisations
- research performing organisations
- academies and learned societies in 30 European countries.

ESF coordinates research and provides science policy advice in all scientific domains

EMRC
**EMRC**

**European Medical Research Councils**

**Mission:**
To promote innovative medical research and its clinical application towards improved human health.

**Roles:**
- To advocate on behalf of the biomedical community.
- To advise on policy making, research management, ethics and improved health services, and
- To disseminate knowledge to promote the socioeconomic value of biomedical research to society and decision-makers.

**EMRC’s Scope**

**Biomedical Research**

1. Basic Research
2. Translational Research
3. Clinical Research
4. Epidemiology & Prevention
ESF- EMRC Science Policy Briefings

Reports that

- Address **key science policy issues** relevant to Member Organisations and the scientific community
- Leverage on the **expertise and vision** of top-level researchers
- Provide **evidence-based strategy recommendations** to policy makers and leaders

Science Policy Briefings on Stem Cells, 2002 and 2010

2010: 
**Human Stem Cell Research and Regenerative Medicine: A European Perspective on Scientific, Ethical and Legal Issues**
SPB  5 Main Points

1. Sources of Stem Cells

2. Clinical Applications in Regenerative Medicine and regulations:
   - 2004-2006  Tissues and Cells Directive
   - 2001 Clinical Trials Directive on Medicinal Products

Clinical Applications (cont.)

Clinical proof of concept: Clinical Trials

- 2009 ESF FL Report on Investigator-Driven Clinical Trials

- 2011 ESF-EMRC Position Paper
  Proposal for a Revision of the Clinical Trials Directive (2001/20/EC) and other recommendations to facilitate clinical trials
2. Clinical Applications (cont.)
- Choice of Treatment Strategies
- Safety studies including animal studies

3. Ethical and Legal Issues
- Sources: Tissue banks, “surplus tissue”; consent forms, early human-animal hybrids and induced Pluripotent Stem Cells
- Private companies and personal cell banks: quality assurance & social justice
- Transplants and Advanced Therapy Medicinal Products: 2007 EC Regulation

4. Legislation Across Europe: “ESF countries”:
- 25 prohibit human reproductive cloning
- 7 have laws on hESC research and derivation of new cell lines (but some others, neither prohibit nor allow it!)
- 3 allow the creation of embryos for research purposes, under strict conditions
- 17 have laws on procurement of cells from supernumerary embryos
- 6 have no legislation regarding stem cell research

The issue is very complex: ethical dilemmas vary across stem cells (iPS versus hESC)
5. Access to therapies:

Different legislation may mean different access to treatments, leading to “healthcare tourism” and ethical inequalities in society.

CONCLUSION

- Stem cells grant the opportunity for revolutionary therapies and the challenge of new social dilemmas.

- Europe can meet this challenge incorporating some flagship principles:
  - accurate scientific information
  - diverse ethical principles across nations
  - respect for universal human rights
  - recognition of intellectual property, and
  - integrity in healthcare practice
ESF- EMRC
White Paper

A Stronger
Biomedical Research
for a Better
European Future

Thank you for your attention

European Science Foundation
European Medical Research Councils
Presentation by Anna Veiga

New sources and heterogeneity of Pluripotent stem cells

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Institut Universitari Dexeus. Barcelona

Hochedlinger, Development 2009 (adapted from Waddington, 1957)
Pluripotent Stem Cells can be obtained from cells located in the inner cell mass of blastocysts and from nuclear reprogramming (SCNT and iPS).
Nuclear Reprogramming

- Somatic Cell Nuclear Transfer (SCNT)
- Induced Pluripotent Stem Cells (iPS)
Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors.

Takahashi K, Yamanaka S.

Cell. 2006.

Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors

Kazutoshi Takahashi, Koji Tanabe, Mari Ohnuki, Megumi Narita, Tomoko Ichisaka, NIchiro Tomoda and Shinya Yamanaka.

Cell, 2007

Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells

Junying Yu, Maxim A. Vodyanik, Kim Smuga-Oto, Jessica Antosiewicz-Bourget, Jennifer L. Fuchs, Shulan Tian, Jeff Ng, Guðný A. Jonsdóttir, Victor Ruddle, Run Stewart, Igor I. Slukvin and James A. Thomson

Science, 2007

IPS Cells: Induced-pluripotent Stem Cells

IPS are the product of somatic cell reprogramming to an embryonic-like state by the introduction of a defined and limited set of transcription factors and by culturing these cells under embryonic stem cell conditions.

Gene Combinations for IPS induction

An embryonic-stem-cell beauty contest.

Policy Department A: Economic and Scientific Policy

Nature Reviews Cancer 11, 268-277 (April 2011)  
Uri Ben-David & Nissim Benvenisty

Nature Reviews Cancer 11, 268-277 (April 2011)  
Uri Ben-David & Nissim Benvenisty
### Comparison of the tumorigenicity between HESCs and HiPSCs

Nature Reviews Cancer 11, 268-277 (April 2011)  Uri Ben-David & Nissim Benvenisty

<table>
<thead>
<tr>
<th>Factors influencing tumorigenicity</th>
<th>HESCs</th>
<th>HiPSCs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genetic abnormalities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell of origin</td>
<td>ICM cells that have undergone very few divisions*</td>
<td>Mature somatic cells that have undergone many cell divisions and have been more exposed to genetic and environmental mutations*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Might result in mutations and/or aberrations of somatic origin*</td>
</tr>
<tr>
<td>Derivation process</td>
<td>A relatively minor selection pressure*</td>
<td>A major selection pressure owing to forced drastic change of epigenetic landscape*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Might result in mutations and/or aberrations owing to reprogramming stress*</td>
</tr>
<tr>
<td>Viral integration</td>
<td>Not applicable</td>
<td>Most of the current methods still use viral vectors for reprogramming*</td>
</tr>
<tr>
<td>Activation of oncogenes</td>
<td>Not applicable</td>
<td>Current methods upregulate oncogenes in the reprogramming process*</td>
</tr>
<tr>
<td>Cellular adaptation to culture</td>
<td>Prolonged growth in culture often results in gains of chromosomes 12, 17, 20 and X*</td>
<td>Prolonged growth in culture often results in gains of chromosome 12*</td>
</tr>
<tr>
<td><strong>Epigenetic abnormalities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell of origin</td>
<td>Similarity of global gene expression with some cancers (oncoplastic genes are highly expressed)*</td>
<td>Similarity of global gene expression with some cancers (oncoplastic genes are highly expressed)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Epigenetic memory of somatic transformations and/or susceptible traits of the somatic tissue*</td>
</tr>
<tr>
<td>Derivation process</td>
<td>No substantial epigenetic aberrations are known to occur in the process*</td>
<td>Cancer-related epigenetic abnormalities arise during reprogramming*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relaxation of imprinting might also occur in the process*</td>
</tr>
<tr>
<td>Cellular adaptation to culture</td>
<td>Relaxation of imprinting might occur in culture*</td>
<td>Relaxation of imprinting might occur in culture*</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Feature</th>
<th>Embryonic stem cells</th>
<th>Adult stem cells</th>
<th>Induced pluripotent stem cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artificial system</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Pluripotent</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Efficient differentiation</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Expansion in culture</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Rare cell type</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Immune compatible</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Teratoma risk</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Lutolf, Nature 2009
Single cell transcriptional profiling reveals heterogeneity of human induced pluripotent stem cells

- Single cell analysis of gene expression profiles of 362 hiPS and hESCs revealed more heterogeneity in hiPSCs than hESCs.
- Expression levels of ectoderm, mesoderm and endoderm are uniform across hESC and do not in hiPSC.
- Quantitative analysis of teratoma formation revealed a slower kinetics using hiPSCs.
- Gene expression profiling of 282 single hESCs and hiPSCs analysis indicated the heterogeneity in hiPSCs.
Epigenetic memory in induced pluripotent stem cells


• Low-passage induced pluripotent stem cells (iPSCs) derived by factor-based reprogramming of adult murine tissues harbour residual DNA methylation signatures characteristic of their somatic tissue of origin, which favours their differentiation along lineages related to the donor cell, while restricting alternative cell fates. Such an ‘epigenetic memory’ of the donor tissue could be reset by differentiation and serial reprogramming, or by treatment of iPSCs with chromatin-modifying drugs.

• These data indicate that nuclear transfer more readily establishes the ground state of pluripotency than factor-based reprogramming, which can leave an epigenetic memory of the tissue of origin that may influence efforts at directed differentiation for applications in disease modelling or treatment.

Donor cell type can influence the epigenome and differentiation potential of human induced pluripotent stem cells

Kasai Kina1,3,5,6, Bai Zhuo1,5,6, Akiko Doi1,5,7, Kitaw Ng1,3,7, Juli Unterschild1,3, Patrick Cahan1,5,3, Chun Honkawa4,5,6, Yimin Liu7,8, Martin J. Avery9, M. William Leouch1,3, Hu Li7, James J. Collins3,7, Andrew P. Feinberg3 & George Q. Daley5,6

As a consequence of both incomplete erasure of tissue-specific methylation and aberrant de novo methylation, CB-iPSCs and K-iPSCs are distinct in genome-wide DNA methylation profiles and differentiation potential. Extended passage of some iPSC clones in culture do not improve their epigenetic resemblance to embryonic stem cells, implying that some human iPSCs retain a residual ‘epigenetic memory’ of their tissue of origin.
Cell Therapy: problems to be solved

- Immunologic rejection
- Tumor formation (Teratomas hESC and iPS)
- Oncogenesis – Insertional mutagenesis iPS
- Differentiation efficiency – Purity of cell populations
- Large scale cell production
- GMP production

ClinicalTrials.gov

- Safety Study of GRNOPC1 in Spinal Cord Injury
- Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (hESC-RPE) Cells in Patients With Stargardt's Macular Dystrophy (SMD)
- Safety and Tolerability of Sub-retinal Transplantation of hESC Derived RPE (MA09-hRPE) Cells in Patients With Advanced Dry Age Related Macular Degeneration (Dry AMD)
- Sub-retinal Transplantation of hESC Derived RPE(MA09-hRPE)Cells in Patients With Stargardt's Macular Dystrophy
GRÀCIES PER LA VOSTRA ATENCIÓ!

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Human pluripotent stem cells for disease modelling and cell replacement therapy

Presentation by Petr Dvorak

1. Definition and origin of pluripotent stem cells – accessibility and ethical issues

2. Pluripotent stemcells from bench to the bed side – obstacles and challenges

3. Modelling human diseases and current clinical trials – hope for personalized medicine
Stem cells: criteria and definition

- **Self-renewal**
  - Capacity to make more copies of itself

- **Clonal capacity**
  - Symmetric division
  - Asymmetric division

- **Differentiation**
  - **Clonality**
  - **Pluripotency**
  - **Multipotency**
  - **Oligopotency**
  - **Unipotency**

- **Embryonic stem cells**
- **Adult stem cells**
- **Induced pluripotent stem cells**

Origin and developmental ontogeny of stem cells - important issue for cell replacement therapy

- **Embryonic SCs**
- **Primordial germ cells**
- **Gametes**

- **Ectoderm**
  - Nervous tissue – neural SCs
  - Skin – skin SCs

- **Mesoderm**
  - Bone marrow and blood – hematopoietic and mesenchymal SCs
  - Muscle and bone – tissue-specific SCs

- **Endoderm**
  - Lung, liver, pancreas – organ-specific SCs
  - Esophagus, stomach, intestine – intestinal SCs

- **Embryonic SCs**
- **Primordial germ cells**
- **Gametes**

- **Polar trophectoderm**
  - Extraembryonic ectoderm
  - Chorionic ectoderm
  - Placental trophoblast

- **Trophoblast**
  - Mural trophoblast
  - Ectoplacental cone
  - Trophoblast giant cells

- **Parietal endoderm**

- **Vesical endoderm**

- **Placenta**
- **Parietal yolk sac**
Origin and developmental ontogeny of stem cells - important issue for cell replacement therapy

Embryonic SCs

Primitive ectoderm/epiblast

Primitive endoderm

Trophectoderm

Ectoderm
- nervous tissue
- skin

Mesoderm
- bone marrow and blood
- muscle and bone

Endoderm
- lung, liver, pancreas
- esophagus, stomach, intestine

Embyronic SCs

- Neural SCs
- Hematopoietic SCs
- Mesenchymal SCs
- Intestinal SCs
- Organ-specific SCs

Induced pluripotent stem cells

(Yamanaka 2006)

Alternative source of pluripotency - Induced pluripotent stem (iPS) cells
- stem cells created from differentiated cells by a simple genetic trick

Kinetics of fibroblast to iPS cell reprogramming - not too long way to go back

Somatic cells
- e.g. skin fibroblasts

Oct4
Sox2
c-Myc
Klf4

Thy1 (and other fibroblast genes)

Retroviral activity

pluripotent stem cell markers

pluripotency genes
telomerase
silent X chromosome

Stable reprogramming to stemness

Time in days

0 4 8 12

iPS cells

Human ES cells and iPS cells are arguably equivalent in all basic functions, however…
Pluripotent stem cells in treatment of human diseases

*Three major access roads to get:*

- **Generation of mutant pluripotent stem cells for studies of the pathophysiology of diseases and drug development**

  - Mechanisms of self-renewal
  - Mechanisms of commitment and differentiation
  - Mechanisms of cell division and cycling
  - Genomic instability and DNA repair
  - Development and testing new drugs
  - Testing of (embryotoxicity of new compounds

- **Ex vivo repair of genetic mutations in patient-derived somatic cells that are reprogrammed into pluripotent stem cells (iPS cells) followed by differentiation into desired cell types and transplantation**

- **Replacement of missing or damaged cells by functional cells derived from pluripotent stem cells**
Major barriers for pluripotent stem cells on the way from laboratories to patients

- Understanding the mechanisms of self-renewal and development of new culture systems
- Understanding the mechanisms of differentiation and development of efficient differentiation protocols
- Safety of pluripotent stem cell-derived transplants
- Immunological incompatibility and population diversity of pluripotent stem cell lines
- Ethical and legal barriers
- Patenting issues

Tumor formation is still a concern!

Cancer stem cell hypothesis
Tumors are maintained by a small population of stem cells that might even be at the origin of a tumor and are the only cells capable of tumor re-initiation
Catecholamine polymorphic ventricular tachycardia (CPVT) is an inherited arrhythmia syndrome, which can lead to sudden cardiac death (SCD) in young people from ventricular fibrillation during physical or emotional stress.

Patient-derived IPS cells & calcium channel stabilizers

+LEOPARD syndrome
Long QT syndromes
Phase 1 clinical trials using GMP-grade hES cells

- Spinal cord injury – hES cell-derived oligodendrocytes

- Stargardt macular dystrophy and dry age-related macular degeneration – hES cell-derived RPE cells

Thank you for your attention!
Committee on the Environment, Public Health and Food Safety

Workshop on "Stem Cell Research and Patenting"

19 March 2012

Ron and his youngest New Year’s Eve party

Ron’s wife Carolyn said recently
‘the girls have lost their father, I have lost my husband, friend
and confidant. We are devastated.’
Thank you for listening
PRIORITY: Good Internationally.

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A
ECONOMIC AND SCIENTIFIC POLICY

Role
Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

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- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents