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**Patentability of Stem Cell Inventions   
in the United States, Europe and Sri Lanka**

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### **Abstract**

The present paper aims to look into the patentability of stem cells, which have become a focus of scientific research in recent decades. The interest of researchers in stem cells results from their ability to self-renew, which unveils a great therapeutic potential, especially for regenerative medicine and drug development. In these circumstances, patent protection remains a vital factor affecting the development of life-science innovation. Nevertheless, the patentability of stem-cell subject matter cannot be taken for granted, not only due to provisions in patent law itself (such as patentable subject matter and exclusions, novelty, inventiveness, disclosure or enablement, and industrial applicability), but also because of ethical considerations and regulatory restrictions. As a result, some types of inventions based on stem cells encounter significant restrictions. This paper does not discuss the above-mentioned subjects in depth, but aims to provide an overview of the unique challenges that stem-cell patentability faces in the United States, Europe and Sri Lanka. Each region has its own approach to the imposition of patentability requirements and/or limitations. A comparative study of stem-cell patentability in these countries will be followed by an attempt to identify best practices and to provide recommendations for developing countries that wish to enter the research race, face the existing challenges in advancing innovation, and adapt to the ever-changing scientific landscape.

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### **I. Background on stem cells**

The first step in understanding the patentability environment of stem cells is to understand what stem cells are, why they are fascinating for scientists, and the differences between the types of stem cells where research outcomes and their patent eligibility are concerned. This section of the paper will provide a definition of stem cells, their classification, and research application.

The path towards the discovery of stem cells begins in the mid-1800s, with the observation that some cells generate other cells. The first stem cells as such, those generating blood cells, were discovered in the early 1900s. Their scientific name was coined by a Russian histologist, Alexander Maksimov.

Like other cells, stem cells are building blocks. However, their uniqueness lies in their ability to give rise to a variety of differentiated and specialized cells in the body. They are, therefore, called non-specialized, generic cells. They are characterized by their ability to divide and self-renew, as opposed to specialized cells, such as blood cells, which do not normally have such an ability. This ability to divide, their so-called potency, may result in the creation of other stem cells or specialized cells. One of the classifications of stem cells follows this logic.

Because of the above properties, stem cells are vital to the development, growth, maintenance and tissue repair of our organs. For the very same reason, their discovery is considered a breakthrough in the biomedical sphere and stem cells have become the focus of scientific research and clinical trials, giving them significant value in the research and therapeutic world. Their application and potential have sparked hope among medical professionals and scientists when it comes to the possibility of curing the major medical challenges of our century.

Stem-cell research finds application in drug screening and development, toxicology, and the study of regenerative and ageing mechanisms, as well as organism development with the aim of improving the quality and length of human life. Stem-cell-based therapies developed to date encompass bone marrow transplants[[1]](#footnote-0), skin replacement, and even brain cell transplantation in the treatment of Parkinson’s disease, the latter so far with serious side effects[[2]](#footnote-1). Further applications are being pursued, including therapies for diabetes, heart disease, muscle damage, neurological and neurodegenerative disorders[[3]](#footnote-2).

As mentioned above, stem cells can be categorized according to their potency. A stem cell may be totipotent, pluripotent, multipotent or unipotent[[4]](#footnote-3). A totipotent stem cell (e.g. an embryo) is able to produce a fertile adult individual and differentiate into all possible cell types: any adult human or extra-embryonic tissue, such as the placenta[[5]](#footnote-4). Pluripotent stem cells are able to differentiate into almost all cell types; they can give rise to any adult tissue, but are unable to organize these cells into an integrated body. Multipotent cells differentiate into cells of specific categories, while unipotent cells, e.g. muscle stem cells, differentiate only into their own kind.

The other classification is based on the origin of stem cells. Advances in stem-cell research show that there are two naturally occurring types of stem cells: “embryonic” (or early) and “adult” (or mature or somatic) stem cells. As the name suggests, embryonic stem cells (ESCs) are to be found, first and foremost, in the embryo, more specifically during its blastocyst[[6]](#footnote-5) stage of development[[7]](#footnote-6). They are pluripotent. Modern research has revealed that embryonic stem cells are also to be found in the umbilical cord blood, amniotic fluid and placenta. Adult stem cells, on the other hand, originate within adult body tissues and organs. They are now believed to be present in all organs of the body, though it is difficult to observe them. They are inactive, waiting for a stimulus from the organism that a specific tissue needs to be repaired. They are of different kinds and, unlike embryonic stem cells, are more limited in their ability to differentiate into different types of cells[[8]](#footnote-7). Some of them are multipotent and some unipotent. However, knowledge of their origins and potential is still relatively limited.

Scientists have recently created stem cells of a third kind that are not naturally occurring but induced. Following the controversy around the use of embryonic stem cells (described later in this paper), they have learned how to reprogramme somatic cells (meaning cells from an adult body) so they can perform their pluripotent functions anew. Thanks to a process of genetic modification that results in the expression of certain genes and factors, the cells can become just like embryonic stem cells. For this reason, they are referred to as iPSCs (induced pluripotent stem cells). Whether or not there are any major differences between embryonic stem cells and genetically modified adult stem cells (iPSCs) remains to be seen.

There are some significant differences between embryonic and adult cells, and this affects research choices and strategies. It is important to note that both are useful, and it is hard to determine whether one is better than the other. However, they have different features, which affect their performance in different situations.

Embryonic stem cells multiply rapidly but are carcinogenic: their division mechanisms are similar to those observed in tumours. They are basically immortal and can be grown in a culture relatively easily. Somatic stem cells generally do not induce tumours but it is hard to multiply them in large quantities. Typically, there is a small number of stem cells in each tissue and, once removed from the body, their capacity to divide is limited, making the generation of large quantities of stem cells (a culture) difficult[[9]](#footnote-8).

Moreover, it is expected that tissues derived from embryonic and adult stem cells will differ in the likelihood of their being rejected after transplantation. It is thought that adult stem cells and tissues derived from the patient’s own body are less likely to be rejected by the immune system.

For research purposes, embryonic stem cells are obtained from unplanted embryos harvested for the purposes of in-vitro fertilization (IVF), for which parents must have given consent to donate the eggs. The fertilization of eggs purely for research purposes is so far generally prohibited[[10]](#footnote-9). James Thomson, a pathologist, became the first scientist to successfully isolate and maintain human embryonic stem cells in 1998[[11]](#footnote-10).The embryos were cultured, which enabled the cells to give rise to all the tissues of the body. The outcome of Thomson’s experimentation paved the way for future experiments, which included the stimulation of unfertilized human ova to make them divide and develop by parthenogenesis[[12]](#footnote-11) and the transplantation of a cell nucleus from a mature human cell into a non-fertilized human ovum.

At some point, the above methods necessarily involved the destruction of human embryos, the controversy surrounding which will be addressed in later sections of this paper.

### **II. Stem-cell research** – **protection and investment**

It should be noted that the biotech industry incorporating the above-mentioned stem-cell branch is highly intensive, when it comes to both research and development (R&D) and patenting. Needless to say, conducting any biotechnological research is costly, which leads scientists and those interested in furthering R&D to look for different funding possibilities. It is recognized that patenting, as well as both public and private funding, is crucial for this industry. For instance, Recital 17 of the Biotech Directive, described in more detail later, states that research aimed at obtaining and isolating elements valuable to medicinal production should be encouraged by means of the patent system.

This is because one of the main reasons for granting patent protection is to spur innovation. The patent system provides inventors with a temporary period of market power (resulting from a legal monopoly), during which they are allowed to recoup the investment they have expended on their invention. In this way, patent protection should stimulate investment in research and development. In the case of the biotech industry, the possibility of relying on the monopolistic rents secured by patents is usually a prerequisite for upfront investment. If no patents are available, the investors’ business is considered to be jeopardized[[13]](#footnote-12). Additionally, patents often serve as a litmus test when it comes to assessing the value of an invention or innovation[[14]](#footnote-13).

In reality, the amount of R&D innovation that is spurred by patents, as well as its value, depends on how effective patents are: how strong the granted exclusive right is and how well the patent specification is drafted. The term length and the breadth of a patent also affects the incentive for innovation. Where the term length is concerned, the TRIPs Agreement establishes a minimum term of 20 years, counted from the filing date[[15]](#footnote-14), which so far has been maintained by the countries under investigation in this paper. Patent breadth determines, in essence, the boundaries of the patent right and is based upon the claims made in the patent granting process. Anticipation of a narrowing of claims can reduce the incentive for investors to support innovation.

As far as funding issues are concerned, many have argued over the years that public funding is a crucial step in the success of stem-cell research[[16]](#footnote-15). Many see it as a symbol that provides the research with a “stamp of approval”. In addition, it is also felt that public funding allows the transition from lab to commercialization to go more smoothly.

In 2017, the estimated amount of federal funding for all stem-cell research in the United States was $1.58 billion[[17]](#footnote-16). Of that amount, $213 million was spent on human embryonic stem-cell research. Non-embryonic human stem-cell research received $480 million, more than twice the amount spent on other types of research. If we include funding for human-induced pluripotent stem cells ($347 million) and umbilical cord blood/placenta stem cells ($34 million), then total federal funding for all categories of human non-embryonic stem-cell research amounted to $861 million. In 2017, the U.S. government spent four times as much on all categories of human non-embryonic stem-cell research as on human embryonic stem-cell research.

The United States does not currently have legislative policies addressing stem-cell research. Instead, research funding is restricted by federal science funding constraints. In 1996, the Dickey-Wicker Amendment, a legislative act, prohibited federal funding for stem-cell research that would destroy or harm a human embryo. Under this Amendment, stem-cell research could only be performed on already existing stem-cell lines. In an executive order issued in March 2009, President Barack Obama revoked President Bush's directive of 9 August 2001 and permitted federal funding for “scientifically worthy” stem-cell research, including hESC research to “the extent permitted by law”[[18]](#footnote-17). President Obama did not lift the restrictions placed upon stem-cell research by the Dickey-Wicker Amendment, which was a legislative act; the only policy that Obama was able to change was an increase in the applicability of federal funds to a few hundred human embryonic stem-cell lines that had already been created prior to President Bush’s Executive Order of 9 August 2001.

The Dickey-Wicker Amendment was renewed on 11 March 2009 in section 509 of H.R. 1105, the “Omnibus Appropriations Act, 2009”. As of 2009, the amendment remained the only legal obstacle to the federal funding of experimentation on human embryos. The Dickey-Wicker Amendment only applies to federal funding, not private funding of stem-cell research. It has been attached to the appropriations bill for the Department of Health and Human Services every year since 1996. In 2010, the Bayh-Dole Act changed federally funded research by allowing non-profit organizations, including universities, to retain ownership of their inventions when they conduct research with federal funds.

In 2011, the National Institutes of Health (NIH) invested over $1 billion in stem-cell-related research[[19]](#footnote-18). It both conducts research in in-house institutes, such as the Center of Regenerative Medicines, and outsources by providing funding to universities and research institutions. The NIH imposes obligations on researchers. It requires them to disseminate unique research resources as a way of developing science. In addition, they must commercialize their inventions to benefit society.

Much funding for stem-cell research is provided by philanthropic organizations. Most of these organizations establish their own requirements for the granting of funding. In the United States, the pressure to commercialize is strong and is generally evident in both federal funding and private funding requirements.

In Europe, each country regulates stem-cell research and its funding independently, taking into account moral and ethical concerns, as described later. Additionally, research is supported by the European Union with a system of grants. In 2007, the EU established the 7th Framework Programme (FP7), which remained in effect until 2013[[20]](#footnote-19). This programme established the premise of “European added value” as a qualification for receiving research funding, laying down, among other things, how results had to be shared and popularized. Support continues under *Horizon 2020* (2014 – 2020) – the current EU framework programme for research and innovation.

Overall, public funding is essential for scientific progress in the field of stem-cell research. This type of research has been shown to lead to a wide array of possible treatments. In addition, with public funding, more requirements and restrictions can be imposed to ensure that the practice is scientifically[[21]](#footnote-20) regulated.

Where privately funded research is concerned, the requirements and restrictions are less strict. There are currently very few limitations placed on the private funding of stem-cell research. Scientists can generally conduct research on whatever cell lines they want, unless specifically prohibited by law. In addition, it has been argued that private funding allows research to be done more rapidly, which in turn leads to the possibility of finding a cure for a disease sooner. In such situations, patent systems may create additional indirect barriers by curtailing investment recoupment and, as a result, act as a policy setter, which we shall examine in more detail.

Apart from the objective of promoting innovation, as discussed above, the other key function of patent systems is to encourage the disclosure of information about inventions, and so increase the social value generated by inventors. Historically, such disclosure has also been seen as a catalyst for innovation. In exchange for receiving a patent, an inventor must publicly disclose his invention. Many see this as a way of promoting innovation, as opposed to the alternative of keeping the invention a trade secret. On the other hand, some inventors have stated that they have chosen not to patent their inventions because of the disclosure requirement. The effect of this strategy on research investment has not yet been empirically determined[[22]](#footnote-21).

However, the effect of large-scale patenting on the dissemination and progress of knowledge can sometimes be stifling. This is because the patent system creates a negative right and a legal monopoly to use an invention, whereas science is said to develop by incremental contribution and the freedom of researchers to experiment. This approach does not often make for corporate profits. Furthermore, scientific research advances most strongly when it is driven by spill-overs, the sharing of knowledge and experience, and divergent approaches to the same problem[[23]](#footnote-22). This type of collaboration was adopted in the International HapMap Project for mapping the human genome, which has many similarities with stem-cell research. Such an inclusive approach contrasts with the patent philosophy, which is by nature exclusive.

Consequently, the more patents are granted for stem-cell inventions and the broader they are, the more restrictions there are on access to scientific information, and this results in additional costs in gaining access, for instance, through licences. Patents may also be used as tools for suppressing competition and monopolizing a market[[24]](#footnote-23). The solution would seem to be public funding, as stressed above, but unfortunately this is often insufficient for financing such extensive projects as stem-cell research.

There is one further clash between scientific research and the patent system. It lies in differing approaches to profit-seeking and social responsibility. While scientists are good at discovering and innovating, they still have to get over the hurdle of transforming these discoveries and innovations into commercial products, for which obtaining patents is an important aspect. For this very reason, private-sector investment is necessary for medical and biotechnological innovation, and companies, investors, shareholders and practitioners consider the possibilities for commercialization and patentability when deciding whether or not to invest. The potential commercialization of inventions, patents granted and future financial gains are therefore crucial factors, which may lead the pharmaceutical industry, for instance, to give preferential treatment and invest more heavily in more profitable drugs, such as Viagra[[25]](#footnote-24), rather than those of greater objective value to society. This poses dilemmas for academia, which is expected, by society, to conduct socially viable research and, by investors, to follow marketplace trends.

For all the reasons highlighted above, stem-cell research, innovation and patentability involve a whole array of interesting policy considerations.

### **III. Policy considerations**

Because of the usefulness and attractiveness of stem-cell research for the biotech industry and society at large, as described in the previous sections, there are a couple of policy issues that are worth highlighting.

First and foremost, it should be borne in mind that patent law, which is the special point of interest of this paper, is only one of a set of laws and regulations that affect scientific research, and stem-cell research in particular. The obstacles to stem-cell research therefore also need to be seen in the light of policies concerned with health care systems, research funding and the protection of human dignity. The complexity of the regulations relating to stem cells is closely correlated with the complexity of the technology. Each region will naturally have its specific characteristics where such policy considerations are concerned, as clearly shown on the interactive map created by the Hinxton Group[[26]](#footnote-25). In Europe, for instance, patent law will at some point come into conflict with human rights issues, while in the United States there is tension between state-law research-funding regulations and federal patent law.

In this policy jungle, it is important not to forget the essential feature of patent law, namely the right to exclude others from using a patent, not a right to practice the protected invention[[27]](#footnote-26). The patentability criteria with respect to stem-cell technology and inventions now in place in the regions under investigation in this paper may acquire new meanings when looked at against this complicated background, just as national patent laws become more meaningful when the international IP law framework is taken into account. This paper will therefore attempt to include references to other relevant policies, when deemed necessary or interesting.

As far as the international intellectual property framework is concerned, umbrella provisions delimiting stem-cell research and its patentable inventions are contained in Article 27, points 1 and 2, of the Agreement on the Trade-Related Aspects of Intellectual Property (hereinafter the TRIPs Agreement).

The first part of this article obliges WTO Member States[[28]](#footnote-27) to grant patents for any invention and in all fields of technology, provided that the inventions concerned meet certain patentability criteria. These are the same for all WTO Member States, but may be assessed and applied differently, which leaves room for adjusting the patentability threshold to the situation of a particular country. Stem-cell inventions are, therefore, obvious candidates for patenting, providing they meet the criteria of novelty, inventive step or non-obviousness and industrial applicability applied by the relevant country. For example, the United States allows the patenting of stem-cell inventions and granted patents, but has quite recently changed the assessment criteria for an invention, raising the bar for patenting elements occurring in nature. We shall deal with this below and in more detail in section IV.

The second part of Article 27 allows Member States flexibility to exclude certain inventions from patentability, thus mitigating the absolute requirement contained in point 1 of the article. These exclusions are permitted with a view to compliance with laws of a higher rank than those relating to trade and IP, inter alia laws concerning human rights. This is particularly relevant for our topic, as we are concerned with the moral and ethical sensitivities of different nations. The exclusion is not, however, absolute as it cannot be justified by the mere prohibition of exploitation of an invention by law. The commercial exploitation of the relevant invention has to affect public order or morality. This provision has given rise to issues in the European context, where patent applications relating to stem-cell inventions have been challenged on the basis of European provisions implementing Article 27 of the TRIPs Agreement, the details of which will be presented below, and in more detail in section IV.

Where specific regional patent laws are concerned, those relevant to our topic are: for the United States, the Constitution[[29]](#footnote-28) and the Leahy-Smith America Invents Act (AIA); for Europe, the Convention on the Grant of European Patents of 5 October 1973 (hereinafter the European Patent Convention or EPC), Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter the Biotech Directive or the Directive), and relevant national patent laws; and, for Sri Lanka, the Intellectual Property Act No. 36 of 2003. Needless to say, the laws in the United States and in the European Union are very much influenced by precedential case law, which plays a crucial role in asserting patentability criteria for stem-cell inventions.

As mentioned above, the TRIPs Agreement obliges WTO Member States to grant patents in all fields of technology for all inventions, be they products or processes. This reflects the basic social philosophy of the patent system, which is to encourage and promote development. This incentivizing philosophy creates tension as to where the line between discoveries and inventions should be drawn. Patent systems usually allow exclusive rights for inventions, but not for discoveries, with an aim of preventing the monopolization of knowledge, while at the same time allowing some recoupment of investment when useful improvements are produced.

The fact is that to a great extent human beings take ideas and inspirations for inventions from nature and its phenomena[[30]](#footnote-29). This is certainly the case in stem-cell research, as already highlighted. Policies enacted to regulate it aim to strike a balance between granting a monopoly on using the elements of nature and boosting the research effort, which is so costly for stakeholders. Interestingly, in the United States, the task of striking this balance is left to the courts, the detailed results of which will be presented in Section IV, whereas the European Union decided in 1998 to enact specific legislation regarding the patentability of biotechnological inventions[[31]](#footnote-30).

The so-called Biotech Directive regulates issues concerned with the legal protection of biotechnological inventions. Firstly, the Preamble states that a mere discovery cannot be patented and a mere DNA sequence without indication of a function does not contain any technical information and cannot constitute a patentable invention[[32]](#footnote-31). Secondly, however, articles 3 and 5 open the doors for patenting isolated[[33]](#footnote-32) biological matter or human body elements, even if their structure is identical to a structure occurring in nature.

The Directive has been adopted by all EU Member States. Additionally, the European Patent Organization and European Patent Office decided to include references to the Directive in the Implementing Regulations to the EPC, stating that it “shall be used as a supplementary means of interpretation”[[34]](#footnote-33). As a result, its provisions have a great influence on the patentability of biotechnological inventions, including those relating to stem cells, in European countries.

Articles 3 and 5 of the Biotech Directive are an example of a policy tailored specifically to boost the European biotech industry at a certain time, following a similar permissive approach taken in the United States. However, the borderline between unpatentable discoveries and patentable inventions has since shifted considerably in the USA, resulting in divergent approaches between Europe and the USA to assessing the patentability of elements isolated from the human body or natural environment.

As already mentioned, the second policy issue with respect to stem-cell research and technology concerns morality and ethical issues. Although moral and ethical controversies around stem cell-research have arisen mainly in the European context, they are also pertinent for some of the U.S. states[[35]](#footnote-34).

In Europe, these controversies have found their way into patent law, whereas in the USA they are reflected mainly in the state laws regarding public funding or legality. This difference is often explained by the contrasting approaches to patent law adopted on either side of the Atlantic Ocean. The USA is said to believe in the moral neutrality of the patent system (which is federal). It is expected only to assess whether an invention merits being granted a legal monopoly and does not preclude its commercial success or failure. Europe, on the other hand, has a tendency to view the patent system as a servant of public policy. Taking a moral stand is seen as performing the very function of the patent law, which is to stimulate and reward innovation useful to society[[36]](#footnote-35).

Examples of this stand can be found in at least two decisions of the Boards of Appeal of the European Patent Office: the so-called *Plant cells* case (T 0356/93) of 21 February 1995 and the *Oncomouse* case (T 0315/03) of 6 July 2004. The European patents in question were opposed on the grounds of Article 53 EPC. In the *Oncomouse* case, the Technical Board of Appeal performed a moral arbitrage by balancing the costs and benefits of the invention in a utilitarian manner. It was decided that the suffering of transgenic mice, which were implanted with an oncogene for furthering research on tumour development and tissues, was outweighed by the potential benefits that such cancer research would bring to society[[37]](#footnote-36). In the *Plant cells* case, genetic modification of plants was deemed comparable to traditional breeding and, for this reason, morally acceptable[[38]](#footnote-37).

The *Plant cells* case provides useful definitions of morality and *ordre public[[39]](#footnote-38)*. The latter is regarded as the protection of public security and the physical integrity of individuals as members of society. Morality, on the other hand, is understood to be a belief that some behaviour is right and acceptable, whereas other behaviour is wrong, the belief being founded on the totality of accepted norms that are deeply rooted in a particular culture. Consequently, it is clear that moral standards will differ between countries and societies.

Most notably, such differences will be observed in the wording of the laws of a specific country or region. Thus Article 5 of the Biotech Directive states that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable invention. Furthermore, Article 6 declares as unpatentable inventions the commercial exploitation of which would be contrary to public order or morality, in particular processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. Analogous wording is to be found in Article 53 EPC and Rule 28 of the EPC Implementing Regulations.

On the other hand, Section 33 of the AIA, adopted in the USA in 2011[[40]](#footnote-39), includes a limitation preventing only the patentability of inventions directed to or encompassing a human organism. As far as cloning is concerned, there are currently no federal laws that ban it completely[[41]](#footnote-40).

In the case of stem-cell research and inventions, the moral and ethical controversies surrounding them are confined mainly to human embryonic stem cells (hESCs) and cloning techniques such as, for instance, somatic cell nuclear transfer (SCNT)[[42]](#footnote-41).

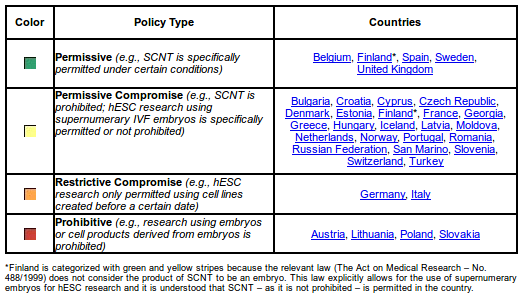
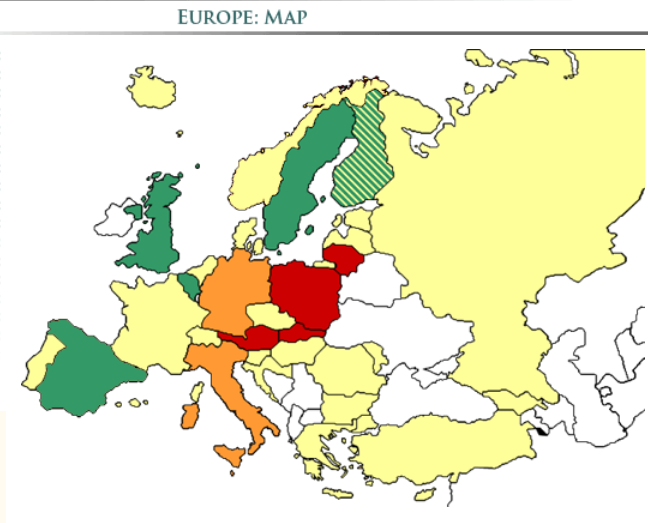
To be more precise, in the light of the above provisions, human embryonic stem cells as such do not fall under the patentability exceptions. Firstly, they are not the same as an embryo, only a part of it[[43]](#footnote-42). Secondly, isolation from a human organism renders them potentially patentable under Article 3(2) of the Biotech Directive. However, it is precisely the isolation process and methods necessary to harvest them that create a moral and ethical problem. hESCs appear only temporarily at a very early stage (around the fourth or fifth day) in the *in utero* development of an embryo, and their isolation is highly likely to destroy the embryo[[44]](#footnote-43) (in the past, and at the time of the crucial judgements described in the next section, the isolation of hESCs actually precluded the death of embryos).

At this point, it seems useful to go a little deeper into understanding the ethical issues relating to the destruction of human embryos, as differences in ethical approach affect choices adopted at the policy level (not only with respect to patentability, but in general). There are at least two ethical views regarding the destruction of embryos for research purposes: a “sanctity of life” view and a “quality of life” view. The deontological position of the sanctity-of-life approach is that the rights of an individual human being (who develops from an embryo), such as the right to life, are inviolable. Therefore, given that stem-cell research involves the destruction of embryos, it would be unethical to pursue it. By contrast, the quality-of-life approach is utilitarian: there is a duty to alleviate suffering; therefore, given the potential benefits of human embryonic research, it would be unethical not to pursue it[[45]](#footnote-44). This argument is all the more powerful if society regards progress as an important value in itself.

The impasse is additionally reinforced by differences in basic philosophical and ethical understandings of when life begins (not necessarily based on scientific definition), as well as how and by whom questions relating to human dignity are decided[[46]](#footnote-45), which also involves different religious views[[47]](#footnote-46). As a result, ethical judgements on the destruction of embryos for research purposes will be influenced by the values held by society and their order of importance.

Value hierarchies differ not only between regions but may also change over time due to political and other changes. Up until 2009, for instance, the United States placed constraints upon federal funding for stem-cell research on moral grounds connected with the destruction of human embryos. This led the research community to believe that the United States had adopted a sanctity-of-life position. Federal funding for and research into hESCs had been limited by Presidential actions. At the time, federally funded stem-cell research was in fact restricted to the use of a limited number of already existing cell lines. In 2006 and 2007, Congressional bills allowing the federal funding of embryonic stem-cell research were vetoed. Then, in 2009, these restrictions were lifted by executive order, which expanded NIH support for further human stem-cell research. The purpose of this executive order was to enhance the ability of America’s scientists to make important new discoveries and develop new therapies for the benefit of the human population. By allowing this expanded federal funding, the United States moved from a position of seeing embryonic stem-cell research as something that violated human life to a position where research involving embryonic stem cells was seen as possibly leading to cures for serious diseases, and therefore not to pursue it would be unethical.

As far as European countries are concerned, moral and ethical standards regarding stem-cell research differ considerably, which is clear from the Hinxton Group map:



*Source:* [*http://www.hinxtongroup.org/wp\_eu\_map.html*](http://www.hinxtongroup.org/wp_eu_map.html)

The differences are still considerable, even though EU countries are bound to comply with the Charter of Fundamental Rights of the European Union, and especially Article 1 thereof, which states that human dignity is inviolable and must be respected and protected, and Article 2(1) and 3(2), which prohibit making the human body or its parts a source of financial gain[[48]](#footnote-47). Where patent law is concerned, the Biotech Directive and the EPC[[49]](#footnote-48) would seem to bring some degree of harmonization. In practice, though, national patent laws present significant differences.

For example, Austria, the Netherlands and Italy exclude any use of human embryos (not only “use for industrial or commercial purposes” as worded in the Biotech Directive) from patentability. Italy, furthermore, expressly exempts human embryonic stem cells and human embryonic stem-cell lines from patentability, excluding “the human body from the moment of conception” and prohibiting “any use of the human embryo, including human embryonic stem-cell lines”[[50]](#footnote-49). Germany, Estonia and Austria have preserved the wording of the Biotech Directive but additionally refer to respective national fertilization and embryo-protection legislation for interpretation purposes[[51]](#footnote-50). France, Italy and Switzerland refer in their patent laws additionally to human dignity, and Italy and Belgium even to rulings of the European Court of Human Rights[[52]](#footnote-51). Interestingly, Switzerland (a member state of the EPC but not of the EU) exempts from patentability “inventions the use of which violate human dignity”, including procedures for cloning human beings and the resulting clones, processes to produce chimeras from human germ cells, human totipotent cells or human embryonic stem cells and the beings produced thereof, processes of parthenogenesis by use of human germ cells and the produced parthenotes, processes for modifying the germ-line genetic identity of human beings and the germ-line cells thereof, unmodified human embryonic stem cells and stem-cell lines, and the use of human embryos for non-medical purposes[[53]](#footnote-52).

The policy picture emerging from the above description clearly shows that in both the USA and Europe there are widely differing ethical views regarding stem-cell research. Moreover, these ethical disagreements are also reflected in research funding and the granting of patent claims deriving from such research[[54]](#footnote-53).

In the next section, we shall present a detailed analysis of the case law affecting the patentability of stem-cell inventions in the USA, Europe and Sri Lanka.

### **IV. The status of patent protection of stem-cell inventions**

#### **A. United States**

Social and economic funding issues aside, the patentability of stem cells and stem-cell inventions is dictated by the U.S. patent laws. United States patents are examined and granted by the United States Patent and Trademark Office (hereafter the USPTO). The rules governing the granting and examination of patents fall under Title 35 of the United States Code and Title 37 of the Code of Federal Registrations[[55]](#footnote-54). 35 U.S.C. § 101 states that a patent may be granted for any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”[[56]](#footnote-55). To be patentable in the United States, the invention must be new, non-obvious, and useful. There are certain subject matters that the USPTO has historically excluded from patent protection, including laws of nature, natural phenomena and abstract ideas. Although laws of nature, natural phenomena and abstract ideas are not patentable under 35 U.S.C. § 101, an “application of a law of nature….to a known structure or process may deserve patent protection”[[57]](#footnote-56). To transform such an unpatentable subject matter into a patent-eligible subject matter, a patent must do more than state the law of nature and use the words “apply it”. There must be an inventive application of the law.

While no specific statutory legislation exists concerning the patentability of stem cells, in the Leahy-Smith America Invents Act (AIA), Pub. L., 112-29, sec 33(a), 125 Stat. 284, there is a provision stating that: “Notwithstanding any other provision of law, no patent may issue on a claim direct to or encompassing a human organism”[[58]](#footnote-57). The legislative history of the AIA clarifies that, under this act, stem cells are patent-eligible, but patent claims directed to or encompassing a human organism, including human embryos, are prohibited. Other provisions in the AIA further re-affirm both the patentability of stem cells and prior decisions made by the USPTO concerning patents issued on stem cells, which did not include claims directed to human organisms. Since the AIA, the United States has continued to issue a wide range of stem-cell patents, ranging in scope from products to methods, but there have been some restrictions following the Supreme Court decisions in the cases of *Mayo* (2012) and *Myriad* (2013), and then the decision of the United States Court of Appeals for the Federal Circuit in the case of *Roslin* (2014), which further defined and narrowed the bounds of subject matter eligibility under 35 U.S.C § 101.

##### 1. Patents on stem cells issued before *Mayo, Myriad, Roslin*, and *Sequenom*

A number of stem-cell patents have been issued and are still valid in the United States. The first of these were concerned with hematopoietic[[59]](#footnote-58) stem cells, fetal/neonatal cells and mesenchymal[[60]](#footnote-59) cells. Birds and mice produced the first patented embryonic stem cells. The first human ESC patents were issued to James Thomson of the University of Washington. Since these first patents were issued, there have been over 1,000 stem-cell patents issued in the United States.

Decisions made prior to 2012 were based upon the Supreme Court’s holdings in the *Chakrabarty*[[61]](#footnote-60) and *Funk Brothers* cases[[62]](#footnote-61). In both of these, the Supreme Court made it clear that naturally occurring organisms are not patentable. In *Funk Brothers Seed v. Kalo Inoculant Co*., the patent at issue claimed a mixture of nitrogen-fixing bacteria that could be used to fertilize a wide array of plants. The Supreme Court rejected the patent on the grounds that it claimed a property of natural phenomena. In *Chakrabarty*, the Supreme Court came to a different conclusion, holding that the bacterium claimed in the patent had markedly different characteristics, which was not naturally occurring and was a product of human ingenuity.

The Wisconsin Alumni Research Foundation (WARF) holds one of the most controversial stem-cell patent portfolios in the United States. The WARF, a patent and licensing arm of the University of Wisconsin, engages in a range of research projects and its patent portfolio includes a broad range of patents, including patents involving embryonic stem cells and stem cells in general. The WARF’s patent portfolio has given rise to legal actions, but is still standing, which could lead one to believe that there is little risk of an actionable legal challenge to this portfolio.

Nobel Prize winner Shinya Yamanaka has also been granted a number of U.S. patents relating to stem cells. His research focuses mainly on the process of producing induced pluripotent stem cells[[63]](#footnote-62). One of Yamanaka’s most important patents is U.S. Patent 8,058,065, which covers a method used to create iPSCs by reprogramming a cell’s nucleus. This is achieved by introducing certain genes into the cell’s chromosome and culturing the cell under certain conditions to obtain pluripotency.

The above-mentioned patent applications were filed before the Supreme Court handed down its decisions in *Mayo* and *Myriad*, and the United States Court of Appeal for the Federal Circuit ruled in *Roslin* and *Sequenom*. All but one of the above-mentioned patents were granted after those decisions were handed down, the exception being a patent that described a method for making particularized blood cells from adult stem cells. After the decisions in *Mayo*, *Myriad*, *Roslin*, and *Sequenom,* these patents may now be called into question.

##### 2. *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 566 U.S. 66 (2012)

In *Mayo Collaborative Services*, Prometheus Laboratories was the exclusive licensee of two patents, which were at issue. These two patents concerned the use of thiopurine drugs to treat autoimmune diseases and determine whether a given dosage level was too high or too low. After the introduction of thiopurine drugs into the bloodstream, the body metabolized the drugs. The metabolization rate of these drugs was different in each human body, which meant that it was hard to determine the correct dose that should be given to patients.

Prometheus Laboratories sold the diagnostic tests that embodied the processes described in the patents to Mayo Clinic Rochester and Mayo Collaborative Services, which then used these tests. In 2014, Mayo announced its intention to use and sell its own test, which used somewhat higher metabolite levels to determine toxicity. Prometheus brought an infringement action. While the district court found that Mayo’s test infringed upon one claim in Prometheus patents, it ultimately granted summary judgment in favour of Mayo. The district court held that the patents essentially claimed natural law or phenomena. On appeal, the federal circuit court reversed the decision, ruling that the steps claimed in Prometheus’ patents satisfied the federal circuit’s machine or transformation test. Mayo filed a petition for *certiorari*.

The patents in question set forth processes embodying researchers’ findings that identified correlations between metabolite levels and the harm or effectiveness of the drugs. Each patent claim included an administering step, which instructed the doctor on how to administer the drug to their patients. In addition, the claims included a determining step, which told the doctor to measure the metabolite levels after the administration of the drugs, and a wherein step, which described the various metabolite levels and at what level side-effects or harm could be seen. The doctor would then increase or decrease the dosage of the drugs, depending upon these levels.

The Supreme Court clarified that while the machine or transformation test is an important and useful tool in determining patent eligibility, it is not a definitive step. In addition, the Supreme Court was required to determine whether the claimed processes transformed what would normally be unpatentable laws of nature into patent-eligible applications of the law. The Supreme Court held that the steps in the patent claims involved well-understood, routine activity that had previously been engaged in by those working in the field. In addition, allowing the underlying natural laws to be tied up in a patent would inhibit their use in making further discoveries. The Supreme Court therefore held that the claimed processes did not transform what would otherwise be unpatentable laws of nature into something that could gain patent-eligibility status.

##### 3. *Association for Molecular Pathology v. Myriad Genetics Inc*, 569 U.S. 576 (2013)

Myriad Genetics applied for patents for diagnostic testing for hereditary breast cancer after discovering the location and sequence of the BRCA-1 and BRCA-2 genes. The mutation of these two genes can increase the risk of breast and ovarian cancer. After discovering these two genes, Myriad developed medical tests that would discover the mutations and assess the risk of cancer. If Myriad were to be granted these patents, the company would gain the exclusive right to isolate an individual’s BRCA-1 and BRCA-2 genes for testing and synthetically create a BRCA complementary DNA. There was much uncertainty and concern over the exclusivity that Myriad would acquire if they were to be granted patents on the above-mentioned genes.

The district court held that Myriad’s patents were invalid under 35 U.S.C. § 101 because the patents covered products found in nature. On appeal, the Supreme Court in part reversed and in part affirmed the earlier ruling, revisiting the meaning of “markedly different characteristics” from what is found in nature and the determination of whether such “markedly different characteristics” result from human ingenuity[[64]](#footnote-63). The Supreme Court noted that the case did not involve method claims, which would involve new applications of knowledge concerning the genes, or the patentability of naturally occurring DNA that had been altered in some way. It decided that Myriad had not created or altered the genetic information encoded in the genes, nor the genetic structure of the DNA.

In addition, Myriad’s claims were not rescued by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together. A naturally-occurring DNA segment is not patent-eligible merely because it has been isolated, but cDNA is patent-eligible because it is not naturally-occurring. Myriad did not create or alter the genetic information encoded in the genes or the genetic structure of the DNA. The Supreme Court did find that complementary DNA[[65]](#footnote-64) could be a patentable subject matter, as it is different from the DNA that occurs in nature. c-DNA is not a product of nature, as the laboratory technician must remove introns from the DNA sequence to make something new.

##### 4. *In re Roslin Institute*, 750 F.3d 1333 (Fed. Cir. 2014)

Dolly the sheep was the first mammal to be cloned from adult somatic[[66]](#footnote-65) cells. As a clone, Dolly was produced with an identical genetic copy of a cell, cell part or organism. Dr. Keith H.S. Campbell and Sir Ian Wilmut were the scientists who performed this cloning procedure. The method used by Campbell and Wilmut was considered a scientific breakthrough. Dolly came into being through the fusion of the nucleus of an adult, somatic mammary cell with an enucleated oocyte[[67]](#footnote-66). An exact genetic replica of the adult mammal results from the cloned animal. Campbell and Wilmut obtained a patent on this method of cloning animals, which was assigned to Roslin, but the patent at issue dealt with the clones themselves.

In 2008, the USPTO rejected Campbell’s and Wilmut’s patent claims due to non-statutory subject matter under 35 U.S.C. § 101. The USPTO stated that the subject matter was ineligible for protection because the clone constituted a natural phenomenon that did not possess markedly different characteristics from those found in nature. In addition, the USPTO determined that the claims were anticipated and obvious under §§ 102 and 103 when compared to prior art. Unfortunately for Dolly, and Roslin, Dolly’s DNA was an exact genetic replica of another sheep and did not have markedly different characteristics from those of farm animals found in nature.

Roslin did not dispute the fact that the genetic material from the donor sheep that created Dolly could not be patented. Instead, Roslin contended that the clones were eligible for patent protection because they were a product of their ingenuity and not a product of nature. Roslin claimed that its clones were distinguishable from the donor animals used to create them.

The Federal Circuit Court upheld the decision of the USPTO. The Court concluded, in line with the Supreme Court’s ruling in *Myriad*, that Roslin did not create or alter any of the genetic information of its claimed clones. In addition, Roslin did not create or alter the genetic structure of the DNA it used to create its clones, Dolly included. The word “cloned” in Roslin’s claims indicated genetic identity. Roslin did not suggest that the clones were distinct in any way from the donor animals. Instead, all that Roslin did was to preserve the donor DNA in such a way as to make an exact copy of the mammal from which the DNA was taken. Such a copy was not eligible for patent protection.

##### 5. *Ariosa Diagnostics Inc. v. Sequenom Inc*., 788 F.3d 1371 (Fed. Cir. 2015)

In *Sequenom*, the U.S. Court of Appeals for the Federal Circuit invalidated patents held by Sequenom Inc. The company had been granted patents on methods which used cell-free fetal DNA (cffDNA)[[68]](#footnote-67) found in maternal plasma and serum for the efficient detection of fetal genetic defects. These fetal genetic tests avoided dangerous, invasive techniques that could be harmful to the mother and the fetus. The patent instructed technicians to take a maternal blood sample, keep the part that was previously considered medical waste and discarded, amplify the genetic material that was present, then identify paternally inherited sequences as a means of distinguishing fetal and maternal DNA. Sequenom reiterated that the claimed method did not pre-empt other demonstrated uses of cffDNA. While the Court acknowledged that Sequenom’s patent methods represented an important scientific advance, cffDNA found in maternal blood is a natural phenomenon. In addition, the methods of DNA testing and detection were well-understood and routine methods. Essentially, the Court ruled that cffDNA composition was not patent-eligible and that methods of testing for fetal genetic defects through the use of cffDNA were obvious. Although Sequenom claimed that its method did not completely pre-empt other uses of cffDNA, the Court ruled that this did not make its method patent-eligible. Sequenom petitioned for *certiorari*, but the Supreme Court denied the request to review the U.S. Court of Appeals for the Federal Circuit’s decision. The Sequenom case reaffirms the Supreme Court’s caution that “a groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry”[[69]](#footnote-68).

##### 6. Implications for patentability after *Sequenom*

Over the last five years, the United States has significantly narrowed the scope of patent-eligible subject matter in the field of biotechnology. Subject matter that was previously considered patentable may now be rejected as unpatentable. Considering the complexity of the rules and the difficulties in understanding and applying the exceptions allowed by the Supreme Court, most scholars believe that the Court should provide further guidance on stem-cell patentability. Even though the Supreme Court has not classified stem cells as patent-ineligible subject matter, the worry that stem cells may be so classified is on many investors’ minds. In addition, even though the United States does not currently have a morality clause, one might wonder whether U.S. stem-cell patent policies will eventually become as narrow as those of the EU.

#### **B. Europe**

In Europe, patents may be granted either via a national route or via the EPC regional route. The national laws of most European countries should, as mentioned above, be compatible with the TRIPs Agreement (including Article 27, which is relevant to our topic) and, in the case of EU Member States, with the Biotech Directive (of which Articles 5 & 6 are relevant here). The European Patent Convention (of which Article 53 and associated Rules 26, 27 and 28 of the Implementing Regulations to the EPC are of relevance) is binding only on members of the European Patent Organization and, most importantly, on the European Patent Office which is the European Patent (EP) granting institution. Therefore, patent applications in respect of stem-cell inventions may be filed either nationally or regionally (directly or through the Patent Cooperation Treaty system).

Stem-cell inventions are subject to all the patentability requirements usually applied, including the threshold of being an invention as opposed to a discovery (found in Article 52 EPC). Additionally, their current patentability status in Europe has been shaped by three important decisions, one taken by the Enlarged Board of Appeal (EBA) of the EPO and two by the European Court of Justice (ECJ). All three of these cases involve issues of morality and ethics, as briefly outlined in section III.

##### 1. *WARF/Thomson case* no. G02/06 of 25 November 2008

Contrary to developments affecting the Wisconsin Alumni Research Foundation (WARF) patent portfolio in the USA, one of their patents filed with the EPO through the PCT system has become the landmark case for rejecting the patentability of hESCs in Europe.

EP application no. 96903521.1[[70]](#footnote-69), under the title “Primate embryonic stem cells”, related to a method for preparing primate (including human) embryonic stem cells derived from an embryo, allowing their *in vitro* maintenance for a long period of time without losing their potential to differentiate into any cell of the body. The EPO Examining Division refused to grant the patent inter alia because the disclosed method of obtaining stem cells used a primate (including human) embryo as the starting material, which was destroyed in the process. This was found to contravene Article 53(a) of the EPC, as well as Rules 28(c) and 26 of the Implementing Regulations (Rule 26 referring to the inclusion of the Biotech Directive as a means of interpreting the EPC).

The negative decision was appealed in 2004. The Technical Board of Appeal competent in the case referred a number of points of law to the Enlarged Board of Appeal (EBA), the EPO's supreme judicial body, which is the highest instance of appeal responsible for ensuring uniform application of patent law, is independent of the Office in its decisions, and is bound only by the EPC[[71]](#footnote-70). In November 2008, the EBA confirmed the Examining Division’s decision and judged that it was not possible under the EPC to grant a patent for an invention which – as described in the application – at the time of filing could be prepared exclusively using a method which necessarily involved the destruction of human embryos, even if the said method was not part of the claims. The EBA stressed, however, that its decision did not concern the general question of human stem-cell patentability. Interestingly, it also rejected the request for an ECJ preliminary ruling on the issue, for lack of any legal and institutional link between the EPO appeal boards and the EU.

The decision was binding only on the EPO[[72]](#footnote-71), therefore at the time only the regional route seemed closed for hESCs patents. It provoked both positive and negative reactions: the positive ones stressing that it would be easier for biotech companies to operate in Europe as compared with the USA, where similar patents on the use of human embryonic stem cells have been granted; the negative ones stressing the stifling effect of a lack of adequate incentives for furthering stem-cell research.

##### 2. *Oliver Brüstle v. Greenpeace e.V.* (Case C-34/10) of 18 October 2011

Another landmark case in Europe originated from a national filing and went up to the ECJ. In December 1997, a German scientist, Dr Oliver Brüstle[[73]](#footnote-72), filed a patent concerning isolated and purified neural precursor cells, processes for their production from embryonic stem cells (ESCs), and their use for treatment of neural defects (German patent no. 197 56 864). It was claimed that the transplantation of cerebral cells derived from embryos into the nervous system would make it possible to treat numerous neurological injuries and conditions, including Parkinson’s disease[[74]](#footnote-73).

Greenpeace challenged the patent on the grounds that some of its claims relied on cells obtained from hESCs, thereby rendering the invention unpatentable under the respective provisions of the German patent law implementing Article 6(1) and (2) of the Biotech Directive[[75]](#footnote-74). The German Patent Court (*Bundespatentgericht*) declared the patent invalid in part (the first claim relating to precursor cells obtained from hESCs, and claims 12 and 16 relating to processes for the production of precursor cells derived therefrom). The decision was appealed and went before the German Federal Court of Justice (FCJ), which in turn, in December 2009, applied for a preliminary ruling from the ECJ.

The ECJ was confronted with three questions regarding the interpretation of the Biotech Directive. The first concerned the meaning of the term “human embryo”, and how wide an interpretation it should be afforded. The second regarded the meaning of the phrase “uses of human embryos for industrial or commercial purposes” in Article 6(2), the Court having to establish whether there exists an exception for scientific research and, consequently, whether the fruits of hESCs research are patentable. The third question related to the patentability of the technical teaching: whether it is to be considered unpatentable even if the immoral use of human embryos does not form part of it and is not claimed, but is only a necessary precondition.

The court recognized that the term “human embryo” should be seen as an autonomous concept of EU law, which must be interpreted in a uniform manner throughout the Union and should be understood in a wide sense. Accordingly, a “human embryo” is reckoned to include any human ovum as soon as it is fertilized, since it has commenced the process of development as a human being, as well as a non-fertilized human ovum with a transplanted cell nucleus from a mature human cell, and a non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis[[76]](#footnote-75). In the light of the written observations presented in the case, the latter two categories were considered by the Court to be capable of commencing the process of human development, even though they had not been fertilized, a statement that was later reviewed in the *ISCO* case described under point 3.

In the answer to the second question, the Court made a distinction between scientific research and the commercial/industrial uses of its outcomes. It observed, however, that the subject invention of a patent has to be susceptible of industrial/commercial application, which is one of the patentability requirements. In such a situation, the purpose of the scientific invention to be patented acquires industrial and commercial traits and cannot be, for this reason, considered patentable where hESCs research is concerned. Only use for therapeutic or diagnostic purposes applied and useful to the human embryo can be patentable[[77]](#footnote-76).

In response to the third question, the Court excluded from patentability inventions whose technical implementation, applied for in the patent, necessitates the destruction of human embryos at any stage (also as a base material), even if it does not form part of the patent specification. The aim of this finding was to prevent abusive patent drafting.

The ECJ preliminary ruling has a binding effect not only on the German Federal Court of Justice, but also on all the national courts of the Member States, setting forth the standard uniform interpretation of EU law. Interestingly, on 27 November 2012, following the ruling, the German FCJ amended the judgment of the Federal Patent Court[[78]](#footnote-77) and maintained Dr Brüstle’s patent, with the proviso that the embryonic stem cells must not be obtained by destruction of human embryos[[79]](#footnote-78). Appropriate disclaimers in claim 1 and claims 12 and 16 were added[[80]](#footnote-79).

##### 3. *International Stem Cell Corporation (ISCO) v. Comptroller General of Patents, Designs and Trademarks* (case C-364/13) of 18 December 2014

The last of the important cases for determining the patentability threshold for stem-cell inventions in Europe originated from the United Kingdom and was also judged by the ECJ in a preliminary ruling. The applicant and appellant was on this occasion an American corporation, referred to in short as the ISCO, specializing in regenerative medicine, which had purchased two patent applications: GB0621068.6, concerning the production of human stem cells from parthenotes, and GB0621069.4, concerning human synthetic corneas and corneal tissues derived from parthenotes (both filed on 23 October 2006).

In August 2012, both applications were rejected by the UK Intellectual Property Office, taking into account the *Brüstle* judgement, as they involved the destructive use of parthenotes[[81]](#footnote-80). The applicant’s main counterclaim was the scientific fact that a parthenote cannot develop into a human being and therefore should not be considered a human embryo. The case went up to the High Court of Justice (England & Wales), which requested another preliminary ruling on 17 April 2013, asking for a clarification as to whether parthenotes should be considered human embryos in the light of current scientific knowledge.

In response, the ECJ ruled that an unfertilized human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a “human embryo”, if it does not, in itself, have the inherent capacity to develop into a human being (i.e. is not totipotent)[[82]](#footnote-81).

##### 4. The patentability status of stem-cell inventions in Europe

The above cases have clearly shaped the status of stem-cell inventions originating from humans. The policy objections in Europe relate to moral/ethical considerations associated with the destruction of human embryos, which, at the time the judgements were issued,[[83]](#footnote-82)was deemed necessary to obtain stem cells for scientific research.

As the *Brüstle* casefollowed the logic applied by the EBA in the *WARF case*, and the *Brüstle* and *ISCO* outcomes were also both recognized by the European Patent Office, which amended its guidelines accordingly, the patentability status of such stem-cell inventions should be fairly homogeneous across Europe.

In summary, isolated adult stem cells, as such, are not excluded from patentability, unless they are totipotent, i.e. able to develop into a human being (such as an embryo). Whenever an invention relies on the destruction of human embryos (irrespective of when such destruction takes place), the invention will not be granted patent protection. Pluripotent ESCs are not to be considered human embryos, as they do not in themselves have the capacity to develop into a human being. Induced pluripotent stem cells, which do not involve “uses of human embryos” and are likewise not capable of development into a human being, are therefore patentable[[84]](#footnote-83), provided they meet the other patentability criteria. Stem-cell inventions based on parthenotes are also patentable, as parthenotes are not considered human embryos because they lack the inherent capability of developing into human beings.

It is important to remember that the above restrictions do not prevent scientific research in the realm of hESCs as such[[85]](#footnote-84). The policy that has emerged from the annotated case law only restricts commercial incentives resulting from patent protection for inventions that are morally/ethically questionable, leaving the determination of the legality of such research to individual European countries.

#### **C. Sri Lanka**

The situation in Sri Lanka concerning stem-cell patentability is very different from the other countries as Sri Lanka is a developing nation and stem-cell research and related technologies are still in their infancy. Research in this field takes place mainly in universities and is concerned predominantly with cancer stem cells and the use of commercially available cell lines and cord blood cells. To conduct this type of research or use the related technology, ethical clearance from the ethics committee of the particular university and patient consent are required. Research of this kind is funded by public or collaborative grants. Therefore, ownership of any resulting invention will depend on an agreement based on an act or policy implemented by the particular institute. The country is still in the process of drafting national ethical guidelines for stem-cell research[[86]](#footnote-85).

Only five patents relating to stem cells have been applied for in Sri Lanka. Four of these are foreign patent applications (via the PCT route), and only one a local patent application. Only two patents have so far been granted, both involving inventions relating to adult stem cells, more specifically neural and hematopoietic stem cells. The remainder are still at the formality and substantial examination stages[[87]](#footnote-86).

In Sri Lanka, the National Intellectual Property Office (hereinafter the NIPO) is the governing body for granting patents, operating under the Intellectual Property Act no. 36 of 2003[[88]](#footnote-87). This Act was designed to promote national creativity, protect creative efforts and honour Sri Lanka’s international obligations, particularly under the TRIPS Agreement. As per Chapter 9 clause 63, an invention is patentable if it is new, involves an inventive step and is industrially applicable. The said clause, together with clauses 62(1) and (2), provides a clear definition of an invention: “an idea of an inventor which permits in practice the solution to a specific problem in the field of technology” and “[…] may be related to a product or a process respectively”. Patentability is further clarified by clause 62(3) of the Act, with sub-clause 62(3.b)[[89]](#footnote-88) specifying which life forms and processes can be patented. Under this clause, only transgenic micro-organisms are patentable, in accordance with the Supreme Court Determination of the IP Bill in 2003. Clause 62(3.f)[[90]](#footnote-89) prevents patentability within the country of inventions which are detrimental to public order and morality, human, animal or plant life or health, or which would constitute a threat to the environment.

As mentioned above, in 2003 the Supreme Court issued a Determination of the Intellectual Property Bill. Three local petitioners raised objections against clauses 62, 83, 84, 87, 90, 91, 92, 93 and 94 of the Bill. Clause 62 was challenged on the ground that it was inconsistent with Article 12(1) of the country’s Constitution. This article guarantees that all citizens are equal before the law and are entitled to equal protection by the law. The petitioners argued that a provision which permits the patenting of micro-organisms, without any limitations or protection, cannot satisfy article 12(1)[[91]](#footnote-90). In the absence of a definition of the term “micro-organism”, the petitioners claimed that it would be possible for a variety of pathogens to be patented, which would pave the way for patent holders to monopolize research on diagnostics and the development of cures. Furthermore, this would increase the prices of downstream research products. The Supreme Court agreed with the petitioners and stated that, in the absence of a definition of “micro-organisms”, patents in this area could become inappropriately broad. To remedy this, the State amended the clause by restricting patent protection to transgenic micro-organisms. The current Act now specifies that only transgenic micro-organisms requiring direct human interventions, as defined in the various articles, are patent-eligible. The Supreme Court Determination provided useful indications to policy-makers in Sri Lanka on how to use the flexibilities contained in the TRIPS Agreement to promote and support local innovation, while at the same time affording protection to genuine and man-made inventions[[92]](#footnote-91).

Sri Lanka does not have any legislation analogous to the EU Biotech Directive. The aforementioned clauses of the IP Act are therefore relevant to the granting of patents. Moreover, the NIPO is likely to follow the EP patent guidelines where moral and ethical issues are concerned[[93]](#footnote-92).

Apart from the Intellectual Property Act, stem-cell research will adhere to relevant national policies and to university and institutional policies. The Biotechnology Policy is a national policy devised to foster and promote local innovation on the part of researchers and industry. One of the main thrusts of the biotech policy is the development of a legislative framework relating to IPRs and technology transfer. The NIPO collaborates by providing guidelines on IPRs for universities, institutes and industry. In addition, for health-related research, the Ministry of Health has drafted a research code: the Code of Conduct for Health Research in Sri Lanka. Clause 8.1b of this code relates to the management of IP rights, stating that an institution or university must have a policy to protect the intellectual property rights of the institution, its researchers and sponsors. The policy is required to prevent undue delays and restrictions in publication. Universities and institutes are therefore obliged to have their own IP policy. University policies follow the concept of the U.S. Bayh-Dole Act, which gives them the authority to market their research. In the near future, Sri Lanka will adopt its first Innovation and Entrepreneur Strategy[[94]](#footnote-93), which is now in the final-draft phase. Clause 3.6 of the draft refers to the adoption of a modern IP policy framework to foster the commercialization of research.

Apart from recent developments in stem-cell research, biotechnology in Sri Lanka is in a transitional phase from conventional to modern. To promote local R&D and the biotechnology industry as a whole, it is important to develop a national innovation ecosystem for the country. At present, the country is progressing towards creating its first biotechnology park. Based on a public-private partnership, its purpose will be to promote and facilitate biotech research and its commercialization. This will mark the beginning of a new era for stem-cell research. This is therefore the right time to develop a national apex committee[[95]](#footnote-94) to oversee stem-cell research in Sri Lanka and a set of national ethical guidelines. This should create a correct balance between researchers, IP right-owners and society generally. Sri Lanka therefore needs to interpret exceptions to patent rights in a manner appropriate to its biotechnology patent law and policies in order to promote local biotechnological innovation and minimize the implications of such exceptions for the legitimate interests of stakeholders[[96]](#footnote-95).

### **V. Lessons learned and recommendations for developing countries**

Having presented the respective laws and regulations regarding stem-cell research and patentability in the USA, Europe, and Sri Lanka, in this last section we shall attempt to highlight important issues connected with stem-cell research and technologies and provide recommendations for developing countries looking to promote innovation in this area.

The market for stem-cell technologies and therapies is expected to grow exponentially within the next decade. Globally, it is expected to be worth $38.9 billion by 2023[[97]](#footnote-96), driven in part by the role of stem-cell technologies and therapies in therapeutic applications for chronic illnesses. Chronic diseases and injuries are on the rise and have a profound economic and societal effect in both developed and developing countries. Many billions of dollars will be spent over the next decade in treating these diseases. Stem-cell therapies and technologies have also been shown to be extremely relevant to the health and economic needs of developing countries, where they could have a huge impact, the extent depending on how well these technologies are regulated, financed and protected.

For these reasons, our first recommendation is that stem-cell research and technologies should be promoted, invested in and protected. Given that stem-cell research shows such promise for curing many diseases and conditions, restrictions on funding such research should be kept to a minimum. Considering the benefits that stem cell research can have on human health, investment in these research areas should be embraced and expanded.

In today’s globalized marketplace, where the mobility of products and technologies is more prominent than ever, it is especially important for countries to provide the most advantageous and innovative environment in which to sustain growth. This is also true for stem-cell research and technologies, for which this “innovation ecosystem” is crucial. Unfortunately, in many least developed and developing countries, we see a system where modern and scientific needs are at odds with legal systems, including patent laws. Therefore, developing countries should, first and foremost, enact laws, regulations and guidelines dealing with all important aspects of stem-cell research and technologies, including patentability and funding.

This is not easy, as we have seen in the present paper. Stem-cell research, technologies and therapies tend to be heavily regulated and vary from country to country. Patentability requirements also differ considerably. While there are minimum patent standards in place for WTO member states, the substantive standards are not harmonized, which leads to differences internationally and within individual countries. In the United States, for example, the patent system is federal, whereas the regulation of certain aspects of stem-cell research is controlled by the individual states, with sometimes large differences from state to state. Taking into account differences in the political organization of the two regions, a similar pattern can also be observed among European countries, which creates barriers to the development of this area of research.

The lesson that developing countries can learn from this situation is that laws concerning stem-cell or any other biotechnological research should always be holistic, coherent and consistent. As we have seen, they involve moral and ethical issues, as well as issues relating to funding, patentability, marketing clearance, knowledge dissemination and spill-overs. And there are, of course, other issues that have not been addressed in this paper. It would also be helpful and useful to provide up-front and clear definitions of such crucial terms as “stem cells”, “embryos”, “inventions” and “discoveries”. These should remain consistent between the various legal documents.

The analysis provided in this paper shows that there are many possible approaches to the patentability of stem-cell inventions, as taken by different countries. It is therefore advantageous for developing countries to study those approaches and their impact on the innovation ecosystem. To sum up, over the past century the United States has emerged as the leader in the area of stem-cell research due to its regulatory approach. While the scope of patentable subject matter in the USA may once have been the broadest, over the years the courts have continued to narrow and restrict the scope of stem-cell technologies that are acceptable for patentability. Some commentators would say that recent developments and court rulings have made it more difficult to obtain patent protection in the United States, which could have a chilling effect on stem-cell innovation. Others, however, highlight the possibility that these developments may open the market in stem-cell research to more players, which will have a positive effect on the prices of the downstream treatments available to society.

Meanwhile, Europe has from the beginning adopted stricter regulation where exclusions from patentability are concerned, and has provided for clauses regarding morality and public order. Over time, this initial position has been questioned and somewhat liberalized in favour of stem-cell technologies and their patentability, as seen in some important legal decisions. This may serve as a role model for developing countries, encouraging them to respect their cultural traditions when deciding on laws and regulations governing stem-cell research and technologies. The European situation would seem to indicate that placing moral or ethical restrictions[[98]](#footnote-97) on research does not prevent the creation of an environment allowing stem-cell technologies and therapies to survive.

Apart from strong support from government fostered by clear regulatory policies, stem-cell research also needs financial backing. Investing in stem-cell technologies and therapies is an expensive business, which is why well thought-through funding policies are extremely important. It appears from the above analysis that financial support for stem-cell research works better when it comes from a mixture of sources, government/public and private, and also from the revenues generated by the patent protection system.

When financial support comes primarily from the government, patent laws may need to be less strong, since there is not as much need to recoup initial investment as there would be if the support was private. The patentability threshold could then be set higher, allowing the innovative knowledge falling outside the patentability criteria to be used by other players. The condition here, however, should be the mandated disclosure of research outcomes to prevent the adoption of a trade-secret strategy (as with NIH policies and EU grants). Additionally, because the government, by providing funding, can use its power to initiate innovation, it can better control what research is undertaken and so maximize the benefit to the country as a whole.

The patent laws a particular government puts in place can also serve this aim to some extent. By determining the patentability threshold and exclusions, policymakers may indirectly approve of and support certain research directions and ideas. As we have seen in Europe, the depth and strength of the “destruction of embryos” controversy has given additional impetus to research into alternative stem-cell technologies, such as those based on adult stem cells[[99]](#footnote-98).

It is argued that the patentability of technologies and therapies of this kind is extremely important because of investment issues. It is most crucial for companies that do not have the necessary resources and rely heavily on third-party investors. Whenever private funding is involved in stem-cell research, patents serve, firstly, as a value indicator, secondly, as revenue security and, thirdly, as a means of protection against infringements. This should be carefully taken into account. The involvement of private bodies in such research may also serve as a counter-balance to governmental decisions in the ever-changing political climates of different countries. The stakeholders will make sure that groundbreaking technologies and therapies are not stifled by a stroke of the government’s pen.

All in all, careful and well thought-through funding policies are crucial for the friendliness of the innovation environment. Unpredictability in funding inflicts a heavy cost on scientific progress and damages countries’ competitive positions, precluding the development of great inventions. The more competitive a country is in the field of stem-cell research, the greater its motivation to promote protective policies that safeguard its research advantages and promote innovation.

As mentioned in the previous paragraphs, developing countries are faced with the difficult task of balancing different interests. One clear recommendation arising from the above analysis is that developing countries should ensure that the legislation and statutes they enact protect the public interest. However, by completely removing or disregarding the legal monopoly protection so beneficial to inventors and innovators, a country will not appear very attractive to investors. It should therefore aim to reward investors and innovators for their efforts by entitling them to patent protection, but also make sure that the interests of the public are promoted and protected.

This also involves the aspect of providing enough support for local industries to boost their development. On the one hand, patents granted to foreign entities create barriers to competition on the part of local players. On the other hand, patenting would seem to be crucial for local businesses as it secures their intellectual creations and market position. Legislation and statutes governing patentability should therefore be drafted with caution to reflect the desired policy, which may change over time, and should be clear and concise in order to decrease the level of uncertainty for innovators. It should be borne in mind that the exclusive right granted by a patent is not a right to practice, but a right to exclude others from practicing an invention. An undesired by-product of the system might therefore be the restriction of knowledge and expertise, and the use of patents as blocking tools to keep out competitors. On the other hand, when patent protection is diminished, companies may be tempted to rely more on secrecy and forego dissemination of knowledge altogether. An appropriate solution might be a targeted research exception to a patent right designed to spur knowledge dissemination.

Given the above findings, and taking into account new developments in the area of stem-cell research, patent laws should be drafted in such a way as to encourage inventions. Clearly, their role should be to promote development in science and technology, while protecting the exclusive rights of inventors. Patent legislation should also be drafted to encourage the dissemination of information. If warranted by the situation in a particular country, a patent right should not be granted if the invention is detrimental to public order or morality. In addition, each country will need to determine its patentability criteria in terms of novelty, non-obviousness, industrial applicability and inventiveness, but care needs to be taken to define these terms with the future of stem-cell development and the promotion of uniform patent legislation in mind[[100]](#footnote-99). An exemption clause will need to be included in any patent law to protect the public interest and spur scientific development.

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28. Currently 164 member states. [↑](#footnote-ref-27)
29. The U.S. Constitution, Article 1 Section 8 Clause 8 states that, “The Congress shall have the power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” [↑](#footnote-ref-28)
30. Consider, for example, the stuka (a dive bomber), the construction of which was inspired by the behaviour of common swifts. [↑](#footnote-ref-29)
31. This means that legislation inspired by the same philosophy will have effect in all EU Member States. [↑](#footnote-ref-30)
32. Please see Recitals 16 and 23, respectively, of the Preamble. [↑](#footnote-ref-31)
33. As opposed to discoveries. [↑](#footnote-ref-32)
34. As specified in Rule 26, see <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/r26.html>. [↑](#footnote-ref-33)
35. According to the Hinxton Group map, restrictive policies towards stem-cell research (especially human embryonic stem cells (hESCs)) are in force Arizona, Florida, Louisiana, Maine, Michigan, Minnesota, North Dakota,Pennsylvania and South Dakota. [↑](#footnote-ref-34)
36. E. Bonadio, *Biotech Patents and Morality after Brüstle*inEuropean Intellectual Property Review 2012, Issue 7. [↑](#footnote-ref-35)
37. Interestingly, the patent on the oncomouse was granted in the USA and refused in Canada. For details, see WIPO Magazine, *Bioethics and Patent Law: The Case of the Oncomouse*. [↑](#footnote-ref-36)
38. E. Bonadio, ibid. [↑](#footnote-ref-37)
39. D.E. Eyre, G.W. Schlich, *Strategies for Stem Cell Patent Applications in the Light of Recent Court Cases*, January 2016. [↑](#footnote-ref-38)
40. Which became effective on September 16, 2012. [↑](#footnote-ref-39)
41. Fifteen American states (Arkansas, California, Connecticut, Iowa, Indiana, Massachusetts, Maryland, Michigan, North Dakota, New Jersey, Rhode Island, South Dakota, Florida, Georgia, and Virginia) ban reproductive cloning, and three states (Arizona, Maryland, and Missouri) prohibit use of public funds for such activities. [↑](#footnote-ref-40)
42. “SCNT is a technique for cloning. The nucleus is removed from a healthy egg, which becomes the host for a nucleus that is transplanted from another cell, such as a skin cell. The resulting embryo can be used to generate embryonic stem cells with a genetic match to the nucleus donor (therapeutic cloning), or can be implanted into a surrogate mother to create a cloned individual, such as Dolly the sheep (reproductive cloning).” Available at: <https://www.hhmi.org/biointeractive/somatic-cell-nuclear-transfer-animation> (accessed 16 November 2015). [↑](#footnote-ref-41)
43. They are only pluripotent and not totipotent, which means that they cannot themselves develop into a living organism. [↑](#footnote-ref-42)
44. N. King & J. Perrin, *Ethical issues in stem cell research and therapy*, 2014. [↑](#footnote-ref-43)
45. N. Allum et al., *Religion and the public ethics of stem-cell research: Attitudes in Europe, Canada and the United States*, 2017. [↑](#footnote-ref-44)
46. S. Packer, *Embryonic stem cells, intellectual property, and patents: Ethical concerns* in Hofstra Law Review, Vol. 37, Issue 2, 2008. [↑](#footnote-ref-45)
47. These will not be discussed in this paper for lack of space. [↑](#footnote-ref-46)
48. Evoked by the Advocate General in the Brüstle case, which will be described in detail in Section IV of the present paper. An example of the only piece of relevant legislation that is fully harmonized among the EU Member States. [↑](#footnote-ref-47)
49. The European Patent Convention does not act as a directive, however. There has to be an implementing instrument in each EPO Member State. However, adopting one only means that the country agrees to grant protection on its territory to patents granted exclusively by the European Patent Office. It does not necessarily oblige Member States to bring their laws entirely into line with the EPC. As of 1 March 2018, the European Patent Organization had 38 Member States. [↑](#footnote-ref-48)
50. S. J. R. Bostyn et al, *Final Report of the Expert Group...,* European Commission, 2016, page 138. [↑](#footnote-ref-49)
51. Ibid. For example, the German Patent Act refers to the Embryo Protection Act, which is a criminal law regulating assisted procreation and prohibiting inter alia the use of IVF techniques for purposes other than to initiate and pursue a pregnancy, the artificial alteration of human germ line cells, the cloning or formation of human animal chimaeras and hybrids, and oocyte donation. [↑](#footnote-ref-50)
52. Ibid, page 138. [↑](#footnote-ref-51)
53. Ibid, page 138. Patent Act, 2 June 2007, Art. 2. [↑](#footnote-ref-52)
54. D.E. Eyre, G.W. Schlich, *Strategies for Stem Cell Patent Applications in the Light of Recent Court Cases*, January 2016. [↑](#footnote-ref-53)
55. United States Patent and Trademark Office, *United States Code Title 35- Patents*, 2017. [↑](#footnote-ref-54)
56. United States Patent and Trademark Office, *35 U.S.C. 101 Inventions patentable.* [↑](#footnote-ref-55)
57. *Mayo Collaborative Services, DBA Mayo Medical Laboratories, Et. al. v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). [↑](#footnote-ref-56)
58. United States Patent and Trademark Office, Leahy-Smith America Invents Act, 2011. [↑](#footnote-ref-57)
59. Hematopoietic stem cells are immature cells that can develop into all types of blood cells, including white blood cells, red blood cells and platelets. They are found in the peripheral blood and the bone marrow. Also called blood stem cells. [↑](#footnote-ref-58)
60. Mesenchymal stem cells (MSCs) are a type of tissue or 'adult' stem cells. They are ‘multipotent’, meaning they can produce more than one type of specialized body cell, but not all types. [↑](#footnote-ref-59)
61. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). [↑](#footnote-ref-60)
62. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). [↑](#footnote-ref-61)
63. A new way to “reprogramme” adult, specialized cells and turn them into stem cells. For details see Section I of this paper. [↑](#footnote-ref-62)
64. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc*., 569 U.S. 576 (2013). [↑](#footnote-ref-63)
65. cDNA is known to be synthesized, or manufactured from a messenger RNA (mRNA) template. It is synthesized in a reaction that is catalyzed by the reverse transcriptase and DNA polymerase enzymes. [↑](#footnote-ref-64)
66. Somatic cells are body cells other than gametes (eggs or sperms). [↑](#footnote-ref-65)
67. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014). [↑](#footnote-ref-66)
68. Cell-free fetal DNA (cffDNA) is naturally occurring extracellular fetal DNA that circulates in the bloodstream of an expecting mother. [↑](#footnote-ref-67)
69. *Ariosa Diagnostics Inc. v. Sequenom Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). [↑](#footnote-ref-68)
70. EP publication no. 0770125. Details at <https://register.epo.org/application?number=EP96903521>. [↑](#footnote-ref-69)
71. It consists of five legally qualified and two technically qualified members appointed by the EPO Administrative Council for a term of five years. [↑](#footnote-ref-70)
72. And the lessons learned from it were included in the EPO Guidelines, section G-II, 5.3. To be found at   
    <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_3.htm> [↑](#footnote-ref-71)
73. A director of the Institute of Reconstructive Neurobiology at the University of Bonn, Germany. [↑](#footnote-ref-72)
74. S.H.E. Harmon, G. Laurie, A. Courtney, *Dignity, plurality and patentability: the unfinished story of Brustle v Greenpeace* in European Law Review, 2013. [↑](#footnote-ref-73)
75. Art. 2 of the Patent Law (German “Patentgesetz”). Additionally, provisions in the Law regarding the protection of embryos in connection with the importation and use of hESCs (Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen) state that the importation and use of pluripotent ESCs are prohibited unless they and their acquisition meet a range of stated conditions. Ibid, page 2. [↑](#footnote-ref-74)
76. European Court of Justice, *Oliver Brüstle v Greenpeace e.V.*, case C-34/10, 18 October 2011, “Brüstle” case, par. 35, 36. [↑](#footnote-ref-75)
77. Ibid, par. 46. [↑](#footnote-ref-76)
78. German case X ZR 58/07. [↑](#footnote-ref-77)
79. S. J. R. Bostyn et al, *Final Report of the Expert Group...,* European Commission, 2016, page 140. [↑](#footnote-ref-78)
80. Claim 1 disclaimer: “whereby no isolated purified precursor cells of human embryonic stem cells are used when embryos have been destroyed for their production”, claims 12 and 16 disclaimers: “whereby no human embryonic stem cells are used when embryos have been destroyed for their production”. [↑](#footnote-ref-79)
81. United Kingdom Intellectual Property Office, *Decision BL O/316/12 by Dr L Cullen* of 16 August 2012. [↑](#footnote-ref-80)
82. European Court of Justice, *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trademarks*, case C-364/13, 18 December 2014, “ISCO” case, par. 38. [↑](#footnote-ref-81)
83. There are said to be morally acceptable methods of obtaining hESCa from human embryos, which do not cause them to die – a view that is not unanimously held. For a discussion of the issues involved, see S. J. R. Bostyn et al, *Final Report of the Expert Group...,* European Commission, 2016, pp 168. [↑](#footnote-ref-82)
84. S. J. R. Bostyn et al, ibid, page 143. [↑](#footnote-ref-83)
85. U. Storz, *The limits of patentability: Stem cells.* A chapter from A. Hübel, U. Storz, A. Hüttermann, *The Limits of Patentability: Plant Science, Stem Cells and Nucleic Acids*, 2013. [↑](#footnote-ref-84)
86. Interview of 13.02.2019 with Guideline Committee Official Dr. Sameera Samarakoon, IBMBB, University of Colombo. [↑](#footnote-ref-85)
87. WIPO IPAS version 3.5, accessed on 17 January 2019. [↑](#footnote-ref-86)
88. Sri Lanka Intellectual Property Law Act no. 36 of 2003, published as a supplement to Part II of the Gazette of the Democratic Socialist Republic of Sri Lanka of November 14, 2003. Pages 49-50. [↑](#footnote-ref-87)
89. Clause 62(3.b): Plants, animals and other micro-organisms other than transgenic micro-organisms and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes: Provided, however, that a patent granted in respect of micro-organisms shall be subject to the provisions of this Act; [↑](#footnote-ref-88)
90. Clause 62(3.f): Any invention the prevention within Sri Lanka of the commercial exploitation of which is necessary to protect public order or morality, including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment. [↑](#footnote-ref-89)
91. The Supreme Court Determination of the IP Bill of June 9, 2003 in relation to Petitions Nos. 14/2003, 15/2003 & 16/2003, p. 1074. [↑](#footnote-ref-90)
92. R. Fernando, *Reaping the fruits of patentability of microorganisms. Prospects and challenges to Sri Lanka as a developing country*, Judges Journal 2017, Vol IV, 9. [↑](#footnote-ref-91)
93. Interview of 17.01.2019 with a NIPO official. [↑](#footnote-ref-92)
94. Innovation and Entrepreneurship Strategy of Sri Lanka 2018-2022. [↑](#footnote-ref-93)
95. An apex body is a collaborative organization. Ideally, it will be a consortium of representatives of nearly every relevant sector and stakeholder group. [↑](#footnote-ref-94)
96. R. Fernando, ibid. [↑](#footnote-ref-95)
97. Healthcare Analyst, Inc. *Global Stem Cell Technologies and Applications Market US $38.9 Billion by 2023*, 2018. [↑](#footnote-ref-96)
98. The TRIPs Agreement gives member states the freedom to incorporate morality and public order clauses in patent law (Article 27.2). [↑](#footnote-ref-97)
99. D.E. Eyre, G.W. Schlich, *Strategies for Stem Cell Patent Applications in the Light of Recent Court Cases*, January 2016. [↑](#footnote-ref-98)
100. This is a general recommendation, without going into the issues of novelty, non-obviousness, industrial applicability/utility, which are not specifically covered in this paper. Each country generally determines these matters for itself and it would be hard to give a specific definition/applicability. [↑](#footnote-ref-99)