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Stem cells

- can stem cells be patented and how?

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SUPERMAN Christopher Reeve broke his spine in a riding accident and never regained the use of his lower limbs. Until his death in 2004, he was a leading advocate of stem cell research focused on the treatment of various neurological diseases.

A pivotal moment in stem cell therapy occurred in 2006 with the groundbreaking discovery by Yamanaka and Takahashi that multipotent adult stem cells can be reprogrammed into a pluripotent state. This breakthrough led to the development of human-induced pluripotent stem cells (hiPSCs), which allow for stem cell therapies without the need for embryos. This advancement also represented a significant legal milestone, as hiPSCs enabled the patenting of stem cell-related inventions by eliminating the reliance on embryos as a source.

Since then, stem cell therapy has progressed from foundational research to a robust clinical discipline, with nearly 10,000 clinical studies listed on clinicaltrials.gov. This surge in research offers hope for innovative treatments for severe diseases, including cardiovascular, metabolic, and neurological disorders. The rapid technological advancements in this field require substantial investments in preclinical and clinical development, making patent protection essential to secure returns on these investments. Patents also serve as a vital resource for disseminating critical knowledge, thereby fostering further innovation.

How to patent stem cells?

The legality of stem cell patenting has evolved alongside scientific breakthroughs and varies across jurisdictions. Here, we examine the current landscape in Europe and the USA.

Europe

In Europe, the primary consideration for patent eligibility is the criteria "destruction of embryos." Generally, while embryonic stem cells are not excluded from patentability, those derived from destroyed embryos cannot be patented. Today, there are minimal restrictions on patenting stem cells in Europe, as they can be generated from fetal or adult cells without the use of embryos.

Patents for stem cells as products (composition of matter) in Europe involve defining a stem cell composition with unique structural features that demonstrate specific technical or biological effects. These features may include the tissue of origin or surface markers that, when induced or enriched, confer advantageous properties (e.g., tissue repair) to the stem cell composition. Similar to small molecules and other biologics, the use of stem cells for specific treatments can also be patented by detailing the stem cell composition and the relevant indication.

USA

In the USA, embryonic stem cells are not generally excluded from patentability. However, the obtained stem cells, regardless of their origin or differentiation capacity, must be considered "made by man" rather than products of nature.

Traditionally, in the US, "anything under the sun made by man" is patentable. This broad definition allows for patent protection for any isolated or engineered stem cells, irrespective of their source or type. Following the Supreme Court's Myriad decision in 2012, the USPTO has since aligned its practices, allowing for more straightforward eligibility assessments.

Today, eligibility rejections under §101 can often be avoided by determining whether the claimed product is identical to a naturally occurring counterpart. If it is not, the patent claims must articulate those distinctions. If it is the same, the invention may need to be claimed by the method of its creation or through a treatment method. More often than not, similar to Europe, there are ways to differentiate the invention from its natural counterpart, making it patentable as a product.

The ability to patent hiPSCs has spurred continuous growth and innovation within the stem cell sector, as evidenced by the increasing number of patent applications filed (see Fig. 1).

Stem Cell patent activity over past decades