

Securing IP in Stem Cells

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Stem cells are at the centre of research into regenerative medicine. They have the ability to continuously produce newly differentiated cells and replace damaged cells with healthy new cells. They are also a valuable tool for drug discovery and development. The transition to successful clinical treatments using stem cells has been slow and difficult. However, there is still commercial optimism as the use of stem cells becomes more established and therapeutic applications of stem cells start to enter the market.

Obtaining effective patent protection for inventions related to stem cells is vital.

Criteria for Patentability

Any invention must meet certain key criteria for patentability. Firstly, it must be patent-eligible subject matter. The boundaries of what is considered patentable subject matter differ in each patent office, but in the US and Canada, stem cells and their commercial uses can be patented.

An eligible invention must also be new, useful and inventive compared to previously known information (called "prior art"). For stem cells, there can be difficult issues in drafting patent claims, since they are a complex living system. Proving to patent offices that an isolated stem cell is new and inventive compared to previously known cells, and therefore patentable, can be a challenge.

Embryonic Stem Cells

Embryonic Stem ("ES") cells are derived from the inner cell mass of a developing embryo and are characterized by their ability to differentiate into every cell type (i.e. pluripotency). While a number of human ES cell lines are now available, their creation traditionally required the destruction of a human embryo which has generated substantial controversy.

United States

In the US, ES cells are considered patentable subject matter, as are methods for isolating or producing ES cells, even if the invention requires that a human embryo be destroyed. The recent US Supreme Court decision in *Mayo v. Prometheus* has rekindled the debate regarding whether certain types of inventions are patent eligible. In the meantime, isolated stem cells continue to be patentable subject matter in the US Patent Office.

Canada

In Canada, isolated stem cells are also patentable subject matter. Processes or methods that involve embryonic stem cells or the harm or death of an embryo are not excluded from patentability.

Adult Stem Cells and Induced Pluripotent Stem Cells

Adult stem cells are found in most tissues and are characterized by their ability for self-renewal and for differentiating into specialized cell types. Patents directed towards adult stem cells have been less controversial than ES cells. Recent advances in molecular biology have led to the development of induced pluripotent stem cells ("iPSCs"). iPSCs are technically not adult stem cells, but rather cells that have been reprogrammed, typically using transcription factors, to generate new cells with many of the characteristics of stem cells. Cancer stem cells have emerged as a promising research tool and drug target. They have the ability to form tumours and give rise to all cell types in a particular cancer.

Isolated adult stem cells, cancer stem cells and iPSCs are patentable subject matter in the US and Canada. Any claims to compositions or methods that involve adult stem cells, cancer stem cells or iPSCs must still meet the usual criteria for patentability such as novelty and inventiveness. Notably, distinguishing iPSCs from previously known adult stem cells that they may claim to emulate is a challenge and some patent applications may have to focus on the methods of making the iPSCs.

Conclusion

Consistent strategies can be applied in the U.S. and Canada to patent adult stem cell and iPSC inventions. Patents can cover the cells per se as well as their uses and methods of production. The law should continue to evolve and further clarify the boundaries of patentability. Strong patent protection will be needed as a key driver of investment into stem cell technology and regenerative medicine.

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