



## Patent Protection for Stem Cells - Expanding Opportunities

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Therapeutic applications of stem cells are central to the promise of regenerative medicine. An increasing number of stem cell therapies are being approved for clinical use and by some estimates the global market is expected to grow to ~5 billion dollars by 2024. However, commercializing any therapeutic application is difficult. Careful consideration of patent strategy at the outset of R&D is critical for establishing a competitive advantage.

Different jurisdictions have different restrictions on what may be patented. In most cases, claims directed to isolated stem cells as well as therapeutic uses of those cells are permissible in Canada and Europe as long as the claims meet the remaining criteria for patentability such as novelty and inventiveness. In the United States, isolated products of nature are no longer considered patentable subject matter. This may limit the availability of patent protection for cells that are not “significantly different” from those found in nature. Nevertheless, it is often possible to obtain effective protection by adopting different claim strategies. For example, in the U.S. one strategy is to pursue product claims to any commercially relevant combinations of stem cells and other elements (such as a scaffold or agent that results in the combination having characteristics that are markedly different from those found in nature), while pursuing relatively broad method claims that refer to the cells *per se* for the treatment of a medical condition. Claims to recombinant stem cells should be considered patentable subject matter in the U.S., Canada and Europe.

Cell-based therapeutics will often have complexities in their manufacture not seen with small molecules. Claims directed towards advances in the analysis, preparation or storage of stem cells can have significant commercial value. Remember to try and expand your reach beyond immediate therapeutic applications and work with a patent agent to consider whether additional opportunities exist for patent protection.

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