

PTO Approves the Validity of Additional Stem Cell Patents Essential to Medical Research

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The Patent and Trademark Office recently upheld the validity of two stem cell patents that are held by the Wisconsin Alumni Research Foundation (hereinafter "WARF"), the '780 patent and the '806 patent. These patents are for primate and embryonic stem cells, and were the result of the work of Professor James Thompson. The '780 patent claims a purified preparation of primate embryonic stem cells which are "capable of proliferating as an in vitro culture for more than one year."¹ The '806 patent builds on the methods articulated in the '760 patent but also describes human embryonic stem cells that are derived from pre-implementation embryos.² These discoveries will hopefully lead to a more abundant supply of diverse cell types for medical research and testing and make it possible to create human tissue that will perfectly match the donor.³

The PTO had previously rejected these two patents and another, the '913 patent, which covered the in vitro replication of human embryonic stem cells. WARF amended the patent applications and submitted them for reconsideration. The PTO agreed to reexamine the '780 and '806 patents because of challenges by New York-based Public Patent Foundation and California-based Foundation for Taxpayer and Consumer Rights.⁴ These two organizations were concerned that the issuance of these patents was "outrageous and overreaching" and would "creat[e] a chilling factor for U.S. researchers."⁵ They also objected on grounds of obviousness and anticipation in light of prior art.⁶ The PTO decision rejected all of the challenges.

WARF has rebutted the so-called chilling effect challenge by making it easier for academic and nonprofit organizations to obtain licenses to use the patented stem cell lines. Since January 2007, WARF has allowed such organizations to use the stem cells for free for research purposes, but required that a license be obtained in order to bring the research results to the market.⁷ WARF also allowed the California Institute for

¹ Fact Sheet, Wisconsin Alumni Research Foundation, *Summary of Key Patents*, available at http://www.warf.org/news/news.jsp?news_id=226.

² *Id.*

³ Letter from Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation to Colleagues and Friends (Mar. 11, 2008), available at http://www.warf.org/news/news.jsp?news_id=226.

⁴ *Id.*

⁵ *PTO on Re-Examination Upholds Two More WARF Embryonic Stem Cell Patents*, 75 BNA PAT., TRADEMARK & COPYRIGHT J. 1859 (March 14, 2008) (unavailable without subscription).

⁶ *Id.*

⁷ *Id.*

Regenerative Medicine to use the stem cells without paying fees for a license and without even having to obtain an agreement from WARF.⁸ In total, since 1999, WARF and its affiliate WiCell have granted 914 free academic licenses, shipped cells to more than 563 researchers in 25 countries and 40 states, and granted 25 commercial licenses to industry partners.⁹ These actions prove that “academic scientists using these cell lines and methodologies face no restrictions on patenting or publishing their own novel work.”¹⁰

Sources:

Press Release, Wisconsin Alumni Research Foundation, *Patent Office Upholds Remaining WARF Stem Cell Patents* (Mar. 11, 2008), available at http://www.warf.org/news/news.jsp?news_id=226.

Letter from Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation to Colleagues and Friends (Mar. 11, 2008), available at http://www.warf.org/news/news.jsp?news_id=226.

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⁸ *Id.*

⁹ Press Release, *supra* note 4.

¹⁰ *Id.*