



## Patent Watch

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### **Executive Summary of Patent Watch Project's Discovery of the First US Patent for Reproductive Human Cloning**

The first US patent for reproductive human cloning has been issued by the United States Patent and Trademark Office (PTO). The patent, US 6,211,429, was granted April 3, 2001, but lay unnoticed until Patent Watch Project discovered that it contains claims applicable to cloning of *both* humans and nonhuman animals. The owner of the patent is listed as being the University of Missouri, but inspection of files lodged with the PTO reveals that financial interest in the patent is shared with Biotransplant Inc. (BTRN, Nasdaq) of Charlestown, Massachusetts. Although the patent was issued in 2001, its approval was conducted during the period from April-August 2000, during the second Clinton Administration.

Specifically, claims 19 and 20 of the patent are directed to a "method for producing a cloned mammal", and include steps of nuclear transfer into a mammalian oocyte, and the step of implantation of the so-formed embryo into a recipient maternal mammal to produce a cloned mammal. The methods of the invention are defined as broadly covering all mammals, and specifically include those made from "human oocytes", at column 9, lines 32-39 of the patent. Also, the description of the patent places the public on notice that "the present invention encompasses the living, cloned products produced by each of the methods described herein" (column 7, lines 5-7). Patentees have the right until April 3, 2003, to present such product claims. However, even in the absence of such a claim broadening, the patent owners now have rights over the product, i.e., any cloned human embryo or person born under the process, via operation of the statute 35 U.S.C. 271(g) [Process Patent Amendments Act of 1988], which extended process claims to cover materially unaltered products of patented processes.

It appears from the record that the inclusion of humans within the scope of mammals may have been intentional, in that the following transpired:

- . the patent examiner recognized the broad expanse of the claims as covering a scope of cloning all "mammals";
- . the PTO never demanded the inclusion of a "nonhuman" disclaimer;
  
- . nowhere in the patent was the word "nonhuman" used;
  
- . the patent *does* contemplate the use of human oocytes (vide supra);

. the patent owners filed for and received an official "Certificate of Correction" on the patent *after* its issuance but took no action to "correct" the omission of "nonhuman".

Significantly, the patent represents a desire on the part of the patentee to commercialize human cloning, and perhaps also indicates a new willingness on the part of the PTO to grant patent claims covering such processes. To date, however, no clear ethical guidelines have ever been placed into patent law, and moreover, the imminent commercialization of human cloning processes militate that laws banning such techniques outright need to be passed.

On certain earlier occasions the PTO has rejected other patent applicants who have filed for human cloning processes, based upon an unofficial policy dating from a pre-Dolly, 1987 PTO memorandum. However, no patent rules or laws have ever been promulgated which would definitively rule out the commercialization of humans. Although the European Patent Office has issued rules which ban the patenting of human cloning and the commercialization of human embryos and fetuses, which rules have become law in many EU nations, no similar laws exist in the US. It is noteworthy that the global TRIPs agreement (at its Article 27.2), as well as NAFTA, explicitly allows for any nation to prohibit patenting of inventions which are contrary to morality and/or good public order; yet unlike the EU nations the US has not followed suit.

Although this newly-uncovered patent is "assigned" to the public University of Missouri system, control of it is shared with Massachusetts-based Biotransplant, with whom the University has had a long-standing research collaboration. The principle inventor on the patent, Randall Prather, University Professor of Reproductive Biotechnology, has recently announced that he, along with Biotransplant scientists, has cloned miniature swine for possible organ transplantation into humans. In a quote from June 2001, Prather stated that: "What has been developed for animals has always been applied to humans. I'm sure the technology will spill over". He predicts that "in 15 years" human cloning will no longer be unsafe, at which time the patent will still have two years of enforceability left.

On April 16, 2002, Biotransplant announced that fellow Massachusetts-based Advanced Cell Technology Inc. (ACT), will now license its patents to a Biotransplant company. Among the ACT patents licensed to Biotransplant is US 6,235,970, a patent explicitly for recovering stem cells from destroyed, cloned human embryos: it is ACT's avowed "therapeutic cloning" patent. The Missouri patent is not involved in the three-way patent battle among Geron, ACT and Infigen Inc. now underway at the PTO, since that battle only concerns claims directed to nonhuman animal cloning.