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Human Cloning and the United States Patent Office

Human cloning, both reproductive and therapeutic, has been a topic of heavy moral and political debate for the past decade, and in the past 5 years, as more progress is made and commercially relevant methods and products are developed, opponents of cloning have been looking increasingly to the patent office as a roadblock for research and development. A number of justifications have been proposed for the rejection of patent applications for cloning-related activities, but they have not been able to stand up to arguments in court, and furthermore, the USPTO is not the proper avenue to regulate human cloning; legislation should be enacted in Congress to ensure effective regulation.

Before the Patent Act of 1952, a criterion was frequently used for assessing patentability that required that an invention should not be “injurious to the well-being, good policy, or sound morals of society.”(Lowell v. Lewis, 15 Fed. Cas. 1018, No. 8568 (C.C. Mass. 1817)(Story, J.) This was known as the “moral utility” requirement. Over time, though, the requirement was considered to be fulfilled as long as the invention served at least one moral purpose. In 1999, the Court of Appeals for the Federal Circuit did away with the requirement once and for all in a decision in *Juicy Whip v. Orange Bang*, in which it stated:

It has been said that inventions that are injurious to the well-being, good policy, or sound morals of society are unpatentable but this principle has not been applied broadly in recent years.... Congress never intended that the patent laws should

displace the police powers of the States...[t]hose powers by which the health, good order, peace and general welfare of the community are promoted.... Of course Congress is free to declare particular types of inventions unpatentable for a variety of reasons.... Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have [some immoral application]. (*Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999))

The ‘moral utility’ argument then, is put to rest. Another avenue for preventing the patenting of human cloning is the 13th Amendment, which provides that “[n]either slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction.” (U.S. Constitution, Amendment XIII) The argument in this case is that in patents related to cloning, where the inventors claim the rights to the ‘products’ of the processes, which could include humans in the case of reproductive cloning, they are effectively claiming the ownership of a human being. A patent, though, gives the holder the right to exclude others from making, using, or selling the invention. Thus, it does not give him or her the right to enslave the human produced in the process, only to prevent others from producing the human in the same way or selling the human. If the Thirteenth Amendment should be extended to specifically address this patent issue, it is the place of Congress and the Supreme Court to make that judgement, not the USPTO.

U.S. Patent No. 6,781,030, “Methods for cloning mammals using telophase oocytes,” contains claims for cloning that apply to humans; consequently, it has been controversial since it was granted on August 24, 2004. Critics say that it violates an amendment to the 2004 Consolidated Appropriations act that bars funding for patents “on claims directed to or encompassing a human.” The Patent Office disagrees, pointing out

that the Congressional record states that the amendment “would not affect claims directed to or encompassing ... methods for creating, modifying, or treating human organisms.” This suggests a shift in policy; formerly, the Patent Office had a policy of not granting patents on inventions comprising humans, but in the face of Supreme Court decisions holding that the USPTO does not have that power, it has since backed off of making moral decisions in favor of deferring to Congressional legislation.

There are two important problems with approaching the regulation of human cloning via the USPTO. One is jurisdiction, and the other is effectiveness. The USPTO was formed to encourage the useful arts, not to make judgements on morality and then discourage those activities that it finds to be immoral. Since many cloning patents (it is widely agreed) should have no trouble fulfilling current statutory requirements for patentability, the USPTO would need to bring morality into the argument in order to deny patents for cloning. Thus, the USPTO cannot deny patents to human cloning developments without broadening its jurisdiction outside that which was awarded to it in the Patent Act of 1952.

As far as creating regulations, the USPTO only issues patents. If it refuses to grant a patent for human cloning, it merely withholds the inventor’s right to exclude others from practicing the art or selling the products; it does not actually forbid cloning, or otherwise restrict the practice, and even the restriction that it does impose lasts only twenty years. The USPTO is staffed with technical experts who are well-schooled in scientific matters, but who are not necessarily experienced or skilled in public policy.

They are not elected officials, and Congress, as an elected body, is charged with the task of making laws for the people of the United States. It is clear that this young branch of biotechnology requires regulatory oversight, but the USPTO is not a regulatory organization, and is not equipped with the power, expertise, or public accountability needed to effectively fill that position. Congress has the flexibility to take a much more discerning role in enacting legislation, and so it is the agency that should be charged with controlling cloning practices in the U.S.

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