Volume 39 Number 3

NEW ENGLAND LAW REVIEW

SYMPOSIUM

STEM CELL RESEARCH AND HUMAN CLONING:
WHERE DO WE DRAW THE LINE?

The Reality of Restricting Patent Rights on Morally Controversial Subject Matter

Jennifer McCallum

New England School of Law, Boston, Massachusetts
2005

THE REALITY OF RESTRICTING PATENT RIGHTS ON MORALLY CONTROVERSIAL SUBJECT MATTER

JENNIFER MCCALLUM*

The patent system was instituted by Congress in the United States as a way of rewarding inventors for disclosing inventions that eventually become freely available for the benefit of the general public. It is a *quid pro quo* between the federal government and the public, whereby an inventor receives the right to exclude others from making, using, selling or offering to sell the claimed invention for a period of time in exchange for disclosing the invention in a manner that allows another to make and use the invention when the exclusivity period expires.

Under the current system, anyone who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may file a patent application with the U.S. Patent & Trademark Office (USPTO). Several categories of subject matter are not patentable, such as atomic energy, natural phenomena and mathematical formulas, for example. Patentable subject matter includes biotechnology inventions, such as stem cells, cloning, antibodies, DNA and transgenic plants or animals.

The four criteria utilized to determine the patentability of an invention are: 1) the invention must be useful in a practical sense and its useful purpose must be identified in the patent application itself; 2) the invention must be novel, in that the product claimed is or was not previously known, used or available in the claimed form prior to the filing of the application; 3) the invention must be non-obvious, not simply an obvious improvement of an existing product or service; and 4) the invention must be described in sufficient detail to allow someone skilled in the relevant field to use it for the stated purpose in the application. Under current law, there is no moral

* Jennifer McCallum is a Biotechnology Patent Attorney and Trustee of The McCallum Law Firm, LLC in Erie, Colorado. She received her Ph.D. in Reproductive Physiology from Colorado State University and her J.D. from the University of Colorado.

determination made at the USPTO and a patent examiner *may not* reject a patent application on moral grounds.

The majority of market sectors utilize the patent system because of the exclusive right to exclude others from making, using or selling a particular invention which allows for a greater chance at a return on development dollars. The biotechnology industry is particularly interested in this exclusive monopoly because of factors unique to their industry. First, the biotechnology product cycle is extremely long. On average, it takes twelve to fourteen years to bring a product to market at an average cost of $1.7 billion.[1] Of those candidates that become products, only one in eight will make it through the regulatory process to become a product, leaving the development costs of all of the failed products squarely on the shoulders of the products that do pass regulatory muster. With a twenty-year patent term and a twelve- to fourteen-year product cycle, this leaves six to eight years for companies to recoup their development costs. Without the right to exclude others from making, using, selling or offering to sell the end-product, it is unlikely companies would bring products to market at all because the exclusive right to market the product is apt to be the only way to recoup costs or make a profit.

Due to the high development costs in this market sector and long product cycle, the majority of market participants rely on investors. Patents help to attract and retain investors as they provide an indication of the caliber of the science behind the products, as evidenced by the issuance of patents, as well as the only chance for a monopoly during the short period of time available to attain any type of return on investment.

Currently, biotechnology inventions are examined like any other inventions by the patent office. They routinely examine patent applications directed to genetically modified plants or animals, stem cell therapeutics and animal or human cloning products, for example. However, the patenting of morally controversial inventions has recently created a question of whether it might be in the public's best interest for the USPTO to restrict patent rights on morally controversial subject matter.

One reason for this concern stems from the fact that with many biotechnology inventions, there is a fine line between use and misuse. Clearly there are inventions related to controversial subject matter that the general public does benefit from, such as genetically modified plants used to increase the yields of food production crops or produce insulin for people with diabetes, while stem cell therapeutics may be useful to cure

---

1. *See* BIOTECHNOLOGY INDUS. ORG., *Biotechnology Industry Facts*, *at* http://www.bio.org/speeches/pubs/er/statistics.asp?p=yes& (last visited Feb. 28, 2005); Nancy Kercheval, *Conversation With ... Ellen Hemmerly*, DAILY REC. (Balt., MD), Dec. 5, 2003, at 25A.

diseases that are otherwise incurable. With that said, there are some members of the public that are skeptical about the benefits of technologies that alter plant or animal genomes and are fearful of gross misuses, such as production of designer children and human reproductive cloning.

Thus, we must ask who should provide oversight for morally controversial technologies. Would Congress better serve, protect and represent the people by restricting patent rights on morally controversial inventions?

Congress is provided with the power to "promote the Progress of Science and the useful Arts" in Article 1, Section 8, Clause 8 of the Constitution.[2] Under the current system, a patent examiner may not reject a useful, novel and non-obvious invention that is adequately described in the written description portion of a patent application. The patent system was designed to draw useful inventions from inventors into the public domain and there have always been other means available to protect the general public or deter research in undesirable areas. For example, the U.S. Food and Drug Administration (FDA) provides oversight in the area of food and drug safety. The government can also cease funding research for controversial technologies. There are many current laws available to enforce the public sentiment and new laws can also be enacted.

If the criteria for patentability were to be amended to allow patent protection for only the altruistic uses of a technology and excluded misuses, it would be difficult for the USPTO to determine whether an invention constituted an altruistic purpose or a misuse as it is a system based on either granting or denying issuance of a patent application.[3] It is not equipped to deal with complex social concerns and making these types of fine distinctions would be difficult on an examiner-by-examiner basis. Even if a compromise could be reached and an altruistic use versus a misuse could be clearly defined for patent examiners, patents would ultimately issue with complete instructions for the altruistic use and it would be but a short stretch of the imagination to use such an invention for an ill-conceived purpose. In essence, the information that enables the altruistic use would function as a roadmap for persons with ill intentions and the patent owner would be unable to prevent the practice of the misuse as he or she would be able to do if the morally controversial subject matter were patent protected. Such subject matter would become freely available for all to use in the absence of any type of law forbidding the misuse.

The question then becomes whether Congress is supporting gross misuses by not restricting patent rights on morally controversial technologies. It very clearly is not. A patent is not a license to practice the

---

2. U.S. CONST. art. I, § 8, cl. 8.

3. 35 U.S.C. § 2(a)(1) (1994 & Supp. 1999); 35 U.S.C. § 131 (1994 & Supp. 1999).

invention and is merely a right to exclude others from making, using and selling an invention. If a patent does not issue or morally controversial subject matter is considered unpatentable, the USPTO is in effect allowing anyone to practice the invention, instead of merely the inventor.

Another possible solution for Congress would be to limit the patentable subject matter to morally uncontroversial subject matter. Unfortunately, there are many difficulties with banning particular subject matter and this remedy may function to curtail promising research, rather than eliminating undesirable research. As previously mentioned, patent protection fuels commercial research and the lack of patent protection will severely curtail it in potentially promising areas due to a lack of funding. In light of the ambiguity as to what is or is not patentable subject matter, inventors are apt to focus their efforts on clearly patentable subject matter, potentially abandoning research with great potential. Additionally, it will be difficult to determine who will be the authority defining the class of subject matter to be banned, as there are apt to be many different opinions on what should or should not be banned. Additionally, the U.S. Supreme Court has weighed in on this question and clearly established the patent system is not the appropriate forum for moral determinations by concluding that "anything under the sun that is made by man" is patentable.[4]

An alternative solution would be for Congress to bolster existing laws or enact new laws directed to specific behaviors and protocols viewed as morally controversial. On March 4, 1997, President Clinton announced, "no federal agency may support, fund or undertake [human cloning research]."[5] Several states have followed suit by enacting legislation on their own, including criminal statutes and legislation providing for an analysis period. Michigan enacted a permanent ban on both therapeutic and reproductive cloning in 1998.[6] California took a different approach and enacted a moratorium on reproductive cloning for five years in order to assess the moral and ethical issues inherent in the technology.[7] Additionally, many congressional bills have been proposed, although none have passed to date.

Regulatory oversight is already being provided for morally controversial technologies by existing regulatory bodies, such as the Food and Drug Administration (FDA) and Department of Health and Human Services. Their jurisdiction and regulatory authority could easily be

4. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

5. Remarks Announcing the Prohibition on Federal Funding for Cloning on Human Beings and an Exchange with Reporters, 33 WEEKLY COMP. PRES. DOC. 278 (Mar. 4, 1997).

6. *See* MICH. COMP. LAWS § 333.16274 (2000).

7. *See* CAL. HEALTH & SAFETY CODE § 24185 (West 2005).

expanded to include a more in-depth review of these technologies considered to be morally controversial.

For example, one such subject area considered morally controversial by some is human reproductive or therapeutic cloning. The Department of Health and Human Services is already providing regulatory oversight in this area via the Fertility Clinic Success Rate and Certification Act that applies to those involved in assisted reproductive technologies or embryo laboratories.[8] This would arguably cover both reproductive and therapeutic cloning as the definition of "assisted reproductive technology" includes all treatments which include the handling of human oocytes or embryos, including *in vitro* fertilization. The Act requires all fertility clinics to provide yearly reports regarding pregnancy statistics to the Department of Health and Human Services and could be further bolstered to include additional details pertinent to the regulation of human cloning. The key factor in utilizing this regulatory mechanism is that it is already in place, staffed with knowledgeable people in this field and mandated by Congress to provide oversight in the area of human reproduction.

Another regulatory body already in existence to deal with controversial new technologies is the FDA. It is skilled in dealing with new drugs and medical devices. It routinely deals with investigational new drug applications, has experience with controversial topics and is staffed by experienced, highly trained teams capable of providing oversight. It has also demonstrated a proactive approach in controversial areas by stating it has jurisdiction over them, such as with human cloning.[9] In October of 1998, the FDA stated that it had jurisdiction over all clinical research using cloning technology to create a human being via the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. It also requires an investigational new drug application for cloning technology, which ensures detailed oversight throughout the regulatory review process.[10] The FDA appears to find cloning technologies no different than any other drug or device and will provide the same detailed analysis to morally controversial technologies as it does to all other types of technologies.

There are also many scientific organizations that can assist in promoting the responsible use of biotechnologies. The scientific community has a history of coming together to make agreements and prohibitions as a group. One such example is when a moratorium was called for at an international meeting at Asilomar, California, where

8. *See* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, § 8, 106 Stat. 3146 (1992) (codified as amended at 42 U.S.C. § 263a-7(1), (2) (1994)).

9. Letter from Stuart L. Nightingale, M.D., Associate Commissioner, Food and Drug Administration to Institutional Review Boards 1 (Oct. 26, 1998), *at* http://www.fda.gov/oc/ohrt/irbs/irbletr.html.

10. *Id.*

scientists urged the government to adopt guidelines regulating recombinant DNA experimentation.[11] The scientists insisted on the development of "safe" bacteria and plasmids that could not escape from the laboratory. Scientific organizations could also facilitate education of the general public and are highly qualified, due to their scientific background and participation in new biotechnologies.

In conclusion, the reality of restricting patent protection for any type of morally controversial subject matter is that there will be consequences to those actions. The general public will have to decide if it is willing to discourage or marginalize cutting-edge research as it is highly unlikely investors will provide research dollars for technologies that do not qualify for patent protection. This is a significant and timely question in light of issues, such as antibiotic resistant infections, an increase in chronic disease, the aging population and rising healthcare costs. Biotechnology products hold potential cures for diseases that are currently untreatable and may offer production efficiencies traditional products do not. The big questions for society to answer are what type of healthcare choices it wants in the future, and what it wants to pay for those choices. It is necessary to understand, however, that patent protection for morally controversial technologies will have a significant effect on the options available to answer these questions.

11. *See* Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, *at* http://www.uth.tmc.edu/uth_orgs/ngs/Courses/Ethics/Summary Statement.pdf (last visited Mar. 3, 2005) (discussing the Asilomar Conference).