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INVENTING
BIOLOGICAL ORGANISMS:
A Reader of Selected Articles

Prepared by Gus Koehler, Ph.D.

CALIFORNIA RESEARCH BUREAU



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INTRODUCTION

The ability to patent biological inventions is central to protecting scientists' work and the development of California's biotechnology industry. What can be patented, for how long, and the extent of global protection are critical issues. However, patenting biological organisms, particularly human genes and other human parts, is controversial. Economists question whether patenting is the quickest and best way to diffuse new knowledge throughout the marketplace.* Some bioethicists question whether genetic information is the common heritage of mankind, making gene patenting inappropriate.

Historically, the controversy over patenting of humans, animals, and plants has revolved around these three fundamental issues:

- The ethics of patenting biological organisms or their parts,
- Bioindustry development, and
- Economic advantages or disadvantages of patenting.†

The U.S. Supreme Court has established that the patent system is not the appropriate forum for resolving questions of morality. The court has also concluded that “anything under the sun that is made by man” is patentable.‡ This Supreme Court decision has, for the most part, been adopted in principle by many other countries, including the European Union and Japan. Generally, patents extend to any type of living being (other than humans) as patentable subject matter. This means,

...one can patent as *products* [an] organism's parts (such as flowers, fruits, seeds, and fertilized eggs), genes and other DNA (whether natural, recombinant, or synthetic), cells and cell lines, and gene and cell products (e.g., proteins and antibodies). One can also patent specific *uses* of any biological agent, whether the “agents” are novel or preexisting (e.g., patenting a bacterium for use as an insecticide or human stem cells to treat disease). Additionally, biotechnical *processes* for manipulating these biological materials and organisms can be patented (e.g., gene-splicing techniques). All of these can be claimed with one patent application.§

* Joan Robinson, *The Accumulation of Capital*, London, Macmillan, 1956.

† The following two articles and attached readings influenced the following questions. Harriet Strimple, “Comments on the Proceedings of the Conference on Biotechnology, Patents, and Morality”, and Michele Svatos, “Patents and Morality: a Philosophical Commentary on the Conference ‘Biotechnology, Patents, and Morality,’” in Sigrid Sterckx, *Biotechnology, Patents, and Morality*, Ashgate, Brookfield, Vermont, 1997, p. 283.

‡ *Diamond v. Chakrabarty*, 447 US 303, 309 (1980).

§ N. Hettinger, “Owning Varieties of Life,” Center for Biotechnology Policy and Ethics, Texas A&M University, 1994, p. 6.

The ethical domain is left to legislators, scientists, and the public. Patent examiners attempt to avoid such issues. Congress can redefine the scope and activities of the U.S. Patenting Office, and is considering legislation amending the patent process (HR 400, Rep. Coble).

Numerous philosophical, social, and legal issues will continue to surround patenting of biological organisms as the global development of the biotechnology industry continues, and as it merges with new technologies (nano-biotechnology for example).

The following issues and questions are raised in this collection of articles.

What Are The Ethical And Social Implications Of Patenting Biological Inventions?

- A patent provides credibility for an invention and approval for commerce. What role, if any, should the morality of an invention play in the approval and granting of a biological patent? Should multicellular organisms be excluded from patenting, for example, due to concerns about their change in status from a naturally created animal into a commodity for sale? Alternatively, given that they are rightfully the property of their inventor, should animal rights that apply to “naturally created animals” apply in whole or in part to invented animals as well? Should an entirely different intellectual property protection system be established that, evaluates the morality of an invention involving living organisms, and does not grant monopoly rights?
- “Germ line engineering” involves making inheritable changes in an organism. Do moral issues arise when the current patenting system is extended to a new type of invention such as germ line engineering produced by a new technology? Should patents on germ line engineering be permitted on the descendants in perpetuity?
- Should some biological inventions be kept in the public domain and not be patentable? Would this slow or speed the development of socially important products? Conversely, does patenting new biotechnology products (agricultural seeds that are resistant to pesticides, for example) accelerate the development of products that have high social utility?
- New scientific discoveries may lead to unexpected inventions. For example, unlike a copying machine, organisms cannot be easily standardized, they are released into and interact with the environment, reproduce, and may gain unexpected or inappropriate advantage over other organisms. How far should a patent examiner go to evaluate such risks prior to granting a patent?
- Is it useful, when describing the scope of patenting, to distinguish between patenting and owning particular individual animals versus patenting all mammals with a certain gene? (To say that we own an animal is different from saying that we invented it.)

- Should the patenting process control the research direction that biotechnology takes? For example, should patents on the transfer of genes be limited taxonomically to families, genus and species but not be permitted between orders or above?
- Should protections and guarantees, including sharing in any profits, be extended to the human subjects or communities that DNA material is collected from?
- Should human genes themselves be patented or should the process used to make a successful therapy be patented leaving the involved human genes in the public domain?
- Should there be certain types of exceptions to patent protection for plants or animals resulting from a long period of careful selection by farmers and/or animal breeders be they in the developed or developing countries?
- Does patenting of genetically engineered animals or plants provide an unfair and/or restrictive commercial advantage to bioindustry over plant or animal breeders? For example, animal breeders may wish to improve a patented organism through traditional means that don't involve bioengineering. Farmers may wish to use their "farmer's privilege" to hold back seed from a genetically engineered crop for planting the following year.
- Does patenting tend to encourage the development of one form of agriculture or animal husbandry (such as vertically integrated corporate pesticide and fertilizer management) over another (family farm)? Could family based farm economies in particular agricultural sectors in rural societies be heavily impacted?

What Conditions Should Be Met To Patent A Biological Invention?

- What is the difference between a biological discovery (discovery of DNA is not patentable) and an invention (gene therapy is patentable)?
- How minor can the utility of an improvement or innovation in an organism be in order to be patentable?
- How long should a guaranteed minimum patent term be, from the date of its filing or later court challenges?
- How many "newly invented patentable animals" are possible from a particular genome? For example, should a company that has found one way to bioengineer a plant or animal be given an exclusive patent for all genetic engineering possibilities associated with its natural genome even if another company uses entirely different processes or develops a different trait than the patent holding company?
- Should a company that develops a therapy or test for a human gene be given a patent over all possible medical uses of that gene?

From a Business Perspective, does Patenting contribute to the National and Global Development of the Biotechnology Industry?

- Given the relatively early stage of the global development of biotechnology, do patents hinder or accelerate the industry's development? Do patents slow or encourage entry into the field, research, and cooperation among scientists, farmers, traditional healers, seed conservation organizations, animal breeders, companies, and nations?
- Does patenting genetically engineered food stocks and animals confer an unfair advantage for more developed countries over less developed countries?
- Should there be national and global policies for the identification and exploitation of genetic resources that emphasize equitable and innovative relationships between public and private institutions and communities and individuals? Alternatively, should such relationships be market driven?
- What advantages or disadvantages do current variations in national patenting laws create for bioindustry or a nation's citizens?
- From an internal corporate perspective, does patenting of biological organisms lead to the efficient allocation of corporate resources, encourage copycat inventions, increase secrecy, result in substantial legal and administrative costs, and arbitrarily focus research on patentable inventions?
- What effect do patent infringement disputes in the United States, and in other countries have on the discovery and exploitation of new biological inventions?
- Could dividing the human or other genome into a number of individually patented segments by a large number of public and private entities spread around the world increase the cost of or slow genetic research?
- Are patented tagged genes being licensed for research at a cost permitting adequate access for basic research purposes?
- Should publicly funded research institutions receive private industry funding contingent upon the funder having exclusive licensing rights, or to patent a discovery?
- What global and national implications, if any, does patenting biological inventions have for national food security, agricultural and rural development, conservation of medicinal plants, biodiversity, and for environmental conservation?
- Many biotechnology companies develop biological inventions using biological materials provided from international *ex situ* seed or genetic material collections. How should national intellectual property rights be addressed in such situations?

- Do international agreements such as NAFTA and GATT provide adequate ethical guidelines and legal protection for patenting plants, animals, and human biological materials?

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