

Sheldon Mak Rose Anderson

GENETIC ENGINEERING & THE PATENT OFFICE

by

Sheldon Mak Rose & Anderson

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On April 7, 1987, the United States Patent and Trademark Office announced that it "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101." An emotional controversy has centered on this announcement. The announcement has become the lightning rod for all of the practical and moral questions surrounding the overwhelming potential of genetic engineering. The Patent Office has been bitterly attacked by a wide range of special interest groups including small farmers, environmentalists, animal rights activists and religious fundamentalists. The Senate responded by passing an amendment to an appropriations bill, which would have prohibited the Patent Office from expending public funds for the issuance of new animal life-form patents. (The amendment was subsequently dropped.) The House of Representatives also initiated hearings into the propriety of patenting new animal life-forms.

Although questions surrounding genetic engineering should be raised and addressed, the Patent Office has been wrongly singled out as the source of so-called problem. The Patent Office did not participate in the development of genetic engineering technology and it does not regulate genetic engineering experiments. The function of the Patent Office is to administer the patent process pursuant to the patent law. Its discretion with respect to policy decisions, including decisions about genetic engineering, is limited. Congress, and not the Patent Office, has the responsibility for making such policy decisions.

Congress has never passed a law specifically addressing the patentability of new man-made life forms. Patentable subject matter is defined by 35 U.S.C. § 101 which states:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Whether genetic engineering "inventions," are patentable is a question of whether such new, man-made life-forms are items of "manufacture" or "compositions of matter."

In the absence of legal precedents on the question, the Patent Office would be obligated to analyze Section 101 on its own and come to its own interpretation of whether genetic inventions are patentable subject matter. However, there are several recent legal precedents on the question, and the Patent Office is obligated to follow them.

The leading decision on the patentability of genetic inventions was rendered in 1980 by the United States Supreme Court in *Diamond v. Chakrabarty*. In that case, the Court considered whether genetic engineering inventions were items of "manufacture" or "compositions of matter." After reviewing the history of the enactment of 35 U.S.C. 101, the Supreme Court decided that Congress intended for patentable subject matter to include "anything under the sun that is made by man." Thus, the Court held that Mr. Chakrabarty's man-made life form (a new bacterium) was patentable subject matter.

The Board of Appeals and Interferences extended the Chakrabarty decision beyond simple bacterium life-forms to higher man-made plants in 1985, and to higher man-made animals in 1987. These decisions held that new man-made life-forms of all varieties (except humans) are to be treated no differently under the patent law than other inventions. Accordingly, the Patent Office's recent announcement regarding genetic engineering invention did not make new policy, but merely assured genetic researchers that the Patent Office would abide by the patent

law.

If thorny questions remain unanswered, Congress should resolve them. The ultimate responsibility for making the difficult public policy decisions relating to genetic experimentation and the patentability of genetic inventions is entrusted to the Congress and not the Patent Office. Congress, however, needs the expert assistance of the scientific community to resolve these difficult questions. The scientific community should monitor present genetic engineering regulations and guide Congress in the formulation and implementation of new genetic engineering regulations in response to future changes in technology.

As to whether genetic engineering inventions should be patentable, the answer is most assuredly "yes." The reasons for maintaining a patent system for conventional inventions are equally operative for genetic engineering inventions. The patent system protects expensive investments in research and development by extending to the researcher exclusive rights in new inventions for 17 years. As with more conventional inventions, genetic engineering inventions are dedicated to the public after the expiration of the 17-year patent term. The patent system requires the inventor to set forth in the patent a detailed description of how to prepare and use the invention, so that other researchers in the field can immediately have the knowledge possessed by the patentee.

Patentability of genetic engineering inventions will spur research and development in this exciting new field by helping to protect research and development investments. The patent system encourages the expenditure of funds for research. Patent protection in the United States will maintain the present technological superiority held by our aggressive, young genetic engineering industry over the rest of the world, thereby giving the United States a potentially large new source of foreign trade revenue. The potential for social good appears to be enormous.

In summary, the Patent Office should be allowed to continue granting patents for genetic engineering inventions without interference. If the scope and methods of genetic engineering experimentation need to be regulated, such regulation should be left up to the Congress in consultation with the scientific community. To outlaw or deny patentability to genetic engineering inventions would be to handicap human progress.

Sheldon Mak Rose & Anderson PC
100 E. Corson Street, Third Floor
Pasadena, California 91103-3842
626-796-4000
626-795-6321 fax