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Patenting of Microorganisms and Higher Life Forms: Social and Ethical Concerns

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Recently, when I appeared on a Boston radio program to address the patenting decision on microorganisms, a caller asked whether a human clone could be patented. Recalling the Supreme Court's decision in *Diamond* v. *Chakrabarty*, the first idea that flashed through my mind was, Is it manufactured? But obviously, if the product is a person, he cannot be patented on constitutional grounds. Persons have rights; they cannot be owned or enslaved (at least in modern, enlightened societies). However, for any life form that does not possess personhood, and which came into being through a process conforming to the Court's conception of manufacture, the question of patentability remains open.

The caller's question first seemed farfetched and irrelevant, but upon further consideration, I began to realize that questions of this nature are now meaningful and fall within the boundaries of legal and moral discourse. The *Chakrabarty* decision opens up many new problems in patent law and social ethics. I shall address some of these in the following areas: (i) the relevance of life to a product of manufacture, (ii) patenting and the regulatory void, (iii) patenting human genes, (iv) patentability of higher life forms, and (v) patenting and the social good.

The Relevance of Life

In *Diamond* v. *Chakrabarty* the fundamental distinction between living organisms and inert matter was ruled irrelevant by the Supreme Court insofar as patenting is concerned. The Court held that the rearrangement of living matter in novel structures or combinations is no less a product of manufacture than analogous human arrangements of inert substances such as minerals. Writing the opinion for the majority, Justice Burger stated: "Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human made inventions."

Some have interpreted the Court's decision as incorporating a metaphysical bias that advocates a chemical reductionist view of life processes. Indeed, the majority argued that the "manufacture" or "composition of matter" should apply no less to life forms than to machine parts or chemical products. In its amicus curiae brief (7), the People's Business Commission placed the distinction between inert matter and life processes at the cornerstone of the patenting issue.

> Here we confront the essence of the matter which is inherent in the case now before the Court. To justify patenting living organisms, those who seek such patents must argue that life has no "vital" or sacred property; that all of life's properties can ultimately be reduced to the "physico-chemical." But once this is accomplished, all living material will be reduced to an arrangement of chemicals, or mere "composition of matter." Where this

happens, all life will move toward that "periphery" in which . . . life does not have to be treated as life at all.

The commission's argument raises three issues. First, Is life more than the sum of its chemical parts? Second, If there are any emergent characteristics to life forms, do they have any relevance to the legal argument that biological entities may be termed a "composition of matter" or a "manufacture" for patenting purposes? Third, If we patent lower organisms, would that, as the commission argues, "invariably lead to the patenting of higher life forms"?

If there is a nonchemical quality that distinguishes life forms from inert matter, it is not likely that science will recognize or acknowledge its existence. One could of course posit or try to demonstrate the existence of an élan vital and then declare that our respect for such life forces demands that their material embodiment be excluded from patentability. Following the argument, why should our respect for such posited life forces be restricted to patenting and not apply to ownership? No one seriously questions our right to own bacteria, whatever their metaphysical makeup. Therefore, on its own presumption, the argument that life is more than the sum of its chemical parts, and thus is not patentable, is not persuasive. Nor does it follow that patentability debases the significance of life per se any more than ownership does. Finally, there is no compelling argument that the patenting of microorganisms will inevitably lead to the patenting of higher life forms, although without congressional action that could certainly take place.

Because there are unavoidable and irreducible differences between inert substances and life forms (this is true whether we adopt a vitalist or a reductionist metaphysics), the decision to patent microorganisms will introduce formidable problems in patent law. These issues will either find their resolution through a broad policy on the part of Congress or be left to a case-by-case analysis in the courts. I shall cite one such problem: Do the patent-rights for an engineered microbe extend to its progeny? Since microorganisms reproduce themselves, we could easily have a situation in which a patented bacterium escapes its proprietary confinement and multiplies. Except for the initial handiwork involved in the genetic alteration of the organism, we shall assume that human intervention plays no role in the propagation of the bacterium. Should each of the daughter cells be considered a product of manufacture, no less than the parent cell? If not, then the patenting decision may be a moot point. However, if patent rights are found to cover all progeny of the life forms in question, then we are introducing a new notion of manufacture into our ordinary discourse. Our language will have to tolerate statements such as: "A manufactured object can mutate and thus spontaneously revert back to a nonmanufactured object." "A manufactured object can reproduce itself." "A manufactured object can evolve."

Another important question with which the Patent and Trademark Office and the courts will have to deal is the novelty of a genetically manipulated organism: i.e., Does it occur or has it occurred in nature? Will it be sufficient to show that the organism has never been isolated under natural conditions? Or will verification that it is unstable in the wild suffice? And what if there is evidence that it could have existed during some past age when conditions were different than they are today? There is no precedent in patent law to answer these queries. Therefore, the courts will have to create policy or Congress will have to establish new rules for patenting life forms sui generis.

Patenting and the Regulatory Void

By now it is generally known that a substantial regulatory apparatus has been put into place for recombinant DNA activities funded by the National Institutes of Health. It mostly affects academic research. Industrial recombinant DNA work is covered by a voluntary compliance program that is being administered by the National Institutes of Health. What relation, if any, does patenting have to the issue of regulation?

The reason I would want regulation of industrial practices in genetic engineering (not only recombinant DNA but other processes that produce new or modified life forms) is that I take seriously the following prospects.

(i) Recombinant DNA research as well as other bioengineering techniques radically transforms natural systems.

(ii) Synthetic biology, like synthetic chemistry, is not likely to become a widely applied industrial tool without some adverse impacts.

It is reasonable to anticipate that the Supreme Court's decision in *Chakrabarty* will provide greater economic incentives to firms for investing in genetic engineering research and development. (Ultimately, this is an empirical question, since the effect of patents on industrial developments could be minor.) If the industrial activity develops more rapidly as a result of investment confidence spurred on by the extension of patent rights to microorganisms sui generis, then those apprehensive about the present policy of voluntary regulation for the biotechnology industry should be more concerned after the *Chakrabarty* decision. Taken simply as a symbolic action at the very least, the Court's patenting decision acts a stimulant for commercial gene-splicing activities at a time when there is still concern about the large-scale production and distribution of modified life forms. Genetic engineering firms preparing for modest scale-up operations with 500- to 2,000-liter fermentors are locating in densely populated urban centers.

Patenting Human Genes

Whereas humans are not patentable entities, the Supreme Court has left open the possibility of patenting human genes. Bacteria that possess the genes for human insulin or interferon are already in advanced stages of development. Beyond the issue of the patentability of a bacterium with a single gene insert, let me pose a concrete question: Can we patent Shockley's genes? Patentability is not excluded because matter is living nor, apparently, because the entity consists of a system of cells. But of course, Shockley's germ plasm is not patentable on the grounds that it is a product of nature. However, suppose his genes were engineered in some fashion. Then his germ plasm might indeed qualify as a manufacture or a new composition of matter according to the *Chakrabarty* decision.

Who would want to patent Shockley's genes, or any one else's for that matter? And what could possibly be done to change them to qualify as a manufacture or new composition of matter? With the growth of human reproductive technologies, commercial sperm depositories have been established to exploit the demand for artificial insemination and in vitro fertilization. A recent *New York Times* report cited 17 sperm banks in the United States (4). If there are profits to be made in huckstering human germ plasm, patenting may be sought as a means of protecting one's investment.

I can foresee another circumstance where patenting human genes may generate commercial interest. And this is where we begin to see how frivolous and exploitable recombinant DNA research and industrial cloning can become. Consider a new line of cosmetic creams with oils or hormones produced from the genes of a glamorous star. Is my imagination playing tricks on me or could this form of genetic peddling have an appeal to Madison Avenue?—"Cosmetics with the Hormones of Your Favorite Personality." It hardly matters if the personality proteins are not the slightest bit different from those of us common folk.

In both of the examples I cited, there is an unsettling aspect to the patenting of human genes. Perhaps it is because it fosters a genetic aristocracy; who you are as a person will become secondary to your genetic blueprint. Or perhaps it is because there is something venal about the private appropriation of human genetic resources.

To return to an ancillary question, What modifications could be made in human germ plasm to qualify it as a product of manufacture? Perhaps someone will discover the sequence that enhances the biochemical activity associated with certain desirable traits, or that gives people an advantage over viral disease or cancer, or that allegedly promotes longevity. Eleven years ago an eminent biologist, Salvador Luria, alerted us that his field was developing the instruments for shaping human evolution (6):

> (W)e should not ignore the possibility that genetic means of controlling human heredity will be put to massive uses of human degradation even outside the military context. Huxley's nightmarish society might be achieved by genetic surgery rather than by conditioning, and in an even more terrifying way since the process would be hereditary and irreversible.

We are all vulnerable to fantasies of an archetypal offspring. By extending the rights of patenting to human genes through modified germ plasm, we have tacit approval to unleash the terrifying power that Luria described.

Patenting Higher Life Forms

If we genetically modify the germ plasm of a bull to qualify as a product of manufacture, can we patent the germ plasm? Does the patent extend to all of the progeny? Presently, a single bull can provide the sperm for hundreds or thousands of offspring. Someone can own the bull and sell the sperm, but there is no entitlement to the ownership of the progeny.

Let us suppose that in addition to genetically modifying the bull's germ plasm (whereby progeny cows provide a higher yield of milk), we learn how to duplicate the genes in unlimited quantity. The patenting of this product could be tantamount to owning the genetic strain of a species. Moreover, we might be able to achieve monoherds, the livestock counterpart to monocultures. But by narrowing the genetic variation of livestock to improve upon certain qualities and promote uniformity, we could be duplicating the hazards faced worldwide in agriculture where the variety of crops has been dramatically reduced. Genetic homogeneity, whether in crops or in animals, is vulnerable to a single catastrophic event that a variegated genetic pool could overcome. Recently, scientists at the University of Geneva reported the successful cloning of a mammal. The *New York Times* story on the event told of some researchers who want to mass-produce prize livestock by the nucleus transplantation technique that gave rise to the mouse clones (8). The confluence of cloning, engineering genes, and patenting higher life forms may not be too far off.

It is notable that some countries which permit patenting of microorganisms do not grant similar patent rights to higher life forms. Under the European Patent Convention and under the German Patent Act, plant and animal varieties and biological processes for their production are excluded from patent protection (5). In the *Chakrabarty* decision the Court drew no such lines on patenting life forms. The brief filed for General Electric argued that each case should be decided on its own merit by the courts, even those cases involving human genetic engineering. I cite a remarkable passage from their brief: "As to humans, constitutional problems would seem to afflict a patent granting someone the right to exclude others from reproducing a human being. A more precise consideration is appropriately postponed until a case or controversy makes a decision necessary" (1).

In his majority opinion Justice Warren Burger made it very explicit that the Court was quite restricted in rendering its decision: "Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend para. 101 so as to exclude from patent protection organisms produced by genetic engineering" (2).

As I have shown, there is more to the patenting decision than legal semantics. The question is, Do we leave these issues to be resolved in the courts on a case-by-case approach or do we need a broad national policy? I propose that we start by convening a commission with the explicit mandate to consider the social and ethical issues of patenting life forms of all varieties. With the commission's recommendations, Congress should accept the tacit invitation of the Supreme Court and develop a policy that is comprehensive and that can serve as a guide for future court cases and as a safeguard for future generations.

Patenting and the Social Good

Few would deny that the right to patent inventions and novel products has been a great incentive for the industrial development of American technology. The patenting of *processes* that utilize life forms is well established. In the case of Chakrabarty's oil-digesting microbe, patents were filed for the process of manufacture, the method of dispersal, and the product per se. It is clearly desirable to clone some human genes in large quantities. Perhaps firms would not develop interferon or insulin through recombinant DNA techniques if they could not be assured, through patents, of capturing a predictable portion of the market. A company that takes risks to commercially develop a product has the right to recoup its expenses and profit from its risks.

Will the patenting of genetically modified bacteria that produce scarce human proteins be in the public interest? Let me use the case of a bacterium that produces human interferon. One recent estimate of interferon's worldwide market potential places it at three billion dollars (3). Where is all this money going to come from—research centers, government grants, the consumer of health care either directly or through third-party payments? Hardly a person would classify the interferon-producing bacterium as frivolous. But what will the patentability of the microbe do to the cost of interferon? This substance is being studied for its potential clinical benefits in the treatment of viral diseases and cancer. Its availability and price should not be determined by what are nearly monopoly conditions. What are the choices before us? Can we assume that through the patenting process we will achieve: (i) the only or most efficient development of interferon, (ii) the greatest availability of

interferon for research and clinical applications, and (iii) the best cost for the product so its full potential can be realized?

During periods of war, patent decisions do not dictate the price and production levels of tanks. We are presently engaged in a war against cancer in which our society has already invested billions of dollars. The weapons to fight this war must serve the public's interest first and foremost. Congress has acted in the past to exclude certain innovative technologies from patentability. The production of fissionable materials and the military utilization of atomic energy were among the technologies excluded. The question remains whether special areas of gene splicing and the manufacture of novel life forms should also be excluded from private control because of overriding national interest. It is an issue which should be considered by our legislative branch of government and not left to the judiciary by default.

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