

Chapter 12

Patenting Living Organisms

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Patenting Living Organisms

A landmark decision

In a 5 to 4 decision (*Diamond v. Chakrabarty*, June 16, 1980), the Supreme Court ruled that a manmade mice-organism is patentable under the current patent statutes. This decision was alternately hailed as having “assured this country’s technology future”¹ and denounced as creating “the Brave New World that Aldous Huxley warned of.”² However, the Court clearly stated that it was undertaking only the narrow task of determining whether or not Congress, in enacting the patent statutes, had intended a manmade micro-organism to be excluded from patentability solely because it was alive. Moreover, the opinion invited Congress to overturn the decision if it disagreed with the Court’s interpretation.

¹Prepared Statement of the American Chemical Society, cited in “Science May Patent New Forms of Life, Justices Rule, 5 to 4,” *The New York Times*, June 17, 1980, p. 1.

²Prepared statement of the Peoples’ Business Commission, cited in “Science May Patent New Forms of Life, Justices Rule, 5 to 4,” *The New York Times*, June 17, 1980, p. 1.

Congress may want to reconsider the issue of whether and to what extent it should specifically provide for or prohibit the patentability of living organisms. While the judiciary operates on a case-by-case basis, Congress can consider all the issues related to patentability at the same time, gathering all relevant data and taking testimony from the interested parties. The issues involved go beyond the narrow ones of scientific capabilities and the legal interpretations of statutory wording. They require broader decisions based on public policy and social values; Congress has the constitutional authority to make those decisions for society. It can act to resolve the questions left unanswered by the Court, overrule the decision, or develop a comprehensive statutory approach, if necessary. Most importantly, Congress can draw lines; it can specifically decide which organisms, if any, should be patentable.

Legal protection of inventions

The inherent “right” of the originator of a new idea to that idea is generally recognized, at least to the extent of deserving credit for it when used by others. At the same time, it is also believed that worthwhile ideas benefit society when they are widely available. Similarly, when an idea is embodied in a tangible form, such as in a machine or industrial process, the inventor has the “right” to its exclusive possession and use simply by keeping it secret. However, if he may be induced to disclose the invention’s details, society benefits from the new ideas embodied therein, since others may build upon the new knowledge. The legal system has long recognized the competing interests of the inventor and the public, and has attempted to protect

both. The separate laws covering trade secrets and patents are the mean by which this is done.

Trade secrets

The body of law governing trade secrets recognizes that harm has been done to one person if another improperly obtains a trade secret and then uses it personally or discloses it to others. A trade secret is anything—device, formula, or information—which when used in a business provides an advantage over competitors ignorant of it—e.g., improper acquisition includes a breach of confidence, a breach of a specific promise not to disclose, or an outright theft. Trade secrecy is derived from the common law,

as opposed to being specifically created by statute; the State courts recognize and protect it as a form of property. The underlying policy is one of preventing unfair competition or unjust benefits. The protection lasts indefinitely. Two well-known examples of long-time trade secrets are the formulas for Coca Cola and for Smith Brothers' black cough drops; the latter is supposedly over 100 years old.

A company relying on trade secrecy to protect an important invention must take several steps to effect that protection. These include: permitting only key personnel to have access, requiring such people to sign complex contracts involving limitations on subsequent employment, and monitoring employees and competitors for possible breaches of security. Even so, there are practical limitations to what can be done and what can be proved to the satisfaction of a court. Moreover, independent discovery of the secret by a competitor is not improper, including the discovery of a secret process by an examination of the commercially marketed product. Most importantly, once a trade secret becomes public through whatever means, it can never be recaptured. Thus, reliance on trade secrecy for protecting inventions can be risky.

Patents

In contrast to the common law development of trade secrecy, patent law is a creation of Congress. The Federal patent statutes (title 35 of the United States Code) are derived from article I, section 8, of the Constitution, which states:

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

This clause grants Congress the power to create a Federal statutory body of law designed to encourage invention by granting inventors a lawful monopoly for a limited period of time. Under the current statutory arrangement, which is conceptually similar to the first patent statutes promulgated in 1790, a patent gives the inventor the right to exclude all others from making, using, or selling his invention within

the United States without his consent for 17 years. In return, the inventor must make full public disclosure of his invention. The policy behind the law is twofold. First, by rewarding successful efforts, a patent provides the inventor and those who support him with the incentive to risk time and money in research and development. Second, and more importantly, the patent system encourages public disclosure of technical information, which may otherwise have remained secret, so others may use the knowledge. The inducement in both cases is the potential for economic gain through exploitation of the limited monopoly. Of course, there are many reasons why this potential may not be realized, including the existence of competing products.

To qualify for patent protection, an invention must meet three statutory requirements: it must be capable of being classified as a process, machine, manufacture, or composition of matter; it must be new, useful, and not obvious; and it must be disclosed to the public in sufficient detail to enable a person skilled in the same or the most closely related area of technology to construct and operate it. Plants that reproduce asexually may also be patented, but slightly different criteria are used.

Although the categories in the first requirement are quite broad, they are not unlimited. In fact, the courts have held such things as scientific principles, mathematical formulas, and products of nature to be unpatentable on the grounds that they are only discoveries of pre-existing things—not the result of the inventive, creative action of man, which is what the patent laws are designed to encourage. This concept was reaffirmed in the *Chakrabarty* opinion.

The requirement that an invention be useful, new, and not obvious further narrows the range of patentable inventions. Utility exists if the invention works and would have some benefit to society; the degree is not important. Novelty signifies that the invention must differ from the "prior art" (publicly known inventions or knowledge). Novelty is not considered to exist, —e.g., if: 1) the applicant for a patent is not the inventor, 2) the invention was previously

known or used publicly by others in the United States, or 3) the invention was previously described in a U.S. or foreign patent or publication. The inability to meet the novelty requirement is another reason why products of nature are unpatentable. Nonobviousness refers to the degree of difference between the invention and the prior art. If the invention would have been obvious at the time it was made to a person with ordinary skill in that field of technology, then it is not patentable. The policy behind the dual criteria of novelty and nonobviousness is that a patent should not take from the public something which it already enjoys or potentially enjoys as an obvious extension of current knowledge.

The final requirement—for adequate public disclosure of an invention—is known as the enablement requirement. It is designed to ensure that the public receives the full benefit of the new knowledge in return for granting a limited monopoly. As a public document, the patent must contain a sufficiently detailed description of the invention so that others in that field of technology can build and use it. At the end of this description are the claims, which define the boundaries of the invention protected by the patent.

The differences between trade secrets and patents, therefore, center on the categories of inventions protected, the term and degree of protection, and the disclosure required. Only those inventions meeting the statutory requirements outlined above qualify for patents and then only for a limited time, whereas anything giving an advantage over business competitors qualifies as a trade secret for an unlimited time. A patent requires full public disclosure, while trade secrecy requires an explicit and often costly effort to withhold information. The patent law provides rights of exclusion against everyone, even subsequent independent inventors, while the trade secrecy law protects only against wrongful appropriation of the secret.

Living organisms

Although the law for protecting inventions is usually thought of as applying to inanimate objects, it also applies to certain living organisms.

Any organism that both meets the broad definition of a trade secret and may be lawfully owned by a private person or entity can be protected by that body of law, including microorganisms, plants, animals, and insects. In addition, plants are covered specifically by two Federal statutes, the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. Furthermore, the Supreme Court has now ruled that manmade micro-organisms are covered by the patent statutes. Its determination of congressional intent in the *Chakrabarty* case was based significantly on an analysis of the two plant protection statutes.

Patent protection for plants was not available until Congress passed the Plant Patent Act of 1930, recognizing that not all plants were products of nature because new varieties could be created by man. This Act covered new and distinct asexually reproduced varieties other than tuber-propagated plants or those found in nature. * The requirement for asexual reproduction was based on the belief that sexually reproduced varieties could not be reproduced true-to-type and that it would be senseless to try to protect a variety that would change in the next generation. To deal with the fact that organisms reproduce, the Act conferred the right to exclude others from asexually reproducing the plant or from using or selling any plants so reproduced. It also liberalized the description requirement for plants. Because of the impossibility of describing plants with the same degree of specificity as machines, their description need only be as complete as is "reasonably possible."

By 1970, plant breeding technology had advanced to where new, stable, and uniform varieties could be sexually reproduced. As a result, Congress provided patent-like protection to novel varieties of plants that reproduced sexually by passing the Plant Variety Protection Act of 1970. Fungi, bacteria, and first-generation hybrids were excluded. ** Hybrids have a built-

* Approximately 4,500 plant patents have been issued to date, most for roses, apples, peaches, and chrysanthemums.

** Originally, six vegetables—okra, celery, peppers, tomatoes, carrots, and cucumbers—were also excluded. On Dec. 22, 1980, President Carter signed legislation (Pub. Law 96-99) amending the Plant Variety Protection Act to include these vegetables, to extend the term of protection to 18 years, and to make certain technical changes.

in protection, since the breeder can control the inbred, parental stocks and the same hybrid cannot be reproduced from hybrid seed.

The 1970 Act, administered by the Office of Plant Variety Protection within the U.S. Department of Agriculture (USDA), parallels the patent statutes to a large degree. Certificates of Plant Variety Protection allow the breeder to exclude

others from selling, offering for sale, reproducing (sexually or asexually), importing, or exporting the protected variety. In addition, others cannot use it to produce a hybrid or a different variety for sale. However, saving seed for crop production and for the use and reproduction of protected varieties for research is expressly permitted. The term of protection is 18 years.

The *Chakrabarty* case

In 1972, Ananda M. Chakrabarty, then a research scientist for the General Electric Co., developed a strain of bacteria that would degrade four of the major components of crude oil. He did this by taking plasmids from several different strains, each of which gave the original strain a natural ability to degrade one of the crude oil components, and putting them into a single strain. The new bacterium was designed to be placed on an oil spill to break down the oil into harmless products by using it for food, and then to disappear when the oil was gone. Because anyone could take and reproduce the microbe once it was used, Chakrabarty applied for a patent on his invention. The U.S. Patent and Trademark Office granted a patent on the process by which the bacterium was developed and on a combination of a carrier (such as straw) and the bacteria. It refused to grant patent protection on the bacterium itself, contending that living organisms other than plants were not patentable under existing law. On appeal, the Court of Customs and Patent Appeals held that the inventor of a genetically engineered microorganism whose invention otherwise met the legal requirements for obtaining a patent could not be denied a patent solely because the invention was alive. The Supreme Court affirmed.

The majority opinion characterized the issue as follows:³

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. §101, which

“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.”

Specifically, we must determine whether respondent’s micro-organism constitutes a “manufacture” or “composition of matter” within the meaning of the statute.

After evaluating the words of the statute, the policy behind the patent laws, and the legislative history of section 101 of the patent statutes and of the two plant protection Acts, the Court ruled that Congress had not intended to distinguish between unpatentable and patentable subject matter on the basis of living versus nonliving, but on the basis of “products of nature, whether living or not, and human-made inventions.”⁴ Therefore, the majority ruled, “[t]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under §101.”⁵ The majority did not see their decision as extending the limits of patentability beyond those set by Congress.

The Court found that, in choosing such expansive terms as “manufacture” and “composition of matter”—words that have been in every patent statute since 1793—Congress plainly intended the patent laws to have a wide

³*v. Diamond v.* (100 S. Ct. 2204, 2207 (1980).

⁴2,210.
⁵p. 2,208.

scope. Moreover, when these laws were last re-modified in 1952, the congressional committee reports affirmed the intent of congress that patentable subject matter “include anything under the sun that is made by man.”⁶ The Court acknowledged that not everything is patentable; laws of nature, physical phenomena, and abstract ideas are not.

The Court found the Government’s arguments unpersuasive. Specifically, that passing the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, which excluded bacteria, was evidence of congressional understanding that section 101 did not apply to living organisms; otherwise; these statutes would have been unnecessary. In disagreeing, the Court stated that the 1930 Act was necessary to overcome the belief that even artificially bred plants were unpatentable products of nature and to relax the written description requirement, permitting a description as complete as is “reasonably possible.” As for the 1970 Act, the Court stated that it had been passed to extend patent-like protection to new sexually reproducing varieties, which, in 1930, were believed to be incapable of reproducing in a stable, uniform manner. The 1970 Act’s exclusion of bacteria, which indicated to the Government that Congress had not intended bacteria to be patentable, was considered insignificant for a number of reasons.

The Government had also argued that Congress could not have intended section 101 to cover genetically engineered micro-organisms, since the technology was unforeseen at the time. The majority responded that the very purpose of the patent law was to encourage new, unforeseen inventions, which was why section 101 was so broadly worded. Furthermore, as for the “gruesome parade of horrors”⁷ that might possibly be associated with genetic engineering, the Court stated that the denial of a patent on a micro-organism might slow the scientific work but certainly would not stop it; and the consideration of such issues involves policy judgments that the legislative and executive

branches of Government, and not the courts, are competent to make. It further recognized that Congress could amend section 101 to specifically exclude genetically engineered organisms or could write a statute specifically designed for them.

The dissenting Justices agreed that the issue was one of statutory interpretation, but interpreted section 101 differently. They saw the two plant protection Acts as strong evidence of congressional intent that section 101 not cover living organisms. In view of this, the dissenters maintained that the majority opinion was actually extending the scope of the patent laws beyond the limit set by Congress.

The stated narrowness of the Court’s decision may limit its impact as precedent in subsequent cases that raise similar issues, although not necessarily. Certainly, the decision applies to any genetically engineered micro-organism. It is a technical distinction without legal significance that most of the work being done on such organisms involves recombinant DNA (rDNA) techniques, which Chakrabarty did not use. The real question is whether or not it would permit the patenting of other genetically engineered organisms, such as plants, animals, and insects. Any fears that the decision might serve as a legal precedent for the patenting of human beings in the distant future are totally groundless. Under our legal system, the ownership of humans is absolutely prohibited by the 13th amendment to the Constitution.

Although the *Chakrabarty* case involved a micro-organism, there is no reason that its rationale could not be applied to other organisms. In the majority’s view, the crucial test for patentability concerned whether or not the micro-organism was manmade. Conceptually, there is nothing in this test that limits it to micro-organisms. The operative distinction is between humanmade and naturally occurring “things,” regardless of what they are. Thus, the *Chakrabarty* opinion could be read as precedent for including any genetically engineered organism (except humans) within the scope of section 101. Whether a court in a subsequent case will interpret *Chakrabarty* broadly or narrowly cannot be predicted.

⁶ 19 R. & C. Cong. 282d (S. P. 1152; H. R. 19,527) (1952).
⁷ Long, 2d ed. (1951), cited in *Union Carbide*, 100 S.Ct. 2211 (1980).

⁷ *Chakrabarty*, 100 S.Ct. 2204, 2211 (1980).

Even if section 101 were interpreted as covering other genetically engineered organisms, they probably could not be patented for failure to meet another requirement of the patent laws—the enablement requirement. It is generally impossible to describe a living organism in writing with enough detail so that it can be made on the basis of that description. Relaxing this requirement for plants was one reason behind the Plant Patent Act of 1930. For microorganisms, the problem is solved by depositing a publicly available culture with a recognized national repository and referring to the accession number in the patent. * While such an approach

● This procedure was accepted by the Court in *Customs and Patent Appeals v. Cent. Am.* in upholding a patent on a process using microorganisms. *Application of Application of 434 under 1390 4 F.2d 1970*. This procedure should also be acceptable for patents on microorganisms themselves.

may be theoretically possible for animals and insects, it may be logistically impractical. However, if tissue culture techniques advance to the point where genetically engineered organisms can be made from single cells and stored indefinitely in that form, there appears to be no reason to treat them any differently than microorganisms, in the absence of a specific statute prohibiting their patentability.

Potential impacts of the decision and related policy issues

During the 8-year history of the *Chakrabarty* case and the surrounding public debate, numerous assertions were made about the potential impacts of permitting patents on genetically engineered organisms. They ranged from more immediate effects on the biotechnology industry, the patent system, and academic research to the long-term impacts on genetic diversity and the food supply. In addition, two major policy issues that have been raised are the morality of patenting living organisms; and the propriety of permitting private ownership of inventions from publicly funded research.

Impacts on industry

The basic question for industry is the extent to which permitting patents on genetically engineered organisms will stimulate both their development and the growth of the industries employing them. To ascertain this requires first an examination of the theory and social policies underlying the patent system.

THE RELATIONSHIP BETWEEN PATENTS AND INNOVATION

The patent system is supposed to stimulate innovation—the process by which an invention is brought into commercial use—because the inventor does not receive financial rewards until the invention is used commercially. The Constitution itself presumes this, as do the statutes enacted pursuant to the patent clause in article I, section 8. Attempts have been made to subject this presumption to empirical analysis; but innovation is extraordinarily complex and involves interacting factors that are difficult to separate. In addition, the existence of patents and trade secrets as alternative means for protection makes it almost impossible to study the effects of patents alone on invention and innovation. *

● A major criticism for the lack of empirical studies has been the lack of appropriate data. The information available on the number of patents applied for and issued does not indicate the importance, economic benefits, or economic costs of inventions (whether patented or unpatented) that may not have existed at all or may have been created more slowly if not for the patent system.

Several reasonable arguments have been presented to support the presumption that the patent system stimulates innovation. First, the potential for the exclusive commercialization of a new product or process creates the incentive to undertake the long, risky, and expensive process from research through development to marketing. At every stage of innovation—from defining priorities and making initial estimates of an invention's value to advertising the finished product—the inventor and his backers must spend time, money, and effort, not only to develop a product but to convince others of its worth. Only a small percentage of new ideas or inventions survive. If a competitor, particularly a larger firm with a well-developed marketing capability, were free to copy a product at this point, smaller firms would have little incentive to undertake the process of innovation.

Second, the information and new knowledge disclosed by the patent allows others to develop competing, and presumably better, products by improving on the patented product or "inventing around" it. Third, patents may reduce unnecessary costs to individual firms, thereby freeing resources for further innovation. Once a patent is issued, competitors can redirect research and development (R&D) funds into other areas. For the firm holding the patent, maintaining control over the technology is theoretically less expensive, since the costs of trade secret protection are no longer required. **

Anecdotal accounts support the proposition that patents stimulate innovation; probably the best known is the story of penicillin. Although

Sir Alexander Fleming had discovered a promising weapon against bacterial infection, it took him, over 10 years to get the money and facilities he needed to purify and produce penicillin in bulk. Only World War II and an international effort finally accomplished that task. Sir Howard Florey, who shared the Nobel prize with Fleming for developing penicillin, attributed the delay to their not having patented the drug, which he termed "a cardinal error."¹⁰

Some have claimed that the monopoly power of a patent can be used to retard innovation. A corporation can legally refuse to license a patent on a basic invention to holders of patents on improvements, thus protecting its product from becoming less attractive or obsolete. On the other hand, unless the corporation can satisfy the market for its product, it is usually in its economic interest to engage in cross-licensing arrangements with holders of improvement patents; it receives royalties and all parties can market the improved product. Cross-licensing has been misused several times by a few dominant firms in an attempt to exclude innovative new firms from their markets. Such arrangements violate the antitrust laws. Whether or not that body of law adequately prevents patent misuse is beyond the scope of this report.

THE ADVANTAGES OF PATENTING LIVING ORGANISMS

Given the presumed connection between patents and innovation, the next question is whether patenting a living organism would add significant protection for the patent holder, or whether alternative approaches would be sufficient. In this context, it is necessary to focus on the present industrial applications—which involve only micro-organisms—to examine alternative forms of patent coverage and to compare the protection offered by trade secrecy with that offered by patents.

Opinions vary widely among spokesmen for the genetic engineering companies on the value of patenting micro-organisms.¹¹ Spokesmen for Genentech, Inc., have stated numerous times

dent Carter's recent report on industrial innovation, the patent policy committee, composed of industry representatives having long experience with the patent system, recommended ways of enhancing innovation and improving the patent system, including the patenting of industrially important living organisms. However, they had no hard economic data to support their recommendation.

and Charles L. *Effects of Patent and Laws, and Practices on Innovation*, vol. 1 (Arlington, Va: Institute for Defense Studies, 1976), pp. 2,9.

U.S. Department of Commerce, *Advisory Committee on Innovation: Final Report*, September 1976, pp. 148-149.

*Patent rights can be very expensive to enforce against an inventor, however, should litigation be necessary.

pp. 170-171.

D. Dickson, "patenting Living organisms: How to Beat the Rustlers," *Nature*, vol. 283, Jan. 10, 1980, pp. 128-129.

that such patents are crucial to the development of the industry, while others have stated their preference for trade secrecy.

Genentech's friend-of-the-court brief filed in the Chakrabarty case stated, "The patent incentive did, and doubtless elsewhere it will, prove to be an important if not indispensable factor in attracting private support for life-giving research."¹² Genentech has also supported increased patent protection because, to attract top scientists to the company, it had to give assurances that they would be able to publish freely.¹³ This severely curtails any reliance on trade secrets.

The rationale behind the contrary position is based on the belief that the industry is moving so quickly that today's frontrunner is not necessarily tomorrow's, and that unique knowledge translates into competitive advantage. Thus, in a strategy similar to that of the advanced microelectronics industry, firms may prefer to rely on trade secrets even for patentable inventions, coupled with an intense marketing effort once an invention has reached the commercial stage. The idea is to get the jump on competitors and to stay in front.

The uncertainty about whether micro-organisms could be patented before the Supreme Court's decision does not appear to have hindered the development of the industry. Clearly, companies did not have any difficulty raising capital—e.g., before the decision, Cetus Corp. had a paper value of \$250 million without holding a single patent on a genetically engineered organism. Moreover, products such as insulin, human growth hormone, and interferon were being made, albeit in small quantities, by unpatented, genetically modified organisms. (See ch. 4.)

Before the decision, companies relied either entirely on trade secrecy for protection, or on a combination of patents on the microbiological process and the product and trade secret protection of the micro-organism itself. Considering

the existence of such protection, the question is what the actual advantages are to patenting the micro-organisms as well.

One advantage results from the ability of a living organism to reproduce itself. Developing a new microbe for a specific purpose, such as the production of human insulin, can be a long, difficult, and costly procedure. Yet once it is developed, it reproduces endlessly, and anybody acquiring a culture would have the benefit of the development process at little or no cost unless the organism were patented.

Often, a company is able to keep the microbe a trade secret, since only the product is sold. However, where the microbe is the product—such as with Chakrabarty's oil-eating bacterium—patenting the organism is the best means of protection. Moreover, even when a microbe itself can be kept under lock and key, a company desiring to patent the process in which it is used must place a sample culture in a public repository to meet the enablement requirement.

A competitor could legally obtain the micro-organism. If the competitor were to use it to make the product for commercial purposes, the company might suspect infringement but have difficulty proving it, especially when the product is not patented. The infringing activity would take place entirely within the confines of the competitor's plant. Mere suspicion is not sufficient legal grounds for inspecting the competitor's plant for evidence of infringement when the unpatented product could theoretically be made by many different methods besides the one patented.*

A second, but less certain, advantage provided by patenting the micro-organism is that even uses and products of the organism not discovered by the inventor would be protected indirectly. That is, while new uses and products could be patented by their inventors, those patents would be "dominated" by the micro-organism patent. Royalties would have to be paid

¹² *Chakrabarty v. Genentech, Inc.*, 473 U.S. 272, 281 (1985).
¹³ *Chakrabarty v. Genentech, Inc.*, 473 U.S. 272, 281 (1985).
 * *Chakrabarty v. Genentech, Inc.*, 473 U.S. 272, 281 (1985).
 President and Board of Directors of Cetus Corp. for personal communication, Apr. 15, 1980.
 13 *Chakrabarty v. Genentech, Inc.*, 473 U.S. 272, 281 (1985).

would answer this assertion is assertion that a lawsuit
 even on the basis of little evidence of infringement
 discovery of discovery which is a violation and
 provide to provide any evidence of evidence of it

whenever the micro-organism was used for commercial purposes. Whether this would be a significant advantage in practice is uncertain. Usually, only one product is optimally produced by a given micro-organism and only one micro-organism is best for a given process. Presumably, the micro-organism's inventor would also have discovered and patented its best use and product.

Another alternative to patenting a man-made micro-organism, besides trade secrecy, is to patent its manmade components. Examples of these include a plasmid containing the cloned gene, a sequence of DNA, or a synthetic gene made by the reverse transcriptase process. These components, which are nothing more than strings of inanimate chemicals, would not be unpatentable products of nature if they were made in the laboratory and were not identical to the natural material. Patenting them would not be equivalent to patenting the entire organism, since their function would be affected in varying degrees by the internal environment of their host. Nevertheless, the inventor of a particularly useful component, such as an efficient and stable plasmid, might want to patent it regardless of whether or not the organism could be patented, since it could be used in an indefinite number of different micro-organisms.

Thus, if Congress were to prohibit patenting of micro-organisms because they are alive, industry could compensate to a large degree by patenting inanimate components. On the other hand, if Congress allows the Supreme Court's decision to stand, certain components will undoubtedly still be patented. In fact, such patents may become more important than patents for micro-organisms, since the components are the critical elements of genetic engineering.

PATENT V. TRADE SECRET PROTECTION

Even with the advantages provided by patenting a micro-organism, a company could still decide to rely on trade secrecy. In choosing between these two options, it would evaluate the following factors:¹⁵

- whether the organism itself or the substance that it makes will be the commercial product,
- whether there is any significant doubt of its meeting the legal requirements for patenting,
- whether there is the likelihood of others discovering it independently,
- whether it is a pioneer invention,
- what its projected commercial life is and how readily others could improve on it if it were disclosed in a patent,
- whether there are any plans for scientific publication, and
- what the costs of patenting are versus reliance on trade secrecy.

The first two factors make the decision easy. Obviously, an organism like Chakrabarty's can best be protected by a patent. In most instances, the substance made by the organism is the commercial product. In that case, if there are significant doubts that the organism can meet all the legal requirements for patentability, the company would probably decide to rely on trade secrecy.

The next three factors require difficult decisions to be made on the basis of the characteristics of the new organism, its product, and the competitive environment. If research to develop a particular product is widespread and intense (as is the case with interferon), the risk of a competitor developing the invention independently provides a significant incentive for patenting. On the other hand, reverse engineering (examination of a product by experts to discover the process by which it was made) by competitors is virtually impossible for products of micro-organisms because of the variability and biochemical complexity of microbiological processes.

Thus, greater protection may often lie in keeping a process secret, even if the microbe and the process could be patented. This is especially true for a process that is only a minor improvement in the state of the art or that produces an unpatentable product already made by many competitors. The commercial life of the process might be limited if it were patented because infringement would be difficult to detect

¹⁵ See, e.g., *Chakrabarty v. Ciba Ltd.*, 429 F.2d 899, 905 (Ct. Cl., 1970); *In re Tilton*, 19, 273, 277.

and not worth the time and money to prosecute. Reliance on trade secrecy might then extend its commercial life.

Most companies would patent truly pioneer inventions, which often provide the opportunity for developing large markets. Moreover, patents of this sort tend to have long commercial lives, since it is difficult to circumvent a pioneer invention and since any improvements are still subject to the pioneer patent. Furthermore, infringement is easy to detect because of the invention's trailblazing nature.

The last two factors involve considerations secondary to a product and its market. Obviously, any publication of the experiments leading to an invention foreclose the option of trade secrecy. Also, company must evaluate the options of protection via either patenting or trade secrecy in terms of their respective cost effectiveness.

IMPACT OF THE COURT'S DECISION ON THE BIOTECHNOLOGY INDUSTRY

The *Chakrabarty* decision will add some protection for microbiological inventions by providing companies with an additional incentive for* the commercial development of their inventions, particularly in marginal cases, by lowering uncertainty and risk. A greater effect will result from the new information disclosed in patents on inventions that otherwise might have been kept secret indefinitely. Competitors and academicians will gain new knowledge as well as a new organism upon which to build. The Patent office had deferred action on about 150 applications, while awaiting the Court's decision; as of December 1980, it was processing approximately 200 applications on micro-organisms.^{16*}

Depending on the eventual number and importance of patented inventions that would have otherwise been kept as trade secrets, the ultimate effect of the decision on innovation in the biotechnology industry could be significant.

Conversely, if the Court had reached the opposite decision, the industry would have been held back only moderately because of reasonably effective alternative means of protection.

Impacts of the Court's decision on the patent law and the Patent and Trademark Office

The key rationale supporting the Court's holding *Chakrabarty's* microbe to be patentable was the fact that it was manmade; its status as a living organism was irrelevant. The Patent Office interprets this decision as also permitting patents on micro-organisms found in nature but whose useful properties depend on human intervention other than genetic engineering,¹⁷ e.g., if the isolation of a pure culture of a microbial strain induces it to produce an antibiotic, that pure culture would be patentable subject matter.

Because of the complexity, reproducibility, and mutability of living organisms, the decision may cause some problems for a body of law designed more for inanimate objects than for living organisms. It raises questions about the proper interpretation and application of the requirements for novelty, nonobviousness, and enablement. In addition, it raises questions about how broad the scope of patent coverage on important micro-organisms should be and about the continuing need for the two plant protection Acts. These uncertainties could result in increased litigation, making it more difficult and costly for owners of patents on living organism! to enforce their rights.

The complexity of living matter will make it difficult for anyone examining the invention to determine if it meets the requirements for novelty, nonobviousness, and enablement. Micro-organisms can have different characteristics in different environments.' Moreover, microbic taxonomists often differ on the precise classification of microbial strains. Even after expensive tests, uncertainty may still exist about whether a specific micro-organism is distinct from other known strains; scientists do not have complete

1111 ¹⁶Report of the Commissioner of Patents and Trademarks, *Annual Report of the Commissioner of Patents and Trademarks, 1980*, p. 100. These figures are based on the data in the *Annual Report of the Commissioner of Patents and Trademarks, 1980*, p. 100.

hid, p. 1.

knowledge of any single organism's biophysical and biochemical mechanisms. Consequently, there may be cases where it is difficult to know the prior art precisely enough to make a determination of novelty.

Similarly, microbial complexity raises problems in determining nonobviousness because there are so many different ways of engineering a new organism with a desired trait—e.g., a gene could be inserted into a given plasmid at several different positions. If a microbe with the gene at one position in the plasmid were patented, could a patent be denied to an otherwise structurally identical organism with the gene at a different position because the second was obvious? Perhaps not. The second organism would probably not be an obvious invention if it provided significantly more of the product, a better quality product under similar fermenting conditions, or the same product under cheaper operating conditions.

As to enablement, the major problem has been discussed previously; placing a culture of the micro-organism into a repository is the accepted solution. One problem with repositories, however, is their potential misuse. In a case involving alleged price fixing and unfair competition—e.g., the Federal Trade Commission found that micro-organisms placed in a public repository pursuant to process and product patents on the antibiotic Aureomycin did not produce the antibiotic in commercially significant amounts; in actual practice, other strains were being used for production, and the company involved was able to benefit from a patent, while, in effect, retaining the crucial micro-organism as a trade secret.^{18*}

Complexity also raises questions about the appropriate scope of patent coverage. In a patent, the inventor is permitted to claim his invention as broadly as possible, so long as the claims

Cyanamid Co., et. al., (C.O. 17-7 905 1747, 1905 n. 101 reman. and remanded, 7 (1966), readopted 72 (1971) (mod. 401 F.2d 514 (6) C.C. 1968) cert. denied, 394 (1969)

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made do not overlap with any “prior art” or obvious extensions thereof—e.g., a person who developed a particular strain of *Escherichia coli* that produced human insulin through a genetically modified plasmid could be entitled to a patent covering *all* strains of *E. coli* that produce the insulin in the same way. Chakrabarty's patent application—e.g., claimed “a bacterium from the genus *pseudomonas* containing therein at least two stable energy generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.” Several species and hundreds of strains of *Pseudomonas* fit this description. A patent limited to a particular microbial strain is not particularly valuable because it can easily be circumvented by applying the inventive concept to a sister strain; on the other hand, a patent covering a whole genus of micro-organism (or several) may retard competition. This problem will probably be resolved by the Patent Office and the courts on a case-by-case basis.

Another aspect of the same problem is whether a patent on an organism would cover mutants. It would not if the mutation occurred spontaneously and sufficiently altered the claimed properties. However, if a new organism were made in a laboratory with a patented organism as a starting point, the situation would be analogous to one where an inventor can patent an improved version of a machine but must come to terms with the holder of the “dominant” patent before marketing it.

The Chakrabarty decision also raises questions about the scope of section 101 and its relation to the plant protection Acts—e.g., plant tissue culture is, in effect, a collection of micro-organisms; should it be viewed as coming under section 101 instead of either of the plant protection Acts? Could plants excluded under these Acts—such as tuber-propagated plants or first-generation hybrids—be patented under section 101? Could any plants or seeds be patented under section 101, and if so, is there still a need for the plant protection Acts? If there is a need, would the Acts be administered better by only one agency? The Senate Committee on Appropriations has directed the Departments of Commerce and Agriculture to submit a report

within 120 days of the *Chakrabarty* decision on the advisability of shifting the examining function to USDA.¹⁹ As of December 1980, this issue was still under study. These questions could be resolved by the courts, but they are probably more amenable to a statutory solution.

Another effect of the decision could be on patent enforcement. The various uncertainties discussed above may have to be resolved through costly litigation. Moreover, in specific cases, the problems associated with describing a micro-organism in sufficient detail may increase the chances that a patent will be declared invalid. In any event, litigation costs would probably increase as more expert testimony is needed.

The fact that organisms mutate might introduce still another complication into infringement actions. A deposited micro-organism is the standard by which possible infringement would be judged. If it has mutated with respect to one of its significant characteristics, a patent holder who is seeking to prove infringement may have no case. While this problem does not appear to be amenable to a statutory solution, the risk of such a mutation is actually quite small.*

Because a living invention reproduces itself, the statutory definition of infringement may have to be changed. Presently, infringement consists of making, using, or selling a patented invention without the permission of the patent holder. Theoretically, someone could take part of a publicly available micro-organism culture, reproduce it, and give it away. Arguably, this is not "making" the invention, and the patent holder would have the burdensome and expensive task of going after each user. The two plant protection statutes deal with this problem by specifically prohibiting unauthorized reproduction of the protected plant. This approach may be necessary for other living inventions,

How all of these uncertainties will affect the Patent Office's processing of applications cannot be predicted. Currently, the average processing time for all applications is 22 months; separate

information on genetic engineering applications is not available.²⁰ It may take examiners longer to process applications on micro-organisms than for those covering only microbiological processes or products because of the interpretive problems mentioned. Moreover, the Patent Office will have to develop greater expertise in molecular genetics—a frontier scientific field that has only recently been the subject of patent applications. On the other hand, the Office generally faces this problem for any new area of technology.

In terms of increased numbers of applications, the decision is not expected to have a significant effect on the Patent Office operations in the next few years. The Office receives approximately 100,000 applications a year, and it has about 900 examiners, each processing an average of about 100 applications per year. Figures on the number of applications on genetically engineered organisms vary, depending on how the category is defined, and precise information has not been tabulated by the Patent Office. Rough estimates indicate that in February 1980 about 50 applications were pending, and by December 1980, that number had increased to about 100. Applications are being filed at the rate of about 5 per month. Also, just over 100 are pending on microbes that have been isolated and purified from natural sources, but have not been genetically engineered. Four examiners are working on both categories as well as others. Thus, in view of the total operations of the office, these applications require only a small part of its resources. Over the next few years, the number is expected to increase because of the decision and developments in the field but not to a point where more than a few additional examiners will be needed.²¹

Impact of the Court's decision on academic research

Many academicians have voiced concerns about the effects on research of the *Chakrabarty* decision and the commercialization of molecular biology in general. They claim that the re-

¹⁹ 96.251, 96th (king. 96th Cong. 1st P. 251)

*Most micro-organisms can be freeze-dried, which virtually eliminates the risk of mutation.

²⁰Gene Tegtmeyer, personal communication, Dec. 1980, p. 11, 1980-1981.

suits of rDNA research are not being published while patent applications are pending, discussion at scientific meetings is being curtailed, and novel organisms are less likely to be freely exchanged. A related concern is that scientific papers may not be citing the work of other scientists to avoid casting doubt on the novelty or inventiveness of the author's work, should he decide to apply for a patent. Finally, there is concern that the granting of patents on basic scientific processes used in the research laboratory will directly impede basic research—e.g., two scientists have recently been granted a patent on the most fundamental process of molecular genetic technology—the transfer of a gene in a plasmid using rDNA techniques.²² The patent has been transferred to the universities where they did their work—Stanford and the University of California at San Francisco (UCSF). Although both universities have stated they would grant low-royalty licenses to anyone who complied with the National Institutes of Health (NIH) Guidelines, subsequent owners of fundamental process patents may not be so altruistic.

There are several reasons for believing that these concerns, although genuinely held, are somewhat overstated. First, patents on fundamental scientific processes or organisms should not directly hinder research. The courts have interpreted patent coverage as not applying to research; in other words, the patent covers only the commercial use of the invention.²³ Also, it would be difficult and prohibitively expensive for a patent holder to bring infringement actions against a large number of geographically separated scientists. Second, patents ultimately result in full disclosure. If patents were not available, trade secrecy could be relied on, with the result that important information might never become publicly available. Third, although delays occur while a patent application is pending, they often happen anyway while experiments are being conducted or while articles

are being prepared for publication because of the competitive nature of modern science.

Essentially, the issue is the effect of the commercialization of research results on the research process itself. Even if patents were not available for biological inventions, the inventor would simply keep his results secret if he were interested in commercialization. Viewed from this perspective, it is difficult to see why the availability of patents should affect the exchange of scientific information in genetic research any more than it does in any other field of research with commercial potential. The *Chakrabarty* decision may inhibit the dissemination of information only if it creates an atmosphere that stimulates academic scientists to commercialize their findings. However, if it encourages them to rely on patents rather than on trade secrets, it will ultimately enhance the dissemination of information.

Impacts of the Court's decision on genetic diversity and the food supply

Some public interest groups have claimed that patenting genetically modified organisms will adversely affect genetic diversity and the food supply. The claim is based on an analogy to a situation alleged to exist for plants. Briefly, the groups claim that patenting micro-organisms will irrevocably lead to patents on animals, which will have the same deleterious effects on the animal gene pool and the livestock industry as the two plant protection Acts have had on the plant gene pool and the plant breeding industry. The alleged effects are: loss of germplasm resources as a result of the elimination of thousands of varieties of plants; the increased risk of widespread crop damage from pests and diseases because of the genetic uniformity resulting from using a single variety; and the increasing concentration of control of the world's food supply in a few multinational corporations through their control of plant breeding companies.²⁴

only limited evidence is available, but no conclusive connection has been demonstrated be-

²²No. 4,337,227, issued Dec. 2, 1980. *Genetic Engineering Co. v. Cheselrough Ponds, Inc.*, 211 F. Supp. 211 (S.D. Cal. 1992) (dictum), aff'd (dictum), 679 F.2d 679, 317 Cir. 963 (2d Cir. 1982). *United States v. 159 F. Supp. 371 (Ct. Cl. 1371 Dugar 1958)*; *5 F. Supp. 55*, 55 F. D.N.Y. 223 (S. D. Ct. E. Ak'o Agate ²³*Br Mad' Co.*, 13 F. Supp. 315 (D.W.V. 305 337).

²⁴Peoples' the less Commission as Amicus Cas Am pp. 6-13, *Chakrabarty*, 100 S. Ct. 221 (100 s. Ct.). 2204 (1980).

tween the plant protection laws and the loss of genetic diversity, the encouragement of using a single variety, and any increased control by a few corporations of the food supply. (For a detailed discussion, see ch. 8.) Therefore, any connection between patenting micro-organisms and potential detrimental impacts on the livestock industry appears tenuous at best. The assumptions that the *Chakrabarty* decision will inevitably lead to patenting animals, and that the consequences will be the same as those claimed to result from granting limited ownership rights to varieties of plants, are speculative.

The morality of patenting living organisms

The moral issue is difficult to analyze because it embodies at least three overlapping questions: whether it is moral to grant exclusive rights of ownership to a living species; whether patents on lower forms of life will inevitably lead to genetic engineering of humans; and whether patenting organisms undermines the generally held belief in the uniqueness and sanctity of life, especially human life.

It is difficult to assess the extent of the belief that patenting living organisms is intrinsically immoral, and no such assessment has been done. Its extent and intensity will probably be directly correlated with the complexity of the organism involved. Fewer people will be disturbed about patenting micro-organisms than about patenting cattle. A belief in the immorality of patenting a living organism is a value judgment to which Congress may wish to give some consideration.

The second aspect of the moral issue revolves around the well-known metaphor of the “slippery slope”—the fear that the first steps along the path of genetic engineering may irrevocably lead to man. Technology, at times, appears to have its own momentum; the aphorism “what can be done, will be done” has been true in the past. Thus, some people fear that patenting micro-organisms may indeed set a dangerous precedent and encourage the technology to progress to the point of the ultimate dehumaniza-

tion—the engineering of people as an industrial enterprise.²⁵

The *Chakrabarty* opinion was written in narrow terms. But while its reasoning might be applied to a future case involving an animal or insect, it simply could not be used to justify the patenting of human beings because of the 13th amendment to the Constitution, which prohibits the ownership of humans.

One way to negotiate the slippery slope is to deal directly with the adverse aspects of the technology. Barriers can be erected along the slope; the Constitution already protects humans. Congress can erect other barriers by statute, specifically drawing lines as to which organisms can or cannot be patented.

The third part of the issue is religious or philosophical in nature. For many, the patenting of a living organism undermines the awe and deep respect they hold for the unique nature of life. Moreover, it raises apprehensions of an ultimate threat to concepts of the nature of humanity and its place in the universe. To these people, if life can be engineered and patented, perhaps it is not special or sacred. If this is true of lower organisms, why would human beings be different? (This and other aspects of the morality issue are discussed in greater detail in ch. 13.)

Private ownership of inventions from publicly funded research

Much of the basic research in molecular genetics has been funded by Federal grants. Most of the work leading to the development of rDNA techniques—e.g., was performed at Stanford University and UCSF under NIH grants. The scientists involved have received a patent on that fundamental scientific process. Some opponents of patenting organisms have argued that private parties should not be permitted to own inventions resulting from federally funded R&D; and in any event, there is something special about molecular genetics that requires the Federal Government to retain ownership of

federally funded inventions and to make them generally available through nonexclusive licenses.

Until recently, there had been no comprehensive, governmentwide policy regarding ownership of patents on federally funded inventions. Some agencies, such as the Department of Health and Human Services (DHHS), permitted nonprofit institutional grantees to own patents on inventions (subject to conditions deemed necessary to protect the public interest) if they had formal procedures for administering them. However, most agencies generally retained title to such patents, making them available to anyone in the private sector for development and possible commercialization through nonexclusive licenses.

The rationale behind the policy was simply that inventions developed by public money should be available to all—including private industry—on a nonexclusive basis. This arrangement had been criticized as not providing sufficient incentive for industry to take the risks to develop the inventions. Of the more than 28,000 patents owned by the Government, less than 4 percent have been successfully licensed; on the other hand, universities, which do grant exclusive licenses on patents that they own, have been able to license 33 percent of their patents.²⁶

On December 12, 1980, President Carter signed the Government Patent Policy Act of 1980. The Act sets forth congressional policy that the patent system be used to promote the utilization of inventions developed under federally supported R&D projects by nonprofit organizations and small businesses. To this end, the organization or firm may elect to retain title to those inventions, subject to various conditions designed to protect the public interest. Such conditions include retention by the funding agency of a nonexclusive, irrevocable, paid-up license to use the invention, and the right of the Government to act where efforts are not being made to commercialize the invention, in cases of health or safety needs, or when the use of the invention is required by Federal regulations.

There is still the question of whether patents on molecular techniques or genetically engineered micro-organisms are sufficiently different to merit exception from any general patent policy decided on by Congress. For some, the molecular genetic techniques are unique because they are powerful scientific tools that can manipulate the life processes as never before. However, in a November 1977 report, NIH took the following position with regard to patents on rDNA inventions developed under DHHS-NIH support:^{27*}

There are no compelling economic, social, or moral reasons to distinguish these inventions from others involving biological substances or processes that have been patented, even when partially or wholly developed with public funds.

The report was prompted by the Stanford-UCSF patent application. Even though the application was in accord with the funding agreements between the institutions and NIH, the universities requested a formal NIH opinion on the issue in view of the intense public interest in rDNA research. NIH solicited comments from a group of approximately 67 individuals, ranging from academic and industrial scientists to students, lawyers, and philosophers.²⁸ The review and analysis of the responses were referred to the Federal Interagency Committee on rDNA Research, the Public Health Service, and the Office of the General Counsel of the Department of Health, Education, and Welfare (now DHHS). A fairly uniform consensus on the above-quoted finding developed in this process; the one significant dissenter, the Department of Justice, contended that the Government should retain ownership of any invention resulting from federally funded rDNA research because of the great public interest in that research.

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Issue and Options

ISSUE: To what extent could Congress provide for or prohibit the patentability of living organisms?

In its *Chakrabarty* opinion, the Supreme Court stated that it was undertaking only the narrow task of determining whether or not Congress, in enacting the patent statutes, had intended a manmade micro-organism to be excluded from patentability solely because it was alive. Moreover, the opinion specifically invited Congress to overrule the decision if it disagreed with the Court's interpretation.

Congress has several options. It can act to resolve the questions left unanswered by the Court, overrule the decision, or develop a comprehensive statutory approach. Most importantly, Congress can draw lines; it can decide which organisms, if any, should be patentable.

OPTIONS

A: Congress could maintain the status quo.

Congress could choose not to address the issue of patentability and allow the law to be developed by the courts. The advantage of this option is that issues will be addressed as they arise in the context of a tangible, nonhypothetical case. Some of the issues raised in the debate on patenting may turn out to be irrelevant as the technology and the law develop. Moreover, many of the uncertainties raised by the *Chakrabarty* decision regarding provisions of the patent law other than section 101 may be incapable of statutory resolution. The complexity of living organisms and the increase in knowledge of molecular genetics will raise such broad and varied questions that legal interpretations of whether a particular biological invention meets the requirements of novelty, nonobviousness, and enablement will best be done on a case-by-case basis by the Patent Office and the Federal courts.

There are two disadvantages to this option. First, a uniform body of law may take time to develop, since judicial decisions about new legal questions by different Federal courts may ini-

tially conflict. Second, the Federal judiciary is not designed to take sufficient account of the broader political and social interests involved.

B: Congress could pass legislation dealing with the specific legal issues raised by the Court's decision.

Many of the legal questions do not readily lend themselves to statutory resolution. However, three questions are fairly narrow and well-defined and may therefore be better resolved by statute: 1) Is there a continuing need for the plant protection Acts if plants can be patented under section 101? 2) If there is a continuing need for these Acts, could they be administered better by one agency? 3) Should the definition of infringement be clarified by amending section 271 of the Federal Patent Statutes (title 35 U. S. C.) to include reproduction of a patented organism for the purpose of selling it?

Congressional action to clarify these issues would provide direction for industry and the Patent Office, and it would obviate the need for a resolution through costly, time-consuming litigation. Lessening the chances of litigation or the chances of a patent being declared invalid will provide some stimulation for innovation by lessening the risks in commercial development. In addition, Congress could determine that the plant protection Acts could be better administered by one agency or should be incorporated under the more general provisions of the patent law; if so, some administrative expenses probably could be saved.

C: Congress could mandate a study of the plant protection Acts.

Two statutes, the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, grant ownership rights to plant breeders who develop new and distinct varieties of plants. They could serve as a model for studying the broader, long-term potential impacts of patenting living organisms. An empirical study of the impacts of the plant protection laws has not been done. Such a study would be timely, not

only because of the *Chakrabarty* decision, but also because of allegations that the Acts have encouraged the planting of uniform varieties, loss of germplasm resources, and increased concentration in the plant breeding industry. In addition, information about the Acts' affect on innovation and competition in the breeding industry would be relevant to this aspect of the biotechnology industry. However, it may be extremely difficult to isolate the effects of these laws from the effects of other factors.

D: Congress could prohibit patents on any living organism or on organisms other than those already subject to the plant protection Acts.

By prohibiting patents on any living organisms, Congress would be accepting the arguments of those who consider ownership rights in living organisms to be immoral, or who are concerned about other potentially adverse impacts of such patents. Some of the claimed impacts are: 1) patents would stimulate the development of molecular genetic techniques, which will eventually lead to human genetic engineering; 2) patents contribute to an atmosphere of increasing interest in commercialization, which will discourage the open exchange of information crucial to scientific research; and 3) plant patents and protection certificates have encouraged the planting of uniform varieties, loss of germplasm resources, and increasing concentration in the plant breeding industry. Also, by repealing the plant Acts, Congress would be reversing the policy determination it made in 1930 and in 1970 that ownership rights in novel varieties of plants would stimulate plant breeding and agricultural innovation.

A prohibitory statute would have to deal with those organisms at the edge of life, such as viruses. Although there are uncertainties and disagreements in classifying some entities as living or nonliving, Congress could be arbitrary in its inclusions and exclusions, so long as it clearly dealt with all of the difficult cases.

This statute by itself would slow but not stop the development of molecular genetic techniques and the biotechnology industry because there are several good alternatives for maintaining exclusive control of biological inventions:

maintaining organisms as trade secrets; patenting microbiological processes and their products; and patenting the inanimate components of a genetically engineered micro-organism, such as plasmids, which are the crucial elements of the technique anyway. The development would be slowed primarily because information that might otherwise become public would be kept as trade secrets. A major consequence would be that desirable products would take longer to reach the market. Also, certain organisms or products that might be marginally profitable yet beneficial to society, such as some vaccines, would be less likely to be developed. In such cases, the recovery of development costs would be less likely without a patent to assure exclusive marketing rights.

Alternatively, Congress could overrule the *Chakrabarty* decision by amending the patent law to prohibit patents on organisms other than the plants covered by the two statutes mentioned in option C. This would demonstrate congressional intent that living organisms could be patented only by specific statute and alleviate concerns of those who fear the "slippery slope."

E: Congress could pass a comprehensive law covering any or all organisms (except humans).

This option recognizes the fact that Congress can draw lines where it sees fit in this area. It could specifically limit patenting to micro-organisms or encourage the breeding of agriculturally important animals by granting patent rights to breeders of new and distinct breeds. Any fears that such patents would eventually lead to patents on human beings would be unfounded, since the 13th amendment to the constitution, which abolished slavery, prohibits ownership of human life.

The statute would have to define included or excluded species with precision. Although there are taxonomic uncertainties in classifying organisms, Congress could arbitrarily include or exclude borderline cases.

A statute that permitted patents on several types of organisms could be modeled after the Plant Variety Protection Act—e.g., it should cover organisms that are novel, distinct, and

uniform in reproduction; such terms would have to be defined, Infringement should include the unauthorized reproduction of the organism—although reproduction for research should be excluded to allow the development of new varieties. In fact, consideration should be given to covering in one statute plants and all other organisms that Congress desires to be patentable. This would provide the advantage of comprehensiveness and uniform treatment; it could also address the problems discussed under option B.

The impact of this law cannot be assessed precisely. A comprehensive statute would stimulate the development of new organisms and their products and would encourage dis-

semination of technical information; however, such a statute is not essential to the development of the biotechnology industry, since incentives and alternative means for protection already exist. The secondary impacts on society of the legislation are even harder to assess because of the scarcity of data from which to draw conclusions. The policy judgments will have to be made by Congress after it weighs the opinions of the various interest groups. Through legislation, Congress has the chance to balance competing views on this controversial issue and, if necessary, to alleviate the primary concerns about the long-term impacts of the decision—that higher organisms will inevitably be patented.