0273-2289/87/1613—0079$03.00

Life Forms Protectable as Subjects of US Patents— Microbes to Animals (Perhaps)

DANIEL S. HODGINS

Arnold, White, & Durkee, PO Box 4433, Houston, TX 77210

Received November 7, 1987; Accepted December 3, 1987

ABSTRACT

Scientists, businessmen, universities, and industries with fundamental or peripheral interests in technology as applied to life processes will be keenly interested in recent US Patent Office decisions. These decisions indicate that new higher life forms, animal or plant, are proper subjects of patents if they are not naturally occurring (and are not human, in the case of animals).

In contrast to plants and other organisms, genetically modified animals have had no mode of protection as intellectual property except possibly as trade secrets or utility patents. The *Ex parte Allen* decision, reached by the Patent Office Board of Appeals and Interferences, directly addressed the issue of animal patentability in view of the broad reading of 35 U.S.C. §101 by the US Supreme Court in the *Chakrabarty* decision. The subject invention concerned polyploid oysters. Claims directed toward polyploid oysters produced by a particular process were rejected under 35 U.S.C. §103 and §101. The Board, reversing the 35 U.S.C. §101-based rejection in view of the *Chakrabarty* decision, indicated that the claimed polyploid oysters were non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 U.S.C. §101.

A similar decision affecting the patentable status of plants or segments thereof had previouisly been reached by the Patent and Trademark Office in the case of *Ex parte Hibberd,* 227 U.S.P.Q. 443 (Bd. Pat. App. 1985). The *Hibberd* utility patent application concerned "genetically engineered" maize which had high levels of the tryptophan.

INTRODUCTION

From a secular point of view, a living organism—at least a simple one—may be interpreted as being a complex mechanism created by a polynucleotide having a particular and unique structure. Further, the function of the mechanism could be viewed as assurance that the reproduction and existence of the polynucleotide continues in a competitive environment. As exemplified by the manifold forms of life present, many mechanisms of assured reproduction have been found to be successful (although species' extinctions indicate failure).

Life forms advertently and inadvertently use each other to assure survival and reproduction. Microorganisms may enrich the soil (e.g., by fixation of atmospheric nitrogen) so that plants may grow more efficiently. Plants, at the end of their life cycle, may be converted to soil nutrients by microorganisms which use plant bodies as food. Likewise, animals feeding upon plants and/or one another will one day return their composite materials to the continuous cycle.

Humankind has been particularly ingenious in devising ways to more efficiently corner a share of the earth's nutrients. For thousands of years agriculture has involved the selection and nurturing of preferred plants and animals. Microorganisms have long been used in fermentative processes to produce diverse materials. These materials include beverages such as beer, foodstuffs such as cheese and bread, and fertilizer such as compost.

Many civilizations have purposely interbred animals or plants with desirable characteristics, or selected and utilized microorganisms that were outstandingly productive. Mankind's manipulations of life forms (e.g., dogs, mules, fruit trees) or products from life forms (e.g., leather, silk, or milk) to ease efforts involved in survival and comfort are probably almost as old as mankind itself. The first selection of the largest beans by a grandmother for next year's crop and the keeping of a more docile wolf for a campfire animal were undoubtedly among the earliest steps that might be characterized as biotechnology. Medically related uses of life forms or their products are also quite old. Plants and their extracts, such as digitalis, have long been used to treat disease.

In 1795 Edward Jenner discovered that the administration of infective cowpox material (vaccinae) to individuals resulted in their developing a resistance to smallpox, then a major scourge. Although some cried that vaccination was "the work of the devil," vaccination became an accepted prophylactic measure after many prominent individuals, such as Thomas Jefferson, had their families vaccinated against smallpox. Today those still exist who believe that biotechnology is "the work of the devil," although their protestations are, at least arguably, more subtle.

The intentional alteration of life forms by techniques involving selection and/or interbreeding, as mentioned earlier, has been a long-accepted practice. It was later discovered that the diversity of characteristics in a species could be enhanced by accelerating the occurrence of random

mutations. This acceleration could, for example, involve treatment of organisms with mutagenic chemicals or ionizing radiation. Such random mutagenesis generally resulted in thousands of different mutations. At most, only a few of these random mutations generally proved to result in organisms having particularly desirable characteristics. When desired organisms were found, they could be appropriately cultivated so that sufficient numbers are available for use.

More modern discoveries and techniques have supplemented or replaced random mutagenesis in the obtaining of new organisms, particularly microorganisms, excelling for a special purpose. The techniques involved have been often awarded, particularly by the popular press, the name "genetic engineering." The insertion of a particular gene (e.g., for insulin) or deletion of gene (e.g., for the protein responsible for induction of ice crystal formation) has become almost routine with microorganisms. Although the analogous alteration of plants and animals is at a less developed stage, this is rapidly changing. Of course, genetic manipulations resulting in the creation of species with new characteristics is but one technological category of the biotechnology field. Like many rapidly developing fields, biotechnology includes a wide variety of established, improved, or newly discovered techniques. The present paper is concerned with a particular aspect of biotechnology, namely the protection of new organisms or newly isolated preexisting organisms as intellectual property.

Living organisms may be classified in numerous ways. For example, a common classification of cellular organisms (contrasted with viruses, which are noncellular) is into kingdoms:

Monera (procaryotes, i.e., unicellular without a distinct nucleus or other organelles, e.g., bacteria and blue-green algae);

Protista (eucaryotes, i.e., unicellular or multicellular with unspecialized cells having a distinct nucleus and usually other internal membrane encapsulated organelles, e.g., yeast, amoeba, fungi);

Plantae (multicellular with specialized eucaryotic cells, photosynthetic, (autotrophic) sexual, e.g., a green colored organism that doesn't run away from you); and

Animalia (multicellular with specialized eucaryotic cells, requires food, (heterotrophic) e.g., sponges, worms, mammals).

MICROORGANISMS

Certain living organisms have been generally termed "microorganisms." Such microorganisms are usually found to be of the *Monera* or *Protista* kingdoms, although, as will be seen subsequently herein, this is not always the case.

Microorganisms have long been intimately associated with patent law. For example, in 1873 Louis Pasteur obtained US patent number 141,072.

This patent had a claim that read "Yeast, free from organic germs of disease, as an article of manufacture." In the century prior to the *Chakrabarty* decision,* numerous US patents issued with claims for mixtures containing microorganisms such as yeast or bacteria or components thereof such as fungal spores (*see* e.g., US 524,824; 1,894,135; 1,980,083; 2,200,532; and 3,133,066).

Thus, microorganisms of both the *Monera* and *Protista* kingdoms have previously been considered patentable, at the very least as components of mixtures. The idea that living matter, in contrast to matter incapable of self-reproduction, may somehow be sacred, has led to the apparent belief by some that living intellectual property is sacrilegious. Although practitioners of civil religions should be respected, vague and demagogic proscriptions of intellectual property rights in living products of a newly burgeoning technology should be avoided. Such proscriptions would be likely to inhibit economic progress and prolong inefficiency in the production of food and treatment or prevention of disease. For example, if patents for synthetic polymers had been proscribed, would we have the wonderous variety of polymer-containing products available today?

In re Bergy; In re Chakrabarty (C.C.P.A.)

In the combined case of *In re Bergy; In re Chakrabarty,*** the Court of Customs and Patent Appeals (C.C.P.A) reversed 35 U.S.C. §101-based rejections by the Patent and Trademark Office of claims directed toward a newly isolated antibiotic-producing microorganism (*Bergy*) and a newly "engineered" pollutant-metabolizing microorganism (*Chakrabarty*). In this case, the decision of the C.C.P.A. was in agreement with arguments of the inventors. The court stated that there was:

> ...no *legally* significant difference between active chemicals which are classified as "dead" and organisms used for their *chemical* reactions which take place because they are "alive." Life is largely chemistry. *Id.* at 975. (Emphasis in original.)†

The Court's overall conclusion was that neither Bergy's "biologically pure culture" of a preexisting microorganism nor Chakrabarty's new microorganism was an unpatentable product of nature and that microorganisms of this type or in this form were included within the ambit of the manufactures or compositions of matter under 35 U.S.C. §101.

Chakrabarty

In *Chakrabarty,* a 5/4 majority of the Supreme Court affirmed the above referenced decision of the CCPA as regarding Chakrabarty. The Court put aside questions of life or nonlife when it stated that

*In re Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. 193 (1980).
**In re Bergy, 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979).
†Ibid., p. 373.

> . . . [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under §101.*

PTO Notice

This Supreme Court decision was followed shortly by a notice from the Patent and Trademark Office dated July 29, 1980** that

> . . . the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability . . . assuming that the products involved were the result of human intervention and were not products of nature . . . .

Despite the furor and protests raised by those essentially considering this the "work of the devil," numerous utility patents subsequently issued based on these decisions. For example, as of May 1987, 261 patents had issued containing the term approved by the CCPA of "biologically pure culture" in their claims (1 from 1975–1980, 34 in 1981, 44 in 1982, 43 in 1983, 50 in 1984, 34 in 1985, 34 in 1986, and 21 as of May 1, 1987). These exemplary patents primarily relate to members of the *Monera* kingdom, e.g., bacteria, although viruses and the *Protista* kingdom, e.g. fungi, are represented. Interestingly, US 4,652,522 (issued March 24, 1987) and entitled "Continuous Lymphocyte Cell Lines, their Production and Use" contains claims directed toward cell lines derived from naturally occurring mammalian cells. These cell lines, which may result from the insertion of DNA isolated from cancerous cells into human white blood cells, have the capacity for indefinitely prolonged growth in vitro (in glass). Although the subject cell lines would be classified as eucaryotic cells of *Animalia* kingdom members, their growth patterns are more like those of *Protista* members (nonspecialized, substantially identical). The incapability of these cell lines of more than *Protista*-like growth patterns apparently allowed their effective categorization as microorganisms. The fact that the individual cells of the cell lines were modified animal cells and that their DNA was that of a mammal such as a human did not preclude their patentability. Many patents have issued for antibody-producing cellular clones known as hybridomas. Hybridomas are hybrids of antibody-producing mammalian cells (usually splenic) and myeloma cells (neoplastic).

Post Chakrabarty Microorganism-Related Decisions

Certain inventions, such as the first isolation of a preexisting microorganism having a desirable characteristic (e.g., the ability to produce a new antibiotic) are likely to be protectable as US patents with claims limited

**In re Diamond v. Chakrabarty*, 447 US at 310; 206 USPQ at 197.
**997 OG 24, August 26, 1980.

to "biologically pure cultures" of the specific microorganisms discovered. This type of limitation to the specific microorganism currently appears required, regardless of the adequacy of screening and isolation methods described in the specification to enable others to obtain such microorganisms. According to the guidance of the Patent and Trademark Office Board of Appeals as expressed in *Ex parte Jackson,** the newly discovered microorganism, to be patentable, must be deposited in an established public repository for living organisms.

A result analogous to that of *Ex parte Jackson* was reached for a newly created ("genetically engineered") microorganism by the Board of Patent Appeals and Interferences in *Ex parte Forman.*** The *Jackson* and *Forman* cases both involved issues of enablement and undue experimentation under 35 U.S.C. §112 first paragraph, and related more to traditional chemical patent practice than to issues of "life." Prior to the decision by the Court of Appeals for the Federal Circuit in the case of *In re Lundak,* † such deposits, consistent with Budapest Treaty requirements, had to be made prior to the effective filing date of the application. The *Lundak* decision, in essence, permitted microorganism deposit in a public repository anytime before issue of a US patent claiming the microorganism to satisfy enablement requirements of 35 U.S.C. §112 first paragraph. If a deposit is *not* made upon filing, the effective priority date may be, however, jeopardized for international applications.

Summary—Microorganisms

Insofar as microorganisms are concerned, utility patent protection is available today for categories of claims such as:

1. Pure cultures of newly isolated preexisting organisms;
2. Specifically identified newly created modified organisms;
3. Processes involving the organisms of categories 1 and 2;
4. Compositions such as vaccines involving organisms of 1 and 2 as well as their components or products.

This listing is exemplary, and the ingenuity of science and claim draftsmanship has already resulted in numerous other species and subspecies of claims, some broader than those above.

Another type of protection for microorganisms as intellectual property may involve trade secrets. The retention of living trade secrets may pose more than the usual difficulties because of their ability to proliferate. Trade secrecy does not of course prevent others from "reverse engineering" or independently creating or finding the same or similar organism.

*Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).
**Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. 1986).
†In re Lundak, 773 F.2d 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985).

PLANTS

Members of the *Plantae* kingdom may be protected as intellectual property by several usable government-sponsored means. These means are: plant patents;* plant variety protection certificates;** and utility patents.†

Plant Patents

Plant patents are obtainable under the Plant Patent Act (PPA) of 1930. As of May, 1987, slightly more than 6,000 plant patents had been issued (more than 2,000,000 utility patents had issued since 1930). The PPA provides the exclusive right to asexually reproduce a subject plant. Plants patentable under the PPA must ostensibly be distinct and new; asexually reproduced (an actual reduction to practice, e.g., by grafting); not tuber propagated; and not found in an uncultivated state.

For a plant patent to be obtained, a deposit of the plant in a public repository is not required, nor is more than a reasonably complete description (35 U.S.C. §112 is not applicable). A plant patent is permitted but a single claim. For example, in US plant patent 5,997 (May 19, 1987) the claim reads:

> A new and distinct cultivar of Dracaena deremensis named "Skunky," as illustrated and described, and particularly characterized by its solid white center stripe extending through the leaf and being approximately the width of the green marginal stripes midway of the length of the leaf, its erect and compact growth habit, and its abundance of regularly spaced leaves which give the plant a bushy appearance.

The cultivar name, a frequently stated but not required item, here hopefully alludes to the white center stripe rather than a flower aroma.

While disclosure requirements are relaxed and publicly available deposits are not required under the PPA, neither a set of claims having a varied scope nor a generic claim is permitted. Asexual reproduction of the subject patented plant or selling or using the plant so produced is considered infringement. The patent is on an entire plant but the sale of plant parts may be prohibited, particularly if the patentee can establish specific derivation of an accused infringing plant from his own patented plant.

According to the Patent and Trademark Office Board of Appeals, a plant patent application may be a continuation of a utility patent application, particularly where the utility application involved a deposit of the subject organism (a microfungi, *Fusarium graminearum*) in a public repository.†† Potential double-patenting problems may have to be addressed with a terminal disclaimer expiring both patents at the same time.

*35 U.S.C. §161 et seq.
**7 U.S.C. §2401 et seq.
†35 U.S.C. §100 et seq.
††*Ex parte Solomons*, 201 U.S.P.Q. 42 (Bd. Pat. App. 1978).

Plant Variety Protection Act

Plant variety protection certificates are available under the Plant Variety Protection Act (PVPA) of 1970 (7 U.S.C. 2401). These certificates are for a term of 18 years and issued by the Secretary of Agriculture. The PVPA is directed to plants that are:

1. Sexually reproduced (i.e., by seeds);
2. Not fungi, bacteria, or first generation hybrids;
3. Distinct and new (as compared to prior publicly known analogous varieties);
4. Uniform (any variations are predictble and commercially acceptable);
5. Stable (on reproduction); and
6. On deposit (in form of their seeds) in a public repository.

About 4,000 plant variety protection certificates, each limited to a single specific plant variety, have been issued since the inception of the PVPA. Plant variety protection certificates are brief, require but one claim, and may involve compulsory licensing. The PVPA prohibits the unlicensed sale of seeds from a certified plant by a commercial distributor. A plant variety protection certificate does allow the retention of seeds from a crop by a first farmer for replanting or direct sale to a second farmer. Experimental use of certified plants for hybridization experiments and development of new plant varieties, for example, is permitted. Although the PVPA provides broader protection for subject plants than does the PPA, neither of these routes, although offering some advantages such as modest cost and simplicity of application, provide the scope of protection available with utility patents.

The PVPA, particularly as amended and supplemented by administrative rulings, was intended to be consistent with the provisions of the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV is adhered to by Denmark, France, Hungary, Ireland, Israel, Japan, the Netherlands, New Zealand, South Korea, Sweden, Switzerland, the United Kingdom, and the United States. The agreement is meant to encourage international protection for sexually reproduced plants analogous to that provided for utility patents by the Paris Convention.

Utility Patents For Plants

Post Chakrabarty Issues

According to the statutory interpretation of the Supreme Court in *Chakrabarty,* utility patents for plants could immediately have been deemed available under 35 U.S.C. §101 *et seq.* Any plant (or animal, for that matter) that was "a product of human ingenuity" should, in the author's opinion, clearly have been a potentially patentable manufacture or composition of

matter. A number of utility patents were, in fact, issued to plants such as sunflowers (4,378,655), rice (4,351,130), and wheat (4,406,086) soon after the *Chakrabarty* case was finally decided. The first two of these patents are drawn to hybrids not protectable under the PVPA, but the last is not.

The Patent Office had effectively adopted a policy that only plants that were not protectable under the PPA or PVPA were eligible for protection by a utility patent. Tuber-propagated asexually reproduced plants, sexually reproduced fungi, bacteria, and first generation (F1) hybrids were considered plants eligible for patent protection under 35 U.S.C. §101. Interestingly, neither fungi nor bacteria are plants.

Ex parte Hibberd

A subsequent decision affecting the patentable status of plants or segments thereof was that of the Patent and Trademark Office Board of Appeals and Interferences in *Ex parte Hibberd.** The *Hibberd* invention concerned maize that produced high levels of tryptophan, a dietarily essential amino acid frequently deficient in vegetable diets. At the time of appeal, the patent application included allowed claims directed toward hybrid seed and hybrid plants (not covered by the PPA or PVPA) as well as finally rejected claims directed toward maize seeds, maize plants and maize cells in tissue culture. The Examiner's basis for final rejection was that the subjects of these claims were protectable by the PPA (tissue culture cells) or PVPA (nonhybrid plants and seeds) and therefore, as intended by Congress, were excluded under 35 U.S.C. §101.

In the *Hibberd* decision, the Patent and Trademark Office Board of Appeals and Interferences reversed the Examiner's final rejections, noting that:

1. The Supreme Court had indicated that man-made life forms were patentable under 35 U.S.C. §101;
2. The legislative history of the PPA and PVPA expressed no intent to narrow the scope of protection available under 35 U.S.C. §101; and a motive to remove obstacles to protection of plants, namely, the "product of nature" doctrine and 35 U.S.C. §112;
3. A tissue culture of plant cells, in any case, was not a "plant" as described by the PPA.

This decision, although administrative and not binding on federal or state courts, settled the issue within the Patent and Trademark Office but did not address potential difficulties involving simultaneous protection under 35 U.S.C. §101 and the PPA or PVPA. A terminal disclaimer, analogous to the situation with utility and design patents, may be appropriate for non-identically claimed plants under the PPA and 35 U.S.C. §101, but possible solutions for conflicts between the PVPA and 35 U.S.C. §101 are more difficult to envision.

**Ex part Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. 1985)

PTO Notice on Plant Patentability

The *Hibberd* decision was followed shortly by a Patent and Trademark Office notice,* authored by Commissioner-Designate Quigg, stating that:

> ...the Patent and Trademark Office is now examining applications including claims to plant life—e.g., plants per se, seeds, plant parts. To the extent that the claimed subject matter is directed to a "non-naturally occurring manufacture or composition of matter—a product of human ingenuity"..., such claims will not be rejected under 35 U.S.C. 101 as being directed to unpatentable subject matter.

Subsequent to the *Hibberd* decision and the PTO notice which followed, a number of utility patents issued which contained claims directed toward plants or plant components such as cells or cell lines. These patents had a primary classification of class 47 (plant husbandry), subclass 58 (miscellaneous processes) amidst the general and mechanical patents in the Official Gazette of the Patent and Trademark Office. Some patents concerning related subject matter also appear in the chemical category as class 800 (multicellular living organisms and unmodified parts thereof), subclass 1 (products) and class 435 (chemistry and molecular biology), subclass 240 (undifferentiated animal or plant cells, e.g., cell lines, tissues; cultivation or maintenance thereof).

Recently Issued Plant Utility Patents

CORN Two utility patents listing Kenneth A. Hibberd as first inventor and being directed to plants issued subsequent to the above referenced decision and notice. The first Hibberd patent** claimed a *maize* seed having an endogenous free tryptophan content of 1/10 mg/g *dry* seed and able to germinate into a plant capable of producing similar seed. The second Hibberd patent† claimed a *monocotyledonous* seed having an endogenous free tryptophan content of 1/10 mg/g seed weight and able to germinate into a plant capable of producing similar seed. Thus, the breadth of the claims had expanded from maize seed having a specific free tryptophan content per dry gram in the first patent, to seed of a monocot (which includes virtually all grasses and cereal grains) having a specific free tryptophan content per g. All flowering plants are either monocots or dicots (a rule-of-thumb distinction being respectively parallel vs spreading leaf vein patterns). The broad scope of the latter Hibberd utility patent, covering practically any member of a great plant group having tryptophan-enriched seed, is particularly illustrative of the potential value of utility patents as compared to plant patents or plant variety protection certificates that protect but a single variety of a single species.

SUNFLOWER SEED Another US patent has issued as an apparent result of the *Hibberd* decision and relates to sunflowers.†† This patent contains

*1060 OG 4, November 5, 1985
*4,581,847—April 15, 1986.
†4,642,411—February 10, 1987.
††US patent 4,627,192 (US '192)—Dec. 9, 1986.

claims directed toward sunflower seeds having a certain high content of oleic acid. Oleic acid is an unsaturated fatty acid thought to be dietarily healthful for avoidance of problems such as arteriosclerosis. Arteriosclerosis is commonly attributed, at least in part, to excess dietary cholesterol and saturated fatty acids. A sunflower seed that is particularly rich in oleic acid and oil derived from such seeds appear to be clearly desirable from a producer's economic view and would also promote the status of public health. This US patent is limited to sunflowers (a particular dicot species), but the prior public acceptance of sunflowers as a food tends to increase the potential value of such a patent.

Perhaps the broadest claim of US '192 is directed to sunflower seeds that have fatty acids that are more than 80% oleic acid. Other more specific claims of this patent address various particular seeds or whole sunflower plants. The value and validity of this patent are dependent on many things common to patents in other fields. For example, one important query might involve the oleic acid content of sunflower seeds which were available from plants known to the world prior to the filing date of the application leading to US '192. If, for example, it were shown that the oleic acid content of such previously available sunflower seeds inherently fell within that described by the broad claim mentioned above, this will have a serious negative effect on the validity of said claim. Previously known sunflower seeds, even if they have the oleic acid related characteristics claimed in US '192, will be producible without infringement of this patent.

Other plants that have been recent subjects of issued utility patents include soybeans, sea kale, and chrysanthemums. It is predictable that plant science will produce an increasing number of utility patents directed toward whole plants, their segments, and components such as synthetically induced DNA fragments.

SUMMARY—PLANTS

Potential advantages of utility patent protection for plants as compared to that available under the PPA and PVPA should include: generic protection of new and valuable plant traits; protection of more than a single variety having valued properties; protection of plant parts; greater protection against experimental usage; availability of an established judicial history to help predict outcome of litigation; and the possibility of obtaining a collection of claims emphasizing both the breadth and crucial details of the invention.

Potential handicaps involving utility patent protection may involve: applicability of 35 U.S.C. §112, 35 U.S.C. §103 and attendant requirements which may involve, e.g., deposits of seeds and proofs of the nonobviousness of improved characteristics; likely greater costs of obtaining a utility patent; payment of patent maintenance fees; and prospects possibly involving double-patenting (utility and plant) objections if more

than one route of protection is chosen (conflicts between utility patents and plant variety protection certificates have not yet been settled).

Developmental efforts are currently underway to produce plants able to generate their own fertilizer and/or be resistant to insect pests. Such plants should be proper subjects of utility patents.

SUMMARY—ANIMALS

Background

Selective breeding has long been used to successfully develop animal lines having particular desirable characteristics such as those involving size (e.g., Great Danes, Chihuahua), strength (e.g., draft horses), product output (e.g., dairy cows), speed (e.g., race horses), beauty (e.g., cats), or edibility (e.g., turkeys). Species, such as donkeys and horses have been interbred to produce sterile hybrids such as mules. In more recent years, taking advantage of artificial insemination techniques, selective breeding has been speeded up by avoiding certain physical limits on the breeding process. This breeding by artificial insemination presently dominates much of current animal husbandry and results in efficient production of animal food products such as meat and milk. The transplantation of fertilized eggs into surrogate maternal animals is also being developed for commercial use to distribute and expand desired traits of female animals, much as the traits of male animals are passed on using sperm preservation and artificial insemination.

In re Merat

The Court of Customs and Patent Appeals (C.C.P.A.), in the 1975 case of *In re Merat,** addressed at least one aspect of the potential patentability of breeding-related animal husbandry. The subject invention concerned a method of using hens of a dwarf chicken strain (consuming dwarfish amounts of feed) to mate with normal sized cocks to produce eggs maturing as normal sized chickens. The cost savings in the production resulted from the lesser amounts of feed needed by the dwarf hens. The claims of the related patent application were directed toward the above method, using hens with an expressed generic sex-linked recessive dwarfish gene. The patent Examiner rejected the claims as drawn to nonstatutory subject matter under 35 U.S.C. §101. This rejection was affirmed by the Patent and Trademark Office Board of Appeals. The Board further added that if the breeding of animals (products of nature) were patentable so too would be the breeding of plants that would obviate the need for 35 U.S.C. §161, the Plant Patent Act. Additionally, the Board entered new rejections based on 35 U.S.C. §103 and §112, second paragraph. On appeal, the C.C.P.A.

**In re Merat*, 519, F.2d 1390 186 U.S.P.Q. 471 (C.C.P.A. 1975).

affirmed the rejections under 35 U.S.C. §103 and §112 second paragraph, while ignoring the issue under 35 U.S.C. §101.

Ex parte Allen

On April 3, 1987, the Patent and Trademark Office Board of Appeals and Interferences decided *Ex parte Allen.** The decision was the first to directly address the issue of animal patentability in view of the broad reading of 35 U.S.C. §101 by the US Supreme Court in *Chakrabarty.* The subject *Allen* invention concerned certain polyploid oysters (having multiple sets of identical chromosomes). Polyploid oysters apparently have superior characteristics, such as rapid growth and uniformly good food quality throughout the year (even in months without an "R").

During prosecution of the *Allen* application, the Examiner allowed claims for methods of inducing oyster polyploidy involving the application of high pressure to freshly fertilized eggs. However, citing *In re Merat,* the Examiner rejected, under 35 U.S.C. §103 and §101, claims directed toward polyploid oysters produced by the allowed methods. The Board of Appeals and Interferences, in view of the *Chakrabarty* decision, reversed the Examiner's 35 U.S.C. §101 rejections and stated that:

> The record before us leads to no conclusion other than that the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 U.S.C. 101.

The rejection by the Examiner, under 35 U.S.C. §103, of the claims toward polyploid oysters were, however, affirmed. Apparently others had previously produced polyploid oysters even though by a different method and of a different species. The principle was apparently reaffirmed that a product made by a particular process is not patentably distinguished if it is not a patentably distinct product.

PTO Notice

Shortly after the decision in *Ex parte Allen,* a related notice issued by the Commissioner of Patents and Trademarks.** This notice indicated that, to be considered patentable in accordance with existing law, products of nature must be given new qualities. It was further noted that a claim including a human being within its scope will not be considered patentable. The Commissioner finally stated that

> Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "non-naturally occurring manufacture or composition of matter—a product of

Ex parte Allen, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. 1987).
**April 7, 1987 (1077 OG 24).

human ingenuity'' (Diamond v. Chakrabarty), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.

Summary and Prospectus

In contrast to plants and other organisms already mentioned animals having improved characteristics artificially conferred upon them have no potential mode of protection as intellectual property except as found in utility patents under the *aegis* of 35 U.S.C. §101. Although the *Ex parte Allen* decision and the notice by the Patent and Trademark Office are both actions of an administrative agency having no binding effect on Article III courts, these actions are likely to have persuasive effects. Sicne the *Ex parte Allen* decision, more than fifteen patent applications have been filed in the US Patent and Trademark Office that include claimed animals.

Inventions previously patented under 35 U.S.C. §101 have included certain in vitro cultures of animal cells and particular hybrid animal cell lines. However, whole animals have now been deemed proper subjects of 35 U.S.C. §101 by the US Patent and Trademark Office. As a result of this decision, much outcry has been emitted by various individuals and groups. Certain valid concerns, such as the avoidance of needless animal pain, may be present, but some of the protestors appear to be solely concerned that nothing be done to an animal that could not also be done to a child. Other protestors appear to be concerned with issues involving the perennially threatened family farm or perhaps with publicity, public fright, and self-aggrandizement. Sentient beings such as the higher animals should not be made to undergo undue suffering, but the sentience of these animals should not endow them with the equivalent of constitutionally guaranteed rights. In the above usage, sentience is defined as being mere awareness or sensation that does not involve thought or perception. The opponents of patent protection for genetically modified animals are attempting to induce prohibitory action by Congress. In a House-Senate conference report, now signed into law,* an understanding is mentioned that the Patent and Trademark Office intended to grant no patents on technologically altered vertebrate or invertebrate animals during the remainder of fiscal year 1987.

The technology is now being developed to synthetically produce animals that have been modified to express desired characteristics. Among the many possible aims of this development could be, for example: disease-resistant animals such as chickens not requiring a diet containing antibiotics to remain healthy; swine, which have low levels of saturated fats; dairy cows producing useful amounts of pharmaceutical substances such as human insulin; livestock adapted to survive on limited resources and/or in hostile climatic conditions; and animals such as mice or rats modified to be susceptible to the AIDS-causing virus (to be used experimentally in

*25. P.L. 100-71, July 11, 1987.

the search for an AIDS cure). Further hearings are scheduled in the House of Representatives by the House subcommittee on Courts, Civil Liberties and the Administration of Justice. The question is not whether animals with improved characteristics will be created, but who will create them and who will most benefit. No other countries have yet, to the author's knowledge, established synthetically-produced animals as being proper subjects of their patents. The current US technical and scientific leadership in the field should be complemented with economic leadership and buttressed with patent protection. Japan, to compare one forward-looking country, has already initiated a national program to develop biotechnology in all its most recent aspects and may be expected to be involved in proprietary development of improved animals.

Regulation of new technology may be warranted, but the passage of laws inhibiting development of new industry is inadvisable. As the days of heavy industry are eclipsed by new technologies such as biotechnology, attitudes, laws, and regulations must be flexible enough to encourage change and progress or we will follow the path toward becoming a less developed country, rich in principles alone. The benefits of our patent system, designed to encourage innovation and new technology, should not be denied to a potentially major aspect of biotechnology, custom-made animal varieties.*

REFERENCES

1. *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. 1987).
2. *In re Bergy*, 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979), *vacated sub nom*, 444 US 1028 and *aff'd*, 447 US 303 (1980).
3. *In re Chakrabarty*, 571 F.2d 40, 197 U.S.P.Q. 72 (C.C.P.A.), *cert. dism'd sub nom*, 439 U.S. 801 (1978), *vacated*, 444 U.S. 1028 and *aff'd*, 447 U.S. 303 (1980).
4. *Diamond v. Chakrabarty*, 447 US 303, 206 U.S.P.Q. 193 (1980).
5. *Ex parte Forman*, 230 U.S.P.Q. 546 (Bd. Pat. App. 1986).
6. *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. 1985).
7. *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).
8. *In re Lundak*, 773 F.2d 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985).
9. *In re Merat*, 519 F.2d 1390, 186 U.S.P.Q. 471 (C.C.P.A. 1975).
10. *Ex parte Solomons*, 201 U.S.P.Q. 42 (Bd. Pat. App. 1978).

*On April 12, 1988, the first US patent directed to an animal issued. US patent number 4,736,866, inventors Philip Leder and Timothy A. Stewart, was assigned to the President and Fellows of Harvard College. This patent is entitled "Transgenic Non-Human Mammals," and claims any such mammal with a recombinant activated oncogene sequence introduced at an embryonic stage (of the mammal or its ancestor). The preferred transgenic mammal was a mouse sensitive to carcinogens.