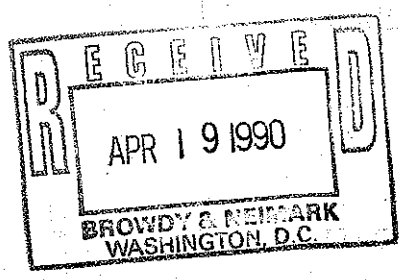
Biotechnology and the Law



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by Iver P. Cooper

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Preface

Economic studies of the patent system often stress the difference between the opportunity cost to the inventor and the opportunity cost to other developers in bringing an invention to the marketplace, and conceptualize the invention as a "public good." The patent system is seen as a means of evening the distribution of these costs.

"Biotechnology" inventions pose a unique problem because "any exchange of reproductive material between the developer and other independent parties creates the potential for multiplying the genotype to the detriment of the developer,"[1] particularly as it normally requires less expertise to multiply the genotype than to develop it. Thus, the lure of the shadowy world of trade secrets is very great, and only the developer with confidence in the patent system will resist it when trade secret protection is commercially feasible (as with fermentation processes).

According to Charles Lewis, formerly a Staff Scientist at the Department of Agriculture, it may take $500,000 and fifteen-to-twenty years from the first cross to the release of a new plant variety. Philip Hill, Research Director of the Keystone Seed Company, told Congress that a celery breeder invests at least twelve years of his life (in breeding to the F6 generation), as well as a great amount of money, in developing a new celery variety, before a return is realized. Calvin Lamborn of Gallatin Valley Seed Company lauded the PVPA, which gave his company the incentive to develop the "Sugar Snap" pea. The po-

[1] Ilona Melstrads, Property Rights for New Genotype Inventions, 3 (Ph.D. Thesis, May 6, 1979, George Washington Univ., Graduate School of Arts and Sciences).

tential had existed since 1885 (the "Butter Sugars" Pea) but lay fallow until the eve of the PVPA.[2]

H. B. Woodruff has observed that Rutger's Institute of Microbiology was financed in part by the returns from sales of Merck's patented antibiotics.[3] Clearly, the patent system can stimulate both basic and applied research in biotechnology.

Product patent protection of novel organisms may have a significant effect on the commercialization of biotechnology. It will allow the developer to safeguard his years of effort against (1) anyone who practices the patented process overseas and exports the product to the United States, without resorting to a chancy §337 action, and against (2) any member of the public who practices the process in the United States in secret, benefited by the *Argoudelis* ruling that allows him access to the patent strain without any notification of the depositor. The product patent would be easier to police (though not, of course, as easy to police as a patent on an end product).

To obtain patent protection, the invention must be adequately claimed and disclosed, within the time allowed by the statute.

It would be a mistake to assume that the protection of living organisms will not require some "customizing" of the patent system. The patent system indeed, has coped before with peculiar species of invention—"fingerprint" claims for complex chemicals and "flow charts" for sophisticated processes are two examples.

We have finally awakened to the potential of the gene. The incalculably valuable genetic heritage of so lowly a creature as the snail darter has been recognized. As the Supreme Court said in *TVA v. Hill:*[4]

> From the most narrow possible point of view, it is in the best

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[2] Hearings before the Subcommittee on Department Investigations, Oversight, and Research, Committee on Agriculture, on H.R. 999 (96th Cong., 1st and 2nd Sess.; July 19, 1979 and April 22, 1980; Ser. No. 96-CCC) at 206 (Lewis), 315 (Hill), 321-24 (Lamborn).

[3] H. B. Woodruff, Patenting of Microorganisms, in ASM Public Forum, Patentability of Microorganisms: Issues and Questions 7, 9 (1981; forum held July 25, 1980).

[4] 437 U.S. 153, 178 (1978).

> interest of mankind to minimize the losses of genetic variations. The reason is simple: they are potential resources. They are keys to puzzles which we cannot solve, and may provide answers to questions which we have not yet learned to ask.
>
> To take a homely, but apt, example: one of the critical chemicals in the regulation of ovulations in humans was found in a common plant. Once discovered, and analyzed, humans could duplicate it synthetically, but had it never existed—or had it been driven out of existence before we knew its potentialities—we would never have tried to synthesize it in the first place.
>
> Who knows, or can say, what potential cures for cancer or other scourges, present or future, may lie locked up in the structures of plants which may yet be undiscovered, much less analyzed? . . . Shear self-interest impels us to be cautious.

The patent system provides the vital incentive to find, preserve, examine, discuss, understand, and utilize novel forms of life.

The years ahead will reveal whether the genetic reserves of our planet are to be wasted or nurtured. It is my earnest hope that the patent system will be midwife to a more healthful era, the Age of Biotechnology.

Iver P. Cooper

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§ 1.01 "Biotechnology" and "Invention"

"Biotechnology" is a new word for an old idea, the idea of a technology based on the use of other living things. Man's growing understanding of the forces of evolution allowed him to harness those forces by breeding desirable attributes into his crops, livestock, and, eventually, fermentation cultures. The first breeding technique was probably the destruction of intractable beasts; later men learned to increase yields by mating the best producers. The elaboration of Mendelian genetics and the recognition of the role of mutation were the first steps away from empirical biotechnology. The development of gene "splicing," cell fusion, and nuclear transplantation techniques herald further great advances toward a sophisticated technology based on the machinery of life.

"Biological invention" is the intellectual work product of the industrial microbiologist, the plant breeder, and the animal husbandman. This treatise examines the protection of biological invention in all its forms: methods of cultivating, reproducing, and preserving organisms; methods of utilizing the organisms in industry, agriculture, medicine and other

"useful arts"; the metabolic byproducts of the organisms, and their uses; and the organisms themselves.

As a science, industrial microbiology is less than 100 years old; as an art, it dates back to antiquity. Today, microorganisms and their enzymes are the bases of industries grossing billions of dollars annually. Under microbial influence, molasses, corn steep liquor, and other raw materials are transformed into a wide variety of commercially important products: acids, alchohols, and solvents; amino acids, vitamins, growth factors, and hormones; food and beverages; and antibiotics.

This versatility is not, of course, attributable to any one microorganism. The world of industrial microbiology is a world of specialists, each the product of genetic diversity.

The biochemical specifications for a particular organism are expressed by the particular sequence of four different bases (nucleotides) appearing along the lengthy ribbon of its DNA (deoxyribonucleic acid) molecules. The DNA molecules consist of two interlocked and intertwined, spiral strands of these simpler chemicals. Before a cell divides, the double helix unwinds, and each strand attracts the components of a new partner strand from the chemicals floating free within the cell, creating two DNA molecules, one for each new cell. "Job orders" based on these "master plans" are coded into the chemical sequence of the related RNA (ribonucleic acid) molecule, which serves as an instruction to the protein-manufacturing unit of the cell, the ribosome. Because the number of possible base sequences on the DNA molecule is immense, life is genetically diverse.

In the case of organisms which reproduce asexually; new organisms are produced mainly as a result of errors in the replication process: mutations. Mutations are rare, easily hidden in the fecund jungles of microbial life. Scientists learned that they could isolate mutants with desired properties by subjecting a bacterial population into environmental conditions heavily favoring bacteria with the desired properties, and then culturing the survivors.

Later scientists discovered that they could increase the frequency of mutation, and hence the likelihood of discovering a novel microorganism, by subjecting the organisms to muta-

genic agents, such as gamma rays, X-rays, ultraviolet radiation or certain chemicals.

Mutation is not the only process by which new microorganisms arise. Occasionally, microorganisms may exchange genetic material, a process known as conjugation. Alternatively, a virus that infects bacteria (a bacteriophage) may carry genetic material from one bacterium to another, a process known as transduction. Viruses themselves are packages of genetic material, though they are inert outside a living host.

The chromosomes of a cell are extremely long filaments of DNA. Human chromosomes contain some 100,000 genes, each of which contains the instructions for making a particular protein. Even a bacterial cell may contain enough DNA for 2,000 to 3,000 genes. The average gene is 1,500 to 2,000 base pairs. The principal DNA base pairs are guanine (G), Cytosine (C), adenine (A) and thymine (T). In addition to chromosomes, certain cells contain small rings of DNA, plasmids, which are also able to replicate.

These plasmids can be manipulated by scientists. Plasmids carrying desired genes can be isolated, and mixed with bacterial cells whose cell walls have been made more porous by treatment with a calcium salt. The plasmids penetrate the cell walls, replicate within the transferee organism, and confer the desired properties. Chakrabarty, whose patent application led to the recent Supreme Court decision, transferred four specialized plasmids, obtained from different strains, to a host organism. The plasmids, activated by ultraviolet radiation, were able to replicate when the host divided, and a "super strain," able to digest each of four different kinds of hydrocarbons, came into being.

A more sophisticated form of genetic manipulation involves breaking open the plasmid rings with restriction endonucleases (a class of enzymes), splicing in foreign DNA using ligating enzymes, and transferring the modified plasmid to a host organism. In this technique, the plasmid acts as a carrier and replicating agent, while the foreign DNA confers the desired characteristics. Certain viruses may also be used as carriers, or vectors.

Another form of genetic manipulation is cell fusion. Cell fusion has been used to recombine plant DNA. The cell walls

are dissolved, and the naked protoplasts fused into a cell. The descendants of this cell bear characteristics of both original cells. While "pomatoes" have not yet been grown beyond the hundred-cell colony stage, full-blown tobacco plants have been developed from fused cells of different species of tobacco.

Cell fusion techniques have also been applied to animal cell cultures. In particular, they have been used to create "hybridomas." The hybridoma is a fusion product of antibody-secreting cells (lymphocytes) and "immortal" cells (myelomas) which is immortal and also capable of secreting antibody. Antibodies themselves are proteins with a particular configuration enabling them to bind to a particular binding site (epitope) on the surface of an antigen. When antibodies are produced by conventional immunization techniques, they are polyclonal in nature, *i.e.*, they are a melange of numerous, distinct immunoglobulin proteins, each recognizing a different epitope on the antigen. The antibodies produced by hybridoma cells are monoclonal in nature; that is homogeneous.

The plant breeder has an advantage over the industrial microbiologist in that the higher plants have evolved through a natural process of gene recombination, sexual reproduction, which lent itself to control by man. The plant breeder also has an advantage over the animal husbandman, in that desirable plants may be reproduced asexually, *i.e.*, without the alteration of traits through gene recombination. Asexual reproduction is not common in animals, but may now be achieved with the aid of man in certain species.

Some of the facets of biological invention will now be examined at greater length.

[1] Isolated and Mutated Microorganisms

Microbiologists study algae, fungi, bacteria, protozoa, and viruses, the simplest forms of life. "The ultimate sources of culture(s) of microorganisms for industry are soil; water; fresh, fermenting, and rotting vegetables; living plants and animals; sewage; fresh and spoiled food; (animal) droppings; and the

like."[1] A particular organism may be living only in a narrow ecological niche, *e.g.*, the beta carotene-producing *Blackestea trispora* is found only on certain tropical flowers. The immediate sources of cultures are therefore permanent culture collections maintained by industrial, university, and government laboratories.

Natural microbial sources are screened by a variety of techniques (some of which are patented) designed to detect and isolate microorganisms of interest. Microorganisms producing organic acids and amines, for example, can be detected by incorporating a pH-indicating dye into the nutrient medium. Antibiotic-producing colonies can be detected by crowding a plate with soil colonies and looking for colonies surrounded by

(*Text continued on page 1-5*)

[1] Hesseltine and Haynes, 24 Sources and Management of Microorganisms for the Development of a Fermentation Industry, in Thoma, Industrial Microbiology 23, 24 (1977).

a vacant ring. Alternatively, a suspension of a test organism may be applied to a sample plate, and the plate inspected for zones of inhibition of test organism growth.[2]

Organisms of interest are then isolated, and their growth requirements, genetic stability, taxonomic classification, pathogenicity, and productivity are determined. A number of terms frequently encountered in descriptions of the growth requirements of organisms are given below.[3]

Aerobe utilizes oxygen

Anaerobe grows in absence of oxygen

Chemoautotroph carbon source is carbon dioxide; energy source is chemical

Chemoheterotroph carbon source is organic; energy source is chemical

Photoautotroph carbon source is carbon dioxide; energy source is light

Photoheterotroph carbon source is organic; energy source is light

Psychrophile grows at low temperatures

Psychotroph facultative psychrophile

Thermophile grows at high temperatures

Mesophile grows at intermediate temperatures

Facultative (adj) factor merely favors growth

Obligate (adj) factor is required for growth

The *genotype* of an organism is the organism's collection of genes. Its *phenotype* are the characteristics of the organism, controlled by its genes, which are observable. The genetic apparatus of an organism includes control mechanisms for determining, in response to its environmental needs, which genes are *expressed* (affect its structure or behavior) at a given moment. A *mutation* is an undirected change in the DNA of

[2] Casida, *Industrial Microbiology*, Chapter 4 (1968).

[3] Glossaries in Brock, *Biology of Microorganisms* (3rd ed. 1979); Pelczar, Reid & Chan, *Microbiology* (4th ed. 1977).

a gene, and may be classified as a point mutation, a deletion, or an insertion. Deletions and insertions cause shifts in the "reading frame" of the genetic code and therefore interfere with the translation of the gene until the shift is corrected.[4] In *Serratia marcescens,* the mutation causing pigmentation loss occurs in one cell out of ten thousand, per generation.[5]

The mutagenic action of X-rays was discovered in 1927. Chemical mutagens—base analogs like 5-Bromouracil; chemicals reacting with DNA-like nitrous acid, hydroxylamine, and nitrogen mustards; and intercalative dyes like the acridines—were soon discovered.[6] These mutagens caused specific types of mutation (*e.g.,* hydroxylamine converts a G-C pair to an A-T pair). A number of mutagenic techniques are patented. Typically, mutagens are employed at levels killing 90 to 99 percent of the population.

Interesting mutant strains are then selected on the basis of differentiable phenotypic characteristics. The mutant cells may be exposed, for example, to adverse conditions, such as antibiotics, and resistant cells selected. To select mutants which are particularly *sensitive* to adverse conditions, a technique called *replica plating* is used.[7] In this technique, the replica plate is pressed face-to-face against the original plate so that both will bear colonies of the same organisms in the same locations. The original plate is then subjected to the adverse condition. Sensitive organisms may be found in colonies on the replica plate whose parent colonies on the sample plate have failed.

Auxotrophic mutants are those which have lost the ability to synthesize a particular metabolite needed for growth. (The parent cells are referred to as *prototrophs*.) *"Leaky" mutants* are those which have only partially lost the growth characteristics of their parent cells.

A large number of processes employing both microorganisms isolated from nature, and mutated microorganisms, have been patented.

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[4] T. D. Brock, *Biology of Microorganisms,* Chapter 11 (3rd ed. 1979).

[5] D. M. Carlberg, Essentials of Bacterial and Viral Genetics 119 (1976).

[6] Brock, *supra,* note 3 at 360.

[7] Casida, *Industrial Microbiology* 148 (1968).

Desired metabolites may be of primary or of secondary importance in the life of a "wild" cell. Secondary metabolites, such as penicillin, are typically produced during the idiophase (post-growth phase), while primary metabolites such as lysine are produced during the trophase (growth phase).

"Wild" strains of microorganisms are not well suited for industrial use. Nature selects for strains which make efficient use of limited resources in competition with other organisms. They have evolved mechanisms which regulate the cell's metabolic processes to prevent over-production of metabolites. The industrial microbiologist, however, desires a wasteful strain which will overproduce when given the most favorable conditions for growth.[8] He screens organisms for those having the least efficient regulatory mechanisms. He then seeks a mutant strain in which production of the desired metabolite is not regulated.

Industrial strains, according to C. W. Hesseltine and W. C. Haynes, should have these attributes:

1. The strain must be genetically stable. A culture that constantly and spontaneously produces one or more different forms is undesirable.
2. The strain must readily produce many vegetative cells, spores, or other reproductive units. Since Basidiomycetes produce only mycelium they are rarely, if ever, used in industrial fermentation.
3. The strain should grow vigorously and rapidly after inoculation into seed tanks or other containers used to prepare large amounts of inoculum before an industrial fermentation.
4. The strain should be a pure culture, not only free of other microscopically visible micro-organisms, but also free of phages.
5. The strain should produce the required product within a short period of time, preferably in three days or less.

[8] A. L. Demain, Cellular and Environmental Factors Affecting the Synthesis and Excretion of Metabolites, 22 J. Appl. Chem. Biotechnol. 345 (1972).

6. The strain should produce the desired product to the exclusion of all toxic substances. The desired product should be easily separated from all others.
7. The strain should be able to protect itself against contamination, if possible. Self-protection might take the form of lowering the pH, growing at high temperature, or rapidly elaborating a desirable microbial inhibitor.
8. The strain should be readily maintained for reasonably long periods of time.
9. The strain should be amenable to change by certain mutagens or group of mutagenetic agents. A mutation program may be conducted with the object of developing strains that give enhanced yields of the product.
10. The strain must give a predictable amount of desired product in a given fermentation time.[9]

In a fascinating article,[10] M. P. Backus and J. F. Stauffer studied the genealogy of the "Wisconsin Family" of strains of *Penicillium chrysogenum*, whose patriarchal strain was Wis. Q176, released in late 1945, and much used as breeding stock during the postwar period.

The average yield of penicillin, after seven days, from Q176 was 640 O.U./ml; from strain 53-399 it was 2658 O.U./ml. Strain 53-399 also represented an improvement on its high-producing great grandparent strain, 51-20; the sporulation rating of 53-399 was 3.1 while the rating for 51-20 was only 1.5. In their review, Backus and Stauffer declare, "there is no one method of securing variants which is overwhelmingly superior. . . . [E]ach of the various techniques . . . made significant contributions to the building up of the stock."

[2] Genetically Engineered Organisms

Genetic engineering is the use of *cloning vehicles* or *vectors*

[9] *Supra* note 1.

[10] Backus and Stauffer, The Production and Selection of a Family of Strains in Penicillium Chrysogenum, 47 (4) Mycologia 429-63 (1955). *See also* Thoma, Use of Mutagens in the Improvement of Production Strains of Microorganisms, 16 Folio Microbiol. 197 (1971).

to introduce foreign DNA into host cells under circumstances guaranteeing that the host cells will cause that foreign DNA to replicate, and that the genes carried by the foreign DNA will be able to express themselves. The "genetically engineered organisms" may be identified by virtue of their new phenotypic characteristics attributable to the composite plasmid.

A *virus* is a genetic element which is metabolically and reproductively inert outside a host cell. A *phage* is a virus that infects bacteria. *Virulent phage* will eventually kill their host. *Temperate phage* do not necessarily bite the hand that feeds them, and their genetic material may become integrated into the host genome. The temperature virus is said to exist in a *prophage* state and the host is said to be *lysogenic.* Temperate phage may be used as a cloning vehicle for the introduction of a desired gene into a host organism.[11] (The comparable natural process is called *transduction.*)

Another possible cloning vehicle is a *plasmid,* a small, circular extrachromosomal genetic component, frequently carrying genes controlling the production of toxins, resistance to antibiotics, and the ability to metabolize unusual substrates. (An *episome* is a genetic element which can replicate either within or without a chromosome.[12])

A *conjugative* plasmid can mobilize the transfer of DNA by conjugation; a *nonconjugative* plasmid cannot. This distinction was of significance in the Chakrabarty patent, U.S. Patent No. 4,259,444.

A *hybrid plasmid* is one which contains DNA from organisms that can ordinarily exchange genetic information. A *plasmid chimera* is a recombinant plasmid whose DNA was derived from organisms that ordinarily do not exchange genetic information. (The general term is *composite plasmid.*) This distinction was of significance in the Cohen and Boyer patents, U.S. Patent Nos. 4,237,224 and 4,459,468.

The *plasmid copy number* is the number of a specific plasmid molecules to be found in a single host cell.

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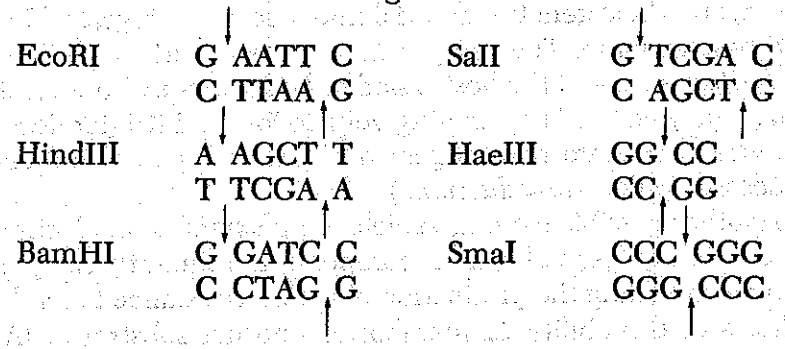
[11] Brock, *Biology of Microorganisms,* Chapter 10 (3d ed. 1979).

[12] Much of the terminology used herein is based on Novick, et al., Uniform Nomenclature for Bacterial Plasmids: a Proposal, 40 Bacteriol. Rev. 168 (1976).

In order to use a plasmid as a cloning vehicle, the plasmid ring must be cleaved with a restriction enzyme.

Restriction enzymes are believed to be a part of their host cell's defenses against incoming foreign DNA. Several of these enzymes, which have the ability to cleave the DNA molecule, have site-specific recognition sites and cleavage patterns, and therefore can be used in the construction of composite plasmids. Examples are given in figure 1:[13]

Fig. 1.



The ends of the resulting fragments are referred to as "sticky" ("covalent") (*e.g.*, EcoRI) or "blunt" (*e.g.*, SmaI).

The opened plasmid DNA is mixed with foreign DNA fragments bearing the desired gene and possessing complementary ends in the presence of another enzyme, DNA ligase. A host organism is transformed by inserting the composite plasmid therein. When the cell replicates, so does the plasmid, thus providing additional copies of the gene.

In order to facilitate the insertion of a foreign DNA sequence, the ends of the foreign DNA may be modified by covalently attaching small molecules of synthetic DNA of desired sequence called "adapters," or a restriction site in the plasmid may itself be altered by insertion of a linker molecule bearing a different type of restriction site.

Phages may be utilized in a somewhat similar manner.

Plasmids have been classified into *compatibility groups.*

[13] Atherton, Et al. Genetic Manipulation for Industrial Processes in Microbial Technology: Current State, Future Prospects, 379, 386 (1979); Kornberg, DNA Replication 337 (1980).

Two incompatible plasmids normally cannot both be stably inherited. Chakrabarty's patent was concerned with overcoming a compatibility problem between plasmids found naturally (though not simultaneously) in their host, rather than with recombining plasmid genetic material with foreign DNA.

DNA has two major functions in the life of a cell: expression, and replication. "Expression" is the general process by which proteins, coded for by particular DNA sequences called structural genes, are constructed when needed. The actual RNA and protein synthesis is called "transcription." "Replication" is the process by which copies of the DNA sequence are transferred to daughter cells.

The cell naturally needs mechanisms to turn on and off the structural genes, as its needs for various proteins fluctuate. One mode of regulation, in which synthesis is turned on by an "inducer" molecule, involves a repressor sequence (which codes for the synthesis of a repressor protein), a promotor sequence, an attachment site for RNA transcriptase (*i.e.*, a "title page"), and an operator sequence (where the repressor protein normally binds, halting transcription), all upstream from the structural gene. The structural gene then codes for an "inducible enzyme," *i.e.*, one produced only in the presence of an inducer molecule, which inactivates the repressor protein.

The control mechanism for a "repressible enzyme" (*i.e.*, one normally produced by the cell) differs from the above in that the repressor protein is normally synthesized in an inactive form. However, one of the end products of the reaction catalyzed by this enzyme can activate the repressor protein so that it will bind to the operator site and shut off the production of the enzyme.

Both regulatory and structural genes may be taken from one organism and placed into the genome of another. Research is also aimed at modifying these genes to alter beneficially the metabolic activity of the cell.

"Expression vectors" are those vectors which are actually to be used to express the desired product in the desired host. They contain the appropriate structural gene, in its entirety, in proper orientation and position to a suitable promoter region. They also contain the genetic instructions for the replica-

tion of the plasmid in the desired host, the "replicon." "Transfer vectors" are the intermediate constructions holding bits and pieces of the desired structural or regulatory sequences. They may be replicated in organisms other than the host desired for the ultimate expression vector. Vectors capable of replication in more than one host are termed "shuttle vectors."

The desired structural DNA may be obtained by several means. First, it may be obtained directly from the genome of a cell. The genomic DNA of a eukaryotic cell may contain, interspersed within a gene of interest, so-called "introns" ("intervening sequences") which are not expressed by the cell. Second, it may be obtained by reverse transcription from mRNA, using the enzyme "reverse transciptase" ("RNA-directed DNA polymerase"). For this approach to be effective, the appropriate mRNA must be isolated from the cell. This is fine if the desired protein is expressed in great quantities by a particular cell, but often the protein of interest is one that is expressed at low levels. Under such circumstances, various enrichment techniques are employed. For example, if a part of the DNA sequence of the desired protein is known, or has been deduced, a complementary probe can be synthesized and used to snare the desired cDNA (complementary DNA) transcripts obtained by reverse transcription. Perseverance also plays a role; one can clone the different DNA fragment into a few hundred different cells and continue experimentation with those expressing the desired protein.

Getting foreign DNA into cells is not without its difficulties. The cell may have its own battery of restriction enzymes with which it can assault the foreign DNA. Large vectors, absent conditions favoring the survival of cells which retain them, tend to be segregated out when the cell replicates.

Finally, one may synthesize the desired DNA sequence. This of course requires knowledge of the sequence, as well as the time and money to invest in the synthesis procedure. Automation techniques have made feasible the total synthesis of several small proteins of biological interest.

Molecular biologists speak of DNA being "transcribed" into RNA and "translated" into protein. In eukaryotic cells, the DNA is first transcribed into hnRNA (heteronuclear RNA).

Such cells then splice out the regions which correspond to "introns," yielding mRNA (messenger RNA). It is the mRNA which in fact is translated into protein.

Prokaryotic cells are unable to perform this splicing operation. Thus, if a genomic copy of a gene is cloned (inserted) into a prokaryotic cell vector, the organism will "mistakenly" transcribe and translate the introns as well as the desired coding sequences, and the resulting protein will differ from the desired protein.

[3] Vaccines

In 1864, Louis Pasteur (1822-1895) conclusively disproved the theory of spontaneous generation of life, and thereby won acceptance of the germ theory of disease. Later, he proved that a specific bacterium was the cause of anthrax in cattle. In 1880, he developed the principle of immunization by inoculating chickens with an eight-week old culture of chicken cholera bacteria. Upon subsequent exposure to a fresh culture, the inoculated chickens did not succumb. Pasteur realized that the bacteria of the older culture had lost their ability to produce disease but still stimulated their host to produce protective substance, *antibodies.* (Any substance inducing antibody formation is called an *antigen,* and blood serum containing antibodies is called *antiserum.*) The stale, or *attenuated,* cultures were called vaccines, from the Latin *vacca,* cow. (The first vaccination was Jenner's use of the cowpox virus in 1798 to prevent smallpox.) Pasteur later used the principle of immunization to save Joseph Meister from the then invariably fatal rabies. *Killed vaccines* are also used for immunization, *e.g.,* "triple typhoid vaccine."

Toxins are the poisons produced by an organism. Kitasato and von Behring injected bacterial toxins into animals so that *antitoxins,* antibodies neutralizing the toxins, would develop. *Toxoids* are made by destroying the poisonous portions of toxins without altering the antigenic portion.

In addition to antitoxins, antibodies include agglutinins, precipitins, lysins, complement fixing antibodies, opsonins, and neutralizing antibodies.

The immunologist's arsenal may be supplemented by *interferon,* a broad-spectrum antiviral agent, and doubtless by other products as well.

Both bacterial and viral vaccines have been patented.

[4] Cell, Tissue, and Organ Cultures

Microbial cells are not the only cells with utility in industry. Cultures of cells of higher organisms are used in the manufacture of virus vaccines, in the screening of drugs for parasitological and toxicological effects, in cancer and physiological research, and in the manufacture of chemical substances. Similar uses have been made of tissue and organ cultures, which additionally may have utility as tissue grafts and organ transplants.

Cells of higher organisms differentiate during development,

(*Text continued on page 1-13*)

yielding specialized muscle, nerve, and skin cells. Cells of a particular morphological and functional type tend to aggregate into a definite structure known as a tissue, and tissues in turn are organized into organs.

[5] Hybrid Cell Cultures

Plant breeders are experimenting with techniques of fusing protoplasts of different plant species to form a single hybrid cell.[14] (Protoplasts are plant cells stripped of their cell walls.) Fusion is initiated by a polyethylene glycol (PEG) solution. The hybrid cell can be induced to regenerate its cell wall and proliferate, and, by subculturing, the breeders can eventually obtain a mature plant whose cells contain a combination of genetic material from both botanical sources. Genetic information is thus exchanged despite the existence of barriers to natural breeding.

Dr. David Evans noted in a 1981 lecture that the following intergeneric cell fusion products had been found to be viable:

Glycine max (soybean) × Nicotiana glauca (wild tobacco)

Glycine max (soybean) × Zea mays (corn)

Glycine max (soybean) × Hordeum vulgare (barley)

Vicia faba (broad bean) × Petunia hybrida (petunia)

Nicotiana tabacum (tobacco) × Lypopersicon esculentum (tomato)

Nicotiana tobacum (tobacco) × Solanum chacoense (potato)

Sorghum bicolor (sorghum) × Zea mays (corn)

Another area of interest is the "hybridoma," a fusion product of cancerous and antibody-producing cells. Hybridoma cells manufacture highly specific "monoclonal antibo-

[14] *See generally* D. Mysiewicz, Hybridoma and Cell Fusion Technology: Realities and Possibilities, 1 Bioengineering News (No. 2, 1980); Bishop, Armed Antibodies, 197 Wall Street Journal (No. 107, 1981); D.A. Evans, Protoplast Fusion (Energy, Bureau, June 25, 1981).

dies," but have the growth characteristics of tumor cells. Hybridoma cells are made by exposing spleen cells to an antigen, mixing the spleen's lymphocytes with cancer cells, adding a fusion initiator, and killing off the undesired cells. These cells are tested for antibody activity, and mass cultured either *in vivo* (by injection into an animal) or *in vitro* (as a suspension culture in a fermenter).

Because of the specificity of each monoclonal antibody, patent protection of these antibodies may be easily "circumin-vented." Dr. Richard Farishian notes that "for every antigen there might be as many as 1,000 antibodies." Patent protection of hybrid cell cultures is now being sought by a number of institutions. Trade secret protection, however, is likely to be important.

§ 1.02 Trade Secrets, Patents, and the Genetic Engineering Industry

Recombinant DNA research is the subject of intense public debate. Some fear the escape of new pathogens; others, the application of its techniques to our own species. Like the fire which Prometheus brought to earth to benefit mankind, recombinant DNA research may have its dangers, though it now appears that those dangers have been grossly overstated. In any event, patent attorneys are concerned entirely with its beneficial aspects, *e.g.*, the conversion of a bacterium into a metabolic factory for human insulin.

At the universities, recombinant-DNA researchers were troubled by the stiffness of the National Institutes of Health (NIH) safety guidelines. Pharmaceutical and chemical firms, however, who believed that they could operate under the guidelines, were primarily concerned with the absence of adequate patent protection for recombinant-DNA organisms.[15]

[15] *See* comments of Dr. W. N. Hubbard, Jr. (Upjohn), National Institute of Health, Recombinant DNA Research (Department of Health, Education, and Welfare; Publication Numbers 76-1138, 78-1139, -1843, -1844, 79-1875, -1876, 80-2130) [hereinafter cited as DNA Research], at 66; Dr. Harry Green (Smith, Kline & French Laboratories), id. at 87; Dr. R.J. Erickson (Miles Laboratories), id. at 87; C.J. Stetler (Pharmaceuticals Mfrs. Ass'n), id. at 106;

Without a proprietary position, such as a patent right, few industrial firms will be keen on spending millions of dollars for research.[16]

In recent years, the microbiological industry has clearly indicated a need for a firm assurance of patent protection. In 1968, one microbiologist stated:

> Government regulation in the form of patent grants is a boon to the industrial fermentation industries. The cost of research is so great that the gamble is considered worthwhile only if it is known that strong patent protection for the product or process can be obtained. Thus, the future statement and workings of our patent laws will have a profound effect on industrial microbiology. . . . Although not presently included in the protection provided by patent grants, it is likely that courts in the United States and in other countries will deem it necessary to provide greater protection than is presently available for . . . microbial cultures, . . . since these are vital factors in the ability of a fermentation process or product to maintain a competitive position in the market.[17]

A 1975 article on pesticides, in referring to "biological controls," noted that "the biggest industry problem seems to be

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Dr. R.V. Johnston (Dow Chemical U.S.A.), id. at 120; C.H. Herr (DuPont), id. at 131.

[16] The estimated average cost of successfully developing a new drug has risen from $534,000 in 1962 to $11.5 million in 1973 ($24 million if the cost of unsuccessful research is included). D. Schwartzman, *Innovation in the Pharmaceutical Industry* 65-70 (1976). The return on research and development (R&D) investment has fallen sharply from 12 percent in 1960 to as low as 3.3 percent today. Id. at 160. Costs to second entrants, however, are only a small percentage of the original developer's costs. Hearings before H.R. Subcomm. on Science, Research and Technology, 95th Cong. 2d Sess. 965 (1977)(Statement of Norman J. Latker, HEW Patent Counsel). According to Schwartzman, "without patents the return from investment in pharmaceutical R&D would fall to zero, and private companies would no longer engage in R&D." D. Schwartzman, *supra*, at 70.

[17] L.E. Casida, Industrial Microbiology 421-22 (1968). While microbiological processes have long been considered patentable, process patent protection has never been very satisfactory to industry. *See* comments of Dr. Richard Donovick (American Type Culture Collection), 2 DNA Research, *supra* note 15, at 75; Dr. R.V. Johnston (Dow Chemical U.S.A.), id. at 120.

the lack of patent protection for bacteria and viruses."[18]

In the absence of effective patent protection, the industry will turn to "trade secret" protection. A "trade secret" is a species of information which, if kept secret, provides a competitive advantage to its possessor. If he confides it to another, his confidant has a legal duty to respect his confidence, and use it only with his consent. This "trade secret" exists only so long as it remains secret, and is not infringed by another who independently discovers and uses it.[19] Contrast this with the patent right, which lasts for a certain and limited time, but is enforceable against all others including independent discoverers.

The value of a "trade secret" thus depends in part on the ease with which it may be kept secret. A simple mechanical design, incorporated into a product, will not remain secret for long, as a competitor can buy a sample and "reverse-engineer" it. It is more difficult to determine the nature of the process by which an article of manufacture came into being. Thus, Staeffer Chemical's process for concentrating sulfuric acid and General Electric's technique for the manufacture of artificial diamonds were successfully shrouded in secrecy.[20] According to L.E. Casida, Jr., the Pfizer Company had a secret process for the commercial production of citric acid by Asperillus niger which had remained secret "for many years in excess of the seventeen-year monopoly of the patent."[21]

Currently, the "trade secret" mentality is taking hold in the newest branch of the fermentation industry. Stanford biochemist Paul Berg warns, "[n]o longer do you have this free flow of ideas. You go to scientific meetings and people whisper to each other about their company's products. It's like a secret society."[22] NIH Director Frederickson, summarizing industry comments, warned Congress that "lack of patents [on recom-

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[18] Seltzer, Zoecon Developes New Insect Control Agents, Chem & Eng'r News, Oct. 6, 1975, at 19, 20. *See also* N.Y. Times, May 16, 1979, at A26, col. 4 (letter of R. P. Mahoney).

[19] *See generally* E. W. Kintner & J. L. Lahr, *An Intellectual Property Law Primer*, New York: Clark Boardman Co., Ltd., 1982.

[20] A. A. Meissner (Professor, Dep't of Chem. Eng'r, Massachusetts Institute of Technology) (Jan. 10, 1974) (private communication).

[21] L.E. Casida, *supra* note 17, at 191-92, 194-96.

[22] Begley, The DNA Industry, Newsweek, August 20, 1979, at 53.

binant-DNA inventions] would discourage the free flow of information because industry would seek to protect innovations through trade secrets."[23] Recently an industry representative told *Business Week*, "[y]ou keep your proprietary strains under lock and key."[24]

The American Society of Microbiology (ASM) has emphasized that a written description of a novel microorganism in a patent specification is of little aid to other scientists if that microorganism is not available through a public depository.[25] The ASM told the Supreme Court:

> The availability of a subculture is especially important for scientific research, because actual strains are needed for experiments. Yet, it is unlikely that commercial firms will deposit newly discovered microorganism cultures in a recognized depository if adequate patent protection is unavailable. The absence of patenting, therefore, would preclude acquisition of strains by researchers and would inhibit the exchange of information that is vital to research.[26]

As President Carter's Advisory Committee on Industrial Innovation pointed out, "life form" patents would stimulate invest-

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[23] D.S. Frederickson, *The Patenting Of Recombinant DNA Inventions Developed Under DHEW Support* 17 (1977).

[24] Where Genetic Engineering Will Change Industry, Bus. Week, Oct. 22, 1979, at 172.

[25] Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980); Feldman v. Aunstrup, 517 F.2d 1351 (C.C.P.A. 1975), cert. denied, 424 U.S. 912 (1975).

[26] ASM Amicus Brief, *supra* note 25. The brief continues: As an example of the operation of the deposit system, cultures of the United States Department of Agriculture Northern Regional Laboratories. If the patent application is upheld, any researcher will be entitled to subculture for use for experimental purposes. Thus, this case presents an illustration of the benefits likely to flow to genetic research from patenting. Id. at 11. "Use" which is solely "experimental" in character is not infringement. *See* Whittenmore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1913) (Story, J.); Chesterfield v. United States, 159 F. Supp. 371, 375-76 (Ct. Cl. 1958); Ruth v. Sterns-Roger Mfg. Co., 13 F. Supp. 697, 713 (D. Colo. 1935), rev'd on other grounds 87 F. 2d 35 (10th Cir. 1936); Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305, 333 (D. W. Va. 1937). *But see* Douglas v. United States, 181 U.S.P.Q. 170, 176-77 (Ct. Cl. 1974); Pitcairn v. United States, 188 U.S.P.Q. 35, 47 (Ct. Cl. 1975).

ment in innovation: "Unhindered by the threat of piracy, there will be stronger incentives to invest money in new and useful technology. . . ."[27]

There exists two avenues by which microbial cultures could conceivably gain patent protection. Under 35 U.S.C. § 101, "[w]hoever invents or discovers any new or useful process, machine, manufacture or composition of matter . . ." may obtain a "utility" patent therefor provided that the patent application, in the words of 35 U.S.C. § 112, describes the "invention . . . [and] the manner and process of making and using it . . . [in] full, clear, concise, and exact terms."

Under 35 U.S.C. § 161, "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, . . . other than . . . a plant found in an uncultivated state," may obtain a "plant" patent therefor, if the "description" required by 35 U.S.C. §112 is "as complete as is reasonably possible."

In 1940, *In re Arzberger*[28] seemingly frustrated the prospects for plant patent protection of microorganisms.[29] The economic desirability of patent protection for microorganisms and the new technology's expansion of the microbiologist's creative resources made the exploration of the utility patent avenue inevitable.

§ 1.03 Fundamental Patent Law Concepts

Pursuant to the United States Constitution, the patent laws were enacted by Congress "to Promote the Progress of . . . Useful Arts, by Securing for Limited Times to . . . Inventors the Exclusive Right to their . . . Discoveries." The present utility patent act was enacted in 1952.

Utility patents on biotechnology may be classified as

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[27] Industrial Advisory Subcomm. Report on Patent Policy in Advisory Committee on Industrial Innovation Final Report 145, 159 (1979).

[28] 112 F.2d 834 (C.C.P.A. 1940).

[29] Id. *But see* Ex parte Solomons, 201 U.S.P.Q. 42 (Pat. Off. Bd. App. 1978) (plant patent issued on a microfungus). *See also* Cooper, Arzberger Under the Microscope, 7 Rutgers J. Computers, Tech. & L. 367 (1980); Daus, Bond, & Rose, Microbiological Plant Patents, 10 IDEA 87 (1966); Irons & Sears, Patents in Relation to Microbiology, 29 Ann. Rev. Microbiology 319 (1975).

product patents, process patents, and use patents. Product patents cover nutrient media, organisms, cultures, compositions containing organisms (such as vaccines and biorational insecticides), plasmids, and metabolites (such as antibiotics). Process patents cover fermentation methods, methods of cultivating or altering organisms, and syntheses utilizing enzymes. Use patents cover new methods of using previously known compounds (such as the use of antibiotic *X*, previously known to be effective against organism A, against organism B).

In order to enjoy the benefit of a utility patent, the right to exclude others from making, using or selling the invention for a period of seventeen years from the date of grant, a number of conditions must be satisfied:

Statutory Subject Matter. The Supreme Court has held that a "living organism" under appropriate circumstances, may be considered a patentable "composition of matter" or "article of manufacture" (35 U.S.C. § 101; *see* discussion in Chapter 2). It did not overrule existing case law regarding the patentability of "products of nature" (*see* discussion in Chapter 3). 35 U.S.C. § 101 has not been used to reject claims to fermentation processes.

Originality. A patent will be issued only to the true inventor or inventors, as provided for in 35 U.S.C. §§ 102(f), 111, 115-118, and 256. Determining "inventorship" is not always easy in a modern research environment, wherein many individuals may play a role in obtaining, isolating, identifying, mutating or testing organisms for their fermentation abilities. Several "inventorship" questions are explored in § 4.01.

Novelty. While 35 U.S.C. § 111 requires that the applicant declare himself to be the "first inventor" of the subject matter claimed, the U.S. patent system's concept of novelty is actually far more complex. 35 U.S.C. § 102, paragraphs (a), (e), and (g), describe the type of evidence tending to negate novelty, while 35 U.S.C. § 104 limits the type of evidence which can be used to establish novelty. As will be seen, a patent may be barred if the invention is disclosed by prior U.S. public use, offers for sale, or applications which have matured into patents, or prior U.S. and foreign patents and printed publications.

Nonobviousness. 35 U.S.C. § 103 requires that the invention go beyond what a person of ordinary skill in the art, guided by

all the patents and printed publications to which he might look for guidance (however unlikely it is that a real-life microbiologist might look at an 1893 Peruvian paper), would find obvious to seek and obtain.

Diligence in Filing. In the United States, inventors are given a one-year period in which to apply for a patent after putting the invention into non-experimental public use or on sale in this country, or after patenting or describing it in a printed publication in this or a foreign country. 35 U.S.C. § 102(b). If the invention is not used, delay in filing may be considered an abandonment of the invention. 35 U.S.C. § 102(c). Inventors may file in the U.S., and claim the benefit of the filing date of their foreign application, if they file their U.S. application within one year of their original filing date. 35 U.S.C. § 119.

Priority. If two inventors who did not work together apply for a patent on the same invention, the PTO will declare an interference for the purpose of determining priority, awarding priority to the first-to-invent (though the burden of proof will be on the second-to-file, the junior party). The concept of first invention is defined in 35 U.S.C. § 102(g). A number of interference cases (*Feldman v. Aunstrup;* Interference of A v. B v. C) are reviewed in Chapter 5.

Enablement. The specification of the application, as filed, must disclose how to make and use the invention. 35 U.S.C. § 112. When the invention utilizes an organism not readily available, case law, PTO regulations, and an international treaty require the deposit of a viable culture of the organism in a recognized culture collection. The organism, of course, is also described according to accepted taxonomic practice. Chemicals are identified structurally or by their physico-chemical "fingerprint." The organism or chemical must have utility outside of research.

Best Mode Disclosure. The specification of the application must put forth the "best mode contemplated by the inventor of carrying out his invention" at the time the application was filed. 35 U.S.C. § 112. Enablement and Best Mode issues are discussed in Chapter 5.

Distinct Claiming. The claims define the intellectual territory awarded by the patent, and therefore must have well-

marked boundaries. 35 U.S.C. § 112. Nor can the claims cover more than what can rightfully be considered the invention; discovery of a single producing strain will not justify a claim to an entire taxonomic family, for example, nor can claims cover what is disclosed by the prior art. As the Supreme Court pointed out in 1892, a patent application is "one of the most difficult legal instruments to draw with accuracy." Claim drafting problems are discussed in Chapter 4.

Candor. The applicant must disclose all prior art references which the examiner might deem pertinent to the question of patentability, or risk rendering his patent unenforceable. *See* 37 C.F.R. § 1.56. "Candor" before the Patent Office was an issue in *Chas. Pfizer v. FTC,* discussed in Chapters 3, 4, and 5.

After the patent issues, the patentee should comply with the patent marking statute, 35 U.S.C. § 287, to enjoy the full benefits of the patent system. The government does not enforce patents; this must be done by the patentee. In a suit, the validity of the patent and its infringement by the defendant will be tried. Infringement issues are discussed in Chapter 4.

While the Patent Office Boards of Appeal, the Court of Customs and Patent Appeals, and several of the federal courts have rendered decisions on several of the issues raised by patent protection of biotechnology, many issues remain unresolved. For what aid it may offer to those seeking to properly disclose and claim a "biological" invention, Chapters 4 and 5 draw examples of claims and descriptions from a number of issued patents. Caution should be exercised in making use of these examples. Descriptions and claims considered adequate by one attorney in the past might be deemed inadequate by another today. Nor does the acceptance by an examiner of a particular claim format guarantee its acceptance, even by the same examiner, in the future. The Patent Office has steadfastly refused to regard issued patents as "decisions" with precedential value.[30] On the other hand, the courts, in a case of first

[30] *See* In re Fischer, 18 C.C.P.A. 1076 (1931); In re Rutledge, 18 C.C.P.A. 1081 (1931); In re Shat, 20 C.C.P.A. 939 (1933); In re Lawson, 22 C.C.P.A. 1016 (1935); In re Murray, 22 C.C.P.A. 1241 (1935); In re Borglin, 24 C.C.P.A. 739 (1937); In re Fischer, 24 C.C.P.A. 1344 (1937). *See also* Fishgold v. Sullivan Drydock & Repair Corp., 328 U.S. 275, 290 (1946); SEC v. Sterling Precision Corp., 393 F.2d 214, 220 (2d Cir. 1968).

impression, may well take note of the Office's past practices.[31] This trend is likely to be accelerated by the development of judicial restraints on the arbitrary behavior of administrative agencies.

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[31] *See* In re Chakrabarty, 596 F.2d at 985-86; Ex parte Brian, 118 U.S.P.Q. 242, 245 (POBA 1958).

CHAPTER 2

Patentability of Biological Invention: Threshold Issues of Law, Science, Policy and Philosophy

§ 2.01 Patentability of Methods of Utilizing Living Organisms
§ 2.02 Patentability of Living Organisms: Early Developments
§ 2.03 Ex Parte Chakrabarty: Proceedings Before the Patent Office
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§ 2.01 Patentability of Methods of Utilizing Living Organisms

In 1908, the Second Circuit Court of Appeals declined to invalidate a patent on a "Process of and Apparatus for Treating Sewage."[1] The apparatus was the now-familiar septic tank, and the process was one of using the septic tank as a "home and workshop" for anaerobic bacteria. In a position of modest prominence in the opinion, the Second Circuit disposed of the contention that the five process claims were void because the process they covered was "a process of nature, and one which

[1] Cameron, U.S. Pat. No. 634,423 (1899).

cannot be covered by any one."[2] Cameron was not attempting to claim the process of anaerobic decomposition, which had gone on for millenia. He claimed only a method of subjecting a flowing current of sewage to the action of anaerobic bacteria in such a manner as to maximize their efficiency. "This certainly involved 'the use of one of the agencies of nature for a practical purpose.' . . . The process is one which puts a force of nature into a certain specified condition and then uses it in that condition for a practical purpose. . . ."[3]

It seems appropriate to consider next the "activated sludge" case, involving the use of *aerobic* bacteria in the treatment of human wastes. The Seventh Circuit briefly gave its opinion that the Jones patent claimed neither a natural process, nor a discovery of a law of nature:

> It is to be noted that in nature's processes and in all artificial filters of the prior art, the aerobic bacteria were fixed, and the polluted water or sewage was brought to the bacteria, while in the activated sludge method, the situation is reversed, so that the bacteria instead of being fixed are put into circulation and brought to the sewage.
>
> It is true that Jones' method makes use of the scientific discovery that aerobic bacteria can live and thrive in or about the pores of microscopically small, spongy particles of flocculi or zoofileol matter which in turn can be derived from sewage itself by long continued aeration under appropriate conditions, but that is not the subject matter of his patents. The invention is of physical methods and apparatus for handling, treating, and controlling the sewage and the bacterial flocculi in such a way as to promote the development and activity of the bacteria and to bring the bacterial matter into play in a new and different way, and it is upon disclosures with respect to those matters that the claims are based.[4]

During World War I, acetone was used extensively by the

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[2] Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 Fed. 453, 462 (2d Cir. 1908).

[3] Id., 463 [footnotes omitted].

[4] City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 582-583 (7th Cir. 1934).

British government in the manufacture of "cordite," an explosive. Charles Weizmann responded to the wartime shortages of acetone by developing a process for obtaining acetone (and butyl alcohol) by fermenting corn meal (or other starchy substances). After the armistice, the Weizmann microbiological process became the cornerstone of the new butyl alcohol industry, serving lacquer manufacturers. Weizmann's exclusive licensee successfully sued for infringement of the patented process, both in this country and in (*see* Chapter 11) the United Kingdom. Only two paragraphs of the American court's opinion are presently pertinent:

> Weizmann was not the first to produce acetone and butyl alcohol by a fermentation process. He made no such claim. Mere production of limited quantities of acetone and butyl alcohol by a fermentation process was not the problem with which Dr. Weizmann was dealing. The problem with which he was dealing and successfully solved was that of isolating a particular bacteria or a culture containing some particular bacteria that would produce butyl alcohol and acetone in commercial quantities better than any other known bacteria. Weizmann discovered a particular species of bacteria new to bacteriologists and invented the process of successfully employing them. This task called for the exercise of inventive genius. He obtained his patent, not for the bacteria per se, but for a process which consists in the employment of certain bacteria to produce large yields of acetone and butyl alcohol under aerobic or anaerobic conditions.
>
> . . .
>
> Lastly the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented. As before stated the patent is not for bacteria per se. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. Undoubtedly there is patentable subject matter in the invention.[5]

[5] Guaranty Trust Co. v. Union Solvents Corp., 54 F.2d 400, 403, 410 (D. Del. 1931), aff'd 61 F.2d 1041 (3d Cir. 1932).

The offhand reference to "microorganisms per se" was to serve as ammunition for the Solicitor in the *Bergy* and *Chakrabarty* cases.

The Patent Office Board of Appeals similarly allowed claims to a fermentation method of producing butyl and isopropyl alcohols without concomitantly producing ethyl alcohol. Rejected claims 14 and 18 referred to "inoculating" a mash with a culture of the applicants' newly discovered bacteria, while rejected claims 15, 16, 17, 19, and 21 used the term "fermenting" instead of "inoculating." With regard to the latter claims, the Examiner argued that ". . . applicants do not ferment the mash. . . ."

> The fermentation is the act of the bacteria and this is an inherent function of the bacteria, a power given it by nature. . . . [C]laim 15 is not a claim for a process in which the power of the bacteria to ferment material is made use of but a claim for the power, the fermentation itself.[6]

Relying on the *Guaranty Trust* and *Corona Cord*[7] decisions, the Board held

> We are unable to agree with the Examiner that processes involving bacterial action do not involve patentable subject matter nor that they are lacking invention in cases where a new bacteria has been used to produce novel and useful results.
>
> It seems to us that the purpose of the patent laws is to promote the progress of the useful arts and that when a useful result has been attained, the acts of the inventor should be viewed as an entirety instead of segregating them into steps and holding that each step is devoid of invention. The discovery of the specific bacteria, its isolation and the inoculation of a suitable mash therewith are all new and their combined result constitutes a definite advance in the art.[8]

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[6] Ex parte Prescott, 19 U.S.P.Q. 178, 179 (POBA 1932).

[7] Guaranty Trust, supra N.5, Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358 (1928).

[8] 19 U.S.P.Q. at 180-81. Compare with the reasoning of Mr. Justice Douglas in Funk Bros. Seed Co. v. Kalo Inoculant Co., 233 U.S. 127 (1948).

§ 2.02 Patentability of Living Organisms: Early Developments

In 1873, Louis Pasteur, the great scientist whose discoveries revolutionized France's wine industry, was granted U.S. Patent No. 141,072. Claim 2 was directed to "yeast, free from organic germs of disease, as an article of manufacture."[9]

At about the same time that the *Guaranty Trust* decision was rendered, the Supreme Court held in *American Fruit Growers, Inc. v. Brogdex Co.*[10] that oranges with borax-impregnated rinds were not patentable "manufactures." The Court did not voice any general objection to the patenting of "living matter" although it was aware that the claimed orange was "alive" (in the sense that the cells of the fruit continued to "respire" and digest sugar even after plucking).[11]

In 1948, the Supreme Court held that a mixture of compatible, nitrogen-fixing bacterial strains was unpatentable for "want of invention."[12] Bergy and Chakrabarty argued that the Supreme Court would not logically have reached this issue in *Funk* unless they had first classified bacteria as "statutory subject matter." (No general objection to the patenting of "living matter" was raised by the parties or expressly considered by the *Funk* court.[13])

Pasteur's patent, issued in 1873, was but the first of several

[9] According to Federico, Louis Pasteur's Patents, 86 Science 327 (1937), Pasteur's claim was "unique," and one which was of doubtful allowability after the *American Fruit Growers* decision.

[10] 283 U.S. 1 (1931).

[11] Id. at 10: "[T]he film . . . does not interfere with the so-called breathing or transpiration of the fruit to an undesirable extent." For more information on the respiration of fruit, *see* Wynne, *Apples: History, Folklore, Horticulture and Gastronomy* 40-41 (1975) ("Even after the apple is picked, it goes on living"); J. McPhee, *Oranges* 15 (1967); F. E. Denny, Effect of Ethylene Upon Respiration of Lemons, 77 Bot. Gaz. 322 (1923); Kidd & West, Physiology of Fruit: I. Changes in the Respiratory Activity of Apples During Their Senescence at Different Temperatures, 106B Proc. Roy. Soc. London 93-109 (1930).

[12] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131-32 (1948).

[13] *See generally* Briefs, id.

"living matter" patents to be issued by our patent office.[14] Even compositions containing more complex living organisms have been patented.[15] In recognition of the growing number of patents in the field, the Patent Office adopted certain "classification definitions" of interest:

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[14] Vaccine patent protection began with Cutter (vaccine prepared by pulverizing pustules and mixing them with lymph)(U.S. Pat. No. 197,612; 1877) and Protze (vaccine carried with a mixture of thymol, glycerine, and water)(U.S. Pat. No. 273,390; 1883).

Early patents on bacterial vaccines include those of Houghton (attenuated blackleg anthrax bacillus) (U.S. Pat. No. 778,767; 1904), Small (attenuated rheumatic fever bacillus)(U.S. Pat. No. 1,636,446; 1927), and Langer (whooping cough bacillus)(U.S. Pat. No. 2,105,486; 1938). Recent patents include those of Bauer (suspension of bacteria inactivated by ethyleneimine)(U.S. Pat. No. 4,058,599; 1977), Stickl (inactivated Corynebacteria acne composition)(U.S. Pat. No. 4,057,627; 1977), Dobrescu (piglet oedema disease vaccine)(U.S. Pat. No. 4,136,181; 1979); Harris (combination vaccine to combat dysentery)(U.S. Pat. No. 4,152,414; 1979).

Early patents on viral vaccines include those of Duval (hog cholera virus) (U.S. Pat. No. 1,210,053; 1916); Proescher (artificially pure culture of bronchio-pneumonia virus for the treatment of swine)(U.S. Pat. No. 1,391,-579; 1921); Degkwitz (artificially grown measles virus)(U.S. Pat. No. 1,607,-447; 1926). Numerous viral vaccine patents have been issued; eight in 1978 alone.

The first product claim on a bacterial insecticide was apparently Edmond's claim to a suspension of Bacillus thuringiensis in mineral oil (U.S. Pat. No. 3,113,066; 1963). At least eight other microbial insecticide compositions have been patented, a recent example being Shieh's *B. thuringiensis* elixir (U.S. Pat. No. 4,000,258; 1976).

Pasteur was not the only inventor to claim a yeast product. Takamine's claim (U.S. Pat. No. 525,824; 1894) was directed to "taka-koji ferment in the form of fine dry powder, comprising young, immature spores of mycelial fungus." Mixtures of yeast with lactobacilli were patented by Owen (U.S. Pat. No. 1,980,083; 1934) and Becze (U.S. Pat. No. 1,894,135; 1933).

[15] Lumb (U.S. Pat. No. 3,013,946; 1961) claimed a composition comprising viable predacious fungi on vermiculite, with a nutrient, for eelworm control. Mann's patent (U.S. Pat. No. 4,061,488; 1977) is directed to a composition of viable seeds with B. uniflagellatus and Bordt's (U.S. Pat. No. 4,070,453; 1978) claimed a "diploid porcine embryonic cell strain." Sanborn (U.S. Pat. No. 2,026,253; 1935) patented "growths of slime-producing microorganisms" for use as filler in the manufacture of paper. Wernicoff (U.S. Pat. No. 3,088,865; 1963) claimed a hormone-treated egg, and Taylor (U.S. Pat. No. 2,851,006; 1958) claimed an egg inoculated with Salmonella phages.

Class 195, Subclass 53: "Ferment-containing Products . . ., Living fungi-containing."

Class 424 (Drugs . . .): subclass 93, "Whole Live Microorganism or Virus Containing" ("Class 424 provides for compositions containing microorganisms, either alive, dead or attenuated.")

Class 435 Chemistry: Molecular Biology and Microbiology, Subclass 172, Mutation or Genetic Engineering; Subclass 174, Carrier-Bound or Immobilized cell; Subclass 235, Virus; Subclass 240, Undifferentiated Animal or Plant Cell; Subclass 243, Microorganism per se; Subclass 253, Bacteria; Subclass 254, Fungi; Subclass 255, Yeast; Subclass 256, Brewer's Yeast; Subclass 257, Unicellular algae; and Subclass 258, Protozoa.[16]

As a general rule, these patents claimed an organism in an inert carrier or in an inert culture medium, though there were a few exceptions.[17]

Even though there was no "longstanding administrative interpretation" excluding "living matter" from patent protection, such an interpretation was briefly adopted by the Patent Office in the seventies.

§ 2.03 Ex Parte Chakrabarty: Proceedings Before the Patent Office

On June 7, 1972, Ananda M. Chakrabarty (General Electric Co.) filed an application, Ser. No. 260,563 for "Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation Thereof."[18] The examiner rejected certain of the claims as drawn to a "product of nature," citing 35 U.S.C. Sec. 101. Eventually, Chakrabarty appealed the examiner's final rejection of the following claims

7. A bacterium from the genus Pseudomonas containing

[16] U.S. Patent and Trademark Office, Manual of Classification (1980) (quoted in Brief for Respondent at 16-17).

[17] Storch, U.S. Patent No. 561,291 (1896); Smith, U.S. Patent No. 3,364,117 (1968); Treichler, U.S. Patent No. 3,923,601 (1975).

[18] In re Chakrabarty, Patent Appeal No. 77-535, Transcript of Record (Rec.), 6.

therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

8. The Pseudomonas bacterium of claim 7, said bacterium being of the species P. aeruginosa.
9. The Pseudomonas bacterium of claim 7, said bacterium being of the species P. putida.
13. The Pseudomonas bacterium of claim 7 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.
15. The P. aeruginosa bacterium of claim 8 wherein the bacterium contains CAM, OCT, SAL, and NPL plasmids.
17. The P. putida bacterium of claim 9 wherein the bacterium contains CAM, SAL, NPL and RP-1 plasmids.
21. An inoculum for the degradation of a pre-selected substrate comprising a complex or mixture of hydrocarbons, said inoculum consisting essentially of bacteria of the genus Pseudomonas at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.
24. The inoculum of claim 211 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.
25. The inoculum of claim 24 wherein the bacteria having multiple energy-generating plasmids are of the specie P. aeruginosa.
26. The inoculum of claim 24 wherein the bacteria having multiple energy-generating plasmids are of the specie P. putida.[19]

The Examiner's Answer (September 23, 1974) to the Appeal Brief contained the first suggestion that this would be more than a simple "product of nature" case.

[19] Chakrabarty Rec. 116-17.

> [Applicant's] bacteria are in effect artificially created mutants, which like naturally occurring mutants are "products of nature" and as such unpatentable.
>
> Furthermore, . . . while the provisions of 35 U.S.C. §101 do not expressly exclude patents to living microorganisms . . . [plant patent act discussed]
>
> . . . 35 U.S.C. §101 neither in words nor in intent encompasses products of nature such as the Pseudomonas bacteria and inoculum appellant is here claiming. To do so would open the flood gates to patentability for all newly produced microorganisms as well as for all newly developed multi-cellular mammals such as newly bred chickens and cattle.[20]

In passing, it is worth noting that several months after the Supreme Court decision in this case, only a trickle of applications had passed through "the flood gates to patentability,"[21] and that the same warning was given by Commissioner Robertson with regard to the Plant Patent Act of 1930.

The Board of Appeals rendered its decision on May 20, 1976. It agreed with Chakrabarty that the claimed bacteria could not be considered "products of nature": "[F]rom the record we must conclude that *Pseudomonas* bacteria containing two or more different energy-generating plasmids are not naturally occurring." It held, however, that the examiner's second "reason" for rejection of the claims under 35 U.S.C. Sec. 101 was correct: "They are drawn to live organisms and hence do not fit any of the categories of patentable subject matter as defined by 35 U.S.C. §101." [Chakrabarty Rec. 92, 96.] As did the Examiner, the Board pointed out that 35 U.S.C. 101 does not specifically proscribe patents on plants, yet it was found necessary to enact a special patent statute; hence, it reasoned, other living organisms must likewise have been implicitly excluded from 35 U.S.C. 101; hence, bacteria are unpatentable, since Congress never favored them with special relief. This syllogism is discussed later in this chapter.

The Board correctly regarded the "clear and distinct rules"

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[20] Rec. 88-89.

[21] Speech, Gerald Bjorge, Battelle Memorial Institute Conference (April 6-10, 1981).

enunciated in *Funk* as tests for "invention," and not for whether an article was a "manufacture." But it never explained why the Supreme Court in *Funk* would have discussed the "want of invention" question if bacteria, even when the "product of invention," were unpatentable.

The Board also engaged in making a "new form of life," to wit, a "red herring":

> If we were to adopt appellant's liberal interpretation of 35 U.S.C. 101, new species of bacteria would be patentable, new types of insects, such as honeybees, would be patentable and new varieties of animals produced by selective breeding and crossbreeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. Finally, if 35 U.S.C. 101 encompasses living organisms which have been modified by the physical incorporation of additional plasmids into the cellular structure why would not 35 U.S.C. 101 encompass living multicellular organisms (including human beings) which have been modified by the physical incorporation (as by [101] artificial transplants) of additional organs such as the liver or heart? Such a modified animal would be patentable, according to appellant's understanding of 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass living organisms whether they be plants, modified microorganisms (such as bacteria), or modified multicellular organisms (such as mammals).[22]

The Board refused to reverse itself upon a request for reconsideration, and appeal was taken to the CCPA.

§ 2.04 Ex Parte Bergy: Proceedings Before the Patent Office

On June 10, 1974, Malcolm E. Bergy, John H. Coats, and Vedpal S. Malik filed an application, Ser. No. 477,766, for a process of preparing lincomycin without the concomitant

[22] Chakrabarty Rec. 95.

production of lincomycin B. The process employed *Streptomyces vellosus* var. *vellosus*, NRRL 8037, a thermoduric *Streptomyces* strain isolated from Arizona soil. The examiner rejected claim 5 of the Bergy application as directed to a "product of nature," citing 35 U.S.C. 101. Claim 5 read:

> 5. A biologically pure culture of the microorganism Streptomyces vellosus, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.[23]

Appeal was taken to the Board, which rendered its decision on June 22, 1976, without citing the Chakrabarty opinion (which was rendered by an entirely different panel).[24] Nonetheless, the same Sec. 101 issue was considered.

The Board adopted the view that "35 U.S.C. Sec. 101 must be strictly construed and, when so interpreted precludes the patenting of a living organism."[25] The Board correctly stated that "only those categories of subject matter specifically enumerated in the statute are patentable" but had difficulty explaining why "a living organism does not fall within the scope of any of the categories listed." The statutory terms "manufacture" and "composition of matter" were certainly *capable* of being interpreted so as to encompass a culture of bacteria purified by the hand of man, without offending the keepers of the King's English or distorting the classical legal definitions of these terms. The Board correctly regarded the judicial classification of mental processes, printed matter and methods of doing business as unpatentable,[26] as being pertinent, but overstated its significance. They signified only that certain subject matter was unprotectible even though not *expressly* excluded by statute. But the Board failed to examine *why* they were deemed unprotectible: were they not "discov-

[23] In re Bergy, 563 F.2d 1031, 1032 (CCPA 1977).
[24] Ex parte Bergy, 197 U.S.P.Q. 78 (POBA 1976).
[25] Id., 79.
[26] MPEP §706.03 (2).

eries" or contributions to "useful arts," in the constitutional sense?

Were they not encompassed in the nineteenth century definitions of the terms "art" and "composition of matter"? Were they excluded for reasons of overriding public policy? The bald reference to these shoals and reefs of Section 101 taught nothing insofar as the patentability of living organisms was concerned.

The Board correctly regarded the Plant Patent Act of 1930 (35 U.S.C. §§161-64) to be pertinent to the patentability of living organisms generally. It erred, however, in regarding the existence of this special legislation as forcing an adverse conclusion, rather than as suggesting the need for further inquiry:

> [35 U.S.C. §101] does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturalists and agriculturalists [35 U.S.C. §§161-64]. If 35 U.S.C. §101 were to be broadly construed there would clearly not have been any necessity for [35 U.S.C. §§161-64].[27]

Parenthetically, it should be observed that the scope and kind of protection accorded by 35 U.S.C. § 161 (for plants) and 35 U.S.C. § 101 (for compositions and manufacturers) are not identical, and Congress could conceivably have provided them both. The structure of a building may be the subject of a utility patent, while its appearance and form may be the subject of a design patent, a trademark, and a copyright, under appropriate circumstances.[28] It should also be observed that the acts which must be performed in order to obtain plant protection are different from those which must be performed to obtain utility patent protection. A plant must be "asexually reproduced," while a machine need not actually be made and operated (unless 35 U.S.C. § 112 requires actual demonstration that

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[27] 197 U.S.P.Q. at 79.

[28] Trademarks and Unfair Competition; J. T. McCarthy §7.34 (1980); Nimmer on Copyright §2.08[D][2][b] (1981); Deller's *Walker on Patents* §172 (2d ed. 1981).

it *can* be made and operated).[29] The requirements for describing a "plant" are less taxing than those for describing a new electrical, chemical or mechanical invention.[30] This treatise will reexamine several of these observations in due course.

Another view was adopted by the dissenting Board Member, Katz. Katz felt that since "bacteria," under the CCPA's *Arzberger's* decision, were not "plants" within the meaning of 35 U.S.C. 161, "the exclusion of plants from 35 U.S.C. does not necessarily apply to bacteria."[31] (This author believes, however, that *Arzberger* was wrongly decided.)

Katz also interpreted the Supreme Court's 1948 *Funk* decision in a manner that presaged the Supreme Court's reliance on *Funk* in *Diamond v. Chakrabarty* [, 100 S. Ct. 2204 (1980)]. He pointed out that the claim to a "bacteria mixture" in *Funk* was rejected by the majority for want of invention," not for being directed to "improper subject matter."[32] And the concurring and dissenting opinions agreed that a "particular mixture of compatible strains is an invention and as such patentable."[33]

One passage in the Board majority opinion is of greater than historical interest, in the light of the epochal *Chakrabarty* opinion:

> If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding or cross breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. §101, such as tuber-propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. §101.[34]

§ 2.05 The CCPA's 1977 In re Bergy Decision (Bergy I)

Following the lead of the Board, Associate Solicitor Bjorge

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[29] 35 U.S.C. §§161, 114.
[30] 35 U.S.C. §§112, 162.
[31] 197 U.S.P.Q. at 82.
[32] Id., 81.
[33] Id.
[34] Id., 79.

abandoned the examiner's product of nature argument when the former argued the appeal to the CCPA:

> I'm quite content to argue this case on the basis of the pure, living-nonliving dichotomy. I think it's a very clean way of arguing it; we don't get into the metaphysical concept of what is or is not a product of nature.[35]

The CCPA agreed with the PTO's tacit admission that the "product of nature" argument, in view of the affidavits submitted on Bergy's behalf, was "wholly lacking in merit." Turning to the newer question in the case, it concluded that the fact that "the biologically pure culture, as claimed, is alive" does not remove it "from the categories of inventions enumerated in §101."[36]

Judges Rich and Markey cautioned that the CCPA was not deciding "whether any living things other than microorganisms, are within §101."[37] Judge Kashiwa's concurring opinion underscored that "(e)ach case must necessarily be considered on its own facts."[38] The majority opinion decried the Board's fear that "all new, useful and unobvious species of plants, animals and insects created by man" would become patentable as "far-fetched."

Appealing as this limitation was to a cautious jurist, the majority had difficulty finding a tenable distinction between microorganisms and other living things. It dubiously argued that "(t)he nature and commercial issues of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses."[39]

What, then, of mare's milk and honey, the biblical viands of paradise? The dissenters (Miller and Baldwin) properly labeled the distinction as "gratuitous": "both the microorganisms claimed herein and honeybees are alive, reproduce, and act

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[35] Author's unofficial transcript of the oral argument, March 30, 1977.
[36] In re Bergy, 563 F.2d 1031, 1035 (CCPA 1977) (Bergy I).
[37] Id.
[38] Id., 1039.
[39] Id., 1038.

upon other materials to form technologically useful products."[40] Von Pechmann would distinguish between a "new plant variety . . . created as a rule for the sake of the plant itself or one of its parts" and "a microorganism [which] is only a technical means for producing . . . chemical substances . . . as metabolic products."[41] This distinction is also unworkable—what of a pig, which is both a food source and a source of insulin? What of yeast, bacteria, and algae which may be both edible and capable of yielding a desirable fermentation product? If it is thought desirable to draw a distinction between unicellular and multicellular organisms, it does not help to becloud it by reference to "reagents and catalysts." Honeybees, silkworms, milk cows, and pearl oysters are multicellular "living factories." In any event, the distinction between unicellular and multicellular organisms appears strained in the light of the existence of kelp, mushrooms, and slime molds.

But there are limits to how far this attack can be pushed, as it does not go to the merits of PTO's own "gratuitous" distinction, the distinction between the living and the dead. During oral argument, Mr. Bjorge was pressed by Judge Rich to explain why the PTO had issued patents on attenuated (diluted but still living cells) vaccines.[42] Mr. Bjorge weakly explained that there was scientific controversy as to whether viruses were alive. Mr. Bjorge ignored the existence of *bacterial vaccine* and *cell culture* patents.[43]

In concluding that biologically pure microbial cultures were patentable subject matter, the CCPA relied heavily on an analogy to the "living process" cases: "processes . . . are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes. . . . It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter

[40] Id., 1039.

[41] Von Pechmann, National and International Problems Concerning the Protection of Microbiological Inventions 3 IIC 295-96 (1972).

[42] Oral argument, *supra* note 35.

[43] *See* Chapter 4.

which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under §101."[44]

Judges Miller and Baldwin responded with a reference to the "algorithm" cases: "claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not."[45] The fallacy in this response is that an "algorithm" is not a tangible thing, like a chemical or an organism, it is a particular type of process: a "mental process."[46]

The dissent was nonetheless correct in stating that the "living process" analogy did not "logically compel" the majority's conclusion; but they failed to recognize that it still lent *some* support to the majority's holding. It was an imperfect analogy, not a false one.

The dissenters also relied heavily on the *expressio unius* construction of the Plant Patent Act of 1930. It is regrettable that the majority peremptorily rejected this construction. It did, however, properly point out that in 1930 the "collective mind of Congress" was not turned to the question of patent protection for microorganisms.

The strongest part of the majority opinion is the treatment of the issue of strict versus liberal construction: "there is nothing in the words of Sec. 101 which excludes patents for living organisms. We cannot agree with the board majority's view that Sec. 101 must be strictly construed. . . . We have never heard a case holding that. . . . We think it is in the public interest to include microorganisms. . . . In short, we think that the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance. . . ."[47]

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[44] 563 F.2d at 1037.

[45] Id., 1041.

[46] Cf. Novick & Wallenstein, The Algorithm and Computer Software Patentability: A Scientific View or a Legal Problem, Rutgers J. Computers, Tech. & L. 313 (1980).

[47] 563 F.2d at 1038.

§ 2.06 The CCPA's 1978 Chakrabarty Decision

In a short opinion, Judge Rich declared on behalf of the court that *Bergy* was "controlling precedent," and reversed the Board.[48] He was joined by Judge Lane, whose absence from the bench at the time of the *Bergy* opinion (Judge Kashiwa of the Court of Claims sat in Lane's stead) had fueled speculation that *Bergy* might be overruled by a new majority on the court.

Judge Markey, concurring, characterized the PTO's position as a desire "to read into the statute the word 'dead' before 'manufacture' and before 'composition.' "[49] (He apparently was impressed by the oral argument in *Bergy* regarding "killed" and "attenuated" vaccines.) He felt that his assumption that the statutory language encompassed "living" inventions did *not* make it necessary that he "assume plants to have been within the scope of the patent statutes prior to 1930."[50] (Unfortunately, he stated only his conclusion, not his reasoning.) He properly chastised the PTO for resurrecting the "product of nature" issue by its citation of *American Fruit Growers* (discussed in Chapter 3.)[51] The golden kernel of his opinion, however, was its final paragraph:

> As with Fulton's steamboat "folly" and "Bell's telephone toy," new technologies have historically encountered resistance. But if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology.[52]

The best that may be said for Judge Baldwin's opinion is that

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[48] In re Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978).
[49] Id., 44.
[50] Id.
[51] Id. ("Unfair analogy to oranges").
[52] 571 F.2d at 44.

it made it evident that his view of the patent law was unique. He challenged the dichotomy, accepted by both the PTO and by the majority, between "products of nature" and "manufactures":

> The law, as propounded by the Supreme Court, defines three alternatives. Between true "products of nature" and statutory subject matter or "manufactures" lies an intermediate category of things sufficiently modified so as not to be products of nature, but not sufficiently modified so as to be statutory "manufactures." Therein are found the borax-impregnated oranges of American Fruit, . . . and, in my view, the organisms now before us.
>
> The present case focuses on the degree and nature of modification necessary to convert an admittedly unpatentable living thing into statutory subject matter.
>
> . . .
>
> I read American Fruit as saying that a modified natural product does not become statutory subject matter until its essential nature has been substantially altered. The issue in the present case becomes whether the modification effected by appellant altered the essential nature of the starting material.
>
> Applying the American Fruit rule to the modification of living organisms and to the case before us, I believe that the essential nature of the unpatentable organism with which applicant started was its animateness or life. Appellant has not changed this essential nature; he has not created a new life. Rather, he has merely genetically grafted an extra plasmid on to the organism and, thereby, made the organism better at cleaning up oil spills. While this improvement in oil digesting ability does exclude the new organism from classification as a mere product of nature, like the borax-impregnated orange which was a better commercial product because it had a longer shelf life, this improvement in the utility for which the unpatentable starting material was already suited does not change the essential nature of the starting material and does not make the modified thing statutory subject matter.[53]

The major premise of Judge Baldwin's opinion is founded on

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[53] 571 F.2d at 45.

an all-too-common confusion between a Section 101 rejection (not the *kind* of invention which can be patented) and a Section 103 rejection (not a sufficient *degree* of improvement over what was known before). This sin is the subject of a lengthy sermon in Chapter 3.

The minor premise of the opinion was simply ludicrous. The *reductio ad absurdum* is easily stated: Isn't, then, the "essential nature" of any nonliving material the fact that it is dead? Must Pygmalion give life to Galatea in order to obtain a patent on a new sculpting material?

Judge Miller's dissent mainly repeated the points he had made earlier. He did, however, respond to Chief Judge Markey's "policy" arguments in a manner which set the stage for the Supreme Court's remand of the case:

> If, after nearly two hundred years, it is desired to interpret the basic patent statute, for the first time, to cover living matter, the presumption poses a formidable and yet unrebutted challenge. Although advancement of technology would naturally be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent.[54]

§ 2.07 The CCPA's Consolidated 1979 Decision On Remand By the Supreme Court

At the behest of the P.T.O., the Solicitor General petitioned for a writ of certiorari in *Bergy I.* Granting this writ on June 26, 1978, the Supreme Court vacated the Bergy I decision and remanded it for further consideration in light of *Parker v. Flook.*[55] In *Flook,* the Supreme Court had interpreted Section

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[54] 571 F.2d at 46.

[55] 437 U.S. 584, 594 n.18 (1978), rev'd In re Flook, 559 F.2d 21 (C.C.P.A. 1977). For interesting commentaries on this remand, *see* Dunner & Lipsey, The Patentability of Life Forms, New Technologies and Other Flooks of Nature, 7 APLA Q.J. 190 (1979); Kiley, Common Sense and the Uncommon Bacterium—Is "Life" Patentable?, 60 J. Pat. Off. Soc'y 468 (1978); and Stiefel, Disturbing Implications in the Flook Case, 183 N.Y.L.J. 1 (April 1, 1980).

An interesting interpretation of the Bergy remand was considered in Amicus Brief for Dr. George Pieczenik, Diamond v. Chakrabarty, 100 S. Ct.

101 in light of another new technology, computer software.[56]

Recognizing that the *Bergy* and *Chakrabarty* cases raised similar issues, the CCPA agreed to reconsider both cases and called for the submission of supplemental briefs directed solely to the question of the effect of *Flook* on the patentability of microorganisms. Several amici briefs were filed during the period of reconsideration. On March 25, 1979, the CCPA, in a four-to-one decision, confirmed its earlier resolution of *Bergy* and *Chakrabarty* by again reversing the P.O.B.A.[57] The CCPA held that the *Bergy* and *Chakrabarty* applications were not directed to unpatentable "products of nature," and that there was no general exclusion of "living matter" from the protection of 35 U.S.C. §101.[58]

The CCPA's 1979 opinion carefully explained some of the ambiguities in the use of the term "invention": "An invention can be statutory subject matter and be 100 percent old, devoid of any utility, or entirely obvious. . . . (An) invention (may be capable) of being defined or *claimed* as a manufacture, or composition of matter, as a process for making the product, and as a process utilizing the product in some way . . . all the claims pertain to the same invention. . . ."[59] As enunciated, the CCPA's statement of these principles seemed highly critical of

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2204 (1980). He pointed out that the recombinant DNA organisms claimed by Chakrabarty had an "informational aspect . . . embodied in the deoxynucleotide sequence of DNA." Id. at 9-10. Pieczenik regarded Benson and Flook as cases in which the Supreme Court had "viewed askance the patentability of information per se or processes whose essential feature is the manipulation of information." Id. at 10. As Pieczenik pointed out, information can be physically embodied in a "camshaft," or "modulated electromagnetic radiation," though cam-driven machines and radio receivers have been held patentable. Id. at 11 n.24. In other words, that the claimed subject matter has an informational aspect does not render it unpatentable when the physical embodiment that is claimed is otherwise patentable.

[56] The Supreme Court demarcated one of the boundaries of patentable invention: "Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under §101." Id. at 595 n.18.

[57] 596 F.2d 952 (C.C.P.A. 1979)(Baldwin, J., concurring; Miller, J., dissenting).

[58] Id. at 973.

[59] 596 F.2d at 964.

the Supreme Court's holding in *Flook*, which reversed another CCPA decision.

In particular, the CCPA remarked:

> We have observed with regret that the briefs filed by the Solicitory General for Acting Commissioner Parker in Parker v. Flook, a case which, as the Court noted, "turns entirely on the proper construction of Sec. 101," badly, and with a seeming sense of purpose, confuse the statutory-categories requirement for the existence of "invention."[60]

The CCPA also found that the dicta in *Flook* shed no light on its *Bergy* and *Chakrabarty* holdings, for reasons to be discussed.

Turning to the merits, the CCPA rejected the contention that Section 101 must be "strictly construed,"[61] reiterated its earlier statement that there is "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,' "[62] and its analogy between a patent on "a living organism" and on "the utilization of its life functions in processes,"[63] and discussed in great detail the "inapplicability of plant protection legislation."[64]

The CCPA also compared the PTO to that famous prophet, Chicken Little. It pointed out that the "sky" would not "fall" if patents were granted on "life itself," as the PTO had long granted patents on compositions including "living" subject matter (such as Chakrabarty's allowed claim 30) as well as processes utilizing the "life processes" of a living organism (such as Bergy's allowed claims).[65] Significantly, the majority did not repeat its attempt to limit the scope of its holding to microorganisms.

Judge Baldwin wrote a concurring opinion which took a radically different view of the case. Section 101, he wrote,

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[60] Id., 962.
[61] Id., 973-974.
[62] Id., 974-75.
[63] Id., 976-977.
[64] Id., 977-84.
[65] Id., 985-86.

"while not as sweeping as its constitutional basis, is expansive in its scope," but "judicially-created exceptions" to the literal language of Section 101 have been drawn. The "common thread," in his opinion, was

> that claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions.[66]

Judge Baldwin's particular application of this principle to the *Funk* and *Cameron* cases will be discussed in the next chapter. For the moment, it suffices to say that Judge Baldwin found that the *Bergy* and *Chakrabarty* claims did not preempt, respectively, the biosynthesis of lincomycin, or the biodegradation of petrochemicals.

Judge Baldwin also decided that "the Plant Patent Act appears to voice both the recognition and the reaction of Congress to the fact that some new varieties of plants were no longer merely products of nature, but were also products of man,"[67] and that the difficulty of providing a sufficient description of to-be-patented plants had also precluded the patenting of plants prior to 1930.[68]

It is worth noting Judge Baldwin's *dictum* that "[a]s a practical matter, I do not foresee the patenting of higher forms of life because of the inherent difficulty in complying with . . . 35 U.S.C. §112. . . ."[69]

Judge Miller's lone dissent urged that the CCPA majority

> had missed the essential thrust of the Court's opinion that, recognizing that Congress could not foresee all new developments in technology and that 35 U.S.C. §101 should be broadly construed, *where there is a basis for substantial doubt over the intent of Congress* regarding the breadth of the language in the statute, the Court will await a "clear and certain signal from

[66] Id., 988.
[67] Id., 997.
[68] Id., 997-998.
[69] Id., 997 n.7.

Congress" on the subject.[70]

Miller submitted that the plant patent legislation (some of which he had sponsored as a Senator) created such a doubt.

§ 2.08 The Supreme Court's Chakrabarty Decision

The Supreme Court, petitioned for certiorari in both *Bergy* and *Chakrabarty*, decided to hear both cases together.[71] Subsequently, Bergy withdrew his claim, so only *Chakrabarty* was argued.[72]

Several amici filed briefs.[73] Some took unusual tacks. Genentech, Inc., a small biotechnology concern, suggested that even if the organisms themselves were held unpatentable, the *plasmids* were patentable chemical compositions of matter. [Genentech Br. 15-17.]

The brief submitted by the Regents of the University of California (UC) argued: "affirmance was appropriate despite incorrect reasoning by the CCPA."[74] This brief sought to dissociate the merits of the *Chakrabarty* case from the arguments made by the author of the CCPA opinion, Judge Rich, who, UC feared, had antagonized the Supreme Court in his computer patent opinions.[75]

The Caltech[76] brief argued that the writ was improvidently granted, as the CCPA had failed to treat the "product of nature" issue when the case was remanded for reconsideration

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[70] Id., 999.

[71] 100 S. Ct. 261 (1979).

[72] 100 S. Ct. 696 (1980).

[73] Amicus briefs in Diamond v. Chakrabarty, No. 79-136, were filed by Genentech, Inc., the Pharmaceutical Manufacturers Association (PMA), the American Patent Law Association (APLA), the New York Patent Law Association (NYPLA), the Regents of the University of California (UC), the American Society for Microbiology (ASM), the Peoples Business Commission (PBC), Dr. George Pieczenik, and, jointly, by a group of researchers and nonprofit organizations interested in biomedical research (Caltech).

[74] UC amicus brief, 6-8.

[75] Id. at 8.

[76] *See* note 73 *supra*.

in light of *Flook*.[77]

The Supreme Court, in a five-to-four decision, held the organism was, as claimed, a "manufacture" or "composition of matter" within the meaning of 35 U.S.C. 101.[78] Chief Justice Burger, writing for the majority, pointed out that to give "ingenuity" "a liberal encouragement," Congress had chosen to couch 35 U.S.C. 101 in "expansive terms," so that statutory subject matter would "include anything under the sun that ... is made by man."[79] Chakrabarty's organism, said the Court, "is not nature's handwork (sic), but his own; accordingly it is patentable subject matter under [35 U.S.C.] §101."[80] The majority rejected the two major arguments advanced by the Government in opposition to patentability: (1) that the passage of the plant patent legislation evidenced a Congressional understanding that the terms "manufacture" and "composition of matter" did not include living things;[81] and (2) that microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection, genetic technology having been unforeseen when Congress enacted Section 101.[82] The majority opinion also disposed, en passant, of the "product of nature" issue resurrected by the Caltech amicus brief, and the various "public interest" objections to the CCPA decision. Justices Brennan, White, Marshall, and Powell dissented.[83]

The various legal issues disputed in these complex proceedings will now be considered.

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[77] Amicus Brief for Caltech at 7-8, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980).

[78] Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980). Several major symposia discussed the impact of the Chakrabarty ruling. The American Society for Microbiology conducted one on July 26, 1980. Pat., T.M. & Copyright J. (BNA), Aug. 7, 1980 at A-8 to -10. The M.I.T. Club of Washington and the National Litigation Center jointly sponsored the other on Nov. 12, 1980. *See* id., Oct. 23, 1980, at A-18.

[79] Id. at 2207.

[80] Id. at 2208.

[81] Id. at 2208-10.

[82] Id. at 2210-12.

[83] Id. at 2212 (Brennan, J., dissenting).

§ 2.09 Flook and "Unforeseen Technologies"

Toward the end of the *Flook* opinion, the Supreme Court remarked: "It is our duty to construe the patent statutes as they now read, in the light of our prior precedents, and we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."[84] After the remand of *Bergy*, the PTO argued that Congress could not have foreseen the extension of patent rights to "living matter" anymore than it could have foreseen the extension of patent rights to computer software. [See, e.g., Petitioner's Br. (S.Ct.), 461 PTCJ at D-4.]

However, the patent laws were enacted to encourage innovation. "By definition, . . . innovation involves the unforeseen."[85] The prominent American astronomer Simon Newcomb "proved" mathematically that flight by heavier-than-air machines was impossible, and outstanding physicists such as Nikola Tesla and Ernest Rutherford scoffed at the idea that man could ever split the atom.[86]

In addition, the legislature cannot claim clairvoyance. If the PTO's strained reading of *Flook* is correct, aircraft and nuclear reactors are unpatentable, and must remain unpatentable until Congress provides otherwise.[87]

Nevertheless, the development of new animal breeds by controlled mating was foreseeable even by the 1790 Congress, which enacted the first federal patent act. Animal breeding

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[84] 437 U.S. at 596.

[85] Amicus Brief for APLA at 5, In re Bergy and In re Chakrabarty, 596 F.2d 952 (C.C.P.A. 1979) (Bergy II).

[86] *See* "Major Mistakes by 12 Great Men of Science," in D. Wallechinsky, I. Wallace & A. Wallace, *The Book of Lists* 249-51 (1977).

[87] "[I]f courts defer completely to Congress, a new technology could not be accorded patent protection until the new area became recognized and clearly defined. Congress would not be able to grant statutory patent protection until the new area was defined enough so that Congress would know to what it was granting the protection. Even after a suitable proposal is drafted, the delays inherent in the legislative process amount to a substantial period of time during which patent protection would be unavailable." Novick & Wallenstein, The Algorithm and Computer Software Patentability: A Scientific View of a Legal Problem, 7 Rutgers J. Computers, Tech. & L. 313, 331-32 (1980)(footnotes omitted). *See* APLA Amicus Brief, at 15, 596 F.2d at 973-74.

had been placed on a scientific footing by Robert Bakewell as early as 1745.[88] Accordingly, it is at least arguable that the 1790 Congress contemplated patent protection for living matter.

Subsequent Congresses had access to similar scientific information. Commencing in 1836, Congress received annual reports on American Agriculture. These reports frequently discussed plant and animal breeding experiments. The development of new plant varieties, as well as new animal breeds, was certainly foreseeable by Congress, when the patent laws were codified in 1874.[89]

Prior to this codification, Louis Pasteur had already developed techniques for culturing microorganisms.[90] It is therefore arguable that the Bergy invention, a purified culture of a microorganism occurring in the soil, was foreseeable by Congress. By 1930, Congress had indicated that it was aware of the possibility of creating new life-forms with the aid of mutagenic radiation or chemical agents.[91] With this information, the "foreseeability" standard would require only the denial of patent protection for organisms developed by controlled genetic manipulations.

Courts do not take the word "foreseeability" literally. The "foreseeability" standard espoused by the PTO was rejected by the CCPA. In *Bergy II*, Judge Rich, speaking for the CCPA, proclaimed, "[t]his court unanimously believes that it is not necessary that Congress shall have foreseen a new field of technology or useful art to bring it within [35 U.S.C.] §101."[92] To its credit, the Supreme Court recognized that such a requirement would "frustrate the purposes of the patent law.

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[88] *E.g.*, the mule was an important item of export as early as 1770, and such an historical figure as George Washington was very active in the promotion and improvement of mule breeding. *See* F.C. Mills, *History of American Jacks and Mules*, 14, 15 n.5 (1971); P.E. Zeuner, *A History of Domesticated Animals* (1963).

[89] *See* Supplemental Brief for Chakrabarty, Pat. App. No. 77-535.

[90] *See* U.S. Pat. No. 141,072 (1873).

[91] *See* S. Rep. No. 315, 71st Cong., 2d Sess. 7 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess. 8 (1930).

[92] 596 F.2d at 973. But *cf.* Twentieth Century Music Corp. v. Aiken, 422 U.S. 151, 156-59 (1975) (Copyright Act construable to cover radio broadcast in Aiken's restaurant of plaintiff's copyrighted work as a "performance": "[T]he statute may be applied to new situations not anticipated by Congress.") *Cf.* Barr v. United States, 324 U.S. 83, 90 (1945).

. . . A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."[93]

The *Flook* caveat against extending patent rights[94] was a generalization from a dictum in an earlier Supreme Court case, *Deepsouth Packing Co. v. Laitram Corp.*[95] The Court held that the patentee of a "combination" invention (a shrimp deveiner) could not enjoin the assembly of the invention abroad, for use outside the United States, even though the components had been manufactured in this country.

> We are here construing the provisions of a statute passed in 1952. The prevailing law [was that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts]; and at that time Andrea, representing a specific application of the law of infringement with respect to the export of elements of a combination patent, was seventeen years old. When Congress drafted [35 U.S.C.] §271, it gave no indication that it desired to change either the law of combination patents as relevant here or the ruling of Andrea.
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> . . .
>
> It follows that we should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress. . . .[96]

Flook dealt with computer program patents.[97] Since there were no prior cases relating to the protection of "living matter" which had to be overruled or modified in order to provide

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[93] 100 S. Ct. at 2211.

[94] *See* text at note 84 *supra.*

[95] 406 U.S. 518 (1972).

[96] Id. at 531.

[97] 437 U.S. 584 (1978). There has been a tempestuous struggle between the CCPA and the Supreme Court over computer program patents in Flook and other cases. *See generally* Novick & Wallenstein, The Algorithm and Computer Software Patentability: A Scientific View of a Legal Problem, 7 Rutgers J. Computers, Tech. & L. 313 (1980).

relief, the CCPA concluded that *Flook* was inapposite.[98] The CCPA position was reinforced by their observation that, if anything, the history of utility patent protection for "living matter" reveals that it is the PTO which has changed a long-standing (though unarticulated) policy by advocating the denial of patent protection.[99]

§ 2.10 The Import of the Plant Patent Act

In *Bergy I,* the PTO's strongest argument was based on the enactment of the Plant Patent Act of 1930. The pre-1930 patent law did not "specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturists and agriculturists. . . . If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for a plant patent act."[100]

In its vacated opinion, the CCPA gave short shrift to the PTO's argument.[101] On remand, however, the CCPA pointed out the flaws it perceived in the PTO's reasoning.

Relying on *United States v. Price,*[102] the CCPA suggested that the views of the 1930 Congress on plant patentability were not necessarily identical with the views of the 1874 Congress, which had codified the patent laws.

It is a well-known rule of statutory construction that statutes in pari materia must be construed together.[103] Another such rule is that "effect must be given, if possible, to every word,

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[98] 596 F.2d at 967 (Bergy II).

[99] Id. at 985-86. As the CCPA noted, Chakrabarty's *allowed* claim 31 is directed to "inoculated" straw. Yet "[t]he bacterium is just as much alive when carried on straw as when it is by itself or carried in a bottle." Note, Living Matter Found Patentable: In re Chakrabarty, 11 Conn. L. Rev. 311, 328 (1979) agrees with the CCPA that there are no prior cases which must be overruled or modified.

[100] Brief for Bergy at 4.

[101] 596 F.2d at 978.

[102] 361 U.S. 304, 313 (1960) ("[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."). Accord, Rainwater v. United States, 356 U.S. 590, 593 (1958).

[103] *See* 2A Sutherland, *Statutes and Statutory Construction* §51.03 (Sands 4th ed. 1973).

clause and sentence of a statute."[104] Applying these rules to the 1874 patent code as amended by the Plant Patent Act of 1930, it must be concluded that pre-1930 utility patent protection for "asexually propagated plants" had been deemed inadequate. But this does not necessarily mean that asexually propagated plants had previously been "nonstatutory subject matter."[105]

Chakrabarty, for example, claimed to have a "logical, consistent explanation of the action of Congress in passing the Plant Patent Act of 1930 which leaves intact the scope and meaning of 35 U.S.C. 101 as now interpreted by the courts."[106] Chakrabarty agreed with the PTO that the 1930 bill was intended to "remove the existing discrimination between plant developers and industrial inventors,"[107] but traced the discrimination to a different source. The PTO believed that "agriculture [lacked] the same opportunity to participate in the patent system as ha[d] been given industry" because the patent laws had been "understood to cover only inventions and discoveries in the field of inanimate nature."[108] Chakrabarty contended that the patent system discriminated against "Luther Burbanks"[109] because the "how-to-make" disclosure requirement could not be satisfied by plant developers.

Chakrabarty relied on a 1930 memorandum signed by Commissioner of Patents T. E. Robertson and forwarded to the House Committee on Patents during its deliberations on H.R. 11372. The memorandum was critical of the Senate version (S. 3530) of the proposed Plant Patent Act:

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[104] Id. §46.06 (quoting State v. Bartley, 39 Neb. 353, 58 N.W. 172 (1894)).

[105] It is proper to construe 35 U.S.C. 101 and 35 U.S.C. 161 in part materia. *See* 35 U.S.C. 161 (1976); In re Le Grice, 301 F.2d 929, 939 (C.C.P.A. 1962); Cf. Yoder Bros., Inc. v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1377 (5th Cir. 1976). Also, it would be improper to regard any of the language of the 1930 Act as superfluous.

[106] CCPA Brief for Chakrabarty at 5.

[107] S. Rept. No. 315 (1930) at 1.

[108] CCPA Brief for Chakrabarty at 6 (quoting Sec'y of Agriculture Hyde).

[109] Luther Burbank was a famous plant breeder of the early 1900s who was instrumental in the drive for plant patent protection. Burbank dramatized the dismal economic plight of the amateur horticulturalist due to lack of protection. His efforts were a major impetus behind passage of the Plant Patent Act of 1930.

> There at once arises the difficulty of defining in a written document . . . the differences which identify a new variety from previously known varieties. For example . . . the color of the bloom. . . .
>
> If it is not possible by ordinary description of the physical qualities of the plant, or the fruit, or the bloom, or all three, to so accurately define this new variety that it can be differentiated from all known varieties and from all subsequently created new varieties, then it is difficult to see how a patent to be granted would comply with the other provisions of the statutes, namely, that the inventor must describe his invention in full, clear, concise, and exact terms. (R.S. 4888.)
>
> . . .
>
> In many instances (if not all) it may be found that no description could be written that would enable any one to identify so as to reproduce from that description (without the extraneous aid of physical cuttings or slips grafted in accordance with the usual methods) the new variety, as the only way asexually reproduced varieties can be reproduced is from a physical cutting or slip from the new variety itself. To state the matter in another way, if after the new variety was produced, and then reproduced asexually, an application for patent was filed with the most explicit description that it is possible to furnish, and all the plants containing such a new species were destroyed, as for example by fire, then there would be no way whatever of reproducing this new species. The written, [sic] description filed in the Patent Office would be useless and hence could not satisfy the conditions of section 4888, Revised Statutes.[110]

According to the PTO, Congress' amendments were too sweeping to be explained so easily. Congress could merely have enacted the predecessor of the present 35 U.S.C. 162 without also enacting the predecessor of the present 35 U.S.C. 161.[111] But Commissioner Robertson's memorandum indicated that the issue of plant patent protection raised the possibility of a constitutional question, *i.e.*, when was the identification

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[110] Brief for Chakrabarty at 10-11.

[111] A Bill to provide for Plant Patents: Hearings on H.R. 11372 Before the House Comm. on Patents, 71st Cong., 2d Sess. 7 (1929-30)(statement of Fred S. Purnell), quoted in Bergy, 596 F.2d at 998 (Baldwin, J., concurring).

of a new plant variety a "discovery" in the constitutional sense?[112] Section 161 was enacted so as to ensure careful deliberation before holding plant patent protection unconstitutional, and it was separated from 35 U.S.C. 101 so that an adverse determination would not dismantle the entire patent system.

Nor were these the only reasons for the enactment of the Plant Patent Act. In *Ex Parte Latimer*,[113] the Commissioner of Patents stated that the fiber of the needle of the Pinus australis tree was an unpatentable "product of nature."[114] Shortly after the passage of the Act, the Editor of the Journal of Heredity wrote:

> It is a little hard for plant men to understand why [Art. I, §8] of the Constitution should not have earlier been construed to include the promotion of the art of plant breeding. The reason for this is probably to be found in the principle that natural products are not patentable.[115]

According to Judge Miller, the 1930 "Congress recognized the dichotomy of animate and inanimate inventions and decid-

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[112] 1889 C.D. 123, 125 (Comm'r Pats.) reprinting 46 O.G. 1638 (1889) ("[T]he mere ascertaining of the character of quality of trees that grow in the forest . . . is not a patentable invention, . . . any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should subsequently be found . . .)."

According to Recent Decisions, 47 G.W.U.L. Rev. 242, 260 (1978); "If Congress had believed that plants were already patentable subject matter, it need not have considered whether plant patents were constitutional." Thus, the 71st Congress believed that plants were not patentable subject matter. This is a non sequitur. The statutory language permitted several interpretations, and these interpretations had to be juxtaposed beside the constitutional language. A plant could be a "composition of matter," without being a "discovery" in the limited constitutional sense.

[113] 1889 C.D. 123 (Comm'r Pats.) reprinting 46 O.G. 1638 (1889).

[114] 1889 C.D. at 127.

[115] Chakrabarty, 100 S.Ct. at 2209 n.8 (quoting Florists Exchange & Horticulture Trade World, July 15, 1933, at 9); Bergy II, 596 F.2d at 983. This was probably the primary reason for the enactment of the Plant Patent Act. The disclosure problem was publicly identified by Comm'r Robertson after the introduction of the original bill, so his letter to Congress did not provide any impetus for the original legislation. Since the original bill did not make any allowance for the disclosure problem, it must have been intended to resolve some other problem facing would-be plant patentees.

ed to extend patent protection for animate inventions, but only to asexually reproduced plants."[116] Judge Miller relied on a passage in the House and Senate committee reports accompanying the bills which later became the Plant Patent Act:

> There is a clear and logical difference between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral.
>
> . . .
>
> Further, there is no apparent difference, for instance, between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law. Obviously, these new compositions of matter do not come into being solely by act of man. The chemist who invents the composition of matter must avail himself of the physical and chemical qualities inherent in the materials used and of the natural principles applicable to matter. . . . The same considerations are true of the plant breeder. He avails himself of the natural principles of genetics and of seed and bud variations.[117]

Judge Miller emphasized the word "inanimate" in the first paragraph, choosing to ignore the qualifying word "certain." Congress had said that the discovery of new variety of plant was more similar to the "development of new [chemical] composition" than to the discovery of "a new useful natural mineral." In other words, once the new variety of plant was cultivated and asexually reproduced, as required by the Plant Patent Act, it was no longer a "natural product."

Justice Brennan and his fellow dissenters in Chakrabarty, like Judge Miller of the CCPA, placed heavy reliance on the plant patent legislation. Brennan called the majority to task for failing to "explain why the [Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970] were necessary unless to

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[116] 596 F.2d at 1001 (Miller, J., dissenting).

[117] Id. (emphasis omitted)(quoting H.R. Rep. No. 1129, 71st Cong., 2d Sess. 7-8 1930); S. Rep. No. 315, 71st Cong., 2d Sess. 6-8 (1930)).

correct a preexisting situation."[118] Congress, Justice Brennan charged, "never meant to make patentable [living inventions] outside the scope of [this] legislation."[119]

The majority did, however, attempt to explain the legislative activity:

> Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. . . . [Another] obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description" requirement of the patent law [35 U.S.C. §112]. . . .
>
> In enacting the Plant Patent Act, Congress addressed both of these concerns.[120]

Justice Brennan's comment on the majority's explanation was that "[i]f the 1930 Act's only purpose were to solve the technical problem of description referred to by the court, . . . most of the Act, and in particular its limitation to asexually produced plants, would have been totally unnecessary."[121] Brennan ignored the majority contention that Congress was attempting to surmount the "product of nature" obstacle by explaining at length "its belief that the work of the plant breeder 'in aid of nature' was patentable invention"[122] and by requiring the applicant to "aid nature" by cultivating and reproducing the new variety. He also ignored the fact that "sexually reproduced plants were not included under the 1930 Act because [it was then believed that] new varieties could not be [sexually] reproduced true-to-type through seedlings."[123]

The dissenters also relied on the language of the Plant Variety Protection Act of 1970.[124] This provided a special form of

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[118] 100 S. Ct. at 2213 (Brennan, J., dissenting).

[119] Id. at 2214.

[120] Id. at 2209.

[121] Id. at 2213 n.4 (Brennan, J., dissenting).

[122] Id. at 2209.

[123] Id. at 2210.

[124] 7 U.S.C. §2321-2583 (1976). 7 U.S.C. §2402 limits "plant variety protection" to "any novel variety of sexually reproduced plant (other than fungi,

protection, called a Plant Variety Protection Certificate, for sexually produced new plant varieties. New species of bacteria or fungi were expressly ineligible. Justice Brennan remarked, "Congress . . . included bacteria within the focus of its legislative concern, but not within the scope of patent protection."[125]

Justice Brennan apparently does not realize that Plant Variety Protection Certificates are not patents. The Committee Report on the Senate version of the Plant Variety Protection Act had stated that the Act did "not alter protection currently available within the patent system."[126]

The purpose of the Plant Variety Protection Act was outlined by Floyd Ingersoll during the subject hearings:

> In the 37 years which have passed since the enactment of the Plant Patent Act improved breeding techniques and seed multiplication procedures have become established whereby many plant varieties may be reproduced from seeds true to form. Such ability of plant varieties to reproduce true to form seeds is not acknowledged in existing legislation, such as the Federal Seed Act which was enacted August 1939, and seed certification. It accordingly follows that the distinction drawn in the Plant Patent Act between plants which reproduce asexually and plants which reproduce sexually is artificial, and that the act should be broadened to include plants which reproduce

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bacteria, or first generation hybrids)"; 7 U.S.C. §2483 gives the certificate holder the right "to exclude others from selling the variety, or offering it for sale, or reproducing it; or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom" (§2483(a)) for seventeen years (§2483(b)). In addition, the owner may require that seeds be sold under their variety name only as "certified seed," limited if desired to a number of seed generations specified (§2483(a)). 7 U.S.C. §2532 permits an owner to release seed for testing only. 7 U.S.C. §2404 provides for two-year term compulsory licenses where there is public interest in wide usage. 7 U.S.C. §2422 requires the applicant to set forth the novelty of the new variety, "genealogy and breeding procedure, when known," "photographs or drawing," (§2422(2)) as required, and to deposit and replenish periodically a viable sample in a public depository (§2422(3)). For laws relating to seed certification, *see* Federal Seed Act, 7 U.S.C. §1551-1611 (1976).

[125] 100 S.Ct. at 2214 (Brennan, J., dissenting).

[126] S. Rep. No. 1246, 91st Cong., 2d Sess. 3 (1970).

sexually.[127]

As in the case of plant patents, these certificates offer only a loose description of the new variety.[128] The Plant Variety Protection Act therefore freed plant breeders, as the Plant Patent Act freed plant cultivators, from the strictures of 35 U.S.C. §112.

§ 2.11 Static v. Dynamic Construction

Courts arbitrating a confrontation between "old law" and "new technology" should ask these questions: Is the statute expansive or restrictive? What is the end or other underlying policy the statute was trying to reach? Would applying the statute to the technological change further this end?[129]

The promethean task of the patent system cannot be accomplished if a restrictive interpretation is placed on the patent statutes. As the Supreme Court said in *Kendall v. Winsor*, "[t]he true policy and ends of the patent laws enacted under this Government are disclosed in [Art. I, §8] of the Constitution . . . 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society."[130]

An expansive reading would be in keeping with Anglo-American legal tradition. Edward Armitage, the United Kingdom Comptroller General of Patents, Designs and Trade Marks, made this significant comment:

In the U.K., as in other countries, the courts have inevitably

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[127] Hearings Before the Subcomm. on Patents, Trademarks & Copyrights of the Senate Judiciary Comm., 90th Cong., 2d Sess. 638, 640 (1968).

[128] *See* 7 U.S.C. §2402 (1976). A typical certificate, that for "Coolguard" lettuce, states: " 'Coolguard' most closely resembles 'Winterhaven' and 'Vanguard'; however, 'Coolguard' has a lighter yellow flower color than 'Winterhaven' and 'Vanguard.' " Other examples may be found in the Official Journal of the Plant Variety Protection Office.

[129] Note, Technological Change and Statutory Interpretation, 1968 Wis. L. Rev. 556, 557.

[130] 62 U.S. 322, 328 (1859) (emphasis added).

been left to interpret the statute law so as to confer patentability on whatever the developing social and industrial scene demanded. From crafts of the 17th century and the mechanical devices of the industrial revolution patents have adapted to the chemical industrial developments of the 19th century and the electric, electronic, plastics, agricultural and nuclear industries of the 20th century.[131]

In 1793, the term "machine" referred to a means for the application of mechanical power.[132] Electrical science was then in its infancy. Nonetheless, electrical devices were later deemed to be "machines" for the purpose of the patent law.[133] "Matter," in 1793, referred to solids and liquids. But would anyone dare argue that a substance which is gaseous at room temperature is inherently unpatentable? Fortunately, the courts have been sympathetic to technological change, and the patent system is an incubator—not a strait-jacket—for invention.

The protection of microorganisms would "promote the progress of . . . useful arts" and thereby give effect to the underlying policy of the patent statute.[134]

§ 2.12 "Life Form" Patents and Human Society

In its brief, the Government alluded to the close relationship between Chakrabarty's discovery and "recombinant DNA" research, "already highly controversial." It suggested that Congress was better equipped to resolve the "ethical, health and

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[131] Armitage, British Patent Law, 200 Years of English and American Patent, Trademark and Copyright Law 9 (1977).

[132] *See* W. C. Robinson, *The Law of Patents* §173 (1890); Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1853).

[133] The earliest electrical patent on record was issued to Thomas Brown on December 20, 1816. *See* 4 The New American State Papers, 1789-1860: Science and Technology: Patents (1973), reprinting H.R. Doc. No. 50, 21st Cong., 2d Sess. (1813) (Sec'y of State Van Buren's "Letter on U.S. Patents, 1789-1830").

[134] *See* Edelblute, Microbiological Application and Patents, in *The Encyclopedia of Patent Practice and Invention Management*, 567-70 (R. Calvert Ed. 1964); Dixon, *Magnificent Microbes* (1976); Ford, *Microbe Power* (1976).

economic problems posed by granting patent protection to living things."[135]

This theme was further developed in the amicus brief filed by the Peoples Business Commission (PBC).[136] PBC claimed that as a result of the Plant Patent Act, "thousands of useful varieties of plants," those which came into being "naturally," were abandoned by farmers in favor of the "superior" human-bred varieties and thus "eliminated from the terrestrial gene pool." As a consequence, the ownership of the "basic plant food supply is increasingly being concentrated within a small number of large multinational corporations."[137] According to PBC, patent protection for microorganisms would have a similar socioeconomic impact.

In answer to PBC, Genentech reminded the Court that its genetically engineered microorganisms were being designed to produce insulin, interferon, and other drugs. In this vein,

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[135] Brief for Gov't, as reprinted in Pat., T.M. & Copyright J. (BNA), Jan. 10, 1980, at D-1, D-6.

[136] PBC summarized its argument as follows:

> 1. That the single area in which Congress has specifically authorized the patenting of living organisms through legislation—the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970—provides ample evidence that the patenting of any form of life (plant or otherwise) necessarily leads to certain genetic and social impacts that are not in the best interests of society or succeeding generations.
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> 2. That the technology of genetic engineering, taken as a whole, is not in the public interest, and should not be unduly encouraged by giving unwarranted economic incentive to corporations in the field of genetic research and development through the vehicle of awarding potentially lucrative patents on living organisms.
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> 3. That if patents are granted on microorganisms there is no scientific or legally viable definition of "life" that will preclude extending patents to higher forms of life, and that, indeed, the various technologies of genetic engineering have already created a climate in which patents on higher organisms can consistently be claimed once the precedent has been set with microorganisms. PBC Amicus Brief Pat., T.M. & Copyright J. (BNA), Feb. 7, 1980 at E.1, E-2 [hereinafter cited at PTCJ].

[137] Id. at E-2 to E-3. PBC's "Genetic Impact" arguments were recited during the floor debate on the "Plant Variety Protection Act Amendments," H.R. 999, 96th Cong., 2d Sess. (passed by House of Reps. Nov. 17, 1980). See Cong. Rec. (1980).

counsel wittily remarked that the naturally occurring life forms most likely to be removed from the terresterial gene pool "are those no one will miss at all."[138]

PBC misstates the effects of patent system on agriculture. As PMA's amicus brief properly points out, "the loss of germplasm is something that has been occurring ever since man first cultivated crops. Today, scientists aware of the problem have set up germplasm preservation centers."[139] Seed from these centers was used in 1971 to reduce the vulnerability of the corn industry to the corn blight which injured it in 1970.[140]

Even if PBC were correct in its appraisal of plant patents, its analogy falters. "[T]here is no comparison between the magnitude of the plant gene pool and that of the microorganism pool."[141] The Pharmaceutical Manufacturers Association (PMA) suggests that patent-seeking plant breeders have in fact increased the size of the plant pool. PMA, obviously, is talking about the "pool" of new varieties available from seed depositories, while PBC is concerned only with the number of varieties actually in cultivation.

PBC also claims that "genetic engineers" will "pollute" the "planetary gene pool," the "ecosystem," and the "biosphere" with undesirable life forms which cannot be "recalled." For example, it wonders what Chakrabarty's organism will eat for "dessert."[142]

NIH has relaxed its regulatory guidelines for recombinant-DNA research,[143] as most scientists no longer perceive it as unduly hazardous.

Even if recombinant-DNA organisms are potentially hazardous, this would not warrant the denial of patent protection. The patent laws do not give the patentee the right to practice his invention. They give him the right to exclude others from practising it without his permission. The patentee of a new drug must still obtain FDA approval if he wishes to market it.

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138 Genentech Amicus Brief at 13.

139 PMA Amicus Brief at 25.

140 Id. at 26.

141 Id. at 24. *See also* Genentech Amicus Brief at 13 n.22: "any shovel-full of backyard sod can yield microorganic life in endless variety."

142 PBC Amicus Brief, PTCJ at E-5, E-6.

143 43 Fed. Reg. 60080-105, 60108-31, 60134-35 (1978).

The patentee of a new aircraft design must still comply with FAA regulations. New machinery must be equipped with OSHA-mandated safety devices. In short, a patented invention must be produced and distributed in accordance with the law, and the conferral of the patent right does not excuse noncompliance with safety legislation.[144]

It is a basic tenet of the patent law that an invention may be dangerous under certain circumstances, yet patentable, if it has a beneficial use. It is for this very reason that this author has argued that even a pathogenic organism having valuable fermentation capabilities should be patentable.[145]

Genentech persuasively argued that Congress, and only Congress, is competent to determine whether the patent statute needs to be tailored in the light of a countervailing public interest. For example, Congress tailored the patent statute to distinguish between nuclear weaponry and peaceful uses of nuclear energy.[146]

> When the section [42 U.S.C. §2181] was enacted atomic re-

[144] *Cf.* In re Hartop, 311 F.2d 249, 263 (C.C.P.A. 1962); In re Anthony, 414 F.2d 1383, 1395 (C.C.P.A. 1969).

[145] Cooper, Patent Protection for New Forms of Life, 38 Fed. B.J. 34, 38 n.27 (1979). In Japan, a stricter view of the safety problem was taken in the "Atomic Energy Generating Apparatus" case, wherein an application was struck for failing to clarify the necessary precautions. I. Hayashi, A Japanese Perspective on Patenting Microorganisms: Prospects and Considerations, 7 APLA Q.J. 306, 317-18 (1979).

[146] Inventions Relating to Atomic Weapons, and Filing of Reports.

(a) No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor.

(b) No patent hereafter granted shall confer any rights with respect to any invention or discovery to the extent that such invention or discovery is used in the utilization of special nuclear material or atomic energy in atomic weapons. Any rights conferred by any patent heretofore granted for any invention or discovery are revoked to the extent that such invention or discovery is so used, and just compensation shall be made therefor.

42 U.S.C. §2181 (1976).

search was controversial in all its parts, and it remains so even to the present day. Yet Congress had the facility, as this Court does not, to limit its "tailoring" of the Patent System by the dictates of policy in a complex field, and it exercised it so as to proscribe only certain patents, while permitting such others as those later issued to Glenn Seaborg for the creation of the isotopes that are Elements 95 and 96 of the Periodic Table. The surgical precision of Congress' action in this regard stands in sharp contrast to the meat-ax approach Petitioner now urges. Thus, Petitioner would have the Court proscribe the grant of patents across the full length and breadth of a "vast" field, one whose span includes everything from beer-making to gene-splicing, and then to do so because a part of that field is "controversial."[147]

The Supreme Court agreed with this analysis.

We have emphasized in the recent past that "[o]ur individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in the process of interpreting a statute." TVA v. Hill, 437 U.S. 153, 194 (1978). Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend [35 U.S.C.] §101 so as to exclude from patent protection organisms produced by genetic engineering. Compare 42 U.S.C. §2181, exempting from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of [35 U.S.C.] §101 as it is. The language of that section fairly embraces respondent's invention.[148]

PBC also contended that, despite the cautious tone sounded

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[147] Genentech Amicus Brief at 8. Shortly after the Chakrabarty opinion was issued by the Supreme Court, the CCPA held that a fuel pellet configured to engage in a nuclear fusion reaction when irradiated with laser light was patentable insofar as it was used for peaceful purposes, though it had obvious utility as an atomic weapon. In re Brueckner, 623 F.2d 184 (CCPA 1980).

[148] 100 S. Ct. at 2212.

by the CCPA, "the patenting of lower organisms will invariably lead to the patenting of higher forms of life."[149]

This contention was challenged by the amicus brief of Dr. George Pieczenik, who pointed out that the "description" requirement embodied in 35 U.S.C. §112 was a "critical limitation" on the patenting of higher organisms.[150]

Even if new biological techniques should permit an Argoudelis-style solution to the Section 112 problem, the patenting of higher forms of life would be beneficial, not detrimental, to the public.[151] If PBC fears that the livestock industry will become "monocultured," its worries are groundless. Breeders are now aware of the dangers of uniformity and will respond appropriately. If PBC is voicing a philosophical objection to the concept of property rights in living things, it is challenging a concept as old as the law itself.[152]

PBC goes so far as to suggest that patents might be granted

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[149] PBC Amicus Brief, PTCJ at E-7. The CCPA had suggested in Bergy II that the PTO's view of the "question presented"—"Whether a living organism is patentable subject matter under 35 U.S.C. §101"—was "overly broad. . . . We are not dealing with all living things. . . . 596 F.2d at 976. In an earlier paragraph, Judge Rich noted that the uses of the Bergy and Chakrabarty organisms were "analogous in practical use to inanimate chemical compositions such as reactants, reagents and catalysts," all of which he viewed as "tools" of the chemical industry, and declared that "we see 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.'" Though this author agrees with Judge Rich's conclusion, he does not believe that it affords a rational legal distinction between microorganisms and multicellular organisms. *See* Cooper, 38 Fed. B.J. at 39-40: Von Pechmann, National and International Problems Concerning the Protection of Microbiological Inventions, 3 Int'l Rev. Indust. Prop. & Copyright L. 295-96 (1972).

[150] *Compare* In re Argoudelis, 434 F.2d 1390 (CCPA 1970) *with* In re Merat, 519 F.2d 1390 (CCPA 1975).

[151] *See generally* In re Argoudelis, 434 F.2d 1390 (CCPA 1970).

[152] Valid property rights in living entities have been recognized as long as humans have existed, from the domesticated goat and plots of Indian corn to today's vast herds of sheep, cattle, and pigs, and vast fields of wheat. Consider, too, the prize bull whose owner, by virtue of a "monopoly" and current technology, earns a good profit while at the same time providing a dairy farmer with an opportunity to improve his herd. Also consider the syndication of race horses. These are all examples of valid property rights held by citizens of this country in living entities. APLA Amicus Brief at 22.

on genetically altered human beings.[153] But the issuance of patents on human life would clearly be unconstitutional.[154]

PBC's opposition to the *Chakrabarty* decision was rooted, this author believes, in its antagonism to "science," "technology," and the patent system.[155] PBC viewed the patent system as a vehicle by which huge biochemical research companies could exercise oligopolistic control over the genetic resources of the planet, a "final and awesome power."[156]

The patent system has been criticized by those hostile to "big business."[157] However, the Supreme Court has carefully distinguished the patent grant from the "odious monopolies" it abhors.[158]

> Though often so characterized a patent is not, accurately speaking, a monopoly, for it is not created by the executive authority at the expense and to the prejudice of all the community except the grantee of the patent. . . . The term monopoly connotes the giving of an exclusive privilege for buying, selling, working or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. An inventor deprives the public of nothing which is enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge. . . . He may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon the expiration of that period, the knowledge of the invention enures to the people, who are

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[153] PBC Amicus Brief, PTCJ at E-7 to E-9.

[154] The Thirteenth Amendment prohibits "involuntary servitude."

[155] "Science" is used to refer to the pursuit of knowledge via the application of the scientific method, *i.e.*, the testing of hypotheses through observation. "Technology" is used to refer to the application of that knowledge to our everyday life, *i.e.*, the transformation of abstract knowledge into a "useful art."

[156] PBC Amicus Brief, PTCJ at E-3, E-4, E-5.

[157] *See* Hamilton, *Patents and Free Enterprise*, Temp. Nat'l Econ. Comm. (Monograph No. 31, 1941).

[158] W. Bowman, Jr., *Patents and Antitrust Law* (1973); P. Meinhardt, *Inventions, Patents and Monopoly* (1946); Stedman, The Patent-Antitrust Interface, 58 J. Pat. Off. Soc'y 316 (1976); Forman, Patent-Antitrust Ecology vs. National Prosperity, 55 J. Pat. Off. Soc'y 86 (1973).

> thus enabled without restriction to practice it and profit by its use. . . . To this end the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it to use.[159]

The relationship of the patent system to technological advancement was recognized as early as the fifteenth century. In 1474, the Senate of the Republic of Venice declared that:

> If provision were made for the works and devices discovered [by men of great genius], so that others who may see them could not build them and take the inventor's honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth.[160]

PBC agrees that "the granting of [life form] patents is sure to escalate the drive toward commercial application"[161] of recombinant DNA techniques, but PBC is unhappy with this result: "The genie will be out of the bottle before most Americans have even realized that the bottle was uncorked."[162]

The Supreme Court recognizes "that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides."[163] Indeed, it has been argued that the pursuit of scientific knowledge is constitutionally protected.[164]

The freedom to probe the unknown is the most precious of our freedoms, and the most dearly bought. Only two decades ago, the cries of the victims of the inquisition were echoed by

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[159] United States v. Dubilier Condenser Corp., 289 U.S. 178 (1933)(footnote omitted). *See also* W. C. Robinson, *The Law of Patents* §§30, 34 (1890). For a discussion of the ease with which certain discoveries may be practised in secret, Alderson, et al., *Patents and Progress* 68 (1965); C. H. Herr, To Patent or to Padlock, 1973 Pat. L. Ann. 121, 126.

[160] Mandich, Venetian Patents, 30 J. Pat. Off. Soc'y 166 (1948).

[161] PBC Amicus Brief, PTCJ at E-6.

[162] Id.

[163] 100 S. Ct. at 2212.

[164] *Compare* Berger, Government Regulation of the Pursuit of Knowledge: The Recombinant DNA Controversy, 3 Vt. L. Rev. 83 (1978) *with* Stone, Knowledge, Survival and the Duties of Science, 23 Am. U.L. Rev. 231 (1973).

those Soviet biologists who dared to question Lysenko's view of evolution.[165]

§ 2.13 Vitalism

The PBC warned that if the Supreme Court ruled in favor of the patent protection of life forms, it would "institutionalize" the "reductionist and cold philosophy" that "life has no 'vital' or sacred property: that all of life's properties can be reduced to the 'physiochemical.' "[166]

PBC appears to desire that the scope of patent protection be limited by the doctrine of "vitalism." This doctrine viewed life as an agency present in living systems which endowed the latter with unique powers and properties. The vitalists believed that organic molecules could not be synthesized from inorganic molecules, that living systems did not obey the laws of thermodynamics, that the tendency of living things to maintain constant internal environments could not be explained in mechanistic terms, and that only life could possess "memory." Each of these vitalistic edifices was to crumble under the onslaught of nineteenth and twentieth century experimental science, but in 1793 they were still intact.

The vitalists were opposed by the mechanists. Descartes, La Mettrie, Diderot, and perhaps Lavoisier, who believed that living things were subject to the laws of physics and chemistry. In the latter half of the eighteenth century, the vitalists temporarily gained a position of ascendancy: William Cullen's "vital solids," J. F. Blumenbach's "vital powers," and John Hunter's materia vitae held the field. Only in France was there much resistance to the rising tide of vitalism, and Americans,

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[165] Z.A. Medvedev, *The Rise and Fall of T. D. Lysenko* (1966); cf. D. Nelkin, The Science-Textbook Controversies, Sci. Am., Apr. 1976, at 33.

[166] PBC Brief at E-9. Shortly after the *Chakrabarty* decision, "[l]eaders of the nation's major Jewish and Christian bodies" issued a statement asking, "Given our responsibilities to God and to our fellow human beings, do we have the right to let experimentation and ownership of new life forms move ahead without public regulation?" N.Y. Times, June 28, 1980, at 6 (emphasis added). It is not clear whether the theologians who issued this statement had a full understanding of what patent protection encompasses.

as a rule, were unacquainted with French scientific scholarship. Hunter's "no chemist on earth can make out of the earth a piece of sugar, but a vegetable can do it," was more likely to sound a familiar chord than Lavoisier's "respiration is therefore a combustion, very slow to be sure, but nonetheless strictly comparable to that of carbon." The philosophical boundary line between living and nonliving matter was starkly drawn in 1790.[167]

No vitalist member of Congress could have dreamed that life could be altered in the test tube. But this historical fact does not justify a restrictive construction of §101. As American Patent Law Association's amicus brief in *Bergy II* pointed out:

> History has shown that the interjection of differentiations based on a mystical "life" component are seldom scientifically valid. Organic chemistry was once at a juncture very similar to that at which molecular biology finds itself today. Although organic chemistry is now generally defined as the chemistry of carbon atoms, the "organic" portion of its name can be traced to the belief of Berzelius . . . that organic compounds, then derived exclusively from natural sources, could arise only through the operation of a "vital force" inherent to the living cell. It is of interest that at the time this view was held, the 1793 definition of patentable subject matter . . . already referred to manufactures and compositions of matter. . . . Clearly Congress had not foreseen the explosive development of this new technology of organic chemistry and one can only wonder what would be the shape of our commercial world if patentability were denied solely because of the presence of this "vital force."[168]

When the issue arose in Germany, the Bundesgerichtshof refused to pay heed to vitalistic arguments:

> Today, prevalent opinion indicates that living organisms consist

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[167] *See* J. Needham, *The Sceptical Biologist* 88-129 (1930); W. R. Coleman, *Biology in the Nineteenth Century* (1971); 2 T. S. Hall, *Ideas of Life and Matter* 219-87 (1969); D. J. Struik, *Yankee Science in the Making* 45, 55-56 (1962).

[168] APLA Amicus Brief at 5, Bergy II, 596 F.2d 952 (CCPA 1979). Gerhardt received a patent on acetylsalicylic acid, a synthetic organic compound, in 1853. There may have been earlier patents of a similar nature.

of a substance constructed of basic elements present on the earth, just as in the case of other material phenomena. Since the discovery in 1828 of a urea synthesis, the possibility for synthetic preparation of organic materials has increased. Prevalent scientific opinion also indicates that the metabolism effecting the material construction and energetic actions of living creatures occurs as a result of reactions which, to the extent their regularity is known, may be classified within the general principles of physics and chemistry. According to the present state of scientific knowledge, the laws of genetics also originate from complicated physical and chemical procedures. The laws governing biological phenomena and forces as far as they could be determined, permit the conclusion that these phenomena and forces are also to a considerable extent subject to casual relationships that might at least be inanimate matter. Accordingly, no sufficient reason is apparent for excluding methodical utilization of natural biological forces and phenomena from patent protection in principle.[169]

Judge Miller's contention that "[t]he nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions,"[170] is scientifically unsound and irrelevant. The CCPA has correctly concluded that there is 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. We think the purposes underlying the patent system require us to include microorganisms and cultures within the terms "manufacture" and "composition of matter" in [35 U.S.C.] §101. Whether they otherwise qualify for patents under [35 U.S.C.] §102 and [35 U.S.C.] §103 is a question not before us. In short, we think the fact that microorganisms are alive is

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[169] Ex parte Schreiner, 1 Int'l Rev. Indus. Prop. & Copyright L. 136, 139 (1970) (Bundesgerichtshof 1969) ("Rote Taube"/Red Dove). The historical significance of Wohler's synthesis is, as usual, overstated. *See* McKie, Wohler's Synthesis of Urea and the Rejection of Vitalism, a Chemical Legend, 153 Nature 608-10 (1944).

[170] 596 F.2d at 1001 (Miller, J., dissenting).

> a distinction without legal significance and that they should be treated under [35 U.S.C.] §101 no differently from chemical compounds.[171]

Bacterial cells are "matter." Since the PTO wishes to read a limitation on the scope of the statutory term "matter" into the Patent Act, a passage from the Supreme Court's opinion in *United States v. Dubilier Condenser Corp.*[172] is instructive: "We should not read into the patent laws limitations and conditions which the legislature has not expressed."[173]

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[171] Id. at 975.

[172] 289 U.S. 178 (1933).

[173] Id. at 199. The CCPA recently held that transitory compounds are patentable even if they cannot be isolated in a "reasonably stable" form. In re Breslow, 616 F.2d 516 (CCPA 1980). Judge Rich refused to "read into [35 U.S.C.] §101 a requirement that compositions of matter must be stable." Id., at 521.

CHAPTER 3

Biological Invention and the Use of "Laws" and "Products" of "Nature"

§ 3.01 The "Law of Nature" Doctrine
§ 3.02 The "Product of Nature" Doctrine
§ 3.03 "Duplicated" Products of Nature
§ 3.04 "Purified" Products of Nature
§ 3.05 "Altered" Products of Nature
§ 3.06 Patentability of the Obviously Desirable Product of a Nonobvious Process

§ 3.01 The "Law of Nature" Doctrine

In *Bergy II,* Judge Baldwin (CCPA) expressed his belief that *Flook* was one of a series of cases whose "common thread" is that

> claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter, or processes to accomplish new and useful end results define statutory inventions.[1]

It is perhaps significant that all save one of the cases discussed by Judge Baldwin related to processes or machines, and not to compositions of matter. The "law of nature" doctrine is not entirely harmonious with the protection of "compositions" under § 101. Suppose that a chemist synthesizes a substance, which is novel in an absolute sense, by process *A*. If so, he is entitled to claim the substance, per se, as a composition of matter, and his product patent is enforceable against another

[1] In re Bergy, 596 F.2d 952, 988 (CCPA 1979) (Bergy II) (concurring op.).

chemist who later devises a radically different process *B* for synthesizing the product. The properties of this "new" substance are dictated by "laws of nature." The product claim covers all uses of the substance, anticipated or not, and thus "indirectly preempts" a phenomenon of nature (the properties unique to its chemical structure). The *Kirk* and *Joly* decisions[2] nonetheless permit this preemption to occur when *at least one use,* other than in research, was proposed for the substance when claimed.

The reasoning outlined above may explain the Seventh Circuit's holding in *Dennis v. Pitner.*[3]

Dennis v. Pitner involved a claim to "an insecticide and vermifuge comprising ground cube root with the fibrous element removed." The Seventh Circuit held that "(a) discovery . . . of a new quality or phenomenon of an old product may be . . . the proper subject of a patent," given that the discovery of the properties of a new mixture of old substances unquestionably may serve as a basis for a patent claim.[4]

In *Kalo Inoculant Co. v. Funk Bros. Seed Co.,*[5] the Seventh Circuit followed its *Dennis* holding, declaring that Bond's "contribution of noninhibitive strains which successfully combine" was more than the discovery of a law of nature, since "he made a new and different composition." The Seventh Circuit took the opportunity to refine its *Dennis* holding, declaring

> as this court said in *Dennis,* . . . the discovery of a natural phenomenon, or of a quality or attribute of a well known article *and application of that quality in a successful combination which is of value to mankind* is entitled to patent protection. [emphasis added.][6]

Nonetheless, the Seventh Circuit Court of Appeals was reversed by the Supreme Court. Judge Baldwin's discussion of

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[2] In re Kirk, 376 F.2d 936 (CCPA 1967); In re Joly, 376 F.2d 906 (CCPA 1967).

[3] Dennis v. Pitner, 106 F.2d 142 (7th Cir. 1939).

[4] Id., 144. But Dennis failed to show he was in fact the first discoverer. Id., 148.

[5] 161 F.2d 981 (7th Cir. 1947).

[6] Id., at 986.

Funk in *Bergy II* is somewhat misleading. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the *first* biotechnology case to reach the Supreme Court, greatly increased the exclusionary effect of the "law of nature" doctrine.[7]

Funk involved the following patent claim:

> An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.[8]

Bond, the patentee, had "discovered that there are strains of each species of root-nodule bacteria which do not exert a mutually inhibitive effect on each other."[9] Mixed strain inoculants had theretofore proven ineffectual because of this effect, and farmers perforce had used different inoculants for different leguminous plants, *e.g.*, alfalfa and soy beans.[10]

The Supreme Court split three ways.

Justice Frankfurter believed that Bond had indeed applied a "law of nature" to a "new and useful end," but rejected Bond's claim as broader than the actual invention: "He appears to claim that since he was the originator of the idea that there might be mutually compatible strains and had practically demonstrated that some such strains exist, everyone else is forbidden to use a combination of strains whether they are or are not identical with the combinations that Bond selected and packaged together."[11] Justice Frankfurter found that Bond's mixed culture had the "new property of multi-service applicability,"[12] but that the "strains by which Bond secured compatibility are not identified."[13] Justices Burton and Jackson agreed that the mixed culture was a patentable discovery, but believed that "(b)acteriologists . . . will not have difficulty in

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[7] 233 U.S. 127 (1948).
[8] Id., n.1.
[9] Id., 130.
[10] Id., 129 and n.3.
[11] Id., 133 (concurring op.).
[12] Id., 135.
[13] Id., 133.

selecting the noninhibitive strains by employing such standard and recognized laboratory tests as are described in the application for this patent."[14]

Justice Douglas, writing for the majority, held the claim invalid for "want of invention." Prior to 1952, the statutory requirement of "invention" encompassed *both* the requirement that the claim be to the *application* of a phenomenon of nature to a useful end, *and* the requirement that the inventor materially advance the state of the art, *i.e.*, the requirements of the present Sections 101 and 103.[15] A careful analysis of Douglas' reasoning shows that it was, in effect, a 35 U.S.C. 103 rejection which treated Bond's discovery of a "law of nature" as prior art against him. Douglas admitted that Bond's "aggregation of select strains . . . is an application of [a] natural principle."[16]

> But once nature's secret of the noninhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way we could call it such unless we borrowed invention from the discovery of the natural principle itself.[17]

Frankfurter ably criticized Douglas' analysis: "Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."[18]

Nonetheless, this error was perpetuated in *Parker v. Flook*, wherein the mathematical algorithm, even if "new," was deemed to be a familiar part of the prior art, and the claim was

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[14] Id., 137 (dissenting op.).

[15] R.S. 4886.

[16] 233 U.S. at 131 (majority op.).

[17] Id.

[18] Id., 134-135 (concurring op.). Frankfurter is quoted approvingly by the Australian Commissioner of Patents in In re Ranks Hovis MacDougall, Ltd., 8 IIC 453 (1977).

examined for the disclosure of some other inventive concept.[19]

How does this affect biotechnology? The PTO could argue that Bergy had discovered "the secret of nature" that *streptemyces vellosus* NRRL 8037 in a suitable environment would produce lincomycin without the concomitant production of lincomycin B," and that the subsequent preparation of a pure culture of *S. vellosus* was routine. The PTO could argue that Chakrabarty had discovered the "secrets" of the genetic expression of certain metabolic properties of bacteria, and the "secret" that certain energy-generating plasmids could be fused together. Given these "secrets" the "logical" next step was to isolate, fuse, and transfer those plasmids to a suitable host.

Fortunately, the Supreme Court did not apply the logic of *Flook* in *Chakrabarty,* and in *Diehr* it came close to overruling the Douglas rule:

> In determining the eligibility of respondents' claimed process for patent protection under §101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.
>
> This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the §101 categories of possibly patentable subject matter.[20]
>
> To accept the analysis proffered by the Government would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious. The analysis suggested by the Government would also undermine our earlier decisions regarding the criteria to consider

[19] 437 U.S. 584, 594 (1978).
[20] Diamond v. Diehr, 209 U.S.P.Q. 1, 9 (1981).

in determining the eligibility of a process for patent protection.[21]

Though the *Dennis* holding may have been discredited to some degree by the reversal of the Seventh Circuit decision, in *Funk*, it was at least partially rehabilitated by the present 35 U.S.C. 100(b):

> The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

In *Ex parte Allen*[21.1] the Board considered whether the claimed polyploid oysters occur naturally without the intervention of man, and found that no evidence supporting that proposition had been adduced by the Examiner. The fact that the development of oysters was "controlled by the laws of nature" did not diminish the human intervention (applying hydrostatic pressure of 6,000-10,000 psi, 15 minutes after fertilization) involved.

§ 3.02 The "Product of Nature" Doctrine

The Manual of Patent Examining Procedure states blithely that "a thing occurring in nature, which is substantially unaltered, is not a 'manufacture.' "[22] and is therefore not patentable. The origin of this "product of nature" doctrine is unclear.

The term "product of nature" is perhaps a feeble attempt to find a counterpoise for two of the statutory terms. The term "manufacture," etymologically speaking, refers to something made by the Hand of Man, and not by Nature alone.[23] (Man, of course, merely guides and exploits *natural* phenomena so

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[21] Id.

[21.1] 2 U.S.P.Q.2d 1425, 1427 (BPAI 1987).

[22] Manual of Patent Examining Procedure Sec. 706.03(a).

[23] Oxford English Dictionary: "Manufacture 1.a The action or process of making by hand. 1605 . . . b. The action or process of making articles . . . by the application of . . . mechanical power . . . 1835 . . . The most perfect manufacture is that which dispenses entirely with manual labor."

as to refine and transform *natural* substances; he is merely, as J. R. R. Tolkien puts it, a "Subcreator" who makes "by the law by which [he's] made.") A "product of nature" may also be compared with the term "new," as a "product of nature" is something preexisting.

Since all articles of manufacture are, to some degree, products of nature, there has been a tendency for courts to confuse the question of whether a patent is directed to a "manufacture" (35 U.S.C. 101) with the question of whether that "manufacture" is nonobvious to a person having ordinary skill in the pertinent art (35 U.S.C. 103). Similarly, the courts

(*Text continued on page 3-7*)

have been known to confuse statutory or relative novelty (35 U.S.C. 102) with "novelty" in an absolute sense.[24]

These musings will be more fully developed in the remainder of this chapter.

§ 3.03 "Duplicated" Products of Nature

Many of man's most valuable chemicals were obtained originally from natural substances, particularly plant and animal tissues.[25] Rather than comb the jungles for cinchona bark, scientists sought to identify, isolate, characterize, and synthesize (from more accessible materials) its active ingredient quinine. Much of the history of chemistry is the history of attempts to synthesize valuable "natural products."

When attempts were made to patent the synthetically duplicated "natural products," it was of course objected that these chemicals, already existing in nature, were not novel. (This objection was reinforced if the chemical had been characterized in a prior publication.) Underlying this objection was the fear that the patent would exclude "Everyman" from enjoying the bounties of nature, even as the early Crown patents had created monopolies over iron, currants and vinegar.[26]

Several cases have discussed these objections, which may one day be raised against patents on microorganisms, or plant and animal varieties. Suppose first that you isolate a previously unreported strain of microorganism in the Dead Sea, and in due course you apply for a patent on a culture of this strain. Unknown to you, an Israeli scientist had, several years before, isolated the same strain, but had failed to publish the discovery. Are you still entitled to a patent? It was not known or used in the United States, or described in a patent or a printed publication, so 35 U.S.C. 102(a) and (b) are not bars. The Israeli scientist did not "conceive" or "reduce to practice" the strain

[24] For a discussion of "absolute" versus "relative" novelty in national patent laws, *see* 2 Baxter, *World Patent Law and Practices* 74.6-74.8 (1981).

[25] Kreig, *Green Medicine: The Search for Plants That Heal* (1964).

[26] From the speech by Sir Robert Wroth on November 20, 1601, quoted in R. A. Choate, *Cases and Materials on Patent Law* 60 n."f" (1973).

in the United States, so, thanks to 35 U.S.C. 104, 35 U.S.C. 102(g) is not a bar. You did not know of the Israeli's work, so 35 U.S.C. 102(f) is not a bar. In other words, your microorganism is novel in the sense of Section 102 even though it is not novel in absolute sense.

Second, suppose that you use the techniques set forth in the Cohen and Boyer patent to introduce exogenous genetic material into a microorganism. What guarantee is there that this particular genetic recombination had not previously occurred in nature? The Cohen and Boyer product patent formally limits its claims to biologically functional plasmids in which the foreign DNA is derived from a source which does not exchange genetic information with the host cell (claim 1) or a prokaryotic host for the parent plasmid (claim 6).[27] Sheldon Krimsky asks "will it be sufficient to show that the organism has never been isolated under natural conditions? Or will verification that it is unstable in the wild suffice? And what if there is evidence that it could have existed in some past age when conditions were different than they are today?"[28] Davis replies, "The patent law must deal with the concrete realities of what can be found in nature and not with the hypothetical possibility that a particular recombinant cell might once have appeared in nature and then died out."[29] The cases which we will now discuss appear to shed some light on the patentability of naturally occurring life forms.

Alizarine is a natural dyestuff, found in the root of the madder plant. It was first extracted in pure form by Robiquet and Colin in 1826, and was characterized as $C_{14}H_8O_4$ by Strecker in 1866. Shortly thereafter, Graebe and Liebermann succeeded in synthesizing alizarine from anthracine. The Supreme Court held that a reissue patent claim to "artificial alizarine, produced from anthracine or its derivatives by either of the

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[27] U.S. Patent No. 4,468,464. And compare U.S. Patent No. 4,237,224, column 6. A list of "exchangers" is published as an appendix to the NIH Guidelines.

[28] Krimsky, *Patentability of Microorganisms and Higher Life Forms*, ASM Forum on Patentability of Microorganisms 17 (1981).

[29] B. D. Davis, *How Real Are the Dangers from Recombinant DNA Activity*, Id. 16 (1981).

methods herein described, or by any other method which will produce a like result" was "wider in its scope than the original actual invention."

> According to the description in No. 95,465, and in No. 4,321, and the evidence, the article produced by the process described was the alizarine of madder, having the chemical formula $C_{14}H_8O_4$. It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially, for the first time from anthracine, if it was set forth as alizarine, a well-known substance. Wood Paper Patent, 23 Wall. 566,593. There was therefore no foundation for reissue No. 4,321, for the product, because on the description given, no patent for the product could have been taken out originally. Still further, the claim of No. 4,321 is not a claim merely for the product of the process described in it, but is a claim for anything which may be called artificial alizarine, produced from anthracine, or its derivatives, by either of the methods described, or by any other method, equivalent or not, which will produce anything called artificial alizarine.[30]

Unfortunately, the first of the paragraphs quoted above is often treated as the holding of *Cochrane* without any reference to its context. While *Cochrane holds* that you cannot preempt a chemical in a form in which it can be obtained naturally, it *implies* that an "old product-by-new process" claim *is* allowable.

Dextrose is a sugar found in nature in the juice of certain fruits, like grapes. It crystallizes into two forms: anhydrous dextrose, and dextrose hydrate (cerelose). The hydrate crystals normally grow in clusters, intertwined into a solid mass. Newkirk developed a process for making discrete dextrose hydrate crystals of high purity. A challenge to his product claims on

[30] Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311-312 (1884).

"product of nature" grounds was thwarted in *International Patents Development Company v. Penick & Ford Ltd., Inc.*:

> Defendant's product is admitted to be hydrate. It is admitted to be 99.5 percent pure or better. The crystal is chunky. The fact that the crystals are more or less stuck together in the massecuite does not change their character as separate individual crystals.
>
> The principal defense against the product patent is that it is a product of nature. The product of Newkirk is not a product of nature. It is made by the conversion of starch through a chemical process by artificially adding water to the starch molecule. You do not find anywhere in nature a separate hydrate crystal because you do not find the crystallization process at work in nature.
>
> There are a number of analogous products, the patentability of which has been sustained. In the Masonite Case the product consisted of all the ingredients of wood or woody material. The product claim was sustained by the court of appeals. The product consisted of nothing but a physical arrangement of woody ingredients in closer contact than they would be in natural wood. A patent was sustained for granulated burned dolomite. Also a patent has been held valid for calcium carbide, aspirin, adrenalin, and baking powder.[31]

It is important to note that Newkirk, unlike the unfortunate Graebe and Liebermann, had presented a carefully limited product claim:

> Claim 2, Patent No. 1,508,569.
>
> Starch converted dextrose having a purity of 99 percent or greater and consisting of a mass of separate, unitary crystals of normal crystalline form substantially unmixed with deformed crystals of the needle-like or flake-like kind.[32]

This lead was followed by *In re Cofer*, involving a claim to "as a manufacture, free-flowing crystals of 2, 2-bis - (2, 3-epoxy-

[31] 15 F. Supp. 1038, 1046, 30 U.S.P.Q. 298, 305 (D. Del. 1936).
[32] 30 U.S.P.Q. at 303 n.1.

propoxyphenyl) propane" ("2, 2-B").[33] This compound was already known in the form of a "viscuous liquid," and the Examiner rejected Cofer claims 1 and 8 as directed to "an old compound in [an obvious] crystalline form."[34] Noting that the free-flowing crystals were easier to handle, and that prior art did not suggest that 2, 2-B could exist in crystalline form, the CCPA reversed the examiner and the Board.[35] While *Cofer* did not involve a "product of nature," it may be inferred from this decision and *IPDC,* that a claim to a known chemical will be sustained if the claim is limited to the chemical obtained in a new form by a nonobvious new process. This doctrine would appear to apply equally to all known chemicals, whether natural or synthetic.

2-methyl-2-pentenoic acid (2M2PA) is a naturally occurring chemical responsible for the characteristic flavor of strawberries. Kratz and Strasburger were the first to establish the presence of 2M2PA in strawberries and to discover that when 2M2PA was added to foodstuffs, it imparted a strawberry flavor and aroma. Their claim to 2M2PA in substantially pure form[36] was upheld even though "2M2PA is a naturally occurring constituent of strawberries and is not 'per se' novel, . . . since the claims do not encompass natural compositions in that 'substantially pure' 2M2PA does not apparently occur in nature."[37]

In *Ex parte Frohardt,* on the other hand, the claim to "streptimidone," found in a fermentation broth, encompassed the broth in that it was not limited to "a pure compound or to the compound freed from the fermentation broth,"[38] and the claim therefore was not allowed.

Thus far we have discussed the duplication of natural products. Another problematic area is that of plasmid synthesis:

> A final point about DNA which may be relevant in terms of

[33] 354 F.2d 664 (CCPA 1966).
[34] Id., 665-666.
[35] Id., 667-668.
[36] In re Kratz, 201 U.S.P.Q. 71 (CCPA 1979).
[37] Id., 76.
[38] 139 U.S.P.Q. 377, 378 (POBA 1962).

patent law is that DNA is a polymer which is a natural product, and most, but not all, sequences of interest in DNA are present somewhere in nature. It is worth recognizing explicitly that most of what recombinant DNA methodology is doing at the present time is taking genes out of one genetic context in nature where, at least for our immediate purposes, they are not directly useful to us and putting them in another genetic context where they are more useful. To what extent the Patent Office and the courts will hold that a preexisting sequence of base pairs which has been isolated and amplified by gene splicing methods is a "product of nature" and therefore not patentable remains to be determined.[39]

Indeed, Jackson points out, "one can calculate that any 12-base pair sequence will occur by chance every 17 million base pairs, or on the average about 0.3 times in the DNA of a bacterial cell, or about 270 times in the DNA of a mammalian cell."[40] (Of course, selection pressures affect the survival of some gene sequences.) Nonetheless, Davis' position seems equally applicable to gene sequences.

§ 3.04 "Purified" Products of Nature

A common chemical operation is the extraction of a pure compound from a chemically heterogeneous natural product. On several occasions chemists have attempted to patent these "purified" products of nature. The courts have held that while a purer product is not necessarily patentable, the purification of an unpatentable product of nature *may* transform it into a patentable "manufacture."

A common microbiological operation is the screening of a soil sample for previously unknown microorganisms. A typical soil sample will contain a variety of microbial flora. It is undisputed that if the organism remains unchanged, it cannot itself become the subject of a utility patent. But the CCPA held in

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[39] Jackson, *Patenting of Genes: Ground Rules* in ASM, *supra* note 28, at 25.

[40] Id., 26.

Bergy that a "biologically pure culture of a single microorganism, extracted from its soil milieu, is a "manufacture."

In seeking patent protection for these "purified natural products," the patent attorney must be careful to point out to the examiner, or to the court, that the increase in the purity of the compound achieved an unexpected result, or that, even though experts desired to obtain a purer product, they could not devise a method of obtaining the latter. Failure to make this showing would be, in essence, a failure to show that the invention satisfies 35 U.S.C. 103.

Typically, the applicant is faced with a situation in which the natural product is used for the same purpose as the pure product. Those skilled in the art would thus expect the purer product to have the same effect, only with greater potency in relation to the quantity employed.

In re Merz invalidated a claim to artificial ultramarine free of floatable impurities. The court distinguished the "aspirin" case, discussed *infra:* "[n]o new use is claimed for the appellant's purified ultramarine. It is the same old ultramarine with the same old use though it may have brighter color and be more desirable as a pigment than formerly."[41]

In re Ridgway held that "while appellants might be entitled to a method on purifying alpha alumina, they would not be entitled to a patent on the article alpha alumina, a natural product, merely because of the degree of purity of the article."[42] Note that the CCPA did *not* reject the 99 percent alpha alumina claim as being a claim to a product of nature; it merely noted *en passant* that alpha alumina, in impure form, was naturally occurring. Of greater relevance to the outcome was the CCPA's finding that the Saunders reference disclosed alpha alumina of 98.8 percent purity and stressed the desirability of producing commercially pure alumina.[43]

In re King related to a claim to the substance hexuronic acid C (vitamin C), isolated by applicants from lemon juice crystals, and possessing antiscorbutic activity. The Board pointed out that "lemon juice has been known for ages as a satisfactory

[41] 38 U.S.P.Q. 143, 145 (CCPA 1938).
[42] 25 U.S.P.Q. 202, 203 (CCPA 1935).
[43] Id., 203-204.

specific for scurvy."[44] Similarly, in *Ex parte Cavallito,* involving an antibiotic compound extracted from ground garlic, the Board pointed out that "ground garlic is recognized to possess bactericidal and antibiotic properties, and it may well be expected that the extract should possess a much greater activity than the material from which it is extracted."[45] *Ex parte Sparhawk* held unpatentable a musklike material extracted, for perfumery purposes, from the odoriferous glands of the muskrat.[46] It is important to note that all three of these cases correctly regarded the question to be whether the pure product was "obvious" over the utilizable parent material, rather than stating it in terms of a nebulous "product of nature"/"article of manufacture" dichotomy.

When the source material has undesirable attributes, the pure isolate has been considered patentable if those skilled in the art had not found a way to obtain it. Thus, acetylsalicylic acid, now commonly known as "aspirin," was first produced in a form contaminated with salicylic acid, a substance injurious to the stomach. Hoffman's process, which produced aspirin in a pure state, "took a comparatively worthless substance and changed it into a valuable one." In *Farbenfabriken of Elberfeld Co. v. Kuehmsted,* a district court held that Hoffman's "aspirin" was patentable as an article of manufacture.[47]

The Takamine patent vindicated by *Parke-Davis & Co. v. H.D. Mulford Co.* claimed a substance possessing the "physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form and practically free from inert and associated gland tissue," *i.e.,* "Adrenalin."[48] This substance was free of the dangerous side effects of powdered suprarenal gland preparations.[49] Judge Hand held:

> Nor is the patent only for a degree of purity, and therefore not for a new "composition of matter." As I have already shown, it does not include a salt, and no one had ever isolated a substance

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[44] 43 U.S.P.Q. 400, 402 (CCPA 1939).
[45] 89 U.S.P.Q. 449, 450 (POBA 1950).
[46] 64 U.S.P.Q. 339 (POBA 1944).
[47] 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889).
[48] 189 Fed. 95, 965 (S.D.N.Y. 1911) (claim 1).
[49] Id., 106.

> which was not in salt form, and which was anything like Takamine's. Indeed, Sadtler supposes it to exist as a natural salt, and that the base was an original production of Takamine's. That was a distinction not in degree, but in kind. But, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent. Kuehmsted v. Farbenfabriken, 179 Fed. 701, 103 C.C.A. 243; Union Carbide Co. v. American Carbide Co., 181 Fed. 106, 104 C.C.A. 522. That the change here resulted in ample practical differences is fully proved. Everyone, not already saturated with scholastic distinctions, would recognize that Takamine's crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.[50]

In 1926 it was found that pernicious anemia patients were benefited by the addition to their diets of substantial amounts of the liver of cattle. The substance now known as vitamin B-12, and formerly as the "antipernicious anemia principle," is produced in minute quantities in cattle, as well as by certain microorganisms. The "principle" was known only to exist in cattle, but Merck scientists discovered that it was a fermentation product of *Streptomyces griseus*. The microbiological vitamin B-12 was "free of toxic substances" and could readily be taken "by persons whose idiosyncratic digestions do not permit them to tolerate liver materials." The Fourth Circuit held that a claim to a vitamin B-12 composition recovered from a fermentation broth was not directed to an unpatentable "product of nature" even though vitamin B-12 was itself found

[50] Id., 103.

naturally.[51] The Fourth Circuit even hints that the "product of nature" doctrine is not a doctrine at all, but a synopsis of the poor batting average of natural product claims in surmounting 35 U.S.C. 102 and 103 rejections: ". . . where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained."[52] In a case relating to a later, continuation-in-part patent, it was held that "(b)efore Rickes and Wood made it available to the world, pure crystalline vitamin B-12, as described and claimed in the '794 patent, did not exist."[53]

Sterling Drug, Inc. v. Watson[54] involved a claim to levo-arterenol, which could raise a person's blood pressure without increasing the rapidity of the heartbeat. Plaintiff had isolated levo-arterenol from the racemic mixture of the two isomers, levo-arterenol and dextro-arterenol. The racemic mixture could not be used therapeutically without "deleterious results."[55] Testimony showed a long period of prior unsuccessful attempts to resolve the racemic mixture (which was not a mere physical mixture) into its isomeric components, without success.[56] The court held that the claim to the salt of levo-arterenol, "being crystalline and substantially pure form and being substantially free from its optical antipode" was directed to an "unobvious" substance.[57]

When the parent substance contains so little of the active ingredient that the utility of the parent substance is marginal, patentability may be found.

In *Charles-Pfizer & Co., Inc. v. Barry-Martin Pharmaceuticals, Inc.*,[58] the tetracycline patent was sustained even though trace amounts had been co-produced in the biosynthesis of Aureomycin. The naturally produced tetracycline, sensitive to

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[51] Merck & Co., Inc. v. Olin Mathieson Chem. Corp., 116 U.S.P.Q. 484, 488-490 (4th Cir. 1958).

[52] Id., 488.

[53] Merck & Co., Inc. v. Chase Chemical Co., 155 U.S.P.Q. 139, 151 (D.N.J. 1967).

[54] Sterling Drug Co. v. Watson, 135 F. Supp. 173 (D.D.C. 1955).

[55] Id., 175.

[56] Id., 174.

[57] Id., 176. *See* claim 10 at 174.

[58] 145 U.S.P.Q. 29 (S.D. Fla. 1965).

alkali, decomposed in minutes. The presence of tetracycline in Aureomycin broths was not recognized by others at the time the Conover application was filed. "Since the prior art Aureomycin fermentation broths and antibiotics contained insufficient tetracycline to be of any benefit to mankind, they do not as a matter of law negate the validity of Conover's patent claims."[59]

In *Ex parte Reed*, the Board considered a claim to the natural growth-stimulating substance alpha-lipoic acid, present in liver in some form in extremely small amounts. In its first decision, the Board pointed out that "liver has been used effectively in growth promotion and stimulation," *i.e.*, the parent substance had therapeutic value.[60] On reconsideration, the Board reversed the examiner, as alpha-lipoic acid did not exist "as such" in the source material," and because "large quantities of liver . . . are needed to obtain the claimed patent factor in effective amounts.[61] *In re Doyle* involved the compound 6-aminopenicillanic acid (6-APA), recovered from the fermentation liquor of penicillin-producing molds. 6-APA, in pure form, is a useful starting material for the production of certain antibiotics. In fermentation broths, it existed only in a dilute form. "[W]hen 6-APA with a purity of less than 90 percent is acylated the amount of an antibiotic of requisite quality obtained is reduced in yield too far for commercial acceptance." Hence, *substantially pure* 6-APA was patentable even though 6-APA was apparently detected by earlier researchers.[62]

While most of the cases relating to purified natural products can be characterized as merely noting that the purification of a useful natural product to intensify its effect would, in most fields of technology, be an obvious goal, two cases seem at odds with this analysis.

General Electric Co. v. DeForest Radio Co. rejected Coo-

[59] Id., 32. Compare Chas. Pfizer Co. v. FTC, 401 F.2d 574, 580-581, 583, 585 (6th Cir. 1968)(tetracycline present in "detectable" quantity in aureomycin broth).

[60] 135 U.S.P.Q. 34 (POBA, June 1961).

[61] 135 U.S.P.Q. 105 (POBA, October 1961).

[62] 140 U.S.P.Q. 421 (CCPA 1964).

lidge's claim to "a wire formed of ductile tungsten."[63] It had been believed by scientists that "tungsten is in nature highly brittle and therefore not capable of being drawn into wire.[64] Coolidge discovered that the *pure* metal was in fact ductile. With considerable forensic agility, the Third Circuit held that he was not entitled to his claim:

> Coolidge took tungsten as it "existed" (WO_3) or as it is found in the earth, its native abode, and by his process converted it into pure tungsten or tungsten that is substantially pure, and, doubtless, was first to discover that when pure it has characteristics, notably those of ductility and high tensile strength, which are wholly different from the characteristics of the impure oxide of tungsten, notable among which is extreme brittleness. What he produced by his process was natural tungsten in substantially pure form. What he discovered were natural qualities of pure tungsten. Manifestly he did not create its characteristics. These were created by nature and on that fact finding the reasoning as to the validity of the product claims will be based.[65]

Clearly, the teaching of the prior art was that pure tungsten would be brittle, whereas instead it was ductile and strong. Coolidge's pure tungsten had, in consequence, uses that impure tungsten or tungsten oxide would not. It could be used as a filament by the lighting industry, while the latter were used "largely, if not exclusively, . . . as an ingredient in the manufacture of metal alloys." It certainly would have satisfied 35 U.S.C. 103. The *General Electric* case is, perhaps, best read as another of the misconceived spawn of the "law of nature" doctrine, discussed *supra*. It is worse than most, in that the court played games with the facts. If tungsten was "not found except as the oxide," it was misleading for it to state that Coolidge did not "create" pure tungsten. He did not create the tungsten atom; but he did create tungsten metal. The Third Circuit admitted in its denial of the petition for rehearing that "it may be that in the complexity of the subject matter of the

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[63] 28 F.2d 641, 643 (3rd Cir. 1928). *See also* In re Marden, 47 F.2d 958 (CCPA 1931).

[64] Id., 642, citing earlier decisions "on radically different records."

[65] Id., 642-643.