
Distinguishing "Products of Nature" from Products Derived from Nature

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INTRODUCTION

Patent practitioners¹ are generally aware of: (a) the unpatentability of a "product of nature"² and (b) the patentability of living organisms.³ However, many practitioners have misunderstandings as to the criteria for distinguishing unpatentable "products of nature" from patentable materials of natural origin. This paper endeavors to explore and dispell those misunderstandings.

An initial exploration of the source of misunderstanding reveals that the courts and USPTO⁴ have held that a "product of nature" is not patentable⁵ while also holding that various chemicals,⁶ biochemicals,⁷ and organisms⁸ derived from nature are patentable. The term "product of nature" has been consistently used to label subject matter as unpatentable. The use of the "product of nature" label in the absence of a clear definition, has undoubtedly been the source of some confusion to both practitioners and their clients (generally scientists and corporate executives). Justice Frankfurter noted the potential for confusion on this point thirty-nine years ago and stated:

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1 Refers to patent agents and attorneys admitted to practice before the United States Patent and Trademark Office.

2 The term "product of nature" will be discussed throughout the paper, as will its use by courts, practitioners and scientists. See also Jacob, M. "Patentability of Natural Products," 52 J. Pat. & Tm. Off. Soc'y 473 (1970).

3 *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

4 Abbreviation for The United States Patent and Trademark Office. The actual holdings are by the Board of Appeals and Interferences of the USPTO.

5 *Funk Bros. Seed Co. v. Kaol Inoculant Co.*, 76 USPQ 280 (1948).

6 *In re Williams*, 80 USPQ 150 (CCPA 1948).

7 *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*, 116 USPQ 484 (4th Cir. 1958).

8 See note 3 *supra*.

It only confuses the issue, however, to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. 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.⁹

The confusion, or least the uncertainty on this point has no doubt been affected by the recent Patent Office decisions of: (1) *Ex parte Hibberd*¹⁰ holding multicellular plants and seeds to be patentable and; (2) *Ex parte Allen*¹¹ holding that non-human multicellular living animals are patentable subject matter within the scope of 35 U.S.C. 101.¹²

Both *Hibberd* and *Allen* are holdings of the USPTO, as yet untested in a federal court¹³—a fact unappreciated by corporate executives investing tens of millions of dollars in the development of plants and animals with the expectation of being provided with a degree of market exclusivity via a U.S. patent enforceable in federal court. In addition, neither *Hibberd* nor *Allen* involves the use of any type of recombinant DNA¹⁴ technology let alone the specific technology used in *Chakrabarty*¹⁵—a fact unappreciated by many patent practitioners. The corn plant developed by Hibberd and his associates was produced

⁹ See note 5 supra. Frankfurter concurring at pg. 283.

¹⁰ *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int. 1985). The *Hibberd* case deals primarily with reconciling the 1952 Patent Act (35 USC Section 101 et. seq.) with the Plant Patent Act (35 USC Section 161) and the Plant Variety Protection Act of 1970 (7 USC Section 2321 et. seq.). An excellent discussion of these issues is contained in Linck, Nancy J. "Patentable Subject Matter Under Section 101—Are Plants Included?" 67 J. Pat. & Tm. Off. Soc'y 489 (1985). The article also includes excellent background information on 35 USC Section 101. However, such is outside the scope of the present article.

¹¹ *Ex parte Allen*, 2 USPQ 2d 1425 (Bd. App. & Int. April 3, 1987).

¹² 35 U.S.C. Section 101: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

¹³ Although U.S. patents are entitled to a presumption of validity in U.S. federal courts, there have been no court rulings on validity of patents covering multicellular life forms.

¹⁴ The term "recombinant DNA" will be used throughout this paper to mean DNA molecules in which base pair sequences which are not naturally contiguous have been placed next to each other by *in vitro* manipulations. The different base pair sequences within a recombinant DNA molecule will frequently have come from an entirely different organism. Note that some texts and journals use rDNA as an abbreviation for "recombinant DNA." However, rDNA has been used for years to refer to "ribosomal DNA" which are genes encoding for ribosomal RNA. Accordingly, the rDNA abbreviation will not be used herein.

¹⁵ A complete description of the technology can be found in U.S. Patent 4,259,444 issued 3/31/81 to Chakrabarty. In short, base pair sequences not normally found in an organism were incorporated into the organism by the *in vitro* manipulation of the inventor.

by conventional cross-breeding¹⁶ and the polyploid oyster developed by Allen and his associates was produced via hydrostatic pressure.¹⁷

A misinformed researcher may fail to advise the patent practitioner of his work because he believes it to be an unpatentable "product of nature." An uninformed corporate executive may invest (or fail to invest) tens of millions of dollars based on erroneous beliefs as to what subject matter is patentable. These decisions may be further ill-advised if based on uninformed expectations as to the enforceability of such patents. The unadvised practitioner may unrealistically raise or deflate the expectations of his clients adding to the uncertainty already surrounding industry.

Having explored the source of confusion and established that such may well exist, let us endeavor to dispell the confusion. This will be attempted by a review of the case law in which "product of nature" rejections and invalidity defenses have been raised. Concomitant with this review will be an effort to provide some guideposts which can be followed in judging what subject matter might be patentable even though it may at first appear to be an unpatentable "product of nature."

EFFECTS OF PUBLIC OPINION

It appears well settled that certain subject matter is not within the scope of 35 USC 101.¹⁸ Laws of nature such as the Law of Gravity, and the Second law of Thermodynamics are not patentable¹⁹—they represent pure conceptualizations not represented by any physical form²⁰ which could be encompassed by one or more of the terms of 35 USC 101. Other subject matter such as methods of doing business

¹⁶ See U.S. Patent 4,581,847 issued 4/15/86 and U.S. Patent 4,642,411 issued 2/10/87 to *Hibberd et al.*

¹⁷ See note 5 *supra*.

¹⁸ See note 6 *supra*.

¹⁹ An early statement on this topic was made by Justice Douglas in *Funk Bros.* (see note 5 *supra*) at pg. 281 as follows:

For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 14 How. 156, 175. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be an invention from such discovery, it must come from the application of the law of nature to a new and useful end. See *Telephone Cases*, 126 U.S. 1, 532-533; *De Forest Radio Co. v. General Electric Co.*, 283 U.S. 664, 684-685 [9 USPQ 297, 303-304]; *Mackay Radio & Tel. Co. v. Radio Corp.*, 305 U.S. 86, 94 [40 USPQ 199, 202]; *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453, 462-463.

²⁰ A conception of the mind not represented in some physical form is not invention. See *T. H. Symington Co. v. National Malleable Casting Co.*, Me. 1919, S. Ct. 542, 250 U.S. 383, 63 L. Ed. 1045.

have been held to be unpatentable, although subject to protection as a trade secret.²¹ Certain mechanical devices have been held to be "combinations"²² and therefore not within the scope of 35 USC 101. However, it is chemical, biochemical and biological materials which have generated the more interesting case law on the scope of Section 101. From time to time the resolution of these cases has attracted the attention of industry, the news media and the public in general. In that these cases generate such attention, the holdings are no doubt influenced, by the feelings, attitudes and opinions of industry executives, so called "consumer advocates"²³ and the general public. *The recognition and appreciation of public opinion influence on the development of the law interpreting Section 101 is the first guidepost to be mentioned in interpreting this area of law.*

Public opinion, or the perception of the courts, USPTO and patent practitioners as to what public opinion might be on an issue has a continuing influence on how the scope of 35 USC 101 is interpreted. The influence of public opinion and the perception of that influence can be seen as a prominent factor affecting many of the court and USPTO discussions analyzed below. However, patent practitioners rarely advise clients on the potential effects public opinion might have on what decision the USPTO will make and how the courts will interpret the scope of Section 101 based on the courts perception of current public opinion.

Those in favor of restricting the scope of Section 101 often argue that recombinant DNA technology is a source of tremendous environmental hazards.²⁴ Accordingly, it seems more than coincidental that

21 The leading treatise on the subject of trade secrets is "Milgrim on Trade Secrets" by Roger M. Milgrim, Matthew Bender (1984 N.Y.). Definitions of a trade secret are offered in Chapter 2 "Definitional Aspects," but the term "trade secrets" is not easily defined.

22 The mere aggregation of a number of old arts or elements which, in the aggregation, perform or produce no new or different function or operation than that theretofore performed or produced by them, is not a patentable "invention." *Great Atlantic & Pac. Tea Co. v. Supermarket Equipment Corp.*, Mich. 1950, 71 S. Ct. 127, 340 U.S. 147, 95 L. Ed. 162 rehearing denied 71 St. Ct. 349, 340 U.S. 918, 95 L. Ed. 663.

23 "Animal rights groups, including the American Humane Association, the National Anti-Vivisection Society, the Fund for Animals, and the American Society for Prevention of Cruelty to Animals, as well as the Foundation on Economic Trends, have petitioned the PTO to reverse its policy, deeming it 'morally reprehensible.' The petitioners' spokesman, Jeremy Rifkin, of the Foundation on Economic Trends, asserted that 'the new patent policy raises moral and ethical issues that are mind-boggling' and attacked the policy as a 'gross violation of the statutory intent of the patent laws.' He indicated that if the PTO does not rescind its policy, petitioners would urge Congress to overrule the agency." See BNA's Patent, Trademark and Copyright Journal, Vol. 33, No. 827, pg 664 (April 23, 1987) discussing the *Allen* decision.

24 *Id.*

Chakrabarty involved a microorganism designed specifically to eliminate an environmental hazard, i.e., degrade oil spills.²⁵ Further, *Ex parte Allen* involved a "slimy" oyster, not a "cute" kitten or seal pup. In addition, the oyster in *Allen* was found to be unpatentable for reasons apart from Section 101, demonstrating conservative judgment by the USPTO with respect to allowing patents to issue.

It may be that little can be done by the average practitioner or corporate executive with respect to influencing public opinion. However, an awareness of the effect of public opinion on holdings interpreting Section 101 is essential in planning future investments. Further, choosing a particular case based on its potential appeal to the public, and judging the timing for raising an issue on that case can be influenced and may well be determinative of the outcome.

CHEMICALS IN NATURE

Before the 1952 Patent Act²⁶ Roger J. Williams applied for a patent²⁷ on the laevo rotary form of a lactone compound.²⁸ The Patent Office took the position that the claimed invention was unpatentable in that a racemic mixture²⁹ was known to exist and such mixture included equal amounts of the dextro and laevo rotary forms. Thus the rejection was a novelty rejection of the type now made under 35 USC 102.³⁰ The Court of Customs and Patent Appeals³¹ reversed the Patent Office holding "The existence of a compound as an ingredient of another substance does not negate novelty in a claim to the pure compound, although it may, of course, render the claim unpatentable for lack of invention."³² Although the *Williams* case deals with a

²⁵ The microorganism claimed in *Chakrabarty* contained "at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway." The organism was included on a carrier material such as straw and spread on an oil spill in water. See note 3 *Supra*.

²⁶ 35 USC Section 101 et seq.

²⁷ See note 6 *supra* (Application for Roger J. Williams, Serial No. 431,531, filed Feb. 19, 1942).

²⁸ The claimed invention was: "The laevo rotary form of alpha-hydroxy-beta, beta-dimethyl-gamma-butyro lactone substantially free from the dextro rotary form.

²⁹ A racemic mixture is a mixture of equal amounts of dextro and laevo rotary forms of a compound. The racemic mixture is optically inactive but the dextro and laevo rotary forms are optically active and rotate light to the right or left respectively. The two forms are mirror images of each other.

³⁰ 35 USC Section 102 Conditions for Patentability: Novelty and loss of right to patent.

³¹ This court no longer exists but became a part of The Court of Appeals for the Federal Circuit in 1982.

³² *In re Williams*, 80 USPQ 150, 151 (CCPA 1948).

novelty rejection the conceptual holding and its reasoning reappear in later decisions involving the scope of Section 101.

Art cited by the Patent Office against Williams disclosed racemic mixtures of lactones. Other art generally disclosed well known methods of separating a racemic mixture into its laevo rotary and dextro rotary forms. However, the art did not show that the known lactone compounds were known to be racemic mixtures. Absent such knowledge there would be no reason to apply known separation techniques to obtain the claimed laevo rotary form.

From *Williams* it can be seen that it is, under certain circumstances, possible to obtain patent protection on a chemical compound that exists in nature. The claims in *Williams* were structured so as to claim a compound (the laevo rotary form free of the dextro rotary form) which does not exist in nature by itself but only in combination with another compound (the dextro rotary form). Further, the compounds existing in nature (the racemic mixture) were not known to include the claimed invention. Williams disclosed the claimed compound to the public and for that disclosure was awarded a patent.³³ Absent the disclosure by Williams, the public would not benefit from the claimed laevo rotary form. Ergo, as a *second guidepost consider claiming chemical compounds not known to exist in nature by claiming them apart from their natural surroundings.*

BIOCHEMICALS IN NATURE

In 1926 it was found that patients suffering from anemia benefit from ingesting substantial amounts of the liver of cattle.³⁴ Liver extracts and concentrates were later developed, although science remained ignorant of what compound in the liver provided the benefit.

Researchers at Merck & Co., Inc. investigated fermentation products as a possible source of the anti-anemia compound. After years of research the desired compound was produced and isolated. A compound identical to the fermentation product was later isolated from liver and referred to as vitamin B₁₂.

The production of vitamin B₁₂ by fermentation is economically much more desirable than production via liver extraction. Further, pure or nearly pure forms of vitamin B₁₂ have greater activity than liver or liver extracts and concentrates. The invention was claimed as

³³ In patent law the disclosure to the public of the invention is considered the *quid pro quo* or consideration from the inventor in return for the patent grant from the government.

³⁴ *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*, 116 USPQ 484 (4th Cir. 1958).

a vitamin B₁₂ active composition recovered from a fermentation product, with the composition having a minimal active strength.

In *Merck* the claimed invention was held to be patentable and not an unpatentable "product of nature." The "claimed vitamin B₁₂" was distinguished from "natural vitamin B₁₂" by its means of production and level of activity. In *Williams* no arguments were made based on claim language directed to methods of production or level of activity. Thus *Merck* and *Williams* are distinguishable with respect to the type of claim language and arguments by which they were able to patent a compound which existed prior to discovery by the respective inventors, but alike in that neither compound, although existing, was known prior to their invention. It is well settled that an unknown compound or composition of materials merely discovered from nature is not patentable.³⁵ Thus it is not the discovery, by itself, of previously unknown compounds in *Williams* and *Merck* that provided for patentability. However, that discovery allowed the respective inventors to fashion an invention which could be claimed as distinct from a "product of nature." This deduction leads to the third guidepost which is that *the discovery of a product in nature, although not an invention, may well lead to an invention by the use of proper claim language.* Claim limitations can be used to describe a physical separation of the discovered compound from its natural surrounding (as in *Williams*) or to describe its means of production and activity (as in *Merck*).

There are a number of variations in which claim language can be used to obtain the desired protection on a compound discovered in nature. One successful variation was used to claim a prostaglandin compound in *In re Bergstrom and Sjoval*³⁶ (hereinafter *Bergstrom*). Prior to *Bergstrom* it had been known that certain secretions and extracts from certain animal glands had a pharmacodynamic effect. The inventors in *Bergstrom* isolated compounds in these secretions which could be used without producing undesirable side effects or reactions. The compounds were claimed as being "sufficiently pure to give a substantially ideal curve on partition chromatography." This language successfully overcame the "product of nature" rejection.

Bergstrom is like *Williams* in that the claimed compound is described as being physically separated away from its natural surroundings and

³⁵ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 76 USPQ 280 (1948). See also cases cited in note 19 supra.

³⁶ *In re Bergstrom and Sjoval*, 166 USPQ 256 (CCPA 1970).

like *Merck* in that the claimed compound had a different functional characteristic than the complete composition existing in nature.

In *Williams* it was mentioned that the rejection was a 102 novelty type rejection. The claimed laevo rotary form was argued as being old in view of the racemic mixture. In *Bergstrom* the court pointed out that

... the criteria for determining whether a given subject matter is "new" within the meaning of Section 101 are no different than the criteria for determining whether that subject matter possesses the "novelty" expressed in the title of Section 102. The word "new" in Section 101 is defined and is to be construed in accordance with the provision of Section 102. Thus, that which possesses statutory novelty under the provision of Section 102 is also new within the intendment of Section 101. We have found no evidence of Congressional intent to define the word "new" as used in Section 101 in any different manner.³⁷

It is well settled that having met the "novelty" requirements of Section 102, one must also meet the unobviousness requirements of Section 103.³⁸ Since "novel" under Section 102 and "new" under Section 101 have the same legal meaning, it seems axiomatic that having met the "new" requirement of Section 101, one must also meet the unobviousness requirements of Section 103 by the criteria for judging unobviousness set down in *Graham v. John Deere Co.*³⁹ (hereinafter *Graham*). Thus a fourth guidepost can be deduced which is that *the patentability of a compound derived from nature can in part be judged by determining the "novelty" of that compound as compared with the "product of nature" (or "prior art") from which the compound was derived.*

CHAKRABARTY

In the cases discussed above, the patentable invention, was in some fashion, taken out of a larger group of compounds existing in nature. In *Chakrabarty* the claimed microorganism was rendered patentable by adding material not normally present in the genome of the organism. Although neither *Williams*, *Merck* or *Bergstrom* involved patenting living material they all involved a "product of nature" issue.

³⁷ *Id.* at page 262. In a footnote the court states: "That such is the case is clear, we think, from House Report No. 1923 and Senate Report No. 1979, 82nd Congress, 2nd Session, accompanying H.R. 7794 which became the 1952 Patent Act. Both reports state the identical language:

Section 102, in general, may be said to describe the statutory novelty required for patentability and includes, in effect, an amplification and definition of "new" in Section 101.

³⁸ 35 USC Section 103 Conditions for patentability; non-obvious subject matter.

³⁹ *Graham v. John Deere Co.*, 148 USPQ 459 (1966).

In each case the claimed invention was found not to be a "product of nature," but to be a "new" compound under Section 101 and as such also "novel" and "unobvious" under Sections 102 and 103 respectively, i.e. "novel" and "unobvious" as compared with the "products of nature" from which they were or might be extracted.

Chakrabarty is distinguishable from the above cases on the "product of nature" issue in that the invention claimed involved changing the molecular structure of a previously known and isolated "product of nature" as opposed to discovering and extracting the invention. Chakrabarty's claimed organism was modified to the extent that it was considered "new" under Section 101 and as such "novel" under Section 102. Functional characteristics of the "new" and "novel" organism so distinguished it from the original "product of nature" organism as to make the claimed organism "unobvious" under Section 103.

Chakrabarty is similar to conventional chemical cases in that basic molecular structure is altered in *Chakrabarty*, as it is in conventional chemical cases, to produce "new," "novel" and "unobvious" chemistry which can be claimed in a patent. However, in another respect *Chakrabarty* is similar to "product of nature" cases like *Williams*, *Merck* and *Bergstrom*. In *Chakrabarty* as in *Williams*, *Merck* and *Bergstrom*, the claimed invention was compared with a "product of nature" for purposes of determining whether the claimed invention was "new," "novel," and "unobvious." The claimed invention of *Williams* (the laevo rotary form) was compared with the racemic mixture existing in nature. The claimed invention of *Merck* (the vitamin B₁₂ fermentation product) was compared to the liver extract existing in nature. The claimed invention of *Chakrabarty* (the organism containing additional DNA) was compared with the organism as it existed in nature. With this analysis a fifth guidepost can be deduced in determining patentability in "product of nature" type cases as follows: *Compare the claimed invention with the product as it exists in nature and determine unobviousness by applying the criteria as established in Graham.*

The *Graham* criteria can be applied as follows: (1) Determine the scope and content of the prior art. More specifically, determine the chemical, physical and functional characteristics of the naturally occurring material, e.g. its structural formula, purity and degree of activity. (2) Ascertain the differences between the claimed invention and the naturally occurring material. This can be done by determining the chemical, physical and functional characteristics of the claimed

invention and comparing such with those characteristics as determined in (1) above. (3) Resolve the level of ordinary skill in the pertinent art. The manner in which this is done varies greatly from case to case. In general one must resolve how one of ordinary skill in the art can use existing knowledge and techniques to obtain the claimed invention from the material as it exists in nature.

THE PROGENY OF CHAKRABARTY

Although *Bergy*⁴⁰ might be considered a sibling and not the progeny of *Chakrabarty*, it was not until the U.S. Supreme Court resolved the public opinion issue of "life," being patentable in *Chakrabarty* that *Bergy* was finally resolved. But for the public opinion issue on the patentability of "life" *Bergy* was more akin to *Williams*, *Merck* and *Bergstrom* than to *Chakrabarty*. The organism claimed in *Bergy* was not the subject of recombinant DNA technology as was the *Chakrabarty* organism. The invention claimed in *Bergy* was extracted from and claimed apart from its natural surrounding much like the inventions claimed in *Williams*, *Merck* and *Bergstrom*.

Both *Chakrabarty* and *Bergy* involved the patenting of a single cellular organism. Thus the next logical step would appear to be the patenting of a multicellular organism. With apparent consideration toward public opinion the USPTO choose to allow the patenting of multicellular plants in *In re Hibberd*⁴¹ prior to multicellular animals. The *Hibberd* case was unlike *Chakrabarty* in that Hibberd and his associates did not employ the use of recombinant DNA technology to produce the claimed invention.⁴² *Hibberd* is also unlike *Williams*, *Merck*, *Bergstrom* and *Bergy* in that the corn plant patented in *Hibberd* was not in existence prior to the work of Hibberd and his associates. There was no corn plant to be discovered and extracted from nature in the manner in which *Williams* discovered and extracted the laevo rotary form of a compound from the existing racemic mixture.

In a similar vein, no polyploid oyster existed in nature prior to the work carried out by *Allen*. The polyploid oyster was produced by the application of hydrostatic pressure to an embryonic oyster. Thus *Hibberd* and *Ex parte Allen* are alike in that neither involved the

⁴⁰ *In re Bergy et. al.*, 201 USPQ 352 (CCPA 1979). See the Linck article cited in note 10 supra for a more detailed discussion of *Bergy* and its history along with that of *Chakrabarty*.

⁴¹ *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int. 1985) See also note 10 supra and Krosin, Kenneth E. "Are Plants Patentable under the Utility Patent Act?," 67 J. Pat. & Tm. Off. Soc'y 220 (1985).

⁴² See notes 14 and 16 supra.

use of recombinant DNA technology to add new DNA and thus create a "new" and "novel" organism as was done in *Chakrabarty*; and neither involved the discovery of something which had existed in nature, which was then claimed apart from its natural environment in some manner in order to scope out a claimable invention based on that discovery.

In that the *Hibberd* case resulted in the granting of a patent and the *Allen* case did not, some basis for distinguishing their facts must be pointed out. In *Hibberd* the claimed corn plant possessed a characteristic not previously possessed by any corn plant. However, in *Allen* the claimed oyster possessed characteristics which had been previously possessed by another oyster. Thus as a sixth guidepost note that *the first to induce a "product of nature" to possess a new characteristic, regardless of the manner of inducement, is likely to have produced a patentable invention.* The new characteristic can be induced by conventional technology such as the cross-breeding applied in *Hibberd* or recombinant DNA technology as in *Chakrabarty*.

The manner in which the "product of nature" is induced to possess a new characteristic is important only with respect to patenting the manner of inducing the new characteristic, not to the patenting of that product with its new characteristic. In the *Williams* case as in *Hibberd* the claimed invention was provided by the application of known procedures to the "product of nature" racemic mixture. The invention was obtained in both cases by an understanding of what actually existed in nature, and using known procedures to manipulate a "product of nature" to obtain the claimed invention. As a seventh guidepost note that *a means of modifying a "product of nature" has little if any effect on the patentability of the modified product of nature.*

CONCLUSION

In each of the "product of nature" cases discussed above, the claimed invention was disclosed to the public by the inventor in exchange for the patent grant. Thus the *quid pro quo*⁴³ of patent law is maintained in these cases just as it is with all other patent grants. A close examination of these cases shows that patents are not being granted on "products of nature" but rather on true inventions derived from naturally occurring substances. In the final analysis all inventions are derived from other naturally occurring substances.⁴⁴ Corn plants and

⁴³ See note 33 supra.

⁴⁴ See text accompanying note 9 supra.

vitamin B₁₂ are no less entitled to patent protection than mechanical engines or electronic computers simply because the subject matter relates to biological or biochemical subject matter as opposed to the subject matter of mechanical or electrical engineering.

For convenience the seven guideposts are put forth below:

1. Recognize and appreciate the influence of public opinion of the development of law interpreting Section 101.
2. Consider claiming chemical compounds not known to exist in nature by claiming them apart from their natural surroundings.
3. The discovery of a product in nature, although not an invention, may well lead to an invention by the use of proper claim language.
4. The patentability of a compound derived from nature can in part be judged by determining the "novelty" of that compound as compared with the "product of nature" (or "prior art") from which the compound was derived.
5. Compare the claimed invention with the product as it exists in nature and determine unobviousness by applying the criteria as established in *Graham*.
6. The first to induce a "product of nature" to possess a new characteristic, regardless of the manner of inducement, is likely to have produced a patentable invention.
7. The means of modifying a "product of nature" has little if any effect on the patentability of the modified product of nature.

The seven guideposts mentioned above are by no means inflexible. No doubt others will find ways to state them more succinctly⁴⁵ and find exceptions to them or even among them. Hopefully, however, they will provide some insight and understanding on how to distinguish an unpatentable "product of nature" from a patentable invention and as such "promote the progress of science and the useful arts."⁴⁶

⁴⁵ For example, Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks released a statement to the public on April 7, 1987 which reads in part: "An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law." See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Broadex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Grayson*, 51 USPQ 413 (Bd. Appl. 1941)."

⁴⁶ U.S. Constitution, Art I, Section 8.