APPENDIX. LEGAL ACTIONS & HISTORY

CONTENTS

APPENDIX

COPYRIGHT & TRADEMARK

Copyright

The first intellectual property right-based legal premise incorporated into indigenous lifestyle and legal practice pertains to national and international copyright issues.

Copyrights laws pertain to the potential utility of written or artistically-created material. Since many indigenous cultures kept much of their history in oral and artistic forms, this information about their family and social history, myths, legends, and music pieces, until recent decades, lacked legal protection.

A brief look at the works of art and history provide us with examples of what has historically happened to important indigenous group lifestyle practices and the related information.

Artistic works have historically been treated as materials which could be bought and sold, and thereby legally controlled by ownership rights. Even artistic pieces such as sacred religious items, family ritual pieces, and ancestral remains become subject to the legal rights dictating the rights of their owners, not their artisans or creators. Unwritten musical pieces, once more popular as objects of curiosity to many history, folklore and anthropology researchers, are currently judged to be uncopyrighted and therefore reproducible, either in writing or music, by researchers or entrepreneurs in search of economic benefits from their sale and dispersal.

Many anthropological and historical writings on traditional cultures and beliefs have, in theory, been protected by copyright upon their publication. They are placed in the public domain through publication, and are controlled by the author and publisher until the copyright expires. The applications of this law to indigenous cultures and their intellectual property deal with published tribal myths, legends, folktales, religious writings, art pieces, and music. In addition, since some of these artistic renderings (such as ritual songs, masks and carvings) might still be in use by developing countries as trade or family secrets, such inclusion of them in the public domain as writings, museum displays, and the like, often causes internal personal, theosophical, and political concern within indigenous cultures.

APPENDIX

Oral history, myths, legends, music, and art

In its simplest form, intellectual property consists of the information that exists as oral histories and as culturally and socially-derived know-how. Oral histories include folk tales, myths, and legends, as well as knowledge essential to personal and social survival. Cultural and social know-how relates mainly to the non-verbal work of the peoples' artisans, philosophers and theosophers. Examples of this knowledge include the religious and metaphysical value of the eagle feather and mescal button, the economic importance of the shaman's hunting and fishing knowledge, and the artist's ability to construct a mask from plant and animal parts.

In recent years, return of this material has become a major issue now troubling many historians, anthropologists, museums, and salesmen. Whereas a decade ago, the claim was that many of these objects were considered sacred, and therefore important to traditional religious practices. More recently, ownership of these items has been also labelled a violation of specific cultural rights, a potential legal issue exacerbated by the mimicry of these artistic designs by non-traditional, and often economically-driven artisans.

When these actions are analyzed in relation to their compliance top the related legal rights, we find that since most of the artistic samples, related folktales, myths, legends, and history, and other anthropology writings, have been published as early as the first colonial settlements, much of this information, written and artistic, are in the public domain. Thus, the results of the numerous aboriginal research projects responsible for this documentation have resulted in a sharing of potential rights to publishing and re-publishing large amounts of already well-known traditional knowledge.

The value of European and Euro-American law in the evaluation of this type of information for the future pertains mostly to unrevealed forms of art and oral history,

which until its publication remains more supported as a trade secret.

Therefore, during the early years of these past one-hundred fifty years of anthropology research, much of traditional oral history recorded and then made public through anthropology, history and folktale writings is in the public doamainm, and in spite of the moral issues involved with this form of cultural-robbery, little can be done except to try and compensate for the financial losses which may have ensued. The one fact about this information in favor of the traditionalists, morally speaking, is the misstating, misrepresentation, or manufacturing of such past knowledge. Much of the information first documented in the late nineteenth century has these potential problems, in part by being contrived for money by the interviewees, a possibility only recently addressed by researchers.

By law, the sum of the events involving the oral and written dissemination of traditional knowledge (even that knwoeldge which was private, sacred, and secret) places it into the public domain. Several decades later, this same knowledge can then be rewritten or retold by anyone with or without an association with the original source, regardless of whether or not is it solely for an economic purpose, such as through story-telling of the writing of a new book.

Thus, in moral terms, the extensive research and documentation of traditional know-how has in turn jeopardized the cultural integrity, meaning and value of that knowledge. Much of this traditional knowledge in essence changes from being equivalent to existing as a culturally-defined trade secret, to a public domain entity. With oral histories and artwork, this outcome has had economic effects due to the lack of control of marketing such items and controlling or receiving even a small, fair portion of the related income accrued from and related manufactures and sales. A similar history exists with trade secrets defined individually, such as the knowledge of medicine possessed by the shaman or medicine man, in which case the legal issues relate more to trade secrecy rights,

rather than the impact of public domain due to past publications by researchers.

Trademarks

Later, and again most recently, trademark laws have been put to use to deal with the abuse or misapplication of traditional nomenclature and intellectual property taking place. Indigenous group names, such as those used to increase the sales of a product (such as "Hopi Blue Corn" snack items), or improve popularity and name recognition (such as the United States numerous athletic teams bearing Native American names), have received the political and public criticism. Even more recently, legal writers have suggested that indigenous groups trademark their cultural name, thereby providing them with some control over the use of such a name in the public eye for potential income.

PATENTS

CONTENTS

APPENDIX

PART I. DEFINING PATENTS

PATENTABLE PLANT MATERIAL

Source: Brian P. O'Shaughnessy. 1994. Patentable Subject Matter. In Kenneth D. Sibley (ed.). *The Law and Strategy of Biotechnology Patents*. Boston: Butterworth-Heinemann. pp. 61-74.

Section 101 of the Federal patent statute discusses novelty, utility ("practical utility" and "operability"), and statutory subject matter.

Products of Nature:

> ". . .a thing occurring in nature, which is substantially unaltered, is not a manufacture." Section 706.03(a), *Manual of Patent Examining Procedure*.
>
> two requirements:
>
> --isolation and purification of a product from its natural state is required,
>
> --there must be a novel use of the product.

The Usefulness of Chemicals

> Chemicals must have a utility to be patented. The patent filed must be specific about that use, not general through the use of "nebulous" expressions. Practical utility must be claimed, although some judges feel all chemical compounds have some form of utility.

APPENDIX

Analysis

During the late nineteenth century, the "Product of Nature" Doctrine was used by the Patent Office to reject patents for products synthesized from newly discovered plants. For artificially-synthesized compounds akin to their natural sources. the "non-obviousness doctrine" was used by courts to argue the patent claim, i.e. in *Cochrane v. Badische Anilin & Soda Fabrik*. 111 U.S. 293 (1884), a patent was submitted for Artificial Alizarine Dye, but since the chemical make up of Alizarine was then common knowledge and that of the artificial dye similar to that made from madder root, the state claimed "[c]alling it artificial alizarine did not make it a new compound of matter, and patentable as such." An "unobvious difference" needs to exist between the claimed product and any prior art product before a patent will be accepted.

In each of these cases, although the chemical end product was not patentable, methods of production of similar product that give the industry an edge on production could be patented, thereby enabling chemical industries to patent numerous new forms of synthesis and manufacturing processes (Burchfiel, 1995, pp. 61-3).

APPENDIX

ISSUES AND SAMPLE CASES

Issue 1. Substances of truly natural origin are not patentable.

Parke-Davis v. H.K. Mulford Co., regarding the patent of adrenalin, was refused the patent due to the ubiquitous nature of adrenalin in many living animals.

Merck & Co. v. Olin Mathieson Chemical Corp. regarding Merck's patent of Vitamin B_{12} as anti-pernicious anemia factor. Since this vitamin was the result of nature, and not any drug company productivity, it is natural in origin and not patentable.

Issue 2. Substances of natural origin which have been modified from their original natural state are patentable, i.e. isolation and purity may be required to patent a product of nature.

The first patent issued in the United States was to Louis Pasteur for "yeast, free from organic germs of disease, as an article of manufacture."

According to the 1952 Patent Act, Congress decided could include "anything under the sun that is made by man." Since the growth and development of microorganisms in vitro could be inferred as a variation of the isolation and purification requirement, microorganims patents became possible. Subsequently in 1967 and 1968 two micro-organism patents were approved.

In 1980, *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 100 S.Ct. 2204, 2207-08, 206 USPQ 193 (1980) Ananda Chakrabarty wished to patent a microorganism capable of breaking down crude oil in oil spills. Initially, the patent application was rejected due to the definition of micro-organism as a "product of nature," which is not patentable according to Section 101.

A subsequent review of Chakrabarty's claim led to its final approval usinhg the argument that Chakrabarty's claim did not solely refer to a microorganism, but rather to a "hitherto unknown natural phenomenon. . . a nonnaturally occurring manufacture or composition of matter--a product of human ingenuity" considered by the court to be of unique nature and utility to mankind.

Chakrabarty's case has allowed for later legal analyses to take place concluding that living things were no longer excludable from patent (O'Shaughnessy, 1994, pp. 65-66).

Issue 3. Organisms from nature are patentable so long as they are not completely of natural origin, or patented in their purely natural state.

The first animal patent, *Transgenic Non-Human Mammals*, U.S. Patent No. 4,736,866, was submitted by P. Leder and T. Stewart to the European Patent Office. This patent, issued on April 12, 1988, was of an organism colloquially named "Harvard Mouse," a genetically-engineered non-human animal containing an oncogene (cancer-producing gene). The European Patent Office, Board of Appeals, Examining Division, made their decision based upon by a review of their Article 53(a), which weighed out the following factors:

"the interest of mankind to remedy disease";

"the need to avoid cruelty to animals";

"the need to protect the environment from the dissemination of unwanted genes."

This legal decision facilitated the later acceptance of three more animal patents (ibid, p. 68):

T. Wagner and X.-Z. Chen. Virus-Resistant Transgenic Mice, U.S. Patent No. 5,175,385. December 29, 1992.

P. Krimpenfort and A. Berns, Transgenic Mice Depleted in Mature T-Cells and Methods for Making Transgenic Mice, U.S. Patent No. 5,175,384. December 29, 1992.

P. Leder and W. Muller. Animal Model for Benign Prostatic Disease, U.S. Patent No. 5,175,383. December 29, 1992.

Issue 4. New and useful chemical compounds from plants are patentable when they display "chemical nonobviousness." Biotechnology and Non-obviousness have important applications in the future development of patentable and marketable plant product ~~industr~~ies.

Source: Shawn P. Foley. 1994. Nonobviousness. In Kenneth D. Sibley (ed.). *The Law and Strategy of Biotechnology Patents*. Boston: Butterworth-Heinemann. pp. 93-116.

Description:

The patent must be copyable by a hypothetical person with "ordinary skills in the art" (p. 95-96)

There must be a long felt need for such products and a period of prior failure during which experts in the field have been unable to achieve the goals of the patent now being applied for (Foley, 1994, p. 101-2).

Non-obviousness requires the absence of *Primae Facie* Obviousness and Structural Obviousness. If the production of the product seems "Obvious to Try," then patentability becomes questionable (p. 106, 109).

Analysis:

In theory, this argument might have related to the patenting of important chemical constituents present in the soap- or steroidal saponin-bearing Euphorbs of India. Due to the uniqueness of this discovery to chemical technologists in the developed countries, and the ability of chemists to purify the saponins responsible for the molluscicidal effect, the end product of a plant ubiquitous to such developing countries as India and Laos became patentable by developed countries where such use of a plant is generally considered to be novel and scarce.

APPENDIX

Related Laws:

United States Code. Section 103, Patent Statute, 1952.

In re Papesch. 315 F.2d 381, 137 USPQ 43, 47 (C.C.P.A. 1963).

> This case shows how courts can prevent biotechnology patents from occuring. Certain trialkyl hetero-aromatics claims were non-obvious, and patentable over prior art. Papesch also discovered the compounds had "unexpectedly potent anti-inflammatory activity," but disclosed this evidence only in an additional affadavit form added later during a dispute with the court. The compound was considered "obvious beyond a shadow of a doubt" to chemists, and so could not be patented as novelty, in spite of its usefulness. The affidavit was not considered.

In re Durden. 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985).

> Invention as a whole requirement. Insecticidal carbonates, using specific heterocyclic oxime starting materials, was a case in which the final product, and the pathway for synthesis were already patented seaprately, although not necessarily for the same reasons. Thus novelty and nonobviousness became hard to prove. This has served as a means to deny many biotechnology claims.

Ex parte Allen. 2 USPG2d 1425, 1427 (Bd. Pat. App. 1987). allows animals to be statutory subject matter. (p. 94)

APPENDIX

HISTORY OF PLANT, PLANT VARIETY, & UTILITY PATENT ACTS

1883. Convention of Paris for the Protection of Industrial Property, 20 March 1883.

1930. Plant Patent Act accepted. 17 year rights was granted for a plant that is asexually propagated.

1961. International Convention for New Varieties of Plants (UPOV).

PVPA rules in compliance with UPOV.

1963. Plant Breeders Rights meeting.

1964. A.A. Hanson and M.G. Weiss (ed.) *Plant Breeders' Rights*. ASA Special Publication no. 3. Madison WI: ASA, CSSA.

1968. Plant Variety Rights meeting.

1969. R.V. Frakes (Program Chair). *Variety Protection by Plant Patents and other Means*. CSSA Technical Series 1. Madison, WI: CSSA.

(At first, this act dealt mostly with Corn, Wheat, and alfalfa, and some cotton and sugarbeet.)

1970. Plant Variety Protection Act accepted.

1980. Utility Patent Act accepted. A Supreme Court decision made microorganisms patentable subject matter.

1983. European Patent Convention (EPC). Commission of the European Communities. Proposal for a Council Directive on the Legal Protection of Biotechnical Inventions.

The EPC precludes patent protection for plant and animal varieties through Article 53(b), but doesn't prohibit protection of plants and animals claimed generically and genetically.

Compulsory (Dependency) Licensing requirement.

1985. The Board of Patent Appeals and Interferences established the 17 year Utility Patent, to help stimulate additional research and inventiveness.

APPENDIX

Ex Parte Hibberd, 1985, Dr. Kenneth Hibberd patented a high-tryptophan producing variety of *Zea mays* (corn). This genetic trait, due to a recessive gene, was later incorporated into other agricultural products including potato (*Solanum tuberosum* L.) and carrot (*Daucus carota* L.) (Bent, 1989, pp. 111-112)

APPENDIX

References

Stephen A. Bent. 1989. Patenting Genes that Encode Agriculturally Important Traits. In C.W. Stuber (ed.). *Intellectual Property Rights Associated with Plants*. ASA Special Publication no. 52 (Madison, WI: CCCA/ASA/SSSA), pp. 109-122.

Orville G. Bentley. 1989. Implications of Plant Patenting for Science, Technology, and Agriculture. In C.W. Stuber (ed.). *Intellectual Property Rights Associated with Plants*. ASA Special Publication no. 52 (Madison, WI: CCCA/ASA/SSSA), pp. 171-173.

Robert J. Jondle. 1989. Overview and Status of Plant Proprietary Rights. pp. 1-15.

APPENDIX

Introduction

The international view of "biological creations" and agricultural advances is that they are distinct from "industrial" inventions. Thus genetic patents and natural product patents are less common in other countries. Changes in this view of plant and their products were brought about by people who felt the need to protect plant-related inventions or who saw the option of protecting animals as patentable objects (i.e. Harvard Mouse patent). As a result, U.S. Law now enables corporations to patent "genes of agriculture" and monopolize certain natural products (Bent, 1989, p. 109).

Examples:

> *Ex Parte Hibberd*, 1985, Dr. Kenneth Hibberd patented a high-tryptophan producing variety of *Zea mays* (corn). This genetic trait, due to a recessive gene, was later incorporated into other agricultural products including potato (*Solanum tuberosum* L.) and carrot (*Daucus carota* L.) (Ibid, pp. 111-112).
>
> Monsanto Company's n-phosphonomethylglycine (Glyphosphate/TM) producing gene (Ibid, p. 115).

Whereas PPA and PVPA protect phenomic (physical) characteristics, features, or traits, Utility Patents [UP] protect a single trait in a particular plant. This trait must not only be novel, but also non-obvious to one of the "ordinary" skill in the current state of the art. This non-obvious doctrine is what allows for the possibility of patenting uses for plants determined through anthropological work. Should that work not be heavily publicized, the "discovery" of a particular plant use made by such a researcher could be argued as non-obvious except to the local people from whom this knowledge came (Bentley, 1989, p. 171-173).

This method of applying traditional knowledge has numerous applications.

bio/phytochemical? medical?

PLANT PATENT [TOWNSEND-PURNELL] ACT (PPA). 1930.

Sources: Bennett, 1994, pp. 172-175; Jondle, 1989, p. 7; Williams and Weber, 1989, p. 92.

35 U.S. Code Sections 161-164 .

Description:

17 year patent.

Plant breeding asexually is viewed as an "aid to nature" (Bennett, 1994, p. 172).

PPA allows for patenting a specific variety of a plant, not a series of varieties in a given trait, i.e. a plant patented as "African Yellow Violet" must bear a flower type matching the patent description.

As of a 1940 decision (*In re Arzberger*, 112 F. 2nd 834, 46 U.S.P.Q. 32 [(Court of Custom and Patent Appeals), 1940]), PPA is not applicable to uncultivated plants, bacteria or fungi, but is only good for seed-bearing plants (monocots and dicots) (Williams and Weber, p. 92)

PPA was amended in 1953 to provide protection for newly found plants once they are asexually propagated and then proven cultivable.

PPA cannot be obtained for seeds, tubers, plant parts, biotechnology processes, recombinant DNA practices, and genes.

These plants must typically be of a distinct phenotype. The nonobvious requirement is met if the plant has a distinctive quality, nonobvious to skilled breeders, produced by its phenotype (Williams and Weber, 1989, p. 93)

PPA does not prevent the sexual reproduction of a patented variety, only the asexual reproduction of such a variety. Therefore, it is assumed by the patent holder that the plants filed for protection by PPA can only be reproduced asexually. Any new varieties of an already patented plant reproduced by the asexual propagation of that patented plant may also be patented as separate inventions.

In *Ex parte Foster*, 90 USPQ 16 (Bd. Pat. App. 1951), the court decided that there is no inventive step for a plant variety when that discovered is made in the wild, even if that plant is later asexually reproduced. In other words, the invention or discovery must be of something that did not previously exist, and a "newly derived" plant must qualify

as an "invention" in order to qualify (Bennett, 1994, p. 173).

Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 193 USPQ 264 (5th Cir. 1976) cert. denied 429 U.S. 1094, 200 USPQ 128 (1976).

> "If the plant is a source of food, the ultimate question might be its nutritive content or its prolifancy. A medicinal plant might be judged by its increased or changed therapeutic value. Similarly, an ornamental plant would be judged by its increased beauty and desirabilty in relation to other plants of its type, its usefulness in the industry, and how much of an improvement it represents over prior ornamental plants, taking all of its characteristics together." This has considered to be a flawed analysis, for a "variety" that is "distinct" may also be "non-obvious" (ibid p. 179).

Sample phrasing for a Plant Patent:

> "We claim, a new and distinct variety of genus. species herein described and illustrated and identified by the characteristics enumerated above together with the parts thereof" (Williams and Weber, 1989, p. 92)

Conclusions:

For patent purposes, botanical descriptions must be concise, and include detailed drawings, color presentation, etc. The court must be able to make a comparitive analysis using the features given in the patent description. Typically, the USDA Agriculture Research Service must also review such patents before they can be approved.

PLANT VARIETY PATENT ACT (PVPA). 1970.

Sources: Bennett, 1994, pp. 175-177; Jondle, 1989, p. 7-9.

7 U.S.C. Sections 2321 *et seq*.

Description:

18 year patent.

$1800.00 fees (as of 1989)

A seed deposit (voucher seed sample) is required, consisting of 2500 seeds, with viable replenishment every three years, or whenever requested.

This plant seed is considered proprietary, and is not available for others to access and make use of. After 18 years, it is put in the National Seed Storage Laboratory.

During the Patent years, new products can be produced from these seeds only under licensure by original owner.

Not good on hybrids.

Administered by the US Department of Agriculture, which offers the patent holder a PVP Certification. PVP Certifications issued then appear in *Plant Variety Protection Office Official Journal*. For Certification, novel varieties must be defined by:

1) distinctiveness: the variety must be distinguishable by its unique characteristics morphologically, physiologically, or otherwise.

2) uniformity: these traits must be uniform in character

3) stability: the plant must show stability in sexual reproduction, and be able to repetitively breed true-to-type.

Unlike PPA, which protects plant phenotypes, PVPA offers protection for specific genotypes.

PVPA cannot be provided for fungi, bacteria, tuber-propagated or uncultivated plants, and first generation plants.

PVPA offers crop (farmer's) and research exemptions.

Farmers can save some of the seeds to replant, assuming the the farmer harvests the remaining plant seeds for reasons

other than reproductive purposes. To satisfy this exemption, at least 51% of the crop harvested from the seed must not be used as next season's seed source.

PVPA also has a research exemption attached to it, enabling researchers to make better use of their crop.

PVPA excludes others from importing or exporting the same, carrying out asexual reproduction of it, or distributing it without prior notice. Owner of the PVP Certification can exclude others from producing hybrids with it. The process of developing the hybrid is allowed due to research exemption. Crop exemption allows the re-seeding of it from self-produced original crop-derived seed. "Brown bag" seed sales by farmers are allowed if stock of sold seed is 49% or less of the seed produced by the original crop.

As for Trade Secret, the sale of a seed or plant discloses its secrecy (Bennett, 1994, p. 177-8).

UTILITY PATENTS (UP). 1980.

Sources: Bennett, 1994, p. 178; Williams and Weber, 1989, p. 96-8.

Description:

35 U.S.C. 100 et seq.

17 year patent.

UP is used for plants or animals with uses applicable to biotechnological processes. Genes, seeds, plant parts, cultivars and hybrids may be patented.

Novelty, usefulness, and non-obviousness are required.

Non-obvious requirement means that an inventive step has to be carried out by one skilled in the art. (Ibid, p. 98)

The rules in use for UP are more stringent.

For plants, a plant or seed deposit is required to ensure availability to the public. This deposit must be maintained for at least 30 years, or 5 years beyond the last request for a sample from the deposit. Generally the Federal Seed Depository in Fort Collins, CO, is used for seed storage.

Public access to seeds is required. These seeds may be used by anyone interested in testing the plant or animal, but not in new plant or animal line production until 17 years have passed.

The seed deposits are required in order to meet the full disclosure requirements of the law.

All of this is practiced in accordance to Budapest Treaty in the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

No farmer's exemption or research exemption is allowed.

Since this is a patent for plant or animal utility, an adequate description of the plant or animal and its specific use(s) covered by the patent must be described. The underlying genetic characteristics responsible for these traits may need to be defined, along with their means of transfer and testing for presence.

Useful and powerful for plants and plant-related inventions and is not restricted to cultivars described in a patent or Plant Variety Protection certificate. Therefore, like uses by other closely related plants which fit the generic description of the patent might be protected by the Doctrine

of Equivalents which states that look-alike cultivars cannot each obtain a utility patent.

For proof of patent, certification is provided by The Plant Variety Protection Office, Division of the Livestock, Poultry, Grain and Seed Division, Agricultural Marketing Service, USDA, Beltsville, MD.

An isolated stand of plants, a collection of their seeds, and an accumulation of their parts can by protected with the Utility Patent Act (Bennett, 1994, p. 173)

Utility patents [UP] protects others from making, using, and selling the plant described. UPs can be held for both sexually and asexually reproducing plants, and are issued for a "new and useful process, machine, manufacture, or composition of matter [i.e. plant], or any new and useful improvement thereof" (35 U.S.C. Section 101; see also Bennett, 1994, p. 178).

Whether or not plants could by themselves be claimed as part of a utility patent remained uncertain until recently due to statutory exemption issues. In recent years, however, this analysis of the law has undergone several significant changes. In the past, PPA and PVPA provided for a marketplace protection of a particular plant, thereby eliminating the need for an application of UP to plants in order to protect their uses. Since PPA and PVPA plants were traditionally of horticultural use, they required special breeding practices to be replicated. This analysis of the usefulness of PPA and PVPA regarding the protection of plants of important non-horticultural, non-agricultural utility was reversed in 1985 due to the *Ex parte Hibberd* legal case (*Ex Parte Hibberd*, 1985, U.S. Patent and Trademark Office permitted patents on organisms, traits, and genes).

Similarly in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), UP right was at first denied, but later accepted making Chakrabarty the first to receive a generic form of protection for an organism granted by a court.

Unlike PPA and PVPA, the utility patent provides coverage for a variety of characteristics of a particular plant or organism. Claims can be directed towards both the phenotype and genotype of that organism. Most importantly, organisms bearing specific genotypes can be claimed whenever recombinant DNA technologies and selective breeding measures

are used by the owner of patent to define that genetic pattern.

APPENDIX

The requirements for acceptance of a Utility Patent include:

--novelty
--usefulness
--nonobviousness (Williams and Weber, 1989, p. 97)

--enablement (seed deposit, allowing others to obtain propagatable material, thus ensuring public disclosure).

Indicators of usefulness, novelty, and non-obviousness:

a) long felt need unsatisfied by inventors

b) failures of others to solve an important problem

c) copying the product

d) commercial success

Proof for non-obviousness:

1) the product is beyond that which is known in the ordinary art

2) the product illustrates the difference between what is being sought to be patented and the knowledge of this art prior to the discovery

3) it can be repeated by individuals with average skills in the art

4) the discover's skills may serve as an initial indicator of non-obviousness

Utility Patents are applicable to "useful genes" discovered by biologists, plant breeders, etc., and provide exclusive protection for that gene and any products or derivatives formed due to its presence. This makes Utility Patents highly useful for food, drug and chemical companies which require long periods of product testing, experimentation, and development.

An example of its use involved the marketing of the Pacific Ocean Oyster as competition with the Atlantic Ocean Oyster. The marketing agent and patent-holder argued that he had exclusive rights to selling Pacific Oysters as a substitute for the Atlantic Oyster. Since this application of Pacific Oyster in the marketplace was obvious, although not successfully tried in previous years, the court refused this

utility patent arguing that the anyone could have tried this marketing venture (Williams and Weber, 1989, p. 104)

As for the application of this law to plants, if the underlying genetics of a plant are unforeseen or unknown, and an important discovery is then made about that plant's chemistry, then that discovery is non-obvious in nature and may be covered by utility patent (Williams and Weber, 1989, p. 99). During the past decade, this application of utility patent has enabled drug companies to retain the sole rights for the novel use of a plant medicine, and allows pharmaceutical industries in developed countries to monopolize potential applications of any newly discovered medicine sources. In this case, it is argued that the tropical plant seed bank(s) fulfills the requirement that active seeds be kept and made available for the use of this new discovery.

With the utility patent, a plant bearing invisible phenotypes still bears an important genotype. A variety of sunflower with a high percentage of oleic fatty acid, or a variety of rapeseed bearing a low erucic fatty acid content in its seed oil (Canola/TM) may be covered by UP. Since these are also varieties, the rights to restricting their use are also manageable through PVPA.

The application of this patent to local natural products use has recently been the case with the Pacific Northwest Taxol, i.e. attempts have been made by Forestry Service and University of Oregon researchers to reproduce *Taxus brevifolia* rich in Taxol through cuttings and clonal propagation of specific communities of *Taxus brevifolia* in situ.

An interesting marketing situation may be posed by actions taken by competing agents. Utility Patent supercedes Trade Secret. If a person independently discovers the same plant characteristic being kept trade secret by another, and files for a utility patent for this secret, he can prevent the original trade secret owner from further use of that trade secret. This event took place several years ago with the use of Yew Tree parts not bearing Taxol, but instead a Taxol-precursor, for the production of Taxol. The holder of this utility patent temporarily prevented Bristol-Meyer from producing a similar Taxol product from parts other than their original patent defined as Taxol sources. For a short while, the holder of the Yew bud-generated Taxol precursor had control of Bristol-Meyer's plans to biotechnologically produce Taxol, until the case was brought to court and the court order prohibiting Bristol-Meyers from using other parts of Taxus was put on hold.

ANALYSIS & ISSUES

Issue 1. Do PPA, PVPA, and UP relate to the rights of the Shaman?

Wild plants are not patentable.

However, PPA and PVPA may still be related to shamanic medicines of a tropical nature. If the plant in question typically doesn't carry out seed propagation, then other forms of propagation, except root propagation, may be put to use.

When deciding between PPA and PVPA, one has to consider whether or not the plant can be reproduced asexually [for PPA] or sexually [for PVPA]. A plant capable of both forms of reproduction may need both types of patent, although filing for mutliple types of patents for a single plant source can usually become problematic should legal cases later erupt.

When deciding whether to use Plant Patent, Plant Variety Protection, or Utility Patent, one needs to consider: the method of production; the potential use of this patent; the availability of resources for the breeder.

For a plant newly isolated from nature, such as by means of its discovery during a tropical ecosytem study, one typically considers first the use of PVPA, followed by Utility Patent.

The key advantage to selecting a Utility Patent is that generic claims become possible, as well as claims regarding plant parts or their components, and, most importantly, any *related plant varieties* of that Genus or species. The main disadvantage to using a Utility Patent is that research and filing procedures can be complex and expensive (Bennett, 1994, p. 178-179).

Issue 2. Plant Genes as Tangible Property.

Plant cell lines may be patentable as intellectual property. Normally, anyone with the right knowledge is, in theory, capable of reproducing a plant thus making the existence of such a plant public knowledge. "Genetic messages" however may be classified as tangible property, capable of legal protection by the *Law of Conversion*. Using this argument, certain aspects of plants are now patentable and become unusable by other researchers until the patent term expires.

Issue 3. International Applications of these Legal Rights

The international applications of these legal rights may strengthen certain forms of plant protection provided by PVPA.

In 1961, the Union for the Protection of New Varieties of Plants [UPOV] met in France and finalized their decisions regarding In essence, UPOV grants protection for new, distinct, stable, uniform varieties, be they from plants of natural or artificial origin. To satisfy UPOV's patenting guidelines, the plant must be "distinguishable from any other variety whose existence is a matter of common knowledge." (UPOV Article 17, from p. 182)

Since common knowledge exists whenever cultivation and marketing have taken place of other varieties, the application of novelty to the plant patenting process is/can be destroyed if the plant in question has already been around or in the marketplace for a year, such as in any country where the breeder may have chosen to grow the plant for research. If the plant was sold in a foreign country four to six years prior to UPOV application, filing for UPOV protection is not possible. Thus tropical or foreign plant discoveries grown in those countries, if they are somehow linbked to the UPOV meeting, are non-admissable as patentable products. Legal coverage doesn't exist for non-signature countries of UPOV.

The United States became a signatory of UPOV in 1978, subsequently amending the United States' PVPA policies in 1980 to conform with UPOV standards. UPOV did not have any effect on PPA.

According to UPOV, the breeder cannot prevent acts utilizing the plant privately for non-commercial purposes, or done as experiments, or to breed other varieties. Farmers may propagate new plants using their own harvested seeds.

Most recently, UPOV underwent another re-write due to the uncertain meaning of "essentially derived variety" as it is related to the Union for the Protection of New Varieties of Plants statutes being created for U.S. Law. In Article 53(b) of European Patent Convention (EPC), patent protection had previously been excluded for "plant...varieties or essentially biological processes for the production of plants and animals." The meaning of the term "biological" and it applicability to plants produced through biotechnology made the application of EPC and UPOV questionable. Thus it was decided that the amount of human intervention needed for the transformation process would be used to determine whether or not a new variety is patentable. It was then decided that bioengineering was not "essentially biological" because it requires human

intervention to take place, thereby making its end-products patentable. However, what may be patented by this argument is the method of alteration, and not necessarily the plant, unless the plant is truly a "new variety". (See also: Hybrid plants/LUBRIZOL (Nov. 10, 1988; T 320/87, OJ 1990, 71), noted in Bennett, 1994, p. 185)

UPOV was revised in March 19, 1991, to clarify this use of the term "essentially derived varieties" (EDV). This decision made the researcher's focus on genotype as applicable to receiving patent rights as was the previous focus on phenotype. Thus UPOV-granted patents can now involve plants bearing unique morphological, physiological, and perhaps chemical differences. To qualify for such a patent grant, one needs to describe the initial genome of the plant, plus a detailed description of the new feature being genetically expressed. Decisions regarding the admissability of these differences as useful and patentable will vary from case to case.

As of September 1993, the updated UPOV had 24 signatures.

TRADE SECRET POLICY

Source: Jeffrey L. Ihnen and Robert J. Jondle. 1989. Protecting Plant Germplasm: Alternatives to Patent and Plant Variety Protection. In C.W. Stuber (ed.). *Intellectual Property Rights Associated with Plants*. ASA Special Publication no. 52 (Madison, WI: CCCA/ASA/SSSA), pp. pp. 123-143.

Trade Secret

Trade secrecy is not legally defined by all States in the United States. It has even less applicability outside of this country.

United States Trade Secret policy has been defined in *Restatement of Torts* (1939), Section 757, Comment b. as:

> "[Trade secret] may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."
>
> (From Ihnen and Jondle, 1989, p. 126)

The Uniform Trade Secrets Act [UTSA], Section (1)(4), defines trade secret as:

> ". . .Information, including a formula, pattern, compilation, program, device, method, technique, or process that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertaineable by proper means by, other other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."
>
> (From Ihnen and Jondle, 1989, p. 129)

UTSA does not require trade secrets to be useful to one's business. *Restatement of Torts* requires that a trade secret 1) be truly secretive, 2) be useful to the claimant's business, and 3) provide a competitive advantage due to its secrecy.

APPENDIX

TRADE SECRET POLICY

Examples of materials used to compose a trade secrets include a formula, a chemical compound, a manufacturing process, a method of treating materials, a pattern for a machine or device, or a list of customers.

Examples of product lines typically resulting from trade secret practices include:

--foods, drugs and cosmetics
--chemical compositions
--data bases
--manufacturing, technical and scientific research processes
--flowcharts and blueprints
--product specifications
--consumer lists
--employee training manuals
--"virtually any body of information"

Several rationales are used to determine when trade secret policy should take effect:

--incentive to innovate
--commercial morality
--sanctity of contract
--the need to enforce confidential relations
--a need for protection of property (technology and knowledge)

(Ihnen and Jondle, 1989, p. 125)

Requirements for maintaining Secrecy (ibid, pp. 127-129)

Trade secret information should not be information that is generally known or available as public knowledge. This information cannot already be published in a book, magazine, trade journal, advertising brochure, or catalog. It may be public information for which the uses to be patented are not publicly known.

A *Trade secret* has only to be maintained a secret, in relative fashion, to such a reasonable extent that if it is shared, then it is shared with those who will not disclose it or be able to commercially exploit it. Disclosures should be confidential, and are to be made under conditions ensuring the need for confidentiality will be met and remain clearly defined.

APPENDIX

TRADE SECRET POLICY

Testing a company's efficacy trade secret policy consists of 1) a general review of the information already available, and 2) affirmative steps taken to protect that information.

In some cases, it is expected that certain portions of the trade secret policies will need to be released with contractors. In such cases, this information is provided on a need-to-know basis, and a security approach is usually required whenever the information release takes place. These security steps are taken to better assure both parties that the information which must be kept secret remains well-defined, thus preventing an unnecessary loss of it or unneccessary disclosures of other portions of the trade secret.

To maintain trade secrecy, the following procedures are typically followed:

--distribution of the company's trade secret policy in written form
--constantly informing fellow workers of the policy
--restricted access to trade secret information sources
--use of physical security measures
--initiation of a clear secrecy labelling policy
--restricted company tours
--restricted access to computer sources
--carefully screening and company presentations with other audiences

Trade secret policy has interesting applications to the seed industry. Selling a bag of hybrid seed with a few inbred parent seeds would constitute the releases of the trade secret--the mother plant--to the public domain.

Another interesting issue involves the use of a Utility Patent to supercede a Trade Secret. If a person independently discovers the same plant characteristic kept trade secret by another, and files for a utility patent for this secret, he can prevent the original trade secret owner from further use of that trade secret.

Contracts

An important application of trade secrecy in biodiversity, biotechnology, and plant genetics studies pertains to Plant and Plant Cultivar protection practices as these relate to the use of seed banks. Through the use of licenses (either written or oral), sales contracts, restrictive use labels, or bailments, one may carry out research on potential new products, in which case the legal measures taken are used to ensure confidentiality and secrecy.

TRADE SECRET POLICY

Licensure is the most common of these practices taken. It may be performed in writing or orally, and is used to establish a business venture between two or more co-signers. An agreement is made through this contract so as to define the degree of confidentiality of the contract, the conditions of sale, and any provisions that might need to be made to ensure delivery. Licenses may also include clauses clearly stating how royalties may be accrued, the time elements through with the various contract processes take place, and the manners in which future negotiations or re-negotiations can occur (ibid, p. 132-3)

Three types of Licenses exist in the American legal system:

Express: written or oral between licensor and licensee.

Implied: "created by the language and conduct of the Intellectual Property owner"

Estoppel or acquiescence: involves unauthorized use of property, and owner's knowledge of such use, and owner's management or mismanagement of this event through acquiescent behavior or abandoned interest, or detrimental reliance by user such as by building a new building on the site (ibid, p. 132).

These Licenses in use may be exclusive, non-exclusive, and restricted, the latter of which is a license which gives duration, type of activity, purpose or use, and geographic area (ibid, p. 133).

Types of contracts which can be made with natural products: licensing agreement, secrecy agreement, condition of sale agreement, and restricted use agreements.

A disadvantage to the use of contracts is that they are often supportable by state or regional laws, which vary from state to state, region to region.

In the case of marketing rain forest products, natural resources may be bagged and labelled for sale to special manufacturers. In this case, no signature may be required from the flora or seed bag buyer. Since it is assumed that only labelled flora and seed bags are being purchased, the purchase of another unlabelled bag may constitutes the pruchase of an illegal counterfeit product.

A Restricted use label may be present on seed bags, preventing the seeds from being used for breeding research and seed production.

APPENDIX

TRADE SECRET POLICY

Bailment

Bailment is a unique process used to protect trade secret materials. The trade secret or a part of the trade secret may be deposited as personal property to another person for its protection. Examples of this include the practices involving germplasm and seed banks, the growth and re-growth of new plant varieties in horticultural houses, store houses, etc.

Future Implications

The value of this form of trade secrecy in biotechnology is its application to plant genetic and germplasm studies. Most recently, trade secrecy policy was applied to genetic research in order to restrict the use of a particular plant germplasm by other researchers. The Iowa company, Pioneer, was recently permitted a trade secret security lock on the "formula" for one of its inbred corn species. The secret "formula" patented by Pioneer was simply the plant's genetic message (ibid, p. 126-7).

Trade secret policy as it applies to plant patents has numerous future implications attached to its use. These implications exist more so as moral issues than as economic issues. Trade secret policies possess no limitation on their duration. So long as a trade secret remains secret, its source cannot be perpetuated without permission from its holder. Thus this policy can have direct impacts on the dissemination of future food and medicine sources should such knowledge remain secretive. With regard to the rights of indigenous groups, here resides an example of the original behavior of past shamanic knowledge. Whereas past indigenous knowledge can be much likened to trade secrets.

Tangible examples of the sharing of these trade secrets include any new botanical products, cell lines, genetically engineered plasmids, and various forms of specifically bred and molecularly-produced biological materials produced from the knowledge given up by indigenous cultures. In return, this new form of the knowledge, especially if it is exploited within the boundaries of a developed country, becomes a secured form of company-owned trade secret.

Due to the recent GATT treaty, indigenous people have experienced some loss of their rights to the use of their own resources, as multinational companies of developed countries make use of their more available legal systems for the protection of these rights.

TRADE SECRET POLICY

The outcomes of such changes in trade secret policies could therefore be injurious to both the indigenous source and natural resource. According to Shiva, this form of biopiracy consists of poor countries, which at first create the market for the natural resources, only to lose it to the patents posed on these goods by rich corporations. In turn, the products of developing countries and their indigenous groups lose their marketability and marketplace value. For the indigenous peoples, their wild-types are called "land-raiser plants" and the "primitive varieties" are produced by their farmers, whereas the more economically productive "elite varieties" are owned and marketed by major industries. Examples of these plants include Monsanto's Soya bean and CIBA's corn, "creations" which the companies then rent out the rights to make use to indigneous people. Since these plants are now patented and owned, it is a crime for others to make use of these seeds without permission from their owner. To overcome this possible threat of genetic engineering and biotechnology to the survival of developing countries and their indigenous cultures, the farmers are now setting up their own seed banks (Shiva, 1997b).

APPENDIX

TRADE SECRET POLICY

Trade Secret Examples

The best protection of shamanic knowledge remains as its retention as an unshared trade secret. Once it no longer remains a secret, it becomes a potential part of knowledge comprising the public domain.

Trade secrets, at times, are introduced to others, specifically outsiders, through contractual means. In this way, the knowledge remains in a state of reasonable secrecy, the definition of which can vary greatly from case to case. Trade secrets are lost whenever this information is too braodly disseminated, either legally or illegally.

A contemporary example of this latter form of trade secret based marketing involves the Cocal Cola/TM recipe. So long as that recipe remains unknown, it remains a patented trade secret that, in theory, cannot be knowingly duplicated or sold. Thus the producer of Coca Cola/TM retains control of the marketing of its product. Should the recipe be relinquished or released to the public, even illegally, for example as an attempt to destroy the company's income and assets, the original recipe becomes public domain.

Similarly, one could argue that the discovery of Digitalis, were it made today, might not be attributable to its researcher and recorder, Dr. William Withering, but rather to the "old lady of Shropshire" from whom he learned of its efficacy. Withering's gain over his counterpart would be the successful documentation in writing of Digitalis use, in lieu of filing for patent, neither of which presumably the "old lady" did.

The next two case studies illustrate the actions and viewpoints currently taken regarding the use of plant medicines. They are meant to illustrate the way in whicvh traditional and modern medical thinking merge, and the ways in which the intellectual property each of these two groups possess can be used to the economic advantage of both culture-generated income projects and to industrially-based biotechnology/plant engineering projects.

Oregon Grape

The Northwestern Native American point of view that Oregon Grape could be used as an anti-viral requires Western, developed country medical knowledge of the existence of the virus, and the association made by healers between viral and bacterial induced infections.

The pharmacal efficacy of Oregon Grape chemistry as an anti-viral agent behooves the discovery of medical knowledge which exists of viral pathogenesis, chemistry, pharmacology, and treatment. By comparing Oregon Grape chemistry with its potential pharmaceutical efficacy, one could conclude that since Oregon Grape lacks the chemistry required for such an event to happen, that perhaps either Oregon Grape has a novel toxicity against viruses previously undiscovered, or that the story of Oregon Grape's efficacy is due more to individual belief systems involving the ailing body and Oregon Grape. In other words, it was the human body's own belief-derived psychochemical cure, not Oregon Grape's physico-chemical cure, that led to the successful cure of a pathology of viral origin.

The use of Oregon Grape as a treatment for viral maladies thus represents a merging of traditional Native American knowledge of medical practice with the belief systems inherent to developed, industrialized country medical practices. This situation thus begs the question regarding the marketing and use of such an anti-viral remedy from Oregon Grape: who, if anyone, has the intellectual property rights to this medical discovery? Most likely, noone has this knowledge as an intellectual right since it currently meets the public domain standards even though few know the exact arguments for this natural remedy.

Marketing the use of Oregon Grape will more likely be a success as an herbal medicine, than as a pharmaceutical company-generated Berberine alkaloid-derived medicine. The marketing of Oregon Grape as an herbal medicine or nutritional supplement, makes it useful only as a trademarked medicine. Even the recipe, in essence, is duplicable, so long as it is not re-written as an infringement of copyright.

Oregon Grape's chemistry becomes patentable due to its potential application to biotechnology through the uses of genetic-rights patent and utility patent. The berberine produced by Oregon Grape has the potential of serving as a heart/blood pressure medicine, and as a food colorant. One could develop and patent a variety of Oregon Grape, reproducable only through sectioning or cloning, and obtain Plant Variety Protection for it. Alternatively, one might produce a cell line for use in plant tissue culture form for

the production of large amounts of biomass from which the berberine could be extracted. This method of patent was carried out in Japan for the use of such plants for the production of food, drug and cosmetic dyes. Thirdly, one can patent the use of berberine as either a specific form of food and drug dye, or as a useful source of heart medicines for sale across the sea. Since these are utility patents, they allow the knowledge of Oregon Grape's use to be publicized, with the hopes of securing marketing agents on behalf of the patent holder. Therefore, unless Oregon Grape is a a unique efficient source for the extraction or berberine alkaloids, it won't be a success in an economic sense. Thus, rather than wild strains, unique plant varieties, such as the Eruca sativa responsible for the healthy Canadian Low-Erucic Acid Rapeseed (Canola/TM) oil are more often granted utility patents.

CASE STUDY 2. THE CANCER CURE

The Unidentified Trade Secret Cancer Cure of a Shaman

Should trade secret information of the shaman be revealed by researchers and made public?

How do we prevent the overharvesting of this new miracle drug?

An example of application of trade secrecy policy may exist with a plant of potential use as a miraculous cure, the knowledge of which is currently lacking from the public domain. In this case, the medicine man or herbalist has discovered a plant in the Columbia River valley which has direct applications to chemotherapy protocols. In this case, the knowledge of the plant isn't revealed, thereby qualifying it for the implementation of trade secrecy policies. It is then decided this plant should remain intellectual property of the medicine man and the few members, if any, of indigenous society who learned of it and witnessed its use.

A number of moral issues can erupt from this scenario. Should the medicine be revealed in order that its importance benefits other non-traditional societies with potential patients for this new-founded remedy?

In this case, the argument can be made that the deduction of chemotherapeutic potential made by the herbalist came as a direct result of information gleaned from the scientific literature on plant growth behavior and its resulting chemistry, the impact of growing conditions and ecosystems on plant evolution and chemistry, and the role of each of these in the evolution of cancer drugs in the plant kingdom. For the medicine man, these were then combined with his or her personal experiences and know-how, and then case studies initiated to determine the efficacy of such use. The information then accrued through the use of this medicine by the herbalist also becomes intellectual property rights knowledge.

Since this study came as a direct result of traditional societies making use of European and Euro-American knowledge, developed by comparing Columbia river flora lists with the National Cancer Institute studies of similar or related plants in order to deduce the medicinal value of such a plant, the moral issue becomes one of instant concern. Has the herbalist robbed society of an important piece of medical knowledge? Since the basic knowledge for this discovery exists in the public domain, the moral and ethical impacts of implementing trade secret policy become minimized. In theory, the herbalist argues that anyone else could make the same finding, assuming they had the time and desire to implement the work needed to make such a discovery.

Thus the answer to thee second question 'what to do with this plant to prevent overharvesting?' has been answered. The herbalist refuses to reveal his or her trade secret, and the plant is therefore not overharvested due to the introduction of this knowledge into public domain, with the potential for mishandling and misuse by other herbalists in the herbal medicine field.