Several categories of materials cannot be patented. The most obvious are substances that occur naturally. The US Patent and Trademark Office (USPTO) and courts have traditionally used the term 'work of nature' to exclude subject matter from patent protection.[46] The Manual of Patent Examining Procedure states: ". . . a thing occurring in nature, which is substantially unaltered, is not a 'manufacture'."[47] In practice, naturally occurring chemicals can be patented if their structures have not been published. Simply isolating a natural product, even if the isolate is purer than its natural equivalent, is unpatentable unless there is an unexpected effect.[48] If a useful natural drug has been published, a drug company would be forced to find a novel derivative in order to secure a composition patent.[49] The case General Electric Co. v. DeForest Radio Co.[50] demonstrates that the courts are reticent to grant a patent for a substance that occurs in nature. In this case, DeForest converted tungsten, a very brittle metal, into what he termed to be an 'entirely new metal' that could be used for the filaments in light bulbs.[51] The court conceded that the invention was a 'tremendous' technical advance but the fact that the metal existed in its pure form in nature was decisive. The court invalidated the product patent.[52] Based on public policy, the court could not allow a patent to be granted for natural material that could prove essential for competing concerns. The ultimate goal of patents is to promote invention and not grant a monopoly *per se*. A process that allowed protection with a patent, yet this was a far weaker form of protection.

The term 'composition of matter' as in 35 U.S.C. § 101 includes: "... all compositions of two or more substances" and ". . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."[53] The inventive step is easier to demonstrate when there is a mixture that is not found in nature.

2. *Novelty*

US patent law offers a monopoly period in exchange for a detailed disclosure, so that the public may replicate the invention.[54] A successful patent, of whatever category, must also be useful[55], novel[56] and be non-obvious. Utility is a test to make sure the

46 Funk Bros. Seed Co. v. Kalho Inoculant Co., 333 U.S. 127 (1948). The case particularly addressed the terms "product of nature" and "product derived from nature." *Id.* at 134-35. These were held to be legal conclusions and not definitions. A product with a natural source could still be subject to patent protection.

47 M. Jacob, *Patentability of Natural Products*, 52 J. PAT. & TRADEMARK OFF. SOC'Y 473 (1970) (citing the Manual of Patent Examining Procedure § 706.03(a)).

48 Ex parte Gray, 10 U.S.P.Q.2d (BNA) 1922, 1924 (Bd.of Pat.App. & Int. 1989).

49 *See Medicinal Plants: Pills in a Haystack*, ECONOMIST, Feb 24, 1990, at 87.

50 28 F.2d 641, 642 (3d Cir. 1928).

51 *Id*.

52 *Id*. at 643.

53 Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.C., 1957).

54 The Uruguay Round Agreements Act, signed in 1994, changed the term of a US patent to 20 years from the earliest filing date. 35 U.S.C. § (c)(1).

55 35 U.S.C. §101.

56 *Id*. at §§ 101-102.

public can benefit, which is easy to satisfy in the case of most drugs. Novelty makes sure that the claimed inventor has patented something that is new. Increasingly, evidence of TM can be used to destroy novelty in some jurisdictions, but in the US the situation is much more difficult.

According to 35 U.S.C. §102 (a) a person shall be entitled to a patent unless: "the invention was known or used by others in this country, or patented or described in a printed publication[57] in this or foreign country, before the invention thereof by the applicant for a patent." If an invention were known or used[58] in the USA, there is no need for it to be in a printed publication in order to bar a subsequent patent by another party. 'Knowledge' does not refer to what is known or understood in an abstract sense.[59] Private or secret knowledge will not destroy novelty.[60] Novelty can be destroyed by the invention existing in a printed publication in the USA or abroad. Knowledge or use abroad will not render a US invention invalid if it is not printed. The latter point relates particularly to foreign TK.

35 U.S.C. §102 (b) states: "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . ." The critical word here is application. An application will be barred if all elements of the invention have appeared in a printed publication in the US or abroad more than one year prior to the application. Public use or sale in the US more than one year prior would also bar an application.

There have been proposals to reform §102 (b) so that the geographical limitation would remain in place in cases of undisclosed third party conduct, but would be removed if an inventor commercialized their invention outside of the US beyond the one year grace period.[61] Both sections make clear that foreign prior art must be a printed publication to destroy novelty. The situation may have been clear in 1836, when the first geographical limitation entered US patent law. Because of difficulties of access, an unprinted foreign invention was not accessible by the general public in the US. Now, with ease of transport, there is concern than the limitation facilitates encroaching on the public domain. More seriously, according to some, it may not be the best way to promote the dissemination and promotion of technology.[62] The fact

57 A printed publication must be fixed in a tangible medium of expression and be disseminated as well as accessible. Typewritten and accessible patent applications in foreign countries are not printed publications. See Steven J. Rothschild & Thomas P. White, *Printed Publication: What is it Now*?, 70 J. PAT & TRADEMARK OFF. SOC'Y 42 (1988).

58 A prior user must physically embody the invention and not conceal the use, in other words it must be accessible to the public. *See* 1 DONALD CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDTY AND INFRINGEMENT § 3.05 [2][a] (1995).

59 United States v. Adams, 383 U.S. 39, 148 U.S.P.Q. (BNA) 479 (1966). The court in this case stated that an inoperable or failed invention would not anticipate. In the case Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 632, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed Cir. 1987) it was decided that even if the inventor did not recognize a function or process, if it was inherent (considering someone skilled in the art), then it can anticipate.

60 35 U.S.C. §102(g) states that novelty will not be destroyed if: "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."

61 William LeMarca, *Reevaluating the Geographical Limitation of 35 U.S.C. §102 (b): Policies Considered*, 22 U. DAYTON L. REV. 25, 50-52 (1996).

62 John Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 104-05 (2001).

that most TK is unwritten presents a problem. A foreign company could apply for a US patent based on foreign TM that is only known from oral sources. In this case, they may be held to be bio-pirates, but they would be following the letter of US law. There could also be another example of bio-piracy. For instance, if TM has been printed by ethnographers, a one year time limit would begin at the date of publication. Even if a TM practice were ancient, and published without the permission of the community, there could be a bar to a patent application under 35 U.S.C. §102 (b).[63] Even academics with no thought of financial gain could be considered bio-pirates.

The above considerations aside, the US patent law offers another hurdle. TM developed over a period of time and faces problems in that it may be difficult for an individual to demonstrate that they were the first to invent. 35 U.S.C. §102 (f) states the originator must: "… himself invent[64] the subject matter sought to be patented." Much TK – as well as TM – does not have a well defined author. Others in the community could make a claim to have contributed to the invention.[65] Some authors have suggested that some drugs could face lack of novelty issues on the basis of TM:

> For example, the Rosy Periwinkle originally was used in its "natural" form in Madagascar to treat diabetes. Its derivative drugs, vincristine and vinblastine, are used to treat Hodgkin's disease and childhood leukemia. These drugs were patented. Now, however, after many years, research is being conducted to develop a diabetes drug from the Rosy Periwinkle. This new drug, if it is ever developed and marketed, may not be patentable because the use of this particular plant to treat this particular disease is neither novel nor non-obvious.[66]

As with so many other examples of the patentability of TM, this would depend on the exact facts of the case. The question would revolve around the connection between the substance as described in the TK and the drug. If there was a significant difference between the two (for example if the drug did not exist in a pure form in nature)[67] a patent could be granted even if it was clear that Rosy Periwinkle was used to treat diabetes.

Issues of novelty (as well as obviousness) relate to the technology used in the invention. An imitative pharmaceutical company, perhaps based in a developing country, may infringe outright. This may be a matter of policy in order to make drugs available for a low price. Research based companies in developed nations with strong patent protection can synthesize non-infringing alternatives.[68] It therefore appears that, in this instance, there is a bias against patenting TM as used in small to medium sized

63 *See* Gelvina Rodriguez Stevenson, *Trade Secrets: The Secret to Protecting Indigenous Ethnological (Medicinal) Knowledge*, 32 N.Y.U. INT'L. L. & POL. 1119, 1137 (2000).

64 US patent laws only reward the inventor. If it is possible to prove that an invention was discovered in a foreign country and simply imported into America the patent would be invalid. Cuno Eng'g Cort. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941).

65 *See* Mark Hanning, *An Examination of the Possibility to Secure Intellectual Property Rights for Plant Genetic Resources Developed by Indigenous Peoples of the NAFTA States: Domestic Legislation under the International Convention for Protection of New Plant Varieties*, 13 ARIZ. J. INT'L & COMP. L. 175, 196 (1996).

66 *See* Hanellin, *supra* note 17, at 179.

67 The case Merk & Co v. Olin Mathieson Chem. Corp., 253 F. 2d 156 (4th Cir. 1958) held that vitamin B12 was patentable in crystalline form even though it was derived from an unpatentable natural substance. It did not exist in crystalline form in nature, so it differed in kind from the impure natural state.

enterprises, particularly in developing countries. It is clear the US patent law was formulated long before the debate on patenting TM existed, but this is cited as one more example of the divide between north and south. In other instances, it appears that US law offers options that are under-exploited by those wishing to protect TM. A good example is the provisions for patenting a joint invention.

3. *Joint Invention*

A common refrain is that patent law does not allow TK holder contributions to be recognized. Both statue and case law in the US contradicts this view. 35 U.S.C. §116 states that an invention can be made by two or more persons even if they did not work physically together (or at the same time) and did not make the same type of contribution, and did not make a contribution to every claim. The case law[69] suggests that even if drugs were developed from plants identified in literature surveys, this would be enough to qualify as a joint invention. Some element of reliance appears to be enough, although there is no definitive judicial statement on the minimum standard needed for collaboration.[70]
If the invention simply provided knowledge that was already in the public domain the provider would not qualify as an inventor. There is a need to demonstrate some degree of conceptual connection between the information and invention. Some authors suggest that in recognizing TK, there is a risk:

> Legislatures and courts have developed carefully calibrated regimes that effectively balance the competing interests of the inventor in obtaining a patent monopoly and of the general public in preventing the grant of an undeserved monopoly right that diminishes the public domain. Amending patent law to provide rights to traditional knowledge would disturb this balance, risking wide-range disruption of the entire system that would require even more legislative work than creating a narrow, new regime.[71]

The worst case scenario is far from proven. It is difficult to appreciate how applying for a patent held between joint inventors would cause large scale disruption. The examination process remains the same. The passage above seems to suggest that TK is part of the public domain, and in recognizing it as a contribution to the final invention, it would somehow alter the patent granting process. Recognizing a TK holder as a joint inventor does not conflict with international obligations. In the future it is possible that some provision regarding registering a patent as a joint invention could be part of prospection agreements.

68 Curtis M. Horton, *Protecting Biodiversity and Cultural Diversity Under Intellectual Property Law: Toward a New International System*, 10 J. ENVTL. L. & LITIG. 17 (1995).
69 *See* Michael J. Huft, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U.L. REV. 1712-1722 (1995).
70 *See id.*
71 Jacoby and Weiss, *supra* note 10 at. 99.