## IV. *US PATENT SYSTEM*

### 1. *Categories of Patent*

The Patent Act governs what can be protected via patents in the US.[41] The invention must fall in one of three categories: 'manufacture,' 'process,' or a 'composition of matter.'[42] In practice, not all categories offer the same level of protection. For instance, a drug may not be protected by a utility patent because it is not possible to prove it is a 'manufacture' or 'composition of matter'. In this case, the process itself could be patented. This was the case with Reserpine, a drug used to treat hypertension, which was derived from the plant *Rauvolfia sepentia*.[43] Process patents can protect the method used to produce (either manufacture or isolate) a drug. These patents are regarded as fairly weak in relation to a patent on the product itself. An alternative way to make a substance could be found that would not infringe. In contrast, even if a producer found a way to make a substance in a different way and protected by a 'composition of matter' patent, it would infringe. A patent on composition is effectively protection for a product. For example, if an inventor discovers that a particular ratio of non-patentable natural substances can be used to treat a particular disease, then a composition patent could be issued that gave the owner the right to use this combination.

So called use patents are sometimes referred to as weak patents in a business environment. For example, Company One could have invested a considerable amount of money and hold a use patent on a drug. Company Two could, using published data, obtain approval to use a drug for a single indication not covered by Company One's use patent. Company Two could then sell the drug for every indication at a low price. They would have expended much less money than Company One, and would effectively drive the price down.[44] A use patent is in a particularly precarious position if the substance is natural or commonly available and has multiple uses. Some authors suggest that although the US has very strong patent protection for natural substances, particularly when compared with other industrialized nations, it is not strong enough to encourage investment in natural drugs.[45]

41 35 U.S.C. §§ 101-104 (1988).
42 *Id.* at § 101.
43 U.S. Patent No. 2,833,771 (filed 1958).
44 *See* STEPHEN L. DEFELICE, FROM OYSTERS TO INSULIN: NATURE AND MEDICINE AT ODDS 28 (1986). The weak position of use patents in the business world is covered by the author in his attempt to protect carnitine. He summarizes the arguments of several companies: "How can we justify the expenditure of large sums of money for a substance with a poor patent position to our stockholders? How would our management look if we spent millions of dollars to develop carnitine, only to have another company, using already published data, obtain FDA approval to use it for a single indication not covered by your use patent and sell it at a very low cost to everyone for every indication?"
45 *See id.* at 53. "Relatively few NDA's for natural substances are submitted to the FDA for review. There is little doubt that limited exclusivity is not a powerful incentive for undertaking research and development of natural substances." However, the author makes it clear that natural substances are problematic for a number of reasons, particularly the FDA policy towards herbal mixtures. *See id.*at 55. ". . . the FDA would more likely than not request that the specific active ingredient be isolated. Lacking sufficient patent protection and technology, few companies would go forward with this enormous effort. Many natural molecules are large and complex and cannot, even if chemically characterized, be produced in large quantity." *Id.*


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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.

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