

substances and that have been incorporated into mainstream medicine are morphine (1806), quinine (1823), atropine (1833) and digitalis.³

In 1982, it was estimated that about 50 % of all filled prescriptions in the US originated from drugs that were derived – one way or another – from natural substances. This generated US sales of about 20 billion.⁴ Another estimate found that 3/4 of the plants used in prescription drugs originally came to the attention of drug companies because of their use in TM.⁵ In 1995, the worldwide market value of TM derived pharmaceuticals was estimated to be \$43 billion.⁶ While one could argue about the precise values, TM has significant pharmaceutical applications. Drug companies are interested in acquiring TM, both natural substances, as well as the knowledge about how to use them. In the past, such knowledge was regarded as free information. The assumption was that no one had a right to this information, especially because there usually needed to be a long process of development to make TM into a patentable drug. Modern conceptions of the issue leave little doubt that TM can be an IP right. Considering the large profits generated by modern drugs, there has been increasing pressure to protect TM with patents. Several well-known cases of western companies patenting drugs based on TM has also raised concerns. Some advocates who don't support the patent system but who do wish income to 'trickle down' to the communities who developed the TM suggest that an entirely new legal framework be established. Patents are appreciated by this group as unsuitable:

First, the invention is not dated, so that it is not possible to determine the critical date. As it would have been used for a long period of time, it would lack novelty. Also, the inventor is not determined, since it is knowledge that belongs to the who community. Patents are granted to individuals, or a small group of them, not to an undetermined group of people.⁷

The main question that emerges is feasibility. Are patents suitable for protecting TM and, if not, what are the alternatives?

The Controversy

Bio-piracy is a term minted in the last decades to describe taking biological materials – including TM – and patenting them in the west.⁸ When this happens TK right holders allege a property right has been violated. The source of the information, as well as

3 See BARRIE G. JAMES, *THE FUTURE OF THE MULTINATIONAL PHARMACEUTICAL INDUSTRY TO 1990* 61 (1977).

4 See NORMAN MYERS, *A WEALTH OF WILD SPECIES* 90 (1983) citing an unpublished study by Norman Farnsworth in 1982.

5 See Jack Kloppenburg Jr., *No Hunting! Biodiversity, Indigenous Rights, and Scientific Poaching*, 15 CULTURAL SURVIVAL Q. 14 n. 3 (1991).

6 See Someshwar Singh, *Traditional Knowledge Under Commercial Blanket*, THIRD WORLD NETWORK, <http://twinside.org.sg/title/blanket-cn.htm> (last visited Sept. 5, 2006). The Third World Network is an independent non-profit network of organizations. The calculation of this sales figure is difficult and of course subject to error.

7 Eliana Torelly de Carvalho, *Protection of Traditional Biodiversity-Related Knowledge: Analysis of Proposals for Adoption of a Sui Generis System*, 11 MO. ENVTL. L. & POL'Y REV. 53 (2004).

8 Paul J. Heald, *The Rhetoric of Biopiracy*, 11 Cardozo J. Int'l & Comp. L. 519 (2003).

the material itself, is not acknowledged. No compensation is paid. When a patent is issued, it is not held by the inventor. The patent will prevent the holder of the TK from taking out a patent themselves. Despite the accusations, however, a patent is granted for an invention that may have little in common with TM as practiced by an indigenous community. Bio-piracy is a very political issue.

This highlights the so called north-south divide.⁹ The accusation is that wealthy nations in the north rely upon colonial era conceptions of property in order to gain access to TK, including TM, for free. TK is not usually protected using a system of written laws in southern countries. It may be controlled as collective property by trained practitioners (such as a Shaman).¹⁰ The fact that the legal systems may be different – they may be termed traditional legal systems – does not make them less valid. It does, however, make compliance difficult. This quickly leads into the issue of disclosing the origin of biological materials as a pre-requisite for patent protection. Indeed, without knowing the origin there can be no thought of benefit sharing.¹¹ Yet from a ‘northern perspective’ these proposals could hamper research and lead to higher drug costs. On the other side, some have suggested that protection of medical knowledge, including drugs, with patents is fundamentally incorrect.¹² While this subject captures media and public attention, the patent system is unlikely to be replaced any time soon.¹³ The real questions are how patents can be used to protect TM, and how patents based on the misappropriation of TM can be stopped. Some consideration will also be paid to other legal methods of protecting TM that have been proposed as alternatives to patents.

TM involves both the substance itself (assumed here to be botanical) as well as the practices used to prepare it for use. Both India and China¹⁴ have ancient medical traditions, but they use very different methods of protecting it. The TM of these two countries will be used as a lens to explore some of the issues involved in patenting. There are then two important divisions in the analysis. The first is the kind of protection provided in national legislation. The second issue is the kind of protection offered to TM of other countries in the west as well as in international agreements. America will receive special attention. Prior use or (unpublished) knowledge of an invention in

9 See generally Gavin Stenton, *Biopiracy Within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process can be Towards Countries of the South*. E.I.P.R. 26(1), 17-26 (2004).

10 See generally Craig D. Jacoby and Charles Weiss, *Recognizing Property Rights in Traditional Biocultural Contribution*, 16 STAN. ENVTL. L.J. 74, 90-91 (1997).

11 See Dr. Gerard Bodeker, *Traditional Medical Knowledge, Intellectual Property Rights & Benefit Sharing*, 11 CARDOZO J. INT'L & COMP. L. 785 (2003).

12 Examples of opposition include Indira Ghandi's statement that "... [t]he idea of a better-ordered world is one in which medical discoveries will be free of patents ...". See Robert Gutowski, *The Marriage of Intellectual Property and International Trade in TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?* BUFF. L. REV. 713, 744 (1999) (reproducing a speech given in 1982 to the World Health Assembly).

13 For a discussion of the alternatives to patent protection, with particular reference to monopoly contracts, see Lester I. Yano, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*, 41 U.C.L.A. L. REV. 486 (1993). The author notes that other alternatives would take a prohibitive amount of time to develop.

14 In China, TM comprises between 30 and 50 % of the total consumption of medicine. See WHO Fact Sheet, *supra* note 1.