

applies. TM will continue to be difficult to patent in India. The Amendment lists what are not inventions:

the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.⁸⁵

The principal Act of 1970 has a similar provision, but it does not specifically consider an invention to be a new use of a known substance that results in enhancement of the ‘known efficacy.’ While case law will have to be developed, this appears to be favorable to patenting some TM. However, given that the US has a huge pharmaceutical market, there have been instances where Indian TM has been patented in America.

2. *Tumeric*

In 1995, the US patent office granted a patent (5,401,504) for tumeric (*Curcuma longa*) for the ‘invention’ of wound healing. The applicants were a team of two scientists (expatriate Indians) from the University of Mississippi. The plant was well known in India for both culinary use and as a traditional medicine. Greeks and Romans also knew it for its medical properties. The Council of Scientific and Industrial Research in India challenged the patent. It was invalidated⁸⁶ for lack of novelty by the USPTO, who cited prior art in Indian TK. This is the earliest example of a successful challenge to a patent based on TK.⁸⁷

3. *Indian Bio-Diversity Act*

As a result of several cases dealing with the purported infringement of TK, the First Inter-Ministerial Committee on Protection of Rights of Holders of Indigenous Knowledge was convened in New Delhi.⁸⁸ The Committee focused primarily on protection and explored possibilities for future legislation. This meeting gave impetus to the Biological Diversity Act 2002,⁸⁹ which specifically addresses TK. Broadly, it seeks to regularize access to genetic materials on the one hand, while protecting TK on the other. It provides for more centralized decision-making. Chapter 3 of the Act gives exclusive rights to the Central government in the form of the National Biodiversity

⁸⁵ *Id.* at § 3.

⁸⁶ See Reexamination Certificate B1 (3500th) (Apr. 21, 1998) (canceling claims in U.S. Patent No. 5,401,504).

⁸⁷ See Graham Dutfield, *Trade Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L. L. 239 (2001).

⁸⁸ See Srividhya Ragavan, *Protection of Traditional Knowledge*, 2 MINN. INTELL. PROP. REV. 1, n. 272 (2001), for a discussion of the minutes.

⁸⁹ Biological Diversity Act 2002. English text of Act is available on http://grain.org/brl_files/indiabiodiversityact-2002.pdf (last visited Sept 1, 2006).

Authority (NBA) to be located in Chennai, although regional offices can be established with permission of the Central Government. Thus, local offices can address community needs.

Chapter 2 (6:1) of the Bio-diversity Act establishes that no person shall apply for an IP right by whatever name in or outside of India for any invention: “based on any research or information on a biological resource obtained in India” without prior approval of the NBA. If a person applies for a patent, permission of the NBA may be obtained after the patent’s acceptance but before the sealing of the patent by the patent authority. The Act clearly covers TK with the inclusion of the phrase ‘information on a biological resource.’

Chapter 2 (6:1:2) of the Bio-diversity Act establishes that while approval may be granted, the NBA may: “...impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits.” This provision clearly follows the benefit sharing provisions of 8(j) of the CBD.

The new act has also drawn criticism in that even an Indian citizen or company registered in India will have to obtain permission in order to utilize⁹⁰ biological resources according to Chapter II (7). Chapter II (7) states this will not apply to local communities as well as those practicing TM. Nevertheless, the fear is that this may in fact prevent basic research by non-local groups (such as universities) in India. The controlling body apparently holds that while domestic companies will have to register with authorities, no up front payment will be involved. Benefit sharing will be negotiated on a case by case basis.⁹¹

Chapter 5 (4) of the Bio-diversity Act states that the NBA shall give public notice of every approval for use of biological resources. This public scrutiny serves as a safety valve to allow other right holders to come forward. This is in keeping with India’s proposal to revise the TRIPS agreement.⁹² The Bio-diversity Act clearly signals India’s intention of asserting rights to both biological resources and TK. It specifically addresses the problem of foreign companies patenting Indian TM.

The overall effect of the Act remains to be determined. If the law is too restrictive it could hamper research with burdensome administrative procedures. At best, however, it could protect national sovereignty in biological resources, including TK. While it is designed to protect the needs of local communities, the structure of the NBA suggests it will be more of a government organ. This being said, in an increasingly international environment it may require considerable resources to challenge the validity of US patents, as the neem controversy demonstrates.

4. *Neem*

The neem tree is a source of TM used in India. Although the issue is not specifically related to patenting TM, it highlighted many of the concerns countries have about pro-

90 The exact words are: “... commercial utilization or bio-survey and bio-utilisation.”

91 See P.T. Jyothi Datta *Bio-diversity Bill: Choking bio-piracy or research?* THE HINDU (2002), <http://www.blonnet.com/bline/2002/12/15/stories/2002121501710300.htm> (last visited Sept. 5, 2006).

92 See Kruger, *supra* note 40.