## V. *INDIA*

### 1. *Patents*

The Indian Patents and Designs Act of 1911 was modeled after English law.[78] The high cost of pharmaceutical products led to changes in the 1970 Indian Patent Law. Chapter II of the 1970 Indian law (inventions not patentable) would make it very difficult for most TM to be protected.[79] Section 3(e) states: "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance." This provision would apparently require the applicant to demonstrate that the mixture yielded unexpected results. Section 5 of the 1970 Indian law is detrimental to drugs in general and to TM in particular. For inventions: "intended for use, or capable of being used, as food or as medicine or drug,"[80] no patent can be granted for the substance itself, but claims for the method or process of manufacture would be allowed.[81] By dispensing with product patents, the law gave particular incentives to finding efficient methods of manufacture. It also left generic drug manufacturers with many possibilities. At the same time, it aggravated western pharmaceutical companies. As an unintended consequence for TM, new methods of manufacture may be difficult to formulate. This would effectively require melding TM with science. While China has invested substantial sums to integrate scientific methods with TM, India has not.

India received the deadline of January 1, 1995 to comply with WTO requirements as established in TRIPS Article 65.4.[82] This article allows for product patent protection to a particular area of technology to be delayed for an additional five year period. The Patents (Amendment) Act 2005[83] introduces product patents for medicines for the first time in 35 years. The Amendment omits section 5 of the 1970 Act.[84] This removes the stricture against patenting medicines. In the case of TM, section 3 (d) still

78 Indian law has been criticised for following western models: "Implying that the solution is based on the same intellectual property concepts of the West, which many developing countries have accused of producing an intolerable injustice. I have tried to highlight how flippant consideration of the inherent epistemological diversity between the North and South has skewed the biodiversity debate, and masked the unacceptability of a patent right or claim as an answer to biopiracy." Remigius N. Nwabueze, *Ethnopharmacology, Patents and the Politics of Plants' Genetic Resources*, 11 CARDOZO J. INT'L & COMP. L. 585 (2003).

79 Patents Act of 1979 http://indialaowinfo.com/bareacts/pat.html# Toc 4994653) (last visited Sept. 5, 2006). For a general discussion of the Indian Patents Act and medicine, see PHILIP W. GRUBB, PATENTS FOR CHEMISTS 251 (1982). Chapter I 2 (l) notes that medicine or drug includes: "(I) all medicines for internal or external use of human beings or animals, (ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals." While not noted specifically, TM could be included in this list as well, although other aspects of the Act would make it difficult for TM to be included under patent protection.

80 Indian Patent Act of 1979 5(1)(a).

81 *See id.* at 5(1)(b).

82 Compliance with TRIPS will lead to many changes. See Fact Sheet: Changes to India's Patents Act and Access to Affordable Generic Medicines after Janurary 1 2005. http://healthgap.org/press_releases/04/121404_HGAP_FS_INDIA_patent.pdf#search=%22India%20patents%20 act%22 (last visited 1 Sept 1996).

83 The Patents (Amendment) Act 2005. English text at http://patentoffice.nic.in/ipr/patent/patent_2005.pdf#search=%22India%20patents%20act22 (last visited 1 Sept 1996).

84 *Id.* at § 4.

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 (*Curcurma 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 invalidated[86] 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) (cancelling 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/india-biodiversityact-2002.pdf (last visited Sept 1, 2006).