

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.

tecting their TM. Indian texts dating back two millennia state that neem could be used as an insect repellent, medicine, and cosmetic. W.R. Grace & Co. – Conn. filed patent applications (the US, European and New Zealand applications are considered here) covering a hydrophobic extract of the neem tree, an oil, for use as an insecticide and fungicide.⁹³ The chemical called Azadirachtin was identified as the active substance. A process to stabilize this chemical in water was patented, as was the stabilized form of the chemical.⁹⁴ The company did not apply for an Indian patent because the law at the time did not grant patents for agricultural products.⁹⁵ The foreign patents therefore drew a rapid response from India.

5. The Neem Patent at the EPO

The European Patent Office (EPO)⁹⁶ did not uphold the granting of the patent; it rejected it for lack of inventive step. Article 52(1) of the Munich Convention states that patents are granted on the basis of novelty, inventive step, and suitability of industrial application. Novelty is determined in relation to the state of the art, which according to Article 54(2) of the Munich convention means: "... everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." Unlike the case for the US system, where there is a clear division between information originating inside and outside the state, there is no such distinction here. The EPO can consider prior art that could be embodied orally or in practice, and not simply according to printed sources. These provisions clearly protect TK, the bulk of which is not written. In the neem case, however, the EPO did not consider TK rights *per se*.

6. Geographic Disparity in US Patent Law

The patent on the chemicals derived from neem was upheld in the US. Indian TK did not serve as prior art. While some authors have suggested that it is unconstitutional for the US to retain geographic disparity in its patent laws (35 U.S.C. §102),⁹⁷ other authors note that by not allowing foreign material to serve as prior art, there is an incentive to commercialize products in the USA. This could lead to compensation for the keepers of TK through contract law.⁹⁸ Under this view, the US does not allow patents to encompass what is in the public domain, but instead encourages the develop-

⁹³ See generally Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279 (1999).

⁹⁴ See U.S. Patent No. 5,281,618 (issued Jan 25, 1994).

⁹⁵ See Indian Patent Act 1970 3(h) stating that a "method of agriculture or horticulture" is not an invention and therefore cannot be patented.

⁹⁶ The European Patent Organization was put into place by the Munich Convention of 1973. As of March 2003 there were 28 member states. The system centralized the application process, while a valid patent is issued in as many states as requested in the application.

⁹⁷ See Bagley, *supra* note 72.

⁹⁸ See Craig Allen Nard, *In Defense of Geographic Disparity* 8 IIC 909 (2003).