Appendix C
Strategies and laws to promote traditional medicinal knowledge[1]

The value of traditional medicinal knowledge (TMK) in meeting the primary health needs of populations around the world is well documented. Recognizing the widespread use of traditional medicine in various regions including Asia, Latin America and Africa (e.g. up to 80% of the population in Africa depends on traditional medicine for its health care needs),[2] the World Health Organization (WHO) has pursued strategies and activities 'to facilitate integration of traditional medicine into the national health care system[s] by assisting Member States to develop their own national policies on traditional medicine'.[3] A 2003 resolution at the World Health Assembly urges WHO member states to:

> …take measures to protect, preserve and to improve if necessary traditional medical knowledge and medicinal plant resources for sustainable development of traditional medicine, depending on the circumstances in each country; such measures may include, where appropriate, the intellectual property rights of traditional practitioners over traditional medicine formulas and texts, as provided for under national legislation consistent with international obligations, and the engagement of WIPO in development of national *sui generis* protection systems.[4]

A national *sui generis* law which deals specifically with the protection of traditional medicinal knowledge is the Act on Protection and Promotion of Traditional Thai Medicinal Intelligence (1999 [BE 2542]) [hereinafter 'Thai Act']. The Act distinguishes among different categories of 'traditional formulations': '*national formulae*' are formulations which are crucial for human health and are held by the State; '*private formulae*' can be freely used by the owner (third parties must obtain permission from the owner to use the formula); '*general formulae*' may be used freely by anybody and comprise traditional formulae that have been widely used or whose intellectual property protection have expired (see Kuanpoth 2001).[5] The Act stipulates that the Minister of Public Health has authority to decree a certain formula of traditional Thai medicine as a 'national formula' (section 17). To be eligible, the traditional formula must be of significant benefit or have special medical or public health value (section 17). After the announcement, the rights of such a formula belong to the State. The use of a national formula for R&D of drugs for commercial benefit is subject to permission from the authorities and the payment of fees (see section 19); criminal sanctions are provided for in the case of infringement (section 78; Kwanpoth 2001, pp. 6–7).

The request for the registration of a 'private formula' can be submitted by an inventor or developer of the formula, or an inheritor of the inventor or developer of such a formula (section 21). The Act grants the owner of the registered personal formula exclusive rights to use the formula for research and to sell and distribute any product developed or manufactured by using the formula (section 34). Some exceptions to the exclusive rights are provided for in section 34, for example, in the production of drugs for household use or by state hospitals. The rights over a registered personal formula remain in force throughout the life of the owner and subsist for a further period of fifty years from the date of the applicant's death (section 33). In its report on *Protection and Promotion of Traditional Medicine – Implications for Public Health in Developing Countries*, the South Centre (2002) suggests 'the Thai Act provides a model of a special regime for the "protection" and the "promotion" of TRM which does not prevent the traditional healers from continuing to produce preparations for

individual use'. Along with some implementation issues, the report notes concerns over the long period of protection for traditional medicine registered as private formula. Commentators have also raised the need for frameworks and principles to govern access and benefit-sharing (ABS) with traditional communities who are custodians of relevant TK given the Thai Act does not address this explicitly (Robinson & Kuanpoth 2009).

Along with a Committee on Protection and Promotion of Thai Traditional Medicinal Intelligence, the Thai Act establishes the Fund on Traditional Thai Medicinal Intelligence. The income of the Fund would mainly come from state subsidies and the private sector. A number of Ministerial regulations to implement the Thai Act have been scrutinized by the Council of State and will have to be approved by the Cabinet before the provisions of the Act are fully implemented. Robinson & Kuanpoth (2009) suggest that the delay of the implementation of the regulations has left the traditional medicine law of Thailand ambiguous in many areas, including the issues of who has authority to grant access permits, the sharing of benefit among custodian communities, prior informed consent, the continuing traditional practices of traditional healers, and issues of competing or overlapping jurisdiction of different Ministerial departments over protected forest areas.

Meanwhile, there are interesting developments in the region in relation to the promotion of TMK, particularly within the context of the Association of Southeast Asian Nations (ASEAN). The delegates of the Conference on Traditional Medicine in ASEAN Countries, held in Bangkok on 31 August–2 September 2009, adopted the Bangkok Declaration on Traditional Medicine in ASEAN. In the Declaration, the delegates acknowledge that traditional medicine is often the most widely available and affordable source of health care in ASEAN, and reiterated the WHO's specific objectives in its *Traditional Medicine Strategy for 2002–2005* to support countries to integrate traditional medicine with national health care systems. The Declaration also recognized that ASEAN Member States 'possess an abundance of untapped and newly discovered herbal and medicinal plants and other natural resources, as well as *indigenous traditional knowledge and practices* which have evolved from different ethnological, cultural, geographical, philosophical backgrounds, and the need to ensure sustainable management of biological diversity' (emphasis added). Among other things, the signatories to the Declaration undertook to 'to develop specific activities to enhance collaboration in Traditional Medicine by involving practitioners and providers, industries, non-profit and professional organisations, academia, communities as well as partner organisations as key partners' (para. 3).

The Bangkok Declaration will lead to an action plan, and will be integrated with other ASEAN initiatives.[6] This may present opportunities, for example, for exploring regional frameworks or measures to regulate ABS relating to TMK. Such frameworks could potentially address ABS relating not only to TMK within national borders, but also to transboundary TMK (see the example of medicinal uses of the *Kwao Krao* plant in Chapter 4, Box 4.3). These initiatives will also need to be coordinated with international work and norm setting relating to genetic resources and associated TK, notably under the Convention of Biological Diversity (CBD) of 1992. As discussed in Chapter 4 of this book, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) of 2007 furthermore refers to the right of indigenous peoples to their 'traditional medicines' and to maintain their health practices, including 'the conservation of their vital medicinal plants, animals and minerals' (Article 24; see also Article 31(1)). The principle of free, prior and informed consent (FPIC) of TK custodians and arrangements for benefit-sharing in relation to use of

TK is discussed in Chapter 4, along with the ongoing work of the CBD Secretariat and the World Intellectual Property Organization (WIPO) in these areas.

Sources: Kuanpoth 2001; South Centre 2002; Robinson & Kuanpoth 2009

Notes

[1] Invaluable comments have been received from Jakkrit Kuanpoth towards this case study. Full references for this Appendix are found in the reference list of Chapter 4.

[2] See World Health Organization (WHO) 2002, *WHO Traditional Medicine Strategy 2002–2005*, WHO, Doc. WHO/EDM/TRM/2002.1, p. 1, available at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (accessed 26 November 2008). See also WHO, International Union for Conservation of Nature (IUCN), and World Wide Fund for Nature (WWF) 1993, 'Guidelines for Conservation of Medicinal Plants', IUCN, Gland, Switzerland.

[3] See the WHO website, 'WHO Traditional Medicine Strategy', available at: http://www.who.int/medicines/publications/traditionalpolicy/en/index.html (accessed 20 April 2010).

[4] World Health Assembly (WHA) Resolution WHA56.31 (28 May 2003), para. 2(6), available at: http://whqlibdoc.who.int/wha/2003/WHA56_31.pdf (accessed 18 May 2010).

[5] The Minister of Public Health has the power to notify a formula of traditional Thai drugs as 'general formula' (section 18).

[6] See Association of Southeast Asian Nations (ASEAN) 2009, 'Conference on Traditional Medicine in ASEAN Countries', *ASEAN Bulletin*, 1 September 2009, available at: http://www.aseansec.org/Doc-Bangkok-Declaration-on-Traditional-Medicine.pdf (accessed 16 March 2010). See also Lee-Brago, P. 2010, 'ASEAN Agrees to Further Promote Integration of Traditional Medicine', *The Philippine Star*, 7 January 2010, available at: http://www.philstar.com/Article.aspx?articleId=538589&publicationSub CategoryId=75 (accessed 30 January 2010).