

not be secret. It has been a common refrain that the patenting process is inimical to many conceptions of how TK should be regulated in traditional societies. Trade secret protection – the limiting of disclosure – would appear to be closer to a ‘state of nature’ than patents. Yet in both systems, the profit from the information may be restricted or may be distributed in any way that the group chooses. However, in trade secret law the information must be secret.

In contrast, patents allow non-commercial research to take place. After the period of protection expires, the information will enter the public domain. One is left to wonder what the consequences to all of human society would have been if the information from several plant derived ‘wonder drugs’ of the early part of the last century were still trade secrets.

Specifically in the case of pharmaceuticals, it appears unlikely that a public authority would allow a drug to be marketed without having a detailed understanding of the methods and materials used in its manufacture. Finally, as with GI and trademark protection, trade secret protection is ideal for a well developed commercial concern. It may be useful for protecting other forms of TK, but for TM, it appears totally unsuitable.

XI. CHINA

1. Statutory Protection

The legal methods of protecting Traditional Chinese Medicine (TCM) are distinctive. The reasons for this revolve around the peculiarities of TCM. The result is that while China has specific legislation, it might not be an appropriate model for other nations to follow. There has traditionally been little regulation of TCM in China, although the last several decades have witnessed increasing legislation. In 1992 the Regulations on Protection of Traditional Chinese Medicines (effective 1 January 1993)¹⁶² was enacted. The aim of the law is to encourage research and development of new varieties of Traditional Chinese Medicine (TCM). The law is not applicable after patent rights have been applied for.¹⁶³ It is therefore a *sui generis* system designed to operate in conjunction with patents.

The Chinese regulation stipulates that: “This Decree is applicable for all varieties of traditional Chinese Medicines produced and/or prepared within the territory of China, including traditional Chinese proprietary medicines . . .”.¹⁶⁴ The Chinese regulation does not specifically address the issue of TK. It envisages that the IP rights would be vested either in an individual or corporate structures. There is no provision for a community to own rights in TCM. The regulation introduced graded protection of stable

162 Regulations on Protection of Traditional Chinese Medicines Article 2, (Promulgated by Decree No. 106 of the State Council of the People’s Republic of China on October 14, 1992). An English translation is available at http://cq.netsh.com/bbs/751605/html/tree_5837217.html (last visited Sept. 5, 2006).

163 See *id.* art 2.

164 *Id.*

varieties of traditional Chinese Medicines (TCM), as Article 3 makes clear. The insertion of the word ‘stable’ here suggests that the mixtures must be replicable, and that there must be complete disclosure. This may present some difficulty to practitioners of TCM, as some remedies may contain secret materials. There are to be two grades of protection, Grade 1 and Grade 2. Briefly, the former must have special therapeutic results to a given disease.¹⁶⁵ The latter group must have “noticeable therapeutic results to a given disease.”¹⁶⁶ Article 13 stipulates that: “The ingredient and formulae, and its technical know-how of the preparation for varieties under Grade 1 protection shall be kept as a secret within the protection period.”¹⁶⁷ This same concern with secrecy does not apply to Grade 2.

2. Patent Law

There has also been recent change in China’s patent laws to include TCM. This is allowed under TRIPS 27.1, which states patents: “... shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” The Patent Law of the People’s Republic of China¹⁶⁸ did not previously allow TCM to be patented. Before January 1 1993, methods used to prepare drugs could be patented, but products and usage could not. After this date, it was possible to protect products, methods and usage. There have been a number of filings regarding TCM. Since 1992, when the patent law was amended, there have been an average of 1400 cases per year.¹⁶⁹ Patents may be granted for inventions, utility models, and designs.¹⁷⁰ TCM would be protected as an invention. Article 22 of the Chinese Patent Law states that any invention must possess novelty, inventiveness and practical applicability tests. The test for novelty means that no identical invention has been disclosed in publications in China or abroad, or has been publicly used or made known to the public by any means.¹⁷¹ This is perhaps the most difficult hurdle of Chinese TM to cross, as there has been a wealth of literature devoted to TM in China spanning an enormous period of time. A similar observation could be made on the issue of public use. Remedies that have been essentially protected as a trade secret could still be patented. Commonly known treatments could not be.

¹⁶⁵ See *id.* art 6.

¹⁶⁶ *Id.* art 7.

¹⁶⁷ See *id.* art 13.

¹⁶⁸ Patent Law of the People’s Republic of China, adopted at the 4th Meeting of the Standing Committee of the Sixth National People’s Congress on March 12, 1984; amended in accordance with the Decision of the Standing Committee of the Seventh National People’s Congress on Amending the Patent Law of the People’s Republic of China at its 27th Meeting on September 4, 1992, see http://sipo.gov.cn/sipo_English/flfg/zlflfg/t20020327_33872.htm (last visited Sept. 5, 2006).

¹⁶⁹ See generally Yongfeng, Zheng, *The Means and Experiences of Patent Protection of Traditional Medicine in China* 3-11. http://r0.unctad.org/trade_env/test1/meetings/delhi/Countriertext/CHINAspeech.doc (last visited Sept. 5, 2006).

¹⁷⁰ See Patent Law, *supra* note 81, art. 2.

¹⁷¹ See *id.* The tests for inventiveness and practical utility are also covered in Art 22.