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 China[168] 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/Countriestext/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.

Article 25 of the Chinese Patent Law states that methods for the diagnosis or treatment of diseases cannot be patented. A new use for a known drug is patentable. According to a patent examiner from the Patent Office of the Peoples Republic of China,[172] a medicine may be composed or prepared from a mixture of several herbs as long as no identical method has been published before the application. This mixture can be said to be newly created. A drug may also be made from a substance not previously known. In the latter case, evidence must be submitted regarding medical effectiveness. A medicine may also be composed from several known herbal medicines if the constitution or ratio has been changed so that the new mixture has new properties, such as increased effectiveness or fewer side effects.

TCM has incorporated scientific techniques, which makes determination of novelty more straightforward.[173] A good example is a "Technique of Preparation of Ripe Rhubarb by Heat Pressing." This involves isolating the active ingredients from rhubarb by heating at high pressure with the use of supplementary materials.[174] While rhubarb is well known, the method of extraction was the invention. In another case, the invention relates to the method of delivery. In the patent titled "Injection of Root of Red-rooted Salvia" the patent relied upon a form of the drug that could be easily used in a clinical environment because it could be injected.[175]

In 2004, the Chinese Ministry of Science and Technology has made the modernization of TM one of the 12 main focal points of its current 5-year plan. An entire technology park in Houzhou has been devoted to the scientific study of Chinese Medicine.[176] Most of the investment occurs in state institutions. Much of the impetus arises from fears that foreign pharmaceuticals will dominate the Chinese market.[177]

The TK content in TCM is not easy to define. On one hand there is a philosophical basis, while on the other hand TCM is increasingly being integrated with western medical practices. There may be less of a focus on conserving indigenous practices. This is in contrast to such countries as Thailand or the Philippines, which are exploring many possibilities besides the patent system.[178] It may be that Chinese legislators find patents a more formidable form of protection. Considering that TCM has been integrated with scientific techniques, patents may be suitable for China and less so for other nations.

172 *See* Yongfeng, *supra* note 169.

173 *See* Liu, *supra* note 27 at 198-99. She lists five examples of patents that overcome the novelty requirement by using new techniques or methods. Her example numbers 1 and 5 are used here.

174 U.S. Patent No. 85100957, http://211.152.9.47/sipoasp/zljs/hyjs-yx-new.asp?recid=85100957&lexin=0> (last visited Sept. 5, 2006).

175 U.S. Patent No. 94114040.7, http://211.152.9.47/sipoasp/zljs/hyjs-yx-new.asp?recid=94114040.7.X&lexin=0> (last visited Sept. 5, 2006).

176 *See* Paroma Basu, *Trading on Traditional Medicines*, 22:3 NATURE BIOTECHNOLOGY 263 (2004).

177 Teresa Schroeder, Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit from One of Their Most Valuable Cultural Resourcs? 11 Pac. Rim. L. & Pol'y J. 687 (2002).

178 *See* Benjamin Liu, *Past Cultural Achievement as a Future Technological Resource: Contradictions and Opportunities in the Intellectual Property Protection of Chinese Medicine in China*, 97 U.C.L.A. PAC. BASIN L.J. 86 (2003).

The statutory protection of TCM appears to offer an alternative in cases where scientific techniques are not integrated into TCM. There is apparently no need to fully characterize the drug, beyond being a stable mixture. The main focus is on clinical effectiveness. This form of protection appears to be much easier and less expensive to obtain than a patent. The Chinese example, however, shows that patent protection for TCM is still widely used and is growing in popularity. There is no doubt wide scale public acceptance of patents that a statutory system would find hard to match.

3. *A Database of Traditional Chinese Medicine?*

While southeast Asian countries such as India are enthusiastic about the establishment of database protection of TM, China does not seem to be moving in that direction. It is possible that given their current level of protection, via patents and the regulation of 1992, there is adequate protection and there is no need for a database. On the other hand, there are a number of factors that make a TCM database a very different undertaking from southeast Asia. One of the most obvious factors is language. For instance, China, Korea and Japan have a partially shared history in the development of TM. The result is that there can be the same formula titles used for traditional remedies, yet these will be pronounced differently in all three countries. It is difficult to communicate precise information about some aspects of TM given this level of uncertainty.[179]
The titles of TCM as expressed in Chinese characters have an ideographic meaning as distinct from a phonetic one as in an alphabetic system. When Chinese characters are translated into English directly – without explanation – a scientist would not understand their meaning. Many words indicate not only specific herbal materials and effectiveness but also expressions familiar only to Chinese culture. The problem is particularly acute with remedies involving multi-herb formulations.[180]
A recent attempt to classify TCM into a database involved seven distinct groups of information: 1. A systematic botanical description; 2. Herbal formulae with bibliography; 3. Diseases or symptoms treated; 4. Traditional processing methods to remove toxic ingredients; 5. Chemical structures of ingredients; 6. Safety and toxicity data; and 7 Clinical reports of interactions with western drugs.[181] While some of this information is relevant only when using these drugs, other aspects are essential when determining prior art for the purposes of a patent. Items 1-5 are essential, while safety items 6 and 7 are less of a concern at that stage. The authors did note that they had particular difficulty in translating the titles of the formulae as well as interpreting the symptoms and diseases as they were described in the literature.
While several of these issues arise for any proposed TM database, it appears that the situation for TCM and similar systems make preparing such a database difficult and

179 *See* J. Park, H.J. Lee & E. Ernst, *What's in a name? A systematic review of the nomenclature of Chinese medical formulae* 30 AM J CHIN MED 419 (2002).
180 *See* M.Q. Zhang, *A treatise on the standardization of prescription's name, in* EXPERTS MEETING FOR THE STANDARDIZATION OF TITLES OF CHINESE PRESCRIPTIONS 33, 39 (I.M. Chang ed. 1996).
181 Yeong-Deug Yi & II-Moo Chang, *An Overview of Traditional Chinese Herbal Formulae and a Proposal of a New Code System for Expressing the Formula Titles* 1 EVIDENCE-BASED COMPLEMENTARY AND ALTERNATIVE MEDICINE (eCAM) 125 (2004).