

COMMENT

PAST CULTURAL ACHIEVEMENT AS A FUTURE TECHNOLOGICAL RESOURCE: CONTRADICTIONS AND OPPORTUNITIES IN THE INTELLECTUAL PROPERTY PROTECTION OF CHINESE MEDICINE IN CHINA

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I. INTRODUCTION

The latter part of the 20th century has witnessed a renewed interest in Chinese medicine (CM) both in China and abroad.¹ What was once dismissed as superstition or the remnants of an unenlightened China has suddenly become the key to providing public healthcare in developing countries and a ray of hope in developed countries.² At the same time, entrepreneurial individuals and organizations perceive CM as a moneymaking business and fuel for technological development. The Chinese state views its extensive experience with CM as representative of a competitive advantage in the post-WTO global economy. Therefore, it is actively promoting CM research, education, and investment.³ One essential aspect of these activities is the protection of CM as

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1. See Kelvin Chan & Jian-Qian Zou, *The Way Forward for Chinese Medicine*, in *THE WAY FORWARD FOR CHINESE MEDICINE* 413 (Kelvin Chan & Henry Lee eds., 2002).

2. See Kelvin Chan et al., *The Progress of Chinese Medicine in Mainland China*, in *THE WAY FORWARD FOR CHINESE MEDICINE*, *supra* note 1, at 192; VOLKER SCHEID, *CHINESE MEDICINE IN CONTEMPORARY CHINA: PLURALITY AND SYNTHESIS* 34 (2002).

3. See Volker Scheid, *Remodeling the Arsenal of Chinese Medicine: Shared Pasts, Alternative Futures*, in 583 *ANNALS AM. ACAD. POL. & SOC. SCI.* 137 (2002) (“The Chinese government has envisaged earnings from the sale of Chinese medicines abroad in 2000 to exceed U.S. \$80 million and is actively promoting a strategy to increase these revenues in the future.”); GAN ET AL., *THE DEVELOPMENT STRATEGY PLAN OF MODERNIZATION OF THE PRACTICE AND USE OF CMM* (1998).

a type of intellectual property under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS agreement).⁴

The TRIPS agreement and the propertization of knowledge engendered bitter North-South divide. The Chinese genuinely welcomed TRIPS in the area of CM because it can be used to protect native interests and knowledge. Current discussions of CM development regularly refer to the benefit of patent protection, and discussions of intellectual property rights (IPRs) in China regularly legitimize the patent system through reference to the development of CM.⁵ At the same time, NGOs, conservationists, anthropologists, traditional communities, and some developing countries perceive inadequacies in the patent system.⁶ They have urged the protection of traditional medicine under a *sui generis* system created specifically for the protection of traditional knowledge (TK).⁷

Critics of existing IPRs protection of traditional knowledge highlight anecdotes of exploitive abuse.⁸ However, these critiques rarely engage the social choices behind the doctrines. On the other hand, in-depth analyses of the underlying policy considerations for patent and TK IPR systems do not mention the particular social context confronting CM in 21st century China.⁹ This paper attempts to bridge the gap by examining the economic and informational interests underlying CM and IPRs protection. Section II provides background information on the practice of CM, the current economic interest in CM, and the perceived goal of protecting CM through an IPRs regime. Section III looks at the theory underlying patent law and assesses the difficulties China may encounter in realizing its CM aspirations through the patent system. Section IV considers the theories underlying a *sui*

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, WTO Agreement, Annex 1C, art. 31, in *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* 321, 334 (1999), 33 I.L.M. 81 [hereinafter TRIPS Agreement].

5. See, e.g., Chan & Zou, *supra* note 1, at 424.

6. For background information, see Ida Madieha Azmi, *Intellectual Property Aspects of Biological Resources-The Malaysian Perspective*, in *INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY* 140-51 (Michael Blakeney ed., 1999); Ong Chui Koon, *Intellectual Property Protection of Traditional Medicine and Treatments in Malaysia*, in *INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY*, *supra* note 6, at 152-72.

7. See generally Koon, *supra* note 6, at 171; Uma Suthersanen, *Legal and Economic Considerations of Bioprospecting*, in *INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY*, *supra* note 6, at 69.

8. See, e.g., Koon, *supra* note 6, at 171.

9. For examples of scholarship that examines IP policy in general, outside the context of China, see WILLIAM KINGSTON, *INNOVATION, CREATIVITY AND LAW* (1990) (discussing the relationships between information, market force, and IPR system); Suthersanen, *supra* note 7.

generis alternative for the IPRs protection of TK and examines its associated difficulties. Section V contrasts the difficulties of protecting CM under the patent system and under a TK IPR system. Section VI concludes that a more satisfying answer is possible if China first prioritizes its interests and then infuses patent protection with elements of TK IPRs.

Before proceeding with the substantive discussion, it is important to note the unique legal position CM occupies in the IPRs scheme. The manufacture and sale of CM products necessarily calls forth considerations of trade secret law, unfair competition law, traditional trademark laws, and laws governing geographical indications.¹⁰ Within patent law and TK IPRs, CM products trigger equally contentious moral questions regarding the preservation of biodiversity and the patenting of living organisms. This comment eschews the complex interactions of these issues and instead simply analyzes the effect of patent law and TK IPRs on the information Common and resultant market competitiveness. Therefore the discussion is oversimplified, and its final recommendations are qualified by these additional considerations. Although definitive answers must come from a more in depth analysis of the national situations, this comment provides a list of what China must consider in implementing IPRs that promote their CM aspirations while domesticating the TRIPS agreement.

II. BACKGROUND

A. DEFINITIONS

CM is the sum of healthcare practices in China since the beginning of Chinese history.¹¹ Attempts to define CM beyond the

10. Most importantly, the Regulations on Protection of Traditional Chinese Medicines, Decree No. 106, ch. 2, arts. 6, 7 and ch. 3 (1992), provide a formalized set of special trade secret protection for CM innovations with periods of protection varying according to the importance of the invention. However, the trade secret protection is fundamentally a mere elaboration of what the CM practitioners have been doing (and sometimes quite successfully) for years—keeping the formulation to themselves.

11. The use of herbal remedies and acupuncture in China began at least around 2800 B.C. For the next two thousand years physicians and pharmacists began formalizing and theorizing the practice of medicine. CM had spread to the neighboring regions of Korea and Japan by the First Century. By 1 A.D., texts documenting general medical theory, and information on specific diseases and treatment, as well as medicinal substances and their methods of preparation, had all come into existence. These compilations were updated every dynasty, and the most well known compendiums of pharmacopoeia, BEN CAO GANG MU [COMPENDIUM OF MATERIA MEDICA] featured nearly 2000 substances encompassing plant, animal, and other materials, and collected over 10,000 prescriptions. It was published in 1596 A.D., brought to Europe, and translated first into Latin, then into English, French, German, and Russian. During this period, European physicians also acquired acupunc-

tautological invocation of China usually fall into two camps. Within modern Chinese discourse, CM is a systematic practice of distinguishing among various illness-causing imbalances of *qi*. CM achieves health by restoring a patient's internal *yin-yang* equilibrium via herbal remedies and physical manipulation.¹² Popular accounts interpret CM as a historically substantiated system of holistic medical interventions using natural products, based on an intuitive understanding of the interaction between the human body and the environment.¹³ The terms "historical," "holistic," "natural," and "intuitive" are used dialectically to illustrate the difference between CM and the biomedicine practiced in the healthcare institutions of developed nations; the latter is perceived to be "scientific," "reductionist," "synthetic," and "analytical." These sets of contrasting definitions risk constructing an imaginary CM practice—the former fantasizes a non-existent coherence, and the latter polemicizes a non-existent dichotomy. Any concrete definition of CM needlessly risks marginalizing specific practices due to its inherent pluralism and syncretism.¹⁴ As I will discuss later, the inability to define CM has ramifications for the IP protection of CM.

B. THE ECONOMIC IMPORTANCE OF CHINESE MEDICINE

Chinese herbal preparations alone account for thirty to fifty percent of all medical intervention in China, and CM delivers healthcare to over twenty percent of the world's population.¹⁵ In

ture via Dutch trade with Japan. The development of CM throughout this history was uneven, with stagnation accompanying those eras in which patients turned to the supernatural for help. However it was not until the introduction of Western medicine in the 19th and 20th centuries that CM faced its greatest challenge. With the demise of the Chin dynasty in 1911, the new Republic of China discouraged the practice of CM as part of a program to modernize itself through adopting Western technologies. The trend reversed when the Chinese Communist party came to power and CM was integrated into the state healthcare system. Since the 1980s, the Chinese government has been actively promoting the documentation, research, and business of CM. See Kelvin Chan, *The Historical Evolution of Chinese Medicine and Orthodox Medicine in China*, in *THE WAY FORWARD FOR CHINESE MEDICINE*, *supra* note 2, at 8-20.

12. See Zhan-wen Liu, *Philosophical Aspects of Chinese Medicine from a Chinese Medicine Academician*, in *THE WAY FORWARD FOR CHINESE MEDICINE*, *supra* note 2, at 23-31 [hereinafter Chan, *The Historical Evolution of Chinese Medicine*].

13. For example, a physician of CM may examine the tongue color and read the pulse profile of a patient reporting for arthritic pains and interpret the symptoms as a case of "obstruction" type symptoms resulting from the depletion of *qi* and *blood*. The prescription could include a complex formula containing over ten herbs or even poisonous inorganic elements of sulfur in order to replenish the *yang qi*, cool and strengthen the *blood qi*, and pacify the liver *wood* element.

14. See generally SCHEID, *supra* note 2.

15. See World Health Organization, *Traditional Medicine*, Fact Sheet No. 134, at http://www.who.int/health_topics/traditional_medicine/en/ (last visited Dec. 30, 2002).

addition, modified forms of CM are well established in Korea, Japan, Malaysia, and other neighboring countries. CM has also emerged as a major alternative to biomedicine in developed countries. For example, acupuncture institutions have been set up in all developed nations including Australia, Great Britain, and the United States to deliver healthcare alternatives to or complementary with standard biomedicines.¹⁶ The World Health Organization (WHO) has set up the International Acupuncture Training Center and the International Society of Acupuncture and Moxibustion in China to train overseas physicians and to research acupuncture.¹⁷

The demand for herbal health products and functional food expands the impact of CM knowledge beyond the economics of healthcare. By some estimates, the global sale of herbal products is now a 25 billion dollar international business and increasing, although only 3% of the trade originates from China.¹⁸ CM-related trade includes ingredients and components of CM, manufactured CM formulations, CM supplies and equipments, and functional food items.

The interplay between the pharmaceutical industry and CM further increases the economic importance of CM. It is believed that at least 25% of all prescription drugs have their origin in plant chemicals and 75% of these were found by examining the use of these plants in indigenous communities.¹⁹ Knowledge of the therapeutic effects of plants and animals has consistently provided biomedical researchers with directions for drug development, especially for illnesses for which there is currently no satisfactory treatment. For example, herbs identified in CM have been explored extensively for the treatment of cancer.²⁰ Two developments in the functioning and aim of the pharmaceutical industry will further elevate the role of CM in modern biomedical research. First, instead of developing compounds to alter the biochemistry of specific diseases, the modern drug discovery effort focuses on developing biologically active chemical "libraries" containing millions of molecules and studying these libraries via

16. See Christoph Kunkel et al., *The Progress of Chinese Medicine in Some Countries in Europe: Belgium, Germany & Holland*, in *THE WAY FORWARD FOR CHINESE MEDICINE*, *supra* note 2, at 240-53.

17. Chan, *The Historical Evolution of Chinese Medicine*, *supra* note 11, at 18-19.

18. See Teresa Schroeder, Comment, *Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit From One of Their Most Valuable Cultural Resources?*, 11 *PAC. RIM L. & POL'Y J.* 687, 688 (2002).

19. World Resource Institute, *A Short List of Plant-Based Medicinal Drugs*, at <http://www.wri.org/wri/biodiv/pharmacy.html> (last visited Jan. 6, 2002).

20. Jennifer Man-Fan Wan, *The Progress of Using Chinese Herbal Medicines in Cancer Research*, in *THE WAY FORWARD FOR CHINESE MEDICINE*, *supra* note 2, at 136-37.

the High Throughput Screening technology. Under the new paradigm, any technique capable of enriching the biological activity of the chemical libraries can increase the hit rates of the screening process and the number of potential drug leads. A library created from plant materials listed in the *Materia Medica* of CM is thus a very powerful library for drug screening. Second, current medical challenges in developed nations often involve degenerative or chronic diseases featuring complex environmental interactions, long epidemiological histories, and, slow onset of symptoms. CM boasts the ability to modify and boost the body to overcome or mitigate chronic diseases without the need to delineate the complex underlying biochemical process. These two developments link historical CM knowledge with the contemporary drug discovery process.²¹ Incidentally, pharmaceutical companies in developing nations have been accused of engaging in biopiracy, or the practice of collecting biological samples and local medical knowledge from communities within developing nations without remuneration.²²

In addition to generating valuable goods and services, CM is also a competitive tool accompanying China's entry into the global market. In contrast with its belated development in key technological areas such as medicinal chemistry, bioengineering, and telecommunication, China possesses the most advanced CM knowledge. The advantage in this area may spearhead China's entry into the lucrative field of pharmaceuticals. Apart from its economic importance, CM embodies national history and cultural heritage. Therefore the Chinese government and con-

21. For the effort of combining the above mentioned effort, see Beijing Genomic Institute, *BGI Super Computer Center: Platforms*, at <http://coe.genomics.org.cn/platform.htm> (last visited Jan. 6, 2002) ("HTS has been well developed recently and widely used by all pharmaceutical companies in the world for discovery of new drug lead compounds. The traditional Chinese herbal medicine offers the rich source for nature compounds, which may have higher hits rate for HTS. The goal of applying HTS in Chinese herbal medicine is try to develop more new effective drugs from TCM. The [targets] are related with obesity, inflammation, cancer, asthma, and cardiovascular diseases.")

22. See Lakshmi Sarma, Note, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 *TEMP. INT'L & COMP. L.J.* 107 (1999); Ketih Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 *IND. J. GLOBAL LEGAL STUD.* 11 (1998). A famous example is the turmeric patents, where a plant known for its wound-healing properties in India was patented for the same utility by an American in United States. See David Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 *COLUM. J. ENVTL. L.* 253, 278-79 (2000). In an analogous vein, a U.S. seed firm has brought seed from Mexico, patented the Enola beans with a yellow hue in U.S., enforced this patent against all beans imported from Mexico with a yellow hue, and levied a 6% royalty on the imported beans. See Gillian Rattray, *The Enola Bean Patent Controversy: Biopiracy, Novelty and Fish-and-Chips*, 2002 *DUKE L. & TECH. REV.* 8 (2002).

cerned citizens view the unacknowledged and uncompensated use of CM by foreign companies as an abuse or misuse of cultural relics and a violation of national identity.²³ The State Administration of Traditional Chinese Medicine under the Ministry of Public Health is now the central administrative body that oversees the development of CM and issues regulations governing the practice of CM.²⁴

C. JUSTIFICATION FOR THE CREATION OF IPR FOR CHINESE MEDICINE.

Given the multitudinous economic benefits, it is no surprise that discussions of CM increasingly drawn on IPRs. CM supporters believe that a systematic grant of IPR to CM knowledge and products can incentivize investment in CM products and an expansion of the CM knowledge base.²⁵ From the healthcare perspective, CM remains the most prominent alternative/complementary medicine in developed nations, and IPR can channel resources to validate the use of CM in order to preserve patient choice and diversify the medical repertoire. It is analogous to the support pharmaceutical and biotech industries in developed countries have shown for the expansion of IPRs to include their efforts to convert natural preparations into orthodox treatment. The Chinese government, ever conscious of its

23. For discourse on China's CM aspiration, see generally Schroeder, *supra* note 18.

24. *Id.* at 702. Schroeder listed some of the prominent regulations: "Law on Drug Management 1985; Law on Certified Physicians 1998; Regulations on the Protection of Wild Medicinal Resource; Regulations on the Protection of TCVM Drug Varieties; Regulations on the Management of Medical Institutions; The Regulation of Anhui Province on the Development of Traditional Chinese Medicine (2001); The Regulation of Beijing Municipality on the Development of Traditional Chinese Medicine (June 22, 2001); The Notice of the Ministry of Health Concerning Restriction the Production of Health Foods Using Licorice Root; Chinese Ehedra; Desert Cistanche; Snow Lotus and Their Product in Raw Materials (June 1, 2001); The Regulations of Shanxi Province on the Development of Traditional Chinese Medicine (May 21, 2001); The Measures of Tianjin Municipality for Administration of Chinese Traditional Medicine Pieces for Decoration (Apr. 30, 2001); The Regulations of the Inner Mongolia Autonomous Region on Traditional Mongolian Medicine and Traditional Chinese Medicine (Feb. 12, 2001); The Regulations of Gansuu Province on Developing Traditional Chinese Medicine (Nov. 27, 2000 & Dec. 2, 2000); The Regulations of Jiangxi Province on the Development of Traditional Chinese Medicine (June 27, 2000) (www.chinalegalchange.com); Circular of State Administration of Chinese Traditional Medicine Ministry of Foreign Trade and Economic Cooperation State Administration of Import and Export Commodity Inspection and Customs General A Administration on Implementing the Quality Registration; Inspection and Releasing System of Chinese Traditional Medicines to be Exported."

25. *Id.* at 715-16 ("Better protection for patentees will not only reward Chinese creation of [Traditional CM] products, it will also encourage foreign investment. Enforcing patent rights could also encourage standardization in the final products.").

new global role under the WTO membership, believes that IPRs can transform CM into one of China's primary assets in the global competition for technology and market share. The development of CM under an IPR system also fosters the use and awareness of the budding IPR in China.²⁶ The goals of IPRs include the maintenance and preservation of Chinese cultural heritage. An IPR system would also provide China with the ability to exclude others from the unauthorized use of CM product, and processes, thereby stemming the tide of biopiracy within its borders.²⁷

Proposals to propertize CM knowledge trace either the patent paradigm or the traditional knowledge paradigm. The Chinese government currently employs the patent system to protect CM.²⁸ While the patent paradigm enjoys the convenience of an established legal framework and international recognition, it is only applicable to a fragment of total CM knowledge.²⁹ In contrast, a *sui generis* system to propertize traditional knowledge can be tailored to cover a significant portion of the total CM knowledge. However, such protection remains largely theoretical because the practical uncertainty of adopting an unprecedented system cast doubts on its feasibility. Many scholars and advocates of developing nations continue to urge the WTO to adopt traditional knowledge IPRs into the TRIPS agreement.³⁰ Therefore, an analysis of IPRs for CM must consider the strengths and weaknesses of both the patent approach and the traditional medicine approach, beginning with their rationales and methods of operation.

26. For discussions on the role IPRs play in the development of CM, see Jing Hong, *Zhongyao Zhishi Caichan Quan Baohu de Duice* [An Intellectual Property Rights Response of Chinese Medicine], 1 WORLD SCIENCE & TECHNOLOGY—MODERNIZATION OF TRADITIONAL CHINESE MEDICINE 32 (1999).

27. Of course, China cannot change through domestic laws the U.S. patent law that enables the pirates to patent the misappropriated information or plant in the U.S. Although the U.S. should examine patent applications more carefully and change its patent law to better reflect the role of TK as prior art that destroys patentability, the scope of the international dialogue is beyond the scope of this paper.

28. The Traditional Chinese Medicine Patent Database contains a collection of CM related patents. Traditional Chinese Medicine Patent Database, at <http://tcm.patent.com.cn/englishversion/>.

29. For Brazil's suggestion of a *sui generis* system of protection, see World Trade Organization, *Review of Article 27.3(b)—Communication from Brazil*, IP/C/W/228, at 36 (Nov. 24, 2000) ("Protection provided by the conventional IPR regime is limited . . . by conceptual factors, since certain aspects of the knowledge produced in most traditional communities are not necessarily within the scope of the TRIPS Agreement.").

30. *Id.*

III. PATENT AND CM

A. THE PATENT MODEL AND THE PROMOTION OF PHARMACEUTICAL INNOVATION

Under neo-classical economy theory, the patent system promotes the effective allocation of resources to innovation and avoids what G. Hardin describes as the tragedy of the Commons.³¹ The tragedy is that under a system where individuals are allowed to maximize their self-interest using a common resource (such as herding on a common grass lot), rational actors would expand their economic enterprise (by adding sheep to a herd) until the continuous expansion exhausts the scarce but common resource (the grass). The freedom to use the Common brings an eventual downfall to all.

While the public use of information does not appear to engender the tragedy of the Common because information cannot be depleted in the same sense that tangible resources are exhausted, beneficial inventive activities would be depleted if the inventor could not recuperate the cost of the invention. This is the mirror image of the tragedy, where economically unaccounted resources lead to over-consumption. With information, the existence of economically unaccounted resources causes under-production. But the result is the same whether it derives from the overuse of the environmental Common or the under-production of the information Common. The amount of total information wealth for the society is constrained. One redress is to devote social resources to the preservation and expansion of the information Common, as is done when the public channels funds to individual researchers via universities and government.³² The alternative patent approach is to create a private economic incentive such as the power of monopoly to realize the value of the new information in the inventor.³³ Both approaches essentially require the market system to account for the use of a common resource in order to avoid the tragedy of the Common.

Economic efficiency demands that the invention noticeably enlarge the future information Common. However, even where the patent monopoly is justified by benefit to the public, it alters the competitive environment between market players. A secondary attribute of the patent approach is that the allocation of resources to preserve the information Common is built into the market in the form of a monopoly. Because the winner takes the entire market, the patent system allows nimble innovators to out-

31. See Garret Hardin, *The Tragedy of the Commons*, 162 *SCIENCE* 1243-48 (1968).

32. See Suthersanen, *supra* note 7, at 45.

33. KINGSTON, *supra* note 9, at 81.

compete established market actors but also allows established companies to further consolidate their market power via research and development efforts.³⁴ This is the distributive power of the patent monopoly. A rational government, insofar as it has an economic and political stake in the well-being of its industries, has an economic and political stake in the intellectual effort it chooses to propertize. It would attempt to control the distributive power and use the patent system to increase the market competitiveness of domestic companies vis-à-vis foreign producers. Thus from the government's perspective, the most appropriate patent system improves the competitiveness of national industry in two ways—by enlarging the information wealth and by reserving legal monopolistic power for its own industries.

B. CURRENT PROTECTION OF CM UNDER THE PATENT SYSTEM

Under Article 27.1 of the TRIPS agreement, “[P]atents 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,” where “inventive step” and “capable of industrial application” could be synonymous with “non-obvious” and “useful” respectively.³⁵ Because TRIPS does not define invention, and offers two versions of the key terms, WTO member nations are free to create national patent systems that best promote their own interests. However, the process of translating economic considerations into a legal framework is not always easy.

Patent protections have been extended to CM-based pharmaceuticals. Countries as diverse as China, Japan, the United States, the United Kingdom, and Germany have issued patents to CM practice, and products from acupuncture processes to herbal mixtures.³⁶ There is a flurry of CM related

34. It has been argued that bigger enterprises have more funds for research and development activities than will be available for smaller companies. However, the bigger an enterprise is, the less receptive it is to new ideas and innovation. Consequently, there comes a point at which smaller firms can implement competitive innovations at a lower cost and counter balance the productive capacity and market presence of the more established companies. *Id.* at 94.

35. TRIPS Agreement art. 27(1).

36. For a list of acupuncture patents in the U.S., see [health.xq23.com](http://www.health.xq23.com), *Acupuncture Resources*, at <http://www.health.xq23.com/pain/Acupuncture.html> (last visited Jan. 6, 2002). Specific examples of U.S. patents range from U.S. Patent 6,393,324, a “method of blood pressure moderation,” to U.S. Patent 6,421,560, a “device for guiding spots for acupuncture and stimulation methods thereof.” US Patent 6,468,541 details a hypoallergenic immune system stimulator and its powdered and capsule form are comprised of four herbs based on CM, and US Patent 5,324,516 details a composition that is comprised of fructose and aqueous extracts of pueraria,

patent activity in China, including the revealing in March 2002 of the new Traditional Chinese Medicine Patent Database, which contains all the 12,000 CM patent applications filed since the creation of the Chinese patent office in 1985.³⁷ A parallel database collects CM information in order to prevent the patenting of previously known CM information.³⁸ It was observed that the Heilongjian Province Chinese Medicine Research Institute's unpatented herbal preparation Xiao Ke Chuang was widely copied in China, but its later invention, Xuan Huang Lian, was a financial success because it was protected under a process patent.³⁹

C. PROBLEMS WITH THE PATENT PROTECTION OF CM

Notwithstanding the ongoing CM patent issuance, the patent system is poorly suited to the preservation and promotion of CM. The theoretical scope of its protection is very limited because the patent system only protects knowledge embodied in inventions. Therefore, pure knowledge in the use of acupuncture points combinations or herbal mixtures is not patentable. Because the patent system protects inventions, the protectable CM product or process is a tiny island in the vast sea of existing practice. To be sure, the patent system would seem to offer some incentive to embody CM in novel commercial products or to further CM research. It is generally agreed that the pharmaceutical industry receives the most benefits under the patent system due to the special strength of chemical patents and the difficulties for competitors to invent around the patents.⁴⁰ In addition, the patent system has the benefit of reserving the wealth of CM knowledge for the public rather than for specific stakeholders. However, the patent system does not conserve CM *qua* CM. Patent holders

phaseoli radiati, and pinelliae tuber sufficient to reduce the effect of alcohol intoxication. Both patents referred to CM.

37. See Traditional Chinese Medicine Patent Database, *supra* note 28. The full record is only available under the Chinese version.

38. The Traditional Chinese Medicine Medical Literature Analysis and Retrieval System (TCMLARS) includes 73,275 references and abstracts to literature on acupuncture and herbal medicines published since 1984. See http://wall.cintcm.ac.cn/webdkrh1/e_index.htm (last visited March 12, 2004).

39. Weibo Zhang, *Lun Zhongyao Qiye Zhishi Chanquan de Baohu* [On the Intellectual Property Protection of the Chinese Medicine Industry], 2 WORLD SCIENCE & TECHNOLOGY—MODERNIZATION OF TRADITIONAL CHINESE MEDICINE 56 (1999), available at http://www.cintcm.com/lanmu/zhongyi_keyan/yanjiu_journal/journal2/page56.htm#3 (last visited March 12, 2004).

40. KINGSTON, *supra* note 9, at 121. It was observed that in the West, chemical patent law allows a patent to cover a molecule and all of the structurally analogous molecules. Moreover, the therapeutic properties of chemicals are not well understood, and therefore it is difficult to replicate a therapeutic result of a patented molecule by uncovering a novel molecule. Recent discussions of CM patent suggest that the same effect may be reproduced for herbal CM. See *infra* note 70.

may choose to channel some profit back to the conservation and development of CM—however, this is not built into the patent system. If modern medicine, using patented pharmaceuticals developed from CM, drives practitioners of CM out of business, it is only the invisible hand of the market at work.⁴¹

Even where the CM product or process is novel, it may fall within specific legal exclusions. For example, the patent law in many countries, including China, excludes “methods for the diagnosis or for the treatment of diseases.”⁴² This would seem to exclude any new techniques of acupuncture or diagnosis.⁴³ In addition, the legal exclusion of a “product of nature” from patent protection further complicates the patentability of herbal preparations. These exceptions have special public interest justifications that outweigh the social benefit of invention or the moral right of inventorship. Unfortunately, they appear to exclude the bulk of CM knowledge.

Due to these theoretical limitations and legal exclusions, the patent system will not protect existing knowledge of and the practice of CM because they are not novel.⁴⁴ Nevertheless this is not a “problem” *per se* if one is aware of the outcome and genuinely wishes to protect only those aspects of CM that are new. For example, the patent system is adept at protecting the modern pharmaceutical effort of distilling biological information and

41. Although one does speak of promoting and conserving basic research in chemistry, biology, or electrical engineering via the patent system, the effect is not inherent in the patent system, but rather, it is a developed manufacturing practice that relies on chemistry, biology, and electrical engineering. When pharmaceutical companies analyze pharmacologically active plants identified through CM, they are using the CM knowledge in the context of biology or chemistry. In a parallel universe, where all pharmaceuticals are herbal and the technological ability to manipulate plants exceeds the ability of organic synthesis, one can imagine the reverse industrial effect, where patents would encourage companies to identify and cultivate plants that contain a particular compound, instead of encouraging the identification and synthesis of a molecule from the plant. Reality is necessarily a mixture of these two modes of research, and the optimist can expect some level of conservation of CM in China based on the native presence of CM.

42. Patent Law of the People’s Republic of China, at http://www.sipo.gov.cn/sipo_English/flfg_e/zlflfg_e/200203270002.htm. TRIPS (last visited March 12, 2004).

43. This is born out of practice. A search for acupuncture under the Chinese patent database revealed only acupuncture devices but no method or process patent. This is an irony considering that the U.S. grants method patent for acupuncture under its patent law. See Tradition Chinese Medicine Patent Database, *supra* note 28 and accompanying text.

44. A search in the Traditional Chinese Medicine Patent Database for Chinese medicine patent applications and an examination of the corresponding patent application (prosecution) history in the patent application database of the Chinese patent office revealed that most CM applications fail to receive a patent. Some are dismissed with prejudice, some are abandoned during the application, and some failed to meet the requirements for an examination on the merits. Therefore the sheer number of CM patent applications masks the difficulties of obtaining a patent.

chemical substances from CM knowledge. It is also consistent with the national program of modernizing/westernizing CM in China.

In practice, the patentability of a particular CM practice or product is very hard to discern. No clear shore separates the isle of invention from the sea of tradition.⁴⁵ The distinction between medically useful patents and statutorily excluded medical treatments seems to turn on semantics.⁴⁶ Similarly, the difference between unpatentable “product[s] of nature” and patentable derivatives is ambiguous.⁴⁷ The combination of a strong desire to provide CM with patent protection, the narrow intersection between patent and CM, and the inherent uncertainty of the legal

45. The ability of the *Puerariae Lobatae* flower to alleviate hangovers was the basis of a U.S. patent already discussed in note 36; however, it's illustrative of various difficulties in protecting CM in China. It had been known in China that the *Puerariae Lobatae* flower is a *cooling* herb that down-regulates excessive heat. Its *sweet pungent* classification targets the *earth phase* organ system of stomach and pancreas. Therefore it is capable of alleviating feverish sensations and dryness of mouth symptoms associated with excessive *exogenous heat* in the stomach system. It is also known that intake of fermented drinks generates *exogenous heat* in the stomach system. It was not known until the introduction of biomedicine that ethanol intoxication creates a feverish sensation and dryness of mouth. There are several product patent claims based on this group of knowledge:

- I. A product consists of the flower of *Puerariae Lobatae* useful for reducing excessive *exogenous heat* in the stomach.
- II. A product consists of the flower of *Puerariae Lobatae* useful for reducing hang-overs from over consumption of fermented beverages.
- III. A product consists of the flower of *Puerariae Lobatae* useful for reducing hang-overs from over consumption of alcohol.
- IV. A product consists of the flower of *Puerariae Lobatae* useful for alleviating ethanol intoxication.

I is not patentable because it is a known principle of CM. IV will be patentable if “ethanol intoxication” is not the same as “excessive *exogenous heat* in the stomach.” Between I & IV are grades of “inventiveness” that depend purely on how a symptom is defined.

46. Statement IV from the previous footnote will not be excluded because the patent is about a product, not a method. However, the claim stating that “[a] method of treating ethanol intoxication consisting of eating the flower of *Puerariae Lobatae*” is unpatentable because it is a method of treating a medical condition. This highlights the subtle question of whether treating hang-overs is a medical intervention, which further turns on the question whether CM's concept of medical interventions is similar to other forms of medical intervention.

47. See JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES, 132-33 (2001). The examples in footnote 46 will fall short of this criterion because all of the claims rely on the use of the flower. However, “the flower of *Puerariae Lobatae*” can be replaced with “a tea consisting of warm water steeped with *Puerariae Lobatae* flower,” “an aqueous extract of *Puerariae Lobatae* flower,” “a powder of dried *Puerariae Lobatae* flower,” and “an eluted component of aqueous *Puerariae Lobatae* flower extract.” A group of modified sugars in the *Puerariae Lobatae* flower was found to alleviate ethanol intoxication. So the phrase can be replaced with “a group of modified sugar extracted from *Puerariae Lobatae*” or even “Isoflavonoids containing a carbon-carbon linked beta-D-glucose moiety at the C-8 position,” as was used in U.S. Patent 5,783,189.

regime will lead to dubious patent grants, confused producers, disappointing protection, and even mistrust of the patent system.

Although WTO member nations are required to promulgate a patent system consistent with the TRIPS agreement, considerable ambiguities exist within the language of the agreement.⁴⁸ Theoretically, each country can design a patent system that better suits its need, and it has been argued that the ambiguities of the patent system give China substantial flexibility in fashioning CM-friendly patent rules.⁴⁹ It is possible to conceive changes that will accomplish this goal. For example, China might remove the exclusion of medical treatments or declare that useful plant and animal extracts fall within the realm of inventions. Moreover, the consistent application of a CM-friendly patent agenda over time can clarify the ambiguous lines as the patent system matures.

While the current ambiguity may indeed provide an opportunity for developing nations, one wonders if CM will be its most direct beneficiary. The patent system both increases the amount of overall informational resources and shifts the resource distribution among market players, but the patent system's maximization of one effect may compromise the other. A strict patent system benefits those nations that already wield strong market power and expertise in a given area, because industries within their borders can invent ahead of the pack against foreign competitions, and there are fewer opportunities for the patent system to redistribute their market power away to upstart companies through a legal monopoly.⁵⁰ Conversely, a relaxed patent system has the reverse effect of benefiting nations that have a weaker market power and expertise in an area. Budding industries within the nations' borders can gain monopolies by inventing near or around existing technology, even if the improvement offers less informational return.⁵¹

48. *Id.* at 90.

49. Some attempts have been made regarding the patentability of one CM formulation that is the context of other existing formulations. See Yongfeng Zeng, *Zhongyao Zhuanli Shenqing de Xianzhuang Fenxi ji Shencha Biaozhun* [A Current Analysis and Examination Standard Regarding Chinese Medicine Patent Application], at <http://www.bio-engine.com/garden/law/patent9.asp> (last visited March 12, 2004).

50. A stringent patent system that rewards only inventive leaps, sparks of genius, and globally unknown discoveries will enlarge the information common to all, but fewer industries can invoke the power of a legal monopoly grant to improve its market position.

51. A more relaxed patent system that rewards incremental improvements, derivative effort, and local knowledge will generate greater distributive consequences, but enlarge the information common to all at a higher overall cost to society.

There already exists a tension between the desire to expand CM information resources and to maintain the competitiveness of the CM industry, where patent protection promoting one interest will generate less improvement of the other interest. Moreover, the unique position of CM in China is that of one of the few advanced disciplines in a technologically-lagging nation. A relaxed patent system can promote growth in lagging industries. But it will also allow foreign competitors to enter the CM markets and patent CM products in China against the native CM industry. A stringent patent system may reserve monopolistic power to Chinese institutions that are higher up on the CM food chain and keep out foreign firms, but it will also keep the patent system out of reach for domestic manufactures in the chemical industry.

The current ambiguity masks subtle policy choices, and it is not yet clear how patent law in China can promote underdeveloped industries while maintaining the CM lead. In order to maximize the competitive advantage, China needs a form of patent protection that reflects the different conditions of CM and other industries. This makes the design of its patent law more complicated than for a country that lags in every respect. The approach must be facially neutral to survive the TRIPS requirement forbidding IP law from discriminating among industries.⁵² A more fundamental problem is that a stringent patent system can reserve competitive power onto Chinese CM industries and avoid the problem of bio-piracy, but it further distances the patent system from the generous protection granted CM.

In summary, current patent law protects a small subset of CM knowledge. Even within the realm of protection, CM inventions receive less protection than other articles or processes of manufacture do because they are prone to fall within legal exceptions. The pressure to protect CM under ambiguous legal doctrines further plagues the quality of CM patents. Although China retains some ability to shape its patent law and clarify legal doctrines over time, it is not clear whether the eventual legal regime will promote CM given the competing interests within Chinese industries, between domestic and foreign pharmaceutical firms, and between information Common and monopolistic power.

52. TRIPS Agreement art. 27(1) (“[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”).

IV. TRADITIONAL KNOWLEDGE PROTECTION AND CM

A. THE TRADITIONAL KNOWLEDGE MODEL AND THE COMPENSATION OF ETHNOBIOLOGICAL INFORMATION

Many scholars have argued that the current patent system cannot protect TK for many of the same reasons discussed in the previous section.⁵³ Ultimately, the patent system encourages new invention, but a TK holder desires protection for his existing ethnobiological knowledge. Justifications for bestowing a property right upon TK vary according to one's intellectual origin. A professional model argues that communities rich in TK provide a valuable service when they maintain, transmit, and disseminate their expertise. Because their knowledge and service are economically important, the society should establish a mechanism to recompense these communities.⁵⁴ A related equity consideration is the general impoverishment and exploitation indigenous communities have suffered in recent history. In light of this history, the external use of TK without compensation or even against the native interest is another form of imperialism, especially when TK is one of the remaining few resources indigenous communities possess.

As compelling as these arguments may be, a theory of justice and victimization is probably less relevant for WTO nations than are arguments based on economic theory. Interestingly, the argument justifying TK is closely related to the argument justifying the patent system. Currently TK is a type of informational Common—it is a public good without an associated price tag.⁵⁵ The use of any specific piece of information does not exhaust the appropriated information. However, a particular type of tragedy associated with the TK Common is that over-exploitation of traditional knowledge and its associated traditional culture will “exhaust” the source of that information and potential for new information. This is the economic euphemism for the demise of a traditional culture and lifestyle. Once the people and lifestyle disappear, the information Common containing the traditional knowledge will be forever lost to humanity, not unlike the loss of a plant species or the ozone layer.⁵⁶ The solution to this tragedy

53. See *supra* notes 7 and 8 and accompanying text.

54. Suthersanen, *supra* note 7, at 68-69.

55. Its value actually derives from its being a public commodity within the local community but private with respect to the rest of the world. Thus, TK can approximate private property when viewed from a distance.

56. The destruction of knowledge is also inefficient. Once the community disappears, resources would have to be poured into recreating the same information, just as cement had to be reinvented even though the Romans used it extensively many centuries earlier. Even without the complete demise of the TK, biopiracy or

is therefore the privatization of traditional knowledge and redirection of economic resources into TK-rich communities.

B. PROPOSED TK PROTECTION FOR TRADITIONAL MEDICINE

Currently TK is not protected under the TRIPS agreement. However, it is recognized in the context of the United Nations Convention on Biological Diversity (CBD).⁵⁷ A few countries have implemented national laws granting special protections to folklores, traditional designs, agricultural know-how, and ethnobiological information.⁵⁸ Even those TK-rich countries that did not create *sui generis* protection have also taken steps to counter the (mis)appropriation of their TK wealth in the form of preventing outsiders from receiving IPRs for products derived

patenting of TK by a known local group is also inefficient because the society is granting the power of monopoly (losing the efficiency of a competitive market) without deriving a corresponding increase in knowledge (since the knowledge was already in existence). It would have been socially cheaper, instead of granting the monopoly, to invest in the TK that possesses the knowledge in the form of TK IPRs and ask the originator(s) to spread his knowledge.

57. Article 8 of the CBD states:

Each Contracting Party shall, as far as possible and as appropriate:

- (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices

Convention on Biological Diversity, available at <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08> (last visited March 12, 2004).

58. Panama promulgated *Special Intellectual Property Regime Governing the Collective Rights of Indigenous People, for the Protection and Defense of their Cultural Identity and their Traditional Knowledge, and other Provisions*, Law No. 20 of June 26, 2000, which reserves collective indigenous rights for the indigenous community and excludes a third party from obtaining IPRs on creations derived from knowledge and practices of the indigenous people. What is traditional is to be determined via a registration system via an application filed by the traditional society. Moreover, the government is now devising a system that compensates the indigenous people for non-native uses of TK. The law of the Philippines is even more explicit, granting an IPR in cultural integrity that allows an indigenous community to issue licenses and permits to those wishing to enter the demarcated area or use TK and collect fees for the license and royalties for research or publications using TK. Brazil, Thailand, and the Organization of African Unity all promulgated their own rules. See World Intellectual Property Organization, *Questionnaires and Surveys: Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge, Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore*, at <http://www.wipo.int/globalissues/questionnaires/index.html> (last visited March 12, 2004).

from TK.⁵⁹ Finally, countries have used existing IPRs creatively to protect some aspect of their TK.⁶⁰

One of the most contentious debates in the WTO is the appropriateness of requiring all member countries to adopt some type of *sui generis* system of protection for TK: developing countries support its protection, and developed countries, especially the United States, oppose its protection. Critics of a *sui generis* protection argue that TK is indistinguishable from information, methods, knowledge, and ideas that properly belong to the information Common. Privatization of well-known TK will increase the cost of productive economic activities without generating a corresponding increase in knowledge. In practice, traditional communities may span a wide area, and TK may be spread among several culture groups spanning different countries; consequently, the proprietization of TK across geopolitical boundaries may pit the interest of one traditional community against that of another in a complex political and diplomatic match. It will also be difficult to assign the proper value to TK. All of these factors add to the cost of implementing a system to distinguish protectable knowledge from public knowledge.

All of these arguments find counter-examples within existing IPRs. The objection that TK belongs to the information Common is similar to the recent debate regarding the patentability of business methods such as reverse auctioning. In that case, the argument did not stop the United States from granting IPR protection to business methods. Privatization of well-known information may increase the cost of existing knowledge, but this increase only reflects the social cost of heretofore unacknowledged or unrecompensed use of TK. The income will support the TK conservation effort, not unlike the incorporation of sustainable development in environmentally responsible accounting practices. The difficulties of valuation are resolved in the patent system by granting monopoly rights and allowing the market to determine the value of the invention. There is no reason why the protection of TK cannot follow a similar approach. Current proposals of a *sui generis* system include a government-sponsored

59. See generally Graham Dutfield, *Protecting and Revitalizing Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India*, in INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY, *supra* note 6, at 100 (discussing India's effort in creating a public database of traditional knowledge to counter foreign patents such as the turmeric patent that claims India TK as a foreign invention).

60. Australia prevented the publication of a book containing information of sacred sites using the common law doctrine of confidential information in *Foster v. Mountford*, 29 F.L.R. 233 (1976), and awarded collective royalty compensation for imported carpets that were claimed to be the work of aborigine artists in *Milpururru v. Indofurn Pty. Ltd.*, 30 I.P.R. 209 (1995).

contractual system that allows traditional communities to trade TK for payment from information users.⁶¹ Alternatively, a regulatory scheme may give TK holders the ability to grant a bio-prospecting license for a fee.⁶² Another proposal involves perpetual property rights to TK vested in the entire traditional community of a particular locale.⁶³ Whatever the result of the discussion may be, developing countries will probably be free to implement a TK-specific IPR regime because the TRIPS agreement guarantees the minimum IPRs a government must provide but does not set a ceiling on IPRs. Therefore, national governments are free to grant IPRs to TK.

C. PROBLEMS WITH THE TK PROTECTION OF CM

The World Health Organization refers to CM as a type of tradition medicine, which it defines as “the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.”⁶⁴ Intuitively, CM appears to be a type of TK. In light of the previously mentioned theoretical inadequacy of applying patent information to CM, TK IPRs appear to be an attractive alternative. Unlike the patent system, TK protection covers the basic knowledge content of CM and preserves existing information. Moreover, TK-specific IPRs can decouple the protection of CM from the promotion of other industries to avoid the conflict of policy considerations between CM and other lagging industries. The TK framework will provide a more direct tool to capture the value of useful CM knowledge and account for externalities resulting from the unauthorized use of CM knowledge through biopiracy or imitation.

However, the propertization of CM knowledge confronts all the criticisms leveled at the propertization of TK in the worst way. As mentioned earlier, CM is now a widespread phenomenon, and the unilateral propertization of CM knowledge in China

61. The Philippine system is an example. See Suthersanen, *supra* note 7, at 68-69.

62. *Id.*

63. Gurdial Singh Nijar, *In Defense of Local Community Knowledge and Biodiversity: A Conceptual Framework and the Essential Elements of a Rights Regime* (Third World Network ed., 1996), available at <http://www.mindfully.org/GE/Community-Knowledge-Biodiversity.htm> (last visited March 12, 2004).

64. World Health Organization, *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine* (2000), WHO/EDM/Traditional Medicine/WHO/EDM/TRM/2000.1, available at <http://www.who.int/medicines/library/trm/who-edm-trm-2000-1/who-edm-trm-2000-1en.shtml> (last visited Feb. 3, 2004).

will surely raise objections from Japan, Korea, Malaysia, and other nations whose medical practices share the CM knowledge Common. The unilateral propretization of CM knowledge in China will also have unpredictable effects on overseas CM practitioners and on China's agenda of promoting CM as the other global healthcare system. The TK content of CM is not easily defined. The CM rubric encompasses a pluralistic and syncretistic body of knowledge that radiates from healthcare outward to the mundane and the philosophical, encompassing divergent concepts including *yin-yang*, tai-chi exercise, healthful diets, and anger management. The selection of what to include and what to exclude will likely be an arbitrary task. Even within the narrow healthcare or pharmaceutical sense (whatever that may be), it is not clear where TK ends and public knowledge begins because contemporary CM practice in China has been influenced by imported biomedicine and vice versa. Similarly, it is difficult to isolate the TK aspect in the numerous projects of modernizing CM or to answer the metaphysical question of whether modernized CM is still TK.⁶⁵ It is also not clear who should be the owners of the new IPRs though the membership of that group will certainly be vast—whether it is the Chinese government, the practitioners of CM, or the communities in which CM is the predominant form of medical care. To further complicate matters, there are ethnic minorities in China with distinct medical practices; it is not clear if their TK should be considered CM.⁶⁶

65. This is merely the mirror image of the problems regarding prior art encountered during the discussion of patent. See *supra* notes 46-49. The situation described in notes 46-49 can be extended in this section as well. For example, the statement "the flower of *Puerariae Lobatae* is useful for reducing excessive *exogenous heat* in the stomach" will probably satisfy the requirement of TK. However, it becomes contentious and comes close to depleting the information common if the statement "Isoflavonoids containing a carbon-carbon linked beta-D-glucose moiety at the C-8 position is useful for reducing excessive *exogenous heat* in the stomach" was treated as TK.

66. For a general discussion of the state of ethnic medicine in China, see Guoben Zhu, *Zhongguo Minzu Yixue Shi Dangdai Weisheng Ziyuan de Zhongyao Zucheng Bufen* [Chinese Ethnic Medicine is An Important Part of the Contemporary Medical Science], at <http://www.cmam.org.cn/lm01/lm01.htm> (last visited March 12, 2004). Chinese Medical Association of Minorities is an organization promoting the study and use of ethnic medicine. According to the organizers: "Although ethnic medicine could be understood as a homonym for traditional medicine, the phrase 'ethnic' is understood in China to mean 'ethnic minorities.' Thus 'ethnic medicine' is the traditional medicine of the various ethnic minorities." *Id.* Within China, the discussion of traditional medicine often implicates ethnic medicine as well. However, the distinction (or the lack of) between CM and ethnic medicine raises a local identity issue and reenacts a local version (CM versus ethnic CM) of the global discursive battle between the dominant medical thoughts and alternative treatments (Biomedicine versus CM). This is problematic enough when Tibet and Mongolian medicines are included in Chinese medicine. It is even more problematic when Chinese ethnic medicine includes the practice of ethnic Thai or ethnic Korean Chinese.

CM is TK that has transgressed its proper place. At one time, it faced extinction under the onslaught of technological hegemony. Now it is a national industry merging with and transforming mainstream practices, and no longer in danger of disappearing. In the same sense that alchemy is traditional knowledge but chemistry is not, the practical incompatibilities between CM and TK IPRs merely signal the gradual acceptance of CM and the lessening need to ensure the survival of CM via conservatory means. In this fundamental sense it fails the conservational model justifying TK IPRs.

Perhaps it is because of the awareness of these thorny issues that the Chinese response to a *sui generis* TK protection of CM has been muted. Countries such as Thailand or the Philippines are aware that patent protection is inadequate for the protection of their TK, and they are exploring the possibilities of TK IPRs. In contrast, China has been actively promoting patent efforts in the CM area and self-consciously excluding any proposal for TK IPRs, despite the difficulties of protecting CM via the patent system.⁶⁷

V. THE PARADOX OF CM

When the patent system is juxtaposed with TK IPRs, the difficulties of providing adequate protection to CM emerge as a set of paradoxes. The first paradox of IPRs for CM is that CM is too modern, advanced, widespread, international, civilized, and powerful to be considered a TK, but not so much so to utilize the existing IPR system. This statement locates the misfit in the current state of CM in China. CM has multiple faces—it is a collec-

67. During the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, the Chinese representative urged the protection of TK through the incorporation of TK into the national healthcare system and the establishment of a patent system that flexibly employs the terms “invention,” “patentability,” “exclusion from patent,” “parallel trade,” and “compulsory licensing,” even though other nations clamored for a *sui generis* system. See generally World Health Organization Geneva, *Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine*, WHO/EDM/TRM/2001.1 (2000) (last modified Feb. 8, 2002). It is interesting that India, a nation that reacted strongly against the foreign patenting of traditional plant medicine, also remains watchful of a *sui generis* system. See World Trade Organization, *Protection of Biodiversity and Traditional Knowledge—The Indian Experience*, WT/CTE/W/156, IP/C/W/198, at 26 (2000) (“Some experts suggested that a *sui generis* system separate from the existing IPR system should be designed to protect knowledge, innovations and practices associated with biological resources. However, the parameters, elements and modalities of a *sui generis* system are still being worked out.”). India is a populous and heterogeneous country featuring several well-established traditional medicines that are marching into the modern era. It and China face a dilemma that cannot be solved by cordoning off a section of the population or knowledge and declaring it traditional.

tion of practices and beliefs regarding the truths about the world, an interconnected body of manifested knowledge, or an adaptive discipline capable of generating information and transformation. Each one of these claims envisions different "needs." Neo-classical economic theory can tell us why one type of protection is better than the other, but the rational choice of whether a body of knowledge requires patent protection (promotion) or TK protection (conservation) depends on the perceived character of the existing knowledge. The process of characterization of a body of knowledge entails the endorsement of one set of characters to the exclusion of another. Unfortunately, CM knowledge straddles the gulf, and any attempt to imbue CM with one set of characteristics excludes the other aspects of CM. This is why the marriage between CM and patent is an unhappy one – the patent system denies the unique history of CM and instead treats it as ordinary food supplements or a subcategory of biomedicine. Even more unfortunately, it is a forced marriage because refusal to submit to either category would leave it with no IPR protection.⁶⁸

The second paradox of IPRs for CM is that while IPRs purport to maintain or enlarge the information Common, the government that promotes IPRs wants to maintain or enlarge its domestic industry. This is a statement about the stress of national IPRs in an international context. The current desire to protect CM is an example of one's having his cake and eating it too. Those who want to promote CM as an internationally recognized national (Chinese) treasure desire to erect a high wall around CM to keep out trespassers. At the same time, they want the wall to be flexible enough for easy expansion of the information territory. The agenda of the developed countries are no different—the U.S.'s vehemence in the promotion of TRIPS can largely be explained by the benefit it would receive through domestic right holders in the entertainment, software, and pharmaceutical industries. But developed countries can have their cake and eat it too because their industrial practice and technical expertise are locked in the same orthodoxy and institutions, with enough market power and information resources beyond those of developing countries to outstrip foreign upstarts from the domestic market. However, a developing country constantly faces foreign competition within its territory.

The third paradox of IPRs for CM is that there is no IPR for a tradition gone modern, an ethnobiology gone global, or a marginalized art gone mainstream. This statement echoes the

68. It is also forced in the sense that developing nations, especially the United States, have applied trade pressure to induce international recognition of IPRs.

first paradox but locates the misfit in the IPRs regime. Prior to the TK IPRs proposals, the dichotomy was drawn between an economically significant inventions and economically neutral knowledge Common. The erupting economical importance of TK is now in the process of creating a new isle of protection out of the economically invisible information sea. Developing countries and traditional societies, which up until now have had little real estate on the isle of patent, are naturally drawn by the flowing milk and honey TK promises, especially when many have seen their traditions as liabilities and not as assets. Necessary for the struggle to form a new TK IPR is a set of jargons that set it apart from existing IPRs. Consequently, the emergent TK contrasts with the traditional patent system and forms a new dialectical pair constructed alone: a hierarchical axis of modern versus traditional. The patent system is justified in terms of expansion and valorizes new developments over existing knowledge, while the TK IPR system focuses on preservation and idealizes the culmination of the past. If a body of knowledge is in danger of disappearing, then TK IPRs are a reasonable form of protection. If a body of knowledge is well established and awaits new development, then the patent system will provide better incentives. The distinction may be clear, for example, between university biochemistry and local knowledge of plants. However, the story of CM exposes the limit of imposing a power negotiated linguistic construction of “invention” or “tradition” onto a body of knowledge that developed without characterizing itself as one or the other.

VI. CONCLUSION: FROM PARADOX TO SOLUTION

These paradoxes expose the deep tension between the desire for IPR protection of CM protection and the limits of IPRs protection. However, this is not an effort to denounce all forms of IP protection of CM, but rather an attempt to define the parameters of protection and the hard choices that must be made to maximize the financial and informational benefit an IPR system can generate. CM appears to fall through the crack between the intersection of a TK IPR system and a patent system because it possesses the character of both. The conceptual solution to this difficulty is to visualize the intersection as an overlap, not a lacuna. The breakdown of the dichotomy between TK and patent makes it possible to render the patent scheme more accessible to CM by legitimizing the aspects of CM that are thought to be traditional or old and by seeing advances not through the lens of biomedicine, but CM. From an economic or informational perspective, there should be no reason to withhold inventions involving a “novel” combination of herbs or a “novel” use of

acupuncture points.⁶⁹ Specific administrative rules developed with the right priorities will lessen legal ambiguities surrounding the coverage of new CM matters.⁷⁰ This is analogous to a recent development in the United States whereby business methods and computer software were incorporated into patent law and copyright law, respectively.⁷¹ In order to reduce the conflicting interests mentioned earlier, decision-makers must articulate and prioritize the values embodied in the currently monolithic desire to protect CM. In the process China may have to accept foreign CM patents as a necessary growing pain. Only with clear guidelines governing the reach of patent coverage and the level of inventiveness can China hope to maximize the sum of the CM information Common and domestic industrial strength. Only then can CM provide China with the competitive advantage necessary to realize its economic aspirations under the WTO.⁷²

69. Some clarification is taking place. Recently, an article regarding the novelty and inventiveness from the patent office clarified some of the legal ambiguities. The current conception seems to be that an herb to a CM formulations as an atom to a molecular medicine. Following the idea of chemical analogues, the recommendation articulated the idea of an herbal analogue, where the use of an analogous herb that leads to the ultimate function lacks inventiveness. However, the unexpected benefit of replacing one herb for another will be deemed inventive. The recommendations are made from a legal doctrine perspective, and not based on explicit discussions of patent policy and national goals. The recommendations envision a fairly strict novelty requirement, which is beneficial for enlarging the information in the common domain. However, it is contrary to the sentiment of offering extensive patent protection CM.

70. There is a Draft Regulation for Administering Chinese Medicine Patent, but it focuses largely on the improvement of the CM prosecution capacity at the patent office and regulations governing confidentiality and non-disclosure prior to the application of a CM patent. It limits what researchers may publish and collaborate regarding a potentially patentable CM innovation. It also creates a national clearinghouse system to monitor and process requests to publicize an innovation. While the improvement of the patent processing capability will produce better patent grants, it is not clear whether the central information control function will serve a useful purpose. In any event, it does not address the problems of ambiguities and problematic legal exceptions. For the draft version of the regulation in Chinese, see <http://www.yaoxue.net/law/htm4/4-002.htm> (last visited March 7, 2004).

71. Business methods, CM, and TK are similar in the sense that all three exhibit more "ideas" than "embodiment" and are thought to be part of the intellectual Common by many. That it was patentable suggests that China may similarly extend its patent law to cover a bigger portion of CM, regardless of whether that is desirable.

72. For an opinion discussing the difficulties of protecting CM under the existing regulatory regime, see Jinbiao Xia, *Zhongyao Heshi Kangqi Zhishi Chanquan Daqi?* [When Can Chinese Medicine Carry the Banner of Intellectual Property?], *ZHONGGUO JINGJI SHIBAO* [CHINA ECON. TIMES], Dec. 10, 2003, available at <http://www.cet.com.cn/20031210/RESTATE/200312103.htm> (last visited March 12, 2004). Xia, typical of CM advocates, provides specific solutions to shoehorn CM into existing IPR regime. This paper argues that the CM-centered approach should be replaced by an IPRs centered approach that locates the problem in the design of an IPR regime.