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## **Observations from a TRIPS Perspective: Do We Need a Traditional Medicine Exemption for Patent Standards?**

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### **INTRODUCTION**

In March of 2011, the Chinese Central Government State Council rolled out the Twelfth Five-Year Plan (Plan),<sup>1</sup> which aims to establish

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a sound protection system for International Patent Regulation (IPRs) for Traditional Chinese Medicine (TCM). The Plan stresses that the strengthening of Traditional Chinese Medicine Protection (TCMP) would have a positive social impact on China.

Five years ago in 2006, the rumor of “abolishing TCM” was denounced by the Ministry of Health and the National Chinese Medicine Administrative Bureau.<sup>2</sup> Moreover, China’s State Council issued “China 2009–2011 Deepened Medicine Health Organizational Reform Implementation Plan” (New Medicine Reform Plan) in January 20, 2009. This plan emphasized a more nationally government-guided support of TCM.<sup>3</sup>

However, although inconsistent with these government policies of support and protection, TCM practice remains largely unprotected. As of 2011, lack of protection has become a serious problem. On the one hand, when those who practice Chinese medicine attempt to protect their new treatment methods and medicines, the first choice is not patenting, but by protecting certain methods with commercial and administrative security. On the other hand, scientific researchers have spent more time publishing their updated papers, rather than spending time applying for appropriate patents.

With a history of 2000 to 3000 years, TCM has formed a unique system to diagnose and cure illness. However, the development of Chinese medicine and its patents is very slow when compared to modern Western plant-based medicines as biological drugs. With large drug companies making increasingly large amounts of money off of patents, the pressure to patent and protect medical technology has increased worldwide, and global competition in the Chinese medicine market has also intensified. Overseas drug manufacturing enterprises have increased efforts to appropriate TCMP. At present, with the exception of China, the top countries applying for TCMP are:

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<sup>1</sup> China has recently decided to establish a protection system for traditional knowledge. Supporting the collation and passing down of traditional knowledge furthers the development of such a protection system. A coordinated mechanism for administration, protection, and utilization of Intellectual Property Rights (IPRs) for traditional medicine needs to be improved. See *China’s Outline of 12th Five-Year Plan*, Mar. 5, 2011, <http://politics.people.com.cn/GB/1026/14159537.html> (last visited on Oct. 4, 2011) [hereinafter 11th Five Year Plan].

<sup>2</sup> *TCM Faces Homegrown Challenges*, CHINA INTERNET INFO. CENTER, Aug. 27, 2008, [http://www.china.org.cn/health/2008-08/27/content\\_16343759.htm](http://www.china.org.cn/health/2008-08/27/content_16343759.htm).

<sup>3</sup> See *New Medical Reform Program Overview*, NEW CHINA NEWS AGENCY, Apr. 8, 2009, <http://politics.people.com.cn/GB/1025/9090406.html>.

Japan, South Korea, United States, and Germany. Surprisingly, the United States has leaped to third place during the past five years.<sup>4</sup>

Before China's entrance into the WTO, the lack of patents for Chinese medicine and new technology did not cause much economic loss. However, after China joined the WTO on November 10, 2001, the economic loss to China due to the plant medicine patent war has been a crushing blow to domestic Chinese TCM enterprises. Thus, the race to properly patent Chinese medicine throughout the world has become a hot-button topic.

In respect to the patent wars and global race to patent TCM, a series of investigations on TCMP development has been conducted by both the Chinese government and scholars, and the author has reviewed the relevant legal flaws in China. Inevitably, the patent war for TCM has attracted global attention. The author's research focus is on whether a reasonable solution would be to lower the patent standards particular to TCM.

## I

### LEGAL PERSPECTIVES OF TCMP: NEW SHACKLES

Given the ancient origins of TCM, it is difficult to identify the exact source of the medical practice. Traditional cures are found in ancient books, such as "Shen Nong Ben Cao Jing" from the Han Tang period and "Ben Cao Gang Mu" from the Ming Dynasty<sup>5</sup>. Accordingly, it has been hard to assign ownership and patents to TCM. A factor that makes patenting especially difficult is that the formulas and methods of ancient Chinese medicine have been passed down mainly in ancient books. Through these books, practitioners have passed down these traditions, improving prescriptions and methods throughout the history of TCM.

One facet of Chinese medicine making it especially hard to patent is that its full efficacy is in compound prescriptions. China's existing patent standard only takes into account one side of medicine, one in which compounds are extremely hard to classify. TCM has its own special characteristics and some crossover into the type of plant

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<sup>4</sup> Zheng Chengsi, *Challenge and Opportunity in International Intellectual Property*, CHINESE ACADEMY OF SOCIAL SCIENCES, <http://www.cass.net.cn/file/2007021587698.html> (last visited on May 31, 2011).

<sup>5</sup> Zheng Yongfeng, *CORPORA OF TRADITIONAL CHINESE MEDICINE PATENT 154* (1994) (on file with author).

medicine generally called “alternative medicine” by the United States and Western countries. According to the international convention, it is a pre-condition for every medical patent to first describe the material and chemical composition of the drug. However, the ingredients in the compounds commonly used in Chinese medicine do not facilitate such concrete descriptions. TCM’s special approaches and methods are fundamentally different from that of Western plant-based medicine. In TCM, the understanding of the human body is based on the holistic understanding of the universe as described in Daoism, and the treatment of illness is based primarily on the diagnosis and differentiation of syndromes. Some practitioners preescribe TCM treatment of diseases through herbal medication, acupuncture, and qi-gong as an “information therapy.” For example, there were noted advances in Chinese medicine during the Middle Ages. Emperor Gaozong (649–683 AD) of the Tang Dynasty (618–907 AD) commissioned the scholarly compilation of a *materia medica* in 657 that documented 833 medicinal substances taken from stones, minerals, metals, plants, herbs, animals, vegetables, fruits, and cereal crops.<sup>6</sup>

Accordingly, it is difficult for local TCM producers to acquire patents due to patent standards for medicines and TCM practitioners’ lack of technology and application of biochemistry. Consequently, there have been few patents issued for Chinese medicine under modern patent rules. Moreover, it is difficult to prove and evidence patent infringement of Chinese medicine because of the special plant compounds. For judges in China today, one major hurdle is how to identify the degree of infringement by means of the compounding of Chinese medicine?

For example, Tianjin Tianshili Drugs Manufacturers Limited (Tianshili Company) sued Dongguan Wancheng Drug Manufacturers Limited for infringement of its product, the “Raise Blood Serum Brain Pellet.” Tianshili won the case after a 19-month trial. However, Tianshili received only one RMB yuan as a kind of symbolic compensation. The core evidence in this case was whether or not the different usage of Chinese angelica and rhizome causes a particular effect in the “Raise Blood Serum Brain Pellet.” Several experts from Beijing Chinese Medicine University were called on to specifically establish a research team to review the conflict. The major point of

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<sup>6</sup> GIOVANNI MACIOCIA, *THE FOUNDATIONS OF CHINESE MEDICINE* 16 (1989).

contention in Tianshili is that a detailed infringement degree could not be identified by the prescription.<sup>7</sup>

In practice, Chinese medicine has only been able to receive approval as a food, nutriment or food additive, rather than a pharmaceutical in most developed countries. Obviously, the difficulties in awarding patents to TCM therapies have greatly hindered the approval of TCMP in the international market.

This essay will now present perspective in theory of TCMP conflicts and puzzles. The author has conducted research from three observational points: first, administrative interruption by relevant local officials; second, sluggish development of Chinese medicine innovation research; and third, neglect of the tendency of more social duty to global public health in the process of perfecting TCMP franchise rights.

#### ***A. Government Administration Colors the Existing Legislation***

The current legislation will likely cause one large-scale Chinese medicine enterprise to monopolize each specific kind of TCM. Although China promulgated “Chinese Medicine Variety Protection Rule” in 1993, it mainly stemmed from the administration of policies, protecting the type of Chinese medicine therapies, rather than the innovation of components such as compounds. Disputes occurring between domestic enterprises were settled by government administration. But obviously this legislation has no connection with international litigation and has no effect outside China. Moreover, it mainly protected the interests of producers by controlling production and circulation, rather than protecting consumers.

#### ***B. The Sluggish Development of Innovation and Research in Chinese Medicine***

Under Article 25 of the 2009 Chinese Patent Law no patent right shall be granted for the methods and diagnosis used in TCM or for the

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<sup>7</sup> From 2001 to April 2008, State Intellectual Property Office processed 9571 cases of patent disputes and investigated 11,639 cases of patent infringement. To better protect intellectual property rights of patent holders, the newly revised Patent Law contains more detailed and specific patent protection measures. For details, see the government website of Intellectual Property Protection in China at [http://english.ipr.gov.cn/ipr/en/info/Article.jsp?a\\_no=265466&col\\_no=925&dir=200902](http://english.ipr.gov.cn/ipr/en/info/Article.jsp?a_no=265466&col_no=925&dir=200902).

treatment of diseases and plant varieties.<sup>8</sup> That means the application for TCMP has no special protection. However, TCMP standards are still an issue of debate in both the academic and practical fields. Some scholars suggest that the scope of protection for Chinese medicine patents should be broadened, but others support united patent standards. I agree with the latter approach, narrower standards, in general.

The former approach, broad patent standards, emphasizes that TCM plant species and resources have been deeply influenced by humans throughout history. This approach puts fourth the idea that TCM led to the formation of different plant species and resources because of the integrated traditional production and processing technology like breeding, cultivating, picking, extracting, concocting and so on. Traditionally, Chinese doctors judge a patients disease and diagnose by observing the appearance of the patient, questioning the patient, feeling for a pulse, and then writing prescriptions based on experience and ancient knowledge. This is the so-called four diagnostic methods of Chinese medicine: “Wang, Wen, Wen, Qie.” Most of the ingredients in Chinese medicine are herbs. Naturally, TCM clinical theory consists of medicinal prescription, diagnosing and treating, and health care methods. It is widely known throughout the world that TCM is regarded as one of the main legacies of Chinese civilization.<sup>9</sup>

In practice, advocates of the broad approach argue that in the long history of social and medical development, TCM has received special treatment from local government administrations, and many Chinese people have become dependent on TCM. Due to the lack of innovation, TCM practitioners have become accustomed to paying more attention to investing in the day-to-day practice and actually treating patients instead of investing in research. In general, most Chinese medicine enterprises show little interest or motivation in developing new medicine and research. One reason for this is the high level of technology needed for research, which requires rather high amounts of capital investment.

As a result, compared with Western medicine in developed countries, Chinese medicine generally falls far behind the use of modern technologies for drug production and purification. Therefore, foreign pharmaceutical enterprises have been more successful in

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<sup>8</sup> PRC Patent Law 2009, art. 25.

<sup>9</sup> XIAO SHIYING, TRADITIONAL CHINESE MEDICINE INTELLECTUAL PROTECTION 116 (2009) (on file with author).

patent application in China than the Chinese domestic enterprises. In addition, some developed countries have also implemented special protection policies to compound prescription medicine in their own domestic markets. Advocates for a broad approach have viewed this as an unfair global competition, and even called it a “Chinese Medicine Crisis.” And some scholars have appealed to again revise the Chinese patent laws to give Chinese medicine special legal protection. The broad approach argues that TCMP scope and provisions should be broadened instead of generalized under patent law. Besides production, processing technology and forms of Chinese medicine should also obtain patent protection. While I do not advocate this approach, admittedly the idea of broadening the scope was created on the idea that Chinese medicine research for core innovation has been weak. In this sense the broad approach is understandable in the short term.

The broad approach is based on the nature of patents and innovation. Undoubtedly, the nature of patents and innovation are the common rule for patent legislation all around the world. No nation shall award patent protection if the medicine fails to prove its own innovative pathological structure, and TCM is no exception.

Therefore I prefer united patent standards for the following three reasons. First, we understand and respect the pathological science standard of medicinal plant patents. As a common rule, the medicinal plant in its natural state shall not be awarded a patent. Similar to most other countries, Chinese patent law protects Chinese medicine formulas and the formula dosage, rather than formula’s methods. With the rapid development of science and technology today, some international pharmaceutical companies can easily distill the therapies of Chinese medicine through depuration and quantification. They may effectively avoid the limitation of “the natural objects principle” via certain new technology, and make legal claims of innovation via pathological research.<sup>10</sup> Most Chinese medicine enterprises have failed to obtain patents due to lack of high technology for pathology prescription. This is due to the domestic lack of technology innovation rather than to an unfair rule.<sup>11</sup> We trust that it is a

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<sup>10</sup> In 2010, China granted 135,000 inventions, up 5.5%. This includes 55,000 from abroad, representing 40.7%. Reported by State Intellectual Property Office of the P.R.C (SIPO), see *Single Year Patent Filings Roll Over IM in China*, SIPO, (Jan. 25, 2011), <http://www.english.sipo.gov.cn/news/official/201101/t20110125-570582.html>.

<sup>11</sup> VOLKER SCHIED, *CHINESE MEDICINE IN CONTEMPORARY CHINA* 116 (2002).

precondition for humans to learn at first before proceeding to the next step.

Second, Chinese medicine in practice does not simply equal patent protection in law. TCMP protection in law should not go beyond patenting of three types: the invention, the model utility, and the design appearance. Though some developed countries have also implemented a kind of special protection policies to compound prescription medicine in domestic markets, this proposal is somewhat different. For example, in Japan and Korea, patent law requests use limitations. Each patent lists particular illnesses that the drug can treat. As a result, it is not regarded as infringement if some others use the same drug preparation in treating other illness. In the United Kingdom, France, Spain and Canada, medicine production patents have a kind of use definition as well. Particularly in 1997, the U.S. created a “Guidance for Natural Plant Mixture Drugs Application,” and started to accept the plant medicine compound prescription preparation as a kind of medical treatment. Thus all relevant actions have not gone beyond the scope of the patent. Accordingly, the 2010 Chinese Patent Law has not broadened the scope to award patents under China’s aims of establishing innovation states in the world.<sup>12</sup>

Third, under the WTO’s Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), patent regulations take effect not only domestically but also multinationally. It is imperative for China to fulfill the TRIPS promise, though China could join the continuing negotiation of international treaties amendments.<sup>13</sup> If competition in Chinese medicine involves unfair competition or monopolies, it should be regulated within the scope of the unfair competition law and the antitrust law rather than the patent law. Furthermore, under the principle of national treatment in TRIPS, if China broadens the scope of patent protection of Chinese medicine, foreign medicine enterprise should be treated as an equal in Chinese market.<sup>14</sup> Obviously, as a solution to strengthen the domestic medicine enterprise, broadening the scope of TCMP is not only

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<sup>12</sup> As for TCMP protection aims, the China State Council had emphasized the establishment of cultivation of core technology in the Eleventh Five-Year Plan. (See The 11th Five Year Plan, [http://english.gov.cn/Special/115y\\_index.htm](http://english.gov.cn/Special/115y_index.htm)).

<sup>13</sup> By 2020, China plans to become a country with a comparatively high level in terms of the creation, utilization, protection and administration of IPRs. See Outline of the National Intellectual Property Strategy, June 5, 2008, [http://english.gov.cn/2008-06/21/content\\_1023471.htm](http://english.gov.cn/2008-06/21/content_1023471.htm).

<sup>14</sup> LONG YONGTU, WTO AND INTELLECTUAL PROPERTY 25 (2001) (on file with author).



impractical, but doesn't align with China's current internationalization strategy.

***C. The Tendency of Increased Social Duty in Global Public Health Has Been Neglected in the Process of Perfecting TCMP Franchise Rights***

Under the principles of TRIPS, theories and knowledge of Chinese medicine can be used and utilized freely for public health care. And this same theory of public health forces every TCM production and method to be permitted for use in other countries. As a patent, TCM should have three main straits of originality, creativity, and usability. The scope of patent protection just focuses on the innovative technology, rather than knowledge itself (except traditional knowledge). The theories and knowledge that comprise Chinese medicine are viewed as fundamental innovation for humanity, and no one has the right to limit the public use of TCM if used for the promotion of human public health.

**II**

**ANTICIPATION OF FUTURE DEVELOPMENT OF TCMP**

Our research discovered that in comparing Chinese medicine protection with other intellectual property protection forms such as trademark and copyright, the patent process should be more sophisticated and have further influence in the market. TCM is no exception.

China has become an international market player under TRIPS. China has no choice but to continue to advocate stricter enforcement of IP protection. Under the non-discrimination principle of TRIPS, a broader protection scope on patent systems for TCM will protect the legal rights of foreign investors in Chinese markets as well. Similarly to most nations, the spirit of Chinese patents abides by a long-term purpose of encouraging innovation, industry and competition. Under such a precondition, to deal with the coming challenge of patent wars on the hot issue of TCMP, China has been engaged in building up a global pharmaceutical market. Inevitably, China shall make an effort to own more core medicine patents, produce national medicine patent pools and foster medicine research teams. Through further emendation of patent systems, China's government is expected to pay more attention to the rapid development of Chinese medicine enterprises. In the meantime, it should consider keeping a balance

between the great efficiency in a more fierce TCMP competition and the legal equity for public health.

In the long run, it is obviously an unreasonable proposal or theory to push China to reduce patent protection thresholds, while disregarding national treatment principles and the public health protection rule. As an alternative, China should enhance TCM pharmacology depuration and quantification technologies, and publish encouraging regulations for the technology research on TCM innovation.

Above all, the author urges stabilizing high patent standards, rather than reducing the patent standards particular to TCM and also proposes that the Government create legislation in the long term. Thus the author suggests earnestly that relevant scholars, enterprises, and individuals make an effort to take detailed and positive actions as to the following changes in patent law.

First, patent systems in China are experiencing a revolutionary reform. More detailed rules, policies, and judicial interpretations are expected to take effect in the coming five years. To prepare for a fierce global patent competition in the Chinese market, not only Chinese medicine researchers and enterprise, but also foreign investors, should learn to fully utilize updated Chinese TCMP measures and the timely amendment, including the utilization of the China TCM Patent Database.<sup>15</sup>

Similar to the majority of countries' medicine patent systems, China adheres to the patent principle of first application. Accordingly, before entering the medicine market in China, the primary action shall be to apply for patent protection promptly, or to obtain China patents through PCT protection. The above suggestion is merely a basic step towards protecting global interests for every Chinese medicine investor. As for legal risks in the Chinese medicine market, these risks involve; Chinese medicine market access, the possibility of similar plants increasing competition in medicine prices, and the ability to directly obtain patent protection after getting patents from other countries or international associations and so on.

Secondly, the author suggests that Chinese domestic enterprises enhance the innovation of TCM core technologies in biochemistry. This may be done via cooperation with developed nations under an international coordination mechanism. For example, using the same

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<sup>15</sup> For detailed information on the China TCM Patent Database, see its formal website at <http://chmp.cnipr.cn/englishversion/login/index.asp> (created and maintained by SIPO beginning in August, 2001).

technology, China's government should look to assist the research of illnesses, encouraging others to produce anticancer and AIDS medicines, and supporting multinational cooperation. As mentioned above, the general superiority and advantages of a Chinese medicine enterprise are China's possession of the original market and a rich clinical history. But as explained before, China has a history of deficiency in research of pathology, high technology for purification, and quantification. For the proposal of TCMP promotion in the new era, China should urge the launch of more programs of multinational cooperation and workshops between Chinese medicine enterprises and Western medicine laboratories. Such actions shall definitely benefit patent internationalization of Chinese medicine core technologies.

Third, strengthening the protection of traditional knowledge is an alternative solution as a complement to patents for TCM. The author ponders that protecting TCM under traditional knowledge protection systems should be reasonable, though still may be impractical in China today. For example, as to the increased TCMP applications from multinational companies in Chinese markets which is triggering a number of disputes with the domestic Chinese medicine practitioners mentioned above, super court should draft a judicatory explanation that China patent implication the application should indicate the original source of medicine under the Convention on Biological Diversity. In fact, the E.U. has a practice of including such regulations that one should indicate the source information when applying for bio-technology inventions with regard to plant and animal materials. It is basic to respect traditional culture and holder's interests in the view of traditional knowledge.

In the end, it is imperative that China play an influential role in intellectual property protection in the process of her economic development. The author believes that the establishment of TCMP systems for both domestic and foreign researchers and enterprises, featuring competitive-neutral standards as a practical mechanism, shall be a requirement for China to make the grade in a developed Chinese medicine market in the next decade.

