STRIKING A BALANCE BETWEEN INTELLECTUAL PROPERTY PROTECTION OF TRADITIONAL CHINESE MEDICINE AND ACCESS TO KNOWLEDGE

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Abstract

Traditional Chinese medicine has played a vital role in the well being of Chinese people for thousands of years. It is a comprehensive system of herb medicine that has been repeatedly practiced and gradually summarized by Chinese people over a long period of time. The current practice related to traditional Chinese medicine has gone beyond the traditional practice. It at least includes mass production of traditional Chinese medicine pills, traditional Chinese medicine herb extract and therapeutic chemicals identified in traditional Chinese medicine materia medica. While traditional practice is in the public domain, the case is less clear for the expansive practice of traditional Chinese medicine, particularly because the public has not practiced such knowledge before. The current intellectual property law is designed to strike a delicate balance between incentives of creation and access to knowledge. It is often construed from a utilitarian perspective. This utilitarian consideration can justify some protection for the new practice. While the current intellectual property law often only recognizes limited defensive rights for traditional knowledge holders, once the rights of non-traditional practitioners are recognized, the rationale of intellectual property legal regime may justify a stronger package of rights, which would include more than defensive rights for traditional knowledge holders.

I. INTRODUCTION

Inspect the state of yin and yang; and adjust them to reach the balance.

- Yellow Emperor’s Inner Canon

Traditional Chinese Medicine, the collective name for a broad range of medicine practices that have been developed in China, has a history of more than 3,000 years. The earliest documentations of traditional Chinese medicine can be dated back to 1,100 B.C. It is a comprehensive system of healthcare that has been repeatedly practiced and gradually summarized by Chinese people over a long period of time. No other healthcare systems in the world — either modern or ancient— have such a long history.

Traditional Chinese medicine embraces a wide range of practices, including various forms of herbal medicine, acupuncture,
moxibustion, massage, qigong, and dietary therapy, etc. Among them, the herbal medicine is probably the most important. The *Treatise on Cold Damage Disorders*, an early doctrine of Chinese medicine compiled in the Han Dynasty (219 A.D.), included 112 herbal prescriptions. These prescriptions typically include a combination of various herbs and are administered according to a unique set of theories. These theories were summarized in the *Yellow Emperor’s Inner Canon*, another early doctrine of Chinese medicine compiled more than 2,000 years ago. The *Yellow Emperor’s Inner Canon* tied *yin-yang* and five elements to a body’s functional entities: lungs are linked to metal; kidney to wood; liver to water; heart to fire; and spleen to earth. While health is the result of the harmonious interaction among these functional entities, imbalance between *yin* and *yang* will lead to diseases.

The fundamental principle of traditional Chinese medicine practice is to restore the balance, as it is elegantly stated in the *Yellow Emperor’s Inner Canon*, “Inspect the state of *yin* and *yang*; and adjust them to reach the balance.” By measuring the pulse and inspecting the tongue, skin, and eyes etc., a traditional Chinese medicine doctor can identify the cause of the imbalance: whether it is due to an excess of *yin* or due to a surplus of *yang*. If *yin* is dominant, then herbs that can boost *yang* will be administered. Similarly, if *yang* is excessive, the doctor needs to prescribe herbs to boost *yin*. There are great similarities between the theory of traditional Chinese medicine and Daoism. In fact, the traditional Chinese medicine has heavily influenced and been influenced by Daoism across the history.

The theory of traditional Chinese medicine is not supported by modern evidence-based medicine. Even though there is some research in literature on the theory of traditional Chinese medicine, the methodology is often limited and the reasoning is often flawed. These studies often perform a simple statistical test as a means of proving the theory of traditional Chinese medicine. For example, in an article published by a researcher from Beijing University of Chinese Medicine, the author notices that patients with malignant tumor often

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4. Wei Yun (韦云), *Exing Zhongliu Huanzhe Siwang Shijian he Zhongyi Yinyang Guanxi de Yanjiu* (恶性肿瘤患者死亡时间和中医阴阳关系的研究) [The Death Time of Cancer Patients and Yin and
die in the early morning, which is consistent with the prediction made by traditional Chinese medicine. Assuming the statistical test is performed rigorously, the limitation of this research is that it only proves that the death of patients occurs more often in the early morning. It does not support the overly broad conclusion regarding the validity of the theory of Chinese medicine. This research is an anecdotal evidence of traditional Chinese medicine. It is problematic because other anecdotal evidence that is inconsistent with the prediction of yin-yang may have been ignored and not be reported. Currently, no biomedical evidence at the molecular level can support the theory of yin-yang and five elements. Selective reports of positive evidence usually cannot constitute a valid proof.

From the perspective of modern biomedical science, the theory of traditional Chinese medicine often seems unfounded, and to some extent, superstitious. Some scholars have unduly expanded the doubt on traditional Chinese medicine theory to all traditional Chinese medicine practices. *Lu Xun*, a leading figure of modern Chinese literature, in his work *Call to Arms*, claimed, “Chinese medicine (practitioners) are liars”. \(^8\) The general public’s distrust toward traditional Chinese medicine has intensified in recent years as modern (western) medicine has become widely available. Many Internet websites have begun to criticize traditional Chinese medicine and these criticisms have drawn more and more public attention.\(^9\)

Traditional Chinese medicine is currently in an embarrassing situation. On one hand, the medical community defends and celebrates traditional Chinese medicine, as it is one of the most important heritages of the Chinese culture. On the other hand, some people dismiss it quickly, as it is not supported by modern evidence-based medicine. However, those who accept the traditional Chinese medicine without any reservations probably have been influenced by national pride. Those who have quickly dismissed traditional Chinese medicine probably have not considered the fact that the traditional Chinese medicine has been repeatedly practiced in China for a long time. Prescriptions that are effective have a much better chance to be circulated and be passed down to today.

How traditional Chinese medicine should be considered is likely to remain unsettled for a long time. But without adequately assessing the value and the limitation of traditional Chinese medicine, any policy discussion regarding intellectual property protection of traditional

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\(^8\) *Lu Xun* (鲁迅), *Nahan* (呐喊) [*Call to Arms*] 3 (Sichuan Children Press 2004) (1922).

Chinese medicine would be limited in the scope, and to some extent, meaningless. In the following sections, this article will first examine the value and the limitation of the traditional Chinese medicine and then describe the current practices, with a detailed description of the traditional practice for some unfamiliar readers. It will then discuss the intellectual property protection in China, and point out the fuzzy boundary of public domain in the context of traditional Chinese medicine. Finally, it will discuss how the current theory for intellectual property may support some protection of traditional Chinese medicine.

In the course of this discussion, it is important to distinguish the traditional practice and the new practice. It is also important to recognize that the holders of traditional knowledge and the entities engaged in the new practice can be different. Many articles on intellectual property protection for traditional Chinese medicine focus on the rights of traditional knowledge holders, and simply assume that they are also practitioners of the new practice. This has not always been the case.

Under the current intellectual property legal regime, new therapeutic chemicals that are discovered from plants and new formulations of Chinese medicine are patent eligible. Indeed, they are less controversial. Instead, this article will focus on some more difficult issues, including whether the holders of traditional knowledge have a claim against the general public, whether the practitioners who have transformed the ancient formulation into new practice have any rights in the new practice, and whether the holders of traditional knowledge have certain claims against the new practitioners.

As traditional Chinese medicine shares many aspects with traditional knowledge of indigenous people, this article may also be relevant to the broader discussion regarding traditional knowledge protection around the world, which is currently a pending issue before the World Intellectual Property Organization.10

II. VALUES AND THE LIMITATIONS OF TRADITIONAL CHINESE MEDICINE

Traditional Chinese medicine has been playing a vital role in the prosperity of Chinese people for thousands of years. Although there are controversies regarding the theory of the traditional Chinese medicine, herbs used in the traditional Chinese medicine have been

shown to be effective in treating many different diseases. Some studies have shown the efficacy of herbs in treating liver disease in mice, an important animal model for human disease, while others confirmed the efficacy in clinical studies.

Many researchers suspect that the effects of some traditional Chinese medicine are due to placebo effects. A placebo is a medically ineffectual treatment of a disease. Nonetheless, patients given a placebo treatment often have a perceived or actual improvement. The placebo effect is often explained by psychological therapeutic effect. One important feature of the placebo effect is that its effect is often associated with how the treatment is perceived by the patient. It often shows a positive correlation with the price of the drug or the reputation of the doctor. This relationship is also observed in traditional Chinese medicine practice, which always values the rarity of herbs. Particularly, undomesticated herbs are believed to be better, and certainly more expensive, than farm-grown ones; and herbs that have grown for hundreds of years are considered better than younger ones.

Traditional Chinese medicine also includes some odd materia medica, which are hard to be accepted by the modern medical community. For example, the Compendium of Materia Medica, which is regarded as the doctrine of traditional Chinese medicine, lists boys’ urine as an important medicine for various diseases, and also arsenic trioxide (As$_2$O$_3$), an extremely toxic compound, as antidotes. An

13 Cheng Mingliang et al., Clinical Study of Reversing Hepatic Fibrosis with a New Type of Anthepatic Fibrosis Medicine, 3 CHINESE J. OF INTEGRATED TRADITIONAL AND W. MED. 38, 38–9 (2001).
14 Li Chengxiu et al., The Protective Effects of Traditional Chinese Medicine Prescription, Han-Dan-Gan-Le, on CC14-induced Liver Fibrosis in Rats, 26 AM. J. CHIN. MED. 325, 325-32 (1998).
18 Li Shizhen (李时珍), Ben Cao Gang Mu Xia (本草纲目 下) [Compendium of Materia Medica 2] (“Human urine, tastes salty, cold, not toxic, can be used to treat cold hot headache. Boys’ urine is the best.”) 640 (2003).
19 Li Shizhen (李时珍), Ben Cao Gang Mu Xia (本草纲目 上) [Compendium of Materia Medica 1] (“Arsenic trioxide (pi shi) can be used as antidotes.”) 170 (2003).
informed patient should probably think twice before drinking urine or taking poisons.

As the traditional Chinese medicine is mixed with real medical effects, placebo effects, and maybe toxic effects, it has become imperative to modernize traditional Chinese medicine. 20 I acknowledge that my perspective is influenced by my training in biomedical science, but if one wishes that traditional Chinese medicine to be accepted by the global medical community, traditional Chinese medicine at least needs to meet some minimum standard that is established under modern biomedical science.

After the medical effects of traditional Chinese medicine have been carefully assessed, research in traditional Chinese medicine may at least provide an important alternative medical care system, and facilitate future development of modern medicine. If traditional Chinese medicine is effective, or part of it is effective, a good policy should be designed to facilitate its development so that more people can benefit from this practice. It is worth pointing out that even those odd materia medica may have biomedical evidence to support their medical effects. Excrements have been used in the Chinese medicine to treat some intestinal diseases. It may be a way to pass beneficial intestinal bacteria from healthy individuals to patients. 21

The recent interaction between modern technology and the traditional Chinese medicine have transformed traditional Chinese medicine practice in many different aspects. Generally speaking, the current practice and research efforts can be classified into four different categories: 1) the traditional practice; 2) traditional Chinese medicine pills; 3) traditional Chinese medicine herb extract; and 4) therapeutic effective chemicals identified from traditional Chinese medicine herbs. These categories often have different practice. Under the current legal regime, they often involve different laws and regulations. Research, development, and policy changes in these different categories often have different social and economic impacts.

A. Traditional Practice

Traditional practice refers to the practice whereas a traditional Chinese medicine doctor meets a patient in person and prescribes a set of herbs, which will be adjusted to match the patient’s individual need. China currently has about 408,600 traditional Chinese medicine practitioners with professional doctor license. Together, they provide

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19.2% of total outpatient service every year in China. Today, most traditional Chinese medicine practitioners are trained in universities or similar institutions. After graduation, student practitioners need to pass the National Traditional Chinese Medicine Practice License Certification Test before they can practice. China currently has at least 23 universities that are specialized in Chinese Medicine, with more similar institutions that offer Traditional Chinese Medicine practice training. Among them, Beijing University of Chinese Medicine and Guangzhou University of Chinese Medicine are designated as National Key Universities (Project 211 institutions).

It has been generally believed among practitioners and patients that a patient should seek western medicine for life-threatening conditions. But for chronic diseases or conditions with uncertain causes, traditional Chinese Medicine may provide a better medical outcome. This general belief is also consistent with the general theory of traditional Chinese medicine, because traditional Chinese medicine focuses on the status and functionality of a patient’s body. If a patient has a fever and shows some symptoms of cold, a doctor trained in western medicine will first determine what the cause of these symptoms is, for example, whether it is a bacterial infection. If it is a bacterial infection, antibiotics will be administered. In contrast, a trained Chinese medicine practitioner will determine the status of the patient’s body. There are at least four statuses that are associated with cold symptoms. Figuring out the right status will determine which set of herbs will be used. Then the doctor will tailor the set of herbs to the patient’s individual status. The traditional Chinese medicine practitioners believe that when the body is restored to balance, the disease will just go away.

When a patient decides to take traditional Chinese medicine, he or she can obtain such care from most clinics and hospitals of China.

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22 Zhongguo Wanrenkou 3.06 Ming Zhongyi Shi (中国万人口3.06名中医师) [China Has 3.06 Chinese Medicine Doctors per 10,000 people], http://news.sohu.com/20110914/n319346615.shtml (last updated Sept. 14, 2011).
24 Project 211 is a project of National Key Universities and colleges initiated in 1995 by the Ministry of Education of the People's Republic of China. Project 211 designations often signify academic excellence, and universities with such designation are likely to receive a large amount of research funding from Chinese government.
25 Consultation from a traditional Chinese medicine practitioner.
26 Because of the different focus, the diagnosis from western medicine only provides limited information for traditional Chinese medicine practice.
27 Some of these statuses can be literally translated to “wind cold (fenghan),” “wind hot (feng hot),” and “summer wet (shushi).” It requires years of training and practice to fully understand the exact meaning.
The doctor will first ask the reason for the visit and determine the status of the patient’s body. He will put his fingers on the patient’s wrist, and use them to measure the patient’s pulse. Each finger can sense different information. A lot of information can be gained. For example, a well-trained traditional Chinese medicine doctor can easily determine whether a woman is pregnant just by measuring her pulses. The doctor will then examine the patient’s skins, eyes, and tongue etc., and ask questions about the appetite, sleeping habits, and the color of excrements to confirm his judgment. After successfully determining the patient’s status, the doctor will prescribe a set of herbs. This set of herbs may be adapted from some early records in the traditional Chinese Medicine doctrines. The doctor may also change the amount of herbs based on the patient’s individual profile.

After that, the patient will bring the prescription to the pharmacy. In China, they are typically operated by the same hospital or clinic. The pharmacist will give the patient a bag of mixed herbs based on the prescription. These herbs are often dried and chopped into small pieces. The patient brings the bag home, places all herbs in a pot with water, and soaks the herb for about 15 minutes. Then the patient should boil them together for 30 minutes. Herbs then should be removed. The remaining herb soup is the traditional Chinese medicine, which is black and bitter. A patient typically needs to drink a bowl (about three to four cups) three times a day. And one bag of herbs should be good for two to three days. A patient should see the doctor again after 3-4 days for new prescriptions, and the doctor may administer a different set of herbs if there is any change in the status.

The most valuable asset for an experienced traditional Chinese medicine practitioner is his experience and his ability to tell the status of the body. It is a highly skilled art of observing, inquiring, and analyzing. Unlike some biochemistry tests used in western medicine, the signs of a patient’s symptoms often point to different directions. It often requires years of practice to build up the ability to practice traditional Chinese medicine. The most well-known traditional Chinese medicine practitioners are not known for how many secret prescriptions they possess, but for their mastering of the theories and the ability to successfully apply the theory to difficult cases.

It is often quickly assumed that traditional Chinese medicine practitioners do not innovate, because the set of herbs that are prescribed are usually adapted from ancient traditional Chinese medicine doctrines. However, some experienced practitioners are able to design new sets of herbs based on their deep understanding of the nature of herbs and the traditional Chinese medicine theory. In that

28 Personal communication.
case, patent protection can be easily granted, because the new formulation can meet the inventive step requirement.29

Over the past decades, some patents for the traditional Chinese medicine have been filed,30 but it has never been enforced in the context of traditional practice. There may be two explanations. First, it is not clear how to enforce a patent against individual practitioners. Examining each practitioner’s prescription is not an easy task. Second, because the traditional practice of Chinese medicine heavily depends on the experience, determining the correct status of the patient is extremely important in this process. Administering herbs to a patient with mismatched status would not be useful. Thus, a doctor’s business largely depends on his experience and his individual reputation. Possessing some new prescriptions does not necessarily yield additional value for an individual practitioner’s traditional practice. Thus, intellectual property protection or any kind of similar protection may not lead to a meaningful advantage in the traditional practice setting.31

B. Traditional Chinese Medicine Pills

Traditional Chinese medicine pills refer to a special form of traditional Chinese medicine, which is often prepared in the forms of pills and can be taken by the patient readily. They are known as Zhong Cheng Yao in Chinese. Zhong means Chinese. Cheng means prepared or ready-to-use. Yao means drugs. In the English literature, they are sometimes referred as Chinese Herbal Patent Medicine.32 This name may cause some confusion. It actually has nothing to do with a patent. The word “patent” may come from the early use of patent medicine as a way to refer medical elixirs.33 In order to avoid unnecessary confusion, this article will use the term “traditional Chinese medicine pills” in the following discussion.

Chinese people have practiced traditional Chinese medicine pills for thousands of years. The Yellow Emperor’s Inner Canon has documented several formulas of making traditional Chinese medicine pills.34 As discussed earlier, the preparation process of Chinese

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29 The inventive step is similar to the non-obvious requirement under the U.S. patent law.
31 Trademark may be useful in some settings. However, the doctor needs to see the patient in person. Consumer confusion is not quite likely.
34 Naeser, supra
medicine is not quite convenient. If a patient needs to take a certain prescription for a long time, particularly for the treatment of some chronic disease, he may consider taking traditional Chinese medicine pills instead. The preparation starts with grinding a set of herbs based on the prescription, which is then mixed with water, honey, paste or wax to produce pills. These pills are often small and have the shape of spheres. They can be kept under normal temperature for months. One preparation can last for a long time.

The modern technology has dramatically transformed this practice. Today, pharmaceutical companies can engage in mass production of traditional Chinese medicine pills for some popular formulation. These ready-to-be-taken medicines are not necessarily in the forms of pills any more. They can be prepared in the forms of powders, plasters, tablets, capsules, and dissolvable granules.

Many of these new “instant Chinese medicines” are designed to treat symptoms of some non-life threatening diseases. These new medicines are often placed under the “over-the-counter category”, which means that they can be purchased by patients without prescriptions. This new form of traditional Chinese medicine has appealed to many patients because of its convenience. It has led to great market success for many pharmaceutical companies.

The new practice is quite different from the past practice in two ways. First, in the past, a patient needed to see a traditional Chinese medicine doctor, and the prescription of the pills would be tailored to meet the patient’s personal needs. Second, in the past, only a limited number of formulations can be made into pills, and they were not produced in such large quantities. Today, these new “instant Chinese medicine” pills are made in great quantities and in many different forms. For example, the dissolvable granules are very popular among Chinese people to treat cold symptoms. To some extent, the new pills are administered in a way that is more similar to western medicine.

An important relevant question is how traditional Chinese medicine prepared in this way may provide better benefits compared to western medicine. Medical researchers often justify the value of traditional Chinese medicine for two reasons. First, not every medical effective chemical has been extensively researched and well documented. Thus, it is probably easier to administer the herbs than to identify and purify these chemicals.

35 Id.
36 Id.
37 One may feel that it is desirable to identify the key ingredients for all traditional Chinese medicine. However, any such proposals probably have greatly underestimated the difficulty. The extract of herbs often includes at least hundreds and maybe thousands of compounds and the traditional Chinese medicine often uses multiple herbs together. Moreover, the mechanism of drug, pharmacokinetics dynamics and
Second, traditional Chinese medicine prescriptions often include a set of herbs, which contain several therapeutic effective chemicals and their combinational effects may generate synergistic effects. Western medicine typically focuses on one single chemical agent. The limitation of this approach has been recognized. In traditional drug design, a new drug (a chemical agent) triggers a particular cell signaling pathway and then the cell signaling pathway triggers a particular effect. However, there are often multiple cell signaling pathways. These cell-signaling pathways operate more like webs rather than just one superhighway. They overlap and cross talk with each other. The effects of a particular pathway may be diluted or inhibited by other alternate pathways. For this reason, combination therapies are sometimes considered to be more effective in treating certain diseases. From this perspective, traditional Chinese medicine may have some unique advantages. The mixture of chemicals in traditional Chinese medicine may target multiple cell signaling pathways at cellular level, and the activation of multiple cell signaling pathways may exercise a synergistic effect. The advantage of this combinational therapy of traditional Chinese medicine has begun to draw more attention in the biomedical research community.

Unfortunately, very few traditional Chinese medicines have been rigorously tested and accepted by the global medical community for drug use. Many researchers believe that this is due to the strict requirement of drug approval process and the lack of clinical trials. For example, in the United States, herbs are often classified under dietary supplements category. It is illegal to market a dietary supplement product as a treatment or cure for a specific disease or condition. In order to claim therapeutic effects, a drug needs to be approved under the drug category.

The quality control standard under the drug category is very high. It creates at least two challenges for traditional Chinese medicine. First, the FDA typically requires a clear description of the nature of metabolism are often not clear. Without the knowledge of the possible mechanisms, identifying the medical effective chemicals is extremely difficult.

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39 Id. at 985.
40 Alternative pathway is often used to explain why the therapeutic effects of some drugs that have shown to be effective in mice cannot be repeated in humans. In most cases, these drugs target the same cell-signaling pathway both in humans and in mice, but alternative pathways are different.
41 Woodcock, supra note 38, at 985.
the active compound and its quantity for drug to be tested in clinical trials. This leads to a catch-22 problem. Without properly determining the effects of traditional Chinese medicine in clinical trials, limited resources will be used to identify the key ingredients. But without the knowledge of the key ingredients, it cannot meet the disclosure requirement for a typical clinical trial.

Another challenge for traditional Chinese medicine is that the variation in harvesting, preserving, extracting and preparing the herbs leads to variations in the quantity of active compounds in different batches. This may cause three problems. First, this creates concern of quality control in using herbs medicine as drug. Second, the variation in the content also causes a problem in designing clinical trials. Subjects in clinical trials are taking compositions with different quantities. Variation in the quantity may lead to inconsistent results. Third, the result of clinical trials cannot be used to predict the effects of the drug in the market, because the drug offered in the market may be different from what it is used in clinical trials. Thus, for a patient, the black pills prescribed to him or her are only likely to be the same as to what have been tested in clinical trials.

Recently, some pharmaceutical companies are able to standardize the formulation by referencing to the key active ingredients, while others employ a range of analytical technologies to demonstrate batch-to-batch uniformity. These quality control procedures can successfully limit the range of variation. Slight variations of the components should be tolerated, because a slight change of quantity is not likely to trigger a different cellular response. In addition, individual patients may respond differently to the same drug, because individuals’ genetic backgrounds are also different. If variation of human subjects can be tolerated in a clinical study design, slight variation of drug components should be tolerated as well. In fact, there is no principle in statistics that would not allow a slight variation in drug ingredients.

By adopting a strict quality control procedure, some countries have achieved great success. Kampo medicine is one of these successful examples. Kampo medicine is the name for the use and the adaptation of traditional Chinese medicine in Japan. Traditional Chinese

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44 FAQ: About GW, GW PHARMACEUTICALS, http://www.gwpharm.com/FAQ.aspx (last visited April 12, 2015) (“GW’s lead product, Sativex, is an oral spray which consists of a formulated extract of the cannabis sativa plant that contains the principal cannabinoids delta-9-tetrahydrocannabinol, or THC, and cannabidiol, or CBD, as well as other minor cannabinoids and other active non-cannabinoid plant components. In order to achieve a fully standardized formulation of these complex extracts, GW employs a range of advanced analytical technologies to demonstrate batch-to-batch uniformity.”).
Medicine was introduced to Japan between the 7th and 9th centuries. The term Kampo literally means “Chinese prescription” in Japanese. Since then, the Japanese have developed their herbal medical system based on traditional Chinese medicine, which has incorporated a large number of traditional Chinese medicine prescriptions. In 1980s, the Ministry of Health, Labor and Welfare of Japan approved 210 prescriptions of traditional Chinese Medicine for medical use. These medicines are composed of exactly the same quantity of ingredients under standardized formulations and are produced under strict manufacturing conditions. This has led to a great commercial success. In 1994, the Kampo Medicine has generated over 150 billion Japanese yen of revenue in Japan.

C. Traditional Chinese Medicine Herb Extracts

Extracts of herb often contain medical active ingredients. Typically, with some simple process, the extracts can be directly used for various medical purposes. Extracts of the traditional Chinese medicine herbs have been widely used. Some of them are quite popular, for example, the ginseng extract and the ginkgo leave extract. The controversies related to Chinese medicine herb extract have never been at the center of disputes in recent years. This is probably because compared to the traditional knowledge of some other countries, Chinese medicine herbs have been well documented, both in ancient texts and modern textbooks. In addition, extract from one single plant has rarely been considered as an important part of traditional Chinese medicine practice.

However, controversy regarding the extract of herbs from other countries has been an important source of disputes internationally. One famous case is related to the neem tree. Indians have used the neem tree as a fungicide for many years. In 1994, the European Patent Office granted WR Grace a European patent on methods of using extracts from the neem tree to control fungal infection. The Indian government opposed the patent on the ground that the fungicidal activity had been known in India for thousands of years. The patent was revoked. In order to further address concerns of biopiracy, the Indian government has established the Traditional Knowledge Digital
Library as a repository for Indian medicine. The purpose is to give the
patent examination officers of other countries an easy way to conduct
prior art search in indigenous knowledge, and also to meet some
countries’ publication requirement for prior art.\textsuperscript{49}

\textit{D. Therapeutic Effective Chemicals Identified from Chinese
Medicine Materia Medica}

Therapeutic effective chemicals in traditional Chinese medicine
have also been extensively researched. Modern biomedical science
focuses on the interaction of chemicals at the molecular level. The
richness of chemicals in traditional Chinese medicine \textit{materia medica}
provides an important source for effective treatments. One good
example is the discovery of \textit{Qing hao su} (a.k.a artemisinin).\textsuperscript{50}
Traditional Chinese medicine practitioners have used various herbs to
treat malaria in Southern China for thousands of years. In early 1970s,
Youyou Tu, a Chinese medical scientist, collected 2000 traditional
Chinese medicine prescriptions, ancient texts, and folk remedies to
treat malaria. She made 380 extracts from 200 herbs, and discovered
the extracts from \textit{Qing hao} (\textit{Artemisia annua}, a.k.a. sweet
wormwood), which is effective for treating malaria in humans.\textsuperscript{51}
Her discovery has saved millions of lives both in China and Africa.
Because of her contribution, she won the 2011 Lasker Award in
Clinical Medicine, one of the most respected medical science prizes in
the world.\textsuperscript{52}

A relevant question is that, since the \textit{Qing hao} (sweet wormwood)
extract has been found to be effective in treating malaria, and a
medical practitioner can simply administer \textit{Qing hao} extracts to his
patients, one may wonder what the value of further research (\textit{e.g.}
obtaining the pure substance) is. Further research can be justified in
many different ways: 1) The discovery of the true identity of the
therapeutic substance can facilitate a better understanding of the
disease mechanism; 2) Once the true identity of the effective chemical
is discovered, it can be chemically modified to increase the potency
and reduce the toxicity; 3) The pure form can be administered with a
higher dose without administering other potentially harmful chemicals.

\textsuperscript{49} Du Ruifang (杜瑞芳), Chuanong Yiya de Zhishi Chanquan Baohu (传统医药的知识产权保护)
\textsuperscript{50} Louis H. Miller & Xinzhuan Su, \textit{Artemisinin: Discovery from the Chinese Herbal Garden}, 146(6)
\textit{CELL} 855 (2011).
\textsuperscript{51} Evelyn Strauss, \textit{Award Description: Lasker–DeBakey Clinical Medical Research Award, LASKER
FOUNDATION}, http://www.laskerfoundation.org/awards/2011_e_description.htm (last visited Apr. 15,
2015).
\textsuperscript{52} The Lasker Awards Overview, http://www.laskerfoundation.org/awards/index.htm (last visited
April 12, 2015) (“Lasker Awards often presage future recognition by the Nobel committee, so they have
become popularly known as ‘Americ’s Nobels’.”).
at the same time; and 4) The pure form can be delivered in a more effective way. For example, the pure form of the chemical can be administered through intramuscular injection, which is likely to be more effective in some cases.

Intellectual property protection of the purified therapeutic effective chemicals from herbs has been generally recognized, even though some controversies exist regarding whether these purified chemicals are products of nature. However, most pharmaceutical companies will seek patent protection for the natural substance and its chemical derivatives. These chemical derivatives are not products of nature. Some of these herbs used by multinational pharmaceutical companies are from traditional knowledge. Those defense strategies used by some countries, such as the aforementioned Traditional Knowledge Digital Library, are often ineffective to invalidate these patents, as the purified substances are often not clearly identified or sufficiently described in the traditional knowledge.

III. INTELLECTUAL PROPERTY PROTECTION AND TRADITIONAL CHINESE MEDICINE

It is generally believed that there was no intellectual property protection in ancient China, at least not something that is similar to the modern intellectual property legal regime. In contrast, in the ancient China, imitation and being copied by others are highly regarded, because it is a sign of potency and influence. Useful arts that are associated with high economic returns are kept as secrets within a family or between master and apprentice. One may consider it as one kind of trade secrecy. However, this is different, because legal sanctions are generally not available for misappropriation. The accumulation and the development of traditional Chinese medicine is through a combination of publication of important doctrines (such as Treatise on Cold Damage Disorders) and secret transmissions. Secret transmission often includes some prescriptions or practices that were

53 Under the current patent system, natural products often cannot be patented. But it would become patent eligible if purification and concentration creates a new thing commercially and therapeutically. See Parke-Davis & Co. v. H. K Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (holding that a patent on an adrenalin compound isolated and purified from the suprarenal glands of animals is valid). Even though Parke-Davis is not exactly about patent subject matter, this case is generally considered as the foundation of modern biotechnology. There is very little controversial regarding patent eligibility for these therapeutic effective chemicals, because the structure, the use and the synthesis or the preparation of those isolated compounds is not a part of traditional knowledge. Even if these compounds can be found in the nature, the isolation and the purification have transformed to a thing that is distinctively different from what exists in the nature.

54 Id.

developed by individual experience, which are generally known as zu chuang mi fang (secret prescription from forefathers). Disruption of such transmission, particularly in wartime, was common, and the knowledge is likely to be lost forever.

Only until quite recently, the Chinese lawmakers have begun to recognize that some sort of legal protection is necessary for traditional Chinese medicine. The development of this recognition is intertwined with the development of the market system. China started the economic reform, switching from a planned economy to a market-based economy in the early 1980s. Before the 1980s, most government activities that related to traditional Chinese medicine were limited to collecting and publishing traditional Chinese medicine prescriptions.\footnote{Bryan Bachner, Intellectual property rights and china: The Modernization of Traditional Knowledge 42 (2008).}

The introduction of the market system in the 1980s has quickly changed the practice of Chinese medicine. In the late 1980s, some pharmaceutical companies began to produce traditional Chinese medicine pills in large quantities. As the result, a patient can directly buy these Chinese medicine pills over the counter. It was a huge commercial success. But it quickly turned the market into chaos. Many pharmaceutical companies began to copy each other’s successful formulations with some minor changes. The drugs with the same name often had different formulations. And very few pharmaceutical companies were willing to invest in new products.

In 1992, China announced \textit{Regulations on the Protection of New Traditional Chinese Medicines} to protect traditional Chinese medicine with “stable quality and clear medical effect”.\footnote{Zhongyao Pinzhong Baohu Tiaoli (中药品种保护条例) [Regulations on the Protection of New Traditional Chinese Medicines] (promulgated by the St. Council, Oct. 14, 1992, effective Jan. 1, 1993) art. 3 (Chinalawinfo).} According to the regulation, the Chinese Food and Drug Administration would grant 30, 20 or 10 years exclusive manufacturing and sale rights to pharmaceutical companies with successful application. This regulation has restored the market back to the order and many new drugs have been made available. In 2007, China accepted the \textit{Agreement On Trade-related Aspects of Intellectual Property Right} (TRIPS Agreement). According to the agreement, any law that is inconsistent with the TRIPS Agreement would be preempted. In fact, according to the \textit{Drug Administration Law of China} enacted in 2001, China has stopped the enforcement of \textit{Regulations on the Protection of New Traditional Chinese Medicines}.\footnote{Du, supra note 49, at 115.} Currently, only up to 5-year inspection period is provided. During this inspection period, the
Chinese Food and Drug Administration would not approve any similar drug application filed by other manufacturers.

The newly enforced patent law provides 20 years protection, which is considerably longer than the 5-year maximum inspection period provided by the Drug Administration Law of China, but the coverage of the patent law is much smaller. Similar to the patent law in the United States and in Europe, the Chinese patent law requires novelty and inventive step (non-obviousness). Most traditional Chinese medicines that can be previously protected under Regulations on the Protection of New Traditional Chinese Medicines are now denied patent protection, because these ancient formulations often cannot satisfy the inventive step requirement.

Many Chinese scholars call for intellectual property protection for traditional Chinese medicine. Some of them call for legal reform of patent law without clear justification, while others try to stretch the interpretation of intellectual property law by various means to cover traditional Chinese medicine. However, these researches probably fail to recognize that intellectual property is designed to protect a different kind of economic life and order, which is tied more closely to industrialization and development of new technology. Traditional knowledge, including traditional Chinese medicine, is not the original intended target of intellectual property protection. Thus, to discuss the scope of rights under the theory of intellectual property law imposes a mismatched framework for traditional knowledge. But some legal proposals have to be developed under the theory of intellectual property law, not simply because that the traditional knowledge is more similar to the intended target of intellectual property law, but also because claiming one’s right is imposing a duty upon others. Rights and duties are correlative concepts. If a person has a right against the second person, this is equivalent to the second person having a duty to honor the first person’s right. If China wants to extend protection to traditional Chinese medicine, it would have to impose a duty on other countries. It is not possible to impose such rights on other countries without mutual understanding. As different countries may have different views toward what is fair, the theory of intellectual property at least provides a shared common ground for discussion.

59 See Cai Zhongde & Lei Yan (蔡仲德, 雷燕), Jianli Zhong Yiyao Zhuanyou Quan Falv Baohu Zhidu de Tantao (建立中医药“专有权”法律保护制度的探讨) [Discussion of Strengthen IP Protection for Traditional Chinese Medicine], 1 ZHONGGUO YAOFANG (中国药房) [CHINA PHARMACY] 1, 1-2 (1999).
60 Du, supra note 59.
In the United States and Europe, normative theories of intellectual property seek to strike a balance between the public domain and private monopolies.\(^\text{62}\) In patent law and copyright law, the protection period is limited. After the protection period, the protected entity will fall into the public domain. In trademark law, a mark or a symbol is not elevated from public domain until it is used in commerce. Similarly in trade secrecy law, one cannot claim information that is generally known by the public as its trade secret. The importance of the public domain rests on innovation concerns and liberty concerns, as new innovations are derived from earlier innovations. Private monopolies are often viewed as restraints on the free use of such knowledge.\(^\text{63}\) The bifurcation between public domain, which cannot be protected, and protected property is an important feature of modern intellectual property law.

The most commonly cited ground against intellectual property protection for traditional Chinese medicine is that traditional Chinese medicine, like other traditional knowledge, is in the public domain. This argument clearly has significant merits, because traditional Chinese medicine has been practiced for thousands of years. Under the current intellectual property legal regime, anyone who wishes to claim absolute protection for traditional Chinese medicine must have to argue that traditional Chinese medicine is not in the public domain. To claim that traditional Chinese medicine is not in the public domain is inconsistent with the history of traditional Chinese medicine. However, the term traditional Chinese medicine includes several practices that are related to traditional Chinese medicine. While the traditional practice is clearly in the public domain, the argument is not quite strong for the new practice. The arbitrary classification of everything into two categories: public domain in which nothing can be protected, and protected property, fails to consider the fuzzy boundary of the public domain.

\textit{A. The Public Domain and the Traditional Practice}

Public domain is often viewed as a negative space.\(^\text{64}\) In the intellectual property lexicon, negative space refers to an area where little or no intellectual property protection is offered. Except in the case of \textit{zhu chuang mi fang} (secret prescription from forefathers), the doctrines and the prescriptions of traditional Chinese medicine have been shared among traditional Chinese medicine practitioners for


\(^{63}\) Id. at 41.

thousands of years. It is hard to see how a particular traditional Chinese medicine practitioner’s rights or position regarding to traditional Chinese medicine is different from another. In terms of their rights and positions, they are more or less equal. As the result, there is no justification for any traditional Chinese medicine practitioner to claim a right, thus impose a duty on another traditional Chinese medicine practitioner. This is exactly the definition of negative space. However, the conclusion would be different if one compares the rights and the position between a traditional Chinese medicine practitioner and a non-practitioner. It seems that they are in different positions. Certainly, to what extent when the difference between these positions is large enough to create such rights is a different question.

In the debate regarding traditional knowledge, community ownership is often used to justify protection of traditional knowledge of indigenous people. Community ownership distinguishes the rights of traditional knowledge holder against another indigenous person and an outsider. Members of the community are viewed as equal holders of the traditional knowledge, and do not have rights against other members. Thus, members of a community create an area of negative space, which has a limited boundary. This concept of negative space boundary is consistent with the view regarding community ownership. A person within the circle has limited rights against another in the circle, but he may have stronger rights against people outside the circle.

The early intellectual property law also suggests that the negative space has a geographic boundary. In the 18th century, the British government encouraged people to bring existing technology from the European continent by granting monopolies to these technologies. Before the enactment of the Leahy-Smith America Invents Act, public use outside the United States was not considered as prior art under the U.S. patent law. Also in trademark law, an unregistered trademark is only protected in the zone of actual use and natural zone of expansion. And in early copyright law, foreign work would lose protection (fall into the public domain) because of noncompliance with formalities of U.S. law, while being protected in Europe. All of them at least suggest that the geographic boundary of negative space exists and public domains of different countries are to some extent different.

It is only because of the international trade and the TRIPS agreement, there seems to be an increased general understanding toward global public domain. Public domains of different countries has begun to be connected. The TRIPS agreement does not define a

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unified global public domain, but the language seems to assume the existence of such global public domain. For a community, which has not agreed to the terms of the TRIPS agreement, it is hard to see how its traditional knowledge possessed by the community members should be considered as knowledge within the global public domain. One who claims that indigenous people’s knowledge belongs to the global public domain simply has ignored the complexity of public domains at the international level.

While this argument may be more applicable to indigenous people with limited access to the global public domain, it is less applicable for traditional Chinese medicine, because China is an active participant of international trade and has agreed to the terms of TRIPS agreement. If China could assert rights for its culture, history and traditional knowledge, other countries may similarly claim their rights on their traditional knowledge. The global exchange of knowledge would be blocked and the benefit of information exchange would be lost.

B. The Public Domain and the New Practices

Knowledge in the public domain is a diverse pool. Some knowledge can be easily accessed and enjoyed by the public, while some cannot. Some additional efforts are required for the public to enjoy the knowledge. The concept of derivative work is quite common in the context of copyright, such as novel sequel and movie adapted from a novel. In the context of patent law, the value of an improvement patent is widely recognized. An improvement patent is one which adds new feature to the original patent. While the holder of the original patent can block the use of the technology in any form, the holder of an improvement patent has the right for the new feature.

Generally speaking, intellectual property can be extended to derivative knowledge gained from the public domain. For example, a translator has copyrights on his translation of an ancient Greek play or epic poem, and an innovator can file a patent for his new feature which can be an addition to a device that is already in the public domain.

This concept of improvement becomes problematic in certain areas of useful arts, whereas the derivative knowledge cannot be reduced to

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66 In the United States, bare minimum of creativity is required for copyright protection. See Feist Publications, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 345 (1991) (“Original, as the term is used in copyright, means only that the work was independently created by the author (as opposed to copied from other works), and that it possesses at least some minimal degree of creativity. To be sure, the requisite level of creativity is extremely low; even a slight amount will suffice. The vast majority of works make the grade quite easily, as they possess some creative spark, ‘no matter how crude, humble or obvious’ it might be.”).
a practice that is markedly different from the primary knowledge. Suppose there is a lock and one thousand keys in a box, and only one of them can be used to open the lock. Efforts to identify the right key are beneficial because it can increase the efficiency. The public has tried to use each of them to open the lock. Thus, selecting the right key is derivative because it is an assessment of each existing key. It seems that the knowledge of the existence of the right key is in the public domain, but the knowledge of which one is right has not been possessed by people in the public. If it is not possessed, how can such knowledge be claimed to be in the public domain?

One may argue that the protection of this kind of derivative knowledge does not generate something new or it does not involve sufficient inventive concept, but if the monopoly power of intellectual property law is justified by utilitarian concern, why cannot efficiency be a legitimate justification?

One may also argue that the protection would deprive existing rights of the public. But existing rights of the public deserves more analysis. Suppose only one person in the public has used the right key before the availability of such knowledge, and now because of the availability of such knowledge, there are 100 persons in the public that are using the right key. It seems that the producer of the derivative knowledge may have a stronger claim against the 99 persons, even though the producer of the derivative knowledge is less likely to be able to assert any rights against the first person.

Thus, the issue turns to how to distinguish this person from the remaining 99 persons. Usually, distinction is not a problem under existing intellectual property law, because patent law requires inventive steps. A new device can be easily distinguished from existing devices. Similarly, a new novel is typically quite different from what is available in the public domain.

The traditional practice of Chinese medicine is in the public domain. Legal reform should not disturb the existing rights of current and future practitioners. In contrast, the expansion of traditional Chinese medicine into new fields has yet to be possessed by the public. It is one thing that the current intellectual property legal regime does not protect certain forms of practice, it is another to assert that all forms of practices are in the public domain, precluding any possible protection.

IV. PROPERTY ARGUMENTS FOR PROTECTING SOME FORMS OF TRADITIONAL CHINESE MEDICINE

Traditional Chinese medicine includes very different practices. The traditional knowledge holder can be different from the practitioner of new practice. They may seek very different rights, and they may
assert rights against each other. While some issues are less controversial, for example, under the current intellectual property legal regime, patent protection can be extended to new therapeutic chemicals and new formulations, some other issues are difficult to resolve. This part of the article will examine the rights of traditional knowledge holder, the rights of new practitioner, and whether the holder of traditional knowledge have certain claims against the new practitioners.

The current intellectual property theory often justifies intellectual property protection by Locke’s labor principle, the economic theory and moral rights. While the current intellectual property theory does not support a broad scope of rights of the traditional knowledge holder and the practitioner of new practice, the rationale of these theories at least can support some possible claims.

A. Locke’s Labor Principle

Among all theories for intellectual property, the Lockean theory of property rights seems to be the most intuitive. A person who labors upon unowned land acquires natural property rights to the fruits of his or her labor. This theory finds favor among many scholars on property. In the context of intellectual property, the public domain seems to have the characteristic of the unowned land, and the fruit of the labor is the intellectual product.

Scholars often argue that Locke’s theory is not sufficient to justify protection of traditional knowledge, because only the laborers deserve the property rights and they are long dead. This argument assumes that the identity of laborers must be individuals and is probably closely tied to the romantic notion of the autonomous creators. However, the romantic notion of individual creators is not shared universally. In the history of China, Confucianism has dominated the major political and philosophical thinking for a long time. Confucianism often emphasizes the norm of a community and often treats the family and the community as a unit.

There are at least two possible ways for the descendants of the laborers to claim such rights. First, the descendants of the laborers can claim the laborers are the members of the community and the rights

68 Id. at 171.
69 Munzer, supra note 62, at 59.
71 Confucius’s followers, Lunyu (论语) [The Analects] (475 BC–221 BC) (a collection of sayings and ideas attributed to the Chinese philosopher Confucius and his contemporaries).
belong to the community. The community, a continuously living entity, is both the laborer and the rightful owner. Second, the descendants of the laborers acquire the property rights from inheritance. Inheritance allows the original laborers to pass the rights to their descents upon death. Intellectual property rights are a kind of rights that can be passed.

One would point out even if a community can acquire and maintain such rights, by the time when the descendants acquire such fruits, any possible rights of intellectual property on traditional knowledge would have expired. The current intellectual property legal regime does not support an indefinite term for intellectual property rights. This gravity pull toward public domain is not consistent with Locke’s labor on desert principle. In fact, Locker’s principle supports a much stronger property rights. If a person acquires property rights from his or her labor, it is not clear why a laborer would lose his or her rights on the fruits of the labor after certain time.

The challenge for Locke’s principle is that if China can claim rights on its traditional knowledge, many other countries can similarly claim their rights on traditional knowledge. A “Rights War” on traditional knowledge among these countries is not desirable, because it is difficult to ascertain the boundary of such rights and also it seriously blocks the exchange of knowledge. But one can still argue that these countries still have rights but they voluntarily give up their rights in exchange of the access of the knowledge of other countries. For some indigenous people with limited interaction with the global community, they have not been benefited from such exchange; they probably have not given up their rights, and thus retain some claims regarding their traditional knowledge. But this argument is not likely to be applicable to China, as China is a member of the WTO, and is quite active in the global information exchange.

**B. Economic Theory**

In the United States and China, debates about intellectual property rights tend to center on a utilitarian perspective. The purpose of intellectual property system is to maximize social welfare. It is often argued that monopoly rights are necessary to incentivize the original creators to engage in the creation. This incentive argument is often combined with the theory of public goods. Public goods are non-rivalrous and non-excludable in nature. A non-rivalrous good is a kind of...
of goods that can be consumed by a person without preventing simultaneous consumption by others. A good is non-excludable if there is no effective way to prevent non-paying consumers from enjoying the goods. Some often cited examples for public goods include lighthouse, national defense, clear air, and fireworks. As this argument goes, intellectual property is a kind of public goods. It is non-rivalrous and non-excludable in nature. Production of such goods can benefit a large number of people at little or no cost and maximize social welfare. But without legal protection, the producers of such goods have no effective way to recover the cost in producing such goods, which in turn will deter the creation at the first place.

This argument is particularly strong for high-tech industry, because high-tech has a very high up-front cost. The cost does not just include the cost for developing a successful product, but also includes the cost of previously failed projects. The patent system grants the inventor a limited period of monopoly power over the market, so that the inventor can charge a higher price and make sufficient profits to cover the cost. However, a high price prevents a certain number of people, who are willing to pay the product at the price higher than the manufacturing cost (the marginal cost) from enjoying the product. Thus, by denying those people from accessing to the new invention, the monopoly power generates deadweight loss and reduces social welfare. It is often believed that the patent system is “a necessary evil.” From a utilitarian perspective, it is justified because the potential social welfare increase is greater than the deadweight loss.

The difficult question turns to whether the protection should be extended to some expansive practice of traditional Chinese medicine, which cannot be protected under the current intellectual property law. As discussed earlier, unknown therapeutic effective chemicals in the traditional Chinese medicine materia medica often do not have any difficulties in obtaining patents, and new formulation for traditional Chinese medicine can also be protected under the patent, even though the strength of such patent is relatively weak because of the nature of the formulation patent.75

The difficult issue here is whether the new practice of the ancient formulation in the form of traditional Chinese medicine pills should be protected. Under the current intellectual property law, the ancient formulation cannot be patented, as they are often considered to be in

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75 A formulation patent is not likely to be powerful. This is because the innovation is the set of herbs, the claim in the patent would be a subset of each element in the original set. If the claim is very specific, thus includes all herbs in the set, other parties can easily substitute some of these herbs and receive similar medical effects. If the claim only includes a small number of essential elements, it runs the risk that some early texts have disclosed this small set of herbs, and thus not novel.
the public domain. However, the ancient formulation has yet to be tested in clinical trials. The need to protect a formulation is straightforward, because it incentivizes pharmaceutical companies to engage in research and test it in clinical trials, and in the end, prepare them in the forms of pills, which can benefit the general public. The public has not possessed the ancient formulation in the form of traditional Chinese medicine pills yet. Under the current intellectual property law, resources would be only directed to the new formulations. But the ancient formulations are likely to be more effective, because they have been practiced and modified for thousands of years, as the non-effective ones are less likely to be transmitted to the next generation. If there is any resource for clinical trial, the priority probably should be given to the ancient formulations.

It is also important not to interfere with the rights of the traditional practitioners. The new practice of traditional Chinese medicine provides a natural way to distinguish the traditional practice and the new practice, because one is offered through outpatient service with personalized adjustment, and one is offered through over-the-counter. Thus the interference with the rights of traditional practitioners is limited.

Under the economic theory, if monopoly rights can be justified by the need to encourage innovation, the protection of the new practice can be justified by 1) the need to check true or false information in the traditional knowledge and 2) the need to overcome regulatory hurdles. The purpose of protection is not to interfere existing practice in the public domain, but instead to encourage the generation of necessary knowledge to maximize social welfare.

1. The need to check true or false information

   In the case of the neem tree, the Indian government has established the Traditional Knowledge Digital Library for more than 1200 formulations of Indian medicine as a way to invalidate any patent claim related to these traditional formulations. But since the neem tree has been used as fungicide by Indian people for years, why has it not been successfully commercialized in the international market? Put it in another way, if these traditional formulations are really valuable, people should have rushed to commercialize these formulations since it is readily available.

   One of the most important characteristics of traditional knowledge is that it is a box of unverified claims. It contains useful information,

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76 The packaging of traditional Chinese medicine is considered to be in the public domain. The combination of the ancient formula and the packaging technique will not meet the inventive step requirement (non-obvious).
exaggerations, myths, and lies. Not all parts of traditional knowledge are valuable.

This problem also exists for the traditional Chinese medicine. It is often claimed that ganoderma or ginseng have the power to save people from death. The current medical community often discredits these claims. But how about a boy’s urine or excrement? Even if they are medically effective, are their medical effects significant enough to warrant administering them to patients?

These uncertainties pervade the entire body of the traditional knowledge. Traditional knowledge is valuable, but expanding traditional knowledge into a broader practice comes with the cost of ascertaining the value of such information. There is a great risk for a company to commercialize the traditional knowledge, because the company needs to pay the necessary cost to bring it to the market. Without any protection, once a product becomes popular, other companies can free ride the first company’s efforts.

The Indian Traditional Knowledge Digital Library has led to some undesirable consequences. It prevents further commercialization of traditional knowledge. The Indian government claims that, “Denying the patent means upholding the value of ‘traditional’ for millions of people not only in India but throughout the South. The free tree will stay free.”77 “But recognizing the value of traditional knowledge does not necessarily need to deny any rights of derivative knowledge holder, particularly none of these indigenous people have understood the effects of the neem tree well enough, verified it by experiments, and further provided it to the international market. After WR Graced filed the patent for the neem tree extract, the price of the neem seed quickly went up from 300 rupees a ton to over 8000 rupees a ton.”78 It shows there is a great demand for the neem tree extract in the international market. It also brings significant profits to the local neem tree plantation owners. If the neem tree is useful and can benefit the public, providing the neem tree to the international market promotes social welfare. A policy that can facilitate the public to benefit from the neem tree should be celebrated. The contribution of derivative knowledge creator was actually significant in this case. Even though indigenous people’s rights should also be recognized, it can be recognized through some other means, not necessarily by denying the rights of both derivative knowledge holder and traditional knowledge holder.

77 Patent battle, supra note 48.

2. Incentives are necessary to overcome regulatory hurdles

In late 1980s, some pharmaceutical companies discovered the market for traditional Chinese medicine pills and made great financial success. Soon, more pharmaceutical companies joined the competition. These pharmaceutical companies often copied each other’s products. When any new product has become successful, a large number of pharmaceutical companies will rush into the market. During the early 1990s, the market was in chaos. There were over 150 pharmaceutical companies that manufactured the same *Calculus Bovis Antidote Pills*, more than 140 pharmaceutical companies produced *Red Sage Pills*, and over 100 pharmaceutical companies were engaged in manufacturing *Angong Calculus Bovis pills*.

From a consumer’s perspective, there is nothing inherently wrong with the competition. Particularly for existing products, the competition can quickly drive the price down. But the over-competition made the profit margin so small that no pharmaceutical companies were willing to introduce new products. This is because the first pharmaceutical company often had much higher cost in introducing a new product. Particularly, it needed to pay significant cost associated with drug approval. It was much harder for them to cut the price. As free-riding pharmaceutical companies did not face such cost, the direct result was that pharmaceutical companies were only be interested in copying others’ successful products.

In 1992, China announced *Regulations on the Protection of New Traditional Chinese Medicines* to protect traditional Chinese medicine with “stable quality and clear medical effect”. The regulation was designed to address the problem described above. According to the regulation, the Chinese Food and Drug Administration would grant 30, 20 or 10 years exclusive manufacturing and sale rights to pharmaceutical companies for new medicine with “stable quality and clear medical effect”.

The regulation requires traditional Chinese medicine to have “stable quality and clear medical effect”. In practice, this is a very low standard under the current clinical trial standard. This new regulation has facilitated the development of the traditional Chinese medicine pills. More traditional Chinese medicine pills have been made available in the Chinese market. But pharmaceutical companies are

not willing to do it further. They generally do not have any interest in proving these medicines under a more rigorous clinical trial standard, and have very little incentives to market it in the international market.

Admittedly, market monopoly is not the only way to encourage innovation. Government funding can also be used to support the production of public goods. Currently, many medical research institutions in China receive substantial funding from the Chinese government for traditional Chinese medicine research. For example, the National Basic Research Program of China has funded a limited number of clinical trials. But this is far from being sufficient. Most researches are directed to identify the medical effective chemicals in traditional Chinese medicine. Only limited resources are spent in clinical trials, and there is no funding to make traditional Chinese medicine to meet the clinical trial standard in foreign countries. As research in traditional Chinese medicine are not considered as the top priority, these government funding is relatively limited. Clinical trials are generally prohibitively expensive. When the government funding is limited, the market probably should play a more active role. Some protection should be offered. It does not necessarily need to be in the form of a patent that grants an exclusive period for 20 years. But some protections are necessary to cover the cost for clinical trials.

It is worth pointing out the protection is not based on the novelty of the formulation; rather it is based on the amount of transaction cost necessary to bring it to the market. For these concerns, Provisions for Drug Registration has provided 5-year observation period for a new drug without a new chemical entity. This observation period can address some of these economic concerns discussed above. But it may not be sufficient, as the low clinical trial standard does not lead to modernization of traditional Chinese medicine. Once a drug is approved under this low standard, no pharmaceutical companies are willing to pay the cost for future research and testing it under a more rigorous clinical trial standard. Thus, modernization of traditional Chinese medicine requires a higher standard, and a stronger protection than the observation period is needed. If the benefit of providing these medicines to the public is greater than the associated cost, this new protection would maximize social welfare.

C. Moral Rights

Moral rights are often traced to the idea of personhood in the natural-rights tradition. It recognizes that intellectual products are the

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83 Id.
84 Linong Ji et al., Efficacy and Safety of Traditional Chinese Medicine for Diabetes: a Double-blind, Randomised Controlled Trial, 8(2) PLoS ONE 1, 1 (2013).
manifestations or the extensions of the personalities of their creators.\(^85\) Moral rights are often more applicable in the context of copyright. As an artist defines himself in and through the art, his work can be viewed as a natural extension of his personalhood. Thus, an artist should be entitled to have some control on his extension, his intellectual products. In the United States, the legal regime grants the author plenary rights. For example, the Visual Artists Rights Act protects the right of an author to claim authorship and misuse of her name.\(^86\) Similarly, the Copyright Law of the People’s Republic of China grants the author the right of publication and the right of authorship.\(^87\)

In the context of useful arts, moral rights sometimes are also recognized. Admittedly, in the context of patent litigation, moral rights are rarely the focus of disputes. Most disputes regarding inventorship are related to the invalidity of a patent, which is more related to economic return.\(^88\) One possible explanation is that forms of useful arts are often dictated by the law of nature. An inventor is less likely to be free to express his personalhood and embody it in the intellectual product. Nonetheless, the fact that a patent can be invalidated solely because the listed inventors are not real inventors, even though the patent holder (assignee) is the same, shows the legal regime recognize the rights of the inventor.\(^89\) This recognition is also consistent with the authorship rule in academia. A scientist who has made the first discovery will be highly regarded, and his work will be properly attributed by others.

For traditional knowledge, some scholars have rejected extending these rights to indigenous people based on moral rights theory. Their argument is based on the fact that the traditional knowledge has been created, transmitted and summarized by many different indigenous people from different generations. These scholars asked, “In what

\(^{85}\) Fisher, supra note 67.

\(^{86}\) 17 U.S.C. § 106A (“Rights of certain authors to attribution and integrity:
  (a) Rights of Attribution and Integrity— Subject to section 107 and independent of the exclusive rights provided in section 106, the author of a work of visual art—
  (1) shall have the right—
  (A) to claim authorship of that work, and
  (B) to prevent the use of his or her name as the author of any work of visual art which he or she did not create.”)

\(^{87}\) Zhuzuo Quan Fa (著作权法) [Copyright Law] (promulgated by the Standing Comm. Nat’l People’s Cong., Sep. 7, 1990, effective July 1, 1991) (2010) art. 10 (Chinalawinfo) (“The term copyright should include the following personal rights and property rights: (1) The right of publication, that is, the right to decide whether to make a right available to the public; (2) The right of authorship, that is, the right to claim authorship and to have the author’s name indicated on his works.”).


\(^{89}\) 35 U.S. Code § 115 (Inventor’s oath or declaration (b) Required Statements. — An oath or declaration under subsection (a) shall contain statements that— (2) such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.”).
sense, if any, could a community have a personality? But this reasoning has presumed the romantic notion of authorship. It ignores the fact that even though people in a community may have diverse personalities, which has made the personality of a community hard to delineate, the significant gap between a community as a whole and the outside world can maintain a distinct personality for a community. The sense of identity for a community is common. Citizens of a country celebrate gold medals in the international Olympic games. Similar, an ethnic group can be proud of its tradition and its culture.

Moral rights are mainly non-economic in nature. It typically does not provide a scope of rights that is as broad as patent right and copyright. As moral rights are aimed to protect the personhood of a creator, in the context traditional knowledge, it at least provides the creator of intellectual products the right of attribution. The concern for the moral right is a real concern in the context of traditional knowledge disputes. In the case of the neem tree, one concern for the Indian government is “[uphold] the value of ‘tradition’ for millions of people”.

Some controversies have arisen in the past few years between China and some other Asian countries. In the 1990s, South Korean pharmaceutical companies developed a new product called Heart-rescuing Teapills. It was a huge commercial success and made over 70 million US dollars from its revenue. They are also exported to many other Asian countries, including China. Traditional Chinese medicine practitioners and scholars found out that the formula was based on the formula Six-Ingredient Spirit Teapills from traditional Chinese Medicine. Many Chinese people felt that it was outrageous. This has created great concerns among Chinese scholars and policy makers. Many of these scholars accused the foreign company “stole” the traditional Chinese medicine. Part of the outrage among the public is due to insufficient recognition to the original holder of the traditional knowledge. Assuming Heart-rescuing Teapills is based on Six-Ingredient Spirit Teapills, it seems that China does have a claim for the right of the attribution. But South Korea probably has a claim too, particularly if Six-Ingredient Spirit Teapills was introduced to Korea a long time ago, and Korean people have made some changes to it. Nonetheless, moral rights do not need to be mutually exclusive. It is entirely appropriate to recognize the contribution of both countries as how it is done in academia.

90 Munzer, supra note 62, at 71.
91 Patent battle, supra note 77, at 40.
92 Cai & Lei, supra note 59, at 1.
93 Id. at 1.
Moral rights do not support a wide scope of rights. The economic theory does not support Chinese entities to claim more than moral rights. This is a good example where the holder of traditional knowledge and the current practitioner are different. If the Korean company has invested a significant amount of money and made Heart-rescuing Teapills through clinical trials, it should be the Korean company to enjoy the economic benefit of the market. But recognition of moral rights is important. If it is not properly addressed, it will lead to public outrage, and in turn would have a negative impact on the economic return.

D. Unjust Enrichment and Misappropriation

Unjust enrichment refers to the case that one person is enriched unjustly or by chance at another’s detriment. The rationale behind unjust enrichment probably is related to Locke’s principle, under which a person should deserve the fruits of his labor, thus each person should deserve a fair share of fruits in proportion to his labor. In the case of Kampo medicine in Japan or maybe Korean medicine, it is difficult to see how current Chinese medicine practitioners have made any significant contributions to the development of such practice, as traditional Chinese medicine was introduced to these countries hundreds of years ago.\(^{94}\) If one would like to claim the contribution of ancestors, it runs into the problem that was discussed in the earlier section, where British people may claim rights on any use of Newton’s laws of motion, and Italian people can claim rights on pizza.\(^ {95}\)

There may be a stronger misappropriation claim for indigenous people in the context of traditional knowledge. Misappropriation is a special form of unjust enrichment, under which a person uses improper or dishonest means for enrichment at another’s detriment.\(^ {96}\) In a typical case, an outsider came to a village of indigenous people, learned something from a particular person in the village, and commercialized it without consent. Additionally, the outsider may further use such knowledge to develop patentable inventions or copyrightable works. No matter whether the intellectual property rights are available to the outsider, a particular person at the current time has made significant contribution to the benefits of the outsider. He should deserve a fair share of his contribution. This contact person’s knowledge is from the community. The community as a whole should similarly have some derivative claims from this contact

\(^{94}\) Dharmananda, supra note 45.

\(^{95}\) Munzer, supra note 62, at 78.

\(^{96}\) Id. at 75.
person’s contribution. This is different from the case where Italian people can claim rights on pizza, because here a particular person has made verifiable contribution to a particular outsider’s benefits at the current time. The rights of the indigenous people are not a broad right for its knowledge, but it is based on their contribution to this particular outsider’s commercial success.

Similarly, in the context of pharmaceutical industry, whereas a pharmaceutical company learns the existence of a particular medical effective plant from a particular traditional Chinese practitioner, this particular practitioner should be able to claim his fair share of contribution. As the community of traditional Chinese medicine practitioner provides necessary knowledge to this particular practitioner, it should have a derivative claim for this particular person’s contribution.

The contribution is real. Some countries have established a database for traditional knowledge, and pharmaceutical companies are willing to enter into a contract with these countries for access of such knowledge. Additionally, these countries also have some rights on its native flora and fauna. The access to such database can save pharmaceutical companies significant amount of money in establishing a chemical library for drug screening. For example, in 1991, Costa Rico reached a contract agreement with Merck Pharmaceutical Ltd., under which Costa Rico granted Merck the right to evaluate the commercial prospects of certain plant, insect, and microbial samples collected in Costa Rica. In return, Merck agreed to pay Costa Rico $1 million over two years, and a royalty for successfully developed products. 97 Similarly, if an agreement between Traditional Chinese Medicine Practitioner Association and pharmaceutical companies -whether they are Chinese companies or foreign companies -can further advance modern medicine, such arrangement is also beneficial and desirable.

The exact value of such contribution is hard to evaluate. It may be easy to overestimate the contribution of the traditional knowledge practitioner if the drug search is not specifically targeted to a particular plant. As pharmaceutical companies test millions of possible compounds for medical effects and push thousands of promising compounds into drug pipelines for further experiments, 98 it is a matter of chance if any of these compounds ultimately get through the pipelines. Especially if the case is that the compounds would be tested anyway, or a similar compound can be found from another source, it

98 Mike M Hann & Tudor I. Oprea, Pursuing the Leadlikeness Concept in Pharmaceutical Research, 8 (3) CURR. OPIN. 255, 257 (2004).
is not clear how to determine the value for such knowledge. In addition, a significant cost of drug development is in clinical trials, any cost saving at early stage is relatively a small percentage of the total cost. From this view, the contribution of the traditional knowledge holder somehow is limited. But even so, as pharmaceutical company generates billions of dollars in terms of revenue, a small percentage is still significant. If a new drug is developed based on the contribution of a current Chinese medicine practitioner, it is appropriate to pay the particular practitioner for his personal contribution, and the Traditional Chinese Medicine Practitioner Association or similar entities for its collective efforts to collect, assess and summarize the medical effectiveness of the plants. This should be distinguished from the case of Kampo Medicine, where no current traditional Chinese practitioners have made verifiable contribution.

The right proposed here is different from some general intellectual property rights, as it is a claim on the contribution. It is also limited in the scope, as it has no power to exclude others from engaging in the practice. It only offers a moderate amount of compensation for the contribution. Ignoring such rights would often lead to public outrage. The neem tree case probably would come out quite differently if WR Grace gives the people in India some proper recognition, for both the contribution and the moral rights.

This proposed right is also different from contract right, as it is not based on previously negotiated contractual terms. Transforming a contractual relationship to a more royalty-like right claim would certainly remove the initial transaction cost. The success of some early examples would also encourage more countries to participate in establishing and sharing its traditional knowledge and bio-resources. It may further reduce the cost for pharmaceutical companies, as pharmaceutical companies do not need to negotiate with every database holder and only need to pay the database holder from which a successful product has been developed.

V. CONCLUSION

The purpose of intellectual property law is to strike a delicate balance between incentives for creation and access of knowledge. The development of intellectual property protection is tied closely to industrialization and modern economic life and order. Applying the current intellectual property law strictly on traditional knowledge imposes a mismatched framework on the rights of traditional knowledge holder.

Cohen argued that it is the legal protection that gives the value to intellectual property, and thus the rights to intellectual property
Indeed, it might be quite possible that our society can be operated under a different order - a society without any intellectual property protection at all. But once rights are given to a certain group of people, it would be difficult not to recognize the rights of another group. The sense of fairness and moral rights often demands a similar treatment. Today, the debate regarding traditional knowledge protection is often fueled with the intuitive recognition of fairness and moral rights.

In the article, Munzer et al., recognized a modest package of rights for traditional knowledge holders, which is more defensive in nature. Particularly, these rights can be used to block the enforcement of or to invalidate another variety of intellectual property, such as an outsider’s patent. This kind of defensive “rights” denies both the rights of traditional knowledge holder and the outsider in the same time. If social welfare can be increased by the outsider’s patent, why isn’t a better policy to recognize both the rights of the traditional knowledge holder and the rights of the outsider together? Some arguments against traditional knowledge protection often focus on the technical details of the current intellectual property law. But the intellectual property law is not specifically designed to address these issues. While traditional knowledge does not fall into the designed scope of protection areas, the rationale of intellectual property protection suggests that there is a need to protect the rights of derivative knowledge holder, and traditional knowledge holders have a stronger package of rights against the derivative knowledge holder, which is more than merely defensive rights.

Traditional Chinese medicine has been playing a vital role in the prosperity of Chinese people for thousands of years. It is part of Chinese people’s identity. As a kind of accumulative knowledge of practice, we still have very little understanding about traditional Chinese medicine. For better or worse, it is important to modernize traditional Chinese medicine so that it can be better integrated into the new framework of biomedical knowledge, as it may eventually prove to be part of the key to some of new cures of various diseases. Striking a delicate balance between protection and access of knowledge is essential for the prosperity of Chinese people in the next millennium and the welfare of all people around the world.

100 Government funding can be used for research, innovation and creation.