Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan

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Taiwan has aimed to develop a local Chinese herbal medicine (CHM) industry targeting the global market. The main patent issues concern whether the inventions constitute patentable subject matter, and their patentability. Currently, it is difficult for CHM inventions to comply with patent standards developed in conjunction with the Western pharmaceutical industry. Despite its increasing prominence, thus far, Taiwan is the only country in the world to address specifically the characteristics of herbal medicines. Based on examining currently available literature and conducting interviews with patent examiners and CHM professors in Taiwan, this article compares CHM with Western and indigenous medicines. This article assesses the inefficiencies of the current patent law and explains the necessity for the new examination guideline. It is concluded that this new examination guideline will meet the needs of the CHM industry.

Keywords Chinese herbal medicine; patent law; patent examination guideline; Taiwan

As a subset of traditional Chinese medicine (TCM), the practice of Chinese herbal medicine (CHM) has long flourished in East Asian countries like China, Korea, Japan and Taiwan before the advent of Western pharmaceuticals in the nineteenth century. Today, the practice of Western medicine has shifted from curative medicine to preventive medicine due to the rise of the aging population, especially in the developed world. Currently, over 130 countries in the world are using CHM; more than 120 countries have CHM research institutes studying the composition and effects of natural remedies (Chen). The popularity of CHM is due to the rise of many non-fatal chronic diseases among the elderly. It is vital to provide suitable drugs for the elderly, who require three to four times more medication than the younger generation. CHM appeals to the older people because TCM is renowned for maintaining the overall balance of the human body and increasing its natural defense against diseases.

Nowadays, CHM has gained much popularity in the West. A study carried out from 1990 to 1997 in the United States suggests a substantial increase in the number of people seeking alternative medicine and the total amount of out-of-pocket expenditure for alternative medicines is comparable to the total US physician services in 1997 (Eisenberg et al., 1998). Today, 21.5% of the population uses CHM and the usage is likely to rise, as Taiwan is rapidly transcending into an aging society. In order to combat aging, the Taiwanese people have spent a considerable amount of money in purchasing health food products/dietary supplements-NT $20 billion in 1998 alone. According to a survey conducted by the Taiwan Economic
Research Institute, the value of the Taiwan CHM market was estimated to be around NT$48.06 billion in 2005 (Department of Industrial Technology, 2006), and the value of the global herbal medicine market is predicted to reach US$40 billion in 2006 (Kaphle et al., 2006).

In 2000, the United States Food and Drug Administration (FDA) introduced a Draft Guidance for Industry Botanical Drug Products, which recognizes the possibility of botanicals to be marketed as prescription drugs in the United States (the draft is now Guidance for Industry Botanical Drug Products). The opening of the US market helped boost the growth of the biotechnology industry in Taiwan. As part of a national policy, starting from 2001, Taiwan aims to spend US$1.5 billion to build up the CHM industry over the course of five years (Information Center of Herbal Medicine Industry, DoIT, MoEA(a)). The research focus will be on asthma, anti-aging, liver-related diseases and immune-related diseases. According to Lin I-Hsin, chairman of the Committee on Chinese Medicine and Pharmacy at the Department of Health:

Taiwan has the potential to become the world’s largest supplier of herbal medicines in the future. Currently it ranks in the top three, alongside Japan and Germany for R&D, manufacturing and quality control of herbal medicines in compliance with the international Good Manufacturing Practice (GMP) standards (Chung, 2004).

For CHM industries to safeguard their intellectual creations, patent protection is the form of intellectual property that is heavily pursued by its major actors. However, the question is whether the current patent system meets the CHM industry needs. This article distinguishes CHM-related inventions from other forms of medical-based inventions. It assesses the opportunity for designing tailor-made patent regulations for CHM-related inventions, which should be different from the conventional patent regulations currently applied for the protection of Western medical inventions. It also examines the legal difficulties confronting pharmaceutical industries in obtaining patent protection for the products of CHM under the current system. The broader question examined in this article is whether the patent law currently implemented in Taiwan is adequate in protecting CHM-related inventions. If not, will the newly introduced Draft CHM Invention Patent Examination Guideline (Taiwan Intellectual Property Office (TIPO), 2002; the Draft) in 2002 correct its inadequacies? The outcome of our investigations should provide some suggestions about the possible implications of the Draft to the development of the CHM industry in Taiwan.

What is CHM?

CHM is a type of traditional medicine. The definition of what constitutes a “traditional medicine” is a topic of scholarly debate. This article adopts the definition of the World Health Organization (WHO), which defines traditional
medicine to be the sum total of all the knowledge and practices, whether explicable or not, used in the diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing (World Health Organization, 1978, p. 8). However, this definition does not imply that traditional medicine is static. With the help of modern technology, traditional medicine has proven to be an invaluable asset in modern drug discovery.

Chinese medicine can be classified according to different usages into three main categories: (1) Chinese traditional medicine; (2) Chinese national minorities’ medicine; and (3) herbal medicine. According to the Draft (p. 2), CHM consists of two types of medicines, including Chinese traditional medicine and herbal medicine. Chinese traditional medicine means that it has been codified down into the classic medical literatures (classics) and has been applied using TCM theories. The term involves the components of the Chinese medical system, such as the understanding of “Qi,” “Ying-Yang” and “Meridian”, prescription of herbal formulas, acupuncture and such. On the other hand, herbal medicines might or might not have been codified. Some are retained as secret family recipes and passed down through oral means. They might not have applied the theories of TCM but rather accumulated through trial-and-error experiences of herbal use (the Draft, p. 2). The Draft, however, does not cover Chinese national minorities’ medicine, which are used by doctors of different Chinese national minorities such as Mongolian or Tibetan medicine.

Before the advent of the Draft, there was no definition of CHM under the Taiwan Patent Law. The definition of pharmaceuticals parallels article 6 of the Taiwan Pharmaceutical Affair Act, where medicines or drugs are “... listed in the Taiwan Pharmacopoeia or in the Pharmacopoeia of other countries; used in diagnosing, curing, alleviating or preventing the diseases of human beings; and/or sufficient to affect the body structure and physiological functions of human beings ...”. Chinese medicine is defined separately in article 10 as “... preparations of inherited formulation prepared in accordance with traditional Chinese prescriptions, and have medical efficacy, as selected and published by the central competent health authority”. Under the FDA Guidance for Industry Botanical Drug Products, if a botanical product is for diagnosing, mitigating, treating, curing and preventing disease, then it is a drug under section 201(g)(1)(B) of 21 U.S.C.21 (ff). For the definition of herbal medicines, the FDA recognizes herbal medicines only as medicinal products containing active ingredients of exclusively plant material with not well-defined active ingredients.

**Differences between CHM and Indigenous Medicine**

In general, CHM is the oldest and most widely used traditional medicine today. It has several characteristics, which make it different from other indigenous remedies, folk medicines or shaman healings that dominate the current scholarly literatures.
on traditional medicine: “CHM has a complex and predominately rational theoretical basis; it is contained in a large collection of classics; the theoretical principles are related to the dominant cosmological concepts; a class of secular medical practitioners is guardians of this classic medicinal tradition, which divides CHM from folk medicine” (Croizer, 1970). Its long history has complicated the issue in identifying ownership, and unlike indigenous medicines that are limited within a certain geographical region, CHM spreads globally.

**Differences between CHM and Western Medicine**

CHM differs from Western medicine in its basic medical orientation, physiological theories, etiology, diagnostics, therapeutics and pharmacology (Fang, 2003). The major difference between CHM and Western medicine is their fundamental difference in medical theories. While Western medicine adopts the Cartesian reductionism approach separating the body and the mind, CHM is holistic. CHM is an art as well as a science. It exists not simply as medicine or therapy but also represents ancient Chinese philosophy, describing how humans interact with the natural world. CHM focuses on health maintenance and, in the treatment of diseases, emphasizes the enhancement of the body’s resistance to diseases (Lu et al., 2004).

Unlike Western medicines, which aim to identify a particular chemical, hormonal or biological imbalance and to treat the symptom with a counteracting medicine (normally a bioactive compound with well-defined disease target), CHM seeks to cure by reaching a point of equilibrium in the human body or the balance of *Ying* and *Yang*. CHM practitioners argued Western medicine focused on the *Ying* part of the body, i.e. the substance of the body cells and chemicals, whereas CHM works more on the *Yang* part, or the energy that animates those cells (Chan, 2000). Lastly, CHM is a form of personalized medicine that emphasizes the difference between individuals, which differs from the “one-size fits all” paradigm of Western medicine. This is the reason why many patients, who appear to have the same disease under Western medicine, would be treated differently by CHM. Because human bodies are different, and similar CHM formulas might be prescribed to patients with different diseases (Department of Kampo Medicine, Keio University), nowadays, Western practitioners have also recognized the idea of individuality where arguably the same drugs might have different effects on different individuals.

**Characteristics of CHM Medicine**

Unlike Western medicine, which is either a small molecule drug (chemical drug) or a large molecule drug (protein drug), CHM prescriptions are composed of natural products such as plants, animals or minerals in which 90% are plants. The ancient Chinese have identified and categorized the various properties of different plants. Therefore, traditional herbal formulas have different properties and effects, leading to different results in the body. According to Lee (2004), such properties include the
four essences (cold or cool drugs for Yang diseases, warm or hot drugs for Ying diseases), five flavors (pungent, sour, sweet, bitter and salty), four directions of action (ascending, floating, descending and sinking) and seven effects (single, additive, synergic, antagonistic, inhibitive, destructive and opposite). The active ingredients are often unidentifiable and the isolation or extraction of the one single active ingredient is difficult.

Contrary to the popular belief that CHM are medicines solely for chronic or minor diseases, CHM actually has two types of prescription drugs. One type is the single application of one kind of herb (Dan Xing) and this type is often used for acute diseases. The other type is the combination and matching of more than two herbs compatibly and purposely according to specific diseases and conditions (Fu Fang); through their combination, they are suitable for complicated diseases or chronic diseases. In CHM, Fu Fang is considered more useful than Dan Xing; however, the interactions between different herbs are currently yet to be understood under Western science, and, hence, new drug discovery in Taiwan focuses mainly on Dan Xing.

Thus, many different herbs with different pharmacological actions are typical in CHM. The use of several types of plants is not common in Western herbal medicines. As mentioned earlier, CHM is a form of individualized medicine. When a patient goes to a Chinese doctor, the doctor first identifies the “Zeng”, using observation, listening, questioning and palpation according to TCM theory. The “Zeng” is the clinical data of the patient. After the “Zeng” is identified, the doctor will prescribe the proper treatment. The prescription of herbal formulas uses TCM theory to balance the different effects of the plants, eliminate toxicity and enhance efficacy. This is the process by which herbal formulas can achieve their effects as recorded in the classics; the pharmacological effects and the harmless combination of herbs are through the correct application of the TCM theory, not because natural products are indeed safe and non-toxic.

Manufacturing of CHM Medicine

The manufacturing of CHM products is largely different from Western drugs. Currently, Taiwan focuses its R&D in the area of extraction and concentration. The first step in CHM drug manufacture is to select the appropriate herb, which is then cleansed and rinsed. Afterwards, the clean raw materials will be softened and cut into standardized thin pieces. The raw materials will be processed and treated according to their various characteristics (this is to detoxify the plants). After that, the raw materials will be set and weighed according to their weight ratio adopted from ancient prescription. The processes that follow are extracting, filtering and concentration to stabilize the herbal extract. In the last stages, the extract will be granulated and sifted to be packaged into a final product. The final product is often referred to as scientific Chinese medicine. The major obstacle for Taiwan to focus on in this field, instead of the Western single compound, is that most Taiwanese
pharmaceutical firms are small- and medium-size enterprises. The high risk and financial burden involved makes it difficult to conduct the screening processes and go through all the stages of clinical trials. A second reason is that the pure compound might lose its original characteristics and thus face tougher toxicity tests. Nevertheless, with government support, this is becoming an area of interest for the CHM industry.

Rationale for the Draft

Owing to the differences mentioned above, before the advent of the Draft, newly established biotechnology companies filed most CHM patent applications, while the majority of traditional herbal manufacturers sought protection under trade secrets, which prohibits continuous innovation in CHM. In the past, the CHM industry manufactured solely on extraction and concentration of CHM drugs; however, this is a low entry-barrier and low profit-margin market, and, hence, the ultimate goal for CHM industry building is new drug development with products able to receive patent protection. The significance of using CHM knowledge in new drug development is to integrate the TCM theory; hence, CHM inventions might not meet the current chemical drug patent standard.

The advent of the Draft has differentiated Taiwan from Germany and Japan. In Germany, herbal medicines or phytomedicines are seen as preparations exclusively derived from plant material either from a plant or from its extracts for healing purposes with no theories involved in their preparation. TCM or Kampo has been practiced in Japan since the fifth century (Department of Kampo Medicine, Keio University). As one of the first countries in the world to make it scientific, Japan has abolished all the TCM medical theories but retained just the herbal knowledge. Nowadays, more than 70% of the doctors in Japan who were trained under the Western medical system prescribe Kampo extraction (Department of Kampo Medicine, Keio University). Kampo extractions in Japan were studied scientifically for their single compound as well as for the safety and efficacy of its formulas (Department of Kampo Medicine, Keio University).

For Germany and Japan, the issue of theory is trivial. Herbal products are reimbursed by their national health insurance systems. Although in the past they were not able to market herbal products as prescription drugs, both countries still held large shares of the global herbal market. Their success model indicates the acceptance of Western drug-like herbal medicines in the main pharmaceutical markets today. Besides following the German/Japanese model, Taiwan has decided to integrate TCM theories into drug discovery.

According to an interview with the CEO of Hedonist Biochemical Technologies Co. in Taiwan, the process of patent application motivates the issue of turning CHM inventions into Western medicines. Hedonist was one of the local companies in Taiwan to have their drug passed by the FDA. The drug development process at Hedonist was to utilize TCM theory in finding a formula; then, the company used
the platform it developed to turn the CHM ingredients into Western medicine ingredients (e.g. substituting CHM ingredients A, B and C with known Western generic ingredients A1, B1 and C1 that have similar medicinal effects). Because those Western ingredients are common in the Western drug market, drugs developed by Hedonist are more likely to gain acceptance in the Western market and it would be easier to file a patent for the chemical structures. Unlike the conventional drug-developing process of “target to drug to phenotype”, the drug-development process adopted by Hedonist provided a similar effect as the new found “drug discovery in reverse” in Western medicine. This process enables the company to attain higher efficiency and to improve their understanding of the safety of new compounds before pre-clinical development. The success of companies like Hedonist signals the significance of TCM theories in future drug development and the need for a patent examination that could meet the need for inventions utilizing the theories.

**Patenting CHM Inventions**

According to Koon (1999), there are several possible types of end products deriving from traditional medicine including traditional knowledge, methods of treatments, products and processes. The first two are, however, not inventions under the current Taiwan Patent Law. In Taiwan, invention refers to the creation of technical concepts by utilizing the rule of nature; therefore, it needs to have some degree of technical character. Despite the controversies of patenting traditional medicines, the patenting of products and processes of CHM inventions is not a novel idea. Before the advent of the Draft, patents related to CHM inventions have been issued by TIPO. There are three types of patents in Taiwan: invention, utility model and design. In this article, patents refer only to invention.

Nowadays, there are 21,388 CHM-related patents under the international classification of A61K35/78 in the TIPO CHM patent database, which includes both device and method. Before the advent of the Draft, there was no difference in patent examination between CHM and Western pharmaceuticals. Among the high number of patents already granted to CHM-related inventions, methods are the majority. From 1979 to 2002, among the 35 CHM patents granted, only 15 were for devices and there were no patents granted for devices before 1990 (Taiwanese National Federation of Industries Patent Database). It is not surprising to see the reason why so few patents are granted for devices. Four types of device can be subject to CHM patent applications in Taiwan:

1. crude medicinal material (e.g. Ginseng); currently, very few have been granted a patent as they are considered as mere discovery;
2. combination of different crude materials; patents of this kind are granted mainly for dietary supplements, and few had been granted to medicines;
3. extracts and their combinations; patent application for this type is the highest for device;
pure chemical compounds from plants (traditionally this has been the way of discovery for Western drugs; major obstacles include finding the compound that is bioactive from a pool of compounds inherent in a plant and patent applicants have to avoid the product-of-nature doctrine).

Under the Western pharmaceutical industry paradigm, the first aspect of drug discovery is the shaping of the compound, and the core of the compound is a chemical believed to have a profile of biological activities for clinical use (Hara, 2003, p. 170). The categorization of CHM products presented above suggests that the crude materials for CHM inventions are plants that contain tens or even hundreds of compounds that have potential therapeutic value. Therefore, countries such as Japan and Germany, with a long-established herbal medicine industry, have aimed largely at the extraction of essences from the plants. However, CHM offers several leads in drug discovery (Information Center of the Herbal Medicine Industry, DoIT, MoEA(b)):

1. Traditional formulas: formulas that have appeared in the traditional text or concentrated products made from those texts (might have lost its novelty so innovation includes the changes in delivery model and finding new uses).
2. Non-traditional formulas: formulas that have not appeared in traditional text (they might be long existing family secret recipes that might not have lost their novelty as long as the secret has not been disclosed to the public).
3. Botanically derived drugs or herbal extracts (including mixed or pure compounds; they could be derived from plants in traditional or non-traditional formulas).

As mentioned earlier, CHM new drug discovery is the ultimate goal and it follows the Western drug discovery mode of finding the lead compound, going through investigational new drug (IND), clinical trials and new drug approval (NDA). The only difference with the Western drug seems to be that the raw materials are from plants; however, it is not entirely accurate because the Western pharmaceutical industry has long used natural products for drug discovery. One plant species often contains 1,000 unique chemical entities and they provide chemists with chemical structures not plausible in synthesis in the laboratory. A survey has shown that 60% of the anti-cancer drugs and 75% of the anti-infectious drugs approved from 1981 to 2002 are of natural origin and 61% of all new chemical entities discovered in that period were inspired by natural products (Gupta et al., 2005).

However, a product-of-nature barrier (a thing occurring in nature that is substantially unaltered) prohibits patenting of those inventions. Pharmaceutical companies have come up with ways to bypass this restriction, one being the synthesis method and the other through structure modification. In both methods, either a plant is discovered using pharmacological values or using ethnomedicinal knowledge. In the synthesis method, the company duplicates the chemical structure,
and a synthesis version of the natural compound is made. However, it is unpatentable if the invention differs from the natural product only if synthesized.\textsuperscript{20} The common practice in the United States is to isolate and purify (the technical character that transforms a discovery to an invention), driving the invention away from the natural to differ not only in “degree but in kind”\textsuperscript{21}. This position is also supported by the European Union (EU) Directive 98/44/EC on the Legal Protection of Biotechnological Invention. It is explained in the Dutch case, \textit{BASF AG v Bureau voor de Industriële Eigendom},\textsuperscript{22} that the nature of the product cannot be changed solely because of an alteration in the impurities. The chemical compound it contains and the compounds active on its target will remain unchanged. Furthermore, an invention might be patentable if the invention can demonstrate “unexpected properties”\textsuperscript{23}. This is one feasible step but because it is difficult to obtain patents on synthetic versions of naturally occurring pharmaceuticals, pharmaceutical companies favored the other approach, which is to change the structure of the compound from the natural version, but preserve the pharmacological value.

Currently, the dominant Western drug discovery process from natural products has four goals (Fabricant and Fansworth, 2001): (1) to isolate bioactive compounds for direct use as drugs; (2) to produce bioactive compounds of novel or known structures as lead compounds for semi-synthesis to produce patentable entities of higher activity and/or lower toxicity; (3) to use agents as pharmacologic tools; and (4) to use the whole plant or part of it as a herbal remedy. The development of the CHM industry follows similar steps: the role of CHM knowledge is to identify the effects and characteristics of different types of plants and the most valuable aspect is in revealing the toxicity of the plants. In other words, CHM knowledge provides a rational lead to the correct collection and understanding of the effects of different plants. CHM knowledge also reveals the toxicity level in a plant, helping to solve the major obstacle in new drug discovery.\textsuperscript{24}

However, if the CHM invention is not a pure compound, then there are some complexities in filing a patent application for CHM inventions. The first problem is the difference in the names used in the classics. Many plants have been named differently in different sources, therefore lacking uniformity. For example, \textit{Smal lanthus sonchifloius} in the folk medicine and \textit{Saussyrea lanicep Hand-Mazz} in the classics are two different types of plants with very different pharmacological uses but their name is similar in the Chinese language (the Draft). The second problem relates to the crude materials and the difficulties in allocating the effective active ingredients,\textsuperscript{25} for example the famous St John’s Wort preparation contained a complex balance of more than two dozen bioactive compounds. These difficulties have been acknowledged in the EU and the FDA food and drug regulations but not yet in the patent laws. The third problem is that unlike chemical compounds, which could be identically reproduced, plants are living organisms that vary in characteristics even within the same varieties of plants. The fourth problem is that impure substances are abundant in plants. Lastly, it is difficult to prove the pharmacological efficacy of CHM. The Draft was introduced to tackle the above-mentioned problems.
Patentability of CHM Inventions under the Taiwan Patent Law

Judging from the above section, it is obvious that patent law practice has influenced drug discovery using natural products in Western medicine. However, it will be detrimental to public health if the only method of obtaining patent protection is to follow the methods mentioned above. The question should be asked: will the other uses of plants such as combination of different plants be able to provide cures to diseases unmet by Western drugs? If so, is it equitable that despite the high expenses and efforts contributed, the invention is unable to obtain a patent? This is a major setback for the development of the CHM industry; nevertheless, several options are available for a government to tackle this obstacle. The government could create a sui generis system; make amendments to the patent law; draft special legislation;\(^{26}\) or direct CHM inventions to meet basic patentability criteria (e.g. more process-related inventions than products).

Since the Taiwan Government adopted the approach to protect CHM inventions through patent, a patent examination guideline amenable to CHM inventions has been drafted.\(^{27}\) Currently, no country that protects herbal medicines through patent provides any special treatment to herbal medicines. Herbal medicines are subject to the same requirements as chemical drugs. To this end, Western herbal medicines are largely identical to conventional chemical synthesis drugs. Could this happen to CHM development in Taiwan? To answer this, it is essential to examine each element of the patent law.

Patentable Subject Matter

Taiwan extended its product patent protection to pharmaceuticals in 1986, and the pharmaceutical invention patent includes three types: product invention, method invention and use invention.\(^{28}\) One can file a patent application for new chemical compounds, new use for pharmaceutical compound, new use for pharmaceutical composition, new delivery model, CHM extracts, methods of preparation and extraction, CHM-contained foods and cosmetics, to name a few (the Draft, p. 11). In general, the subject matter has to be an “invention”\(^{29}\) and not every invention is patentable. Under the Draft, “CHM invention” means the technical involvement of a natural product of plants, animals, minerals, algae and fungus; the extraction of the aforementioned natural products or their combination; or highly purified or chemically modified substance from the above-mentioned natural products. CHM-related inventions are patentable only if they are not considered as unpatentable subject matters as set out in the Taiwan Patent Law, article 24,\(^{30}\) which is modeled on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), article 27.3.\(^{31}\) Nonetheless, TRIPS provides the minimum standard, which member countries can adjust in order to meet their policy needs. Therefore, recent amendments in the Taiwan Patent Law include the inclusion of animals and plants as patentable subject matters.
Patentability Requirements

In the current patent system, an invention has to satisfy the examiner in many aspects including its novelty, inventive step, industrial applicability and enablement. According to TIPO Guidelines for Patent Examination (the Guidelines), an invention refers to any creation of technical concepts by utilizing the rules of nature. According to the Guidelines, inventions that are mere discovery, against the rule of nature, not using the rule of nature, or non-technical in character are not considered as inventions.

Novelty

An invention has to pass the novelty test before proceeding to the others, as failure to satisfy the novelty requirement will render the invention non-patentable (the Draft). Novelty has barred many CHM products from patentability because they are based on traditional formulas, have the same medicinal use and are already available to the public. In Japan, claims lack novelty when the claimed medical uses can be deduced from prior art based on a common mode of action. Claims may lack novelty when the claimed medical uses can be ascribed to pharmacological effects closely related to those in prior art. Thus, any new drug claiming the same medicinal use, and where such use can be easily deduced from drugs that are publicly known or recorded in the database, will be deemed as non-novel.

TIPO adopts the standard of absolute novelty; it means the inventions have to be new and nothing similar has appeared before the date of filing. As long as it is available to the public, the information therein will be seen as “prior art”. According to the Guidelines, publication means open distribution, so it includes any form of distribution and in any language. This holds true as in the US case, Milton Hodosh v Block Drug Co., where the parties argued over the credibility of the prior arts already disclosed. Similar positions can be found in the UK case, Merrell Dow v Norton, where Lord Hoffmann gave the example of Amazonian Indians using cinchona bark to treat malaria for centuries even though quinine was only isolated from the bark in 1820. Lord Hoffmann stated that it was not necessary for an active substance to be identifiable or reproducible for it to have been made available to the public, even if the active substances were not disclosed. Novelty in patent law reflects the basic principle in property law that ownership of a “thing” is acquired by being the first in time to possess it. In order to transform something belonging to nature or the public domain, the discoverer has to transform the discovery into an invention to demonstrate the possession. In the US case, Merck & Co. v Olin Mathieson, the scientists satisfied this requirement by removing the B vitamin from its natural environment, putting it into a form that was not previously known—isolated or substantially pure.

In order to assist examiners to search for “prior art” in relation to CHM, TIPO has established a database of classics and traditional formulas that are in the public domain. Currently, there are more than 400 CHM classics, a total of 21,388 CHM...
patents filed by both nationals and foreigners in the countries listed (Japan 7,973; United States 3,574; China 5,902; Europe 1,419; United Kingdom 152; Patent Cooperation Treaty 1,252; Germany 1,058; Taiwan 58) and 11,504 kinds of indigenous Taiwanese plants documented in the TIPO CHM Patent Database. The establishment of the patent database also enables industries to avoid duplications in R&D as evident in China, where as high as 90% of the CHM research efforts in 1994 were duplicated.

Inventive Step/Non-Obviousness

A patent examiner who acts as a theoretical person having ordinary skill in the arts (PHOSITA) determines the inventive step or non-obviousness. In Taiwan, failure to satisfy the non-obviousness requirement bars the patentability of the invention.\(^{42}\) The prior art cited shall be taken in consideration collectively\(^ {43}\) and the invention will be compared with the prior arts in structure, alleged objectives, function, integrated structure and manufacturer method.\(^ {44}\) Theoretically, this will presume that most inventions based on the traditional formulas will be deemed as obvious.

CHM inventions often use products of nature as the starting material. Besides chemical modification, if isolated and purified compounds can prove unexpected results, then it defines the inventiveness in the claimed invention (Crespi, 1991). A similar position is adopted in Japan. The Japanese Examination Guidelines for Pharmaceutical Inventions also state that an invention may not involve an inventive step if the medical uses of the invention and the prior art can be correlated with each other in view of the mechanism of the biological effect. However, if unexpected advantageous effects can be recognized, the claims may involve an inventive step. This also applies to a new combination of known drugs and optimizes the dosing schedule/dosage amount to reduce toxicity and improve efficacy.

Although the product of nature doctrine was well established in the US case \textit{Ex p Latimer},\(^ {45}\) let us not forget that one of the functions of patent law is to encourage industry development. If the product-of-nature doctrine is strictly applied, then both the pharmaceutical and biotechnology industry will face a major setback as it is clearly stated in \textit{Merck v Olin Mathieson},\(^ {46}\) “That all of the tangible things which man deals and for which patent protection is granted are products of nature, in the sense that nature provides the basic source materials”. This slippery-slope theory implies that in an all-or-none situation, granting property rights to potential product-of-nature inventions averts this principle by “structure modification”, “unexpected properties” and/or “isolation and purification”.

According to the Guidelines, the prior art and the invention should belong to the identical or relevant technical field with similar technical problems and have similar technical characteristics. If they belong to different or non-relevant technical fields, the prior art will be deemed as relevant when they share the same technical characteristics.\(^ {47}\) Before the amendments to the Guidelines in 2004, an invention
satisfied the inventive step if it showed “outstanding technical features” or “obvious progress”. Otherwise, secondary considerations are also available such as solving long-existing technical problems and success in the relevant market or inventions showing unexpected character.

**Industrial Applicability**

The invention must also have industrial applicability to be patentable; yet, this requirement has a low threshold in Taiwan. The rationale for this is that if the industrial applicability is lacking, it might not meet market demand; thus, it is unlikely that the patent holder can exercise his monopoly right to hurt the public interest. This might not be a problem in the mechanical or electrical engineering field, but CHM inventions, unlike Western pharmaceuticals, are not all based on a single chemical or protein. Rather, the raw materials are mostly plants. This might not be a problem if the invention is a purified compound derived from plant sources. However, if the invention is an extraction, then the active ingredients might be difficult to identify and the compounds will be impure. Furthermore, as the raw materials are plants, their therapeutic value varies according to the place where they were grown, the season they were harvested, the processing methods, hence creating more unpredictable variables than the Western pharmaceuticals (the CMC problem: chemistry, manufacturing, control) and thus might not be identically reproducible or industrially mass producible.

**Enablement Requirement**

According to Taiwan Patent Law, article 25(1), a patent applicant should disclose the invention accurately and adequately to enable the PHOSITA to understand and apply the content of the invention. If the invention is a pharmaceutical, the applicant should provide the evidence that this invention has the claimed pharmacological effect. This includes providing the in vivo or in vitro test results, but no human clinical trial data are needed. In the US case *In re Brana*, the Federal Circuit stated that proof of an alleged pharmaceutical property for a compound by a statistically significant test with standard experimental animals is sufficient to establish efficacy and that FDA approval is not a prerequisite to find a compound useful. In the Japanese Examination Guidelines for Pharmaceutical Inventions, pharmaceutical test data or equivalent should be disclosed in the specification and the Japan Patent Office does not accept only in vitro test results. According to the Guidelines, requirements for pharmacological efficacy should include: (1) if the pharmaceutical is a novel substance, the method and result of the pharmacological test should be recorded; (2) if the invention is an alteration or a combination of known substances, then the literature of the known substances and bioactive data should be cited and the pharmacological test results in proving the superior pharmacological effects over the old substance should be provided.
The Draft CHM Invention Patent Examination Guideline

The Draft addresses some of the following critical issues:

1. The Draft urges for uniformity in the naming of the same plants, as they might be named differently in different classics. When the plants are known to the PHOSITA, then the name in taxonomy should be given. If a generic name is given, then it should refer only to those mentioned in the classics. If not, the name should be given. Lastly, if the plant is a new variety, then the taxonomical name may be omitted (the Draft, pp. 28–29). The *Taiwan Traditional Materia Medica* (Department of Health, Taiwan, 2004) was also introduced in May 2004, serving to standardize this problem in inconsistency.

2. The Draft also clarifies the difference in plants according to the environment where they were grown and harvested. The Draft suggested that if the plant is known to the PHOSITA, then the need to specify the place and season is omitted. However, if different parts of the same plant have different therapeutic characteristics and might affect the use this should be indicated in the specification (the Draft, p. 29).

3. CHM product patent has been categorized into four types:
   - **CHM Combination Preparations**: unlike Western pharmaceutical products where a combination means a mixture of known compounds, in CHM it means the mixture of plants or parts of plants. Because it is often difficult to identify the active ingredients, it is essential to identify the plants used. If the therapeutic value claimed for a plant part is different from the traditional use, the parts have to be labeled. If the invention focuses on the percentage of different combinations or ingredients, it should be clearly disclosed and an example should be given. Furthermore, if the product could not be characterized on the basis of chemical composition, another option is to define it through the product-by-process method. However, the invention claimed for the purpose of patent protection will cover only the product but not the process itself.
   - **CHM Extracts**: the invention based on extracting and purifying plant parts. Plant extracts means to locate the main active ingredients (the essence) but not the single active ingredient. To disclose the invention, at least one chemical, physical or bioactive characteristic should be given (the Draft, p. 30). Similar to the CHM combination preparation, if the extractions cannot be identifiable through chemical names and structures, the option is to define them through the product-by-process method. To determine the novelty of the extracts, the inventor is expected to prove the difference between the extract and the prior art by using chromatographic fingerprints (the Draft, p. 77).
   - **CHM Active Compound**: the claimed invention is extracted from the plants but has been highly purified. This type of invention will be examined according to the Western pharmaceutical compound standard.
• **CHM Delivery Systems**: the claimed patent will include the type of delivery system (dosage forms, dosage schedule or dosage amount) chosen. The proportion of CHM ingredients used should be disclosed in the specification.

• What is more groundbreaking is the fact that TCM theories specifically associated to drug efficacy are mentioned (the Draft, pp. 32–39). As disclosed earlier, for the purpose of a patent application, after a specific compound in Western medicine has been identified to have an effect on a designated target, the inventor must show that this compound works by describing in detail the pharmacological effect, effective doses, method of administration, conditions for preparation and must undertake the necessary toxicity tests of the invention. Therefore, the Draft suggests that when the medicine is for the treatment of “Zeng”, in the specification, the inventor should disclose the raw materials, the TCM theory applied and proof of efficacy. The long history of CHM has also complicated the names of “Zeng” as they were often used differently in different dynasties. The abstract “Zeng” should be described concretely and should provide statistics about the therapeutic efficacy (the Draft, p. 32). If the medicine is for the treatment of a Western disease, then the inventor should disclose the relationship between the “Zeng” and the Western disease, the application of TCM theory and evidences of efficacy. The medicine will be studied under the Western pharmacology if the medicine is for use to cure a Western disease.

(4) The Draft mentioned in particular extracts that come from medicinal plants treating a “Zeng” as codified in the traditional formulas; extracts from part of the plant might not have the same medicinal value as the plant itself. Therefore, PHOSITA might not be able to relate its TCM knowledge from traditional formulas to the CHM extracts. To solve this problem, the inventor should disclose the efficacy of the extracts or cite references proving its efficacy in the specifications; this applies to extracts coming from non-traditional formulas. If the invention is directed to a Western disease, even if the traditional formula is useful in the treatment of the disease, it might not be the same for the extract; therefore, pharmacological test data will be needed to support the claim (the Draft, pp. 44–46). The Draft has broadened the patentable subject matter, although Western standards are still required in defining efficacy due to the technical difficulties related to the sole use of TCM theories to prove drug efficacy. However, without precedents to evaluate the validity of the Draft evaluating whether the application of CHM theory could actually satisfy the TIPO or the court statistically is an issue of further study.

**Conclusion**

The article points out that, unlike Germany and Japan, the development of the CHM industry in Taiwan has multiple approaches and the patent law that has
evolved with the recent development of Western pharmaceuticals is not amenable to the development of CHM inventions. The advent of the Draft has brought the CHM industry’s role in solving patentability problems and establishing workable examination standards to light. Based on the current chemo-pharmaceutical patent standard, the Draft expands the possibility of protection to CHM inventions, such as the use of product-by-process, and surpasses many former patenting obstacles. The Draft also offers more options of protection to CHM product inventors and its effect on the CHM industry will be an indicator for the world to assess its effectiveness. However, as most of the raw materials are imported, whether or not to include the disclosure of origin and benefit sharing, as indicated in the Convention on Biological Diversity, into the Draft has been an ongoing debate. While some favor alignment with the international trend, others oppose the idea, fearing that the inclusion will cause significant burdens to the infant CHM industry, the main reason why the Draft is not yet in force. Nonetheless, the Draft sets a milestone and a sign of determination on the part of TIPO in setting the standard of this field.

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Notes

I would like to thank Marcelin Tonye Mahop, Angela Adrian and Buddy I.-C. Hsiao for their comments on an earlier draft of this article. All errors and omissions are those of the author.

1 In Korea, CHM is known as Han Ya.
2 In Japan, CHM is known as Kampo.
3 When over 7% of a country’s population is aged 65 and older, that country is considered an aging society. In 2005, the aged group accounted for 9.56% of the entire population or around 2.16 million people in Taiwan.
4 The earliest archeological evidences of CHM practice in China were discovered in a burial site in Hunan province, which dated back to 168 BC where 11 medical works dating back to 3 BC were found. Famous classics include the Yellow Emperor’s Classic of Medicine (Huang- Di Nei Jing) written in the second century BC and the Treatise on Febrile Diseases (Shang Han Lung) written in the third century AD. The earliest material medica was written in the first century AD by an unknown author. Sheng Nong’s Herbal (Sheng Nong Ben Cao Jing) written by Li Shi-Zen during the Ming Dynasty (1368–1644), in which 1,892 drugs were listed, was the most well known.
5 The use of the word “traditional” does not imply the venerable character of CHM but rather means that this knowledge is inherited, established and territorial and is the foundation basis of civilization, is distinct and recognizable.
Greek physician Galen has proposed a similar idea, where sickness was caused by the imbalance of four humors: blood, lymph, black bile and yellow bile. Treatment consisted of rebalancing humors by prescribing opposite therapy (Knoll, 2004).


C. S. (2004): The idea of reverse drug development, chemogenomics or chemical genomics starts with a known drug that causes an interesting disease-relevant phenotype \textit{in vitro} or \textit{in vivo}, and then identifies the cellular target(s) for that drug.

Koon (1999, p. 161): “Traditional knowledge: Includes traditional beliefs, experiences and observations about the knowledge of medicinal plants; Methods of treatments: The diagnosis, medicinal and non-medicinal therapies; Product or process: This included plant, animal or mineral products and their preparation methods”.

See Taiwan Patent Law, article 24.

Ibid., article 21.

See TIPO Guidelines of Patent Examination.

See Taiwan Patent Law, article 2. According to the Guidelines of Patent Examination the various patents are as follows: design patent is granted to the creator of a design; utility model patent is awarded for a creation of modification to the shape, structure or device of an object—shape: the two- or three-dimensional structure/appearance of an object which may be defined by lines and planes and that is functional; structure: the internal or integral structures of an object; this does not include the chemical structures of pharmaceuticals; device: the purposeful combination of a plurality of independent objects; it should not be a simple collection of objects.

For example, Taiwan patent number 243681, the purifying process of active ingredient ginsenoside Rh2; Taiwan patent number 246923, the process of extracting anti-bacterial devices from leeks.

See the website available at [http://www.patent.org.tw/] (Mandarin only).

However, unlike Germany, CHM has a long history of usage in Japan; the Japanese government allowed the use of traditional formulas as medicines indicated in the classics.

If the secret recipe is in public use but the composition of the formula is not available to the public, the formula has not lost its novelty under the Draft. See the Draft, p. 72.

Cochrane v Badische Anilin & Soda Fabrik 111 US 293, 311–12 (1884).

In re Merz 97 F.2d 599, 601 (CCPA1938).


In re Merz, 97 F.2d 599, 601 (CCPA1938).

Personal conversation with Prof. Dr Wu from the Institute of Biomedicine at National Yang Ming University, Taipei, Taiwan, 31 August 2006.

See Taiwan Administrative Supreme Court decision No. 83 Pan Tzu 523.

For example the adoption of a Plant-Derived Drug Act as proposed by Hanellin (1991).

Personal interview with Mr Chang, TIPO patent examiner on 10 August 2006.

See supra n. 12.
In the United States 35 U.S.C. §101 (1991), “whoever invents or discovers any new and useful art, machine, manufacture or composition of matter or any new and useful improvement . . .”. However, there is no definition of invention under the United Kingdom Patent Act 1977 as well as under the European Patent Convention.

The following items shall not be granted an invention patent: animals, plants and essentially biological processes for production of animals or plants, except the processes for producing micro-organisms; diagnostic, therapeutic methods or surgical operation methods for the treatment of humans or animals; an invention that is contrary to public order, morality or health.

Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed 4 years after the date of entry into force of the WTO agreement.

Failed to enable could lead to loss of patentability; see Taiwan Administrative Supreme Court decisions, 89 Pan Tzu 1480, No. 75 Pan Tzu 2055, No. 86 Pan Tzu 3262. See also TRIPS, article 29(1).

According to the Guidelines, inventions can be divided into several categories: Pioneer Inventions—an invention that has never existed in the prior art; Transplanted Inventions—known art or knowledge in one technical field being transplanted into another field resulting in an outstanding feature or obvious progress or solving problems in other fields; New Use of a Known Article—Patentable if not obvious to those skilled in the arts; Change of Elements—inventions where some elements are changed; Combination of Invention—mere combination of prior arts is not patentable but is if outstanding technical features or obvious progress are found; Selective Invention—invention disclosing smaller area purposely selected from the larger prior art area, especially in chemical and material inventions.

According to Taiwan Patent Law, article 22, an invention will lose its novelty if the following occurs: before applying for a patent, the patent has been published or put to public use; before applying for a patent, the invention has become known to the public. Where an invention is under either of the circumstances set forth in the preceding paragraph due to any of the following causes, and a patent application has been filed within 6 months from the date of occurrence of fact of the foregoing causes, such an invention shall be free from the restrictive conditions set forth in the preceding paragraph; where the invention is created as a result of research or experiment; where the invention has been exhibited at an exhibition sponsored or approved by the government; or where the invention has been disclosed in an occasion not intended by the patent applicant. An applicant claiming the application of the cause set forth in item 1 or item 2 of the preceding paragraph shall indicate the facts and the relevant dates in his/her application and submit evidential documents within the time limit specified by the Patent Authority. Notwithstanding the absence of the conditions set forth in
paragraph 1 of this article, if the proposed invention can be easily accomplished by a person having ordinary knowledge in the art based on prior art before the application for patent is filed, no invention patent should be granted for such an invention under this act.

38 See Taiwan Patent Law, article 22(1).

39 Milton Hodosh and Richardson-Vicks Inc. v Block Drug Company Inc. et al. 786 F.2d1136, 229 USPQ 182 (1986).

40 Merrell Dow Pharmaceuticals v Norton & Co. [1996] RPC 76.

41 Merck & Co. v Olin Mathieson Chemical Company 253 F.2d 156 (4th circuit, 1958)

42 PHOSITA will be a major obstacle in reviewing patent applications where most examiners are not acquainted with the CHM theory. In Taiwan, professors of CHM-related studies have been asked to give support to the examiners. In the European Patent Office, the standard is whether the invention is obvious to try. In the United States, the standard is even lower: even if obvious to try, the Patent and Trademark Office has to consider whether there is reasonable expectation of success, by trying all parameters of each possible choice with due experimentation and there is no indication in the prior art leading to a successful result, and, lastly, whether the prior art merely suggests the exploration of a promising field of experimentation and gives only general guidance as to the particular form of the claimed invention or how to achieve it.

43 See Taiwan Administrative Supreme Court Decision No. 88 Pan Tzu 3417.

44 See Taiwan Administrative Supreme Court Decision No. 88 Pan Tzu 3507.

45 Ex P Latimer [1889] Comm’r Dec 123.

46 See supra n. 39.

47 See supra n. 14.

48 Outstanding technical features mean the invention cannot be easily deduced from original analysis or experiments for those skilled in the arts. Obvious progress means that difficulties in the prior art are solved with outstanding effect.

49 See Taiwan Administrative Supreme Court Decision No. 91 Pan Tzu 2421. Non-industrial applicable inventions are inventions that are not completed, not able to be used in business or non-applicable.

50 See Taiwan Administrative Supreme Court Decisions No. 82 Pan Tzu 2252, No. 83 Pan Tzu 523 and No. 85 Pan Tzu 2751, where the applicant was denied a patent due to lack of sufficient evidence in proving the pharmacological efficacy. In No. 71 Pan Tzu 697, a combination of chemical compounds does not have industrial applicability if it cannot prove the therapeutic value through animal test or pre-clinical trial test results.

51 In re Brana 51 F.3d 1560 (Fed. circuit, 1995).

52 Tokyo IP High Court Decision (Case No.: Hei-8 (Gyou-ke) 201).

53 The name Chinese Traditional Materia Medica was changed to Taiwan Traditional Materia Medica on 31 August 2005 by order of the Department of Health.

54 Failure to disclose the plants used might be seen as lack of technical character. See the Draft, p. 13.

55 There are currently three types of delivery model for CHM: traditional (in the form of soup, powder or capsule), scientific (concentrated capsule) and Western pharmaceutical style.
According to the Taiwan Medical Product Patent Examination Guideline 1991, a patent applicant does not have to provide information on toxicity unless it is obvious. According to the Draft, toxicity in CHM might be beneficial if proper use of the theory is applied; an applicant will only be asked for toxicity if the PHOSITA has any reasonable doubt. See the Draft, p. 50.

See Taiwan Administrative Supreme Court decision No. 86 Pan Tzu 1244: a CHM product for the cure of diabetes, which contained more than nine different kinds of plants, was refused a patent due to lack of industrial applicability. The court concurred with the TIPO that the data-proving efficacy was not conducted under a Western statistical standard to allow a PHOSITA to repeat the invention.

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