論專利法和傳統中藥之間的兼容性

——以在专利申请中产品界定为例

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I 引言

在 WHO 报告中，传统中药（Traditional Chinese Medicine）被视为四个主要传统医学系统之一，即传统中药、印度阿育吠陀和阿拉伯尤那尼医学以及各种形式的土著医学。这些不同形式的传统医学具有一些共同的哲学和自然特征。传统中药所代表的医学实践以中国传统哲学为基础，该哲学含有一些概念比如“气”、“阴阳”、“五行”和“辩证论治”，并且其药品一般采用动物、矿物和植物来制备 。传统中药的理论基础和物理特性使其区别于西医。

随着传统中药越来越受欢迎，过去十年间专利法和传统中药之间的关系因世界范围内传统中药产品被频繁授予专利而备受瞩目。大多数国家根据与化学品和药物制剂相同的审查指南来审查传统中药发明。然而，由于传统中药在物理特征和医学理论方面的特殊性，其常常难以符合专为西医化学品和药物制剂设计的专利法的现行框架。专利法和传统中药发明之间兼容性的基本问题由此产生。实践中，当将专利调查指导原则应用于传统中药时，各个国家针对各种传统中药产品专利性问题采取不同的态度。一般来说，西方国家比如美国和欧盟国家的审查比亚洲地区比如中国大陆和台湾更加严格。考虑到传统中药的特别特征及其快速发展，台湾知识产权局在其指导原则中引入了关于传统中药发明调查的特别的一章，该章是世界上唯一为传统中药专利调查而定制的审查原则。

专利法要求在专利申请书中清楚定义一个发明，从而专利权的边界得以确定，相关技术人员也可以由此而实现发明。 目前，主要通过三种方法界定传统中药发明：化学成分、物理特性以及制法限定物质(product-by-process claim)。本文以界定专利申请中传统中药发明的角度讨论兼容性问题。

II 傳統中藥在專利法中的界定問題的產生

1. 传统中药的概念

在国际上，学术界一种主流观点认为包括中药在内的传统医药不具有专利性，其理由之一是认为传统医药不具有新颖性。“传统”这个词多少有些误导，会让人误以为所有传统中药是古老的，因而不合适申请专利保护。其实，“传统中药（Traditional Chinese Medicine）”这个词首先在二十世纪五十年代在外文杂志中用于描述区别于西医的中国医疗实践。 事实上，传统中药是一个不断发展进步的系统，并非一成不变的。

与西医相比，中药的特点主要体现在医学理论和药物的物理特性两方面。传统中药将人体看作是一个内在关联的系统，并且在该指导原则下治疗疾病。其基本原理是“辩证论治”理论，意思是“辨别病症并确定治疗方法”。传统中药认为某种形式的疾病反映人类机体的紊乱，并针对这些“症”采取治疗。 然而，西医倾向于直接治疗疾病。关于传统中药和西医之间差异的一个共同观点是“中医治本，西医治标。”

中医在这一理论的指导下，发展了传统中药，将机体作为一个整体进行治疗。传统中药医药一般可被分成两类：单方和复方。 大多数西药具有清楚的化学结构或者明确的有效成分，而传统中药在化学成分方面往往非常复杂。

2. 界定问题

专利可大致分为产品专利和方法专利。对于方法

专利，可申请专利的传统中药工艺范围广泛，从原材料的培育到药品的制造工艺均可申请。对于一些传统中药工艺是否可被视为诊断或治疗方法存在争议，因而无法申请专利，但传统中药工艺并不会导致发明难以界定。

如上所述，传统中药药品包括单方和复方。传统中药药品的化学结构通常不清楚，甚至其有效成分也不清楚。该特点使得传统中药难以作为药品进入西方市场。为了使传统中药现代化以满足西方标准，传统中药工业一直致力于从传统中药药品中界定并提取化学成分或有效成份。这些提取可以是化学分子或有效成分。然而，研究显示西方方法可能会降低传统中药的医疗作用，因为单一一种有效成份仅作用与身体的一个部位，根据系统观点的指导，当所有传统中药药品共同作用于人体时，其医疗作用最佳。

专利法的通用原则是申请人必须精确并清楚地公开发明。实践中，各个国家采用各种方法定义传统中药的实践表明他们对这些方法的态度事实上是源自西药的标准。

III 在專利申請中界定傳統中藥

1. 通过化学成分界定

当一种物质由化学成分定义时，其界定非常准确，实施不会有任何专利权界限不清的问题。传统中药现代化的一个方法别称作“中西医结合法”。在该方法中，对传统中药药品执行实验方法，以查明生物有效的化合物或成分。采用该方法获得的药品符合西方的医学观点，并且其中一些药品可由化学结构定义。例如，美国专利，“用于治疗皮肤病症的化合物”，提取自草药材料黑胡椒，并由化学成分定义。

然而，由于大部分传统中药药品或草药材料的化学成分非常复杂，很难找出并提取生物有效的化合物。目前，通过有效化合物界定的方法尚未被广泛用于传统中药专利申请。

2. 通过物理特性界定

大多数国家允许通过物理特性定义一种物质。例如，在 EPO 专利调查指导原则中，一种产品可由“特征值”的“参数”定义，如一种物质的熔点，钢铁的弯曲强度和电导体的电阻等。

上面提到的“中西医结合法”也被用于寻找传统中药药品的有效成分。一些有效成分是单一的化学化合物，而另外一些是化学成分不明或不稳定的有效成分。然而，对于传统中药药品，有效化合物不清楚，因为它们的化学成分太过复杂，因而难以界定生物活性化合物。

当一种传统中药药品的有效化合物难以界定时，台湾和中国大陆允许将药品作为一个整体定义其物理特性。在台湾传统中药调查指导原则中，声明一种传统中药可通过物理特性、化学特性或其它特征定义。物理或化学特性包括分子量、融点、紫外光谱和熔点等。这些指数可与提取物的指纹图谱一起用于完备的说明传统中药药品的物理和化学特性。

虽然该方法不界定生物活性化合物，但是可能适合于传统中药的特征，因为传统中药是采用系统方法治疗疾病。化学成分和药品之间化学反应的复杂性被认为对于传统中药药品很重要。通过界定传统中药药品的主要成分，该方法适合传统中药的特征。

3. 通过制法限定物质界定 (product-by-process

claim)

制法限定物质是通过生产方法定义产品。 制法限定物质方法针对的仍然是一个产品专利，其专利性仅取决于产品本身而非用于描述产品的方法。 制法限定物质的界定方法通常用于无法通过物理结构界定的发明，如制药领域的化学发明。

3.1. 制法限定物质方法的缺陷

制法限定物质实质上是一个产品权利要求， 其中描述的生产方法并不受保护。然而，它并不通过物理特性或结构定义产品，而是通过描述生产工艺来界定产品。这首先会给专利局的审查带来难题。 由于工艺和质量标准可能并不提供产品的结构和物理特性，因而通过阅读工艺和质量标准，专利局可能无法得知产品到底是什么。根据在美国的情况，专利局有时会将工艺视为产品的限制，在另一些场合则不会如此。 这一不足还会使得专利产品和其它以不同工艺制造产品之间界限不清。研究者可能并不清楚列举的工艺制造出什么，但是如果采用新工艺制造了另一种产品，他可能难以说清两种产品之间的差异。 这些问题将挑战整个专利系统的各个方面，包括专利调查和专利侵权的判定。

实践中，矫正制法限定物质不足有两个原则：必要性规则和保护范围的制法限制。根据必要性规则，只有当产品无法被适当定义，并且除非通过参考其生产工艺，否则无法与以其的工艺区分开时，才可使用制法限定物质。许多国家或地区例如欧盟、中国大陆和台湾都遵循该原则。在一些国家，制法限定物质中定义的生产工艺一直被用作侵权判定的限制条件。如在 Atlantic Thermoplastic Co. v. Faytex Corp 中证明的，专利局声明即便制法限定物质的专利性基于产品自身， 除非生产中采用相同工艺，否则不得违反制法限定物质。

3.2. 传统中药和制法限定物质的界定方法

目前，大多数传统中药发明通过制法限定物质定义。这部分是由于传统中药药品的复杂化学结构使得它们难以通过其它方式定义。对于传统中药而言，制法限定物质最适合于其特有的技术特征。在“辩证论治”原则的指导下，传统中药将人体作为一个相互关联的实体进行治疗。 因而，草药或动物材料之间化学反应所获得的复杂化学成分对于传统中药的医疗作用很重要。事实上，研究已经证明传统中药药品中一些纯化的医用化合物不如原始药物成分中的有效。 从传统中药中提取生物活性化合物的西方方法，虽然更适合产品要求书的确定性要求，但是可能会导致一些传统中药药品疗效降低。

另一方面，制法限定物质的方法在实践中也会带来问题。例如，在传统中药发明的侵权纠纷中，常常会出现这种情况：被告对原始中药组方进行小变更并且将该药物作为专利传统中药药品上市，用于相同的医学目的。由于传统中药组方的小变更并不会很大程度地改变最终药品的医疗作用，在侵权检验中识别工艺限制将妨碍传统中药发明的专利实施。

IV 結論

各个国家的专利报告显示了具有传统中药传统的国家与具有西医传统的国家之间在传统中药发明界定中的分歧。在一些地区，比如美国和欧盟，申请者需要通过化学结构或有效成分定义传统中药发明，而在中国大陆和台湾，专利报告显示标准较松，可通过定义传统中药药品的主要成分来满足该标准。实践的分歧可能根源于不同的医学传统以及该传统带来的市场许可要求。例如在美国，为了获得上市许可，申请者必须界定一种药品的生物活性化合物并且解释其医学机制。 然而，由于传统中药药品的复杂化学成分，常常难以查明药品的机制。

从传统中药发明的界定还可以看到传统中药行业给专利系统的确定性带来了挑战。如同上面讨论的，虽然传统中药研究中引入了西方方法，但是仍然难以找出传统中药药品中的有效化合物。在专利申请中，大量传统中药药品通过制法限定物质定义。在侵权纠纷中，专利局将难以构建传统中药药品要求书并确定侵权。

专利法和传统中药之间的兼容性问题，尤其是常常难以确定传统中药发明侵权这一事实，还带来了仅专利法是否能够肩负起保护传统中药发明这一任务的问题。在实践中会发现许多传统中药从业医生有他们自己的处方，他们将其作为商业秘密。传统中药给专利法带来的挑战敦促更多的法律形式，比如行政法、商业秘密法等，来共同保护中药发明。（作者系香港大學法學院博士研究生）

Examining the Compatibility between the Patent Law and Traditional Chinese Medicine

—— *From the Perspective of Identifying TCM in Patent Applications*

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Part I: Introduction

According to the World Health Organization's (WHO) 2001 report, traditional Chinese medicine (TCM) is regarded as one of the four major traditional medicine systems, which include traditional Chinese medicine, Indian ayurveda, Arabic unari , and various forms of indigenous medicine, and shares some common philosophic and physical features with other forms of traditional medicine. Traditional Chinese medicine has a long history of practice in the world, especially in areas like Mainland China, Taiwan, Japan, and Korea. TCM is based on traditional Chinese philosophy, which contains the concepts of "Qi," "Yin & Yang," "Five Elements," and "Bian Zheng Lun Zhi," and its chemical therapy is normally made from a combination of animal, mineral and plant materials . The theoretical basis and the physical properties of TCM distinguish it from Western medicines.

With the increasing popularity of traditional Chinese medicine, the relationship between patent law and TCM has, in the last decade, been highlighted by the boom of patents granted to traditional Chinese medicine practitioners and researchers worldwide. Most countries have been examining the TCM inventions under the same guidelines as those used for chemicals and pharmaceuticals. However, as TCM is special in both physical features and medical theory, it is often difficult for it to fit in the current framework of patent law that is designed for Western chemicals and pharmaceuticals. The difficulties in patenting TCM inventions raise the fundamental issue of the compatibility between the patent system and TCM inventions. In practice, when applying their patent examination guidelines to TCM, countries have been taking different approaches to various patentability issues, which results in divergent attitudes on the patentability of TCM. In general, the examination practices of Western countries, like the US and EU countries, have showed to be more stringent to Asian regions such as Mainland China and Taiwan. Considering the special features of TCM and its rapid development, the Taiwan Intellectual Property Office introduced a special Chapter

for the examination of TCM inventions in its Guideline, which remains as the only guideline in the world specifically tailored for TCM patent examination.

The article analyzes compatibility issues from the perspective of identification of TCM inventions in the patent application. Patent law requires that an invention needs to be defined in the specification in a clear and precise way. Currently, TCM inventions are identified mainly by three methods: effective compounds, physical properties, or the product-by-process claim. The article examines how those methods have been used in countries' practices and to what extent the methods are suitable for TCM inventions.

Part II: Traditional Chinese Medicine and Its Identification Problem in Patent Law

1. Concept of Traditional Chinese Medicine

The word traditional is to some extent misleading and conjures the image that all traditional Chinese medicines are old, and thus unsuitable for patent protection. The term, traditional Chinese medicine, was first used in the 1950s in a foreign language magazine to refer to the Chinese medical practice as distinguished from Western medicine. In fact, traditional Chinese medicine is an evolving system that is neither unchanging nor unchanged. The new traditional Chinese medicines developed by the industry have been attaining patents worldwide.

The features of traditional Chinese medicine in comparison to Western medicine can mainly be discussed from the perspectives of both medical theory and physical properties of medicine.

Traditional Chinese medicine views the human body as an inter-related system and treats diseases under this pretext. The essential principle of TCM is the theory, "Bian Zheng Lun Zhi," which means "pattern differentiation and treatment determination." Traditional Chinese medicine takes the view that a certain pattern of disease is the reflection of a disorder of the human organism. Therefore, the root of the disease may lie in other parts of the body, toward which the medical treatment should be directed. However, Western medicine intends to apply treatment directly to the disease. One common opinion regarding the theoretical difference between traditional Chinese medicine and Western medicine is that "Chinese medicine treats the root while Western medicine attends to manifestations."

Under the guidance of its theories, traditional Chinese medicines are developed to treat the body as a whole. The medicines of TCM can be generally divided into two groups – single prescription and complexity prescription – depending on the number of natural materials used in the production of the medicine. Most of the Western medicines have clear chemical structures, or are composed of effective agents, whereas medicines of TCM are far more complex in their chemical components.

2. The Identification Problem

The patentable subject matters of TCM include process and product. The patentable TCM processes can range from the cultivation of raw materials to the manufacturing process of medicine. Although there are controversial views on whether some of the TCM processes may be regarded as a diagnostic or therapeutic process, and therefore, not patentable, the TCM process should not cause difficulty in the identification of the invention.

As mentioned above, TCM treatments include single prescriptions and complex prescriptions. The combination formulas of complex prescriptions alone may also become the subject matter of a patent. A TCM practitioner usually writes down the combination formula as the prescription according to the particular situation of the patient, who would then get the combination of the medical herbs according to the formula and make the medicine, e.g. medical soup, himself or herself. The medical effect of a TCM is mainly decided by its formula. The TCM formula is the combination of natural materials, the quality of which largely depends on natural conditions such as the geographic origin or harvest season, which is critical information to disclose in the patent. However, the Western standard of medicine may go one step further to ask for the disclosure of the effect agents contained in each type of the natural material.

The chemical structure or effective agents are normally unclear or unknown in a TCM treatment. This feature makes it difficult for TCM to enter the Western market as medicine. To modernize the TCM to meet the Western standard, the TCM industry has been trying to identify and extract the chemicals or effective components from the TCM medicines. Those extractions can either be defined with chemical formulas or effective agents. However, it is argued that the Western

approach may reduce the medical effect of TCM because a single effective agent targets only one part of the body; yet, a systematic view of the medical effect of the TCM medicine works best when all of the TCM medicine works as a whole to the body.

It is the universal principle of patent law that the applicant must disclose the invention in a precise and clear way so that a person skilled in the art may be able to understand it. There are three primary ways to define the TCM medicines in the patent specification: define it by its chemical formula or effective agents, by its physical properties, and by the product-by-process claim. The countries' practices of using those methods in defining TCM show that their attitudes towards the method are, in fact, resulted from the standard of Western medicine.

Part III: Identify TCM in the Specification

1. Identification by Chemical Formula

Defining a substance by its chemical formula ensures that the disclosure is unambiguous and that there will not be any construction problems in the latter stage of enforcement. One approach of modernizing TCM is called "Chinese-Western medicine integrated approach" . Under this approach, experimental methods are run on the medicines of TCM to identify the bio-effective compound or composition. The medicines achieved by the method fit the Western medical point of view, and some of them can be defined by chemical structure. For instance, the US patent, "compounds for use in the treatment of skin conditions," is the extract from the herbal material, black pepper, and the product claim was defined by its chemical formula.

However, as most TCM medicines or herbal materials are very complex in chemical composition, it is difficult to locate and extract the bio-effective chemical compounds. Currently, the method of identifying by effective compounds has not been widely used in the TCM patent application.

2. Identification by Physical Properties

Most countries allow a substance to be defined by its physical properties. For instance, in the EPO patent examination guideline, a product may be defined by "parameter" of "characteristic values," such as the melting point of a substance, the flexural strength of steel, the resistance of an electrical conductor, etc. In some regions, the method is restricted to the situation in which the product cannot be defined by physical structure.

The Western approach of TCM research mentioned above has been used to identify the effective agents of TCM medicine. Some of those effective agents are single chemical compounds, whereas the others are compositions for which the effective compounds can be identified as the inventive substance .

However, for TCM treatments, the effective compounds are not clear since the chemical composition of them are so complex that it is difficult to identify the bioactive compounds. Because the effective compounds of a TCM medicine are difficult to identify, an approach has been introduced in Taiwan and Mainland China to define the physical properties of the medicine as a whole. In the Taiwan examination guideline for TCM, it is stated that a TCM extract may be defined by the physical properties, chemical properties, or other characteristics. The physical or chemical properties include molecular weight, melting point, ultraviolet spectrum, molten point, etc. Those indexes can be used in associate with the fingerprint of the extract to give a full overall illustration of the physical and chemical characteristics of the TCM medicine.

Although the bioactive compounds are not identified, the method probably suits the features of TCM, which takes a systematic approach to treat disease. The complexity of the chemical composition and the chemical reactions among them are regarded to be important for the TCM medicine. The identification of the main components of a TCM medicine suits the special features of TCM.

3. Identification by the Product-by-Process Claim

A product-by-process claim defines a product by the method of production. A product-by-process claim is still a product claim, in which the patentability is solely based on the product instead of the process used to describe the product.

The creation of a product-by-process claim suits the products that cannot be identified in physical structure. In reality, the product-by-process claim has been frequently used on pharmaceutical and chemical inventions. The necessity of such a type of claim is perfectly justified for the pharmaceutical industry by the fact that millions and billions of dollars have been dumped into the research of pharmaceutical and chemical drugs, a great amount of which can not be defined by structure.

3.1. Deficit of the Product-By-Process Claim

There are generally two types of patents: product and process. The product-by-process claim was essentially a product claim, in which the process described is not subject to protection. However, instead of defining a product by physical properties or function, it describes the product with the process of production. Although this feature of the claim helps to define the product inventions that cannot be defined in a way other than process, it also gives rise to various problems.

All controversies about the product-by-process claim have the common root in the deficiency of the claim that, although the product-by-process claim is a product claim, it by its nature does not disclose what the product actually is. This first gives trouble to the patent construction of the courts, which would have the problem of figuring out what the product exactly is by reading through the process and specification, which may not provide the structural or physical properties of the product. As a result, the courts, as evidenced in the US, sometimes regard the process as a limitation to the product and are inconsistent in other occasions. The deficiency would also create an unclear divide between the claimed product and other products that are made by different processes. A researcher may have an idea of what had been created by the recited process, but it would be difficult for him or her to tell the differences between the two products if the other product was made by a new process. Clearly, those problems will challenge the whole patent system in various aspects of both patent examination and the courts proceedings. It is, therefore, no doubt that the

CCPA had “consistently stated” that the general rule of claiming an article was by its physical structure, not by its manufacturing process.

Two principles have been used in the practice to remedy the deficit of the product-by-process claim: the rule of necessity and process limitation to the scope of protection.

The rule of necessity established that the product-by-process claim can only be used when the product cannot be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. The principle has been followed in many countries or regions, for instance, EU, Mainland China, and Taiwan. In the US, the principle was first established in the In re Painter case . In some countries, the process of production, as defined in the product-by-process claim, has been used as limitation in the infringement test. As shown in the Atlantic Thermoplastic Co v Faytex Corp, the court stated that even though the patentability of a product-by-process claim was based on the product itself, the product-by-process claim would not be infringed unless the same process was used in the production.

3.2. TCM and the Product-by-Process Claim

Currently, most TCM inventions are defined by the product-by-process claim. This is partly because of the complex chemical structure of TCM medicines, which make them difficult to be defined by any other means. Although, the product-by-process claim may not be the last option for TCM medicines, , it is regarded as the best suited to the technical features of TCM medicines. Guided by the principle of “Bian Zheng Lun Zhi,” TCM treats the human body as an inter-related entity. Therefore, the complex chemical composition that resulted from the chemical reactions among the herbal or animal materials is important to carry out the medical effect of TCM. In fact, research has shown that some purified medical compounds from TCM medicines are not as effective as the original medical compositions. Although the Western approach of extracting bio-active compounds from TCM, better suits the requirement of definiteness of the claim, it may cause some TCM medicines to lose their original features.

The controversy of the product-by-process claim is essentially arisen from the deficit that a product-by-process claim may not be able to clearly depict the physical structure of the product. Although the product-by-process claim was introduced to provide incentives to certain industries, especially those in which the products cannot be defined by their physical properties, it also creates problems as to the definiteness of the claim. For instance, in the infringement disputes of TCM inventions, the situations often appear to be that a respondent made minor modification to the original combination and marketed the medicine for the same medical purpose as the patented TCM medicine. As the minor modification to the TCM combination will not change the medical effect of the final medicine a great deal, recognition of the process limitation in the infringement test would hurdle the patent enforcement of TCM inventions. Furthermore, the rule of necessity will also impose a heavy burden on an applicant who has to prove that no other way is available for identification. As most TCM medicines are complex in structure, imposition of the principle may cause redundant burdens in the patent applications.

The debate of the process limitation represents the conflict between encouraging the invention on one side and the general principle of patent system on the other side. To an industry like that of the TCM that has heavy R&D expenses and where the products are difficult to be identified by physical properties, the process limitation would severely impede the innovation of the industry. Therefore, under this circumstance, it is appropriate to grant broad protection to the claim and shift the task of claim construction to the later court proceedings.

4. Conclusion

The patent reports from various countries show divergence in the identification of TCM inventions between countries with TCM traditions and countries with Western medical traditions. In regions like the US and EU, the applicants intend to define the TCM inventions by the bioactive compounds, whereas in Mainland China and Taiwan the patent reports show a relaxed standard that can be fulfilled by defining the main components of a TCM medicine. The divergence of the practice is probably rooted in the different medical traditions and the subsequent requirements of market approval. For instance, in the US, the applicant has to identify the bioactive compound of a medicine and explain the medical mechanism in order to attain the market approval. However, due to the complex chemical composition of TCM medicine, it is usually difficult to find out the mechanism of the medicine.

It can also be seen from the identification of TCM inventions that the TCM industry challenges the concreteness of the patent system. As been discussed above, although the Western approach has been introduced in the TCM research, it is still difficult to locate the medically effective compounds in a TCM medicine. In the patent application, a large number of TCM medicines are defined by the product-by-process claim. In the infringement dispute, the courts will have trouble to construct the claims of TCM medicines and determine the infringement.

The development of TCM is based on its unique theory that distinguishes it from Western medicine. Although the Western approach of medical research helps to identify the effective compounds and to explain the medical mechanism, it is differentiated from the theoretical basis of TCM and may decrease the medical efficacy of TCM medicine. Therefore, the practice of patent law should give special consideration to the features of TCM, such as allowing the methods of identification that can best keep all main components within the patent claim, as demonstrated in the Taiwan patent examination guideline.

The compatibility issues between the patent law and TCM, especially the fact that it is often difficult to determine the infringement of TCM inventions, also raise the question about whether patent law can alone take the task of protecting TCM inventions. For instance, it can be found in practice that many TCM practitioners have their own prescriptions, which are kept as trade secrets. The challenges to the patent law brought by the TCM urge more legal forms, such as administrative law, trade secret law, and other sui generis laws, to cooperate to protect TCM inventions.