The Dilemma and Resolution: The Patentability of Traditional Chinese Medicine

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ABSTRACT

Traditional Chinese Medicine (hereafter referred to as TCM) is made by Chinese herbal formulae and includes a ratio of pharmaceutical elements, which contain known health-enhancing functions. The trial process of the invention of TCM requires a lot of creative work and involves some risks. Winning patent protection for TCM presents technical barriers on the patent examination. To address the problem of patent protection for TCM requires an understanding of history, medicine, pharmaceutical science, and modern drug development. The patentability of TCM may ultimately depend upon the determination of the scope and right contents of TCMs and the creation of a special patent examination system for this purpose.

Keywords: Chinese Herbal Formulae, Dilemma, Patentability, Patents, Traditional Chinese Medicine (TCM)

1. TCM’S DEFINITION, CHARACTER AND SCOPE

TCM is the general term for traditional medicines in China, which have played an important role in the development of China’s national and cultural approach to wellness and health care delivery. It has a very long history as the main weapon against disease in China. The definition of TCM is, under the guidance of TCM theory, medicine derived from natural products used to control physical and mental illness incorporating chemical, biological agents found in nature (Lin & Tang, 2010).

1.1. The Concept and the Scope of TCM

In order to better define the requirements for patent protection, the object of this paper is to focus on process innovations without violating the premise of the basic theory of TCM. TCM will be defined by dividing them into five parts on a theoretical basis:

Part 1: Chinese herbal medicine which refers to medicinal plants, animals, minerals from which have been removed non-medicinal parts.
Part 2: Pieces of Chinese herbal medicine, which refers to Chinese herbal medicine that can
be directly used under the guidance of the TCM theory.

Part 3: The combination of Chinese herbal medicines, which refer to two or more components of Chinese herbal medicines that have been combined in processing for addressing a definite set of syndromes and prescriptions.

Part 4: Preclinical drugs derived from Chinese herbal medicine, including tablets, pills, ointments, injections and aerosols which refer to preclinical drugs made for health care or disease prevention. Examples include watermelon frost tablets, injections of Zhichuan Ling and Liu Wei Di Huang balls. The preclinical drugs of the Chinese herbal medicines have some characteristics of clinical re-use, safe and effective dosage, and reasonable quality and process stability.

Part 5: Extracts from Chinese herbal medicine, which come from the raw materials of Chinese herbal medicine, through purification processes to get complex single body fluids (paclitaxel), or active sites (such as ginseng saponins) or a mixture of various ingredients (such as Ginkgo extracts).

1.2. The Characteristics of the TCM

Compared with western medicine, TCM’s main differentiated features can be summarized as follows.

First, the cultural heritage and strong experiencial guidance. TCM is derived from a knowledge system based on a centuries-long struggle with disease. Chinese herbal medicine processing technology, and medication methods have been developed in practice through this historical base. TCM has strong empirical characteristics.

Second, the relatively public nature of this knowledge. Because Chinese medicine has a strong heritage, and has been formed from common practice and transmission of ideas from generation to generation in the course of its development, confidentiality has not been a primary goal, which means these formulae are public resources belonging to the entire nation and to mankind.

Third, the dialectic nature of the cures and standardization difficulties. TCM emphasizes compounds, leading to the composition and content of complex medication. Even just one Chinese medicine may contain multiple ingredients that may reach tens or even hundreds of species. Thus, in TCM research, how to standardize the effective material in TCM is more difficult than similar effective material in western medicine, and this may be the most characteristic feature of TCM.

Fourth, the relatively weak reproducibility of the formulae and strong individuality of the solutions. The doctor uses different TCM for individual people, even in different seasons. Doctors may also prescribe a different dosage for different effect.

2. THE DILEMMA OF THE TCM PATENT PROTECTION

TCM has its unique architecture and features, which are different from western medicine. Due to this uniqueness, experts maintain that TCM may need a special patent protection system which is different from traditional patent system. But now, TCM patent protection systems are mainly designed for inclusion within “western drug patent systems”. This western patent system cannot reflect well the needs of Chinese medicine patent protection, and also cannot reflect either Chinese legislative will or the pursuit of value of those practitioners hoping to employ the patent system to protect their knowledge while encouraging further research and experimentation.

2.1. TCM Lacks Clear Title and Ownership

TCM has been created over generations with inputs undefined by the practitioners. It is, in some respects, a public good. Traditional patent systems may be unable to protect these public manifestations of common knowledge. This
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