

Examining the Compatibility between the Patent Law and Traditional Chinese Medicine:  
From the Perspective of Identifying TCM in Patent Application

Part I: Introduction

In the WHO report, the traditional Chinese medicine (TCM) is regarded as one of the four major traditional medicine systems, namely traditional Chinese medicine, Indian ayurveda and Arabic unari medicine, and various forms of indigenous medicine,<sup>1</sup> in which TCM shares with other forms of traditional medicine some common philosophic and physical features.<sup>2</sup> The traditional Chinese medicine has a long history of practice in the world, especially in areas like Mainland China, Taiwan, Japan and Korea. TCM represents the medical practice that is based on Chinese traditional philosophy that contains the concepts like “*Qi*”, “*Yin & Yang*”, “*Five Elements*” and “*Bian Zheng Lun Zhi*”,<sup>3</sup> and its chemical therapy is normally made from the combination of animal,

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<sup>1</sup> WHO/EDM/TRM/2001.1. “Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine.”

<sup>2</sup> See *ibid.* For instance, TCM and other traditional medicine use combination of herbal materials to cure illness and take systematic view on the human body. Some of the common features make it possible to discuss the application of patent law on TCM by looking at its application on other traditional medicine.

<sup>3</sup> Liu, Zhan-wen. 2002. “Philosophical Aspects Of Chinese Medicine From A Chinese Medicine Academician.” In *The Way Forward For Chinese Medicine*. Eds. Kelvin Chan and Henry Lee: TAYLOR & FRANCIS. It is noted that the term “*Bian Zheng Lun Zhi*” is sometimes expressed as “*Bian Zheng Shi Zhi*” in Chinese.

mineral and plant origin<sup>4</sup>. 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 the patent law and traditional Chinese medicine has, in the last decade, been highlighted by the boom of patents granted to traditional Chinese medicine worldwide. Most countries have been examining the TCM inventions under the same guidelines for chemicals and pharmaceuticals.<sup>5</sup> 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 US and EU countries, have showed to be more stringent to Asian regions like Mainland China and Taiwan. Considering the special features of TCM and its rapid development, the Taiwan Intellectual Property Office introduced a special Chapter for examination of TCM inventions in its Guideline, which remains as the only guideline in the world specifically tailored for TCM patent examination.<sup>6</sup>

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<sup>4</sup> Chan, Kelvin. 2002. "The Historical Evolution Of Chinese Medicine And Orthodox Medicine In China." In *The Way Forward For Chinese Medicine*. Eds. Kelvin Chan and Henry Lee: TAYLOR & FRANCIS.

<sup>5</sup> Taiwan is the only exception where the Patent Examination Guideline has a special chapter for TCM examination.

<sup>6</sup> See 台湾专利审查基准汇编, 第二编, 第十二章. The chapter, named "Examination Guideline for Traditional Chinese Medicine", was introduced in the 2007 version of the Taiwan Patent Examination Guideline. (see Taiwan IP Office website:

The article observes compatibility issue 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' practice and in what extent the methods are suitable for TCM inventions.

Part II of the article will discuss the concept of traditional Chinese medicine and introduce the identification issue. Part III focuses on the identification of TCM in patent law. Part IV provides some suggestions and gives conclusion.

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

### 1. Concept of Traditional Chinese Medicine

The word “traditional” is in some extent misleading, which delivers the image that all traditional Chinese medicines are old and, thus, unsuitable for patent protection. The term, “traditional Chinese medicine”, was first used in 1950s in foreign language magazine to

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[http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=447&guid=e3de95be-d2f5-427a-a340-b2c8d7e4a60f&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=447&guid=e3de95be-d2f5-427a-a340-b2c8d7e4a60f&lang=zh-tw) )

refer to the Chinese medical practice as distinguished from western medicine.<sup>7</sup> In fact, the traditional Chinese medicine is an evolving system that is neither unchanging nor unchanged.<sup>8</sup> The “new” traditional Chinese medicines developed by the industry have been attaining patents worldwide.<sup>9</sup>

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

The traditional Chinese medicine views human body as an inner-related system and treat the disease under this guidance. The essential principle of it is the theory, “*Bian Zheng Lun Zhi*”, meaning “pattern differentiation and treatment determination”<sup>10</sup>. The traditional Chinese medicine takes the view that a certain pattern of disease is the reflection of disorder of human organism.<sup>11</sup> Therefore, the root of the disease may lies in other parts of the body where the medical treatment should be directed toward. However, western medicine intends to apply treatment directly to the disease. One common opinion regarding to the theoretical difference between traditional Chinese medicine and western

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<sup>7</sup> Volker Scheid, *Chinese Medicine in Contemporary China*, Duke University Press (2002), Page 3 (Introduction part). In this sense, as pointed out in the book, the term “traditional Chinese medicine” was used in the same meaning as “Chinese medicine”.

<sup>8</sup> Volker Scheid, *Chinese Medicine in Contemporary China*, Duke University Press (2002), Page 3 (Introduction part).

<sup>9</sup> Even for “old” traditional Chinese medicine, there is still some room for patenting. For example, some of the *Miao yao*, one particular type of traditional Chinese medicine, have been kept in the local minority group – the *Miao* group – during the history of whole practice, and are arguably able to meet all three criteria of patent examination. The “old” traditional Chinese medicines are not in the scope of the discussion of the article.

<sup>10</sup> Volker Scheid, (2002) *Chinese Medicine in Contemporary China*, Duke University Press, Page 200.

<sup>11</sup> *Ibid.*

medicine is that “Chinese medicine treats the root while western medicine attends to manifestations.”<sup>12</sup>

Under the guidance of its theories, the 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.<sup>13</sup> Most of the western medicines have clear chemical structure, or composed of effective agents, whereas medicines of TCM are far more complex in their chemical components.<sup>14</sup>

## 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 manufacture process of medicine.<sup>15</sup> Although there are controversial views on whether some of the TCM processes may be regarded as diagnostic or therapeutic process and, therefore, not patentable<sup>16</sup>, TCM process will not cause difficulty in identification of the invention.

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<sup>12</sup> Ibid.

<sup>13</sup> 朱晟 何端生 (2007) “中药简史” 广西师范大学出版社. The single prescription contains only one type of TCM materials. For example, *ginseng* alone can be used to produce a TCM. The complexity prescription, however, is composed of more than one type of materials.

<sup>14</sup> 孔宪泽 詹华强. 2006. “从西方思维看中药现代化.” 三联书店, pp 59 – 61.

<sup>15</sup> 肖诗鹰 刘铜华, ( 2005 ) “中药知识产权保护和申报技术指南”, 中国医药科技出版社, pp 39 – 40.

<sup>16</sup> See 肖诗鹰 刘铜华, ( 2005 ) “中药知识产权保护和申报技术指南”, 中国医药科技出版社, pp 41 – 42.

As mentioned above, medicines of TCM include single prescription and complex prescription. The combination formulas of complex prescription alone may also become the subject matter of 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. It is regarded that the medical effect of a TCM is mainly decided by its formula.<sup>17</sup> 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.<sup>18</sup> Disclosure of that information of an invention is important for others to realize it. 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.

A TCM medicine is normally unclear in its chemical structure or even unknown in its effective agents. This feature makes TCM difficult to enter the western market as medicine.<sup>19</sup> 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 formula or effective agents. However, it is argued that the western approach may reduce the medical effect of TCM, because a single effective agents target only one part of body, and under the

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<sup>17</sup> 张仁平, 台湾中草药保护之回顾与前瞻(下), 智慧财产权月刊 90年12月.

<sup>18</sup> See 台湾专利审查基准汇编, 第二编, 第十二章, 3.3.1.2.

<sup>19</sup> See 张成文等, 植物提取物是中药走向国际市场的现实表达方式(陈冲主编, 中药现代化研究, (2006) 化学工业出版社, pp 88-96.) Currently, most TCM medicines are marketed as food or nutrition in the western market.

guidance of systematic view the medical effect of the TCM medicine works the best when all TCM medicine works as a whole to the body.<sup>20</sup>

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 realize it.<sup>21</sup> To define the TCM medicines in the specification, there are mainly three ways: define it by chemical formula or effective agents, by physical properties, and by the product-by-process claim. The countries' practice of using those methods in defining TCM show that their attitudes of the methods is, in fact, resulted from standard of western medicine.

### Part III: Identify TCM in the Specification

#### 1. Identify by Chemical Formula

When a substance is defined by chemical formula, the disclosure is unambiguous and there will not be any construction problem in the latter stage of enforcement. One approach of modernization of TCM is called “Chinese-Western medicine integrated approach”<sup>22</sup>. Under the approach, experimental methods are run on the medicines of TCM

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<sup>20</sup> 张仁平, 台湾中草药保护之回顾与前瞻 (下), 智慧财产权月刊 90 年 12 月.

<sup>21</sup> See e.g. 35 U.S.C 112 Specification.

<sup>22</sup> Eric Ziea & Joseph Sung, Irritable Bowal Syndrome: A Chinese-western integrative approach for treatment, See the website of Hong Kong Jockey Club Institute of Chinese Medicine: <http://www.hkjcicm.org/5news/3/1.asp> . (visited at 21 Dec. 2008.)

to find out the bio-effective compound or composition. The medicines achieved by the method fits 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 chemical formula.<sup>23</sup>

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.<sup>24</sup> Currently, the method of identifying by effective compounds has not been widely used in the TCM patent application.

## 2. Identify 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 melting point of a substance, the flexural strength of steel and the resistance of an electrical conductor, etc.<sup>25</sup> In some regions, the method is restricted to the situation when the product can not be defined by physical structure.<sup>26</sup>

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<sup>23</sup> US Patent Number **7,361,685**.

<sup>24</sup> 郑永锋，中草药专利问题探讨，《中药、草药专利审查基准之研究、增订及利用中医辨证作为审查可行性之探讨》。

<sup>25</sup> EPO Patent Examination Guidance, Chapter III paragraph 4.11.

<sup>26</sup> For instance, EU and Taiwan.

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 where the effective compounds can be identified as the inventive substance<sup>27</sup>.

When the bioactive ingredients are identified, defining a TCM medicine is essentially the task of defining the effective compounds. This is because a composition can be defined by the inventive compounds contained in the composition.<sup>28</sup> The method of identification by physical properties has been widely used as the approach to define a compound of unknown structure.<sup>29</sup> In the US patent, “pharmaceutical composition for the treatment of cardiovascular and cerebrovascular disease”, the composition was consisted of effective compounds, which were further defined by the physical properties of each compound.<sup>30</sup> The invention is composed of four herbal components, namely Radix Saldix Miltiorrhizae extract, Radix Notoginseng extract, Radix Astragali extract and Borneol or oil of Lignum Dalbergiae Odoriferae. Each extract was defined by effective compounds. For example, the Radix Saldix Miltiorrhizae extract was claimed to comprise 45%-70% salvianolic acid B, 2%-10% salvianolic acid E, 4%-20% rosmarinic acid, 1%-10% lithospermic acid, and more than 70%, preferably more than 80%, salvinolic acids.<sup>31</sup> However, as some of the compounds, for instance, salvianolic acid B, are complex in its structure, various

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<sup>27</sup> A composition is essentially the invention of the compound, which contains the inventive steps. (See Grubb, Patent for Chemicals, Pharmaceuticals and Biotechnology, (2004), Oxford. Pp 226 – 227.)

<sup>28</sup> See Grubb, Patent for Chemicals, Pharmaceuticals and Biotechnology, (2004), Oxford. Pp 226 – 227.

<sup>29</sup> See Grubb, Patent for Chemicals, Pharmaceuticals and Biotechnology, (2004), Oxford. Pp 220 – 221.

<sup>30</sup> US Patent Number 7,438,935.

<sup>31</sup> Ibid.

parameters, like wavelength, mobile phase and theoretic plates, were used to define the physical properties of it.<sup>32</sup>

However, for TCM medicines, the effective compounds are not clear since the chemical composition of them are so complex that it is difficult to identify the bioactive compounds.<sup>33</sup> When the effective compounds of a TCM medicine are difficult to identify, the approach that has been introduced in Taiwan and Mainland China is 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.<sup>34</sup> The physical or chemical properties include molecular weight, melting point, ultraviolet spectrum, molten point, etc.<sup>35</sup> Those indexes can be used in associate with the fingerprint<sup>36</sup> 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. By identifying the main components of a TCM medicine, the method suits the special features of TCM.

### 3. Identify by the Product-by-Process Claim

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<sup>32</sup> Ibid.

<sup>33</sup> See 张仁平, 台湾中草药保护之回顾与前瞻 (下), 智慧财产权月刊 90 年 12 月.

<sup>34</sup> See 台湾专利审查基准汇编, 第二编, 第十二章, 3.3.1.3.

<sup>35</sup> See 台湾专利审查基准汇编, 第二编, 第十二章, 3.3.1.3.

<sup>36</sup> Fingerprint of the extract provide the types of the chemical components contained in the extract.

A product-by-process claim defines a product by the method of production.<sup>37</sup> 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.<sup>38</sup>

The creation of 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.<sup>39</sup> The necessity of such 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.<sup>40</sup>

In practice, the controversy about the product-by-process lies mainly in two issues: the rule of necessity (whether the product-by-process claim can only be used on products that cannot be identified other than process) and the protection scope of such a claim (whether process used to define the product should be used to limit the protection scope).

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<sup>37</sup> MPEP 2113.

<sup>38</sup> See, for example, MPEP 2113.

<sup>39</sup> Mark D. Passler, Product-By-Process Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L. Rev. 233.

<sup>40</sup> It is revealed in Passler's article that the average research spending to discover one new chemical compound of the pharmaceutical companies in 1990 was 230 million USD and only one out of every 5,000 or 10,000 of the compounds could eventually enter the market. (see Mark D. Passler, Product-By-Process Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L. Rev. 233, footnote 4.)

### 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,<sup>41</sup> 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 producing. Although this feature of the claim helps to define the product inventions that can not be defined in the way other than process, it also gives rise to various problems.

All controversies about the product-by-process claim have the common root on 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.<sup>42</sup> This first gives troubles to the patent construction of the courts.<sup>43</sup> The courts would have problems 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 the result, the courts, as evidenced in the US, would sometimes regard the process as limitation to the product and

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<sup>41</sup> Although the case law of the US show controversy on whether the process in a claim should be used to constrict the scope of protection, there is no conflict on the issue that the subject matter of a product-by-process claim is the product. (see e.g. *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 1279 (Fed. Cir. 1992) at 845. In the case, the court noted that a product-by-process should be examined based on the product itself even though it decided that the process language in the claim should limit the scope of the protection.)

<sup>42</sup> Gary Newson, *Product-by-Process Patent Claims: Arguing for a Return to Necessity and Reduction in the Scope of Protection*, 40 *Ariz. St. L.J.* 327.

<sup>43</sup> Greory S. Maskel, *Product-By-Process Claim Construction: Revolving the Federal Circuit's Conflicting Precedent*, 17 *Fordham Intell. Prop. Media & Ent. L.J.* 115.

do not in other occasions.<sup>44</sup> The deficiency would also create the unclear shore between the claimed product and other products that are made by different process. A researcher may have idea of what had been created by the recited process, but it would be difficult for him to tell the differences between the two products if the other product is made by a new process.<sup>45</sup> 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.<sup>46</sup>

### 3.2. Rule of Necessity

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 followed in many countries or regions, for instance, EU, Mainland China, and Taiwan. In the US, the

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<sup>44</sup> It was argued that the US courts’ controversy on the construction of the product-by-process claim lies in the fact that sometimes the process may be more important to identify what the product is, while sometimes it does not. Thus, the courts would tend to use the process as limitation to the scope of right when it does not give much information on what the product is. (see, Greory S. Maskel, Product-By-Process Claim Construction: Revolving the Federal Circuit’s Conflicting Precedent, 17 *Fordham Intell. Prop. Media & Ent. L.J.* 115.)

<sup>45</sup> Gary Newson, Product-by-Process Patent Claims: Arguing for a Return to Necessity and Reduction in the Scope of Protection, 40 *Ariz. St. L.J.* 327.

<sup>46</sup> *Atlantic Thermoplastics Co v. Faytex Cor.*, 970 F.2d 834; 1992 U.S. App. LEXIS 15888; 23 U.S.P.Q.2D (BNA) 1481.

principle was first established in the *In re Painter* case<sup>47</sup>. However, after that, a number of cases had departed from the rule of necessity.<sup>48</sup> In 1974 the PTO modified the Examination Manual, which stated that a product-by-process would be permitted so long as it satisfies the requirement of Section 112 of the Patent Act – the definiteness requirement.<sup>49</sup> It was not until then, was the rule of necessity officially abolished for the product-by-process claim in the US.

To the product-by-process claim, the effect of the rule of necessity is essentially to constrain the scope of applicability of the claim by excluding the products that can be defined by other means. Also, the reasonable expectation of what the invention actually covers would be improve by encouraging the applicants to define articles with physical structures, which will also benefit the court proceeding on patent construction<sup>50</sup> and prevent the applicant to use the product-by-process claim as the hedge against the possibility of invalidation of the broader product claim.<sup>51</sup>

However, 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

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<sup>47</sup> Lawrence A. Hymo and Richard A. Anderson, Product-By-Process Claims: Time for Reexamination, 132 The Federal Circuit Bar Journal, Vol. 3 No. 2 Summer 1993.

<sup>48</sup> Examples can be see in the following cases: *In re Pilkington* (411 F.2d 1345 (CCPA 1969)), the court stated that Congress placed no limitation on how an applicant claim his invention; *In re Hughes* (496 F.2d 1216, 1218 (CCPA 1974)), the court recognized the right of the applicant to define the product by the process even though it may be defined in terms of structure and characteristics; *In re Stepan* (394 F.2d 1013, 1019 (CCPA 1967)), the court pointed out the rule of necessity was not supported by the patent statute.

<sup>49</sup> See MPEP (version 1974), 706.03 (e).

<sup>50</sup> Greory S. Maskel, Product-By-Process Claim Construction: Revolving the Federal Circuit's Conflicting Precedent, 17 Fordham Intell. Prop. Media & Ent. L.J. 115.

<sup>51</sup> *In re Hughes*, 496 F.2d 1216, 1219; 1974 CCPA LEXIS 155; 182 U.S.P.Q. (BNA) 106.

complex in structure, imposition of the principle may cause redundant burdens in the patent applications.

### 3.3. Process Limitation to the Scope of Protection

Although it is agreed that the patentability of a product-by-process claim is solely decided on the basis of the product itself, it is not clarified in the patent examination manual of any country whether the making process would constitute limitation in the infringement test.

The rationales of both side can be observed in the two US cases: *Scripps Clinic v Genentech Inc* and *Atlantic Thermoplastic Co v Faytex Corp.*<sup>52</sup> In the *Scripps*, the patent owner, Scripps Clinic, held the protein patent, Factor VIII:C, that was claimed by the process of chromatographic absorption, and the respondent, Genentech Inc, later produced the protein using the process of recombinant-DNA techniques. The court ruled on the infringement of the protein patent, despite the fact that Genentech Inc has manufactured it with different process.<sup>53</sup> The *Scripps* case was decided in 1991. Six months later, however, the Federal Circuit decided on the *Atlantic* case, in which the court regarded the process as the limitation to the patent and overruled the infringement claim. The *Atlantic* case was about a shock absorbing innersole claimed by a product-by-process

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<sup>52</sup> In fact, before the two cases, no Federal Circuit case had addressed the issue of whether a process would constitute a limitation to the product-by-process claim. (Mark D. Passler, Product-By-Process Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L. Rev. 233, 246.)

<sup>53</sup> *Scripps Clinic v Genentech Inc*, 927 F.2d 1565, 1583.

claim. In the case, Atlantic Thermoplastic, sued the respondent, Faytex Corp, for manufacturing the innersole. This time, the court overruled the infringement claim on the ground that the production process of Atlantic Thermoplastic constituted limitation to the patent and Faytex Corp did not commit the infringement since the manufacturing method of it was different from what Atlantic Thermoplastic claimed in the patent.<sup>54</sup> In the later district court cases, some courts followed the first precedent while others followed the second.

The rationale of the *Scripps* case was that the patentability of a product-by-process claim should be decided solely on the product instead of process.<sup>55</sup> The court held that patentability and infringement should be examined on the same standard, and, therefore, the process provided no limitation in the infringement analysis.<sup>56</sup> Taking a divergent approach as the *Scripps* panel, the *Atlantic* court, based its conclusion by examining a number of the Supreme Court cases and academic literature,<sup>57</sup> noted that even though the patentability of a product-by-process claim was based on the product itself,<sup>58</sup> the product-by-process claim would not be infringed unless the same process was used in the production.<sup>59</sup>

It is criticized that if the process provides no limitation to the scope of right, problems will be created in the stage of claim construction. By focusing solely on the product the approach ignores the meaning of the claim by excluding the part of description of

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<sup>54</sup> *Atlantic Thermoplastics Co v. Faytex Cor.*, 970 F.2d 834, 838, 839.

<sup>55</sup> *Scripps Clinic v Genentech Inc*, 927 F.2d 1565, 1583.

<sup>56</sup> *Scripps Clinic v Genentech Inc*, 927 F.2d 1565, 1583.

<sup>57</sup> See *Atlantic Thermoplastics Co v. Faytex Cor.*, 970 F.2d 834, 838 – 843.

<sup>58</sup> *Atlantic Thermoplastics Co v. Faytex Cor.*, 970 F.2d 834, 845.

<sup>59</sup> *Atlantic Thermoplastics Co v. Faytex Cor.*, 970 F.2d 834, 845.

process.<sup>60</sup> As the result, the general rule was broken that “every limitations and its equivalent” of a claim need to be represented in the accused behavior.<sup>61</sup> The practical problem is also caused when the product cannot be adequately defined by physical properties. It will, thus, be difficult to know what the product really is and decide on the infringement.<sup>62</sup> However, if the process in the claim is used to as limitation, it will render the product-by-process claim a *de facto* process claim.<sup>63</sup> The product-by-process claim was supposed to provide incentives to industries where new products are difficult to be defined other than process. The introduction of the product-by-process claim as an exception to the general rule of identification is a “pragmatic adjustment to the needs of science, not law.”<sup>64</sup> Undoubtedly, the *Scripps* approach that ignores the process limitation can provide wider scope of protection and incentive of invention for the industry.<sup>65</sup>

The technical features of TCM mainly lie in the types and proportion of the materials used in the composition.<sup>66</sup> Thus, the disclosure of the composition of materials is important for the enablement of the invention. However, 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

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<sup>60</sup> Greory S. Maskel, Product-By-Process Claim Construction: Revolving the Federal Circuit’s Conflicting Precedent, 17 Fordham Intell. Prop. Media & Ent. L.J. 115.

<sup>61</sup> *Smithkline v Apotex*, 439 F.3d 1312. (Judge Newman Dissenting at 1321)

<sup>62</sup> Greory S. Maskel, Product-By-Process Claim Construction: Revolving the Federal Circuit’s Conflicting Precedent, 17 Fordham Intell. Prop. Media & Ent. L.J. 115.

<sup>63</sup> This is especially true in determination of infringement, given the fact that in most jurisdictions a process patent will also cover the product that is directly made by it.

<sup>64</sup> *Smithkline v Apotex*, 439 F.3d 1312. (Judge Newman Dissenting at 1321).

<sup>65</sup> Greory S. Maskel, Product-By-Process Claim Construction: Revolving the Federal Circuit’s Conflicting Precedent, 17 Fordham Intell. Prop. Media & Ent. L.J. 115.

<sup>66</sup> See 张仁平, 台湾中草药保护之回顾与前瞻 (下), 智慧财产权月刊 90年12月.

combination will not change the medical effect of the final medicine in great deal, recognition of the process limitation in the infringement test would hurdle the patent enforcement of TCM inventions.

It is proposed that the principle of equivalence should be used in dispute to determine the infringement between the two TCM medicines made from the two sets of combinations with minor difference.<sup>67</sup> When employed, the principle is proposed to be guided under the TCM theory to explain whether two medicines from the similar combination have the same medical effect and can be regarded as the same medicine.<sup>68</sup>

#### 3.4. 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. However, to TCM medicines, the product-by-process claim may not be the last option. It is regarded that the product-by-process claim can best suit 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.<sup>69</sup> 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

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<sup>67</sup> See 游云, 中药复方专利保护及其侵权分析, 中国中医科学院 2003 级博士论文, pp 48 – 50.

<sup>68</sup> See 游云, 中药复方专利保护及其侵权分析, 中国中医科学院 2003 级博士论文, pp 48 – 50.

<sup>69</sup> Volker Scheid, (2002) *Chinese Medicine in Contemporary China*, Duke University Press, Page 200.

medicines are not as effective as the original medical compositions.<sup>70</sup> The western approach of extracting bio-active compounds from TCM, although suits better the requirement of definiteness of claim, may cause some TCM medicines to lose the 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. While the product-by-process claim was introduced to provide incentive to certain industries, especially those where the products cannot be defined by physical property, it also creates problems to the definiteness of the claim. The debate of the process limitation represents the conflict between the encouraging invention on one side and general principle of patent system<sup>71</sup> on the other side.

To an industry, for instance the TCM industry, with heavy R&D expense 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.<sup>72</sup>

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<sup>70</sup> See 张仁平, 台湾中草药保护之回顾与前瞻(下), 智慧财产权月刊 90年12月.

<sup>71</sup> The product-by-process claim has long been regarded as an exception to the general principle of the patent law, which traditionally defines a product by physical properties. (see *Smithkline v Apotex*, 439 F.3d 1312. (Judge Newman Dissenting at 1321, 1322))

<sup>72</sup> It is possible that, at the later stage of court proceeding, the development of technology may be able to define the product or identify the different properties between the two products. (see Gary Newson, *Product-by-Process Patent Claims: Arguing for a Return to Necessity and Reduction in the Scope of Protection*, 40 *Ariz. St. L.J.* 327, 340 – 341.)

#### 4. Conclusion

The patent reports from various countries show divergence in the identification of TCM inventions between countries with TCM tradition and countries with western medical tradition. In regions like 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 relax standard which 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 requirements of market approval resulted from it. 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.<sup>73</sup> 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 brings challenges to definiteness 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

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About science advancement will help to define the physical properties – (see *Scripps*, the science advancement may diminish the need of filing a product claim by process. – cited in the *Smithkline*, 1323. Also, in *Scripps*, the protein was a novel substance with unclear structure.)

<sup>73</sup> See, for example, US Guidance for Industry Botanical Drug Products, June 2004.

infringement dispute, the courts will have trouble to construct the claims of TCM medicines and determinate the infringement.

The development of TCM is based on its unique theory that distinguished from western medicine. Although the western approach of medical research helps to identify the effective compounds and explain the medical mechanism, it goes apart from the theoretical basis of TCM and may decrease the medical effective of TCM medicine. Therefore, the practice of patent law should give special concern to the features of TCM. One way of it is to allow the methods of identification that can best keep all main components within the patent claim as shown 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 that 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 secret. 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.