

Exuberance or Bubble? Study of Nano-Based Herbal Medicine Patents in the PR China

Tse-Ping Dong† and Chun-Hsien Sung

Graduate Institute of Global Business and Strategy, College of Management, National Taiwan Normal University,
162, HePing East Road, Section 1, Taipei city, Taiwan

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The growing economic and therapeutic importance of Chinese herbal medicine (CHM) has prompted the governments of East Asian countries to develop it into an industry. The current research on the application of nanotechnology in CHM is deemed a new field of study. This article focuses on the issue of overly broad patent applications and assignments in the PR China by examining a case in which a patentee successfully registered more than 900 nano-based CHM patents in China's State Intellectual Property Office (SIPO), all of which were based on the same preparation process. This article further shows that the proliferation of nano-based CHM patents in China is due to the illusion of biomedical technological progress and that the current irrational exuberance for patents not only is a bubble that will burst, but also presents barriers to innovation and invention in the emerging biopharmaceutical industry and the nano-based CHM market.

Keywords: Chinese herbal medicine (CHM), Nano-based patenting, nanotechnology, biopharmaceutical industry, SIPO

The issue of patents for nanotechnology in Chinese herbal medicine (CHM) has been discussed widely. A reasonable analysis of data however reveals that Chinese nano patenting activity and patent pendency are not as dynamic as they are purported to be. The single case examined in this article is a good example of overbroad application issues in China's patent system. The case involves a Chinese patentee, Yang Mengjun, who once was labeled as a nano bio-pirate by the Caption Cook Award for Biopiracy because he had 466 patents for nano-based CHM in 2004 (ref. 1). However, this deterred neither Yang from applying for more patents nor China's State Intellectual Property Office (SIPO) from processing and approving his patent applications. Today the number of patents issued to Yang by the SIPO has surpassed the 900 mark.

Meanwhile, China identified development of nanotechnology as a major strategic policy in science and technology during the period 2006 to 2020. The overall aim is to reach a proportion of 2.5 per cent to the gross domestic product in nanotechnology R&D expenditures.² However, Yang's case demonstrates that application of nanotechnology to CHM and basic research on nano CHM, are both inadequate. It also casts reasonable doubt on the actual achievements in

relation to the numbers of filed patents in China, which ranked 4th among international patents filed in the World Intellectual Property Organization (WIPO).³ Furthermore, China ranked 19th among the nanotechnology patent assignees in the United States Patent and Trademark Office and 18th in the European Patent Office.⁴ The phenomenon of Yang's more than 900 patents is not a unique case. Indeed, Yang's application pattern has been cloned by many other patentees in China such as Chengdu Simo Nano Tech Co Ltd which has successfully applied for 27 nano-based CHM patents at SIPO. Another patentee, Huazhong Science and Technology University, also registered 19 nano-based patent applications at SIPO.⁵ Most of China's nanotechnology patents were filed domestically, and therefore international patenting activity is relatively scarce.

According to the World Health Organization (WHO), traditional medicine is the 'sum total of all knowledge and practices, whether explicable or not, used in the diagnosis, prevention and elimination of physical, mental or social imbalance and relies exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing...'⁶ Nowadays, a number of East Asian countries, namely, Mainland China, Hong Kong SAR, South Korea, Japan and Taiwan, are using this knowledge to expand CHM into an industry

†Email: Corresponding author: tpdong@ntnu.edu.tw

aimed at the development of new drugs. Their purpose is to expand the market potential of CHM products from food and dietary supplements to prescription drugs thereby, offering a choice in terms of drugs to the global population. Currently, the global herbal medicine market is valued at US\$ 60 billion annually and the sale of herbal medicines is expected to achieve an average annual growth rate of more than 6.4 per cent.⁷ The CHM market was projected to expand considerably in the years to come.⁸ This potentially lucrative market that is developing as a key industry in East Asian countries is however being restricted by China's limited patent system. Although the danger of the 'tragedy of anticommons' is not yet evident, based on a single process, Yang's 900+ patents have successfully blocked other innovators.

Patenting CHM and Nanotechnology

The patenting of nano-based CHM combines two of the most difficult subjects in the current patenting regime. First, nanotechnology, the meaning of which is still controversial, has raised numerous patenting issues ranging from patenting in basic science to concern about existence of pre-nano patents covering their nano counterparts. The current definition, which is based on mere physical limitation, tends to be an unorthodox way of defining a new field.⁹ The National Nanotechnology Initiative (NNI) defined nanotechnology as 'the understanding and control of matter at dimensions of roughly 1-100 nm, where unique phenomena enabled novel applications.' However, this definition excludes numerous devices and materials of micrometer dimensions.¹⁰ Patent policies are often concerned with procedural issues such as patent examination, classification, and analysis¹¹ and to a lesser extent with theoretical issues regarding patenting of atomic or molecule structures. How patent policies evolve, affect the scope of nanotechnology patenting and the prevention of illegal copying of an atomic or molecular-sized device.¹² The WIPO brought out explicit guidelines for determining whether the reproduction of a known product or structure would meet the requirements of a novel and inventive step.¹³ Trailing the path of biotechnology, nanotechnology has initiated a trilateral project on nanotechnology patenting between the world's three most important patent offices [European Patent Office (EPO), Japan Patent Office (JPO) and the United States Patent and Trademark Office (USPTO)].¹⁴ Needless to say, the issue of patenting CHM inventions is as troublesome.

Second, because disclosure is a component of patent application, CHM has faced patenting obstacles due to difficulties in assigning pharmaceutically effective chemical ingredients in drugs. This is due to the presence of a combination of multiple herbs, which makes it difficult to identify the effective compounds.¹⁵ Furthermore, assigning the right species of plants, confusion over plant species in different traditional texts and standardization of herbal efficacy, are all potential obstacles to patenting in CHM. In order to overcome these obstacles, in 2008, Taiwan implemented the CHM Patent Examination Guidelines, which was the first attempt worldwide to resolve these issues.¹⁶ Like biotechnology inventions, the characteristics of nano-based CHM present inherent difficulties that need clear delineation and relying on past experience in biotechnology patenting could help characterize the situation in nano-based CHM.¹⁷

Nano-based Patents and the Product of Nature Doctrine

'Product of nature' is a patent doctrine barring the patenting of biotechnological inventions. This doctrine stipulates that one cannot patent what occurs naturally and is already available in the public domain. This doctrine has become particularly relevant for patent issues following the Supreme Court's ruling in *Diamond v Charkrabarty* in which the court famously quoted that 'everything under the sun that is made by man' is patentable.¹⁸ This ruling created the provision for patent protection to microorganisms worldwide and became an international norm included in Article 27(3) of the TRIPS Agreement.¹⁹ As a result, natural materials are patentable if they have been substantially altered to become a man-made invention. Since biotech inventions often use natural materials in the process of invention, the product of nature doctrine could be avoided through isolation and purification resulting in unexpected properties.²⁰

The demise of the exclusion of the product of nature doctrine in patents can be attributed to two separate theories. The first relies on the assertion that a purified product differs in form from one in a natural state. The second theory is based on a slippery slope argument, that is, all inventions are products of nature.²¹ For example, in *Merck & Co v Olin Mathieson Chemical Company*,²² scientists satisfied this requirement by removing the B12 vitamin from its natural environment and putting it into a form that

was not previously known to be isolated or substantially pure. The rationale was that without isolation and purification process, the property might not be found and the superior property would not be likely to enter the market and benefit the public. This precedent facilitates application for patent protection for an isolated and purified CHM extract with unexpected properties.

Biotech Case Study: *Scripps v Genentech* and *Amgen v Chugai*

Once the method for claiming a biotech patent is established, a subsequent issue relates to the scope of the patent, that is, how broad the patent can be. *Scripps v Genentech*²³ illustrated the problem of scope. Genentech invented a recombinant process to produce the human blood clotting protein VIII:C, which had significant advantages over the earlier patented technique of purifying a substance drawn from natural blood. In the first part of the case, the court ruled that it was a legitimate product patent of Scripps and that Genentech's new method thus constituted infringement, even though Genentech was able to provide the product in a purer and larger therapeutic quantity. It is relevant here to note that Scripps had discovered a method of using monoclonal antibodies to isolate Factor VIII:C from blood plasma. Scripps did not invent Factor VIII:C itself, but, nonetheless, received the product-by-process patent for Factor VIII:C obtained by this purification method, as well as a product patent on the highly purified Factor VIII:C.

The decision to grant the patent was incongruous because theoretically, recombinant products are identical to their natural counterparts. The basic principle behind recombinant products is that they mimic nature. Moreover, the differences between recombinant and natural proteins are not protein *qua* protein but the description of the product-by-process by which they are produced, which constitutes a product-by-process claim. This case clearly illustrates both the danger of granting overbroad patent to the first inventors and thus impeding subsequent inventors despite the use of different technologies. Similarly, in *Amgen v Chugai*, Amgen used recombinant DNA technology to produce erythropoietin (EPO) as a life saving drug because it had the potential to deal with end-stage renal diseases, AIDS, and cancer. However, Amgen suffered the same fate as Genentech because its patent was held by district judges to infringe on Genetics Institute's patent on purified, naturally occurring EPO.²⁴

Nano-based CHM Patents: Case Study

It is widely believed that the patenting culture is still immature in China²⁵ and due to the difficulties and uncertainties in patenting nano-CHM, the number of patents granted is limited.

In view of the above, the sheer numbers of Yang's patents is questionable, besides their validity, since these patents constitute method as well as product (or use). Such practices could severely retard the development of nanotechnology and also do not conform to the goal of Chinese Patent Law, which is to encourage invention-creation, to foster the spread and application of invention-creation, and to promote development of science and technology.²⁶ A search for 'Yang Mengjun' on EPO's esp@cenet patent database yielded 983 results. Further, 384 patents out of 500 that are available online are titled '(nano + name of traditional CHM formulation+ its preparation process)'. On the SIPO patent database, Yang has 941 nano-based CHM patents. Since the majority of his patents are similar, only two examples are mentioned here, as illustrations. CN 1,368,367 titled, 'Nano medicine 'Zhixie' and its preparing process,' explains that the invention is a nano-sized (0.1-200 nm) medicine for treating diarrhoea, and is prepared from the nanometre powders of scandent hop, dockleaved knotweed herb and longipeduncle kadsura root by stem through proportioning, microwave extracting, pressure reduction concentrating, and supersonic-jet spray drying. The grain fineness is about 1200-1500 mesh particles, and grain diameters are 0.1-200 nm. The advantages of the invention are its high biological utilization rate and significant curative effect. CN 1,368,320, entitled 'Nano medicine 'Shengerfa' and its preparing process' also describes the invention as a nanometre (0.1-200 nm) medicine. Shengerfa, which is used for growing hair, is prepared from the nanometre powders of 10 Chinese medicinal materials including prepared rehmannia root, fleece flower root, red peony root, etc., by proportioning, microwave extracting, pressure reduction concentrating and supersonic-jet spray drying. The grain fineness is again 1200-1500 mesh particles, and grain diameters 0.1-200 nm. Once again the advantages of high biological utilization rate and high curative effect are identical to the previous example. Similar to Yang's patent applications, in the case of Chengdu Simo Nano Technology Co, its 27 registered patents have the same sort of patent description: 'uses the medicinal and edible dual-purpose Chinese medicine and insoluble component

and water-soluble component of the substance'.²⁷ Another remarkable patentee is Wang Jingshan. Although his set of 51 nano-based CHM patents is smaller than Yang's, he successfully applied for a wildcard patent titled 'Application of nanometer technology in Chinese medicine form improvement.' The description includes 'crushed (materials and some recipes) in superfine crusher into nanometer powder, which can be further processed to nanometer extraction liquid or powder and nanometer medicine in various forms.' The scope of this granted patent actually covers all the nano-based CHM patents mentioned above. In other words, if this wildcard 'improvement' is registered, SIPO may not be able to grant patents to any other nano-based CHM technique in future. Although it is not possible to access all the nano-based CHM cases in SIPO, these examples suffice to show that the patent application system in SIPO is not only overloaded but also chaotic.

Details of Yang's Nano-CHM Patents

The common characteristic of the Yang Mengjun's inventions is that they are generally based on the *Fu Fang* formulation encoded in the Chinese Pharmacopeia.²⁸ Yang's patents do not describe isolation or purification of the herbs; changes or substitution including addition or deletion in the amount of herbal materials used; changes in dosage or formulation; nor any novel, special process for formulations. Besides, the patents claim that therapeutic efficacy of the nano-based CHM is same as the traditional CHM, i.e. there is no evidence to show unexpected properties or properties superior to the prior art. The crux of the patent is the use of his technique of making nanoparticles out of CHM raw materials according to the *Pao Zhi* and *Yin Pian* process. In the absence of any significant difference from the prior art, a person having ordinary skill in the art (PHOSITA) is only likely to notice the difference in size, which violates the fundamental *quid pro quo* principle that underlies patent law. Based on this single method, Yang has successfully claimed the rights to both the process and product of nano-sized traditional CHM formulations; although such inventions should have been eligible only for a process patent not for product patent or patent for new use.

Further, effects of nanoparticles are currently unknown and it is risky to rely on the safety standards of the prior art for their nano counterparts. Nano-based CHM inventions might also need to consider

characteristics of natural herbs as well as the effect of *Pao Zhi*.²⁹ It is well known that *Pao Zhi* often changes the characteristics of the natural herb. Hence, when a nano material is made, the characteristics of the herb may change through 3 stages: (1) natural herb; (2) herbs after *Pao Zhi*; and (3) herbs after transformation to nano material. The characteristics and efficacy of nano CHM material are far removed from the traditional formulae, and due to limited information, the patent office often grants overbroad and overlapping patents at an early stage of technology development. Yang's patent gives rise to several doubts on nano-based CHM patenting: (1) whether or not a product patent should be granted for such inventions or a process patent should suffice; (2) whether or not a person can apply for and receive 900+ nano-based CHM patents based on a single process; (3) what is the appropriate process to receive a nano-based CHM product patent?

Patentability Issues

Patent applications in China undergo both initial and substantive examinations. There is no doubt that, Yang's nano-based CHM inventions and his granted patents are very much within the scope of invention as per the Chinese Patent Law.

With regard to the initial examination, Article 26.3 of the Chinese Patent Law provides that the description of the application for an invention patent shall set forth the invention 'in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out.'³⁰ The 'clear and complete description,' according to Rule 17 (ref. 31) of the Implementing Regulations of the Chinese Patent Law, must include an abstract briefly stating the main technical points and the contents must provide sufficiently specific details. These details should include the technical field, background art, contents of the invention, description of figures (if any), and mode of carrying out the invention. The content requirements are as follows:

Technical field: Specifying the technical field to which the technical solution for which protection is sought pertains;

Background art: Indicating the background art which is useful for understanding, searching and examination of the invention, and when possible, citing the documents reflecting such art;

Contents of the invention: Disclosing the technical problem that the invention or utility model aims to settle and the technical solution adopted to resolve the

problem; and stating, with reference to the prior art, the advantageous effects of the invention;

Description of figures: Briefly describing each figure in the drawings, if any;

Mode of carrying out the invention or utility model: Describing in detail the optimally selected mode contemplated by the applicant for carrying out the invention; where appropriate, this shall be done in terms of examples, and with reference to the drawings, if any.³⁵

With regard to the substantive examination of a patent relating to medical use, the medicament as well as method for its manufacture are patentable. However, Article 25.1(3) of the Chinese Patent Law does not allow grant of patent for 'method of diagnosis' or 'treatment of diseases'. Such application shall merely contain 'medical use of a substance adopts pharmaceutical claim' or 'use claim in the form of method for preparing a pharmaceutical,' e.g., particular substance for manufacturing of a medicament and particular substance for manufacturing of a medicament for the treatment of a disease.³²

Yang's nano-processing of CHM is related to the manufacturing of a medicament, and falls within the scope of 'method for preparing a pharmaceutical.' However, there are issues regarding novelty, obviousness, and utility of Yang's granted patents. The following paragraphs will address the issues of novelty, obviousness, and utility in Chinese patent jurisprudence and show that Yang's patents do not meet the requirements of the Chinese Patent system adequately. On the other hand, because very limited information is available regarding patentability of nano-processes in China, the following paragraphs will also examine the patentability of Yang's nano inventions from the point of United States' laws.

Novelty

In China, an invention loses novelty if prior to the date of filing, the invention has been disclosed in publications or publicly abroad or communicated to the public by any other means in the country. Moreover, no other application describing an identical invention that was published after the said date of filing should have been filed previously with the Patent Administration Department under the State Council.³³ Although Yang's nanometre (0.1-200 nm) medicines present a significant outcome as far as size of traditional CHM powders are concerned; the change in approach, function, or nature is nevertheless an issue.

In the US, it is an established legal principle that mere difference in dimension cannot add novelty to a new product.³⁴ The United States Patent and Trademark Office (USPTO), citing *in re Rose*,³⁵ suggested that miniaturization down to the nano-scale, by itself, is not patentable. In Yang's case, his invention was based on a single process. Once the process was granted a patent, it entered the public domain and became a prior art. If one takes into account Judge Frank's dissenting opinion in *Schering Corp v Gilbert*,³⁶ Yang's invention is merely 'a process for preparing the same'. Yang's subsequent inventions should be denied patents since the process itself has lost novelty, and apart from the process of making nano-size CHM raw materials, nothing else novel was contributed to the public.

Obviousness

According to the Chinese Patent Law, the obviousness of the invention is assessed in comparison with existing technology. The new invention must provide 'prominent substantive features' and represent 'a notable progress.'³⁷ The former means that, 'having regard to the prior art, it is non-obvious to a person skilled in the art'; the latter requires a product of 'advantageous technical effect as compared with the prior art.'³⁸ Yang's process of making nano-sized CHM may be regarded as an invention of 'non-obvious combination', which means that the technical effect after combination (nano-size techniques and CHM) is greater than the sum of the technical effects of the individual features (higher biological utilization rate).³⁹ However, obviousness is assessed in terms of a PHOSITA who theoretically possesses all available prior art; the invention has to be unobvious to a PHOSITA in order to satisfy this requirement. In Yang's case, his process may be granted a process patent for inventing a method to make nano-sized CHM raw materials; however, the invention does not warrant a product patent because apart from difference in size, nothing else appears to be different from the prior art. In the first nanotechnology case decided by the Federal Circuit, *in re Kumar*,⁴⁰ the Court provided guidance for overcoming obviousness rejections based on overlapping sizes of nanoparticles based on difference in size range rather than difference in size alone.

In re Geisler,⁴¹ it was stated that mere recognition of latent properties in prior art does not render an otherwise known invention, non-obviousness. However, if Yang was able to show 'unexpected

results⁴² in his invention as compared to prior art, it would be possible to overcome the obviousness bar of mere change in size and inherent anticipation, which is also the way of avoiding the ‘product of nature’ doctrine in Europe. Yang’s patents, however, failed to provide any of the above-mentioned evidence. Instead, it claimed that the efficacy and therapeutic activity of the nano-based CHM is the same as the traditional formula encoded in the Chinese Pharmacopeia.

Utility

The requirement of utility (industrial applicability in China) is often easy to meet as long as there is a real world application for the invention. Utility means practical utility such that an invention can be made or used and can produce effective results.⁴² However, since nanotechnology is a nascent industry of which predictability or unpredictability is yet to be established, as in biotechnology, utility has to be specific, substantial, and credible.⁴³ It has also been suggested that utility requirements should be applied stringently to nanotechnology innovation if there is a significant risk that growth of nanotechnology will be retarded by broad upstream patents.⁴⁴

As stated in *Nelson v Bowler*,⁴⁵ adequate proof of pharmacological activities constitutes showing of practical activity. Yang could have showed that his invention is administered more easily than the drug in conventional form, e.g., by topical administration or inhalation. Yang could measure pharmacokinetics and pharmacodynamics to demonstrate more effective uptake and distribution of his nano-based CHM *in vivo*. Although, after *in re Brana*,⁴⁶ it was established that a proper clinical trial is not obligatory in a patent application, since drug regulation is administered by the Federal Drug Administration (FDA) and not the USPTO. Yet, pre-clinical test data such as *in vitro* or *in vivo* animal studies could have been provided by Yang as proof of the correlation with the prior art. In *Cross v Iizuka*,⁴⁷ the Court ruled that the demonstration of the easiest way to establish activity, such as *in vitro* activity, is sufficient to support a patent application. Since safety of the nano-based CHM inventions are not yet proven, granting patents to such inventions contradicts Article 27(2) of the TRIPS Agreement, wherein members may exclude from patentability certain inventions so as to protect human and plant life.⁴⁸ Although CHM has been proved to be safe after accumulation of thousands of years of empirical studies, Yang cannot take a free

ride on this data for his nano-based CHM. Since safety and efficacy data remains un-confirmed, these inventions fail to establish utility and thus are not patentable.

Yang’s Nano-based CHM Patents: Potential Impacts

Inherent Risks of Nano-Based CHM

Currently, nano applications of CHM focus on improving the manufacturing process. The intention of these inventions is to minimize the particle size from 100 nm to 10 nm, with the belief that such ingredients are more pure, simple, and easily absorbed by the human body.⁸ Several promised advantages of nano application in CHM drug discovery include: (1) Increase in bioavailability results from reduction of particle size expanding the possibility of particle dissolution and distribution. This allows higher levels of active ingredients to be absorbed by the human body and lesser use of raw materials;⁴⁹ (2) Nano-based CHM particles enhance the accuracy of releasing the active ingredients at the desired area thus, increasing drug efficacy. This results in enhanced drug delivery and targeting;⁵⁰ (3) New chemical and physical properties and possible new therapeutic efficacy;⁵¹ (4) Enhanced water solubility;⁵¹ and (5) Possible increase in the different modes of delivery methods.

Despite these promises, there are not enough studies to substantiate these effects in nano-based CHM. Properties often change when size approaches the nano level; theories suggest that the change in properties is related to the percentage of atoms at the surface of the substance.⁵² Furthermore, naturally occurring nanoparticles may behave differently from engineered nanoparticles, and the safety of macro-sized particles does not necessarily translate to the safety of nanoparticles. Due to their size, nanoparticles are associated with high surface area to volume ratio. This in turn results in limited capacity for active compounds and makes them potentially unstable.⁵³ Nanoparticles might demonstrate toxic responses and unforeseen responses in the human body⁵⁴ since their small size also makes it easy for them to penetrate cells in lungs, brains, and other organs.⁵⁵

Overly Broad Patents

The cases discussed above illustrate that Yang successfully used a single process to claim more than 900 traditional CHM formulations merely by

narrowing them to the nano scale. Yet, it is not fair that pre-nano patents should be held to include their nano-counterparts because, it would multiply significantly the number of patents that nanotech companies have to deal with. Arguably, pre-nano patents should not be infringed because there is something unique about the nano scale that affects the behaviour of materials in ways that pre-nano inventions did not anticipate.⁴⁹ As in the cases of *Scripps* and *Amgen*, Yang's patents were overbroad in terms of covering the product instead of the process. The impact of such patent proliferation means that future litigation is inevitable, especially when nanotechnology becomes financially lucrative.¹⁰

Yang received only one European patent, EP1945171, titled a 'Medical device's manufacture and usage in medicine for rehabilitation treatment of chronic diseases'. Considering the fact that China's CHM market touched RMB 110.3 billion (about US\$ 16.5 billion) in 2005, which comprised a quarter of China's medical industry, the likely impact of Yang's patents is not to be underestimated. In the midst of uncertainty in nanotechnology patents, SIPO, like its US counterpart, has seen patent proliferation, and unlike in the past when pharmaceutical patents were granted to MNCs, these nano-based CHM patents have been granted to an individual. Since SIPO is an International Search and Examination Authority in the Patent Cooperation Treaty (PCT) system, its results could be relied upon and recognized by developing countries in Asia. Patents granted by SIPO are no longer relevant only in the domestic context, especially now that patent offices are seeking harmonization to increase efficiency. Poor quality patents will only create obstacles in this regard. Furthermore, the same CHM herbal plant could be used in different *Fu Fang* formulations that are subject to different conditions. Because Yang received a product invention patent covering the nano-sized raw materials within the formula, an inventor in the future might risk patent infringement suits on a non-patented formula, that includes the patented nano-sized raw materials.

Patenting of nano-sized raw materials might deter research in not only CHM but also other systems of traditional medicines that use the same raw materials in their formulations. The herb, turmeric, for example, is used extensively both in India and China.⁵⁶ Since natural substances cannot be invented, a product patent on a natural substance confers the power to

monopolize innovation in other fields relating to the substance.⁵⁷ Granting a product patent on nano-sized raw materials in CHM has the same impact as patenting genes in the biotech industry, which are fundamental building blocks of the technology. If the present trend of patenting activity continues, the tragedy of anti-commons is a likely phenomenon in nano-based CHM and deterring further innovation and entry of domestic or foreign innovators into Chinese nano-based CHM market. It is foreseeable that in future, nano-based CHM business in China is likely to face considerable uncertainty in relation to the validity of broad and potentially overlapping patents. Furthermore, anyone who wants to carry out R&D on nano-based CHM should be wary of infringing Yang's nano-scale CHM formulations and nano-sized raw materials within the range of 0.1-200nm.

Patenting Nano-Based CHM: Potential Approach

Similar to biotechnological inventions, nano-based CHM products are inherently unpredictable. This unpredictability⁵⁸ occurs due to: (i) the sophistication of scientific procedures used, (ii) methodologies based on chance occurrences, and (iii) the complexity of cellular systems that are manipulated; resulting in grant of overly broad patents. Granting a product patent on a nano-based CHM without offering anything new to the public actually deters the development of this field of technology and industry. A more favourable approach is to deal with the issue by looking at solutions available in the existing systems. For example, instead of product patents, process patents constitute a more suitable form of protection for Yang's nano-based CHM. A process patent would protect the invention from disclosure without over-rewarding the inventor. Limiting patents to process claims would retain incentives for competitors to develop superior methods of production. Moreover, process patents would also assure a more efficient allocation of resources.⁵⁹

The grant of product patents is very troubling in economic terms. It is essential that the government designs a patent system that will provide economic vitality without expanding the patent scope to unknown territory and hindering downstream innovation. As stated earlier, if the slippery slope statement is applied, everything is considered as a product of nature and therefore all properties are inherent and anticipated. If this theory is applied to

nano-based CHM, very few inventions will receive a product patent. In order to claim a product patent for a product of nature such as CHM, numerous attributes may be considered, such as superior property or uses that are not available in prior art and are not obvious to a person skilled in the art. Claims could be subject to the substantial transformation test (STT) advocated by Demaine and Fellmeeth, which judges the invention on two grounds: (1) whether the characteristics of the product are substantially different from the natural product; and (2) whether the characteristics are inherent in the product or conceived by the patent applicant.⁶² If the characteristics are not substantially different, the claimed product is unpatentable because it is naturally occurring. In this case, the inventor would be contributing to the public while not deterring the public from practicing what is already in the public domain. The knowledge of characteristics is based not on the actual characteristics of the product of nature, explicit or implicit, but on what is known by an ordinary person skilled in the art at the time of patent filing. Hence, in order to claim a product patent on a nano-based CHM, it is not necessary to define the inherent characteristics of the product before attempting to produce substantially different characteristics, but to surpass what is already known.

Such innovations might be difficult to achieve because CHM has existed for over four thousand years, and the efficacy of herbs and their interaction after *Pao Zhi* have been well documented. However, nano-based patents might be possible if the following conditions are met, namely, the invention is able to overcome deficiencies in nature and the prior art; the CHM inventor is able to discover new properties by adding, deleting, or substituting CHM herbs;⁶⁰ new properties arise from the nanotechnology that overcome the inadequacies of traditional therapies through novel methods of manufacturing or use; discovery of alternative delivery methods; or real 'nano' CHM is produced bottom-up by the manipulation of molecules to recreate the efficacy of traditional CHM formulas. However, although the possibility of nano-based CHM patenting may be based on a multiplicity of conditions, as stated above, the issue is not of just patenting but of choosing the right form of protection and patent scope.

Patent scope raises further questions. When the inventor satisfies the aforementioned criteria, would it

mean that the inventor's product patent covers all subsequent related innovations, as illustrated in the *Scripps* or *Amgen* case? For a long time, a product patent has had a 'one embodiment' doctrine that has allowed the product to cover downstream innovation. However, this jurisprudence was created in the era of predicable art-mechanical inventions and is troubling when applied to unpredictable art-biospace inventions.⁶¹ Patent scope interpretation arises during patent litigation and because it is based on the claim and specifications in the patent documents, it is often the job of the court. Because this field is highly uncertain, it is necessary to establish a clear and consistent definition of an invention that can be understood by both the governing and governed. Therefore, an invention should be defined in the light of art at the time of invention.⁶⁶

By applying this definition, the product patent will apply to only what is actually covered and what is foreseeable to be covered at the time of invention, but not to all subsequent innovations. Hence, ascertaining the PHOSITA is an important prerequisite since he or she is the standard by which the prior art is tested. The government should realize the necessity of a balanced system in patenting this nascent yet unpredictable science, while safeguarding the essence of public domain. Since this issue is far too delicate for the scope of this article, its resolution might need not only cooperation between the patent office and the courts but also involvement of the legislative body. As Judge Burger CJ, who delivered the opinion of the majority of the Supreme Court of the United States in *Diamond v Chakrabarty*, once stated, '...the choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination and study that legislative bodies can provide and courts cannot.'⁶²

Conclusion

Nano-based CHM patenting presents both opportunities and challenges. A vast number of upstream patents will likely cause a company that seeks to produce new therapies, to face a number of disputes such as potentially overlapping or cross infringing patents. Therefore, it is essential to safeguard patentability of nano-based CHM inventions rigorously and restrict the scope of patents to what is known at the time of the invention in order to prevent unjustified broadening of patent scope. It is further suggested that Yang's product patents should

be not only challenged but also invalidated, subject to lack of novelty, inventiveness, and utility as provided under Articles 45-47 of the Law and Rules 58-71 of the Implementation Regulations to the Chinese Patent Law. Because nano-based CHM has the potential to significantly improve human life and alleviate sickness, it is important to grant economic incentives to innovators in this field while keeping the public science domain open for subsequent innovators. In the case of Yang, SIPO simply has failed to achieve this goal; in other words, the proliferation of nano-based CHM patents in China promotes merely an illusion of biomedical technological progress. The present irrational exuberance regarding patents is not only a bubble that will surely burst but also act as a barrier to innovation and invention in the emerging biopharmaceutical industry and nano-based CHM market. In their approval of nano-based technology patents, authorities should be more cautious and operate in strict compliance with patent principles.

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