Observing Recent Foreign Developments upon Bio-medicine、 Marketing Medical Devices、 Technology Development Project and the Newest Litigation Trend Concerning the Joint Infringement of Method/Process Patents

1、**Chinese REACH has put into shape, how about Taiwan REACH? - A Perspective of Chinese Measures on Environmental Management of New Chemical Substances**

Taiwan food industry has been struck by the government agency's disclosure that certain unfaithful manufacturers have mixed toxic chemicals into the food additives for the past 30 years, and the chemicals may seriously threaten public health. This event has not only shocked the confidence of the customers to the industry, but also drew public attention on the well-management and the safe use of chemicals.

In order to manage the fast advancing and widely applicable chemical substance appropriately, the laws and regulations among the international jurisprudences in recent years tend to regulate unfamiliar chemicals as “new chemical substances” and leverage registration systems to follow their use and import. REACH is one the most successful models which has been implemented by European Union since 2006. China, one of our most important business partners, has also learned from the EU experience and implemented its amended " Measures on Environmental Management of New Chemical Substances" (also known as "Chinese REACH") last year. It is not only a necessity for our industry which has invested or is running a business in China to realize how this new regulation may influence their business as differently , but also for our authority concerned to observe how can our domestic law and regulation may connect to this international trend. Therefore, except for briefing the content of Chinese REACH, this article may also review those existing law and regulations in Taiwan and observe the law making movement taken by our authority. We expect that the comparison and observation in this article may be a reference for our authorities concerned to map out a better environment for new chemical management.

2、**The study on Taiwanese businessmen Join the Bid Invitation and Bidding of Science and Technology Project**

China government invests great funds in their Science and Technology Project management system, containing most of innovated technology. It also creates the great business opportunity for domestic industry.

China government builds up a Bid Invitation and Bidding Procedure in the original Science and Technology Project Regime recent years, in order to make the regime become more open and full of transparency. It also improves Regime to become more fairness and efficiency. Taiwan industry may try to apply for those Science and Technology Project, due to this attractive opportunity, but they should understand china's legal system before they really do that.

This Article will introduce the "Bid Invitation and Bidding Law of the Peoples Republic of China", and the "Provisional Regulation on Bid Invitation and Bidding of Science and Technology Project", then clarify applied relationship between the "Bid Invitation and Bidding Law of the Peoples Republic of China", and "Government Procurement Law of the Peoples Republic of China". It also analyzes "Bid Invitation and Bidding Procedure", "Administration of Contract Performance Procedure", "Inspection and Acceptance Procedure", and "Protest and Complaint Procedure, providing complete legal observation and opinion for Taiwan industry finally.

Keyword

Bid Invitation and Bidding Law of the Peoples Republic of China; Government Procurement Law of the Peoples Republic of China; Provisional Regulation on Bid Invitation and Bidding of Science and Technology Project; Applying for Science and Technology Project Regime; Bid Invitation and Bidding Procedure; Administration of Contract Performance Procedure; Inspection and Acceptance Procedure; Protest and Complaint Procedure.

3、**Comparing the Decisions of the United States Supreme Court regarding Preempting Marketing Medical Devices and Drugs from State Tort Litigations with the Decision of a Hypothetical Case in Taiwan**

The investment costs of complying with pertinent laws and regulations for manufacturing, marketing, and profiting from drugs and medical devices (abbreviated as MD) are far higher than the costs necessary for securing a market permit. The usage of MD products contains the risk of harming their users or the patients, who might sue the manufacturer for damages in the court based on tort law. To help reduce the risk of such litigation, the industry should be aware of the laws governing the state tort litigations and the preemption doctrine of the federal laws of the United States. This article collected four critical decisions by the United States Supreme Court to analyze the requirements of federal preemption from the state tort litigations in these cases. The article also analyzed the issues of preemption in our law system in a hypothetical case. These issues include the competing regulatory requirements of the laws and regulations on the drugs and MDs and the Drug Injury Relief Act versus the Civil Code and the Consumer Protection Law.

The article concluded: 1. The pre-market-approval of MD in the United States is exempted from the state tort litigations; 2. Brand-name-drug manufacturers must proactively update the drug label regarding severe risks evidenced by the latest findings; 3. Generic-drug manufacturers are exempted from the product liability litigations and not required to comply with the aforementioned brand-name-drug manufacturers' obligation; 4. No preemption issues are involved in these kinds of product liability litigations in our country; 5. The judge of general court is not bound by the approval of marketing of drug and MD; 6. The judge of general court is not bound by the determination and verdict of the Drug Injury Relief Act.

4、**Through Computer-Aided Detection Software, Comparing by Discussing and Analyzing the Regulatory Requirements for Marketing Medical Devices in the United States and in Taiwan**

Computer-Aided Detection (CADe) software systematically assists medical doctors to detect suspicious diseased site(s) inside patients' bodies, and it would help patients receive proper medical treatments as soon as possible. Only few of this type of medical device (MD) have been legally marketed either in the United States of America (USA) or in Taiwan. This is a novel MD, and the rules regulating it are still under development. Thus, it is valuable to investigate and discuss its regulations. To clarify the requirements of legally marketing the MD, this article not only collects and summarizes the latest draft guidance announced by the USA, but also compares and analyzes the similarities and differences between USA and Taiwan, and further explains the logics that USA applies to clarify and qualify CADe for marketing, so that the Department of Health (DOH) in Taiwan could use them as references. Meanwhile, the article collects the related requirements by the Administrative Procedure Act and by the Freedom of Government Information Law of our nation, and makes the following suggestions on MD regulations to the DOH: creating product code in the system of categorization, providing clearer definition of classification, and actively announcing the (abbreviated) marketing route that secures legal permission for each individual product.

5、**A Discussion on the Recent Cases Concerning the Joint Infringement of Method/Process Patents in the U.S. and Japan**

In the era of internet and mobile communication, practices of a method patent concerning innovative service might often involve several entities, and sometimes the method patent can only be infringed jointly. Joint infringement of method/process patents is an issue needed to be addressed by patent law, since it is assumed that a method patent can only be directly infringed by one entity to perform all the steps disclosed in the patent. In the U.S., CAFC has established the "control or direction" standard to address the issue, but the standard has been criticized and it is under revision now.

In Japan, there is no clearly-established standard to address the issue of joint infringement, but it seems that the entity that controls and benefits from the joint infringement might be held liable. Based on its discussion about the recent development in the U.S. and Japan, this article attempts to provide some suggestions for inventors of innovative service models to use patents to protect their inventions properly: they should try to avoid describing their inventions in the way of being practiced by multi-entities, they should try to claim both method and system/apparatus inventions, and they should try to predict the potential infringement of their patents in order to address the problem of how to prove the infringement.

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