Fantastic Drugs: The Curse Of Patent Cliff IP

Experts discuss the latest regulations for the pharmaceutical industry with **Johnny Chan**, as well as sharing tips on how to protect companies' patent portfolios, particularly during times when their drugs are about to fall off the patent cliff.

Change is coming to the pharmaceutical industry.

The United States is the traditional choice of territory for the pharmaceutical and biotech industries, while China has been working hard to establish itself as the emerging territory of choice. "China has done many things to encourage and make itself attractive for the industry, from incubators in different cities, to ample capital investments, to new laws and regulations," says Ethan Ma, a partner at Orrick, Herrington & Sutcliffe in Shanghai. "For example, in May 2017, the China Food and Drug Administration, which integrated into State Administration for Market Regulation in 2018, published four draft regulations for public comments to encourage innovation in medicines and medical devices. The four regulations are still in the process of formulation and have not been formally adopted yet, but they will lead to a comprehensive reform on clinical trial management of medicines and medical devices, examination and approval of the listing, drug innovation and development of generic drugs, life cycle management, and technical support in a long term."

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Ma says that the proposed policies include:

(Circular 52) Relevant Policies on Accelerating Evaluation and Approval for the Marketing Authorization of New Drugs and Medical Devices to Encourage Innovation in Drugs and Medical Devices. Circular 52 encourages innovation through reform of the new drug and device approval processes, Ma says. "It proposes to accelerate approval for drugs and medical device meeting urgent clinical needs; to encourage development of new

drugs and medical devices for orphan diseases; and to grant priority review to drugs and devices which are developed under a compulsory license."

(Circular 53) Relevant Policies on Reforming the Administration of Clinical Trials to Encourage Innovation in Drugs and Medical Devices. Circular 53 proposes a new approach to clinical development with greater flexibility to encourage innovation. The circular also proposes l to take a clearer position on the acceptance of foreign data, he says. "Under the proposed policies, if the clinical data generated in an overseas clinical trial satisfies the requirements to register the drug or medical device in China, those data can be used to support a market authorization application in China, after there has been an onsite inspection."

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(Circular 54) Relevant Policies on Implementing Drug and Medical Device Lifecycle Management to Encourage Innovation in Drugs and Medical Devices. Circular 54 mainly proposes to reform post-marketing surveillance, drug promotion and clinical trial sample testing, Ma says.

(Circular 55) Relevant Policies on Protecting Innovator Interests to Encourage Drug and Medical Device Innovation. To further protect drug innovators' rights, Circular 55 proposes to establish a patent linkage system and refine regulatory data protection for drugs, says Ma.

In October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices, Ma says. "The regulation aims to meet the clinical need of the general public and to promote structural adjustment and technology innovation in the Chinese drug and medical device industries."

Being relatively wealthy with one of the fastest growing aging populations in the world, Taiwan is another jurisdiction that provides a good opportunity for the pharmaceutical or biotech industry, says Ruey-Sen Tsai, a partner at Lee and Li in Taipei. "Similar to China, Taiwan has introduced several pharmaceutical IP-friendly legal amendments in the past few years, such as patent linkage and data exclusivity."

How to Stay Away from the Patent Cliff

For many years, the pharmaceutical industry has been diversifying strategies to combat the effects of the patent cliff.

The term "patent cliff" generally refers to the phenomenon of patent expiration leading to an abrupt drop in sales for products that capture a high percentage of a market. "In the pharmaceutical industry, falling off the patent cliff can translate into an enormous sales drop for major manufacturers due to the entry into the market of biosimilars and generics," says Tran Le Luu Phuong, an associate at Gateway Law Corporation in Singapore. According to estimates by Evaluate, a provider of commercial intelligence for the pharmaceutical and medical device industries, US$251 billion in sales are at risk as a result of patent expirations between 2018 and 2024.

To combat the effects of the patent cliff, pharmaceutical giants have traditionally attempted to replace their blockbuster drugs with new drugs from their research pipeline to offset the impending decline in sales, Tran says. "With rising R&D expenditures, however, some companies have also acquired smaller biotech companies to complement their research capabilities."

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> *- Lin Li Lee, partner, Tay & Partners, Kuala Lumpur*

On the legal front, the pharmaceutical industry has adopted the strategy of filing multiple patents – patent clusters – to protect different features other than the main active drug ingredient,

she says. “In the same vein, drug companies have also sought to avoid competition by adopting product-related innovation strategies including for example product-line extensions (i.e., introducing variations to the existing products) and indication extensions (i.e., identifying new ways of application of an existing product).”

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>
> *- Jing Xian Lim, associate, Tay & Partners, Kuala Lumpur*

Another strategy to extend market exclusivity is through obtaining supplementary protection certificates. “SPCs are an additional protective mechanism introduced by the European Union to ‘compensate’ the patent owners for the efforts put into R&D and the time lost between patent filing and obtaining authorization to enter the products into the market,” she says. In addition, pharmaceutical companies in the US may seek to extend market exclusivity by way of paediatric exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act.

“Although more controversial, some drug companies have also sought to combat competition from biosimilars and generics by negotiating exclusive contracts with payers and hospitals. The contracts often offer significant discounts and rebates to entice the latter to continue administering the former’s products,” she says.

All in all, more often than not pharmaceutical companies employ multi-pronged strategies in an attempt to extend the market exclusivity of their products, she says. “How the strategies are devised and implemented in turn depends on a multitude of factors, including, for example, the companies’ R&D and financial capabilities, as well as the dynamics of the generics market and the competition that the generics manufacturers pose.”

Pharmaceutical companies in other parts of Asia implement similar strategies to avoid the patent cliff.

One of the most common strategies to prolong the life span of patented drugs is through a technique known as “product hopping” or “evergreening,” says Lin Li Lee, a partner at Tay & Partners in Kuala Lumpur. “Drug makers would produce ‘new’ drugs, which may have modified dosage forms or pharmaceutical formulations, which often may not have therapeutic functions. This ordinarily inordinately delays the entry of generic products with similar active ingredients into the market.”

There are also instances where patentee pharmaceutical companies grant licenses to generic companies to manufacture and supply generic drugs by sharing the originating product specifications and formulations with the generic companies when the drug patent is near its shelf life. In return, the generic companies pay royalties to the patentee pharmaceutical companies, says Lee.

Mergers and acquisitions of pharmaceutical companies have also been one of the strategies to combat the inexorable pressure from patent cliff, she says. “Apart from diversifying the research and development process of pharmaceutical products and risk portfolios of the patentee pharmaceutical companies, this would also help expand their geographic market area in the pharmaceutical and biotechnology industry.”

When pharmaceutical companies are involved in drug patent disputes, an effective strategy for settlement between the patentee and the generic company is a “pay-for-delay” arrangement whereby the generic company agrees to keep their generic version of product off the market for a specific period of time in exchange for some benefits from the patentee, says Jing Xian Lim, an associate at Tay & Partners.

Other strategies include prolonging the active period of drugs in the body of the patient after administration, narrowing the price gap between original and generic drugs, building rapport with medical practitioners and marketing tools such as introducing new packaging, and tying and bundling of services, Lim says. “Although these strategies may assist to offset generic competition, some may be construed as being anti-competitive and prejudicial to public interest.”

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To combat the effects of the patent cliff, some pharmaceutical businesses in Taiwan have taken steps to create more extensive branding and trademark and trade dress schemes, Tsai says. "For example, the image of the brand Viagra is so strong in patients' minds that it still retains its market share after the loss of patent protection," he said.

Choosing the right proprietary name and design for a pioneer product can be crucial in maintaining its competitive advantage. "Creating market differentiation such as introducing new delivery systems or packaging also raises awareness of consumers," he says. "The other approach for brand-name firms to cope with the patent cliff is to introduce their own generic version of the products. For example, Sandoz, the generic arm of Novartis, has proven to be a success."

Lower-priced generic drugs will join the game and create competition in the marketplace after the patent expiration, he says. "However, this doesn't mean that the original brand-name drugs will lose their edge completely. In markets such as Taiwan, studies have shown that plenty of patients and medical personnel in hospitals still have a preference for the brand-name drugs even when cheaper generic alternative exists."

Even though the entry of generic drug manufacturers will alter the competitive landscape, the flip side is that the general public will have access to affordable medicine, he adds.

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Incubating Drug Patents

According to our experts, the pharmaceutical industry finds it very difficult to build and monetize a patent portfolio to replicate the success of IP in the technology sector.

Building and monetizing a patent portfolio for the pharmaceutical sector is very different from the doing the same in the technology sector (particularly the telecommunications sector), Tsai says. "For example, standard essential patents are generally not found in the pharmaceutical sector."

Due to the long journey from R&D to commercialization – and fewer breakthrough innovations in recent years – patent decisions in the pharma industry should be strategic, he adds. "Choosing the right alliance and licensing partners in different drug development stages is especially important."

Malaysia is considered to be an extremely diverse country and accordingly has a flourishing biotechnology industry where private companies work in partnership with universities to develop their inventions. "Typically, the company provides the initial technology, and the university provides test data to validate the technology. A patent may be filed jointly to cover both the technology and the data, often with the company funding the IP but having the rights to commercialize the same while under the protection of the patent," says Chris Hemingway, director at Marks & Clerk in Kuala Lumpur. "The patent portfolio can thus be successfully monetized through sales of patented products and/or licences to the patented technology." AIP