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New rules in Taiwan pharma to enact patent linkage

By Roger Chang, Lee and Li

In Taiwan, brand names are entitled to patent term extension and five-year data exclusivity, while generics have the benefit of abbreviated new drug applications (ANDA) and experimental exemptions. But Taiwan provides nothing like the US patent linkage or the European 11-year data exclusivity to the pharma industry.

The current regime has long been criticized as providing insufficient protection to an industry that requires tremendous risk and capital investment. After efforts spanning a decade, however, our congress has finally passed a bill on patent linkage, titled the Pharmaceutical Affairs Act.

Patent linkage bill passed

Passed by Taiwan's congress on 29 December 2017, the Pharmaceutical Affairs Act establishes a patent linkage mechanism in the pharma industry. It was promulgated by our president on 31 January 2018, and is expected to take effect around early 2019.

Brand name firms' role

Under the new law, an NDA holder bears a legal obligation to list patents relevant to its drugs.

Listable patents include those covering a substance (compound, salt, ester, isomer, polymorph), composition or formulation, and medical use. Claims are required to be identified for medical use patents, but in general only patent numbers need be specified in such lists.

NDA holders need to list patents relevant to drugs under current market approval within three months after the new law takes effect. For market approval obtained after the effective date of the new law, NDA holders have to list relevant patents within 45 days upon receipt of the market approval. The Taiwanese Food and Drug Administration (TFDA) is establishing an IT system for handling future patent listings. Patent listings will be executed online and be publicly accessible.

The legal rule in judging whether a patent can be listed refers to the logic of patent infringement assessment. Those which would be infringed by a brand name firm's own drugs are entitled to be listed. The more patents that are listed, the better the chance of NDA holders stopping generics from entering into the market, and for a longer duration. But discretion will be necessary as liability for patent misuse could be triggered by wrongful listing of patents.

The TFDA's role

Based on lessons learned from the Korea experience, our TFDA would not make any substantial judgment or conduct examination of NDA holders' patent listings. A formality check would be done by the TFDA, but the relevancy between listed patents and brand name drugs would not be reviewed.

Anyone, including but not limited to generics, may file opposing comments against NDA holders' listing decision for the purpose of delisting the listed patents. The TFDA will forward the opposing comments to the NDA holders and let them make their own decision on whether to delist the patents. NDA holders and generics will need to bring any disputes to court for resolution.

ANDA filers' role

When applying for generic market approval, an ANDA filer needs to declare one of four scenarios: (1) no listed patents; (2) the listed patents have expired; (3) a generic market approval is being sought until all

the listed patents have expired; or (4) the listed patents are invalid or not infringed.

Scenarios one to three (also referred to as paragraphs one to three) are straightforward. But declaring paragraph four triggers the most significant part of the mechanism, i.e., linkage litigation and a 12-month stay period against generic drugs.

An ANDA filer who chooses to declare paragraph four needs to inform the NDA holder, the patentee, and the TFDA in writing, with reasoning and evidence to support the arguments for patent invalidation or non-infringement. If the patentee files a patent infringement suit against the ANDA filer with the Intellectual Property Court within 45 days, the TFDA will stay issuance of the generic market approval to the ANDA filer for 12 months.

The impact

The TFDA, Fair Trade Commission and National Health Insurance Administration are preparing enforcement rules and detailed plans for executing patent linkage. More details will be released in the coming months.

It is arguable whether patent linkage can really help brand name firms to strengthen their IP protection, especially when the stay period is merely for 12 months. Nevertheless, patent holders now have more options in forming their patent and business strategy to protect their innovations in Taiwan.

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