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Intellectual Property, Taiwan
Important aspects of forthcoming patent linkage system regulations

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Introduction

On 11 September 2018 the Taiwan Food and Drug Administration (TFDA) published a draft version of the new regulations on patent linkage titled "The Enforcement Rules for Patent Linkage" for public comment.

The provisions relating to Taiwan's new patent linkage system were set out in the Pharmaceutical Affairs

Act, passed on 27 December 2017 and promulgated by the president on 31 January 2018.

An analysis of the new regulations, which set out how patent linkage will be implemented in Taiwan, reveals several aspects that will have a significant impact on patent linkage operations in the region.

Patent linkage regulations

Biological patents and biosimilar products

The first and arguably most important aspect relates to biological patents and biosimilar products. Biological patents will be classified as 'new drugs' and therefore eligible for listing in the new system as long as they are not process patents. However, under the existing regulations, even after biological new drug application (NDA) holders have listed their patents, applicants seeking biosimilar marketing approval may not need to make a declaration under Paragraph IV and the marketing approval applications may not need to be stayed for one year because the patent linkage legislation does not define biosimilar products as 'generics'.

Patent listing eligibility

Patents which claim different polymorphs of a medicinal ingredient will be eligible for listing. The definition of 'polymorph' in one of the drafts provided to local industry clearly covered different crystalline, amorphous, hydrated and solvated forms of approved medicinal ingredients. However, the new regulations define 'substance' as "the active ingredient of a drug preparation", without providing further details. Whether different polymorphs of a medicinal ingredient will be eligible for listing thus remains unclear.

Patent listing methodology

The new regulations confirm that patent listings will need to be made via the TFDA's online database. As filing will be performed entirely electronically, written submissions will not be necessary.

Implementation

According to Article 16 of the Matters Requiring Attention in the Legal Operations of the Central Administrative Agency, regulations which apply to new laws must be implemented within six months of the law being passed; an extension of no more than six months may be requested). The new patent linkage regulations are therefore expected to be implemented in early 2019.

Patents covering marketing approvals obtained before the implementation date may be listed within three months of the patent linkage system taking effect. However, as NDA holders might struggle to complete all of the patent listings for existing drugs within this timeframe, the three-month window could be amended. NDA holders will likely require additional time to complete patent listings for generics,

while abbreviated new drug applications would not be stayed until the patent listings have been completed.

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