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Addressing The Gaps Of Patent Linkage In Malaysia With Alternative Measures

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Patent linkage refers to a system which seeks to link up patent protection for marketed pharmaceuticals to approval processes for drugs yet to be sold in the market. Its purpose is to prevent any marketing approval to be granted to generic drugs until after the relevant patents for its pharmaceutical counterpart have expired.

Many countries including Australia, Mexico, Singapore, China, Chile, Peru, Bahrain, and Oman have a patent linkage system or an equivalent in place. However, Malaysia does not have an effective patent linkage system in place. This is notwithstanding that Malaysia is a signatory to the Trans-Pacific Partnership Agreement which requires signatories to have a patent linkage system in place.

As a consequence, many generic drugs may be approved for sale by the National Pharmaceutical Regulatory Agency (NPRA) or the Drug Control Authority (DCA) notwithstanding that the said generic drugs may or may not infringe patents that are still in force, such as the case of *Merck Sharp & Dohme Corp. & Anor v Hovid Bhd 2017 MLJU 77*.

This alert explores possible measures available to pharmaceutical companies to address issues arising from the lack of patent linkage system in Malaysia.

Understanding The Regulatory Powers Of NPRA

NPRA's and DCA's powers to regulate the sale of medicines and drugs are exercised pursuant to the following laws, among others:

- Sale of Drugs Act 1952
- Dangerous Drugs Act 1952
- Poisons Act 1952
- Medicines (Advertisement and Sale) Act 1956
- Control of Drugs and Cosmetic Regulations 1984

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For example, DCA is established pursuant to Control of Drugs and Cosmetic Regulations 1984 whereby under Regulation 7, no person shall manufacture, sell, supply, import or possess or administer any product unless the said product is a registered product, and the person holds the appropriate license issued under the regulations.

Although there is no patent linkage system enforced by NPRA and the DCA, an obligation is imposed on the applicants to declare in its application that the drugs intended to be sold do not infringe any patent and/or intellectual property rights of 3rd parties.

Addressing The Gap – Judicial Review

It must be noted that NPRA and DCA are creatures of statute and their powers are statutory in origin. Therefore, just like any other public body, the exercise of its powers must be reasonable and their decision making authority is subjected to the principles of reasonableness in *Associated Provincial Picture Houses Ltd v Wednesbury Corporation*.

Assuming there is sufficient information brought by pharmaceutical companies to the attention of NPRA and DCA on the potential infringement of the drugs intended for sale- the question arises as to whether NPRA or DCA would be obliged to reject the application for marketing approval, or at least withhold approval until the question of infringement is properly resolved through a civil action filed in Court?

In *Ranbaxy (M) Sdn Bhd v EI Du Pont Nemours and Co [2011] MLJU 1135*, the High Court had held that in considering applications for drug registration, the National Pharmaceutical Control Bureau (as NPRA was known then) does not concern itself with any patent protection aspects of the drug.

It is also clear that under the laws governing the powers of NPRA and DCA, there is no provision which imposed a duty upon NPRA and the DCA to process applications for registration and/or marketing approval based on intellectual property considerations.

Therefore, it may be difficult to argue that NPRA and DCA are obliged to safeguard patent rights of pharmaceutical companies even in situations where evidence of infringement is available to NPRA and DCA. However, such a decision could be subjected to judicial review by the pharmaceutical companies whose intellectual property rights are infringed**.** Therefore, one may argue that NPRA and DCA ought to at least, withhold approval of the application for registration pending the final resolution of the question of infringement either by way of civil action in Court and/or arbitration. This is because the act of approving drugs in the face of evidence of infringement may amount to a decision on the part of NPRA and DCA which may be subjected to judicial review.

Conclusion

In the absence of a patent linkage system in Malaysia, the onus falls upon the shoulders of pharmaceutical companies to be proactive and adopt a monitoring system to ensure that generic drugs that are seeking for marketing approval do not infringe existing patents.

There should be more dialogues between various stakeholders of the industry and the government so that a more effective patent protection system can be established to balance public health concerns and commercial considerations for pharmaceutical companies.

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