TAY & PARTNERS

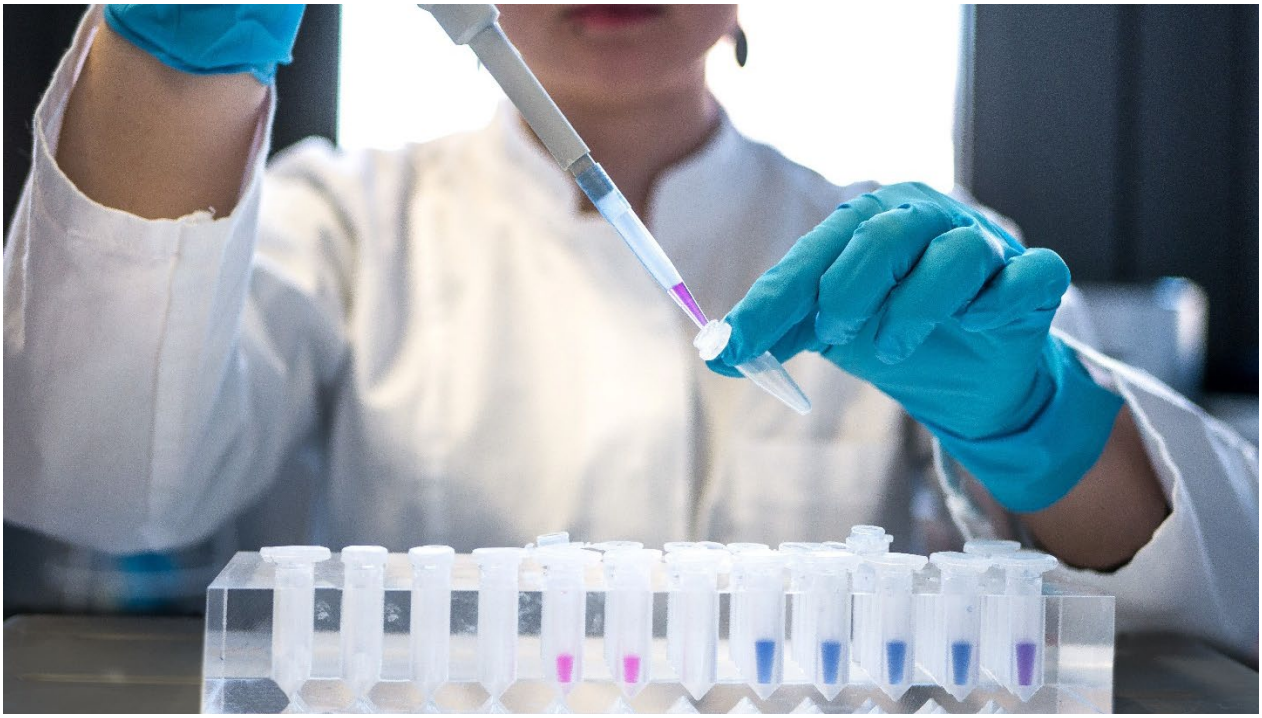
Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states:

> *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."*

Although there is no explicit mention of data exclusivity (**DE**), Article 39.3 is commonly perceived to be the source of protection extended to pre-existing data generated from big-budget clinical trials and research by innovator companies. DE protects against any commercial use by a third party, usually a company seeking to establish bioequivalence of generic drugs or biosimilars by referencing clinical data of medicinal products to obtain marketing approvals for generics or biosimilars. Under the DE mechanism, these companies may only submit their application which relies on the clinical data generated by innovator companies after the DE period expires.

The DE mechanism is intended and thought to serve as an incentive that encourages development of new drug therapies in a heavily invested research-based industry. It delays generic and biosimilar entries into the market. This allows innovator companies to recoup their often blockbuster investment in drug research and development.

DE is a distinct form of intellectual property right which does not necessarily run concurrent with a patent protection term. Its protection stems from the same idea that another may not gain from it during the period of its exclusivity. In some cases, the DE period may even extend beyond the patent term. Notably, eligibility for DE is not subject to patentability requirements such as novelty and inventive step. Hence, DE presents an attractive and viable panacea for pharmaceuticals which cannot get across the patentability line.



DE in Malaysia

In Malaysia, DE took shape in the form of the Directive on Data Exclusivity (Directive No. 2 of 2011)[1] (**DE Directive**) issued by the Director of Pharmaceutical Services under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984. It came into force on 1 March 2011.

DE protection in Malaysia only extends to cover new drug products containing a new chemical entity (**NCE**)[2] and a second indication of a registered drug product[3].

The DE Directive seeks to protect undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves considerable effort. Such test data must be submitted to the Director of Pharmaceutical Services for purposes of scientific assessment for the registration of any new drug product containing a NCE or approval of a second indication of a registered drug product.

As of 10 March 2021, DE has been granted for 88 new drug products containing a NCE[4] and as of 7 September 2020, DE has been granted for 19 second indication of a registered drug product[5] in Malaysia.

---

[1] Directive on Data Exclusivity (Directive No. 2 of 2011) may be retrieved from https://www.npra.gov.my/images/Circulars_Directive/Regulatory_Information/page-10/DIREKTIF_DE-1.pdf.

[2] Means a product that contains an active moiety that has not been registered in accordance with the provisions of the Control of Drugs and Cosmetics Regulations 1984.

[3] Means a single or cluster of therapeutic indications applied subsequent to the first indication approved at the point of registration of the product.

[4] Register of Data Exclusivity Granted in Malaysia (New Drug Product) may be retrieved from https://www.npra.gov.my/images/2019/12/NCE/DE_Table_Update_10-03-2021.pdf.

[5] Register of Data Exclusivity Granted in Malaysia (Second Indication of Registered Drug Product) may be retrieved from https://www.npra.gov.my/images/2019/12/NCE/DE_AI_Table_Update_for_PPO_07-09-2020.pdf.

Fun Facts

	New Drug Product Containing NCE	Second Indication of Registered Drug Product
When to apply?	Within **eighteen months** from the date the product is first registered and granted marketing authorization and granted DE / Test Data Protection in the country of origin or in any country, recognised and deemed appropriate by the Director of Pharmaceutical Services.	Within **twelve months** from the date the second indication is approved and granted DE / Test Data Protection in the country of origin or in any country, recognised and deemed appropriate by the Director of Pharmaceutical Services.
How long is it valid for?	Not more than **five years**.	Not more than **three years**. ***Note**: The period of DE is for data concerning the second indication only.*
When does protection begin?	The date the product is first registered or granted marketing authorization and granted DE / Test Data Protection in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.	The date the second indication is first approved and granted DE / Test Data Protection in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.

Exclusive, but not so Exclusive

DE does not extend to cases where compulsory licenses have been issued, nor would it prevent the Government from taking any necessary action to protect public health or national security, or to allow non-commercial public use, or during a national emergency or public health crisis, or any other urgent circumstances as may be declared by the Government.

DE Process

DE is not automatically conferred on or made available to a product owner. An application for DE for a new drug product or a second indication of a registered drug product must be made via a letter of intent. The letter of intent is to be addressed to the Director of Pharmaceutical Services.

Any person aggrieved by the decision of the Director of Pharmaceutical Services may lodge a written appeal to the Minister within fourteen days from the date the decision is conveyed to him and any decision of the Minister made on the appeal is final.

A person making the appeal may submit any supporting data or documents to the Director of Pharmaceutical Services within 120 days for an application of a new drug product containing a NCE, or within 90 days for an application for a second indication of a registered drug product.

Postscript

Although DE protection is at least a decade old now in Malaysia, its implementation has not been uncontroversial among stakeholders. For instance, commencement of the DE period in Malaysia begins from the approval date outside Malaysia instead of the local grant date. This is perceived as insensible and limiting as the potential benefits the innovator company would stand to reap during the gap period would be loss. For efficacious DE protection, the practice in other jurisdictions such as Singapore, Australia, the United States of America and the European Union where DE protection period begins from the local grant date is food for thought.

While some advocates say that DE is crucial to the promotion of innovation in the pharmaceutical industry, others have contended that there is no evidence that stronger intellectual property protection has encouraged innovation of new drug therapies[6].

Unlike a patent, DE is not subject to a legal challenge in court. Policy makers should be mindful that DE does not confer excessive monopolistic rights on innovator companies, particularly so as the rights conferred ought to be carefully balanced against access to affordable medicines and public healthcare.

LEE LIN LI
Partner, Head of IP & Technology Practice Group.

For further information and advise on this article and/or on any areas of IP & Technology, please contact:
linli.lee@taypartners.com.my

LIM JING XIAN
Associate
jingxian.lim@taypartners.com.my

[6] Fifa Rahman & Fran Quigley, "The illusion of a 'golden balance': Access to medicines and the TPP", 29 September 2015, https://www.malaymail.com/news/what-you-think/2015/09/29/the-illusion-of-a-golden-balance-access-to-medicines-and-the-tpp-fifa-rahma/978703#sthash.YckPjo2Z.dpuf.