

## **The Budapest Treaty in Malaysia and New Directives**

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On 31 March 2022, Malaysia deposited the instrument of ratification at the World Intellectual Property Organization (WIPO) Headquarters in Geneva and officially acceded to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. This brings the total number of contracting parties of the Budapest Treaty to 86 (as of 15 July 2022). Following the deposit, the related provisions in the Patents (Amendment) Act 2022 i.e., Sections 26C and Subsection 78O(1A) came into force on 30 June 2022.

Following the enforcement, patent applicants will now only be required to store a sample of a microorganism in one International Depository Authority (IDA) only instead of multiple national deposits to meet disclosure requirements, avoiding repetition of retention procedures. All member countries of the Treaty recognize a deposit made in any IDA which will be treated as sufficient for patent purposes. Dialogue between the Government and local research institutes and universities on the formation of an IDA has been ongoing and selection of an existing facility hosted at a local research institute or university for approval as an IDA by WIPO is expected.

Previously, the Malaysian IP Office required applicants to execute a Statutory Declaration confirming that they will either furnish a sample of the material to any person requesting a sample or if a deposit has been made, to provide the requestor with a Declaration authorizing the authority to furnish the requestor with a sample. This practice is no longer applicable with the coming into force of the Budapest Treaty provisions. Instead, details of any deposits made under the Treaty such as the name and address of the IDA, date of deposit and accession number must be provided to the Malaysian IP Office either at the time of filing the patent or utility innovation application, within 16 months of the filing date or priority date whichever is earlier or before a request for early publication. The characteristics of the microorganism deposited must be described in the specification filed with the application.

Aside from the enforcement of the Budapest Treaty provisions in the Patents (Amendment) Act 2022, new directives and amendments to the Patents (Amendment) Regulations 2022 were also announced by the Malaysian IP Office.

The first is under the Patents (Amendment) (No. 2) Regulations 2022, which relates to the submission of third-party observations for PCT-derived national phase applications. For national phase applications filed before the PCT publication, the deadline for formal observations is now three months from the PCT publication date. For national phase applications filed after PCT publication, the deadline for formal observations remains three months from national phase entry or reinstatement into the Malaysian national phase. The deadline for third-party observations for direct national applications remains unchanged at three months from publication in the IP Official Journal.

The second notable amendment to the Regulations concerns post-grant amendments. The Patents (Amendment) Act 2022 which came into force on 18 March 2022 introduced substantive post-grant amendments. When filing substantive amendments, the Malaysian IP Office may direct the patent owner to request for re-examination. Failure to comply will now result in deemed withdrawal of the request for amendment. Hence, in order to expedite matters, when filing any post-grant substantive amendments, patent owners may consider voluntarily requesting re-examination rather than awaiting a formal directive.

The Malaysian IP Office has also issued several directives on 30 June 2022. A raft of new official forms is now available incorporating matters relating to the deposition of microorganisms in view of the enforcement of the Budapest Treaty provisions. There is a grace period up to 31 July 2022 within which the old forms may still be used.

Another change that is of interest is the retroactive revocation of Circular No. 1/2016 which allows for the filing of voluntary amendments within 2 months of the first substantive examination report for applications receiving an allowance in the first substantive examination report. This is in view of the provision for substantive post-grant amendments in the Patents (Amendment) Act 2022.

Finally, beginning 30 June 2022, the format of submissions of sequence listings for any application having a filing date of 01 July 2022 (also known as the “big bang date”) or later must be submitted in WIPO Standard ST.26. This means that all applications filed thereafter disclosing amino acid and nucleotide sequences must contain an ST.26 XML compliant sequence listing. Any sequence listing furnished in respect of any applications filed before then should still comply with WIPO Standard ST.25, even if the sequence listing is submitted after 01 July 2022. It is important to note that the Patents (Amendment) Act 2022 indicates that submission of a sequence listing, if any, is a filing date requirement.

The Patents (Amendment) Act 2022 that came into force on 18 March 2022 had deferred the enforcement of provisions related to the Budapest Treaty, public availability of prosecution documents and post-grant opposition. Following enforcement of the Budapest Treaty provisions, the remaining deferred provisions are expected to come into force by March 2023.