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Malaysia to Implement Pharmaceutical Patent Linkage: What Patent Practitioners and Pharmaceutical Clients Need to Know

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Malaysia's National Pharmaceutical Regulatory Agency (NPRA) under the Ministry of Health has proposed the implementation of a formal patent linkage framework for pharmaceutical products. Driven by Malaysia's obligations under Article 18.53 of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), this administrative mechanism will formally tie the marketing authorization of generic drugs to the patent status of the corresponding New Drug Product (NDP). The proposed patent linkage framework seeks to balance regulatory efficiency with intellectual property protection while maintaining access to medicines.

For patent practitioners and pharmaceutical clients, whether local or foreign innovators looking to secure their market exclusivity or generic manufacturers planning market entry, understanding this framework is critical to navigating the regulatory landscape in Malaysia.

Key Takeaways

- Patent linkage is proposed to be implemented in Malaysia from 01 May 2027.
- Product Registration Holders of currently registered New Drug Products must update their patent information with the NPRA during the transitional period (01 July 2026 – 30 April 2027).
- Only Category 4 application activates the patent linkage mechanism i.e., an application by a generic applicant (not the patent owner / licensee) who believes the patent is invalid or will not be infringed or who intends to market the product before patent expiry.
- NPRA oversees regulatory approval, while Malaysian courts determine patent validity and infringement.
- The intersection of patent linkage with the new post-grant patent opposition system creates new strategic imperatives for both innovators and generics.

Critical Deadlines at a Glance

- **01 July 2026 – 30 April 2027:** Transitional period for updating existing active patent information with NPRA.
- **30 Days:** The strict window to notify NPRA of newly granted patents or changes in patent status via the E18 fields in the QUEST3+ system.
- **45 Days:** The notification window to commence legal proceedings upon receiving a Category 4 notice.

- **6 Months:** The strict, non-extendible window following a patent grant publication to initiate post-grant opposition.

Implementation Timeline

Date	Milestone
April 2026	NPRA released the Draft Guideline on the Implementation of Patent Linkage for Pharmaceutical Products in Malaysia.
01 July 2026 – 30 April 2027	A transitional period for Product Registration Holders of existing New Drug Products (PRH NDPs) to update their active patent information through the variation process.
01 May 2027	Proposed full implementation of the patent linkage framework for all applicable pharmaceutical product registration applications.

What is Patent Linkage?

Patent linkage is a regulatory mechanism that links the approval of pharmaceutical products by NPRA with the patent status of the corresponding new drug product. Under the proposed patent linkage framework, the marketing approval processes and patent dispute processes become procedurally linked. However, NPRA will continue to maintain regulatory neutrality and will not determine patent validity or infringement.

CURRENT SYSTEM	PROPOSED PATENT LINKAGE
NPRA assesses quality, safety, and efficacy.	NPRA also considers patent-related declarations as part of the approval process.
Patent disputes occur independently.	Patent disputes become linked to the regulatory approval process.
General approval may proceed regardless of patent disputes.	Marketing approval may be affected by ongoing patent litigation or declarations.
Patent owners generally learn of generics through other means.	Patent owners receive formal notice of relevant generic applications

Which Patents are Covered by the Proposed Framework?

The Malaysian patent linkage framework is designed with distinct boundaries, to balance the rigorous intellectual property protections demanded by the CPTPP with domestic public health imperatives and the need for access to affordable medicines.

The system applies broadly to all pharmaceutical product registration applications intended for human use. Crucially, this mechanism applies to products originating from all countries and is not limited to pharmaceutical products originating from CPTPP member states. The patent linkage mechanism will also apply to registration applications for "For Export Only" (FEO) products manufactured within Malaysia.

However, there are exclusions to the system. Most notably, biologics—including biopharmaceuticals, biological products derived from living organisms, cell and gene therapy

products (CGTPs), advanced therapies, and vaccines—are entirely and explicitly excluded from the patent linkage mechanism.

Furthermore, not all patents associated with a pharmaceutical product will trigger the linkage system. The NPRA mechanism strictly recognizes only the following two categories of eligible patents.

Product Patents: Patents explicitly claiming the active pharmaceutical ingredient (API), the specific formulation, polymorphs, salts, esters, the dosage form, or the dosing regimen. (Note: Polymorphs, salts, esters, dosage forms, and dosing regimens are only eligible if they are claimed as actual product patents, not merely process patents.)

Method of Use Patents: Patents explicitly claiming the approved medical use or therapeutic indication of the registered New Drug Product (NDP).

Conversely, patents that cover only the manufacturing process of the drug, or patents covering the physical packaging of the product, are expressly excluded and cannot be declared or asserted within the NPRA patent linkage system.

Updating Patent Information via QUEST3+

The operational backbone of the Malaysian patent linkage system is NPRA's online regulatory submission platform, known as QUEST3+.

Under the patent linkage system guidelines, the QUEST3+ interface has been significantly modified, specifically within the "E18 – Patent Protection" fields, to require PRH NDPs to declare relevant patent information relating to the NDP. PRH NDPs are required to complete the relevant E18 fields and to provide the prescribed patent information in accordance with the patent linkage requirements.

E18 – Product Under Patent Protection: The PRH NDP must indicate "Yes" if the corresponding NDP is protected by a patent granted by MyIPO, or "No" if no patent exists or if a patent application has been filed but is still undergoing examination.

E18.1 – Patent Information: If "Yes" is selected, the PRH NDP must provide exhaustive details of all active patents associated with the NDP relating to the active substance or approved indication. This includes the exact patent title (matching MyIPO IP Online records), the patent grant number, grant date, expiry date, and the precise name and address of the patent owner and patent licensee.

E18.2 & E18.3 – Grant and Expiry Dates: The system restricts these fields to a single date entry. Where multiple relevant patents exist for an NDP, the PRH NDP is required to enter only the patent with the *latest* expiry date (the patent affording the longest period of protection) to define the maximum boundary of the linkage hold.

E18.4 – Supporting Documents: The PRH NDP must upload mandatory documentary evidence, including the standardized Declaration Form, and the actual patent specification obtained directly from MyIPO. Where applicable to generic applicants, proof of service of notices must also be submitted.

To ensure that the QUEST3+ database remains continuously accurate, PRH NDPs are required to submit the relevant regulatory variation application through the QUEST3+ system within thirty (30) calendar days of the date of grant of a new patent by MyIPO, or any change affecting the patent status of an existing registered pharmaceutical product. Failure to comply with the timeline may result in administrative action and could result in the NPRA failing to enforce a linkage suspension against an incoming generic.

Four Categories of Applications

When submitting a pharmaceutical product registration through NPRA's electronic QUEST3+ system, applicants must classify their application under one of the following four categories based on the patent status of the product.

Category	**Is there a patent in force in Malaysia for the product?**	**Applicant**	**Marketing Intentions / Implications**
1	No	Innovator / Generic	Standard regulatory evaluation and approval. No notification or waiting period applies.
2	Yes	Patent owner / licensee	Standard evaluation and approval. Applicant simply declares patent information.
3	Yes	Generic applicant (not the patent owner / licensee) who agrees not to market the product until patent expiry	Registration may be granted upon completion of the regulatory evaluation. However, the registered product must not be marketed until the relevant patent expires.
4	Yes	Generic applicant (not the patent owner / licensee) who believes the patent is invalid or will not be infringed or intends to market the product before patent expiry.	This triggers the proposed patent linkage mechanism, including notification to the patent owner and a potential suspension of NPRA's registration decision for up to 12 months if patent infringement proceedings are commenced.

What Happens Under a Category 4 Application?

When a Category 4 application is filed, the steps of which are listed in the table below, a 45-day notification period commences. If the patent holder initiates an infringement suit within this window, it triggers an automatic suspension on the generic drug's approval process for up to 12 months. This effectively acts as a "regulatory injunction", granting the patent holder immediate market protection without needing to meet the strict, often burdensome legal requirements necessary to obtain a preliminary injunction from a civil court.

STEP	**DESCRIPTION**
Generic Application Submitted	A generic applicant (PRH Generic) files a Category 4 application with NPRA, declaring whether (a) there is no relevant patent; (b) the patent has expired; (c) the relevant patent is invalid, or will not be infringed; or (d) the product is intended to be marketed before patent expiry.
Written Notice Served	The generic applicant serves written notice on the patent owner/licensee and the PRH of NDP. The recipients must acknowledge receipt within 7 days.
45-Day Notification Period	After the acknowledged notice and proof of service are submitted through the QUEST3+ system, NPRA commences a **45-calendar-day notification period**. During this period, NPRA continues evaluating the application but will not issue a registration decision.
Legal Proceedings (if any)	If the patent owner, patent licensee or PRH of the corresponding NDP initiates patent infringement proceedings before a Malaysian court within the 45-day notification period and notifies NPRA, the patent linkage mechanism is triggered, resulting in the suspension of NPRA's registration decision.
Up to 12-Month Suspension	Upon notification that legal proceedings have been commenced, NPRA suspends its registration decision for **up to 12 months**, unless the suspension ends earlier due to a court decision, settlement, withdrawal of the case, or patent expiry.
Regulatory Process Resumes	When the 12-month suspension period ends, NPRA resumes its regulatory assessment and proceeds with the registration decision, regardless of whether the court proceedings have concluded.

Exceptions to the Patent Linkage Mechanism

The entire patent linkage mechanism, including the 45-day notification and the 12-month Category 4 suspension, will be bypassed entirely and rendered non-applicable in several critical scenarios, as listed below.

- **Compulsory Licensing:** Where a compulsory license has been formally issued under the Patents Act 1983.
- **Government Use:** Where the rights of government use have been explicitly authorized under the Patents Act 1983 to protect public health and ensure access to medicines.
- **National Emergencies:** The system will not restrict the Government of Malaysia from taking any necessary action during a public health emergency, national security crisis, or other circumstances of extreme urgency.

Interplay with Post-Grant Opposition – Section 55A of Malaysia's Patents Act

Since a listed patent is highly visible in the NPRA database, generic companies may have a strong incentive to challenge patents early. Malaysia implemented a six-month post-grant opposition procedure for patents that came into force 31 December 2025. By meticulously monitoring the IP Official Journal (IPOJ) for newly granted patents, generic manufacturers may opt to file a formal Notice of Opposition within the six-month opposition term following the publication of grant.

The statutory window to file a post-grant opposition is exactly six months from publication of grant in the IPOJ, and this deadline is **strictly non-extendible**. If this window is missed, the administrative cancellation route before MyIPO will be permanently closed. To enter the market before patent expiry thereafter, the generic will need to contend with either proactively challenging the validity of a patent in Court or filing a Category 4 application, enduring a likely 12-month regulatory suspension, and defending an infringement suit in Court.

Key Responsibilities for Stakeholders

Innovator Companies (PRH NDP): Maintain patent records actively within the 30-day window. Respond promptly to Category 4 notices within the 45-day window. Prepare to vigorously defend newly granted patents against administrative oppositions.

Generic Companies (PRH Generic): Conduct rigorous patent due diligence before filing. Ensure accurate QUEST3+ declarations. Monitor the IPOJ carefully to utilize the 6-month post-grant opposition window.

Practical Implications for Patent Practitioners

Given the strict 30-day deadline to update QUEST3+ records, the legal and regulatory compliance teams of PRH NDPs should ensure that their local PRHs are alerted immediately upon patent grant.

For companies planning to launch generic products in Malaysia, product launch timelines should account for the 45-day notification period and the likely 12-month regulatory suspension if patent infringement proceedings are commenced.

Foreign patent practitioners are strongly advised to utilize patent watch services to monitor newly granted Malaysian patents. This supports timely patent updates for innovators and crucial patent risk assessments and opposition filings for generic clients.

Ultimately, for innovators, market exclusivity is no longer guaranteed simply by surviving patent prosecution. Originators must take a holistic lifecycle approach, pairing rapid IP declaration in QUEST3+ with readiness to defend against proactive administrative challenges.

Conclusion

Malaysia's proposed patent linkage framework represents a significant development in the country's pharmaceutical regulatory landscape. While this upcoming development will not alter Malaysia's substantive patent law, it introduces new procedural obligations that will require closer coordination between patent, regulatory and commercial teams of pharmaceutical companies.

Pharmaceutical companies and their advisers should familiarize themselves with the proposed framework and review internal procedures ahead of its anticipated implementation in May 2027.