

Intellectual Property Rights and Pharmaceutical Welfare in Selected Southeast Asian Countries

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ABSTRACT

This study examined how patent governance related to medicine affordability and access in Indonesia, Malaysia, Thailand, the Philippines, and Viet Nam. A comparative socio-legal policy design was used. Patent legislation and documented government-use practices were reviewed alongside 2023 health-financing indicators and country-specific evidence on medicine prices, availability, affordability, and procurement. The comparison showed that all five jurisdictions retained substantial public-health flexibilities, although activation conditions and evidence of use differed. Thailand had the clearest record of government-use licensing, while Indonesia and Malaysia also provided documented examples. Welfare patterns did not map neatly onto the formal legal profiles. Countries with similar statutory tools showed different levels of out-of-pocket spending, public health financing, and medicine-specific affordability. The findings indicated that legal flexibility became relevant to pharmaceutical welfare only when institutions could convert formal authority into supply, procurement leverage, regulatory readiness, and financial protection. Patent governance was therefore treated as one part of a broader institutional architecture rather than as a direct cause of medicine access outcomes.



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INTRODUCTION

Access to medicines becomes a welfare problem when treatment exists but remains beyond practical reach. Price is one part of that problem. Public purchasing, insurance coverage, medicine availability, and the amount paid directly by households also shape whether treatment can actually be obtained. Cameron et al. (2009) showed large differences in medicine prices and availability across developing and middle-income countries. Wirtz et al. (2017) later placed affordable essential medicines within the wider architecture of universal health coverage. The present study uses that narrower welfare concern rather than treating market authorization or physical presence as sufficient evidence of access. This distinction matters in health systems where a medicine can be legally marketed and stocked, yet still remain inaccessible to households outside a subsidized or insured channel.

Patent law matters because it can preserve a period in which lower-priced substitutes face legal constraints, yet the welfare effect of that protection is not uniform. Cockburn et al. (2016) found that stronger patent rights may support earlier launch of new drugs in some markets. Duggan et al. (2016) found substantial market effects from pharmaceutical product patents in India, while Chaudhuri et al. (2006) estimated sizeable consumer losses when generic substitutes were removed from the quinolone market. These findings make a simple pro-patent or anti-patent account difficult to sustain. The institutional setting around the patent matters as well.

The same caution applies to secondary patents and later claims. Amin and Kesselheim (2012) documented how additional patents could extend protection around important HIV medicines. Hemphill and Sampat (2012) linked patent challenges and later-filed claims to effective market life, and Kapczynski et al. (2012) showed how common secondary pharmaceutical claims had become. None of

those studies implies that every secondary patent is invalid or socially harmful. They do show why patent quality and the timing of generic entry remain relevant when access policy is assessed.

TRIPS does not require governments to treat exclusive rights as absolute. The Doha Declaration confirmed members' authority to protect public health through available flexibilities, including compulsory licensing. National law may also permit regulatory preparation before expiry and lawful parallel importation. Tenni et al. (2022) found that stronger monopoly rules were generally associated with higher prices or delayed access, while flexibilities could improve access in particular settings. A more recent review by Dunn et al. (2026) recorded continued use and attempted use of TRIPS flexibilities from 2001 to 2024, but also showed how unevenly these tools move from legal text into practice.

Indonesia, Malaysia, Thailand, the Philippines, and Viet Nam offer useful variation without pretending to represent Southeast Asia as a whole. All five are WTO members operating under the TRIPS baseline. Their patent laws contain public-health mechanisms, but their health-financing profiles and documented experience with government use or compulsory licensing differ. Medicine-price studies also reveal different patterns across public and private channels. The comparison is therefore purposive. It asks what can be learned when similar formal policy space is read beside different institutional settings, rather than treating the five cases as a regional sample from which population-level effects can be inferred. The cases also make it possible to compare legal authority that has been used for medicines with authority that is visible mainly in statutory design, which is central to the argument developed below.

Formal access-oriented patent rules matter only when public institutions can turn legal permission into a workable change in supply or purchasing. This capacity is described as institutional conversion capacity. Pharmaceutical welfare refers here to medicine availability, affordability, and financial protection rather than a composite score. Patent governance is examined beside those outcomes and the institutions surrounding them. The study does not estimate the welfare cost of exclusivity and does not infer causation from national spending data.

RESEARCH METHODS

This study uses a comparative socio-legal policy design covering Indonesia, Malaysia, Thailand, the Philippines, and Viet Nam. The cases were selected purposively to provide institutional variation within a shared TRIPS baseline, particularly in government-use experience, public purchasing, health financing, and the availability of medicine-access evidence. The design is intended for structured comparison rather than ASEAN-wide representation. It therefore does not assume that the five countries reproduce the full legal or welfare diversity of the region, and no national patent-strength or welfare ranking is constructed.

The legal analysis draws on patent legislation in force on 9 September 2026, checked against WIPO Lex and official national materials where available. Coding covers compulsory licensing and government use, regulatory-review exceptions, exhaustion or parallel-import rules, and patent opposition or comparable third-party scrutiny. Activation conditions are noted only where current law states them clearly. Practical use is recorded only when a reliable public or peer-reviewed source identifies an executed measure. Thailand's medicine licences between 2006 and 2008, Malaysia's government use of sofosbuvir in 2017, and Indonesia's government use for antiviral and antiretroviral medicines are treated in this way. The absence of a documented instance for another country is not treated as evidence that the legal power has never been used.

Welfare evidence combines comparable health-system indicators with country-specific medicine studies. The system-level measures are 2023 out-of-pocket expenditure, domestic general government health expenditure, the 2023 UHC service coverage index, and the latest available financial-hardship estimate, with its survey year reported because observations are asynchronous. These measures describe the financing environment and are not treated as pharmaceutical outcomes. Medicine-specific studies are included when they report prices, availability, affordability, procurement, or a closely related access measure with a clear sampling frame. Their findings remain within country because medicine baskets, years, sectors, and locations differ. No regression, numerical index, or causal counterfactual is used. Cross-country patterns are interpreted as institutional configurations, and the analysis does not attribute observed welfare differences to patent governance alone.

Table 1 Research and Measurement Architecture

<i>Domain</i>	<i>Observation</i>	<i>Source</i>	<i>Analytical use</i>
Patent governance	Compulsory licensing or government use in current law	WIPO Lex and official legislation	Formal capacity only
Generic-entry conditions	Regulatory review and exhaustion or parallel import	WIPO Lex and official legislation	Conditions relevant to supply
Patent scrutiny	Opposition or comparable third-party challenge	WIPO Lex and official legislation	Procedural capacity only
System financing	OOP, government health spending, and UHC coverage	WHO GHED through WDI and WHO-World Bank	Financing context
Medicine access	Country evidence on price, availability, affordability, or procurement	Peer-reviewed studies	Medicine-specific context
Implementation	Documented medicine-related government use or licensing	Official and peer-reviewed sources	Evidence of operational use

Note. No numerical index is constructed. System indicators provide context and medicine studies retain their own sampling limits.



Analytical association only. The framework does not specify a causal pathway.

Figure 1 Pharmaceutical Welfare Framework

RESULTS AND DISCUSSION

Formal policy space is broad in all five jurisdictions, although the legal routes are not identical. Indonesia's Patent Law, as amended by Law No. 65 of 2024, allows government patent use and retains pharmaceutical exceptions for lawful parallel importation and regulatory preparation before patent expiry. Article 167 is explicitly framed around reasonable prices and post-expiry availability. Malaysia's Patents Act 1983 provides compulsory licensing and government exploitation. The 2022 amendment added a post-grant opposition provision, but WIPO Lex records section 55A as not yet in force. WIPO Lex therefore supports treating the provision as enacted but not yet operational.

Thailand has the clearest record of executed public-health use among the five cases. Its Patent Act permits compulsory licensing and government use, and section 36 contains a regulatory-review exception for pharmaceuticals. Between 2006 and 2008 the government issued licences covering several medicines. Wibulpolprasert et al. (2011) traced the role of evidence, civil society, and political leadership. Mohara et al. (2012) estimated expenditure savings for seven medicines. Those findings concern a defined policy episode, not the general welfare effect of Thai patent law.

Indonesia also has practical experience that should not be hidden behind a simple law-on-the-books comparison. Presidential Regulation No. 76 of 2012 authorized government patent use for antiviral and antiretroviral medicines, following earlier measures for HIV treatment. That history shows that the formal power in Indonesian patent law is not merely theoretical. Even so, the present study does not link those measures to the 2023 financing indicators. The dates, products, and policy settings differ. Indonesia is used instead to show that a jurisdiction can combine a broad legal toolkit with medicine-access outcomes that are also shaped by national insurance, procurement, and generic-market policy.

Malaysia provides a second executed example with a different policy history. In 2017 the government used its statutory rights to obtain access to generic sofosbuvir after price negotiations and attempts to secure voluntary access had not produced an acceptable route. The Ministry of Health tied

the measure directly to hepatitis C treatment access. Later budget modelling examined how compulsory and voluntary licensing options affected the treatment program (Azzeri et al., 2023). This episode gives the Malaysian legal provisions practical meaning, yet it should not be generalized to all medicines. It was a disease-specific intervention connected to public procurement and government facilities.

Republic Act No. 9502 gives Philippine agencies broad public-health authority. Government use may be authorized where public interest requires it and where demand for patented medicines is not met on adequate and reasonable terms. The reform also broadened compulsory licensing and supported parallel importation and regulatory review. The present study does not rely on an executed medicine-specific case comparable to Thailand or Malaysia. Its assessment of the Philippines is therefore about statutory capacity, not proven implementation intensity.

Viet Nam also retains substantial formal room. Article 125 of the Intellectual Property Law limits the patent holder's right to prevent regulatory preparation and lawful circulation or importation of products already placed on the market. Articles 145 to 147 provide grounds and procedures for compulsory licensing, including public and non-commercial use, disease treatment, unmet working obligations, failed licensing negotiations, and anticompetitive conduct. Law No. 131/2025/QH15, effective from 1 April 2026, updated the wider industrial-property framework. Those provisions show legal capacity. They do not show how quickly agencies can assemble supply, procurement, and regulatory arrangements once the power is invoked.

The legal comparison does not produce a scale of stronger and weaker welfare protection. It identifies different routes through which governments may respond when patent-protected supply becomes an access problem. Thailand, Malaysia, and Indonesia provide documented medicine-related implementation. For the Philippines and Viet Nam, this comparison relies more heavily on statutory authority than on an executed medicine-specific episode. Formal availability and operational experience are therefore kept separate rather than treated as equivalent evidence.

Table 2 Comparative Patent Governance and Evidence of Operational Use

<i>Country</i>	<i>Current framework</i>	<i>Main access-oriented tools</i>	<i>Activation or implementation evidence</i>	<i>Analytical reading</i>
Indonesia	Patent Law 13 of 2016, amended by Law 65 of 2024	Government use. Parallel import. Regulatory preparation. Patent challenge routes.	Government use documented for antiviral and antiretroviral medicines.	Formal authority has been used. Current access also depends on financing and supply institutions.
Malaysia	Patents Act 1983, amended by Act A1649 of 2022	Compulsory licensing. Government exploitation. Regulatory review. Exhaustion. Section 55A opposition is not yet in force.	Government use of sofosbuvir in 2017 and earlier antiretroviral use were reported.	Executed use gives the toolkit practical meaning, but the evidence is medicine specific.
Thailand	Patent Act B.E. 2522 of 1979, amended to 1999	Compulsory licensing. Government use. Regulatory-review exception. Exhaustion. Pre-grant opposition.	Government-use licences for medicines in 2006 to 2008 with peer-reviewed evaluations.	Strongest implementation record here. Historical use is kept separate from 2023 financing data.
Philippines	IP Code as amended by Republic Act 9502 of 2008	Government use. Broad compulsory licensing. Regulatory review. Parallel importation. Third-party scrutiny.	Law includes public-interest and medicine-supply grounds. No comparable executed case is relied on here.	Broad legal design. The study assesses formal capacity, not implementation intensity.
Viet Nam	IP Law 2005 as amended, including Law 131/2025 effective 2026	Compulsory licensing. Regulatory preparation. Lawful importation. Third-party input and opposition.	Articles 145 to 147 set public-interest and licensing grounds. No executed medicine case is relied on here.	Current law provides significant authority. Practical use depends on administration, supply, and financing.

Health-financing conditions are uneven. In 2023 OOP payments represented 9.93 percent of current health expenditure in Thailand, 31.08 percent in Indonesia, 37.09 percent in Malaysia, 39.20 percent in Viet Nam, and 44.36 percent in the Philippines. Government health spending as a share of GDP was highest in Thailand at 3.53 percent and lowest in Indonesia at 1.45 percent. UHC coverage was also higher in Thailand and Malaysia. These figures are not patented-medicine prices or patent-

policy outcomes. They show only how differently health costs can be absorbed by collective financing or passed on to households.

Thailand's low OOP share is relevant because legal flexibility works differently in a system able to purchase and finance treatment collectively. Household survey evidence shows sustained financial protection after the expansion of universal coverage (Tangcharoensathien et al., 2020). That does not prove that government-use licensing caused better financial protection. The temporal gap alone would make such a claim untenable. It does suggest why a legal power can be more usable when a purchaser already has coverage rules, procurement channels, and a defined patient population. The licence changes the legal position around supply. Other institutions determine whether that change reaches patients. In practice, a cheaper legal route has little welfare value if no agency can buy the product or no financing arrangement can place it within treatment coverage.

Malaysia shows why the public and private channels should not be collapsed. Babar et al. (2007) documented problems of price, availability, and affordability, while Wong et al. (2019) continued to identify a need for stronger medicine-pricing policy. Public procurement can perform differently. Hamzah et al. (2020) found comparatively favorable purchasing outcomes for many medicines in government procurement between 2010 and 2014. The sofosbuvir episode adds another layer because government use was tied to a defined public treatment route. Broad patent flexibilities can therefore coexist with substantial household payment exposure when access depends on which part of the health system is used.

Maria et al. (2025) found affordable quality-assured medicines and substantial price declines for many commonly used products in sampled Indonesian districts during the national health-insurance period. Patent status was not the exposure, so those findings cannot establish a patent effect. Their relevance is narrower. Patient prices can move through procurement, insurance, generic competition, and market regulation while the patent system remains in place. A broader Indonesian study of price controls likewise found that formal affordability interventions can produce different market responses when access rules, scarcity, and implementation conditions change, although that analysis was not medicine-specific evidence (Kadir, 2026b). Patent governance forms part of that environment but does not explain the observed price pattern on its own.

The Philippine and Vietnamese medicine studies make the same caution concrete in different ways. Lambojon et al. (2020) found continuing variation in price, availability, and affordability among medicines affected by a value-added-tax exemption in the Philippines. Nguyen et al. (2021) found high generic availability in parts of Hanam province and much higher private-sector prices for originator brands, while warning that the study was not nationally representative. Neither study identifies patent law as the causal exposure. Both are useful because they locate access problems closer to the medicine market than national OOP figures do. They also show why cross-country pooling would create more apparent precision than the evidence can support.

Table 3 Health Financing Context and Medicine-Specific Access Evidence

Panel A. Comparable system-level context

<i>Country</i>	<i>OOP share 2023</i>	<i>Government health spending percent GDP 2023</i>	<i>UHC service coverage index 2023</i>	<i>Financial hardship, latest estimate</i>
Indonesia	31.08	1.45	67	26.6 percent, 2023
Malaysia	37.09	1.98	80	17.8 percent, 2022
Thailand	9.93	3.53	82	11.9 percent, 2017
Philippines	44.36	2.16	69	31.0 percent, 2023
Viet Nam	39.20	2.02	71	23.6 percent, 2020

Panel B. Medicine-specific evidence used for interpretation

<i>Country</i>	<i>Medicine evidence</i>	<i>Finding used here</i>	<i>Limit</i>
Indonesia	Maria et al. 2025, selected districts and commonly used medicines	Affordable quality-assured options and price declines appeared in the sampled market.	Patent status was not the exposure, so no patent effect can be inferred.
Malaysia	Wong et al. 2019 and Hamzah et al. 2020	Private affordability concerns coexisted with favorable public procurement for many medicines.	Different sectors and periods cannot be pooled.
Thailand	Mohara et al. 2012	Government-use licences were linked to modeled savings and access gains for seven medicines.	Policy-specific analysis, not a general patent-welfare estimate.
Philippines	Lambojon et al. 2020	Price, availability, and affordability varied among VAT-exempt medicines.	The study does not identify a patent effect.
Viet Nam	Nguyen et al. 2021, Hanam province	Generics were widely available while originator brands were more expensive in the private sector.	Single-province study, not nationally representative.

The comparison is most informative when formal flexibility and institutional conversion capacity are kept separate. The first concerns legal permission. The second concerns whether an authority can secure a supplier, complete regulatory steps, purchase at scale, and finance treatment once the legal barrier is altered. The same implementation problem appears elsewhere in health governance, where formal duties may remain uneven in practice when institutional learning and follow-through depend on local capacity (Kadir, 2026a). Thailand's government-use episode shows those elements working together in a specific setting. Malaysia's sofosbuvir decision shows a similar conversion process around a different disease and procurement route. Indonesia's earlier antiviral measures confirm that government use has also been operationalized there. These episodes are not interchangeable, but they demonstrate why statutory authority acquires welfare relevance only through implementation.

Patent quality remains relevant within that argument, although this study does not compare examination quality across the five offices. Secondary claims can affect uncertainty and the timing of generic competition, as shown by Amin and Kesselheim (2012), Hemphill and Sampat (2012), and Kapczynski et al. (2012). The appropriate inference is limited. Patent scrutiny and challenge mechanisms may affect the legal space in which generic entry occurs, but the present data cannot determine whether a particular office grants too many or too few pharmaceutical patents. The comparison therefore treats opposition and related procedures as institutional capacity, not as evidence of better patent quality. This is especially important in a comparative legal paper because procedural openness can be observed from legislation, while the substantive quality of examination would require patent-level decisions and claim analysis that are absent here.

No simple ordering of the legal profiles matches the 2023 financing pattern, but that mismatch is not presented as a statistical finding. Patent law and health financing measure different parts of the access environment. What the comparison does show is that formal policy space alone cannot tell us whether households face high direct payments or whether a medicine is affordable in a particular sector. The practical question is more concrete. When exclusivity becomes an access problem for a clinically important medicine, can the state activate an available legal route and connect it to supply, procurement, and coverage quickly enough to matter.

The Pharmaceutical Welfare Framework reflects that narrower thesis. Patent governance is placed beside institutional conversion conditions rather than above a directional chain. Availability, affordability, and financial protection are treated as medicine-access outcomes that may be shaped by several institutions at once. The framework therefore avoids calling health financing a mediator and does not imply that a patent rule produces a national OOP level. It is an analytical map for locating where legal authority may become relevant. This formulation is narrower than a patent-to-welfare transmission model, but it fits the evidence more closely and gives the comparison a clearer use.

The study does not observe patent status, effective exclusivity, transaction prices, generic-entry dates, and utilization for the same medicines across all five countries. Country studies differ in baskets, years, sectors, and geography. Financial-hardship estimates are asynchronous, while OOP expenditure extends beyond pharmaceuticals. Evidence of implementation is also uneven. A medicine-level longitudinal design would be needed for stronger causal claims. The present comparison instead identifies which legal and institutional links such a design would have to observe.

CONCLUSION

Patent governance in the five selected countries contains substantial formal public-health space. Government use or compulsory licensing is available across the cases, while regulatory preparation and lawful sourcing rules provide additional access routes. Thailand, Malaysia, and Indonesia also show that some of these powers have been used for medicines. Their existence does not produce a common affordability or financing profile. Patent law is therefore better treated as one institutional component of medicine access than as a stand-alone predictor of welfare.

Institutional conversion capacity is the article's main contribution. A legal flexibility matters when authorities can connect it to a supplier, regulatory approval, procurement, and a financing route that reaches patients. That proposition is supported here through comparative legal evidence and bounded country experience, not through causal estimation. Future work can test it more directly by linking medicine-level patent landscapes to generic entry, procurement prices, utilization, and household payment. For the present evidence, the policy implication is narrower. Access-oriented patent rules should be kept usable, and their practical value should be assessed together with the institutions that turn legal permission into affordable supply.

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