Regionalism and Regulatory Resistance: ASEAN's Governance of Falsified Pharmaceuticals

Hannah Elyse Sworn

Word count: 11,161

Under what conditions can developing countries resist adopting costly economic policies advanced by great powers? Existing work assumes great powers prevail in regulatory conflicts with smaller states, overlooking cases of resistance. I propose a theory of regulatory resistance, arguing that norms allow regional intergovernmental organizations of developing countries to engage in regulatory behavior that conflicts with great powers. Strong regional norms moderate differences and sustain regulatory coordination among members, facilitating collective resistance in ways individual members could not. The structure of great power relations then determines the form of resistance: *passive* non-adoption of regulations when great powers hold a united regulatory position or *active* pursuit of alternative regulations when they are divided. Using primary documents, I process trace the Association of Southeast Asian Nations' (ASEAN) regulation of falsified pharmaceuticals from 2004 to 2022. ASEAN passively resisted united US-EU pressure to regulate falsified pharmaceuticals as a counterfeiting rather than public health issue, upholding its flexible intellectual property norm. From 2018, ASEAN shifted to active resistance by introducing health-centered regulations as China's rise and US-EU fractures divided the great powers. This paper challenges dominant views of economic order shaped primarily by great powers and highlights the importance of political inaction in international politics.

Introduction

Following significant tariff reduction during the 1980s and 90s that liberalized the volume of global trade, international economic cooperation came to focus on establishing regulations to reduce remaining non-tariff trade barriers (Dent 2010). These efforts sought to standardize financial, labor, environmental, and intellectual property (IP) regulations in order to further facilitate cross-border trade and investment. However, the process of standardizing regulations requires at least one state to change its existing domestic rules, imposing significant costs on adjusters while benefiting those that have their preferred regulations adopted by others (Mattli and Woods 2009). These distributive costs trigger significant

conflicts over which states adjust. For example, the cost for American grain elevator operators to implement European Union (EU) regulations on Genetically Modified Organisms (GMOs)—a point of major conflict between the US and Europe—has been estimated as high as USD 400 million (Wu and Butz 2004).

Developing countries are particularly affected by these adjustment costs, which absorb scarce resources, trigger economic vulnerabilities, and impose political challenges on governments. This can be observed across diverse regions and regulatory areas. For example, the prohibitive price of adopting meat processing standards forced many Polish smallholder pork farmers out of business during the country's EU accession process in the early 2000s (Dunn 2003). During the same period, the largest European economies advocated that Asian and Latin American countries adopt transnational interbank payment systems that were "immensely complicated, expensive, and often require a costly tradeoff…in financial sector terms" (Jeffs 2008, 278).

Existing theories of regulation argue that economically powerful states such as the US have the market power and capacity to force smaller developing countries into adopting their preferred regulations.[1] Yet, the empirical record challenges this conventional wisdom that great powers always win out in regulatory conflicts. For example, in the 1980s and 90s Thailand pushed back against US pressure exercised via the International Monetary Fund and World Bank to privatize electricity production, instead preserving its state-owned power company (Jarvis 2010; Williams and Dubash 2004, 420). In the 2010s, Asian developing countries opposed efforts by developed Western governments to impose strict regulations on non-bank credit, which is important for providing inclusive financial services and growth in

[1] The EU is considered a single actor similar to a state in regulatory politics due to the unusually high level of power its members delegate to the body in external economic relations (Büthe and Mattli 2011; Drezner 2008, 38–39; Perlman 2023; Simmons 2001; Söderbaum and Van Langenhove 2005).

these states (Knaack and Gruin 2021). Under what conditions can developing states escape the regulatory pressures imposed by great powers?

I argue that regional intergovernmental organizations (IGOs) can serve as an instrument for resisting costly economic standards. These organizations have historically served as important sites for developing countries to resist the political and economic influence of great powers (Acharya 2014b, 654–55; Getachew 2019; Söderbaum 2004, 433). Regional IGOs possess unique social resources in the form of regional norms, which can attenuate the effectiveness of efforts by powerful external states to shape regional policies. Rather than acting in their narrow or short-term self-interest, members adhere to these norms and act in the interest of the wider group. However, dominant perspectives on regulation neglect the role of norms as a source of agency for developing countries, instead privileging the ability of powerful Western economies to influence regional regulations through their market power (Bruszt and McDermott 2014; Drezner 2008).

This paper proposes a theory of regulatory resistance, which posits that regional IGOs with strong norms on a regulatory issue can collectively engage in behavior that conflicts with the preferences of one or more great powers. Regional norms moderate divergent interests among members and foster a unified position, reducing the body's vulnerability to great power pressure to adopt costly standards. However, because these smaller economies rely on great power markets for trade, the form of regulatory resistance, either passive or active, depends on the homogeneity of great power regulatory preferences and resulting severity of potential market-access retaliation. When great powers have the same regulatory preferences, regional IGOs engage in passive resistance, defined as the non-adoption of great power standards. Under these conditions, regional norms prevent individual members from spreading great power standards to the body. Conversely, when great powers have conflicting regulatory preferences, regional IGOs can engage in active resistance by implementing an

alternative set of standards that conflicts with at least one great power's position. Norms enable members to act as a bloc in favor of their preferred standards under this configuration.

To test the predictions of the regulatory resistance theory against the market power alternative, I process trace the Association of Southeast Asian Nations' (ASEAN) regulation of falsified pharmaceuticals from 2004 to 2022, spanning two periods in which the distribution of preferences among great powers shifted. ASEAN offers unique leverage because it has a strong and well-documented set of regional norms and has no great powers among its members, allowing external pressure to be separated from internal power dynamics. Falsified pharmaceuticals are medicines which are illegally manufactured and sold with little to none of the listed active ingredients, posing a serious threat to public health (Outterson and Smith 2006, 535; Stevens and Mydin 2013, 1–6). While the US and EU treat IP-infringing but medically effective generic drugs as falsified in the interest of their large pharmaceutical firms, developing countries do not for public health reasons (Attaran, Bate, and Kendall 2011, 339; Ho 2011, 16; Negri 2016, 354–55; Outterson and Smith 2006). Based on these latter concerns among its members and its broader non-interference norm, ASEAN has developed a flexible IP norm that members do not pressure others in the body into adopting the IP approach to falsified pharmaceutical regulation (Dent 2010, 64; Scollay 2007, 184).

In 2004, ASEAN made an initial attempt at regulating falsified pharmaceuticals when the US and EU—ASEAN's largest export destinations at the time—undertook a joint project to spread their shared IP-centric falsified pharmaceutical standards. I argue that, under these constraining structural conditions, ASEAN engaged in passive regulatory resistance by not adopting the US and EU's preferred standards. At the same time, the body refrained from enacting any policies that directly conflicted with the US-EU position to preserve their important trade relationship. ASEAN was able to engage in passive regulatory resistance

because its more developed members stayed committed to the body's flexible IP norm, refraining from spreading great power standards to other members or broader ASEAN policy.

However, the rise of China as an economic powerhouse with divergent preferences from these Western powers and rifts between the US and EU created a structural shift in the regulatory regime that enabled ASEAN to shift from passive to active resistance. As China became ASEAN's largest trading partner and the US-EU consensus on falsified pharmaceutical standards faltered, ASEAN worked as a bloc to institutionalize its flexible IP norm in the Regional Comprehensive Economic Partnership (RCEP) trade agreement signed between itself, China, and four other countries in 2020. Secure in the regulatory position of these major trade partners, ASEAN announced a legally binding agreement to regulate falsified pharmaceuticals as a health rather than IP issue within the region and revised its regulatory reporting systems, both contrary to the US position.

This paper makes four key contributions. First, by demonstrating regulatory resistance across both constraining and opportune structural conditions, it challenges the dominant perspective that privileges the role of powerful states in setting regulatory standards and shaping economic order more broadly. Second, it provides one explanation for when we may observe economic divergence—specifically in cases where regional IGOs with shared norms come into regulatory conflict with great powers—rather than convergence, despite the purportedly standardizing effects of globalization. Third, the theory highlights the importance of inaction and 'nondecisions' in international politics, in this case by regional IGOs engaging in passive resistance. While recent work recognizes inaction as a strategy individual states can leverage in international organizations, for example through absences in UN General Assembly votes, it has not been examined as a collective strategy (Morse and Coggins 2024). Inaction is not solely attributable to the low capacity of developing countries, but rather serves as a means to counter hegemonic power. Finally, the paper makes an

empirical contribution by examining ASEAN's regulation of falsified pharmaceuticals and its relationship to great power interests, demonstrating how conflicts over access to medicines and pharmaceutical profits have manifested in this normatively important regulatory issue.

The paper proceeds as follows. The next section develops the theory of regulatory resistance and its relationship to existing market power approaches. I then outline the selection of ASEAN and falsified pharmaceuticals as a case and the process tracing method employed. The following section lays out the broader regulatory conflict over falsified pharmaceuticals and ASEAN's relevant flexible intellectual property norm. Two empirical sections examine ASEAN's regulatory behavior under united great powers and then under divided ones. The conclusion considers the implications of these findings and directions for future research.

A Theory of Regulatory Resistance: Moving Beyond Market Power

A given country's domestic economic regulations reflect its political and economic status quo, making adjustments to transnational standards costly. Updating equipment, (re)training labor, and implementing new standards absorb scarce resources and disproportionately impact small and medium-sized businesses that comprise the bulk of economic activity (Büthe and Mattli 2011, 8; Drezner 2008, 129; Dunn 2003, 1499). Regulatory adjustments can also create economic and political instability. For example, developing countries that adopt liberalizing financial regulations increase their risk of banking crises and lose the ability to distribute scarce capital for political purposes (Drezner 2008, 127–29). When adjustment costs fall on mature sectors that have invested heavily in complying with existing domestic regulations, or produce broader negative effects on society, these groups often impose political costs on their governments (Drezner 2008, 50). Conversely, states which

have their domestic standards adopted by other countries enjoy the substantial economic benefits of their existing investment in, and familiarity with, these rules (Perlman 2023, 7). In this way, regulatory politics are a form of distributional conflict (Krasner 1991; Rodrik 2018).

This paper seeks to explain variation in the regulatory behavior of regional IGOs as its dependent variable and unit of analysis. I broadly examine regulatory behavior rather than specific policies in order to incorporate non-action as an important form of resistance. Regional IGOs emerged across the Global South following WWII and proliferated from the 1990s to facilitate economic cooperation between geographically proximate members. Over time, many of these bodies have gradually expanded cooperation to a myriad of other issues including climate change, migration, and transnational crime. Most regional IGOs have a secretariat and hold regular meetings between leaders as well as issue-specific committees.[2] As sites of economic cooperation, regional IGOs are an important institution where regulatory conflicts arise, both among members as well as between the IGO as a body and external trading partners. Regional IGOs are key actors in regulatory politics because a single regional policy can standardize rules across multiple member states (Deere 2009, 172). These regulatory policies can vary in legalization from intra-regional or external trade agreements with regulatory provisions that are enacted into each member's domestic laws, to joint regulatory plans and documents. The stakes of regional regulation are therefore high, both for members as well as outside states looking to advance their preferred standards overseas.

The top row of Table 1 represents the dominant market power approach to regulatory politics, developed most fully by Drezner, who shows how great powers impose their

[2] Regional IGOs should be distinguished from regional trade agreements. Regional IGO are organizations of states with stable memberships that cooperate consistently on a wide range of issues, while regional trade agreements are one-off arrangements designed specifically to facilitate economic exchange. Regional IGOs often enact their own intra-regional trade agreements and trade agreements with other states or regional IGOs as a bloc, but also cooperate on other issues.

preferred regulations on regional bodies (Drezner 2008). This perspective accounts for variation in structural conditions but assumes that regional norms are weak or inconsequential. The bottom row introduces the variation explained by regional norms in my theory of regulatory resistance, defined as regulatory behavior that conflicts with the preferences of one or more great powers. While regional norms enable regulatory resistance by facilitating a common position among members, I argue that structural conditions determine whether resistance is passive or active.

Specifically, the homogeneity of great power regulatory preferences creates differing risks of economic backlash for the regional IGO if it pursues regulations that conflict with those advanced by the great powers. Smaller states depend on access to the large markets of great powers for trade and therefore are sensitive to the risks of endangering these important export destinations (Manger and Shadlen 2014). When great powers have a shared regulatory preference, structural conditions are most constraining: if the regional IGO adopts conflicting regulations, the group could face punishment from and lose access to both of their markets. Under these conditions, regional IGOs therefore engage in less risky *passive* regulatory resistance, characterized by non-adoption of great power regulations. In the case examined below, ASEAN avoided adopting the US and EU's shared IP-maximalist approach to regulating falsified pharmaceuticals. When great powers have opposing regulatory preferences, structural conditions are most opportune: if the regional IGO adopts conflicting regulations, the group can maintain access to the more amenable great power's market even if the other imposes restrictions. Under these conditions, regional IGOs can engage in *active* regulatory resistance, characterized by the adoption of alternative standards that conflict with the preference of one great power. I show that ASEAN adopted a pro-health approach to regulating falsified pharmaceuticals that conflicted with the US position once China's rise and US-EU fractures divided the great powers.

Table 1: A typology of regionalism and regulation

		Structural conditions	
		United great powers	**Divided great powers**
Regional norms	**None or weak (Market power approaches)**	Adoption of great power regulations	Adoption of one great power's regulations
	Strong (Regulatory resistance)	Passive regulatory resistance	Active regulatory resistance

Market Power Approaches to Regulation

The dominant approach to regulation represented in the top row of Table 1 emphasizes how great powers shape global standards according to their interests. One body of literature with greater focus on domestic factors highlights the role of firms and national regulators from the most powerful developed Western states. For example, Buthe and Mattli argue that US and EU firms have high regulatory capacity and first mover advantage that gives them outsized influence on transnational regulations (Büthe and Mattli 2011, 43–48). Although the authors briefly refer to regulatory competition between "regional or minilateral standard-setting bodies" as a form of public regulatory competition, they do not explore this mode of rulemaking further (Büthe and Mattli 2011, 23). Perlman also highlights how large Western firms leverage private safety data to secure favorable global standards for their proprietary goods, to the detriment of smaller generics-based firms in developing states (Perlman 2023, 12). A second body of market-power explanations pays more attention to regional outcomes but similarly affords little space for the agency of IGOs and their members. This perspective argues that great powers use access to their large markets as a tool to force smaller states into adopting their preferred regulations (Buzdugan 2013; Drezner 2008, 32–33; Krasner 1991; Steinberg 2002, 347). Bruszt and McDermott, for instance, find that the US and largest EU

members function as regional hegemons that create more coherent regulations by "imposing common regional rules" on smaller countries with conflicting standards (Bruszt and McDermott 2014).[3] Drezner similarly posits that great power preferences are the central force shaping global regulatory outcomes because of their unique ability to wield market power against smaller states in negotiations over standards (Drezner 2008).

Yet, Drezner highlights how great power pressures are not a constant, but rather change across both issue area and time depending on whether the preferences of these powerful states align on a regulatory issue or not (Drezner 2008, 72). I adopt this structural variation, which determines the level of pressure small states are subject to, as the horizontal dimension of Table 1. Where regional norms are weak or absent in the top row, my expectation converges with Drezner's account. In the top-left cell, great powers share a regulatory preference but face conflicts with smaller states over the content of standards. Under these conditions, they use their combined market power to incentivize individual countries to pressure others into adopting their regulations (Drezner 2008, 63–66, 75–79, 97). This creates a 'cascade effect' that spreads these standards across countries. In this sense the dominant approach represents a special case of my framework, one in which regional norms do not operate.

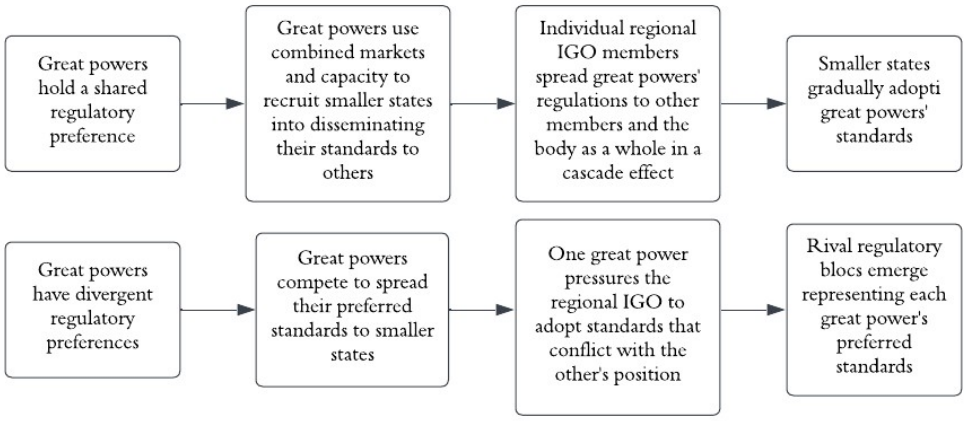
For example, when the African Intellectual Property Organization (OAPI) of francophone West African nations—originally formed in 1976—revised their framework in 1999, the US and EU leveraged trade and market access to pressure the body into adopting stringent regulations inimical to members' interests (Deere 2009, 268, 276–80). Weakened by colonial rule that undermined traditional customs on property rights, OAPI's political leaders were often divided by impulses to commit to "prevailing global discourses about what

[3] The authors argue that regional regulatory outcomes depend on both the domestic capacity of states as well as either a regional hegemon or strong regional institutions, which are substitutable.

constitutes appropriate economic policy" rather than developing a coherent internal position on these regulatory issues (Deere 2009, 247–49). The pro-US WTO Secretariat used Trade Policy Reviews to pressure Cameroon and Côte d'Ivoire into hoisting these regulations into OAPI policy (Deere 2009, 264–65). The 1995 review of Côte d'Ivoire stated that the government had five years to revise OAPI standards with its other members in order to be compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (World Trade Organization 1995, 68).

In the top-right cell, great powers have regulatory preferences that conflict with one another. Under these conditions, each uses all manner of international bodies—including regional IGOs—to spread their preferred regulations in the expansion of 'rival' regulatory blocs. For example, the US and EU have advanced competing visions of GMO regulation using regional IGOs. The EU has leveraged its status as a key export market and aid donor in Africa as well as its weight in international organizations to spur the African Union's (AU) adoption of GMO-limiting regulations (Osiemo 2018, 145, 152–57). The US has also sought to influence the AU and other African regional IGOs in favor of liberal GMO policies using development programs and capacity building, albeit without the EU's success. More recently, China has extended its state-sovereignty approach to cyberspace regulation through joint initiatives with the Arab League and AU, which stand in opposition to the US' economic-growth based regulatory bloc in the United Nations (Hofmann and Pawlak 2023, 2137). The observable implications of the market-power based approaches to regulation across united and divided structural conditions are outlined in Figure 1 below.

Figure 1: Observable Implications of Market Power Theories of Regulation



Structural variation alone, however, cannot explain variation in regional outcomes. Under the same configuration of united great powers, OAPI adopted great power standards inimical to its members' interests while (as explored in the case below) ASEAN exercised passive resistance. This divergence cannot be accounted for by a framework built solely on great power interests because it reflects a variable that market power perspectives overlook: the strength of regional norms. Crucially, norms are not a state-level attribute. Rather, they are shared properties that, in this case, operate at the regional level, between the state and the global system. A purely state or systemic approach cannot observe them directly, so weak norms become observationally equivalent to no norms at all. I argue that norms matter conditional on their strength. By treating regional IGOs as conduits through which great powers advance their standards, market power perspectives overlook the counter-hegemonic effects these bodies can have once norms are accounted for.

Regionalism, Norms, and a Theory of Regulatory Resistance

Regional bodies have proliferated in the global south as a means for developing states to achieve economic autonomy from great powers (Acharya 2007, 636; Getachew 2019, 108–9). These countries have used regional bodies to facilitate intra-regional economic activity,

reduce trade dependence on Western states, pool resources for regional development, and bargain as a bloc for more favorable trade conditions with external economic partners (Phillips 2001, 577). Studies identify bloc voting behavior in the United Nations and IMF among Global South countries (including the 'BRICS'[4] grouping of rising powers) that are dissatisfied with economic and political order (Binder and Payton 2022; Kim and Russett 1996; Woods and Lombardi 2006). Some argue that a new form of post-US hegemonic regionalism is emerging in Latin America, which rejects US market neoliberalism in favor of development and welfare objectives (Briceno-Ruiz and Morales 2017; Riggirozzi and Tussie 2012). As Tourinho argues, coalition and community building among small states is an important source of political leverage against great powers, and is bolstered by "the construction of shared identities that can strengthen their bond and legitimize political claims" (Tourinho 2021, 262).

A growing body of research highlights the importance of social resources in enabling developing countries to spread regulations that oppose US and EU standards, but has yet to consider regionalism in these dynamics (e.g. Pape and Petry 2024). In the area of international finance, for example, emerging economies advanced a 'digital financial inclusion' framing of non-bank finance in the Financial Stability Board during the 2010s (Knaack and Gruin 2021). In doing so, they sought to undermine the Western 'shadow banking' frame, which threatened developing countries' domestic financial sectors. Developing countries have also leveraged expertise and epistemic networks to shape tax regulation in the G20/OECD Inclusive Framework (Hearson, Christensen, and Randriamanalina 2023). Helleiner and Wang argue that BRICS has achieved varying levels of success in challenging different elements of US financial order depending on members' level of shared social purpose—defined broadly as shared identity, values, and ideologies—

[4] Brazil, Russia, India, China, and South Africa.

and the US' existing structural power (Helleiner and Wang 2018, 578). Gallagher also finds that the 2008 Global Financial Crisis and concomitant challenge to neoliberal ideas favoring capital liberalization enabled emerging economies to enact capital control policies in international institutions (Gallagher 2015).

A 2024 special issue on strategies of the weak in international organizations introduces a typology that includes coalition-building, but focuses on states acting within bodies alongside the great powers they seek to resist, rather than on regional IGOs that exclude them (Snidal et al. 2024). While pharmaceutical IP is treated as a case of rhetorical framing between developing and developed states, norms operate differently than frames. Framing shapes the meaning of issues to outside actors while norms shape behavior through shared expectations. Overall, this literature has overlooked regional IGOs as sites of regulatory resistance, despite their conduciveness for establishing shared identities and norms.

This paper bridges the work on regionalism and regulatory politics, arguing that norms enable regional IGOs to resist great power regulations. Regional IGOs are not only sites for aggregating material power, but are also highly advantageous for the development of intersubjective identities, values, and norms that facilitate cooperation (Acharya 2014a). Norms set "standards of behavior defined in terms of rights and obligations" for actors that belong to a particular identity group and can modify interests when "immediate individual gains defeat long-term individual or social purposes" (Finnemore and Sikkink 1998, 891; Kratochwil 1989, 59, 64). Norms comprise a clear expected action, identity, and sense of 'oughtness' among actors (Jurkovich 2020). Regional IGOs are particularly favorable to

forming cohesive norms compared to other plurilateral intergovernmental bodies.[5] Their smaller, geographically proximate members are more likely to share a common identity as a basis for shared expectations of behavior and there are more opportunities for interactions that shape the perceptions and interests of states (Acharya 2014a, 20). For example, the South American Mercado Común del Sur (MERCOSUR) has developed a regional norm on migration characterized by mutual support of free movement and human rights in the 1990s and 2000s (Brumat and Vera Espinoza 2024; Margheritis 2013). This norm grew out of a process of consistent interactions between elites that led to a shared understanding on the need to move away from market to state-based approaches to social issues.

In my theory of regulatory resistance depicted in the bottom row of Table 1, strong regional norms are necessary for both passive and active resistance. This is because there are never perfectly overlapping interests even in the most homogenous IGOs. Norms moderate inevitable differences among members and facilitate regulatory coordination in the face of great power pressures by creating a standard of expected behavior for members. Rather than acting in their narrow or short-term self-interest, members will adhere to norms and hold to the group position on regulatory issues. This enables the body to engage in regulatory behavior that conflicts with great power interests in a way that individual members may not have been able to do alone. The first scope condition of this theory is that there must be some form of conflict in regulatory positions between the great power(s) and regional IGO, without which the body would unproblematically adopt these standards. The second scope condition is that this theory only applies to regional IGOs that do not include great powers among their member states. This allows for a clear separation between internal institutional dynamics and external great power influence, the latter being the primary focus of this paper. Regional

[5] There are other ways that states can have mutual interests. For example, based on their shared exclusion from the US-dominated global economic order, BRICS have aggregated their material power to challenge this system, see Ban and Blyth 2013.

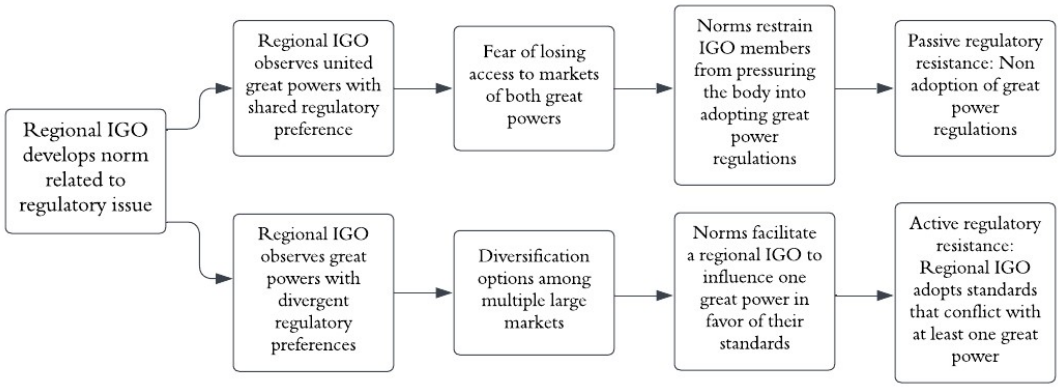
IGOs without a great power in their membership include the African Union, ECOWAS, MERCOSUR, the Andean Community, OAPI (discussed above), and the Gulf Cooperation Council, among others. Individual members may be part of IGOs that do include great powers without violating this scope condition. In fact, overlapping membership is the mechanism through which great powers spread their standards to regional IGOs in market power explanations, and I test this mechanism in my empirical section on passive resistance.

Crucially, the distribution of preferences among great powers can vary across both issue area and time. Across issues, for example, the US and EU previously shared a common regulatory preference on pharmaceutical IP while being divided on GMOs and cyberspace governance. Over time, this distribution can change when great powers rise, decline, or their preferences change as a result of domestic processes as is the case with the EU in the empirical case in this paper.

Figure 2 outlines the observable implications of each type of regulatory resistance. Under the structural condition of united great powers, passive resistance acts as a spoiler on these powerful states' regulatory regimes and deprives them of the economic gains associated with market access on terms that favor their firms. Regional norms enable passive resistance by interfering with the dynamics through which united great powers induce smaller states into adopting their standards. Specifically, we should observe that even when great powers pressure individual regional IGO members into their regulatory regime, regional norms restrain these members from pressuring others in the organization into adopting these standards either individually or as a body. This purposeful inaction is therefore a politically important 'nondecision' with material impacts on great powers (Bachrach and Baratz 1963; Hacker and Pierson 2010, 171). While nondecisions have received more attention in American politics, international relations has not engaged with this concept extensively. An exception is Morse and Coggins, who argue that countries use strategic absences in the UN

General Assembly to avoid offending competing great powers (Morse and Coggins 2024). By contrast, I argue that competing, or divided, great powers spur active rather than passive resistance. When rival great powers make conflicting demands on a state within an organization, silence may be the safest action, but when their preferences diverge more broadly, states obtain an outside option that makes action possible. Under the more opportune environment presented by divided great powers, we should observe members working as a bloc to advance an alternative set of standards by influencing one great power in favor of their preferred regulatory policy.

Figure 2: Observable Implications of the Regulatory Resistance Theory



Case Selection and Methodology

Formed in 1967, ASEAN comprises ten Southeast Asian states: Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam. The body is Southeast Asia's most authoritative intergovernmental organization, cooperating on trade, health, and transnational crime among other areas. ASEAN is selected as a case for two reasons. First, the organization is an 'extreme case,' "considered to be prototypical or paradigmatic of some phenomena of interest," namely regional norms as one of my key explanatory variables (Flyvbjerg 2006, 229; Gerring 2007, 101–5). ASEAN

provides significant leverage on this variable because of its strong set of broad regional norms, termed the 'ASEAN way,' comprising consultation, consensus building, and non-interference. The ASEAN way provides important yet underutilized leverage to study the role of norms in regulatory politics. Prior research suggests that there is a unique form of 'regulatory regionalism' in the Asia Pacific that reflects preferences for cooperating through informal, non-binding channels (Jayasuriya 2009). Corning takes a historical institutionalist approach to argue that the "socio-cultural influence of the…'ASEAN way' that emphasizes voluntarism, consensus-based politics, and the principle of non-interference" creates path dependence on certain regulatory issues, which impedes the effectiveness of US market power in regulatory negotiations (Corning 2018, 5–6, 15). However, these works do not explicate the mechanisms through which ASEAN norms shape specific forms of regulatory cooperation or enable the body to resist the US, beyond serving as a starting point for negotiations or representing a broad 'preference' for how to regulate (Corning 2018, 12).

The second rationale for selecting ASEAN as a case study is that, while many regional IGOs include the membership of a great power, ASEAN does not. This keeps the external vs internal influence of great powers in regional IGOs separate, given that external influence is the second independent variable of my theory alongside norms. For example, the US is a member of the Asia Pacific Economic Cooperation (APEC) forum alongside ASEAN members and Washington's heavy role in this body has been a major point of conflict between Southeast Asian members and the US.

Falsified pharmaceuticals and the closely related regulatory issue of pharmaceutical IP are some of the most prominent and controversial regulatory issues in global trade negotiations between developing and developed countries. In 2001, the Doha round of negotiations commenced at the WTO with the promise to focus on the priorities of developing countries. The round ground to a halt in 2003 over divisions in which

pharmaceutical IP and access to medicines were central. ASEAN's initial efforts to regulate falsified pharmaceuticals took place from 2004 onwards, as depicted in the timeline in Figure 3, at the height of that conflict. ASEAN's regulation of this issue is therefore a hard case for regulatory resistance given that the US and European states were united behind a single set of standards on a highly salient global issue.

I use a diachronic (i.e. over time), within-case analysis of ASEAN's regulation of falsified pharmaceuticals (Gerring and McDermott 2007, 693–94). This achieves control of potential confounding variables by "dividing a single longitudinal case into two," one before and another after a change in a key independent variable to isolate the difference in outcomes between these two periods (George and Bennett 2005, 118). Because regional IGOs vary so extensively, examining ASEAN as a single case "generally offers a better solution to the control problem than comparison of two or more different but similar units" (Goertz and Mahoney 2012, 88; Lijphart 1971, 689). For the purposes of this paper, examining across-time variation keeps regional norms as constant as possible while varying the distribution of preferences among great powers, which shifted from a united stance between the US and EU to a divided configuration between the US and China over the period studied. In addition, as this paper develops a novel theory of regionalism and regulation, a single unit case study is suitable for exploratory theory-testing rather than confirmatory analysis, the latter of which requires further application to other regional IGOs and regulatory areas (Gerring 2004, 349–50).

I use process tracing to test whether the pathway between my variables is consistent with the observable implications predicted by my theory of regulatory resistance. Process tracing is a method that examines "evidence on processes, sequences, and conjunctures of events" to test "hypotheses about causal mechanisms that might causally explain the case" (Bennett and Checkel 2015, 7). This involves first theorizing what causal mechanisms

connect the independent and dependent variables in question, in this case the preceding theory section. Second is operationalizing these as observable implications that we would expect to manifest from these mechanisms as found in Figures 1 and 2 (Beach and Pedersen 2019). Finally, the two empirical sections of this paper will evaluate the evidence to assess whether the predicted observations and real-life sources correspond. In addition, process tracing is well suited for this study's diachronic case study research design, as it helps to assess whether independent variables that change across time—in this case the distribution of preferences among great powers—have an effect on the outcome alongside other causal variables (George and Bennett 2005, 155). I draw on a host of primary qualitative documents—including ASEAN official statements, meeting reports, regulatory documents, newspaper articles, and trade agreement texts—as well as secondary sources as evidence to evaluate the observable implications of the regulatory resistance theory against the market power alternative.

The Politics of Falsified Pharmaceuticals and ASEAN Norms

Falsified pharmaceuticals are a complex regulatory issue situated at the intersection of health and IP. The global trade in these illegally manufactured products is estimated to be worth between USD 10 and 200 billion (Bate 2014; Global risks 2011 2011). Developing countries are particularly affected by falsified pharmaceuticals due to weak health oversight systems and law enforcement (Negri 2016, 351; Ozawa et al. 2018). The magnitude of this problem has only grown with the proliferation of unlicensed online pharmacies and fake medical products associated with the COVID-19 pandemic.

In Southeast Asia, the trade in falsified pharmaceuticals is worth between USD 520 million and 2.6 billion, with a prevalence as high as 50 percent among the region's less-developed countries (Ball and Salenga 2017, 52; Nayyar et al. 2012, 489; Stevens and Mydin

2013, 3; United Nations Office on Drugs and Crime 2019, 171).[6] A growing middle class, ageing population, and expanding health services create high demand for cheap medicines that are often falsified, while high intra-regional flows of goods and people through porous borders facilitate their transit to and through the region (Lamy and Liverani 2015, 246–49; United Nations Office on Drugs and Crime 2019, 159). Fake antibiotics and antimalarials are particularly rampant and contribute significantly to drug resistance, in comparison to the West where lifestyle drugs such as erectile dysfunction and diet pills are most likely to be falsified (Nayyar et al. 2012, 448; Stevens and Mydin 2013, 4; United Nations Office on Drugs and Crime 2019, 131–33).

At the global level, efforts to set common standards toward combating falsified pharmaceuticals have evolved into a protracted conflict over competing interests in pharmaceutical IP between developed and developing countries. The world's most profitable pharmaceutical companies, which are built on revenues from patented medicines, are headquartered in the US and Europe. These states therefore consider IP-infringement of patents and trademarks to be a critical element of falsified pharmaceuticals: medically effective, generic medications that infringe on the IP of branded versions are therefore considered to be falsified (Outterson and Smith 2006, 532). By contrast, developing countries prioritize combatting drugs that are produced and sold with criminal intent to harm consumers through insufficient amounts or none of their active ingredients, regardless of IP status (Attaran, Bate, and Kendall 2011, 339; Ho 2011, 16; Negri 2016, 354–55). This is because many developing states rely on cheaper generic drugs for public health and/or have strong domestic generics industries that benefit from weaker IP rights. In an effort to protect their lucrative market share in pharmaceuticals against generic competitors, the US and EU

[6] Figures vary depending on definitions and methodologies used. Some estimates include 25 percent in Indonesia; 3-5 percent in Malaysia; 1-10 percent in the Philippines; and 33-50 percent across Cambodia, Lao PDR, Thailand, Myanmar, and Vietnam, which are often grouped together in studies.

have blurred the line between these legally distinct terms ‘counterfeit’ (i.e. IP-infringing) and ‘falsified’ (i.e. medically ineffective) to increase and enforce pharmaceutical IP around the world (Lamy 2017, 28; Quet 2017, 155). This hinges not only on advancing an IP approach to regulating falsified pharmaceuticals but also stringent IP that exceed the minimum requirements set by TRIPS, thereby expanding the definition of what is considered falsified.

As the ASEAN way represents a broad set of norms surrounding cooperation that are open to interpretation on specific issues, it is important to outline how these translate into ASEAN’s norm on falsified pharmaceutical regulation (Dent 2010, 64; Scollay 2007). The ASEAN way reflects an informal rather than highly-institutionalized, rules-based method of cooperation (Coe 2019, 114). This approach facilitates cooperation “by enhancing a sense of mutual understanding and trust through dialogue” and is unique vis-à-vis other regional bodies (Katsumata 2012, 78). The ASEAN way reflects values of “economic development, regime security and political stability” shared by the political elites in the region (Acharya 2014a, 29). Governments are particularly concerned with sovereignty and non-interference given “the relatively recent decolonisation process, the challenges of nation-building,” and concerns about external interference by great powers (Beeson 2006, 545; Coe 2019, 115).

Southeast Asia’s political elites gradually constructed the ASEAN way through repeated interaction, making it an elite-driven norm originating from a top-down process among long-serving leaders rather than a bottom-up norm originating from the publics of these countries (Kivimäki 2001, 17; Nesadurai 2009, 97–98). There have been sporadic instances of norm violation within ASEAN, for example when the body chose to exclude Myanmar’s military leader from its summits in 2021 following the coup d’etat and ongoing human rights abuses (Collins and Bon Tai Soon 2024, 337). However, these episodes are exceptions to a robust pattern of adherence to the ASEAN way among its members over 57 years (Coe 2019, 114).

ASEAN has developed a 'flexible IP' norm, which centers around the body's commitment to non-interference. Specifically, the norm allows members the space to dictate their own domestic policies within the TRIPS minimum standard—including increasing their IP standards if they judge it to be in their interest—but rests on the expectation that these will not be forced on other members or the body as a whole (Antons and Thampapillai 2015, 50). The emergence of ASEAN's flexible IP norm can be charted back to the 1995 ASEAN Framework Agreement on Intellectual Property Cooperation, which focuses on implementing TRIPS without imposing any additional obligations on ASEAN members (Ng-Loy 2015, 342). ASEAN's six free trade agreements (FTAs) with external economic partners also embody this norm, featuring very few TRIPS-plus or special IP provisions beyond general affirmations on cooperation and capacity building (Antons and Thampapillai 2015, 45–46; Fowler, Charoenpot, and Byrne 2017, 197; Wattanapruttipaisan 2015, 148). The 2009 intra-ASEAN Comprehensive Investment Agreement also preserves TRIPS flexibilities by explicitly exempting compulsory licensing[7] from the scope of expropriation, removing the possibility for a firm to bring such a case against an ASEAN member in an international tribunal (ASEAN 2009, 55). Beyond these documents, ASEAN has stated its commitment to sharing information and strategies on using public health flexibilities afforded in the TRIPS agreement in the interest of access to medicines (ASEAN 2014b, 2).

ASEAN's flexible IP norm reflects the need for affordable medicines and the important position of generics manufacturers in the region, both of which would be harmed by defining falsified pharmaceuticals as an IP issue. First, apart from Singapore and Brunei, ASEAN members rely on generic medications to meet public health objectives without placing unnecessary burden on government budgets. Affordable medicines are an economic

[7] Compulsory liscensing allows domestic manufacturers to produce and export a drug without permission from the patent holder for public health reasons, national emergencies, or remedying anti-competitive practices and is allowed under TRIPS flexibilities.

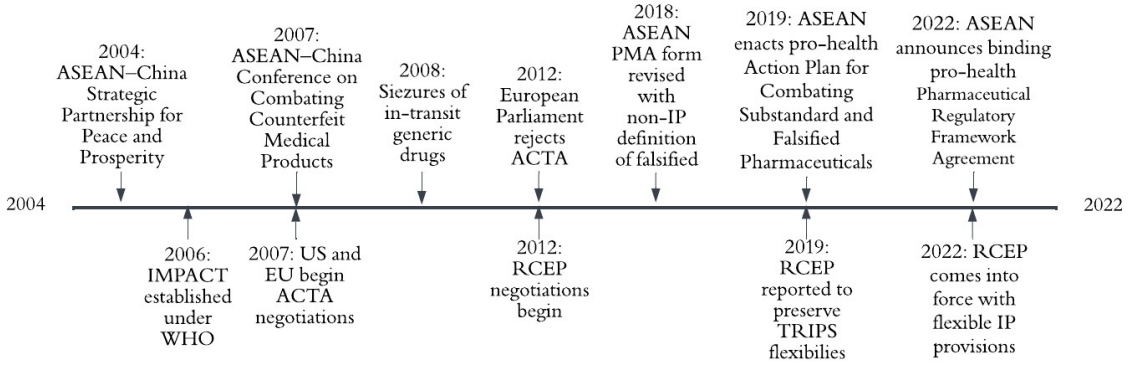
necessity for ASEAN's least-developed members such as Cambodia and Myanmar, which have particularly limited resources for health spending. ASEAN's middle-income members also rely on generics for their expanding government health programs, using TRIPS flexibilities to this end. Malaysia was the first developing country to issue a compulsory license, with Indonesia and Thailand following suit in the following years (Moon and Szlezák 2013, 142–43). These compulsory licenses significantly decreased the price of HIV/AIDS and Hepatitis C drugs, improving access to medications for patients (Ramani and Urias 2015, 81).

Second, a number of members including Thailand and Indonesia have sizable generic pharmaceutical industries (Hassali et al. 2013, 154–61; Husada and Tjandrawinata 2013, 140–41; Teo, Foerg-Wimmer, and Chew 2016, 2–25). These manufacturers play an essential role in providing affordable medicines to domestic markets and government programs: in 2015, between 30 to 70 percent of consumed medicines in Malaysia, Thailand, Indonesia, the Philippines, and Vietnam were produced locally (Teo, Foerg-Wimmer, and Chew 2016, 19–20). In addition, ageing populations, growing middle classes, and expanding health programs have produced an enormous market for generics exports across the world (Tannoury and Attieh 2017). The generics market has become particularly lucrative since the 2010s when patents began to expire on many profitable proprietary drugs, also known as the 'patent cliff' (Kimura and Nakamura 2020, 79). ASEAN members with well-established generics manufacturers are promoting investment in this potentially major export industry. Pharmaceuticals is one of the few sectors within ASEAN that has experienced consistent growth, expanding 57 percent between 2002 to 2007 and 12 percent between 2007 to 2013 (ASEAN 2014a).

United Great Powers and ASEAN's Passive Regulatory Resistance

When ASEAN first made efforts to regulate falsified pharmaceuticals in 2004, the body faced united great powers leveraging their combined economic weight to advance their standards globally. The US and EU shared a preference for IP-centric regulation of falsified pharmaceuticals and sought to spread these through international organizations and trade agreements. As per Figure 1, market-based explanations of regulation would predict that these major trading partners would have their way in influencing ASEAN standards on this issue by applying pressure on individual members who would then spread these to the body in a 'cascade' effect. However, as this section will demonstrate, the presence of ASEAN's strong IP norm under these constraining structural conditions produced passive regulatory resistance. ASEAN avoided adopting US-EU standards but did not actively pursue an alternative policy that conflicted with these great powers' preferences to preserve market access. The evidence presented below suggests that the ASEAN members most likely to act on behalf of these powerful states did not spread these standards to the regional body. Instead, they reaffirmed their commitment to and advocated for ASEAN's flexible IP norm.

Figure 3: Timeline of Key Events in ASEAN's Regulation of Falsified Pharmaceuticals



The 2004 ASEAN-China Strategic Partnership plan included a clause to boost cooperation on falsified pharmaceuticals, with the subsequent 2007 ASEAN–China Conference on Combating Counterfeit Medical Products bringing together ASEAN and East

Asian countries to present on this regulatory challenge (ASEAN & China 2004, 10). During this period, the US and EU worked to advance their vision of falsified pharmaceutical regulation first in the WHO before shifting to plurilateral and bilateral efforts. In 2006, the US and EU pushed for the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) under the WHO (Kimura and Nakamura 2020, 110–11). IMPACT was managed by pharmaceutical industry bodies, Interpol, and the World Customs Organization (WCO)—all of which had interests aligned with the US and EU's pharmaceutical IP agenda (Deere 2009, 117; Sell 2009, 15–19). Despite never being formally endorsed by the WHO World Health Assembly, IMPACT adopted an expansive definition that included both IP infringing as well as non-therapeutic drugs.

ASEAN directly engaged with these events and iterated how IMPACT's standards conflicted with its flexible IP norm. At a WHO executive board meeting in January 2009, Indonesia spoke out on behalf of the Southeast Asian WHO members as opposing " the principles and elements developed by the [IMPACT] Taskforce" (World Health Organization 2009, 147–48). India also spoke "on behalf of the Member States of the South-East Asia Region" at a World Health Assembly debating IMPACT's definition of counterfeit in 2008, stating that "any changes in the definition of counterfeit medicines should state explicitly that generics did not in any way entail patent infringement" (World Health Organization 2008, 117). These conflicts between developing states and US-EU efforts came to a head in 2010, when India, Brazil, and several other developing countries filed a complaint with the WTO accusing IMPACT of being "unacceptably dominated" by the US-EU IP agenda (Liberman 2012, 330–31). In response to this backlash, IMPACT ceased to operate under the WHO and became its own independent organization. The WHO subsequently adopted a pro-health definition of falsified pharmaceuticals affirming access to medicines, stepping away from the US and EU's IP-centric approach.

However, the US and EU continued to undertake parallel efforts to spread their standards through smaller preferential trade agreements. In 2007, the US began negotiations with likeminded states—including the EU—for the Anti-Counterfeiting Trade Agreement (ACTA). ACTA sought to increase the grounds for combatting counterfeit goods, including medicines, based on high IP standards. The implications for developing countries became clear in 2008, when Dutch customs seized a shipment of generic drugs on the grounds of being counterfeit. Authorities claimed they potentially infringed on the IP of large branded drug companies, even though they were not patented in India or their destination countries in Latin America (Bonadio and Cantore 2010, 4; Ho 2011, 40–43). The US and EU continued to pursue bilateral and plurilateral FTAs with developing states that expanded the definition of fake drugs to include IP, as well as backing Interpol and WCO operations that encompassed both falsified and IP-infringing medicines (Negri 2016, 354).

Contrary to the expectations of market-power based explanations, ASEAN steered clear of adopting any regulations that treated falsified pharmaceuticals as an IP issue for over a decade. Following the 2007 meeting with East Asian countries, ASEAN abruptly stopped producing plans, statements, and other documents on falsified pharmaceutical regulation, and did not convene any ASEAN meetings on this issue. This is highly unusual given member governments' explicit awareness of the growing threat posed by falsified medicines in the region and ASEAN's famous status as a 'talk shop' prone to issuing declarations and holding meetings on a wide range of issues (Jones and Smith 2007; Lamy 2017, 225–28). ASEAN left the issue off its regulatory agenda while engaging in token gestures to US-EU preferences. For example, ASEAN's post-marketing alert (PMA) system for reporting unsafe medical products introduced in 2006 included a category for reporting 'counterfeit' products, which was left undefined despite serving as a key regulatory document (Republic of the Philippines Food and Drug Administration 2018). The ASEAN Post-2015 Health

Development Agenda 2016-2020 also briefly mentioned 'counterfeit' drugs under the theme of drug and vaccine security without any elaboration on specific definitions or activities (ASEAN 2018, 65). Falsified pharmaceuticals was raised briefly by a participant in the 4th ASEAN Police Training Cooperation Meeting in 2014 as an area where training was needed, proving an awareness of the need to strengthen ASEAN cooperation in this area, but failing to result in any follow up actions (Faris 2014). ASEAN also took part in a handful of trainings on counterfeit drugs held by the US Patent and Trademark Office and Interpol, but did not take any tangible follow up action to regulate them in this manner (Wongburanavart 2022, 13). While this passive resistance had the side effect of leaving the issue unregulated in the region, ASEAN shirked the US and EU's preferred regulatory standards while avoiding potential conflict with these major trading partners from defining falsified pharmaceuticals as a health rather than IP issue. Ambiguity in the PMA form and broader silence on the issue meant no obvious acts of defiance and therefore less risk of punishment by the great powers, which Morse and Coggins highlight as a valuable strategy for weak states (Morse and Coggins 2024).

ASEAN's evasive behavior can be explained by the structure of its trade relationships during this period, characterized by dependence on the US and EU and therefore vulnerability to punishment by these powers. As shown in Table 2, at the start of this period of regulatory resistance in 2004 the US and EU were ASEAN's largest export destinations, importing a combined 27 percent of ASEAN's merchandise goods. In comparison, China only imported 7 percent of ASEAN's goods. Both the US and EU demonstrated their willingness to leverage market-access threats against ASEAN members in the area of pharmaceutical IP. Most ASEAN members featured on the US' Section 301 Priority Watch List or Watch List—which can result in trade sanctions if the US' IP complaints are not resolved—for compulsory licensing and expanding other TRIPS flexibilities (Yu 2016, 151–52). In 2007, the European

Commission also warned Thailand against forcing foreign drug companies to decrease their prices (Bounds 2007). Potential risks to US and EU market access loomed large for ASEAN, making active resistance through the adoption of a region-wide falsified pharmaceutical policy that conflicted with the US-EU position highly unattractive.

Table 2: Measures of Market Power 2004 to 2019

	United States		European Union		China		ASEAN intra-regional	
	2004	2019	2004	2019	2004	2019	2004	2019
GDP (PPP trillions)	12.22	21.38	11.42	15.69	1.96	14.28	N/A	N/A
ASEAN merchandise imports (percentage share)	14.07 %	12.91 %	13.39 %	10.82 %	7.26 %	14.23 %	24.89 %	23.34 %

Sources: World Bank; ASEAN Statistics Data Portal.

Nonetheless, ASEAN was able to engage in passive regulatory resistance because the body's flexible IP norm interfered with the process through which united great powers spread their standards to reluctant countries. The strongest candidate for a cascade state predicted by market-power explanations was Singapore, which is individually part of a number of US and EU agreements related to pharmaceutical IP and has the most open and knowledge-based economy in ASEAN (Dent 2010, 67). Since strengthening its IP standards to access US GSP benefits in the 1980s, it has complied with the US and EU's regulatory preferences to access high-value investment from these countries. In 2003, the US and Singapore signed an FTA that included various TRIPS-plus pharmaceutical IP provisions (Drahos 2005, 774–76). Singapore also entered negotiations to join ACTA in 2008 (Board on Global Health, and Institute of Medicine 2013, 21; Ho 2011, 72, 77). As a founding member of ASEAN that holds considerable weight in leadership of the organization, Singapore was in an advantageous position "to play a very important role in the development of intellectual

property law and policy in Asia" (Yu 2016, 156). In the same way the US and EU benefit economically from exporting high IP standards to developing countries, Singapore would also benefit from increasing IP standards in the region to protect and facilitate high-value investment and trade with other ASEAN members.

In addition, Malaysia, Brunei, and Vietnam all showed signs of vulnerability to the US-EU driven cascade effect. Singapore, Vietnam and Brunei all joined negotiations for the US-backed Trans-Pacific Partnership (TPP) trade agreements in 2008 and then Malaysia in 2010, the latter three making "wrenching economic adjustments and compromises" to do so (Shambaugh 2018, 108). As two of the original four negotiating members, the TPP represented a particularly important opportunity for Singapore and Brunei to sit at the center of a major trade arrangement involving the US.

However, these countries stayed committed to ASEAN's flexible IP norm by refraining from hoisting these standards into ASEAN regulatory policy, in line with the regulatory resistance theory. When the Singapore-US FTA was signed, the US government stated its intention that the trade agreement would serve as a template for its negotiations with other ASEAN states including Thailand (Debaere and Davies 2009, 5). Despite these intentions, the IP standards found in the US-Singapore FTA did not "become a template for [its] other free trade negotiations," and subsequent trade agreements that Singapore has signed do not contain "anything remotely resembling" this level of IP protection (Ng-Loy 2015, 351–52). The country reaffirmed that "IP should be left to be governed by the TRIPS Agreement" and demonstrated "certain amount of 'pull back' from overly-strong IP protection" by adopting provisions in its subsequent FTAs aimed at protecting public interest and health (Dent 2010, 71–72; Ng-Loy 2015, 352). In 2013, Singapore and Malaysia also co-sponsored a counterproposal in TPP negotiations that omitted stringent IP provisions proposed by the US, instead reaffirming TRIPS standards and the need to protect public

interest (Leaked TPP IP Text Reveals Details Of Conflicting Pharmaceutical Proposals 2013). Similarly, in the same year, the Malaysian government stated it would not commit to a binding timeframe on TPP negotiations to ensure that public health would not be compromised by the agreement, with the cabinet stating that it was "firm in ensuring access to affordable medicine remains its utmost priority which will not be compromised in the ongoing TPPA negotiations" (Inside US Trade 2013).

In addition, in 2007 the Singaporean ASEAN Secretary General at the time called an ASEAN-US FTA unlikely, although until that year the US was ASEAN's top trading partner. A regional FTA represented the central means for the US to achieve its desired cascade effect in the region by involving the domestic adoption of legally binding regulatory provisions on pharmaceutical IP. Instead of endorsing the agreement, the Singapore representative stated that ASEAN's non-binding Trade Investment Framework Agreement would "sustain us for a long time to come" (Lee 2007). By willingly speaking out against the necessity of an ASEAN-US trade agreement, Singapore directly eschewed a role in advocating for US policy in the region. While the US and EU sought to leverage FTAs to divide and conquer ASEAN, the cascade they were designed to produce did not materialize.

Divided Great Powers and ASEAN's Shift to Active Regulatory Resistance

Over time, structural conditions shifted to a divided configuration between China, the US, and EU. Market power theories of regulation would predict that under these divided conditions, the US, EU and China would each pressure ASEAN into adopting its own vision of falsified pharmaceutical regulation in competition with one another. However, rather than these competing great powers influencing ASEAN, the body leveraged this divided structural condition to engage in active regulatory resistance, adopting standards that conflicted with the US. ASEAN's flexible IP norm enabled its members to work together to secure a trade

relationship with China that respected their norm, subsequently implementing pro-health falsified pharmaceutical regulations in the region.

Two factors resulted in the previously united US-EU environment giving way to a divided configuration between China, the US, and EU. First, China grew as a major ASEAN trading partner with divergent preferences from the US and EU on falsified pharmaceuticals. In contrast with the latter two's emphasis on increasing IP standards in favor of their high-earning pharmaceutical firms, China has prioritized three alternative objectives in its trade agreement with other countries: securing scarce raw materials essential to its economic growth, facilitating exports, and cultivating an image of nonthreatening rise (Harada 2020; Yu 2011, 987–88, 1011, 2016, 159). These priorities are fundamentally different from the US and EU in that they do not necessitate transplanting high pharmaceutical IP standards abroad. This reflects China's more nuanced domestic interests on IP protection. On one hand, China has increased its IP laws far beyond TRIPS standards to encourage indigenous innovation in its efforts to become a knowledge-based economy and maintain growth (Yu 2020). On the other, the government has also maintained its ability to provide essential medicines to the public through a high novelty standard for patenting and from 2012 allowed compulsory licensing (although it is unlikely to issue one) (Lu et al. 2015, 225–30).

The US-backed TPP and China-backed RCEP mega-regional trade agreements represented these two diverse approaches, with the US and China competing to secure valuable trade relationships with the dynamic economies of (particularly Asian) developing countries (Hamanaka 2014, 177). The TPP represented an ambitious attempt to spread the US regulatory template—including pharmaceutical IP standards—while RCEP emphasized market access. These parallel projects also took place during the Obama administration's 'pivot to Asia,' in which the US government sought to strengthen US influence in this region. In 2012, the year in which RCEP negotiations began, the Obama administration positioned

the TPP against RCEP and called on the Asia-Pacific region to make a choice between these competing paths (K. M. Campbell 2016).

Second, a US-EU regulatory divergence emerged on falsified pharmaceuticals. While the US position remained unchanged, the EU wavered in its commitment to the more extreme standards due to outcry over access to information (Meissner 2019, 1058). Most notably, in 2012 the European Parliament rejected ACTA after widespread public opposition, contributing to the agreement's ultimate failure (Subramanian 2015, 104–5). This eliminated an important tool for advancing an IP approach to regulating falsified pharmaceuticals.

Contra expectations of market power approaches, ASEAN did not become the object of competing US and Chinese efforts to impose their preferences on the body in this divided structural environment. Rather, ASEAN broke its silence associated with passive resistance and began actively regulating falsified pharmaceuticals in a pro-health manner that conflicted with the US. An important change took place in ASEAN's PMA form, which is used for reporting unsafe medicines. While the previous section discussed the form including an undefined token category for 'counterfeit' medicines, this was reversed in 2018 when the counterfeit category was removed and replaced with one for 'falsified' drugs (Republic of the Philippines Food and Drug Administration 2019). The form explicitly uses the WHO definition of falsified, which emphasizes health and access to medicines rather than IP in regulating falsified pharmaceuticals (New 2017). This marked a change from avoidance and ambiguous language to a firmer stance on treating falsified pharmaceuticals as a public health issue unrelated to IP.

In a shift from near silence on the issue, ASEAN explicitly placed falsified pharmaceuticals on its regulatory agenda from September 2019, when Cambodia hosted the ASEAN Consultative Meeting on Combating Substandard and Falsified Medicines (Sotheary

2019). In the same month, the 14th ASEAN Health Ministers Meeting committed to creating an ASEAN Action Plan for Combating Substandard and Falsified Medicines, which was reiterated at the 22nd ASEAN Plus Three summit in October (ASEAN Plus Three 2019, 5). Crucially, ASEAN chose to formulate the plan in collaboration with the WHO, a pro-health actor in falsified pharmaceuticals since the IMPACT controversy, rather than the pro-IP INTERPOL, WCO, or US government agencies. In June 2022, ASEAN took a major step by announcing a legally binding ASEAN Pharmaceutical Regulatory Framework (APRF) Agreement (ASEAN 2022). Designed to define ASEAN cooperation on pharmaceutical regulation and trade, the agreement includes cooperation on falsified pharmaceuticals as one of its major focuses and reiterates that ASEAN members will adopt regulations aligned with WHO standards (ASEAN 2023, 1). In addition, the APRF enshrines TRIPS flexibilities, namely each member's right "to adopt specific measures in emergency and special situations identified by and relevant to such Member State" (e.g. compulsory licensing) (ASEAN 2022, 3). Given ASEAN's preference for non-binding and informal cooperation, this represents a significant decision to legalize a regional pro-health approach to regulating falsified pharmaceuticals that directly conflicts with the US position. Across these various statements, plans, and agreements ASEAN shifted to using and defining the pro-health term 'falsified.'

The availability of China's market as an alternative to the US and EU introduced options for trade diversification that minimized the risk of ASEAN engaging in active resistance contra to the US position. Table 2 shows that in 2019, China officially became ASEAN's largest trading partner, doubling its merchandise imports from 7 percent in 2004 to 14 percent in 2019. At the same time, the US and EU's importance to ASEAN exports shrunk slightly, with their combined share of regional imports declining by 3 percent. Under the previously united structural environment, ASEAN risked its economic relationship with both major trade partners—the US and EU—if it actively introduced conflicting falsified

pharmaceutical regulations. However, China's position as ASEAN's new primary economic partner introduced the opportunity for ASEAN to secure this trade relationship through RCEP, ensuring stability in case of US backlash against ASEAN's adoption of pro-health falsified pharmaceutical regulations.

ASEAN's flexible IP norm enabled the body to engage in active regulatory resistance by working together to secure its preferred pharmaceutical regulatory provisions in RCEP. In 2012, negotiations began for RCEP, the only mega-regional trade agreement that did not include the US or EU (Petri and Plummer 2020; Yu 2019b, 2019a, 1). RCEP was designed to consolidate and extend trade agreements between ASEAN and its existing FTA partners—China, Japan, South Korea, Australia, and New Zealand—into a wider trade bloc. The agreement encompasses 30 percent of global output and is set to contribute $500 billion to international trade in the next decade (Petri and Plummer 2020). RCEP represented an opportunity for ASEAN to secure health-friendly IP provisions in this major trading bloc, thus ensuring that these partners would not retaliate against pro-health falsified pharmaceutical regulations within ASEAN. In the shadow of these more powerful economies, this would have represented a near-impossible task for individual ASEAN members. This is especially the case given that Australia, South Korea, Japan, and New Zealand prefer higher pharmaceutical IP standards and regularly feature these in their trade agreements with other countries including the US. However, ASEAN's flexible IP norm facilitated a united front among its members to advocate for pro-health IP regulations in the agreement.

The content of RCEP's IP chapter was not a given but rather reflected the concerted efforts of ASEAN working as a united bloc to institutionalize its flexible IP norm in the agreement. In 2015, a draft IP chapter was leaked that indicated Japan and South Korea were pushing for many TRIPS-plus provisions to be included in RCEP (Mathew 2016). This

included a clause to identify and eliminate trade in goods that infringe on IP, a provision directly related to falsified pharmaceuticals that would endanger "the transfer of medicines from one developing country (where they are legal to manufacture) to another developing country (where they are legal to sell) if they pass through a country that declares those medicines infringing" (Chander and Sunder 2018, 342). However, reports in June 2019 suggested these draft provisions had been removed from the text (Townsend 2021, 3). The removal of these TRIPS-plus provisions coincided closely with ASEAN's announcement of the ASEAN Action Plan for Combating Substandard and Falsified Medicines. Importantly, Townend's interviews with observers of the RCEP negotiations found that "the ten ASEAN member states negotiated RCEP as a bloc and were oriented to a consensus-based negotiating position," with the less-developed members relying "on other middle income countries to resist IP measures beyond TRIPS" (Townsend 2021, 4). ASEAN's shared position on pharmaceutical IP allowed the body to punch above its weight in negotiations where the body "could possibly be sidelined by larger and more powerful economies such as China and Japan" (Hamanaka 2014, 180). When the agreement was signed in November 2020, RCEP's final IP chapter was confirmed to reflect ASEAN's flexible IP norm, preserving TRIPS flexibilities and reaffirming the importance of public health (Regional Comprehensive Economic Partnership 2020, 4). Only five months after RCEP formally took effect with its flexible-IP provisions, ASEAN announced its legally-binding APRF agreement. Having cemented these IP regulations with China and the other RCEP members, ASEAN could regulate falsified pharmaceuticals as a health issue without endangering access to these markets, even in the case of US retaliation.

Conclusion

Studies of regulation have focused on the role of great powers in dictating transnational standards, whether it be through their first mover advantage, high-capacity national regulators, or negotiating leverage provided by their market power. This reflects a broader preoccupation in International Relations with the way in which powerful states shape international economic order (Tourinho 2021). This paper seeks to challenge this position by demonstrating that small states matter in shaping economic regulations that have distributive consequences for both themselves and great powers. Even under the most constraining structural environments, where they are subject to the combined pressure of multiple great powers and risk their trading relationships with both, I find that regional IGOs with shared norms can exercise meaningful resistance against great power regulations that conflict with their interests. When there are divisions on regulatory issues between great powers, regional IGOs can exploit this competition to exercise even greater influence over standards and enact regulations that directly conflict with one great power's position.

In an era where globalization is often purported to standardize many aspects of economic policy across countries, these findings offer one explanation for where we can expect to find divergence rather than convergence in regulatory standards (Drezner 2001; Simmons 2001). In this case, gaps in regulatory coordination can occur even when powerful economies such as the US experience negative externalities in terms of lost profits for important pharmaceutical firms (Simmons 2001, 598). Divergence can result from both passive resistance in the face of highly constraining structural conditions as well as active efforts to exploit fissures between great powers to design an alternative regulatory regime.

In contrast with existing work on developing states and regulatory politics that offer epistemic and framing explanations for their influence over international standards, this study is the first to explore the role of norms as a social mechanism through which these states can impact regulations. Rather than wielding knowledge and alternative frames in regulation, the

locus of agency is rooted in standards of behavior that shape the interests of members and facilitate collective action in the face of great power pressures and divergent interests.

The regulatory resistance theory also advances the study of 'nondecisions' in international politics, in this case through collective passive resistance (Bachrach and Baratz 1963; Hacker and Pierson 2010, 171). Inaction and nondecision are often attributed to lack of capacity of political actors, particularly developing countries. However, in doing so, inaction is overlooked as an important weapon of the weak (Scott 1985, 31).[8] Other studies examine inaction through strategic absences in UN voting by individual states but have not addressed inaction as a collective tactic aimed at powerful external states (Morse and Coggins 2024). While challenging to observe, ASEAN provides the opportunity to examine why a body known for its propensity to make statements and hold meetings entered into a surprising, extended period of silence on a pressing regulatory issue. Inaction on regulating falsified pharmaceuticals under passive resistance enabled ASEAN to avoid adopting regulations that ran contrary to the interests of its members. However, this also came at the cost of leaving this serious issue unregulated at the regional level for over a decade.

The final contribution of this study is an empirical examination of the politics of falsified pharmaceuticals in ASEAN, a substantively important regulatory issue with normative ramifications for health and access to medicines. While an extensive body of literature examines how the US and EU have politicized the regulation of falsified pharmaceuticals at the global level,[9] most work on falsified pharmaceuticals in ASEAN focuses on drug resistance and surveillance (Nayyar et al. 2012; Quet et al. 2018). A handful of scholars have raised the puzzle of ASEAN's political inaction on falsified pharmaceuticals, attributing this to security tensions between members (Lamy 2017; Lamy

[8] For international applications, see S. P. Campbell and Matanock 2024; Lugg 2024; Mesquita 2024.
[9] For example, Attaran, Bate, and Kendall 2011; Bate 2014; Liberman 2012.

and Liverani 2015). However, there is no comprehensive account of the politics of ASEAN's regulation of falsified pharmaceuticals and its relationship to great power interests. This paper makes a unique contribution by demonstrating how conflicts over access to medicines and pharmaceutical profits between ASEAN, the US, and EU manifested in the regulation of falsified pharmaceuticals.

This study undertakes an initial test of the theory of regulatory resistance, opening up future avenues for testing these expectations in further cases. Thus far, the way in which regional IGOs exercise resistance against great powers in the regulatory arena has been overlooked. Given the growth of regional IGOs in the developing world since the end of WWII, there is a rich body of empirics from which to draw on for future tests of this theory and provide additional nuance to when and how these bodies shape transnational regulations.

References

Acharya, Amitav. 2007. "The Emerging Regional Architecture of World Politics." *World Politics* 59(4): 629–52.

Acharya, Amitav. 2014a. *Constructing a Security Community in Southeast Asia: ASEAN and the Problem of Regional Order*. 3rd ed. Abingdon & New York: Routledge.

Acharya, Amitav. 2014b. "Global International Relations (IR) and Regional Worlds: A New Agenda for International Studies*." *International Studies Quarterly* 58(4): 647–59. doi:10.1111/isqu.12171.

Antons, Christoph, and Dilan Thampapillai. 2015. "An Overview of Free Trade Agreements in the Asia-Pacific Region with a Particular Focus on Intellectual Property." In *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region*, MPI Studies on Intellectual Property and Competition Law, eds. Christoph Antons and Reto M. Hilty. Berlin, Heidelberg: Springer, 27–54. doi:10.1007/978-3-642-30888-8.

ASEAN. 2009. *ASEAN Comprehensive Investment Agreement.Pdf*. ASEAN. http://investasean.asean.org/files/upload/Doc%2005%20-%20ACIA.pdf.

ASEAN. 2014a. *ASEAN Community in Figures - Special Edition 2014*. Jakarta: The ASEAN Secretariat.

ASEAN. 2014b. *Joint Statement 12th ASEAN Health Ministers Meeting*. Ha Noi: ASEAN.

ASEAN. 2018. *ASEAN Post-2015 Health Development Agenda 2016-2020*. Jakarta: The ASEAN Secretariat. https://asean.org/storage/2018/12/16-ASEAN-Post-2015-Health-Development-Agenda.pdf.

ASEAN. 2022. *ASEAN Pharmaceutical Regulatory Policy*. Bali: ASEAN. https://asean.org/wp-content/uploads/2022/08/Final-Text-APRP-adopted-AEM-and-AHMM.pdf.

ASEAN. 2023. *ASEAN Pharmaceutical Regulatory Framework*. ASEAN.

ASEAN & China. 2004. *2004 Plan of Action to Implement the Joint Declaration on ASEAN-China Strategic Partnership for Peace and Prosperity*. Vientiene: ASEAN & China. https://asean.org/?static_post=plan-of-action-to-implement-the-joint-declaration-on-asean-china-strategic-partnership-for-peace-and-prosperity.

ASEAN Plus Three. 2019. *Chairman's Statement of the 22nd ASEAN Plus Three Summit*. Bangkok/Nonthaburi: ASEAN Plus Three. https://asean.org/storage/2019/11/APT-Chair-Statement-22nd-APT-Summit-FINAL.pdf.

Attaran, A., R. Bate, and M. Kendall. 2011. "Why and How to Make an International Crime of Medicine Counterfeiting." *Journal of International Criminal Justice* 9(2): 325–54. doi:10.1093/jicj/mqr005.

Bachrach, Peter, and Morton S. Baratz. 1963. "Decisions and Nondecisions: An Analytical Framework." *American Political Science Review* 57(3): 632–42. doi:10.2307/1952568.

Ball, Douglas, and Roderick Salenga. 2017. "Pharmaceutical Policy in the Philippines." In *Pharmaceutical Policy in Countries with Developing Healthcare Systems*, ed. Zaheer-Ud-Din Babar. Cham: Springer, 75–96. doi:10.1007/978-3-319-51673-8.

Ban, Cornel, and Mark Blyth. 2013. "The BRICs and the Washington Consensus: An Introduction." *Review of International Political Economy* 20(2): 241–55. doi:10.1080/09692290.2013.779374.

Bate, Roger. 2014. *Phake: The Deadly World of Falsified and Substandard Medicines*. Washington, D.C: AEI Press.

Beach, Derek, and Rasmus Brun Pedersen. 2019. *Process-Tracing Methods: Foundations and Guidelines*. Second edition. Ann Arbor: University of Michigan Press.

Beeson, Mark. 2006. "American Hegemony and Regionalism: The Rise of East Asia and the End of the Asia-Pacific." *Geopolitics* 11(4): 541–60. doi:10.1080/14650040600890727.

Bennett, Andrew, and Jeffrey T. Checkel, eds. 2015. *Process Tracing: From Metaphor to Analytic Tool*. Cambridge ; New York: Cambridge University Press.

Binder, Martin, and Autumn Lockwood Payton. 2022. "With Frenemies Like These: Rising Power Voting Behavior in the UN General Assembly." *British Journal of Political Science* 52(1): 381–98. doi:10.1017/S0007123420000538.

Bonadio, Enrico, and Carlo Maria Cantore. 2010. “Seizures of In Transit Generics at the EU Borders: India and Brazil v. the EU.” *European Journal of Risk Regulation* 1(4): 404–8. doi:10.1017/S1867299X00000854.

Bounds, Andrew. 2007. “Thais Warned on Drug Pricing Pressure.” *The Financial Times*. https://www.ft.com/content/ad6e844a-46a5-11dc-a3be-0000779fd2ac (March 25, 2021).

Briceno-Ruiz, Jose, and Isidro Morales. 2017. *Post-Hegemonic Regionalism in the Americas: Toward a Pacific–Atlantic Divide?* Routledge.

Brumat, Leiza, and Marcia Vera Espinoza. 2024. “Actors, Ideas, and International Influence: Understanding Migration Policy Change in South America.” *International Migration Review* 58(1): 319–46. doi:10.1177/01979183221142776.

Bruszt, Laszlo, and Gerald A. McDermott, eds. 2014. *Leveling the Playing Field: Transnational Regulatory Integration and Development*. First edition. Oxford: Oxford University Press.

Büthe, Tim, and Walter Mattli. 2011. *The New Global Rulers: The Privatization of Regulation in the World Economy*. Oxford ; Princeton, N.J: Princeton University Press.

Buzdugan, Stephen Robert. 2013. “Regionalism from without: External Involvement of the EU in Regionalism in Southern Africa.” *Review of International Political Economy* 20(4): 917–46. doi:10.1080/09692290.2012.747102.

Campbell, Kurt M. 2016. *The Pivot: The Future of American Statecraft in Asia*. New York & Boston: Twelve.

Campbell, Susanna P., and Aila M. Matanock. 2024. “Weapons of the Weak State: How Post-Conflict States Shape International Statebuilding.” *The Review of International Organizations* 19(3): 469–513. doi:10.1007/s11558-024-09546-3.

Chander, Anupam, and Madhavi Sunder. 2018. “The Battle to Define Asia’s Intellectual Property Law: From TPP to RCEP.” *UC Irvine Law Review* 8(3): 331.

Coe, Brooke N. 2019. *Sovereignty in the South: Intrusive Regionalism in Africa, Latin America, and Southeast Asia*. 1st ed. Cambridge University Press. doi:10.1017/9781108654821.

Collins, Alan, and Edmund Bon Tai Soon. 2024. “The Spiral Model, Scope Conditions, and Contestation in the ASEAN Intergovernmental Commission on Human Rights.” *The Pacific Review* 37(2): 328–59. doi:10.1080/09512748.2023.2168034.

Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products, Board on Global Health, and Institute of Medicine. 2013. *Countering the Problem of Falsified and Substandard Drugs*. eds. Lawrence O. Gostin and Gillian J. Buckley. Washington, D.C.: National Academies Press. doi:10.17226/18272.

Corning, Gregory P. 2018. “The Limits of Market Power in Shaping International Regulatory Cooperation: Path Dependence and Loss Avoidance in the Trans-Pacific Partnership Negotiations.” *The Pacific Review* 31(1): 1–19. doi:10.1080/09512748.2017.1298663.

Debaere, Peter, and Christine Davies. 2009. *Thought This Was Easy? U.S.–Thailand Free Trade Agreement*. University of Virginia. Darden Case. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1583771 (March 24, 2021).

Deere, Carolyn. 2009. *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*. New York: Oxford University Press.

Dent, Christopher M. 2010. “Freer Trade, More Regulation? Commercial Regulatory Provisions in Asia-Pacific Free Trade Agreements.” *Competition & Change* 14(1): 48–79. doi:10.1179/102452910X12587274068114.

Drahos, Peter. 2005. “Developing Countries and International Intellectual Property Standard-Setting.” *The Journal of World Intellectual Property* 5(5): 765–89. doi:10.1111/j.1747-1796.2002.tb00181.x.

Drezner, Daniel W. 2001. “Globalization and Policy Convergence.” *International Studies Review* 3(1): 53–78.

Drezner, Daniel W. 2008. *All Politics Is Global: Explaining International Regulatory Regimes*. Princeton: Princeton University Press.

Dunn, Elizabeth C. 2003. “Trojan Pig: Paradoxes of Food Safety Regulation.” *Environment and Planning A: Economy and Space* 35(8): 1493–1511. doi:10.1068/a35169.

Faris, Muhammad. 2014. “4th ASEANAPOL Police Training Cooperation Meeting (APTCM), Bangkok Thailand.” *ASEANAPOL*. www.aseanapol.org/display/2014/03/26/4th-aseanapol-police-training-cooperation-meeting-(aptcm)-bangkok-thailand.

Finnemore, Martha, and Kathryn Sikkink. 1998. “International Norm Dynamics and Political Change.” *International Organization* 52(4): 887–917.

Flyvbjerg, Bent. 2006. “Five Misunderstandings About Case-Study Research.” *Qualitative Inquiry* 12(2): 219–45. doi:10.1177/1077800405284363.

Fowler, Peter N, Teerin Charoenpot, and David Byrne. 2017. “ASEAN and Intellectual Property: Will a Complicated History Lead to a Certain Future?” *Loyola of Los Angeles International and Comparative Law Review* 40(2): 167–95.

Gallagher, Kevin. 2015. *Ruling Capital: Emerging Markets and the Reregulation of Cross-Border Finance*. Ithaca, New York: Cornell University Press.

George, Alexander L., and Andrew Bennett. 2005. *Case Studies and Theory Development in the Social Sciences*. Cambridge, Mass: MIT Press.

Gerring, John. 2004. “What Is a Case Study and What Is It Good For?” *The American Political Science Review* 98(2): 341–54.

Gerring, John. 2007. *Case Study Research: Principles and Practices*. Cambridge University Press.

Gerring, John, and Rose McDermott. 2007. "An Experimental Template for Case Study Research." *American Journal of Political Science* 51(3): 688–701. doi:10.1111/j.1540-5907.2007.00275.x.

Getachew, Adom. 2019. *Worldmaking after Empire: The Rise and Fall of Self-Determination*. Princeton, New Jersey: Princeton University Press.

Global Risks 2011: An Initiative of the Risk Response Network. 2011. Geneva: World Economic Forum.

Goertz, Gary, and James Mahoney. 2012. *A Tale of Two Cultures: Qualitative and Quantitative Research in the Social Sciences*. Princeton, N. J: Princeton university press.

Hacker, Jacob S., and Paul Pierson. 2010. "Winner-Take-All Politics: Public Policy, Political Organization, and the Precipitous Rise of Top Incomes in the United States." *Politics & Society* 38(2): 152–204. doi:10.1177/0032329210365042.

Hamanaka, Shintaro. 2014. "TPP versus RCEP: Control of Membership and Agenda Setting." *Journal of East Asian Economic Integration* 18(2): 163–86.

Harada, Issaku. 2020. "ASEAN Becomes China's Top Trade Partner as Supply Chain Evolves." *Nikkei Asia*. https://asia.nikkei.com/Politics/International-relations/ASEAN-becomes-China-s-top-trade-partner-as-supply-chain-evolves (March 17, 2021).

Hassali, Mohamed Azmi, Jayabalan Thambyappa, Shankaran Nambiar, Asrul Akmal Shafie, and Hans Löfgren. 2013. "TRIPS, Free Trade Agreements and the Pharmaceutical Industry in Malaysia." In *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South*, eds. Hans Löfgren and Owain David Williams. London: Palgrave Macmillan, 152–66. doi:10.1057/9781137315854.

Hearson, Martin, Rasmus Corlin Christensen, and Tovony Randriamanalina. 2023. "Developing Influence: The Power of 'the Rest' in Global Tax Governance." *Review of International Political Economy* 30(3): 841–64. doi:10.1080/09692290.2022.2039264.

Helleiner, Eric, and Hongying Wang. 2018. "Limits to the BRICS' Challenge: Credit Rating Reform and Institutional Innovation in Global Finance." *Review of International Political Economy* 25(5): 573–95. doi:10.1080/09692290.2018.1490330.

Ho, Cynthia M. 2011. "Global Access to Medicine: The Influence of Competing Patent Perspectives." *Fordham International Law Journal* 35(1): 1–97.

Hofmann, Stephanie C., and Patryk Pawlak. 2023. "Governing Cyberspace: Policy Boundary Politics across Organizations." *Review of International Political Economy* 30(6): 2122–49. doi:10.1080/09692290.2023.2249002.

Husada, Richard, and Raymond R. Tjandrawinata. 2013. “The Healthcare System and the Pharmaceutical Industry in Indonesia.” In *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South*, eds. Hans Löfgren and Owain David Williams. London: Palgrave Macmillan, 134–51. doi:10.1057/9781137315854.

Inside US Trade. 2013. “Malaysian Cabinet Directs Negotiators To Refrain From Endorsing TPP Deadline.” *Inside US Trade*. https://www.proquest.com/docview/1426959784/abstract/7094C16114AB4EA1PQ/1 (April 1, 2025).

Jarvis, Darryl S. L. 2010. “Institutional Processes and Regulatory Risk: A Case Study of the Thai Energy Sector.” *Regulation & Governance* 4(2): 175–202. doi:10.1111/j.1748-5991.2010.01077.x.

Jayasuriya, Kanishka. 2009. “Regulatory Regionalism in the Asia-Pacific: Drivers, Instruments and Actors.” *Australian Journal of International Affairs* 63(3): 335–47. doi:10.1080/10357710903104810.

Jeffs, Jennifer A. 2008. “The Politics of Financial Plumbing: Harmonization and Interests in the Construction of the International Payment System.” *Review of International Political Economy* 15(2): 259–88. doi:10.1080/09692290701869746.

Jones, David Martin, and Michael L.R. Smith. 2007. “Making Process, Not Progress: ASEAN and the Evolving East Asian Regional Order.” *International Security* 32(1): 148–84. doi:10.1162/isec.2007.32.1.148.

Jurkovich, Michelle. 2020. “What Isn’t a Norm? Redefining the Conceptual Boundaries of ‘Norms’ in the Human Rights Literature.” *International Studies Review* 22(3): 693–711. doi:10.1093/isr/viz040.

Katsumata, Hiro. 2012. “East Asian Regional Security Governance: Bilateral Hard Balancing and ASEAN’s Informal Cooperative Security.” In *Comparative Regional Security Governance*, eds. Shaun Breslin and Stuart Croft. New York: Routledge.

Kim, Soo Yeon, and Bruce Russett. 1996. “The New Politics of Voting Alignments in the United Nations General Assembly.” *International Organization* 50(4): 629–52. doi:10.1017/S0020818300033531.

Kimura, Satoru, and Yasuhide Nakamura. 2020. 5 *Poor Quality Pharmaceuticals in Global Public Health*. Singapore: Springer. doi:10.1007/978-981-15-2089-1.

Kivimäki, Timo. 2001. “The Long Peace of ASEAN.” *Journal of Peace Research* 38(1): 5–25. doi:10.1177/0022343301038001001.

Knaack, Peter, and Julian Gruin. 2021. “From Shadow Banking to Digital Financial Inclusion: China’s Rise and the Politics of Epistemic Contestation within the Financial Stability Board.” *Review of International Political Economy* 28(6): 1582–1606. doi:10.1080/09692290.2020.1772849.

Krasner, Stephen D. 1991. “Global Communications and National Power: Life on the Pareto Frontier.” *World Politics* 43(3): 336–66. doi:10.2307/2010398.

Kratochwil, Friedrich V. 1989. *Rules, Norms, and Decisions: On the Conditions of Practical and Legal Reasoning in International Relations and Domestic Affairs*. Cambridge & New York: Cambridge University Press.

Lamy, Marie. 2017. "Framing the Challenge of Poor-Quality Medicines: Problem Definition and Policy Making in Cambodia, Laos, and Thailand." PhD. London School of Hygiene & Tropical Medicine. http://researchonline.lshtm.ac.uk/id/eprint/4645490 (March 24, 2021).

Lamy, Marie, and Marco Liverani. 2015. "Tackling Substandard and Falsified Medicines in the Mekong: National Responses and Regional Prospects: Substandard Medicines in the Mekong." *Asia & the Pacific Policy Studies* 2(2): 245–54. doi:10.1002/app5.87.

"Leaked TPP IP Text Reveals Details Of Conflicting Pharmaceutical Proposals." 2013. *Inside US Trade*. https://www.proquest.com/docview/1458554655/abstract/E11A7B5AE74148E5PQ/1 (April 1, 2025).

Lee, Seok Hwai. 2007. "Free Trade Pact with US Unlikely: Asean Chief." *The Straits Times*.

Liberman, Jonathan. 2012. "Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance." *Journal of Law, Medicine and Ethics* 40(2): 326–47.

Lijphart, Arend. 1971. "Comparative Politics and the Comparative Method." *The American Political Science Review* 65(3): 682–93. doi:10.2307/1955513.

Lu, Ming Q., Sandy Bai, Tan Yuyuan, and Cheng Xu. 2015. "Pharmaceutical Intellectual Property Rights in China." In *Approaching China's Pharmaceutical Market: A Fundamental Guide to Clinical Drug Development*, ed. Ming Q. Lu. Cham: Springer, 221–38. doi:10.1007/978-3-319-15576-0.

Lugg, Andrew. 2024. "Re-Contracting Intergovernmental Organizations: Membership Change and the Creation of Linked Intergovernmental Organizations." *The Review of International Organizations* 19(3): 545–77. doi:10.1007/s11558-024-09533-8.

Manger, Mark S., and Kenneth C. Shadlen. 2014. "Political Trade Dependence and North–South Trade Agreements1." *International Studies Quarterly* 58(1): 79–91. doi:10.1111/isqu.12048.

Margheritis, Ana. 2013. "Piecemeal Regional Integration in the Post-Neoliberal Era: Negotiating Migration Policies within Mercosur." *Review of International Political Economy* 20(3): 541–75. doi:10.1080/09692290.2012.678762.

Mathew, Joe. 2016. "Leaked IPR Chapter of Draft RCEP Hints at TRIPS plus Provisions." *Business Today*. https://www.businesstoday.in/latest/corporate/story/leaked-ipr-chapter-of-draft-rcep-hints-at-trips-plus-provisions-63496-2016-04-20 (March 27, 2024).

Mattli, Walter, and Ngaire Woods, eds. 2009. "In Whose Benefit? Explaining Regulatory Change in Global Politics." In *The Politics of Global Regulation*, Princeton: Princeton University Press.

Meissner, Katharina L. 2019. “Cherry Picking in the Design of Trade Policy: Why Regional Organizations Shift between Inter-Regional and Bilateral Negotiations.” *Review of International Political Economy* 26(5): 1043–67. doi:10.1080/09692290.2019.1625421.

Mesquita, Rafael. 2024. “The Only Living Guerrillero in New York: Cuba and the Brokerage Power of a Resilient Revisionist State.” *The Review of International Organizations* 19(3): 611–39. doi:10.1007/s11558-024-09532-9.

Moon, Suerie, and Nicole Szlezák. 2013. “Rule-Makers, Rule-Shapers, and Rule-Takers: What Role for Asia in the Global Governance of Intellectual Property Rules and Global Health?” In *Asia’s Role in Governing Global Health*, eds. Kelley Lee, Tikki Pang, and Yeling Tan. Routledge, 137–57.

Morse, Julia C., and Bridget Coggins. 2024. “Your Silence Speaks Volumes: Weak States and Strategic Absence in the UN General Assembly.” *The Review of International Organizations* 19(3): 515–44. doi:10.1007/s11558-024-09538-3.

Nayyar, Gaurvika ML, Joel G Breman, Paul N Newton, and James Herrington. 2012. “Poor-Quality Antimalarial Drugs in Southeast Asia and Sub-Saharan Africa.” *The Lancet Infectious Diseases* 12(6): 488–96. doi:10.1016/S1473-3099(12)70064-6.

Negri, Stefania. 2016. “Combating Pharmaceutical Crimes through European Criminal Law and Beyond.” *New Journal of European Criminal Law* 7(3): 350–67.

Nesadurai, Helen E. S. 2009. “ASEAN and Regional Governance after the Cold War: From Regional Order to Regional Community?” *The Pacific Review* 22(1): 91–118. doi:10.1080/09512740802651169.

New, William. 2017. “WHO Board Agrees To Drop The Word ‘Counterfeit’ After 30 Years.” https://www.ip-watch.org/2017/01/30/board-agrees-drop-word-counterfeit-30-years/.

Ng-Loy, Wee Loon. 2015. “IP and FTAs of Singapore: Ten Years On.” In *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region*, MPI Studies on Intellectual Property and Competition Law, eds. Christoph Antons and Reto M. Hilty. Berlin, Heidelberg: Springer, 337–54. doi:10.1007/978-3-642-30888-8.

Osiemo, Onsando. 2018. “Saving Africa: The GMO Cold War and the Battle for Africa.” *Journal of World Trade* 52(Issue 1): 143–62. doi:10.54648/TRAD2018007.

Outterson, Kevin, and Ryan Smith. 2006. “Counterfeit Drugs: The Good, the Bad, and the Ugly.” *Albany Law Journal of Science and Technology* 16(3): 525–44.

Ozawa, Sachiko, Daniel R. Evans, Sophia Bessias, Deson G. Haynie, Tatenda T. Yemeke, Sarah K. Laing, and James E. Herrington. 2018. “Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries.” *JAMA Network Open* 1(4): e181662. doi:10.1001/jamanetworkopen.2018.1662.

Pape, Fabian, and Johannes Petry. 2024. “East Asia and the Politics of Global Finance: A Developmental Challenge to the Neoliberal Consensus?” *Review of International Political Economy* 31(1): 224–52. doi:10.1080/09692290.2023.2170445.

Perlman, Rebecca L. 2023. *Regulating Risk: How Private Information Shapes Global Safety Standards*. Cambridge University Press.

Petri, Peter A., and Michael Plummer. 2020. “RCEP: A New Trade Agreement That Will Shape Global Economics and Politics.” *Order from Chaos*. https://www.brookings.edu/blog/order-from-chaos/2020/11/16/rcep-a-new-trade-agreement-that-will-shape-global-economics-and-politics/.

Phillips, Nicola. 2001. “Regionalist Governance in the New Political Economy of Development: ‘Relaunching’ the Mercosur.” *Third World Quarterly* 22(4): 565–83. doi:10.1080/01436590120071786.

Quet, Mathieu. 2017. “Values in Motion: Anti-Counterfeiting Measures and the Securitization of Pharmaceutical Flows.” *Journal of Cultural Economy* 10(2): 150–62. doi:10.1080/17530350.2016.1258001.

Quet, Mathieu, Laurent Pordié, Audrey Bochaton, Supang Chantavanich, Niyada Kiatying-Angsulee, Marie Lamy, and Premjai Vungsiriphisal. 2018. “Regulation Multiple: Pharmaceutical Trajectories and Modes of Control in the ASEAN.” *Science, Technology and Society* 23(3): 485–503. doi:10.1177/0971721818762935.

Ramani, Shyama V., and Eduardo Urias. 2015. “Access to Critical Medicines: When Are Compulsory Licenses Effective in Price Negotiations?” *Social Science & Medicine* 135: 75–83. doi:10.1016/j.socscimed.2015.04.023.

Regional Comprehensive Economic Partnership. 2020. https://www.dfat.gov.au/sites/default/files/rcep-chapter-11.pdf.

Republic of the Philippines Food and Drug Administration. 2018. *Food and Drug Administration Advisory No 2018-232*. Manila: Republic of the Philippines Food and Drug Administration. https://www.fda.gov.ph/wp-content/uploads/2018/08/FDA-Advisory-No.-2018-232.pdf (March 25, 2021).

Republic of the Philippines Food and Drug Administration. 2019. *Food and Drug Administration Advisory No 2019-140*. Republic of the Philippines Food and Drug Administration. https://ww2.fda.gov.ph/attachments/article/583805/FDA Advisory No. 2019-140.pdf.

Riggirozzi, Pía, and Diana Tussie, eds. 2012. *The Rise of Post-Hegemonic Regionalism: The Case of Latin America*. Dordrecht: Springer Netherlands. doi:10.1007/978-94-007-2694-9.

Rodrik, Dani. 2018. “What Do Trade Agreements Really Do?” *Journal of Economic Perspectives* 32(2): 73–90. doi:10.1257/jep.32.2.73.

Scollay, Robert. 2007. “Prospects for Linking Preferential Trade Agreements in the Asia-Pacific Region.” In *An APEC Trade Agenda? The Political Economy of a Free Trade*

Area of the Asia-Pacific, eds. Charles E. Morrison and Eduardo Pedrosa. Singapore: ISEAS Publishing, 164–89. doi:10.1355/9789812304612-009.

Scott, James C. 1985. *Weapons of the Weak: Everyday Forms of Peasant Resistance*. New Haven: Yale University press.

Sell, Susan K. 2009. "Cat and Mouse: Forum-Shifting in the Battle over Intellectual Property Enforcement." *SSRN*: 1–31.

Shambaugh, David. 2018. "U.S.-China Rivalry in Southeast Asia: Power Shift or Competitive Coexistence?" *International Security* 42(4): 85–127. doi:10.1162/isec_a_00314.

Simmons, Beth A. 2001. "The International Politics of Harmonization: The Case of Capital Market Regulation." *International Organization* 55(3): 589–620. doi:10.1162/00208180152507560.

Snidal, Duncan, Thomas Hale, Emily Jones, Claas Mertens, and Karolina Milewicz. 2024. "The Power of the 'Weak' and International Organizations." *The Review of International Organizations* 19(3): 385–409. doi:10.1007/s11558-024-09531-w.

Söderbaum, Fredrik. 2004. "Modes of Regional Governance in Africa: Neoliberalism, Sovereignty Boosting, and Shadow Networks." *Global Governance* 10(4): 419–36.

Söderbaum, Fredrik, and Luk Van Langenhove. 2005. "Introduction: The EU as a Global Actor and the Role of Interregionalism." *Journal of European Integration* 27(3): 249–62. doi:10.1080/07036330500190073.

Sotheary, Pech. 2019. "Asean to Jointly Tackle Fake Medicines." *The Khmer Times*: 13.

Steinberg, Richard H. 2002. "In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO." *International Organization* 56(2): 339–74. doi:10.1162/002081802320005504.

Stevens, Philip, and Helmy Haja Mydin. 2013. *Fake Medicines in Asia*. Emerging Markets Health Network. EMHN Briefing. http://ideas.org.my/wp-content/uploads/2017/03/Fake-Medicine-Asia-Feb-2013.pdf.

Subramanian, Sujitha. 2015. "The Changing Dynamics of the Global Intellectual Property Legal Order: Emergence of a 'Network Agenda'?" *International and Comparative Law Quarterly* 64(1): 103–39. doi:10.1017/S0020589314000426.

Tannoury, Maya, and Zouhair Attieh. 2017. "The Influence of Emerging Markets on the Pharmaceutical Industry." *Current Therapeutic Research, Clinical and Experimental* 86: 19–22. doi:10.1016/j.curtheres.2017.04.005.

Teo, Hui Sin, Christina Foerg-Wimmer, and Pei-Lyn Melissa Chew. 2016. *Medicines Regulatory Systems and Scope for Regulatory Harmonization in Southeast Asia*. Washington, D.C.: World Bank. doi:10.1596/26801.

Tourinho, Marcos. 2021. "The Co-Constitution of Order." *International Organization* 75(2): 258–81. doi:10.1017/S0020818320000466.

Townsend, Belinda. 2021. "Defending Access to Medicines in Regional Trade Agreements: Lessons from the Regional Comprehensive Economic Partnership – a Qualitative Study of Policy Actors' Views." *Globalization and Health* 17(1): 78. doi:10.1186/s12992-021-00721-4.

United Nations Office on Drugs and Crime. 2019. *Transnational Organized Crime in Southeast Asia: Evolution, Growth and Impact*. United Nations Office on Drugs and Crime. https://www.unodc.org/documents/southeastasiaandpacific/Publications/2019/SEA_TOCTA_2019_web.pdf.

Wattanapruttipaisan, Thitapha. 2015. "The Topology of ASEAN FTAs, with Special Reference to IP-Related Provisions." In *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region*, MPI Studies on Intellectual Property and Competition Law, eds. Christoph Antons and Reto M. Hilty. Berlin, Heidelberg: Springer, 27–54. doi:10.1007/978-3-642-30888-8.

Williams, James H., and Navroz K. Dubash. 2004. "Asian Electricity Reform in Historical Perspective." *Pacific Affairs* 77(3): 411–36.

Wongburanavart, Archariya. 2022. *Cooperation in Intellectual Property and the ASEAN Way: Challenges and Opportunities for the ASEAN Economic Community*. Center for International Law, National University of Singapore. https://cil.nus.edu.sg/wp-content/uploads/2022/06/4.-Ideas-in-Progress-2022-Archariya-Wongburanavart.pdf.

Woods, Ngaire, and Domenico Lombardi. 2006. "Uneven Patterns of Governance: How Developing Countries Are Represented in the IMF." *Review of International Political Economy* 13(3): 480–515.

World Health Organization. 2008. *Sixty-First World Health Assembly Summary Records of Committees*. Geneva: World Health Organization. https://apps.who.int/gb/ebwha/pdf_files/WHA61-REC3/A61_REC3-en.pdf.

World Health Organization. 2009. *Executive Board 124th Session Summary Records: Ninth Meeting*. Geneva: World Health Organization. https://apps.who.int/gb/ebwha/pdf_files/EB124-REC2/B124_REC2-en-Meeting9.pdf (March 25, 2021).

World Trade Organization. 1995. *Trade Policy Review Mechanism: Republic of Côte d'Ivoire, Report by the Secretariat*. Geneva: World Trade Organization. Trade Policy Review. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/TPR/S2-0.pdf&Open=True.

Wu, Felicia, and William P. Butz. 2004. *The Future of Genetically Modified Crops: Lessons from the Green Revolution*. Santa Monica, Calif.: Rand.

Yu, Peter K. 2011. "Sinic Trade Agreements." *U.C. Davis Law Review* 44(3): 953–1028.

Yu, Peter K. 2016. "Clusters and Links in Asian Intellectual Property Law." In *Routledge Handbook of Asian Law*, ed. Christoph Antons. Abingdon & New York: Routledge, 147–66. doi:10.4324/9781315660547.

Yu, Peter K. 2019a. “The RCEP Negotiations and Asian Intellectual Property Norm Setters.” In *The Future of Asian Trade Deals and IP*, eds. Liu Kung-Chung and Julien Chaisse. London: Hart Publishing. doi:10.5040/9781509922802.

Yu, Peter K. 2019b. “The Rise of China in the International Intellectual Property Regime.” In *Handbook on the International Political Economy of China*, Cheltenham & Northampton: Edward Elgar, 424–44. doi:10.4337/9781786435064.00033.

Yu, Peter K. 2020. “China’s Innovative Turn and the Changing Pharmaceutical Landscape.” *The University of the Pacific Law Review* 51(3): 593–620.