A Prescription for Better Trade: Healing Indonesia's Protectionism

How Solving Amgen's Market Access Problem Will Reverse an Unhealthy Trade Trend

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Amgen, a US biotechnology leader, is seeking to enter the Indonesian market. Indonesia is the world's fourth most populous nation and maintains the world's largest government-sponsored universal healthcare program. Amgen is successfully treating serious illness in over 100 countries and is encouraged by Indonesia's growth and shifting demand from generic drugs into specialty products.[1] To service its ambitious economic agenda, Indonesia enacted restrictions on foreign companies to localize innovation and economic activity. The biopharmaceutical sector is especially targeted by these policies, which leads to trade barriers that pose considerable business liabilities and unfairly restrict market access for companies offering transformative medicines and world-class biologic manufacturing.

Indonesia's Ministry of Health Regulation 1010 requires foreign pharmaceutical companies either to manufacture locally or to entrust another registered manufacturing company in Indonesia to obtain drug approvals on its behalf.[2] Among its requirements, Regulation 1010 contains a mandatory technology transfer requirement and permits a foreign biopharmaceutical company to import medicines into Indonesia only if it transfers relevant technology so that those medicines can be domestically produced within five years.[3] The first condition is unfeasible given the structure of global pharmaceutical supply chains and the second condition poses a serious threat to IP protection and patient safety.

In this paper, I will argue that the local manufacturing and technology transfer requirements of Regulation 1010 contravene Indonesia's WTO obligations under the General Agreement on Tariffs and Trade (GATT) and Trade-Related Aspects of Intellectual Property Rights (TRIPS). To solve this problem and improve market access, I recommend that the US suspend Indonesia's participation in the General System of Preferences (GSP) by invoking intellectual property and market access conditionality. The benefit of this will be twofold:

combat the proliferation of IP violations by sending a serious message to middle-income and developing countries and encouraging domestic reprisal against Indonesia's overly protectionist trade regime. This will likely catalyze a meaningful change in the domestic politics governing imports and exports, ultimately enhancing Indonesia's development prospects and improving industries where import inputs are critical, as in the case of pharmaceuticals.

The localization barriers erected by the government condition foreign market access on compliance that violates Indonesia's general obligations under the WTO rules, which prohibit discrimination based on whether products are imported or produced domestically. Regulation 1010 forces significant IP-barriers and prevents multinational research-based pharmaceutical companies from achieving marketing authorization for their products.

Under these conditions, the only way Amgen can bring its lifesaving products to market is to give up its lifeblood – relinquishing IP and transferring its relevant technology. Several insurmountable barriers arise from these restrictions; Amgen's products are incredibly complex and require expensive and specialized manufacturing sites. The company does not operate via manufacturing partners. Rather, it leverages a few anchor sites designed to supply the global market. Further complicating matters, Indonesia requires local content requirements above 35% for the production process.[4] These requirements violate the fourth and fifth paragraphs of GATT Article III, respectively. The fourth paragraph establishes the national treatment principle, which requires imported products to be treated no less favorably than domestic products with respect to laws and regulations affecting their sale or use; the fifth paragraph prohibits internal regulation relating to the processing or use of products in specific amounts from domestic sources.[5] No aspect of Indonesia's onerous localization barriers enables Amgen to comply without impairing its business model. Indonesia lacks the inputs, sophisticated technologies, and human capital

required to meet the lowest feasibility hurdles that its own regulations set up for cutting-edge companies like Amgen.

The most harmful consequence to Amgen is the forced technology transfer and lack of IP protection. Amgen incurs meaningful capital outlays to bring its drugs to market. The average cost to research and develop a specialty drug is ~$2.6 billion.[6] Requiring technology transfer to import medicines into Indonesia creates distortions and significantly advantages Indonesia's domestic firms with no clear innovation benefits. Indonesia fails to comply with two important provisions of the WTO Agreement on TRIPS. The first provision covered in Article 27.1 states that "patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[7] There are considerable patent infringement risks associated with mandatory technology transfer by foreign manufacturers. Amgen's patent rights are subject to local discrimination. Interpreting the text of TRIPS Article 39.3 forces the burden on governments to protect against unfair commercial usage. In this regard Indonesia falls short; the country ranks 45/50 on the U.S. Chamber of Commerce IP index which renders Indonesia's IP framework among the worst offenders.[8]

Without offering appropriate safeguards, Indonesia assures US companies like Amgen that any trade benefit will be undermined by innovation theft, thereby setting up an irredeemable deficit and a dangerous precedent for the world's largest market for biopharmaceutical products and IPR holders on most new medicines.[9] The destructive nature of Indonesia's trade barriers combined with a lack of competitiveness in multiple sectors, including the health sector, could be its biggest impediment to becoming one of the five largest global economies by 2030. Indonesia loses 30% of GDP annually due to non-communicable diseases and outbound medical tourism.[10] Although Indonesia's health sector market is growing rapidly its policies foster a lack of

dynamism that results in a low level of clinical research and the inability to develop and retain high-skilled labor (see Appendix A), and attract necessary foreign investment. Empirical models suggest that protection measures are associated with 40% to 80% lower FDI inflows.[11]

Amgen, through the power of PhRMA (the largest US trade group) and its own lobbying efforts, should encourage the current presidential administration to suspend GSP benefits (duty-free treatment) for all or certain eligible products. There are currently 3,572 products covered by the GSP facility that contribute to Indonesia's $12.7 billion trade surplus with the US; in practice, only 20% of Indonesia's products covered under GSP status are exported.[12] The US should review and suspend products that would not have material trading consequences.

The strategic importance of our trading relationship with Indonesia will continue to expand, fueled by Indonesia's increasing dominance in the Southeast Asian region and growing share of the global economy. Progress in addressing IP protection and enforcement concerns now will be critical if our two countries plan to move towards a more fulsome realization of our trade potential in the future. If the US does not defend the fair opportunity to use and profit from IPR then countries like Indonesia will continue to free-ride on American investments while failing to confer benefits to consumers and improve patient outcomes.

Furthermore, the suspension of GSP benefits may have the positive benefit of narrowing the distortionary trade politics in recipient countries like Indonesia, which also belongs to the WTO. GSP recipients who join the WTO have empirically been shown to realize lesser gains in trade, notably in terms of imports because they are less vulnerable to ad hoc conditionality restrictions.[13] This perceived benefit comes at a significant cost in the form of higher trade barriers at home. Exporters are not incentivized to lobby against domestic protectionism and therefore sustain domestic politics that are less conducive to facilitating global trade. By

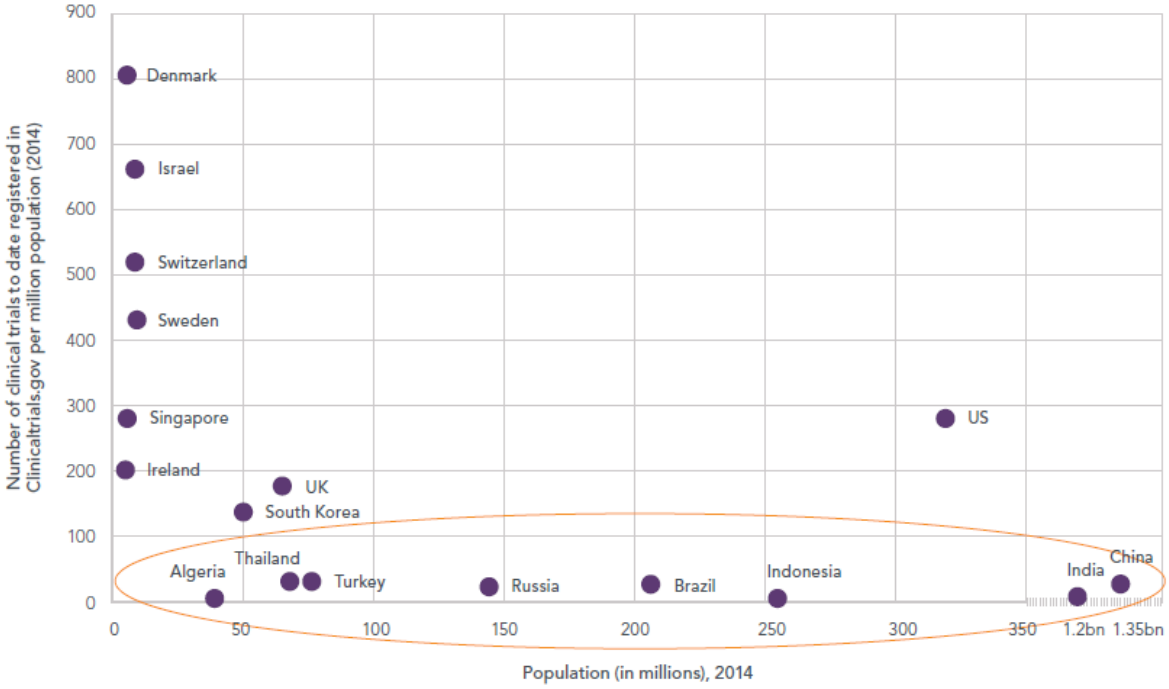
removing GSP benefits the US can reset the balance of the GSP system and encourage economic reforms that facilitate market access for American businesses and improve a country's development prospects.

Indonesia has been on the USTR's Special 301 Priority Watch List since 2009 given its record of failing to enforce and protect IPR.[14] By failing to respond the US weakens the significance of appearing on the list and therefore the efficacy of the Watch List as an enforcement tool and credible threat. Our approach to mediating intellectual property issues should be a blended approach of "carrot and stick." There are mutually beneficial incentive-based policies that the US could explore with Indonesia to encourage market-based growth. The US has already demonstrated a willingness to invest in Indonesian infrastructure with its most recent $5 billion commitment.[15] If Indonesia were to implement tax benefits and adopt a robust IP framework, US biopharmaceutical firms would be more willing to enhance R&D capacity and clinical research activities. Research done by the US Chamber of Commerce in its International IP Index has examined this relationship, finding statistically significant correlations between IP incentives on the one hand, and innovation output and clinical trials on the other hand.[16]

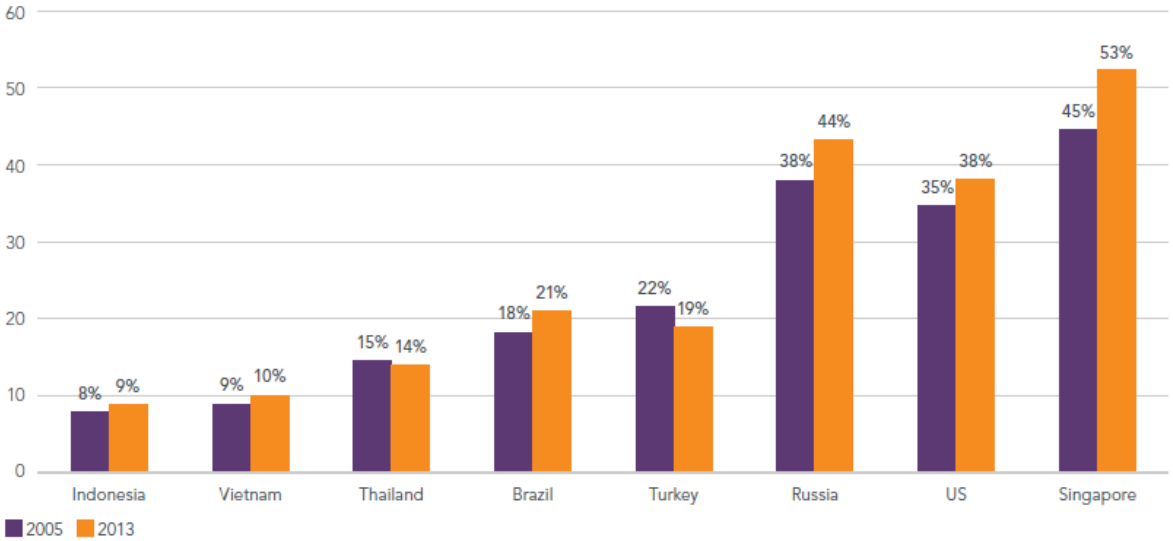
This paper outlines the ways in which Indonesia specifically flouts global trade rules to restrict market access. I have demonstrated how a concrete solution to combat Amgen's import challenges has the potential to yield mutually beneficial outcomes. By suspending Indonesia's GSP access, the US succeeds in boosting biotechnology export and beating back IP violations and trade restrictions that impede global trade growth. If Indonesia responds constructively, it will be better positioned to care for its growing population with revolutionary medicines, stimulate biopharmaceutical R&D, and improve its trading relationships. This is a trade prescription worth filling.

Appendix [17]

Clinical research, sample developed and emerging markets



Share of workforce employed in knowledge-intensive activities (%), 2005 vs. 2013



Source: ILOSTAT database, Employment distribution by occupation, ISCO-88 categories 1, 2 and 3; data for Indonesia (2007 and 2013) and Vietnam (2009 and 2013)

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