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Home remedies: flexibilities to onshore pharmaceutical manufacturing under WTO rules

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ABSTRACT

In the wake of the Coronavirus Disease 2019 pandemic, governments globally have intensified efforts to localize the production of pharmaceuticals, leveraging local content requirements and incentives to mitigate supply chain vulnerabilities. This shift has revealed tensions with World Trade Organization (WTO) regulations, notably highlighted in *Turkey—Pharmaceutical Products (EU)*. This article explores policy-based flexibilities within the General Agreement on Tariffs and Trade (GATT) 1994, the Agreement on Trade-Related Investment Measures, and the Subsidies and Countervailing Measures (SCM) Agreement that may justify measures inconsistent with WTO norms under specific conditions. Analysing public health exceptions, national security imperatives, and government procurement policies, the paper elucidates how these flexibilities can be mobilized to support onshoring initiatives while adhering to international trade obligations. The findings suggest a nuanced approach to reconciling public health goals and economic strategies with global trade rules, providing a critical framework for policymakers navigating the complex interplay between national interests and international legal commitments.

INTRODUCTION

Government efforts to onshore pharmaceutical manufacturing, using local content requirements and incentives, have intensified since the Coronavirus Disease 2019 (COVID-19) pandemic.[1] Some pre-COVID policies to promote local content in pharmaceutical manufacturing had economic rationales, such as developing new industries or reducing trade deficits.[2] More recently, however, these policies have been justified in terms of public health, supply chain resilience, geopolitical risk, and national security concerns. Mitigating the risks associated

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[1] See generally Andrew Mitchell, 'The Geography of Health: Onshoring Pharmaceutical Manufacturing to Address Supply Chain Challenges' (2024) 23 World Trade Rev 1–13 (forthcoming).

[2] See eg Ministry of Chemicals and Fertilizers, Order No 31026/4/2018; Final Panel Report as issued to the parties in *Turkey—Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products (Turkey–Pharmaceutical Products (EU))*, attached to Türkiye's notice of recourse to arbitration (WT/DS583/12 and Add.1), para 7.210.

with the *location* of pharmaceutical manufacturing is central to these justifications. For many governments, pharmaceutical and other medical supply shortages during the COVID-19 pandemic underscored the risks of relying on foreign suppliers for critical products.[3] Local content requirements and incentives are thus intended to ameliorate these risks by bringing some pharmaceutical manufacturing back into a government's territory.

However, policies to promote local content in pharmaceutical manufacturing sit uncomfortably with the rules of the World Trade Organization ('WTO').[4] This tension came to the fore in the recent WTO litigation *Turkey—Pharmaceutical Products (EU)*. The European Union (EU) complained that Turkey's local content policies violated WTO rules. In contrast, Turkey invoked a series of flexibilities related to public health and government procurement, which it claimed justified the policies under WTO law. In a ruling that raised eyebrows[5]—particularly amidst the then-ongoing COVID-19 pandemic—the WTO adjudicators sided with the EU.[6]

A suite of policy-based flexibilities in the GATT 1994 [as cross-applied to the Trade-Related Investment Measures (TRIMs) Agreement] and the Subsidies and Countervailing Measures (SCM) Agreement could potentially save otherwise-inconsistent measures to onshore pharmaceutical manufacturing through local content requirements and incentives. I refer to these as 'flexibilities' because they take various legal forms despite all being ways in which policy-based considerations can be considered.[7] They include derogations within the substantive obligation itself, exception clauses that justify violations of the substantive violation, and definitional aspects of the substantive obligation that can potentially encompass regulatory considerations.

The availability of a given policy-based flexibility depends on the nature of the impugned measure to promote onshoring and on which rule may be transgressed under the WTO framework. For instance, the flexibilities available to justify a subsidy that reimburses sales of domestically manufactured pharmaceuticals are not necessarily the same as those that impose local content requirements for eligibility to tender in government procurement. Likewise, the flexibilities available to justify violations of the TRIMs Agreement Article 2.1 and of the GATT Article III differ from those available to justify Article 3.1(b) of the SCM Agreement.

For these reasons, I begin this article by examining each of the flexibilities potentially applicable to onshoring measures that are incompatible with Article 2.1 of the TRIMs Agreement and Article III of the GATT (GATT and TRIMs section). These include exceptions on public health and essential security interests, as well as derogations on government procurement and subsidies for domestic producers. I then turn to the main flexibility available under Article 3.1(b) of the SCM Agreement, which pertains primarily to the role of regulatory objectives in defining the market-based benchmark under Article 1.1(b) (SCM Agreement section).

GATT AND TRIMS

Public health

The public health exception reflected in Article XX(b) of the GATT 1994 is perhaps the most intuitive flexibility that could justify a measure to onshore pharmaceutical manufacturing that otherwise violates TRIMs Agreement Article 2.1 and GATT 1994 Article III. The outcome of the *Turkey—Pharmaceutical Products* case offers useful—if contestable—insights in this regard.

[3] See eg Department of Health and Human Services (et al), 'National Strategy for a Resilient Health Supply Chain' (July 2021) 9; European Commission, Addressing medicine shortages in the EU (24 October 2023, COM(2023) 672) 1.

[4] Andrew Mitchell, 'Hometown Heroes: Onshoring, Promoting Local Content & WTO Law' (2024) 25 J World Investment Trade 481.

[5] See eg Julia Qin, 'Turkey–Pharmaceuticals: The First WTO Arbitration for Appellate Review' (2022) 49 Leg Issues Econ Integr 415, 419–420, 422–423; Weihuan Zhou, 'International Decisions: Turkey—Pharmaceutical Products' (2023) 117 Am J Int Law 322, 326–329.

[6] Panel Report, *Turkey–Pharmaceutical Products (EU)*, para 7.210.

[7] I note that the legal form and character of the relevant flexibility can have significant implications on matters such as apportioning the burden of proof, but such considerations are beyond the scope of the present article.

The WTO panel (upheld on appeal[8]) appeared to be at pains to emphasize that Article XX(b) could potentially accommodate measures to onshore pharmaceutical manufacturing. It was careful 'to stress that this dispute does not involve any challenge to Turkey's declared objective of preventing a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products' and appeared to accept that 'Members may, in the context of Article XX(b), take measures to address the risk of future shortages of supplies before such shortages actually arise'.[9] It further clarified that

> The Panel is aware that the COVID-19 pandemic has prompted many WTO Members to consider increasing their local production of certain pharmaceutical products to mitigate against risks of disruptions in global supply chains in respect of essential medicines (including the raw materials needed to produce them). The Panel is also cognizant of the growing consensus within the international community that the local production of medicines can provide for greater sustainability of supply chains, especially in public health emergencies.[10]

The panel thus seemed sensitive to the pandemic-related moves by many States to protect themselves against future risks of shortages by developing domestic manufacturing capabilities. It nonetheless adopted a decidedly exacting approach in reviewing Turkey's onshoring measure and rejected Turkey's attempted defence under Article XX(b). In doing so, it briskly dismissed any relevance of the pandemic era pharmaceutical shortages in establishing a public health defence grounded in Article XX(b):

> The COVID-19 pandemic does not demonstrate, however, how over-reliance on imports of globally available pharmaceutical products can lead to long-term risks of shortage of these products, nor how occasional disruptions of supply of *some* pharmaceutical products can be indicative of a potential risk of disruption of supply of *all* pharmaceutical products[11]

As a matter of evidence, this observation is doubtful.[12] As a matter of sentiment, it has proven somewhat provocative.[13] Thus, I will explore in more detail why Turkey's Article XX(b) defence failed and what implications this case could have for other States' measures to onshore pharmaceutical manufacturing. Article XX(b) provides:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: …

The Turkish measure challenged by the EU sought to onshore pharmaceutical manufacturing by requiring foreign producers to commit to localizing their production of certain pharmaceutical products in Turkey. If foreign producers did not make commitments, accept them, or fulfil them,

[8] Note that, *in lieu* of a functioning Appellate Body, the parties appointed a bilateral appellate arbitral mechanism.
[9] Panel Report (n 6) para 7.161.
[10] ibid para 7.209.
[11] ibid para 7.179 (emphasis original).
[12] As discussed in Mitchell (n 1) section 'Onshoring pharmaceutical production: finding the problem to be solved', the pandemic exposed and exacerbated pre-existing structural vulnerabilities in the pharmaceutical supply chain that continue to persist.
[13] See eg Qin (n 5), 419–420, 422–423; Zhou (n 5), 326–329.

their products would no longer be reimbursed by Turkey's social security scheme, which covered almost 90 per cent of the Turkish pharmaceutical market.[14]

Turkey's objective was to gradually transform from imports to domestic production of pharmaceuticals, with a target of 60 per cent of domestic demand (by value) being met by domestic production.[15] Although Turkey seemed to acknowledge that the measure had been at least partly motivated by economic considerations,[16] it argued that enhancing domestic production of pharmaceuticals also served public health objectives.[17] In particular, promoting domestic production would allow for closer regulatory oversight and reduce the risk that arises from reliance on imported pharmaceuticals, such as shortages that could arise from Turkey's currency volatility or its lack of attractiveness to foreign suppliers as a low-price market.[18]

The EU argued that Turkey provided no evidence to substantiate its proposition that reliance on *imported* pharmaceuticals led to a risk of shortages such as past instances where this had occurred. Moreover, the EU argued that Turkey's measure was not calibrated towards specific pharmaceuticals vulnerable to shortages but encompassed all pharmaceuticals irrespective of their risk profile.[19] Indeed, the EU noted that Turkey's scheme prioritized pharmaceuticals for which there were already diversified sources of supply and existing solid domestic production and thus targeted pharmaceuticals for which there was no actual risk of shortage.[20] Turkey responded that its measure involved a longer-term scheme to ensure uninterrupted access to medicines and to prevent shortages from occurring well into the future, thus dispensing with any need to prove that it ameliorated current or past shortages or that its scope needed to be calibrated to products currently at risk of shortage.[21]

The panel sided with the EU. It applied the usual two-step analytical framework for Article XX(b) defences, which begins with whether the challenged measure is 'necessary to protect human, animal or plant life or health' under subparagraph (b) before proceeding to the chapeau inquiry of whether the measure is applied 'in a manner which would constitute a means of arbitrary or unjustifiable discrimination' or as 'a disguised restriction on international trade'.[22] Under the first step of the analytical framework in relation to subparagraph (b), the panel divided its assessment into whether the challenged measure could be properly characterized as a measure designed to protect a public health objective and, if so, whether the challenged measure was 'necessary' to achieve that objective. In that regard, according to WTO jurisprudence, a challenged measure cannot be said to be designed to protect a public health objective if either the objective does not actually protect public health or the measure itself is incapable of achieving the objective.[23] Likewise, a challenged measure cannot be said to be 'necessary' to protect a public health objective if less trade-restrictive ways of achieving the same degree of protection are shown to be reasonably available.[24]

The panel immediately accepted the premise that preventing future risks of pharmaceutical shortages qualified as a 'public health' objective.[25] The panel's evaluation of Turkey's defence

[14] Panel Report (n 6) para 7.122.
[15] Award of the Arbitrators, *Turkey—Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products—Arbitration under Article 25 of the DSU (Turkey–Pharmaceutical Products (EU) (Article 25)*, WT/DS583/ARB25 and Add.1, 25 July 2022 Arbitral Award, para 6.9.
[16] Panel Report (n 6) para 7.144.
[17] ibid para 7.142.
[18] ibid para 7.172, footnote 517.
[19] ibid paras 7.155, 7.160.
[20] ibid paras 2.23, 7.140, 7.155.
[21] ibid para 7.141.
[22] ibid paras 7.132–7.138, 7.164.
[23] ibid paras 7.135, 7.136.
[24] Andrew Mitchell, James Munro and Tania Voon, 'Importing WTO General Exceptions into International Investment Agreements: Proportionality, Myths and Risks' in Lisa Sachs, Lise Johnson and Jesse Coleman (eds), *Yearbook of International Investment Law and Policy 2017* (OUP, New York, NY, USA 2019), 329–330.
[25] Panel Report (n 6) paras 7.160–7.162.

thus began—and ultimately ended—with what it described as the 'threshold issue' of whether Turkey's measure was actually designed to pursue this objective.[26] It held that Turkey failed to adduce sufficient evidence of an actual risk of pharmaceutical shortages due to an over-reliance on imports, finding instead that such a risk was 'theoretical, abstract and hypothetical'.[27] Specifically, the panel pointed to Turkey's failure to provide examples where foreign producers had decided to stop selling pharmaceuticals to Turkey, eg because of higher prices in other markets or the adverse effects of Turkey's currency volatility.[28] Instead, the panel considered that the measure 'appears to pursue an industrial policy objective' given the measure's legislative history pointing to concerns around Turkey's trade deficit.[29] Relatedly, the measure's key metrics and targets seemed to have an economic character, such as achieving 60 per cent market share by value, higher capacity utilization, and higher employment. The panel thus held that there was 'no rational relationship' between the measure's economic goals on the one hand and the objective of ensuring a continuous supply of pharmaceuticals on the other hand.[30] The panel concluded that Turkey's measure was not designed to pursue a public health objective. Given that this conclusion was fatal to Turkey's Article XX(b) defence, the panel found it unnecessary to proceed with the 'necessity' and chapeau stages of the analysis. Accordingly, the EU's proposed less trade-restrictive alternative measures—such as creating contingency reserves of medicines at risk of shortage or diversifying sources of supply—did not feature in the panel's assessment.[31]

On appeal, the appellate arbitrators (agreed to by the parties *in lieu* of a functioning Appellate Body) essentially accepted the approach taken by the panel. In particular, the appellate arbitrators agreed that an inquiry into whether the challenged measure 'is incapable of meeting the stated objective' was an appropriate threshold inquiry of whether a measure is 'designed to' protect human, animal, or plant life or health.[32] The appellate arbitrators also rejected Turkey's assertion that the panel erred by requiring that a measure address a health risk that has 'a substantial degree of probability' of materializing for that measure to be 'designed to' protect human, animal, or plant life or health. In particular, the appellate arbitrators considered that Turkey had misunderstood the panel's approach in this regard. The panel had required a 'substantial degree of probability' that the stated risk would materialize, but rather, it had used this inquiry as 'an indicator of the existence of a risk that is not merely theoretical, abstract, or hypothetical'.[33] The appellate arbitrators' noteworthy deference to the panel's approach on these points left intact the panel's factual findings and legal reasoning.

With that in mind, at least two aspects of the panel's reasoning are worthy of scrutiny. First, the implicit requirement imposed on Turkey to prove with 'some degree of probably' that the risk of pharmaceutical shortages due to over-reliance on imports 'actually' belied the nature of Turkey's objective and the nature of the risks it was seeking to mitigate. Turkey's objective was to build a broad-based domestic manufacturing capacity across a large range of pharmaceuticals.[34] If one accepts the premise that the precise nature of future pharmaceutical shortages is unknowable, Turkey's approach stands to reason. One way to mitigate uncertainty over the source and cause of future shortages would be to develop a capacity encompassing a broad range of product lines. The panel rejected this as 'theoretical, abstract, and hypothetical' and instead called for evidence of past shortages to justify mitigating against future risks. However, if the COVID-19 pandemic demonstrates anything, it is that States cannot anticipate the source and cause of perhaps the

[26] ibid para 7.164.
[27] ibid para 7.180.
[28] ibid paras 7.173, 7.210.
[29] ibid paras 7.191, 7.198, 7.202, 7.204.
[30] ibid para 7.210.
[31] ibid para 7.152.
[32] Arbitral Award, *Turkey–Pharmaceutical Products (EU) (Article 25)*, paras 6.96–103.
[33] ibid paras 6.104–111.
[34] Panel Report (n 6) 2.23.

most acute shortages. For instance, essential Personal Protective Equipment (PPE) like N-95 respirators are cheap to manufacture and stockpile. Still, a lack of supply and manufacturing capacity in the USA has been attributed to 'between 1000 and 2000 deaths from COVID-19 nationwide among health care staff and other essential workers, imposing costs of $5 billion to $10 billion'.[35] If States had been capable of knowing that this risk was 'probable'—as required under the panel's approach[36]—it seems highly unlikely that they would have failed to stockpile sufficient PPE or foster sufficient manufacturing capacities in the first place.

Second, the panel treated Turkey's industrial policy objective as mutually exclusive with the purported public health objective. This belies the political reality that many public policy objectives serve multiple intertwined objectives.[37] The fact that a measure promotes domestic competitiveness or other industrial objectives should not preclude the measure from being characterized as a 'public health' measure under Article XX(b) if it contributes to public health outcomes. Moreover, even if a measure is adopted initially for one predominant motivation, there is nothing in Article XX to suggest that a subsequent change in context or development (eg a pandemic) could not justify the continued maintenance of the measure for another motivation. In that respect, there is a somewhat unreal air to the panel's finding that Turkey's localization measure was wholly 'incapable' of making any contribution to mitigating future pharmaceutical shortages by expanding the depth and breadth of the domestic pharmaceutical sector.[38]

Thus, it is unclear to what extent the panel's approach in *Turkey—Pharmaceutical Products* would be embraced as persuasive and worthy of being followed by adjudicators in future WTO disputes. Nonetheless, the main takeaway from *Turkey—Pharmaceutical Products* is that measures to onshore pharmaceutical manufacturing through local content requirements or incentives to mitigate risks of future shortages should be carefully calibrated to meet that objective. Only pharmaceuticals at risk of shortages due to over-reliance on imports should be subject to such measures. Likewise, the extent of local content requirements or incentives should be limited to what is required to mitigate the risk. Moreover, identifying at-risk pharmaceuticals and the appropriate extent of local content policies should be substantiated with evidence, as should the focus on *imports* as a decisive source of risk. Even if the panel's approach in *Turkey—Pharmaceutical Products* is open to question, long-standing WTO jurisprudence on the chapeau analysis under Article XX (unaddressed by the panel) suggests that these kinds of considerations could play a significant role in the overall success of an Article XX defence.[39]

In this regard, it is important to note that the panel's assessment of Turkey's measure exposed a significant evidentiary difficulty for States pursuing policies to onshore pharmaceutical manufacturing to mitigate the risk of future shortages. Turkey argued that, to maximize the success of its policy, it started by building on its existing pharmaceutical manufacturing capabilities by requiring the localization of product lines that were already produced domestically or had resilient supply chains.[40] This would presumably ameliorate the risk of any unintended consequences from the localization policy. For instance, if Turkey's starting point had been to localize

[35] Philip Ellis, 'Where There's a Will: Economic Considerations in Reforming America's Medical Product Supply Chains' (Paper Commissioned by Committee on Security of America's Medical Product Supply Chain, 2021).

[36] Panel Report (n 6) paras 7.170, 7.171, 7.180.

[37] See Timothy Meyer, 'The Political Economy of WTO Exceptions' (2022) 99 Wash U L Rev 1299, 1353, 1356–1360.

[38] Panel Report (n 6) paras 7.135, 7.206 and, relatedly, para 7.208 ('no rational relationship').

[39] See WTO Appellate Body Reports, *United States—Standards for Reformulated and Conventional Gasoline (US—Gasoline)*, WT/DS2/AB/R, adopted 20 May 1996, 27–29; *United States—Import Prohibition of Certain Shrimp and Shrimp Products (US–Shrimp)*, WT/DS58/AB/R, adopted 6 November 1998, 164–166; *Brazil—Measures Affecting Imports of Retreaded Tyres (Brazil–Retreaded Tyres)*, WT/DS332/AB/R, adopted 17 December 2007, 226–227; *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products—Recourse to Article 21.5 of the DSU by Mexico US–Tuna II (Mexico) (Article 21.5–Mexico)*, WT/DS381/AB/RW and Add.1, adopted 3 December 2015, 7.316; *European Communities—Measures Prohibiting the Importation and Marketing of Seal Products (EC–Seal Products)*, WT/DS400/AB/R / WT/DS401/AB/R, adopted 18 June 2014, 5.306.

[40] Panel Report (n 6) paras 7.141, 7.147, 7.156.

the production of specialized products in which it had no existing capabilities and for which it relied on limited sources of supply, there may have been a risk that the localization would fail and thus result in the very shortages it was intended to avoid. Accordingly, Turkey explained that its policy was structured to incrementally build up its pharmaceutical manufacturing capacity over time by starting with lower-risk product lines and working toward more specialized products.[41] This approach to policy design makes sense if the ultimate objective is a broad-based and resilient pharmaceutical manufacturing sector capable of responding adeptly to any number of unknowable challenges, such as those thrown up by the COVID-19 pandemic.

However, these very features of Turkey's measure intended to ensure that its success could have made it more vulnerable under the existing jurisprudence on the chapeau of Article XX. In particular, the measure's initial prioritization of pharmaceuticals for which there were *already* high supplier diversification and robust domestic market share could suggest that the measure was not properly 'calibrated' to the alleged risks being mitigated, thus suggesting that the measure was an 'arbitrary' or 'unjustifiable' restriction on international trade. Likewise, the measure's ultimate objective of covering *all* types of pharmaceuticals—without considering whether some are more prone to shortages than others—could suggest that it was not properly calibrated to the more granular risk presented by import shortages more specifically. Again, the measure's ultimate target of achieving 60 per cent domestic market share by *value* could incentivize onshoring of more expensive patented pharmaceuticals instead of cheaper but more vulnerable generics. This could similarly suggest that the measure is not properly calibrated to the risks allegedly being mitigated.

The proper role that these features of Turkey's measure should play in an assessment under Article XX appears to be in the eye of the beholder. From a short-term perspective, the design and structure of Turkey's measure could be viewed as a disguised means of achieving greater market share in product lines in which Turkey already had a foothold. From a longer-term perspective, Turkey's measure could be viewed as an incremental and phased approach to building up a more sophisticated and resilient pharmaceutical sector, whose very existence mitigates unknowable future risks associated with relying on imported pharmaceuticals. The panel ultimately opted for a short-term perspective by requiring recent evidence of historical shortages in imported pharmaceuticals, without meaningfully accepting that Turkey's longer-term perspective could manifest as a legitimate public health objective under Article XX(b).[42]

Although Turkey's measure failed under Article XX(b), there can be good reasons for seeking to onshore pharmaceutical manufacturing,[43] and it is thus not necessarily the case that others would likewise fail. Steps to mitigate the risks of pharmaceutical and active pharmaceutical ingredient ('API') supply chain disruptions can be understood as public health measures, and these steps can legitimately encompass location-based considerations such as discouraging high geographic concentration of production or promoting production in locations conducive to smooth regulatory oversight and quality assurance. Although it could reasonably be part of the solution, onshoring alone is not the inevitable solution to these location-based problems. Rather, onshoring as a standalone solution arises from the geopolitical risks—amplified by the pandemic era export restraints—that actions by foreign governments could disrupt supply chains. By their very nature, these geopolitical risks are grounded on mistrust and uncertainty over future events. They may thus be difficult to substantiate with the more exacting evidentiary standard of 'probable' risk required by the panel in *Turkey—Pharmaceutical Products*. But, in my view,[44] geopolitical risks can legitimately be understood as part of safeguarding supply

[41] ibid footnote 597.
[42] Panel Report (n 6) paras 7.172–7.174.
[43] As discussed in Mitchell (n 1) section 'Onshoring pharmaceutical production: finding the problem to be solved'.
[44] ibid.

chains to protect public health. They could thus go some way to justifying measures to onshore pharmaceutical manufacturing on public health grounds.

The Biden Administration's use of the Defence Production Act to incentivize onshore manufacturing of starting materials for sterile injectable medicines illustrates the measure that could potentially pass muster under Article XX(b). Numerous past shortages substantiate that starting materials for sterile injectable medicines are particularly vulnerable to supply chain disruptions.[45] The fact that these starting materials yield especially low profit margins 'makes them more vulnerable', according to the US Food and Drug Administration.[46] Low margins mean declining numbers of pharmaceutical manufacturers that produce these materials, which has resulted in low supplier diversification and high geographic concentration.[47] For instance, 90–95 per cent of sterile injectable medicines used for acute care in the USA rely on key starting materials from China and India.[48] Against that background, the risk of losing access to imported starting materials is grounded in the low incentives for supply chain resilience, numerous past examples of shortages for this particular product, and the lack of supplier diversity and the sharp current reliance on imports.

By contrast, Indonesia's local content requirements appear to be generally applicable to all pharmaceuticals and geared towards economic goals such as enhanced market share.[49] These are the kinds of considerations that led the panel in *Turkey—Pharmaceutical Products* to find that Turkey's local content requirement was not designed to achieve public health objectives. Even under more established jurisprudence, Indonesia may struggle to reconcile these features with the chapeau of Article XX.

India's local content requirements fall somewhere in between these examples. On the one hand, their original adoption was part of India's 'Make in India' industrial policy, and it is not apparent that the originally specified levels of domestic content were calibrated to achieve anything other than economic objectives. On the other hand, India subsequently expanded this policy to reduce reliance on imports of Chinese APIs further. In doing so, it targeted the new local content incentives at 53 particular APIs for which it sought to develop domestic manufacturing capacities.[50] For India, up to 80 per cent of the APIs used in its manufacture of finished pharmaceuticals had been supplied from China, and China's export ban on APIs early in the pandemic exposed India's vulnerability in this regard.[51] Accordingly, the evidence of risks of shortages and some degree of tailoring the measures to at-risk products would support an Article XX(b) defence under the *Turkey—Pharmaceutical Products* approach. In contrast, the original economic objectives of the measures would align more with the reasons for Turkey being unsuccessful.

National security

Given the close link between geopolitical risks and the impetus to develop self-reliance in pharmaceutical and API production,[52] the national security exception reflected in Article XXI(b) of the GATT potentially offers another avenue to justify local content requirements and incentives in the pharmaceutical sector. Article XXI(b) provides, in relevant part:

[45] Ellis (n 35).

[46] Due to the market dynamics discussed in Mitchell (n 1) section 'Features of the Pharmaceutical Market that Engender Shortages' and US Food and Drug Administration, *Pathway to Global Product Safety and Quality: Special Report* (2019).

[47] ibid.

[48] US Senate Committee on Homeland Security & Government Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages* (Majority Staff Report, March 2023), 24.

[49] CSIS, *Economic Impacts of Local Content Requirements in Indonesia* (CSIS Research Report, 2023), 33–34; WTO Committee on TRIM, 'Minutes of the Meeting Held On 17 October 2018'.

[50] Ministry of Fertilizer and Chemicals, 'Production Linked Incentive (PLI) Scheme' (21 July 2020).

[51] Ari Altstedter, 'India to Spend $1.3 Billion to Boost Pharmaceutical Production' *Bloomberg* (22 March 2020).

[52] See eg White House, Executive Order 13944 of 6 August 2020.

Security exceptions

Nothing in this Agreement shall be construed …

(b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests

(i) relating to fissionable materials or the materials from which they are derived;
(ii) relating to the traffic in arms, ammunition, and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
(iii) taken in time of war or other emergency in international relations.

Subparagraphs (i)–(iii) identify the subject matters for which national security measures can be taken under Article XXI(b), and for present purposes, I will focus on subparagraph (iii) as the most viable potential pathway.

Beginning with the emerging WTO jurisprudence on Article XXI(b)(iii), the four cases that have adjudicated this exception to date have been careful to delineate between its 'subjective' or 'self-judging' aspects on the one hand and its 'objective' aspects on the other.[53] This delineation tracks the negotiators' original understanding of the clause.[54]

The 'subjective' or 'self-judging' aspects are found in the chapeau of Article XXI(b)(iii). A State's chosen 'actions' and its 'essential security interests' are qualified by the phrase 'which *it considers* necessary'.[55] It is thus for a State to determine for itself what 'it considers necessary' in this regard.[56] Of course, a State invoking Article XXI(b)(iii) must show that it did indeed 'consider it necessary' to take certain actions to protect its essential security interests.[57] However, the subjectivity inherent in the phrase 'which *it considers* necessary' makes for a particularly low standard of proof centred on a 'minimum requirement of plausibility' and a basic observance of good faith in invoking Article XXI(b)(iii).[58]

Accordingly, even though the term '*essential* security interests' connotes something narrower than 'security interests' or 'national security', each State retains the right to define what it considers to be in its essential security interests.[59] That said, the more sensitive and limited concept of '*essential* security interests' can imbue what qualifies as an 'emergency in international relations' to which those interests relate under subparagraph (b)(iii).[60]

Likewise, States retain the right to decide the nature, form, and scope of the 'actions' they consider necessary to protect those interests in light of the contemporaneous 'emergency in

[53] Panel Reports, *Russia—Measures Concerning Traffic in Transit (Russia—Traffic in Transit)*, WT/DS512/R and Add.1, adopted 26 April 2019, paras 7.77, 7.128, 7.130–7.131, 7.138; *United States—Certain Measures on Steel and Aluminium Products (US–Steel and Aluminium Products (China))*, WT/DS544/R, Add.1 and Suppl.1, circulated to WTO Members 9 December 2022, appealed 26 January 2023, paras 7.123, 7.145–7.146; *United States—Origin Marking Requirement (US–Origin Marking (Hong Kong, China))*, WT/DS597/R and Add.1, circulated to WTO Members 21 December 2022, appealed 26 January 2023, paras 7.185–7.186; *Saudi Arabia—Measures Concerning the Protection of Intellectual Property Rights (Saudi Arabia–IPRs)*, WT/DS567/R and Add.1, circulated to WTO Members on 16 June 2020, dispute terminated while appeal pending, paras 7.242–7.251 (considering TRIPS Article 73(b)(iii), which is equivalent to GATT Art XXI(b)(iii)).

[54] Panel Reports, *Russia–Traffic in Transit*, para 7.91; *US–Steel and Aluminium Products (China)*, Appendix B, 4.44.

[55] Panel Reports, *Russia–Traffic in Transit*, paras 7.128, 7.131, 7.146; *US–Steel and Aluminium Products (China)*, para 7.145; *US–Origin Marking (Hong Kong, China)*, paras 7.185–7.186; *Saudi Arabia–IPRs*, paras 7.249–7.251.

[56] Panel Reports, *Russia–Traffic in Transit*, paras 7.131, 7.146; *US–Steel and Aluminium Products (China)*, paras 7.110, 7.114, 7.122; *US–Origin Marking (Hong Kong, China)*, para 7.160; *Saudi Arabia–IPRs*, paras 7.249–7.254.

[57] Panel Reports, *Russia–Traffic in Transit*, 7.134; *Saudi Arabia–IPRs*, 7.280–7.281. On the other hand, the panel in *US–Origin Marking (Hong Kong, China)* seemed to consider that a respondent's determination of the actions it considers necessary to protect its essential security interests is non-justiciable: see 7.255–7.256.

[58] Panel Reports, *Russia–Traffic in Transit*, 7.132, 7.133, 7.138, 7.145, 7.146; *Saudi Arabia–IPRs*, 7.280–7.281. But see ibid in relation to *US–Origin Marking (Hong Kong, China)*.

[59] Panel Reports, *Russia–Traffic in Transit*, paras 7.130, 7.131, 7.138; *US–Steel and Aluminium Products (China)*, paras 7.110, 7.122; *Saudi Arabia–IPRs*, paras 7.249–7.251.

[60] See eg Panel Report, *US–Steel and Aluminium Products (China)*, 7.141.

international relations'.[61] Significantly, Article XXI lacks any equivalent to the chapeau of Article XX.[62] The 'actions' in Article XXI are thus not constrained by a need to be carefully calibrated to other countries' differing situations or closely attenuated to the precise public objectives being pursued. A State can design its 'actions'; however, it wishes, so long as these actions are not 'so remote from, or unrelated to, the … emergency that it is implausible that [the respondent] implemented the measures for the protection of its essential security interests arising out of the emergency'.[63]

Applying these considerations to local content measures for pharmaceuticals and APIs, it would hardly be implausible for a State to assert that it considers onshoring manufacturing to safeguard against geopolitical tensions is in its 'essential security interests'. Although some commentators have pointed to a concerning trend in which protectionist industrial policies are increasingly cloaked with ill-defined national security concerns,[64] it would be difficult to conceive something more sensitive and primary for a population than its health. Moreover, unlike Article XX(b), the actions taken by a State to onshore pharmaceutical manufacturing would be subject only to a 'plausibility' standard.[65]

The key obstacle to justifying these measures under Article XXI(b)(iii) arises from the 'objective' aspects of a panel's review of defences under this clause. These objective aspects concern whether the 'action' at issue was, in fact, 'taken in time of war or other emergency in international relations'. The temporal requirement that the action 'be *taken in time* of' an emergency presents an immediate difficulty in justifying measures to onshore pharmaceutical production. Based on the plain text of Article XXI(b)(iii), panels have held that the relevant 'emergency' must already have manifested upon the taking of the relevant 'action'.[66] This necessarily excludes actions taken to *prevent* an emergency from materializing in the first place.[67] However, local content requirements and incentives for the pharmaceutical sector are primarily geared towards mitigating *risks* of *future* shortages.[68] It seems strange that measures taken before an emergency—or to prevent an emergency—would not be accommodated under Article XXI(b)(iii), insofar as this seems to suggest that States must wait for harm to occur before being permitted to take action. This would be a legitimate critique of Article XXI(b)(iii), crafted in the late 1940s and perhaps not reflective of the legitimate concerns and context of the modern world.[69] On the other hand, one could argue that measures to prevent future risks are already adequately accommodated under Article XX of the GATT 1994. However, the outcome of the *Turkey—Pharmaceutical Products* cases illustrates the difficulties in successfully invoking those exceptions. The omission of risk mitigation measures from the scope of Article XXI(b)(iii) could provide a solid basis for reconsidering and updating its reach.

Temporally, some of the measures to onshore pharmaceutical and API manufacturing were taken squarely during the COVID pandemic, such as India's local content incentives for APIs.

[61] Panel Reports, *Russia–Traffic in Transit*, 7.138; *US–Steel and Aluminium Products (China)*, 7.114, 7.122, footnotes 667–668; *Saudi Arabia–IPRs*, 7.251–7.255.

[62] See eg Panel Reports, *Russia–Traffic in Transit*, 7.198, 7.108; *US–Origin Marking (Hong Kong, China)* 7.111, 7.264.

[63] Panel Reports, *Russia–Traffic in Transit*, para 7.139; *Saudi Arabia–IPRs*, para 7.252.

[64] See eg Geraldo Vidigal and Stephan Schill, 'International Economic Law and the Securitization of Policy Objectives: Risks of a Schmittean Exception' (2021) 48 Leg Issues Econ Integr 109, 116–118; David Chieng, 'Supply Chains, COVID-19 and the GATT Security Exception: Legal Limits of "Pandemic Exceptionalism"' (2021) 39 Aust Year B Int Law 13, 15.

[65] Which likely means that the full suite of measures outlined in Mitchell (n 1) section 'Overview of measures to onshore pharmaceutical manufacturing', would be captured.

[66] Panel Reports, *Russia–Traffic in Transit*, para 7.70; *Saudi Arabia–IPRs*, paras 7.247–7.248, 7.292; *US–Steel and Aluminium Products (China)*, paras 7.112, 7.140. The panel in *US–Origin Marking (Hong Kong, China)* did not address this point, given it held there was no 'emergency' (para 7.268).

[67] Meyer (n 37) 645.

[68] As discussed in Mitchell (n 1) section 'Main causes of pharmaceutical shortages'. Aside from the measures geared primarily towards industrial policy objectives rather than public health goals.

[69] To address many States' concerns regarding the temporal constraint in the GATT security exception, some FTAs have been subsequently drafted to remove that limitation: see, for example, CPTPP Art 29.2.

Even though such measures have a much longer timescale and would not become effective until after the COVID pandemic subsidized, it is at least arguable that they were 'taken in time of' the pandemic in the sense of when they were first adopted. Other measures, however, are being taken or considered in the pandemic's aftermath or preceded its onset and thus cannot be said to have been 'taken in time of' that emergency.

This leads to the difficulties presented by the other 'objective' aspect of Article XXI(b)(iii), namely, what qualifies as an 'other emergency in international relations'. WTO adjudicators interpreting this phrase have set a particularly high bar. The State interests elicited by the 'emergency' should relate to 'defence and military interests, as well as maintenance of law and public order interests' and involve a 'situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state'.[70] Based on this jurisprudence, 'political or economic conflicts' between States—even those 'considered urgent or serious in a political sense'—will not rise to the level of an 'emergency in international relations' if they do not touch upon those fundamental State interests or have a heightened 'gravity or severity' that is analogous in impact to war.[71] For instance, 'protectionism under the guise of a security issue' will not be protected by Article XXI(b)(iii).[72] In *US—Steel and Aluminium Products (China)*, for instance, US national security concerns about the implications of global excess capacity in steel and aluminium markets, including adverse economic impacts on its domestic industry's capacity to supply its defence industrial base, did not rise to the requisite level of 'gravity or severity of an "emergency in international relations"'.[73] On the other hand, in *Saudi Arabia—IPRs*, the panel accepted that there was an 'emergency' due to the severance of diplomatic, economic, and political relations between Saudi Arabia and Qatar amidst allegations of support of terrorism and extremism.[74] By contrast, the panel in *US—Origin Marking (Hong Kong, China)* held that the tensions between China and the USA over China's response to the Hong Kong prodemocracy protests had not yet 'escalated to a point of breakdown or near-breakdown in the relations between states' as evinced by their continued trading relationship and cooperation in other policy areas.[75]

Applying these considerations to pharmaceutical shortages, several commentators have suggested that the COVID-19 pandemic would constitute an 'emergency in international relations'.[76] Its 'emergency' character was recognized by the World Health Organization and the United Nations Security Council, and its cascading effects increased tensions among States, while the challenges of implementing and enforcing stringent mitigation measures seemed to put pressure on public order. It might seem self-evident, therefore, that the COVID-19 pandemic should constitute an 'emergency in international relations'. However, such an approach could open the door to various protectionist or trade-restrictive measures in other spheres. For instance, in response to China's initiation of WTO litigation over its local content requirements for electric vehicles, the USA has suggested it would invoke Article XXI of the GATT,[77] and

[70] Panel Report, *Russia–Traffic in Transit*, paras 7.74, 7.76. See also Panel Report, *US–Origin Marking (Hong Kong, China)*, para 7.301.

[71] Panel Reports, *Russia–Traffic in Transit*, para 7.75; *US–Steel and Aluminium Products (China)*, paras 7.139, 7.141; *US–Origin Marking (Hong Kong, China)*, paras 7.289, 7.297.

[72] Panel Reports, *Russia–Traffic in Transit*, para 7.81.

[73] Panel Report, *US–Steel and Aluminium Products (China)*, para 7.148.

[74] Panel Report, *Saudi Arabia–IPRs*, paras 7.262–7.265.

[75] Panel Report, *US–Origin Marking (Hong Kong, China)*, paras 7.354–7.356. That said, in *Saudi Arabia–IPRs*, the panel held that the continued participation of Saudi Arabia and Qatar in certain international fora did not negate the finding of an 'emergency' regarding their relationship.

[76] See eg Caroline Glockle, 'Exempting and Justifying Covid-19 Related Export Restrictions Under WTO Law' (2021) 48 Leg Issues Econ Integr 201, 216–220; Chieng (n 64) 27.

[77] Communication from the United States in DS623.

reporting suggests that it would rely on climate change as an 'emergency in international relations'.[78] Given that States retain the right under Article XXI to decide the nature, form, and scope of the 'actions' they consider necessary to protect their essential security interests concerning an 'emergency in international relations'—including actions that are discriminatory, disproportionate, or arguably protectionist—the extension of Article XXI to climate measures would be a remarkable turn in WTO law. Some of the most significant recent WTO disputes pertain to climate measures, such as China's aforementioned dispute over US local content requirements for electric vehicles, China's litigation against the EU's antisubsidy measures on Chinese electric vehicles, Indonesia and Malaysia's litigation against the EU's biofuel regulations, and the EU's litigation against both Chinese Taipei and the UK concerning local content in renewable energy generation.

Thus, why not climate change if the COVID-19 pandemic can qualify as an 'emergency in international relations' under Article XXI? One differentiating feature could potentially emanate from the 'in international relations' aspect of Article XXI(b)(iii). This aspect of Article XXI(b)(iii) has been largely overlooked in WTO jurisprudence thus far. Based on its plain text, however, this language suggests that Article XX(b)(iii) does not cover any 'emergency', but that it must rather be an 'emergency' that occurs 'in international relations'. This textual limitation stands to reason when considering the object and purpose of the WTO Agreement (and the GATT 1947 as its predecessor). The basic function of the WTO Agreement (and, by extension, GATT 1947) was to reduce barriers to international trade. The logical consequence is that States become more responsive to their comparative advantages and that they tend to specialize in those sectors in which they are competitive. Specialization was expected to result in productivity and welfare gains, as reflected in the preamble to the WTO Agreement. Specialization, however, produces interdependence among States. The phenomenon of interdependence can operate only as long as we trust one another to continue to allow the free (or agreed) flow of goods and services across borders unhindered by nonagreed import or export restraints. The key point, therefore, is that trade liberalization relies on trust among the liberalizing States to allow free (or agreed-upon) trade. In the absence of trust, it would be nonsensical for States to allow themselves to become economically dependent on untrustworthy States. Likewise, if an 'emergency' shattered the trust between two previously trusting States 'in their international relations', it stands to reason that they would seek to unwind their economic interdependence that had emerged through their mutual commitments to trade liberalization. Following this logic, it makes sense that the relevant 'emergency' must be one arising between States 'in international relations'. Indeed, when considering the negotiating history of Article XXI(b)(iii), the panel in *US–Steel and Aluminium Products (China)* noted that:

> Regarding the terms "other emergency in international relations", the delegate of the United States explained that "we had in mind particularly the situation which existed before" the participation of the United States in the Second World War. Specifically, the delegate of the United States referred to measures that the United States took at that time "for [its] own protection" and that would have been prohibited by the Charter.[79]

Against that background, it is not immediately clear how phenomena like climate change—which is undoubtedly a global 'emergency'—could qualify as the kind of emergency '*in international relations*' that would call into question the economic interdependence fostered by the project of trade liberalization. The future consequences of climate change could erode trust between States in this way, but this is not evident in the domestic climate mitigation measures

[78] Doug Palmer, 'China's case against US EV subsidies could upend the WTO' *Politico* (3 June 2024).
[79] Panel Report, *US–Steel and Aluminium Products (China)*, su1, 2.18.

challenged in WTO litigation. By contrast, the COVID-19 pandemic led directly to import and export bans of critical products like pharmaceuticals, including—infamously—vaccines. Those kinds of trade-restrictive measures plainly expose the fragility implicit in specialization and economic interdependence between States in relation to these particular sectors in an acute crisis. In that way, the COVID-19 pandemic—undoubtedly a global 'emergency'—also manifested as an emergency '*in international relations*'.

In any case, even accepting that the COVID-19 pandemic at one point justified measures under Article XXI(b)(iii), this situation is subsiding.[80] Moreover, pharmaceutical shortages were common before the pandemic and are typically caused by quality control problems attributable, at least in part, to misaligned incentives in the market for generic pharmaceuticals.[81] Accordingly, in the absence of a pandemic-level event, it is difficult to see how most pharmaceutical shortages—and measures to prevent them—could be characterized as related to an 'emergency in international relations' under the prevailing understanding of this concept in WTO jurisprudence.[82]

The US government has clearly posited reliance on China for APIs and pharmaceuticals as a national security risk,[83] with the Department of Defense testifying in 2023 that '[t]he national security risks of increased Chinese dominance of the global API market cannot be overstated … [s]hould China decide to limit or restrict the delivery of APIs to the United States, it would have a debilitating effect on U.S. domestic production and could result in severe shortages of pharmaceuticals for both domestic and military uses'.[84] A recent Congressional report pointed to a 'March 2020 editorial in state media outlet Xinhua [that] acknowledged China's stranglehold on global pharmaceutical production and suggested China could assume "strategic control" over supplies and limit exports'.[85] The USA's measures to onshore starting materials for sterile injectable medicines are being taken pursuant to a new Presidential Determination under the Defence Production Act which provides that 'essential medicines, medical countermeasures, and critical inputs … are industrial resources, materials, or critical technology items essential to the national defense' and order that 'action to expand the domestic production capabilities for essential medicines, medical countermeasures, and critical inputs is necessary to avert an industrial resource or critical technology item shortfall that would severely impair national defense capability'.[86] This determination envisages that further action will be taken to onshore pharmaceuticals and APIs viewed as vulnerable to supply chain disruptions.

Clearly, the USA considers that actions to obviate geopolitical risks to pharmaceutical and API supply chains serve its national security interests. Likewise, as mentioned earlier, India and the EU have cited geopolitical risks in connection with some of their moves to onshore pharmaceutical and API production. However, except perhaps in India's case (discussed later), it is difficult to see how these actions could be justified under Article XXI(b)(iii). They mostly predate or postdate the height of the pandemic. Their preventative character suggests that they are not 'taken in time of' an emergency but rather seek to pre-empt an emergency, and in any case, pharmaceutical and API shortages would be unlikely to qualify as an 'emergency in international relations' under WTO jurisprudence unless their severity imperils public order or is connected to a breakdown in relations between States.

[80] Chieng (n 64) 27–31.
[81] As described in Mitchell (n 1) section 'Main Causes of Pharmaceutical Shortages'.
[82] Additionally, as the panel noted in *US–Steel and Aluminium Products (China)*, events of a largely domestic character or scope would not be captured by the requirement that the emergency is in 'international relations' (para 7.137).
[83] White House, 100-Day Reviews under Executive Order 14017 (June 2021), 230.
[84] US Senate Committee on Homeland Security & Government Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages* (Majority Staff Report, March 2023), 10.
[85] US-China Economic and Security Review Commission, *Annual Report to Congress 2022* (November 2022), 309.
[86] White House, Executive Order 13944 of 6 August 2020.

It is possible that India's 2020 measure to incentivize the onshoring of certain APIs was 'taken in time of… other emergency in international relations'. Its adoption on 29 October 2020 was not only during the pandemic but also came a few months after deadly skirmishes between Indian and Chinese soldiers over a contested part of their border, which represented a sharp escalation resulting in further clashes in the years since.[87] The onshoring measure was thus temporally connected to this event, and given its violent inter-State character, it could well be characterized as an 'emergency in international relations'. Concerns around the continuing reliability of Chinese imports of APIs would likely meet the 'minimum degree of plausibility' standard given India's high dependence on China for 80 per cent of its APIs.

This is, however, a relatively unique circumstance and perhaps underscores the limitations inherent in the availability of Article XXI(b)(iii) to justify measures to onshore pharmaceutical and API production.

Procurement

Several pharmaceutical onshoring measures being considered or already implemented[88] are linked to government procurement. This is perhaps unsurprising given the propensity for States to operate national health schemes that seek to make medicines available to their citizens.[89] India's 2019 local content incentive accorded preference in government procurement to pharmaceuticals with at least 90 per cent local content for those manufactured domestically and at least 30 per cent local (ie Indian) content for imports.[90] Indonesia has likewise stated that its local content requirements apply only to governmental procurement of medicines.[91] Under these rules, the following aspects and proportions must be sourced from within Indonesia: raw materials (50%), research and development (30%), manufacturing (15%), and packaging (5%).[92] One of the bipartisan legislative proposals currently under consideration in the USA would use the US' Medicare and Medicaid schemes to accord preference to US-manufactured pharmaceuticals. Although this might be linked conceptually to procurement, it would likely not qualify as 'procurement' under WTO rules for the reasons discussed later.

Article III(8)(a) of the GATT 1994 encapsulates the procurement-related derogation from Article III of the GATT 1994 and Article 2.1 of the TRIMs Agreement, and it provides:

> The provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale.

By excluding government procurement from the national treatment obligation, this provision allows States to discriminate in favour of domestic products when engaging in procurement, subject to governmental purposes and commercial (re)sale parameters.[93] This ability to discriminate, however, does not necessarily extend to upstream goods used in the manufacture

[87] BBC, 'India-China dispute: The border row explained' (14 December 2022).

[88] As described in Mitchell (n 1) section 'Overview of Measures to Onshore Pharmaceutical Manufacturing'.

[89] See generally Joëlle M. Hoebert and others, 'National Medicines Policies—A Review of the Evolution and Development Processes' (2013) 6 J Pharm Policy Pract 1.

[90] Ministry of Chemicals and Fertilizers, Order No 31026/4/2018.

[91] directdoc.aspx (wto.org); directdoc.aspx (wto.org). See also Michelle Limenta and Lili Yan Ing, *Indonesia's Local Content Requirements: Assessment with WTO Rules* (ERIA Discussion Paper Series No 414, 2022), 9–10.

[92] Limenta and Ing (n 91) 10.

[93] A State can bind itself to nondiscrimination disciplines in procurement through the plurilateral Agreement on Government Procurement. The scope and content of that instrument are outside the scope of the present analysis.

or production of the thing being procured. Instead, according to WTO jurisprudence, Article III(8)(a) only permits discrimination regarding the thing to be procured.[94] Suppose that government procurement is conditioned on local content being used in the manufacture or production of the thing being procured. In that case, the discrimination arising from the local content measure occurs at the point of the upstream raw material or input, as distinct from the thing being procured. This principle emerged from cases involving renewable energy support schemes in which there was a clear distinction on the facts between the thing being procured and the upstream product being discriminated against. Specifically, in these cases, the relevant governments paid a higher price for electricity generated from renewable sources, as long as those renewable sources such as solar panels or wind turbines were manufactured with a minimum level of local content. The thing being procured was electricity, whereas the products discriminated against were solar cells or wind turbines (or their parts). The Appellate Body held that Article III(8)(a) would exempt procurement of electricity from the nondiscrimination obligation in Article III, but this did not extend to the solar panels or wind turbines (or their parts) for the simple reason that they were not the things being procured. In that regard, the Appellate Body rejected the proposition that, for instance, solar cells are 'indistinguishable' from the electricity that they generate and that they are a necessary 'input' into solar power generation.[95]

As observed by Hestermeyer and Nielsen, the Appellate Body's approach 'seems to severely restrict how remote the content requirement can be in relation to the product procured' and 'has the potential to touch upon content requirements that aggregate all of the goods and services used to produce a good that is procured'.[96] For instance, under the Appellate Body's approach, the conditioning of government procurement of pharmaceuticals on the use of domestic APIs in their manufacture as per the Indonesian and Indian measures would not be covered by Article III(8)(a) because pharmaceuticals and APIs are not in a direct competitive relationship with each other.[97] Such an approach may make sense when the respective products are physically distinct and distinguishable, such as electricity vis-à-vis solar cells and wind turbines. However, it becomes increasingly less intuitive when one of the products is physically embedded into the other product, in the case of APIs and pharmaceuticals. It is possible that this approach would be reconsidered when presented with a fact pattern in which the raw material or input subject to the local content measure is an integral, inseparable, and physically embedded part of the thing being procured.

Relatedly, the Appellate Body's approach left unresolved whether and how local content-style requirements could be used to identify which products qualify as 'domestic' in the first place. This raises issues similar to those in relation to Article 3.1(b) of the SCM Agreement.[98] In particular, Article III(8)(a) recognizes that States are permitted to discriminate in favour of domestic products with respect to government procurement. Implicit in Article III(8)(a), therefore, is an ability to distinguish 'domestic' products from foreign equivalents. The Appellate Body has managed to side-step this issue thus far: '[w]e do not address in this case rules for determining the origin of products purchased' because '[i]t has not been alleged in this case that the Minimum Required Domestic Content Levels are rules of origin'.[99] It is notable, however, that the complainant in that case seemed to accept that 'the cover of Article III:8(a) may *also extend to*

[94] Appellate Body Reports, *Certain Measures Affecting the Renewable Energy Generation Sector/Canada—Measures Relating to the Feed-in Tariff Program (Canada–Renewable Energy/Canada–Feed-in Tariff Program)*, WT/DS412/AB/R/WT/DS426/AB/R, adopted 24 May 2013, 5.62–5.63, 5.74, 5.78–5.79.

[95] Appellate Body Report, *India—Certain Measures Relating to Solar Cells and Solar Modules (India–Solar Cells)*, WT/DS456/AB/R and Add.1, adopted 14 October 2016, 5.13, 5.32, 5.40.

[96] Holger Hestermeyer and Laura Nielsen, 'The Legality of Local Content Measures under WTO Law' (2014) 48 J World Trade 553, 553.

[97] See Appellate Body Report, *India–Solar Cells*, 5.40.

[98] See Mitchell (n 4) section 3.2 'SCM Agreement'.

[99] Appellate Body Reports, *Canada–Renewable Energy/Canada–Feed-in Tariff Program*, 5.63, footnote 500.

discrimination relating to inputs and processes of production used in respect of products purchased by way of procurement'.[100] Accordingly, if a State structures its local content measures on APIs or other inputs into pharmaceutical manufacturing as part of the definition of what qualifies as 'domestic' in its pharmaceutical procurement rules, it may well be covered by Article III:8(a).

A further issue raised by Article III:8(a) is whether a given local content measure qualifies as a 'procurement'. This question arose in the *Turkey—Pharmaceutical Products* case in relation to reimbursement schemes in which a government does not acquire the pharmaceuticals itself but tacitly pays for their purchase by reimbursing all or part of their cost. Although the appellate arbitrators in that case overturned the panel's narrow interpretation that the government must itself be the purchasing entity, they upheld the overall conclusion that Turkey's reimbursement scheme did not qualify as a 'procurement' under Article III:8(a).[101] This was because if the government is not itself the purchaser, it would still 'need to have a certain level of control over the products purchased for governmental purposes' to qualify as a 'procurement'.[102] The Turkish government agency's reimbursements did not involve any control over the pharmaceuticals being procured by pharmacies and on-sold to patients and thus did not qualify.

The result is that government-funded reimbursement schemes that use local content measures, such as the US legislative proposal to use Medicare and Medicaid to give preference to domestically manufactured pharmaceuticals, would likely not be covered by the procurement derogation in Article III:8(a).

Subsidies

Reimbursement schemes and other governmental subsidies to onshore pharmaceutical and API manufacturing could instead be potentially permitted under Article III:8(b), which provides:

> The provisions of this Article shall not prevent the payment of subsidies exclusively to domestic producers, including payments to domestic producers derived from the proceeds of internal taxes or charges applied consistently with the provisions of this Article and subsidies effected through governmental purchases of domestic products.

In essence, Article III:8(b) allows States to subsidize domestic producers without needing to also subsidize foreign producers based in other countries, even though such subsidies discriminate against foreign products by giving a competitive advantage to domestic producers.[103] According to WTO jurisprudence, however, paying subsidies to domestic producers must not violate Article III's national treatment obligation. As Anastasios Gourgourinis explains, 'an investment incentive would indeed violate both Article III:4 of the GATT 1994 and Article 3.1(b) of the SCM Agreement if it includes a "buy-national" requirement, but not if it merely incentivizes engaging in domestic production activities'.[104] Article III.8(b) is thus an expression of the principle that States are allowed to provide *nondiscriminatory* subsidies to their domestic producers.[105] It follows from that principle that the right to subsidize domestic producers under Article III.8(b) does not extend to payments conditioned on the use of locally sourced

[100] ibid (emphasis added).
[101] Panel Report, *Turkey–Pharmaceutical Products (EU)*, 7.37; Arbitral Award, *Turkey–Pharmaceutical Products (EU) (Article 25)*, 6.45, 6.46, 6.54.
[102] Arbitral Award, *Turkey–Pharmaceutical Products (EU) (Article 25)*, 6.54.
[103] Anastasios Gourgourinis, 'Domestic Investment Incentives in International Trade Law' (2023) 22 World Trade Rev 35, 49; Emanuel Ornelas and Laura Puccio, 'Reopening Pandora's Box in Search of a WTO-Compatible Industrial Policy? The Brazil-Taxation Dispute' (2020) 19 World Trade Rev 249, 258–259.
[104] Gourgourinis (n 103) 49.
[105] See Mitchell (n 4) section 3.2 'SCM Agreement'.

materials or components; such a payment would discriminate against foreign sourced materials or components.

Given that the scope of Article III.8(b) is broadly aligned with Article 3.1(b) of the SCM Agreement in this regard, the same considerations apply vis-à-vis the potential coverage of various States' onshoring measures.[106]

As with Article 3.1(b) of the SCM Agreement, WTO adjudicators have struggled to find a balance between requiring subsidies paid to domestic producers under Article III.8(b) to be nondiscriminatory and the need to allow States to identify which producers qualify as 'domestic'. The Appellate Body explained its approach to this balance in *Brazil—Taxation* as follows:

> [C]onditions for eligibility for the payment of subsidies that define the class of eligible "domestic producers" by reference to their activities in the subsidized products' markets would be justified under Article III:8(b). By contrast, a requirement to use domestic over imported goods in order to have access to the subsidy would not be covered by the exception in Article III:8(b) and would therefore continue to be subject to the national treatment obligation in Article III.[107]

Although conceptually sound, identifying the dividing line between permissible eligibility conditions and impermissible local content measures can be challenging in practice.

Finally, one point of divergence between Article III.8(b) of the GATT and Article 3.1(b) of the SCM Agreement concerns the scope of 'subsidies' covered. In particular, Article 3.1(b) covers tax exemptions since these are explicitly incorporated into the definition of subsidies under the SCM Agreement. By contrast, WTO adjudicators have held that the term 'payment of subsidies' under Article III:8(b) excludes tax exemptions.[108] It may seem counterintuitive to ascribe different meanings to the term 'subsidies' in the GATT 1994 and the SCM Agreement. Still, this interpretation is structurally sound when considered in the broader context of Article III. In particular, Article III:2 lays out the foundational rule of the WTO framework that similar imported products should not be subject to discriminatory tax treatment nor be taxed in excess of domestic products. If tax exemptions were to be covered by the Article III:8(b) derogation from this rule, it would allow for discriminatory taxation and deprive Article III.2 of much of its value.[109]

The upshot is that the US legislative proposals to onshore pharmaceutical manufacturing through tax exemptions and credits would not be excluded from the national treatment obligation via Article III:8(b). By contrast, schemes involving more direct financial incentives to domestic producers, such as grants or reimbursements, would be protected by the derogation from national treatment under Article III:8(b) as long as they are free from discriminatory conditions.

SCM AGREEMENT

There are no directly applicable exceptions or derogations to Article 3.1(b), and it is questionable whether Articles XX (General Exceptions) and XXI (Security Exceptions) of GATT 1994 could be cross-applied to the SCM Agreement. If those exceptions were found to cross-apply, the considerations related to the public health exception discussed in the Public health section and the essential security interests exception discussed in the National security section would equally apply vis-à-vis Article 3.1(b) of the SCM Agreement.

[106] ibid.
[107] Appellate Body Report, *Brazil—Certain Measures Concerning Taxation and Charges (Brazil–Taxation)*, WT/DS472/AB/R and Add.1/WT/DS497/AB/R and Add.1, adopted 11 January 2019, 5.112.
[108] Ornelas and Puccio (n 103) 260–261.
[109] Appellate Body Report, *Brazil–Taxation*, 5.120.

If they do not cross-apply, the central flexibility available under Article 3.1(b) of the SCM Agreement would pertain to the role of regulatory objectives in defining the market-based benchmark under Article 1.1(b). In particular, a prerequisite to finding the existence of a subsidy under the SCM Agreement is the conferral of a 'benefit' on domestic manufacturers. Fundamentally, a benefit exists if the relevant governmental incentive or transaction ('financial contribution') leaves the domestic manufacturers better off than would have been the case in the absence of incentive or transaction.[110] This inquiry typically involves a comparison with an equivalent 'market-determined' transaction in the economy of the recipient manufacturer[111] or, concerning alleged tax credits or exemptions, with comparably situated taxpayers who are not recipients of the alleged credit or exemption.[112]

In defining the 'market' or the 'comparably situated taxpayers' against which the governmental incentive/transaction is compared, the regulatory objective of reducing the risk of pharmaceutical shortages could legitimately be considered. WTO jurisprudence recognizes that governments can intervene in markets to address market failures and correct negative externalities and that such interventions form part of the market conditions themselves.[113] It follows that the 'market-determined' comparator for determining whether the governmental incentive or transaction confers a 'benefit' must take the market-correcting regulatory objectives of the government as a starting point. In practical terms, the benefit inquiry then shifts to whether the government is over-paying manufacturers in pursuing these objectives.

The current market dynamics for pharmaceuticals and APIs disincentivize investment in resilient supply chains, especially for generic medicines.[114] These dynamics often produce a high geographic concentration of production and low supplier diversity, which magnifies the risk of shortages. Moreover, the barriers to entry for new suppliers mean that shortages do not produce the typical self-correcting response expected in a regular market. In short, for generic medicines in particular, the risk of shortages due to fragile supply chains tends to be externalized by the existing market participants, with the cost ultimately borne by patients when shortages emerge.

Against that background, measures by States to build more resilience into pharmaceutical supply chains could be characterized as market-correcting. The question for the 'benefit' analysis—and thus, whether a subsidy even exists for the purposes of Article 3.1(b)—is whether a State is over-paying to achieve its market-correcting objectives through particular kinds of tax credits, reimbursements, and other financial incentives for domestic production.[115] For instance, the bipartisan US legislative proposal to provide financial incentives like bonus payments or higher reimbursements under Medicare and Medicaid for the use of US-manufactured pharmaceuticals may not be found to confer a 'benefit' if—considering the regulatory objective to reinforce supply chains—these incentives are commensurate to what would otherwise occur in a properly functioning market or under tax rules.

Two difficulties could arise in characterizing measures by States to build more resilience into pharmaceutical supply chains in this regard. First, a separate stream of WTO jurisprudence suggests that governmental regulations should be excluded from the 'market-based' comparator in

[110] Appellate Body Report, *Canada—Measures Affecting the Export of Civilian Aircraft* (*Canada—Aircraft)*, para 149.

[111] Appellate Body Report, *United States—Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada* (*US–Softwood Lumber IV)*, WT/DS257/AB/R, adopted 17 February 2004, Appellate Body Report, 104.

[112] Appellate Body Report, *European Union—Countervailing Measures on Certain Polyethylene Terephthalate from Pakistan (EU–PET (Pakistan))*, WT/DS486/AB/R and Add.1, adopted 28 May 2018, 5.96.

[113] Appellate Body Reports, *Canada—Renewable Energy/Canada—Feed-in Tariff Program*, 5.175–5.178, 5.181, 5.187–5.191; Panel Report, *United States—Countervailing Measures on Softwood Lumber from Canada* (*US—Softwood Lumber VII)*, WT/DS533/R and Add.1, circulated to WTO Members 24 August 2020, appealed 28 September 2020, 7.649, 7.650, 7.680, 7.681, footnotes 1308, 1384.

[114] As discussed in Mitchell (n 1) section 'Main Causes of Pharmaceutical Shortages' and Wallace J. Hopp, Lisa Brown and Carolyn Shore (eds), *Building Resilience into the Nation's Medical Product Supply Chains* (National Academic Press, Washington, DC, USA 2022), 14–15.

[115] Specifically, the kind described in Mitchell (n 1) section 'Overview of Measures to Onshore Pharmaceutical Manufacturing'.

the benefit assessment.[116] This separate stream of jurisprudence is yet to be reconciled with that described earlier, and it is unclear how they relate to one another.[117] Second, a key issue would likely concern why *domestic* production is necessary to build more resilient supply chains as opposed to more diverse and reliable sources of supply *irrespective* of the location of manufacture. If a State can point to evidence substantiating a need for at least some degree of domestic production in this regard, it could legitimately be treated as part of the market-correcting measure.

Accordingly, if a State can characterize its measures to onshore pharmaceutical manufacturing as market-correcting and can further substantiate why local content requirements and incentives are integral to building a more resilient supply chain, there would be a viable pathway for excluding measures from Article 3.1(b) via the 'benefit' analysis, ie of course, contingent on those measures not being more generous than necessary to achieve their market-correcting objectives.

CONCLUSION

The flexibilities available to justify a given onshoring of pharmaceutical manufacturing depend upon which WTO obligations are engaged by that particular measure. Most measures to onshore pharmaceutical manufacturing will come within the purview of the national treatment obligation of Article III of the GATT, given its plenary scope and Article 2.1 of the TRIMs Agreement.[118] However, subsidies other than tax exemptions or measures that take the form of government procurement are carved out of these obligations as long as any discriminatory effects pertain only to the product being procured or the producer being subsidized. If such subsidies or procurement involves discrimination occurring upstream vis-à-vis raw materials and other inputs or downstream from the production process (eg at the point of sale), they would not be saved by the flexibilities on procurement and subsidies.

Additionally, the public health exception in Article XX(b) will excuse onshoring measures impugned under Article III of the GATT and Article 2.1 of the TRIMs Agreement, as long as those measures respond to 'actual' or 'probable' risks of import-related shortages and are carefully calibrated to addressing the specific risk identified. However, based on the approach of the panel in *Turkey—Pharmaceutical Products*, measures responding to 'hypothetical' risks or that broadly seek to onshore pharmaceutical manufacturing generally—without being targeted at the products most prone to shortages—may fall foul of Article XX(b).

The national security exception reflected in Article XXI(b) could also potentially justify onshoring measures that violate Article III of the GATT and Article 2.1 of the TRIMs Agreement, but only if those measures are taken during an 'emergency in international relations'. Thus, in the absence of a pandemic-level event or an actual geopolitical confrontation akin to the border conflict between China and India, it may be challenging to justify onshoring measures under this exception. This is particularly so given that onshoring measures in the pharmaceutical sector are typically aimed at preventing future emergencies rather than ameliorating present shortages.

Measures that qualify as subsidies under the SCM Agreement and that require the use of domestic over imported content—including through government procurement, reimbursement schemes, and tax exemptions—are unlikely to benefit from these flexibilities. It is possible, however, that measures that frame domestic content requirements as a form of 'rule of origin'—ie as the basis for identifying which products are 'domestic' vis-à-vis 'foreign'—could fall

[116] See Appellate Body Report, *Countervailing Duty Measures on Certain Products from China—Recourse to Article 21.5 of the DSU by China (US—Countervailing Measures (China–Article 21.5)*, WT/DS437/AB/RW and Add.1, adopted 15 August 2019, 5.154, 5.159, 5.160.

[117] Andrew Mitchell, 'The Right to Regulate and the Interpretation of the WTO Agreement' (2023) 26 J Int Econ Law 462, 465–466.

[118] See Mitchell (n 4) section 'GATT and TRIMS'.

outside the reach of Article 3.1(b) of the SCM Agreement considering *Brazil—Taxation*. Additionally, measures that are directed at correcting the market failures that result in fragile supply chains in the pharmaceutical sector could ultimately be excluded from the SCM Agreement via the 'benefit' analysis, as long as these measures do not over-pay manufacturers to remediate such fragilities.

The suite of flexibilities in WTO rules that could facilitate measures to onshore pharmaceutical manufacturing—particularly local content policies—reveal only narrow and rigid pathways to ensuring WTO consistency. Is this a shortcoming in the scope of these flexibilities or in the aspirations pursued by States seeking to onshore pharmaceutical manufacturing? The WTO panel in *Turkey—Pharmaceutical Products* seemed to exclude the possibility that a measure could have economic *and* public health objectives. However, such an approach belies policymaking in a global environment where geopolitical tensions push States to onshore or nearshore sectors that are sensitive due to public policy reasons. A binary between protectionism and legitimate regulation seems simplistic in this environment.

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