BRILL | NIJHOFF

JOURNAL OF WORLD INVESTMENT & TRADE 25 (2024) 481–496

The Journal of World Investment & Trade Law • Economics • Politics
brill.com/jwit

Hometown Heroes: Onshoring, Promoting Local Content & WTO Law

Andrew D Mitchell | ORCID: 0000-0001-8399-8563
Faculty of Law, Monash University, Australia
andrew.mitchell@monash.edu

Accepted 26 June 2024 | Published online 16 August 2024

Abstract

This article examines the complexities and challenges associated with onshoring manufacturing through local content requirements within the context of World Trade Organization (WTO) law. Governments have intensified efforts to relocate production within their territories, leveraging local content requirements and incentives. This shift is primarily justified by the need for supply chain resilience, public health, and national security, aiming to mitigate risks associated with reliance on foreign suppliers during crises. However, these strategies may conflict with WTO obligations, particularly those concerning trade-related investment measures and subsidies. Using pharmaceuticals as a case study, this article explores the rationale, scope, and implications of WTO rules on local content policies. The analysis provides insights into how nations navigate the delicate balance between enhancing domestic capabilities and adhering to international trade laws.

Keywords

onshoring – local content requirements – pharmaceutical manufacturing – trade-related investment measures – GATT – SCM Agreement

1 Introduction

The efforts of governments to relocate manufacturing processes within their national borders have increased momentum. Concerning pharmaceutical

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production, this was particularly notable following the COVID-19 pandemic. Countries including the US,[1] EU[2] and Australia[3] have joined or are considering joining countries like China,[4] Indonesia,[5] Turkey,[6] India[7] and Bangladesh[8] that use local content requirements and incentives to onshore pharmaceutical manufacturing. This trend is not exclusive to the pharmaceutical sector; many nations similarly focus on sectors like technology and automotive manufacturing as strategic areas for onshoring to bolster economic independence and national security.

Previously, the drive to promote local pharmaceutical production often stemmed from economic goals, such as cultivating new industries or narrowing trade deficits.[9] However, the pandemic has shifted the focus towards public health imperatives, supply chain stability, geopolitical safety, and securing national supply chains against disruptions. These concerns highlight the critical need to localise production, particularly pharmaceuticals and medical

1 See eg Department of Health and Human Services (and others), 'National Strategy for a Resilient Health Supply Chahin' (July 2021), 31–32; Department of Health and Human Services, *One-Year Report in Response to Executive Order 14017* (February 2022), 7–8.

2 See eg European Commission, *Pharmaceutical Strategy for Europe*, (25 November 2020, COM(2020) 761) 18; European Commission, *Vulnerabilities of the Global Supply Chains of Medicines* (Staff Working Document, 2022); European Commission, Addressing medicine shortages in the EU (24 October 2023, COM(2023) 672), 1 and 12–13.

3 See eg allocation of AUD 1.5 billion in subsidies for promoting domestic manufacturing in the medical sector: Federal Register of Legislation – National Reconstruction Fund Corporation (Investment Mandate) Direction 2023. See also Anthony Albanese, 'Putting Australian Medical Manufacturers at the Front of the Queue' (Press Release, 30 January 2022).

4 Congressional Research Service, *The Made in China 2025 Initiative: Economic Implications for the United States* (12 April 2019), 1–2; Geneva Network, *Localisation Barriers to Trade in the Biopharmaceutical Industry* (August 2023), 2–3; Mercator Institute for China Studies, *Investigating State Support for China's Medical Technology Companies* (November 2023), 17.

5 CSIS, *Economic Impacts of Local Content Requirements in Indonesia* (CSIS Research Report, 2023), 33–34; Michelle Limenta and Pelita Harapan Lili Yan Ing, *Indonesia's Local Content Requirements: Assessment with WTO Rules* (ERIA Discussion Paper Series No. 414, 2022) 9–10.

6 See Panel Report, *Turkey – Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products*, WT/DS583/12 and Add.1, para 7.122.

7 Ministry of Chemicals and Fertilizers, Order No. 31026/4/2018, <https://pharmaceuticals.gov.in/sites/default/files/PPO%20Revised_0.pdf>, accessed 1 July 2024.

8 Mustafizur Rahman and others, 'Policy Space for Building Production Capabilities in the Pharmaceuticals Sector in Low- and Middle-Income Countries: Evidence from Bangladesh' (2021) 12 Journal of Globalization and Development 221, 238–40 and 246.

9 See eg Ministry of Chemicals and Fertilizers (n 7); Panel Report, *Turkey – Pharmaceutical Products* (n 6) paras 7.210.

supplies, as many countries experienced acute shortages during the pandemic, emphasising the peril of over-reliance on foreign manufacturers.[10]

Despite the practical justifications for these measures, such local content policies can clash with World Trade Organization (WTO) obligations. This was evident in *Turkey – Pharmaceutical Products* (*EU*), where the European Union challenged Turkey's local content requirements, leading to a significant ruling favouring the EU.[11]

In this article, I explore how WTO obligations interact with local content policies, using the pharmaceutical industry as a case study. While this article uses pharmaceutical production as a case study, the issues and findings discussed are broadly relevant to other sectors, including technology and automotive manufacturing. This relevance is underscored by similar policies being applied across these sectors to bolster economic independence, enhance supply chain resilience, and address national security concerns.

By local content policies, I refer to the array of incentives or requirements by States that condition the grant of a benefit on the use of local goods or services.[12] The "benefit" in this respect can take many forms, such as permission to sell goods or services in a market, the receipt of a subsidy, or the ability to participate in tenders for government procurement processes.[13] These policies range widely, from incentives for using domestic materials in production, like active pharmaceutical ingredients (APIs), to promoting the consumption of domestically produced final products.[14] The article explores the rationale behind these WTO rules and the extent to which they *prima facie* restrict local content requirements and incentives, providing critical insights into the tension between global trade laws and national interests in self-sufficiency and public health security.[15]

10 See eg Department of Health and Human Services (n 1) 9; European Commission (n 2) 1.

11 Panel Report, *Turkey – Pharmaceutical Products* (n 6) para 7.210.

12 Holger Hestermeyer and Laura Nielsen, 'The Legality of Local Content Measures under WTO Law' (2014) 48 JWT 553, 554.

13 Alexandre Genest, *Performance Requirement Prohibitions in International Investment Law* (Brill Nijhoff, 2019) 91–92.

14 ibid, 91–92; Hestermeyer and Nielsen (n 12) 554 and 565.

15 Policy-based flexibilities could be available to navigate those prohibitions, but consideration of this is beyond the scope of this article and the subject of another article titled 'Home Remedies: Flexibilities to Onshore Pharmaceutical Manufacturing Under WTO Rules'. The article explores flexibilities related to public health, essential security interests, government procurement, subsidisation, and correcting market failures.

2 An Overview of Local Content Measures

Before discussing the reasons for prohibiting local content measures, I will provide an overview of what they comprise and what motivates States to adopt them.

At a high level of abstraction, local content measures "condition the grant of a benefit on the use of local goods and/or services in producing goods and/or services".[16] The "benefit" in this respect can take many forms, such as permission to sell goods or services in a market, the receipt of a subsidy, or the ability to participate in tenders for government procurement processes.[17] A local content measure can be structured in a mandatory way that precludes a firm from accessing a market unless it complies with the measure. It can also be structured voluntarily, allowing market access but offering incentives for complying with the measure.[18] Local content measures are typically intended to reduce imports, increase local production in the targeted sector, and stimulate investment in local production.[19] However, their implementation can have positive and negative implications.

Potential positives are that local content measures can reduce dependence on foreign suppliers and mitigate risks associated with global supply chain disruptions by promoting domestic production of critical goods. This was particularly evident during the COVID-19 pandemic when many countries faced shortages of essential medical supplies. Local content measures can also safeguard national security by ensuring that critical industries, such as pharmaceuticals, remain under domestic control, reducing vulnerability to geopolitical tensions and potential export bans imposed by other countries. Additionally, local content measures can stimulate domestic industries, create jobs, and promote technological advancements by fostering local expertise and innovation.

Potential negatives are that implementing local content measures can lead to higher production costs due to higher labour and compliance costs. These increased costs can be passed on to consumers, making essential goods less affordable. While local content measures can promote local innovation, they can also stifle technological advancements by limiting access to global

16 Hestermeyer and Nielsen (n 12) 554.

17 Genest (n 13) 91–92.

18 Panel Report, *Canada – Certain Measures Affecting the Automotive Industry*, WT/DS139/R; WT/DS142/R, para 10.73: the fact that compliance with a local content requirement is "voluntary" does not negate this from qualifying as a "requirement" under Art III:4 of the GATT 1994.

19 Genest (n 13) 20; Hestermeyer and Nielsen (n 12) 554.

best practices and technologies. Domestic producers may struggle to compete with international counterparts without access to the latest innovations. Furthermore, local content measures can provoke retaliation from trading partners and lead to trade disputes, resulting in a cycle of protectionism that undermines trade relationships and economic stability.

The US government's use of the Defense Production Act to incentivise domestic production of pharmaceuticals highlights both the potential benefits and drawbacks of local content measures. While the move aimed to reduce dependence on foreign suppliers, it also faced criticism for potentially increasing costs and limiting access to international supply chains. India's 'Make in India' initiative, which includes local content measures for pharmaceutical manufacturing, illustrates the challenges of balancing domestic production with the need for high-quality and affordable medicines. While the initiative aims to enhance supply chain resilience, it has also raised concerns about increased production costs and potential trade conflicts with China, a major supplier of active pharmaceutical ingredients (APIs). The EU's consideration of onshoring critical pharmaceutical production reflects a cautious approach to local content measures. While the EU aims to strengthen supply chain resilience, it is also mindful of the need to maintain cost-effectiveness and avoid trade disputes with key trading partners.

A common motivation for local content measures is to capture positive spillovers from foreign investors by inducing their use of locally-produced materials, components and local labour, thereby stimulating the diffusion of know-how and technology.[20] This motivation is not unique to the pharmaceutical sector. Similar local content measures are observed in technology and automotive industries, aiming to foster innovation, safeguard critical technologies, and reduce dependency on foreign suppliers. These sectors face parallel legal challenges under WTO rules, making the analysis presented in this article widely applicable. Without local content measures, foreign investors with manufacturing operations may import materials, components, and skilled employees from a parent or related company in their home State.[21]

Thus, one reason for seeking to prohibit local content measures is to guarantee foreign investors' operational freedom and thereby maximise the positive effects of outbound investment for investors' *home* States, such as increased exports to the investors' *host* States.[22] A second reason is to reduce the distortions in trade flows that arise from local content measures, which

20 Genest (n 13) 21–22 and 90.

21 ibid 23.

22 ibid 27.

can misallocate resources and have negative welfare impacts on the host States imposing such measures.[23] This is premised on the proposition that if the local economy had a comparative advantage in attracting foreign investors to manufacture locally or supplying locally sourced materials to foreign investors with local manufacturing operations, there would be no need to artificially generate this outcome through local content measures.

Thus, the main *demandeurs* of prohibitions on local content measures have been the primary sources of outbound foreign investment, such as the US and EU.[24] On the other hand, developing countries have preferred greater policy space to use local content measures to capitalise on the benefits of foreign investment. Just last year, for instance, the Africa Group negotiating coalition at the WTO argued that trade-related investment measures such as local content measures should be allowed as part of the "policy toolbox that developing countries require today in order to address development and industrialization objectives".[25] I turn now to the rules addressing local content measures in the WTO framework.

3 Rules on Local Content Measures in the WTO Framework[26]

Two sets of rules in the WTO framework could prohibit the kinds of local content requirements and incentives for onshoring pharmaceutical manufacturing discussed. These rules are equally pertinent to other industries, such as technology and automotive manufacturing, where similar local content policies are employed. The first set of rules is grounded in Article III of the General Agreement on Tariffs and Trade (GATT)[27] and Article 2.1 of the Agreement on Trade-Related Investment Measures (TRIMs Agreement).[28] These are outlined in subsection 3.1 below.

23 ibid 27; Hestermeyer and Nielsen (n 12) 554.

24 Genest (n 13) 37.

25 African Group, 'A Case for Rebalancing The Agreement on Trade-Related Investment Measures (TRIMS) – Policy Space to Promote Industrialisation and Structural Transformation in Developing Countries' (13 July 2023), WT/GC/W/896; G/TRIMS/W/173; WT/COMTD/W/284, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W896.pdf&Open=True>, accessed 1 July 2024.

26 Given that pharmaceuticals are tangible products, I consider only those rules applicable to trade in goods in the WTO framework.

27 GATT Doc, LT/UR/A-1/A/1/GATT/2, signed 30 October 1947, as incorporated in the Marrakesh Agreement Establishing the World Trade Organization, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) Annex 1A, 'General Agreement on Tariffs and Trade 1994' (GATT).

28 ibid, Annex 1A, 'Agreement on Trade-Related Investment Measures' (TRIMs Agreement).

The second set of rules is grounded in Article 3.1(b) of the Agreement on Subsidies and Countervailing Measures (SCM Agreement).[29] These are outlined in subsection 3.2 below. There are no directly applicable exceptions or derogations to Article 3.1(b).

3.1 *GATT and TRIMs*

Local content requirements and incentives will typically violate Article 2.1 of the TRIMS Agreement and at least one subparagraph of Article III of the GATT.[30] This is because these requirements and incentives aim to promote local products over foreign equivalents, thereby producing discrimination that can distort trade and investment flows.[31]

As a starting point, local content requirements and incentives qualify as "trade-related investment measures" subject to the TRIMs Agreement since they influence investment decisions regarding the location for producing and sourcing goods. Article 2.1 of the TRIMs Agreement provides that "no Member shall apply any TRIM that is inconsistent with the provisions of Article III". It specifies local content requirements and incentives in its "Illustrative List" of impugned TRIMs:

> TRIMs that are inconsistent with the obligation of national treatment provided for in paragraph 4 of Article III of GATT 1994 include those which are mandatory or enforceable under domestic law or under administrative rulings, or compliance with which is necessary to obtain an advantage, and which require:
>
> (a) the purchase or use by an enterprise of products of domestic origin or from any domestic source, whether specified in terms of particular products, in terms of volume or value of products, or in terms of a proportion of volume or value of its local production;

According to WTO jurisprudence, a measure fitting this description is necessarily inconsistent with Article 2.1 of the TRIMs Agreement (unless one of the derogations applies).[32] This description clearly captures measures on local content ("the purchase or use by an enterprise of products of domestic origin")

29 ibid, Annex 1A, 'Agreement on Subsidies and Countervailing Measures' (SCM Agreement).

30 Hestermeyer and Nielsen (n 12) 566.

31 Genest (n 13) 28–29 and 60–61.

32 Panel Report, *Canada – Certain Measures Affecting the Renewable Energy Generation Sector*, WT/DS412/R; WT/DS426/R, para 7.119; Appellate Body Report, *Canada – Certain Measures Affecting the Renewable Energy Generation Sector*, WT/DS412/AB/R; WT/DS426/AB/R, para 5.33. I explore these derogations in a separate article titled 'Home Remedies: Flexibilities to Onshore Pharmaceutical Manufacturing Under WTO Rules'.

that are requirements ("mandatory or enforceable") or incentives ("necessary to obtain an advantage").

Additionally, by implication, a measure fitting this description is necessarily inconsistent with Article III of the GATT. It is nonetheless helpful to give a brief overview of Article III, given its pivotal role in this aspect of the TRIMs Agreement and the WTO framework more generally. Article III prohibits WTO Members from discriminating against foreign goods in favour of domestic goods. In particular, Article III.2 prohibits tax discrimination between domestic and foreign goods by prohibiting foreign "like" goods from being taxed "in excess of those applied, directly or indirectly, to like domestic products" or in a way that "afford[s] protection to domestic production". Article III.4 prohibits regulatory discrimination by proscribing "less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use". Given that the very nature of local content requirements and incentives is to privilege domestic products solely by virtue of their domestic character, they have routinely[33] been found inconsistent with Article III.2 when they involve differential taxation[34] and with Article III.4 when they relate to other aspects of a manufacturer's operations.[35]

Turning to the measures to onshore pharmaceutical supply chains, their potential transgression of Article 2.1 of the TRIMs Agreement and Article III of the GATT 1994 seem relatively straightforward. The Indonesian, Indian, and Bangladeshi measures make either eligibility for government procurement or market access more generally, contingent on manufacturers using specific proportions of locally sourced materials.[36] The Turkish and Indonesian measures also seem to require manufacturing operations to be undertaken locally for meaningful market access.[37]

33 In particular, the "likeness" and "less favourable treatment" limbs of the test for Article III are almost automatically fulfilled in relation to local content requirements: see eg Panel Report, *Turkey – Pharmaceutical Products* (n 6) paras 7.112–7.115 and 7.123–7.124. See also Hestermeyer and Nielsen (n 12) 569 and 572.

34 Panel Report, *Indonesia – Certain Measures Affecting the Automobile Industry*, WT/DS54/R; WT/DS55/R; WT/DS59/R; WT/DS64/R, paras 14.110–14.115.

35 Panel Report, *Brazil – Certain Measures Concerning Taxation and Charges*, WT/DS472/R, Add.1 and Corr.1 / WT/DS497/R, Add.1 and Corr.1, para 7.33. It is also likely that such measures would violate Article III.5 of the GATT, but given the way in which claims have been argued in WTO litigation, panels have routinely exercised judicial economy over Article III.5 claims: see Hestermeyer and Nielsen (n 12) 567–568.

36 See eg Panel Report, *Canada – Autos* (n 18) paras 10.126–10.130.

37 See eg Panel Report, *Turkey – Pharmaceutical Products* (n 6) paras 7.123–7.124.

The US legislative proposal to provide financial incentives under Medicare and Medicaid for the use of US-manufactured pharmaceuticals would also seem to squarely "require the purchase or use by an enterprise of products of domestic origin" to "obtain an advantage", contrary to Article 2.1 of the TRIMs Agreement and Article III of the GATT. Likewise, the higher US reimbursements to hospitals that purchase US-made N-95 respirators over foreign equivalents involve offering an advantage for using products of domestic origin. Similarly, one of the US legislative proposals to provide tax credits for US pharmaceutical manufacturing explicitly conditions the amount of tax credits on the extent of the manufacturer's use of local content. It intends to "shift all aspects of the manufacturing process for generic medicines, including materials and testing, to the United States". It would likely violate Article 2.1 of the TRIMs Agreement and Article III of the GATT.[38]

The position is less clear for the other US legislative proposal to offer tax credits for pharmaceutical and API manufacturing undertaken in the US. Although its stated objective is to displace equivalent imported products (particularly from China),[39] it does not link obtaining the credit to using US-sourced inputs, nor condition US market access on manufacturing locally.[40]

Similarly, the position is less clear on the Biden Administration's recent moves to onshore pharmaceutical manufacturing via the Defence Production Act. Its interaction with Article 2.1 of the TRIMs Agreement and Article III:2 of the GATT 1994 will turn on how the incentives for onshoring are structured. If the incentives are *de jure* or *de facto* conditioned on using US-sourced materials at some point in the supply chain, they would likely violate those provisions.

Thus, it is relatively straightforward that efforts to onshore pharmaceutical manufacturing through local content incentives and requirements potentially conflict with Article 2.1 of the TRIMs Agreement and Article III:2 of the GATT

38 Office of Claudia Tenney, 'Congresswoman Tenney Introduces Bill to Promote Production of Generic Medicine in the United States' (Press Release, 28 October 2023) <https://tenney.house.gov/media/press-releases/congresswoman-tenney-introduces-bill-promote-production-generic-medicine>, accessed 1 July 2024.

39 Office of Congressman Carter, 'Carter, Soto, Cartwright, Miller Reintroduce Proposal to Encourage America's Pharmaceutical Independence from China' (Press Release, 26 April 2023) <https://buddycarter.house.gov/news/documentsingle.aspx?DocumentID=11136>, accessed 1 July 2024.

40 117th US Congress, S. 2082, MADE in America Act (16 June 2021) <https://www.congress.gov/bill/117th-congress/senate-bill/2082/text#toc-H7B7F186F48164BD9BF108315D23CAE08>, accessed 1 July 2024.

1994.[41] Measures that do not *de jure* or *de facto* require the use of locally-sourced goods would, on the other hand, not be inconsistent with these provisions, particularly in light of the derogations from Article III.

3.2 *SCM Agreement*

The SCM Agreement prohibits subsidies contingent on the use of domestic goods over imported goods. Specifically, Article 3.1(b) provides:

> 3.1. Except as provided in the Agreement on Agriculture, the following subsidies, within the meaning of Article 1, shall be prohibited:
>
> …
>
> (b) Subsidies contingent, whether solely or as one of several other conditions, upon the use of domestic over imported goods.

Article 3.1(b) covers similar ground to Article 2.1 of the TRIMs Agreement and Article III.4 of the GATT. It is, however, narrower in some respects.[42] It applies only where the local content measure is a "subsidy". It is thus limited to financial incentives to use local requirements as distinct from regulatory requirements. Additionally, the term "subsidy" in the SCM Agreement is limited to the forms listed in Article 1.1(a)(1), namely "direct transfer[s] of funds (e.g. grants, loans, and equity infusion)", "potential direct transfers of funds or liabilities", "government revenue that is otherwise due is foregone or not collected" (e.g. tax credits), the provision or purchase by governments of goods (e.g. procurement), or "income or price support in the sense of Article XVI of GATT 1994". There are also more stringent disciplines on the remedies for violations of Article 3.1(b), and the procurement- and subsidy-related derogations applicable to Article 2.1 of the TRIMs Agreement and Article III of the GATT by virtue of Article III.8 of the GATT are not available for Article 3.1(b).[43] Some have argued that the GATT general exceptions applicable to Article 2.1 of the TRIMs Agreement and Article III of the GATT, such as those relating to public health and essential security interests, should cross-apply to the SCM Agreement and thereby save violations of Article 3.1.[44] This proposition

41 This is subject to the important caveat that one of the various flexibilities discussed in my article 'Home Remedies: Flexibilities to Onshore Pharmaceutical Manufacturing Under WTO Rules' could save otherwise inconsistent measures.

42 See further Panel Report, *US – Conditional Tax Incentives for Large Civil Aircraft*, WT/DS487/AB/R and Add.1, para 7.357.

43 See further Hestermeyer and Nielsen (n 12) 583–584.

44 Ilaria Espa and Gracia Marin Duran, 'Renewable Energy Subsidies and WTO Law: Time to Rethink the Case for Reform Beyond Canada – Renewable Energy/FIT Program'

is untested in WTO jurisprudence. Although it may have merit,[45] its uncertainty is belied by the lack of any explicit incorporation of these exceptions into the SCM Agreement as distinct from the TRIMs Agreement, which has, in turn, informed the balance of academic commentary casting doubt over the proposition.[46]

Local content measures to onshore pharmaceutical production would be covered by Article 3.1(b) only if they comprise a "subsidy". Accordingly, regulatory requirements that pharmaceuticals can only be sold in a country's market if manufactured with some degree of domestic content would not be captured under Article 3.1(b). However, it is apparent that many measures to onshore pharmaceutical production have the kind of financial character that can qualify as a "subsidy". For instance, measures that make eligibility to participate in government procurement conditional on using domestic content would be covered because government procurement can qualify as a subsidy. Likewise, measures that offer tax credits to manufacturers that use domestic content would be covered because "government revenue foregone" can qualify as a subsidy. Financial payments such as reimbursements for domestically-made pharmaceuticals would be covered by "grants" or "transfers of funds".

The key inquiry for Article 3.1(b) is whether these subsidies are "*contingent* … upon the use of domestic over imported goods". In some cases, this can be self-evident. The US measure that conditions a higher reimbursement rate on hospitals' purchase of US-made N-95 respirators over imported N-95 respirators is clearly a subsidy contingent on the use of domestic over imported goods. Likewise, the US legislative proposal to channel higher financial incentives through Medicare and Medicaid for using domestically-produced pharmaceuticals over imported equivalents seems to be a straightforward example of a prohibited import substitution subsidy. Similar issues arise for the Indonesian

(2018) 21 JIEL 621, 645; Bradly Condon, 'Disciplining Clean Energy Subsidies to Speed the Transition to a Low-Carbon World' (2017) 51 JWT 675, 685–90; Luca Rubini, "Ain't Wastin' Time No More: Subsidies for Renewable Energy, the SCM Agreement, Policy Space, and Law Reform" (2012) 15 JIEL 525, 562–63. In an analogous context, the US has argued that Article XXI of the GATT cross-applied to the Agreement on Safeguards despite the lack of any cross-reference or directly incorporated provision to that effect: US First Written Submission, *United States – Certain Measures on Steel and Aluminum Products*, DS544, para 180, <https://ustr.gov/sites/default/files/enforcement/DS/US.Sub1.%28DS544%29.fin.%28public%29.pdf> accessed 1 July 2024.

45 Andrew Mitchell, 'The Right to Regulate and the Interpretation of the WTO Agreement' (2023) 26 JIEL 462, 481.

46 See Nu Ri Jung, 'Are There "Exceptions" to the SCM Agreement? Applicability of the GATT Exceptions Vis-à-Vis the International Rules on Subsidies' (2023) 57 JWT 457, 460–62.

and Indian measures that likewise condition eligibility for government procurement on pharmaceuticals being manufactured with minimum amounts of locally sourced materials. Whether these subsidies[47] can confer a "benefit" in the sense of Article 1.1(b) of the SCM Agreement – including the potential role for regulatory objectives in that assessment – is a separate question.

The question of "contingency" can be more complex, where the intention to use subsidies to displace imported goods is less explicitly embedded in the structure or formulation of the measure.[48] This is because it is insufficient under Article 3.1(b) to show that a measure merely had an import substitution effect or a detrimental impact on imports.[49] As the Appellate Body has explained, "Article 3.1(b) does not prohibit the subsidization of domestic 'production' *per se* but rather the granting of subsidies contingent upon the 'use', by the subsidy recipient, of domestic over imported goods".[50] Indeed, it would ordinarily be expected that subsidies related to domestic manufacturing increase the downstream "use" of the manufactured products by lowering their production costs and improving their competitive position vis-à-vis equivalent imported products.[51] Such subsidies are prohibited under Article 3.1(b) *only* if it can be shown that the downstream use of the goods is somehow linked to the payment of the subsidies.[52]

The same is true for subsidies to domestic producers to increase the upstream "use" of domestically sourced products, albeit with added complexity. Subsidies to domestic producers may not be *explicitly* conditioned on the use of domestically sourced products. Still, the nature of the producers' manufacturing operations or the types of materials or inputs that they use may *necessarily* imply the use of domestically sourced products such that the subsidy is *de facto* "contingent" on the use of domestic goods.[53] On the other hand, according to WTO jurisprudence, the mere fact that the domestic producer receiving a subsidy has an integrated in-house production process that

47 I use the term "subsidy" for ease of terminology, whilst noting that technically these transactions would only be "financial contributions" at this stage of the analysis, insofar as a "subsidy" exists only after an affirmative benefit finding under the SCM Agreement.

48 Panel Report, *US – Tax Incentives* (n 42) paras 7.320–7.321; Appellate Body Report, *US – Conditional Tax Incentives for Large Civil Aircraft*, WT/DS487/R and Add.1, paras 5.12–5.14. See also Kristy Buzard and Panagiotis Delimatsis, 'Subsidies and Investment Promotion Reaching New Heights in the Aviation Sector: The US – Tax Incentives Dispute' (2019) 18 WTR 327, 349.

49 Panel Report, *US – Tax Incentives* (n 42) para 7.357.

50 Appellate Body Report, *US – Tax Incentives* (n 48) para 5.15.

51 ibid, para 5.15; *Brazil – Taxation* (n 35) paras 5.93 and 5.257.

52 Appellate Body Report, *US – Tax Incentives*, (n 48) para 5.18.

53 ibid, fn 49.

manufactures both the components and the final product is not necessarily dispositive of the subsidy being "contingent" on the use of domestically-sourced components.[54]

A related complexity arises from the fact that *non-discriminatory* subsidies supporting domestic producers and production are generally not prohibited under WTO rules.[55] A corollary of the ability to provide non-discriminatory subsidies to domestic producers and production is the need to identify what qualifies as "domestic" production. This issue – often associated with the concept of "rules of origin" – implies that States can set rules and criteria under which a final good (or a producer of that good) can be said to be "domestic", such as a requisite level of domestic effort or value being incorporated into the good.[56] The Appellate Body has recognised that States can set eligibility criteria for "domestic" production subsidies, and even if these eligibility criteria *result* in an increased use of domestically-sourced materials, this alone cannot demonstrate that the subsidy is *contingent* on the use of domestic goods in the sense of Article 3.1(b).[57] For instance, in *US – Tax Incentives*, Washington State had conditioned Boeing's eligibility for a subsidy on a commitment to "manufacture" or "assemble" certain goods in Washington State, but did not explicitly require the "use" of any domestic over imported goods in this regard.[58]

In short, these complexities arise from the need to reconcile two features of WTO rules: (a) the established right to provide non-discriminatory subsidies exclusively to domestic producers and production; and (b) the prohibition on making subsidies contingent on the upstream or downstream use of domestic products. As Ornelas and Puccio explain, the Appellate Body's attempt to navigate a path between these two features of WTO rules is commendable, but the "AB's problem is then to identify what is a permissible eligibility requirement to determine that the good is domestic, as opposed to [local content

54 ibid, para 5.281.

55 Appellate Body Report, *Brazil – Certain Measures Concerning Taxation and Charges*, WT/DS472/AB/R and Add.1 / WT/DS497/AB/R and Add.1, paras 5.246–5.247; Panel Report, *US – Tax Incentives* (n 42) para 7.357.

56 Emanuel Ornelas and Laura Puccio, 'Reopening Pandora's Box in Search of a WTO-Compatible Industrial Policy? The Brazil-Taxation Dispute' (2020) 19 WTR 249, 263–264.

57 Appellate Body Report, *Brazil – Taxation* (n 55) paras 5.281 and 5.291–5.293. See also Appellate Body Report, *US – Tax Incentives* (n 48) para 5.27.

58 ibid, para 5.27.

requirements] prohibited under [A]rticle 3(1)(b)".[59] In their view, the Appellate Body has yet to offer a satisfying solution to this problem.[60]

These complexities make it difficult to ascertain whether the measures to onshore pharmaceutical manufacturing intended to displace imports, but which do not necessarily embed explicit local content conditions, are inconsistent with Article 3.1(b). The Biden Administration's use of the Defence Production Act to onshore production of key starting materials for sterile injectable medicines with a USD 35 million subsidy illustrates the conceptual difficulties in applying Article 3.1(b). On the one hand, this provision of funding for domestic manufacturing of key starting materials would not, in and of itself, fall foul of Article 3.1(b), despite its explicit intention to "promote the onshoring of essential manufacturing capabilities through the [Defence Production Act]"[61] and to "boost production of essential medicines in America" by ensuring "supply chain is going to start here in America".[62] On the other hand, if this funding somehow *necessitates* the use of domestic content and ingredients in the production of the key starting materials, or if the funding is linked to the subsequent use of these key starting materials in downstream US manufacturing of sterile injectable medicines, it may well be inconsistent with Article 3.1(b). This could arise, for instance, from the nature of the recipient of the funding (e.g. as a vertically-integrated manufacturer) or contractual conditions attached to the funding.

The US legislative proposal for a tax credit for domestic pharmaceutical manufacturing that shifts "*all aspects* of the manufacturing process" to the US likewise presents conceptual challenges under the Appellate Body's approach to Article 3.1(b). On the one hand, the proposal explicitly links the tax credit amount to the extent of domestic content used in a US-based pharmaceutical manufacturing process.[63] This appears on its face to be a subsidy contingent on the use of domestic goods prohibited under Article 3.1(b). However, it is

59 Ornelas and Puccio (n 56) 263–64.

60 ibid, 264–66. See also Buzard and Delimatsis (n 48) 349: "the AB unnecessarily blurred the distinction between contingency in law (de jure) and contingency in fact by ruling that identifying a condition requiring the use of domestic inputs would be a necessary element for a determination of a de facto contingency".

61 Department of Health and Human Services, 'Biden-Harris Administration Announces Actions to Bolster Medical Supply Chain' (Press Release, 27 November 2023).

62 White House, 'Remarks by President Biden on New Actions to Strengthen Supply Chains, Lower Costs for Families, and Help Americans Get the Goods They Need' (27 November 2023).

63 118th US Congress, PILLS Act (26 October 2023) <https://www.govinfo.gov/content/pkg/BILLS-118hr6109ih/pdf/BILLS-118hr6109ih.pdf>, accessed 1 July 2024. See "Domestic Content Bonus Credit".

at least possible that this could be characterised under the Appellate Body's framework as an eligibility rule for determining whether the finished product is, in fact, "domestic".

By contrast, the other US legislative proposal for a tax credit only requires the pharmaceutical manufacturing operation to take place in the US, without any additional conditions on using US-sourced materials or inputs in the manufacturing operation.[64] This conceptually resembles the Boeing example from *US – Tax Incentives* mentioned above. It would likely be permissible under the Appellate Body's approach Article 3.1(b), even if it achieves its stated objectives of displacing imports and onshoring production.

4 Conclusion

Measures to promote local content typically violate Article 2.1 of the TRIMs Agreement and Article III of the GATT and, to the extent that they involve subsidies, Article 3.1(b) of the SCM Agreement. The measures pursued by States to onshore pharmaceutical manufacturing are no exception. Those that explicitly embed local content conditions as well as preferences and tax credits contingent on local content, are particularly vulnerable, unless a flexibility applies. The position is less clear for onshoring measures intended to displace imports but which do not necessarily (or, at least, explicitly) impose conditions requiring the use of local content.

It is also important to note that although some measures may be more likely to violate Article 2.1 of the TRIMs Agreement and Article III of the GATT due to their broader scope and coverage, those clauses are also subject to a wider array of policy-based exceptions and derogations. Despite inconsistencies with those clauses, measures related to public health, procurement, and essential security interests could potentially be saved.

By contrast, Article 3.1(b) of the SCM Agreement applies only to measures that qualify as "subsidies", but also appears to be much more limited in terms of the flexibilities available to excuse violations. For instance, although Article III of the GATT explicitly excludes government procurement, Article 3.1(b) tacitly extends to government procurement. Thus, Article 3.1(b) may be more limited in scope, but it may ultimately be a more potent WTO obligation disciplining States' ability to onshore pharmaceutical manufacturing through local content incentives.

64 MADE in America Act (n 40).

While this article uses the pharmaceutical sector as a case study, the findings and legal analyses are broadly relevant to other sectors, including technology and automotive manufacturing. These sectors face similar challenges in balancing local content policies with WTO obligations, highlighting the widespread implications of the issues discussed.

Finally, while this article addresses the conflict between local content measures and WTO obligations, a more comprehensive understanding of the stakes involved requires an examination of the economic implications of these conflicts. Specifically, it would be valuable to explore the potential economic outcomes of adhering to or diverging from WTO rules, including impacts on domestic industries, international trade relations, and overall economic welfare. Such an analysis would benefit from quantitative data or economic modelling. This is a critical area for future interdisciplinary research involving collaboration between lawyers and economists.

Acknowledgements

I thank James Munro, David Chieng and the anonymous reviewers for their comments and suggestions. The National Health and Medical Research Council partly supported this independent research pursuant to the Ideas Grant scheme (project number APP2012233).