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BENCH MEMORANDUM

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VERSANIA – SEIZURE OF VACCINES IN TRANSIT FROM ARION

Bench Memorandum

For the Twenty-First Edition of the

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This memorandum is designed to provide background information and guidance to those serving as panelists for the written submissions and/or the Regional or Final Oral Rounds. The memorandum highlights existing case law or theories on the relevant provisions as well as the expected arguments of each party. It is not meant to provide a definitive answer to any of the legal questions posed.

CONTENTS

1. ABBREVIATIONS USED IN THIS BENCH MEMORANDUM

Abbreviation	**Description**
ILC	International Law Commission
MC12 Decision	2022 WTO Ministerial Decision on the TRIPS Agreement
WCO	World Customs Organization
WTO	World Trade Organization
Vienna Convention	Vienna Convention on the Law of Treaties
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
GATT	General Agreement on Tariffs and Trade
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TFA	Agreement On Trade Facilitation

2. TIMELINE OF THE DISPUTE

Date	Event
November 2020	Zanos files applications for process and product patents for its vaccine candidate 'Zancovac' in Versania, Arion and other countries.
January 2021	Arion enters into a purchase agreement with Zanos for supply of sufficient doses of Zancovac. It purchases sufficient doses to vaccinate its entire population, including booster shots for the immunocompromised population.
March 2022	COVID-19 infection levels in Arion have already reduced significantly and continue to drop.
17 June 2022	Ministerial Decision on the TRIPS Agreement is adopted at the WTO.
June 2022	Study commissioned by Arion and ANCOP shows that two primary doses of the Zancovac COVID-19 vaccine (and a third booster shot for immuno-compromised populations) reduced risk of severe disease by 95%. Concludes that bi-annual periodic booster shots for the entire population would be needed to completely eliminate the risk of asymptomatic and mildly symptomatic cases.
10 July 2022	Arion passes executive order authorising ANCOP to start production and sale of COVID-19 vaccines using the process patented by Zanos.
20 July 2022	Boutica passes an executive order authorising the import of 3,000,000 doses of ANCOP's COVID-19 vaccine over a one year period.
25 July 2022	Zanos files an application with IP Commissioner (Chair of Intellectual Property Board) alleging that ANCOP's production of its COVID-19 vaccines infringes Zanos' patent rights.
28 – 31 July 2022	Intellectual Property Board conducts a hearing on Zanos' application, with both ANCOP and Zanos participating in the hearing.
3 August 2022	ANCOP's vaccines received market authorization in Arion.
5 August 2022	ANCOP's vaccines received market authorization in Boutica.
5 August 2022	Subsequent to the hearing, the Intellectual Property Board issues decision authorising Versanian Customs Office to seize and destroy all shipments of ANCOP's vaccines in transit from Arion to Boutica through Versania.
12 August 2022	ANCOP releases vaccines for shipment to Boutica from its production facility in Arion.
15 August 2022	Versanian Customs Office at the border with Arion confiscated several shipments of ANCOP'S COVID-19 vaccines en route to Boutica.
30 August 2022	Versanian Customs authorities destroy the confiscated shipments.

3. INTRODUCTION

This case concerns in-transit seizure and destruction of COVID-19 vaccines produced under the 2022 WTO Ministerial Decision on the TRIPS Agreement ('MC12 Decision'). The parties to the dispute are Arion and Versania, neighboring countries and founding members of the World Trade Organization ('WTO'). The shipment of COVID-19 vaccines, which was seized and subsequently destroyed by Versanian customs authorities, was in transit from Arion, via Versania, to a third country, Boutica.

The issues concern the enforcement of intellectual property rights against goods in transit, the meaning of the terms 'legitimate trade' and 'country of importation' under the relevant provisions of the TRIPS Agreement, and the scope of the obligation to grant freedom of transit under the GATT 1994. Finally, the issues also address the scope of the MC12 Decision, in particular, a consideration of what "to the extent necessary to address the COVID-19 pandemic" entails.

4. FACTUAL ASPECTS

The complainant, Arion, is a land-locked, lower-middle income country which designates itself as a developing country at the WTO. It has a robust pharmaceutical industry, whose exports account for 25 percent of total global pharmaceutical exports in volume. Traditionally, Arion's pharmaceutical industry produces and exports low-cost generic drugs, however, over the past decade, Arion has also been seeking to develop its local vaccine manufacturing capacity.

Versania, the respondent, is a high-income country, also with a strong pharmaceutical industry which produces high-priced novel drugs and vaccines. Versania, has a long coastline of around 7,000 km, and provides the only convenient access for land-locked Arion to the high seas (see map on page 9).

Boutica is an upper-middle income WTO member, which also designates itself as a developing country at the WTO. It is situated 3,000 kilometers from Arion.

Against the backdrop of the COVID-19 pandemic, Zanos, a leading pharmaceutical company established in Versania developed a COVID-19 vaccine in 2020. Zanos filed both process and product patents for the vaccine (named 'Zancovac') in Versania, Arion, Boutica as well as several other countries. Data from Zancovac's clinical trials led to recommendations that two primary doses of the vaccine be administered to reduce risk of severe disease and death caused by COVID-19, with a third booster shot recommended only for the immune-compromised population.

Soon after, Zancovac was made available for global sale to governments around the world, at USD 22.5 per dose. Both Arion and Boutica were amongst the countries who purchased Zancovac,

importing sufficient doses to vaccinate their entire populations, including booster shots for the immunocompromised populations. Arion, being a lower-middle income country, diverted funds from its disaster-mitigation budget to import the vaccines. Further, recognizing the importance of public health, it also used these funds to invest in its domestic pharmaceutical industry. By March 2022, COVID-19 infection levels in Arion had reduced significantly and have continued to drop since.

ANCOP Ltd. is a major pharmaceutical company established in Arion. In June 2022, a study commissioned jointly by the government of Arion and ANCOP Ltd., showed that two primary doses of the Zancovac COVID-19 vaccine (and a third booster shot for immuno-compromised populations) reduced the risk of severe disease by 95%. In order to completely eliminate the risk of asymptomatic and mildly symptomatic cases, the study concluded that booster shots would be needed every six months for the entire population.

Noting the results of the study, the government of Arion issued a statement indicating that periodic booster shots would prove advantageous for public health, but would also result in a huge financial burden on public funds. It thus declared its intention to transfer the distribution and sale of COVID-19 vaccines to commercial channels, with vaccines being made available for purchase by the general public through pharmacies. The government of Boutica followed suit, and announced similar plans.

Two days after the study was published, ANCOP announced imminent plans to start producing COVID-19 vaccines. ANCOP entered into talks with private pharmaceutical distributors in Boutica, and although it had yet to start producing vaccines, it promised these distributors to deliver COVID-19 vaccine doses at USD 15.5 per dose, that is, USD 7 cheaper per dose compared to the price offered by Zanos. Consequently, many private pharmaceutical distributors in Boutica expressed interest in entering into advance purchase agreements with ANCOP, pending clinical trials and market authorization.

On 10 July 2022, pursuant to paragraph 1 of the MC12 Decision, Arion passed an executive order authorizing ANCOP to start the production and sale of COVID-19 vaccines using the process patented by Zanos. The order authorized the production of 4,000,000 doses for domestic sale within Arion, and further production of 3,000,000 doses for export to Boutica. Ten days later, Boutica also passed an executive order authorising the import of 3,000,000 doses of ANCOP's COVID-19 vaccine over a one year period. Both countries subsequently notified their respective executive orders to the Council for TRIPS pursuant to paragraph 5 of the MC12 Decision.

Soon after, ANCOP started the manufacture of vaccines using the process patented by Zanos. The vaccines were to be shipped from Arion to Boutica via Versania's sea ports. Given the countries'

geographical location, as well as the large volumes of doses to be exported, this was the most convenient and only economically feasible option.

Zanos, concerned that ANCOP's vaccines improperly infringed on the patents that it held in Versania as well as in Arion and Boutica, filed an application with the IP Commissioner (the head of the Intellectual Property Board) in Versania on 25 July 2022. The Versanian Code on Intellectual Property Protection provides, in relevant part,

"Section 61: Border Measures

Where goods infringing on an intellectual property right registered in the territory of Versania, come from third countries, their introduction into Versanian customs territory, whether for free circulation within Versania or transhipment to another country of final destination, shall be prohibited."

In its application, Zanos requested border measures against any consignment of goods infringing an intellectual property right, specifically asking for the seizure and destruction of these goods. The Intellectual Property Board, a judicial body, conducted a hearing, where both Zanos and ANCOP participated. Ultimately, the Board accepted Zanos' application. ANCOP had the right to appeal from the decision of the Intellectual Property Board before the High Courts in Versania. However, after the decision ANCOP informed the Intellectual Property Board that it will not be exercising this right.[1] Subsequently, the Intellectual Property Board authorized the Versanian Customs Office at the border with Arion to seize and destroy all shipments of ANCOP's COVID-19 vaccines in transit from Arion to Boutica through Versania.

On 12 August, 2022, ANCOP released five shipments of vaccines for shipment to Boutica from its production facility in Arion. On 15 August, the Versanian Customs Office at the border with Arion, acting pursuant to the Decision of the Intellectual Property Board and under Section 75 of the 2006 Versania Customs Act, confiscated all five shipments of ANCOP'S COVID-19 vaccines in transit to Boutica. Both Zanos and ANCOP were informed about the seizure on the very day that the seizure was made. However, ANCOP did not respond to the notice, and made no request to retrieve the consignment. The Customs Office eventually destroyed the shipments after 15 days.

Section 75 of Versania Customs Act provides for customs action against goods suspected of infringing intellectual property rights pursuant to a decision of the Intellectual Property Board. It states,

"*Section 75: Customs action against goods suspected of infringing intellectual property rights*

1. Where a holder of intellectual property rights registered in Versania makes an application for customs action pursuant to a decision of the Intellectual Property Board for seizure, detention, destruction or disposal of goods alleged to infringe intellectual property rights under the Versanian

[1] Clarification Questions, Part II, Answer 8.

Code on Intellectual Property Protection, or where the Intellectual Property Board forwards such a decision to a Customs office, the relevant Customs office shall take action as directed by that decision.
2. Where goods alleged to infringe intellectual property rights under the Versanian Code on Intellectual Property Protection are only in transit through the territory of Versania, the Customs Office shall nonetheless be entitled to take such measures against them as directed by the relevant decision of the Intellectual Property Board.
3. Any goods against which action is taken pursuant to this section shall be deemed to have been imported into Versania." [Paragraph 3 of Section 75 was added as a General Clarification within the Clarification Questions.]

The action was met with significant backlash from both Arion and Boutica, with the Minister of Health from Arion publicly stating that Versania's actions are contrary to the object and purpose of the MC12 Decision, as the shipments in question contained COVID-19 vaccines, produced pursuant to the MC12 Decision.

Arion requested consultations with Versania under Article 4 of the WTO Dispute Settlement Understanding ('DSU'), Article XXIII of the General Agreement on Tariffs and Trade 1994 ('GATT'), and Article 64.1 of the TRIPS Agreement. After consultations were unsuccessful, Arion submitted a request to the Dispute Settlement Body for the establishment of a panel.

5. PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

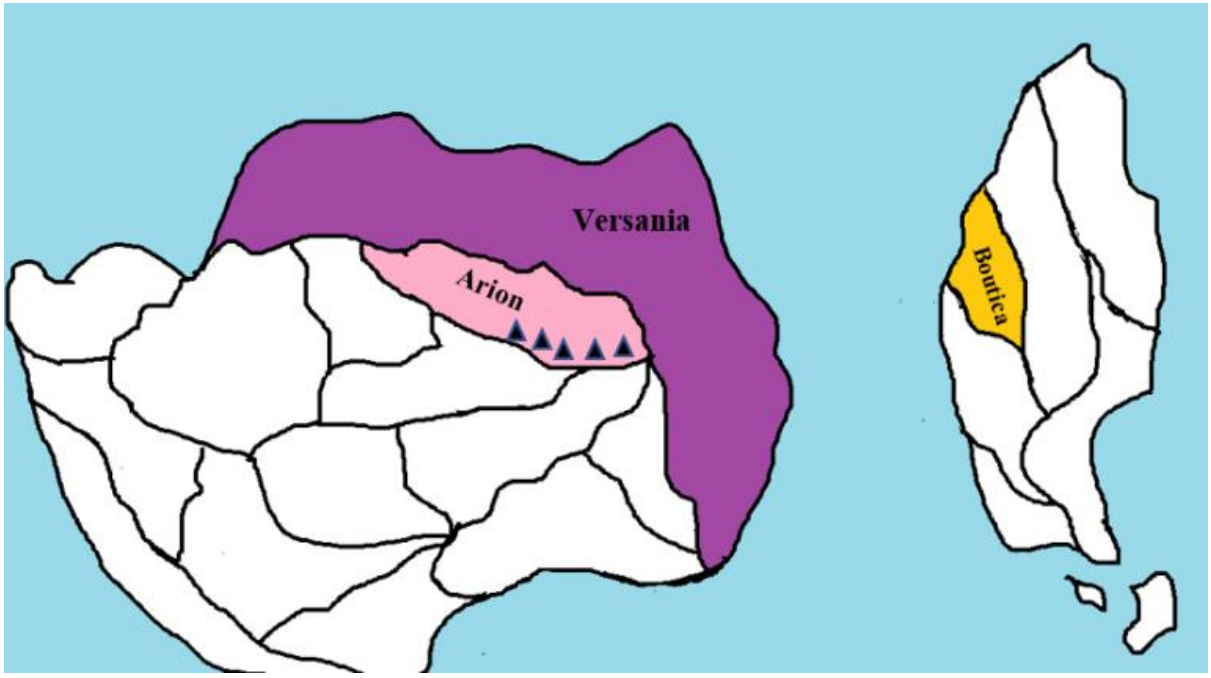
Arion submitted the following claims in its request for the establishment of WTO panel:

I. Versania's seizure of vaccines in transit from Arion to Boutica violates Articles 41.1, 51 and 52 of the TRIPS Agreement.

II. In seizing the vaccines in transit, Versania violates Article V(2) of the GATT which provides for freedom of transit through the territory of each WTO Member.

III. Finally, insofar as Versania claims that it has imported the vaccines in transit from Arion to Boutica, Versania would violate its obligations under paragraph 3(c) of the 2022 Ministerial Decision on the TRIPS Agreement.

MAP



6. WHETHER VERSANIA'S ACTIONS IN SEIZING VACCINES IN TRANSIT FROM ARION TO BOUTICA VIOLATE ARTICLES 41.1, 51 AND 52 OF THE TRIPS AGREEMENT?

6.1. KEY THEMES

The key themes within this issue are:

- The meaning of 'legitimate trade' within Article 41, TRIPS Agreement, and in particular the relevance of the MC12 Decision in determining what constitutes 'legitimate trade'.
  Article 41.1 requires that enforcement procedures should be applied so as to "avoid the creation of barriers to legitimate trade." The issue thus focuses on the meaning of the phrase 'legitimate trade' and whether vaccines supposedly produced under the MC12 Decision constitute 'legitimate trade' under Article 41.1. A related theme here is also the scope of the MC12 Decision, and any limitations thereto from the phrase "to the extent necessary to address the COVID-19 pandemic" in the Decision.

- The meaning of the 'country of importation' under Article 52 and the principle of territoriality of intellectual property rights.
  Article 52 imposes certain conditions that must be fulfilled by "any right holder initiating the procedures under Article 51 [Suspension of Release by Customs Authorities]". It requires that where right holders are initiating the procedures under Article 51, they must demonstrate a *prima facie* infringement of their intellectual property rights "under the laws of the country of importation." The issue thus hinges on the term "laws of the country of importation", and the question arises whether the 'country of importation' under Article 52 includes the country of transit (Versania here) or only refers to the country of final destination (Boutica here).

- The use and relevance of domestic case law before a WTO Panel.
  There is a gamut of domestic and regional case law determining the meaning of 'importation' in the context of intellectual property rights applied to goods in transit. Teams may mention this case law in argumentation, even though domestic jurisprudence does not have persuasive value before a WTO Panel.

Finally, as is clear from the phrasing of the claims, the claim is an 'as-applied' claim, brought by Arion against *Versania*'s actions in seizing the vaccines. It is *not* an as-such claim against Versanian laws.

5.2 ARTICLE 41.1: WHETHER THE SEIZURE OF VACCINES IN TRANSIT CONSTITUTES A BARRIER TO 'LEGITIMATE TRADE'?

5.2.1 Relevant legal provisions and jurisprudence

Article 41.1 of the TRIPS Agreement provides:

> "*Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse*." (emphasis added)

Part III of the TRIPS Agreement, where Article 41 is placed, deals with enforcement procedures. As the Appellate Body has clarified:

> *"Part III has broad coverage. It applies to all intellectual property rights covered by the TRIPS Agreement. According to Article 1.2 of the TRIPS Agreement, the term 'intellectual property' refers to 'all categories of intellectual property that are the subject of Sections 1 through 7 of Part II' of that Agreement."*[2]

Article 41 is the sole provision under Section 1 of Part III of the TRIPS Agreement, entitled 'General Obligations'. According to the Appellate Body, it "provide[s] for an internationally-agreed minimum standard which Members are bound to implement in their domestic legislation."[3]

The phrase 'legitimate trade' in Article 41.1 has never been interpreted by WTO Panels or the Appellate Body. Article 3.2 of the Dispute Settlement Understanding provides that customary rules of interpretation of public international law should guide the interpretation of WTO provisions.[4] Articles 31 and 32 of the Vienna Convention on the Law of Treaties (Vienna Convention) form part of the customary rules of interpretation, and have been previously relied upon by Panels and Appellate Body.[5] Article 31 of the Vienna Convention provides the general rule of interpretation, and requires a treaty to be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[6]

In the context of Articles 13 and 30 of TRIPS, panels have previously relied on the dictionary meaning of 'legitimate': "(a) conformable to, sanctioned or authorized by, law or principle; lawful; justifiable; proper; (b) normal, regular, conformable to a recognized standard type."[7] The Panel in *US-COOL,* in interpreting the phrase 'legitimate objective' in Article 2.2 of the TBT Agreement

[2] Appellate Body Report, *US – Section 211 Appropriations Act*, para. 205.
[3] Appellate Body Report, *US – Section 211 Appropriations Act*, para. 206; Panel Report, *Saudi Arabia – Intellectual Property Rights*, para. 7.183.
[4] Article 3.2, Dispute Settlement Understanding.
[5] *See* Appellate Body Reports, *US - Clove Cigarettes*, para 262; *US – Zeroing Methodology*, para. 268; and *EC- Chicken Cuts*, para. 239.
[6] Article 31.1, Vienna Convention on Law of Treaties.
[7] Panel Reports, *US – Section 110(5) Copyright Act*, para. 6.224; and *Canada – Pharmaceutical Patents*, para. 7.68 (citing New Shorter Oxford Dictionary, page 1563).

relied on the same dictionary meaning,[8] as did the Appellate Body in *US – Tuna II (Mexico)*, highlighting the phrase "lawful; justifiable; proper".[9]

Based on the same dictionary meaning, while interpreting the phrase 'legitimate interests' under Article 13 of TRIPS, the Panel in *US – Section 110(5) Copyright Act* held that the term "relates to lawfulness from a legal positivist perspective, but it has also the connotation of legitimacy from a more normative perspective."[10] In interpreting 'legitimate interests' under Article 30 of TRIPS, the Panel in *Canada – Pharmaceutical Patents* noted that the phrase can be understood as a "normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."[11] The Appellate Body in *US-Tuna II (Mexico)* further noted that "objectives recognized in the provisions of other covered agreements may provide guidance for, or may inform" the interpretation of 'legitimate objective' under Article 2.2 of the TBT Agreement.[12]

Further, the Panel in *Australia- Tobacco Plain Packaging*, in interpreting 'in the course of trade' under Article 20 of TRIPS, noted that the ordinary meaning of the term 'trade' refers to "[t]he action of buying and selling goods and services".[13] However, the Panel held that the phrase 'in the course of trade' is not only limited to buying and selling, but more "broadly covers the process relating to commercial activities".[14] According to the Panel, some commercial activities happening after retail sale are also considered to be in the course of trade.[15]

Article 31 of the Vienna Convention clarifies that the ordinary meaning of the word has to be considered in its context, and in light of the object and purpose of the entire treaty.[16] The context of a treaty includes the entire text of the treaty, including its preamble, as well as any other agreement or instrument completed in relation to the treaty.[17] The Appellate Body in *China – Auto Parts* has held that the context is 'relevant' "to the extent that it may shed light on the interpretative issue to be resolved".[18] Thus, for a particular provision or instrument to constitute 'relevant' context, it must

[8] Panel Report, *US-COOL*, 7.630 (citing The Shorter Oxford English Dictionary, (Sixth Edition) Oxford University Press, Vol. I, p. 1577 (2007).)
[9] Appellate Body Report, *US – Tuna II (Mexico)*, para. 313 (citing Shorter Oxford English Dictionary, 6th edn, A. Stevenson (ed.) (Oxford University Press, 2007), Vol. 1, p. 1577.)
[10] Panel Report, *US – Section 110(5) Copyright Act*, para. 6.224 (emphasis added).
[11] Panel Report, *Canada – Pharmaceutical Patents*, para. 7.69 (emphasis added).
[12] Appellate Body Report, *US – Tuna II (Mexico)*, para. 313.
[13] Panel report, *Australia – Tobacco Plain Packaging*, para. 7.2261, quoting Oxford Dictionaries online, HND excerpts, (Exhibit HND-31), definition of "trade".
[14] Panel report, *Australia – Tobacco Plain Packaging*, para. 7.2261.
[15] Panel report, *Australia – Tobacco Plain Packaging*, para. 7.2263.
[16] Article 31(1), Vienna Convention on Law of Treaties; Appellate Body Reports, *US – Zeroing Methodology*, para. 268; and *EC- Chicken Cuts*, para. 239.
[17] Article 31 (2), Vienna Convention on Law of Treaties.
[18] Appellate Body Report, *China – Auto Parts*, para. 151.

"have some pertinence to the language being interpreted that renders it capable of helping the interpreter to determine the meaning of such language..."[19]

Articles 7 and 8 of the TRIPS Agreement, respectively, lay down the 'objectives' and the 'principles' of that Agreement. The Panel in *Australia – Tobacco Plain Packaging*, in a finding upheld by the Appellate Body, clarified that "Articles 7 and 8, together with the preamble of the TRIPS Agreement, set out general goals and principles underlying the TRIPS Agreement, which are to be borne in mind when specific provisions of the Agreement are being interpreted in their context and in light of the object and purpose of the Agreement."[20]

Article 7 provides:

> "*Objectives*
> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations*." (Emphasis added)

Article 8 provides, in relevant part:

> "*Principles*
> 1. *Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement...*" (Emphasis added)

Thus, in interpreting 'legitimate trade' under Article 41.1, the underlying objective of social and economic welfare (Article 7), and the protection of public health (Article 8) should be borne in mind. At the same time, "mutual advantage of producers and users of technological knowledge" and a "balance of rights and obligations" are recognized in Articles 7 as key objectives.

Further, it can be debated whether the MC12 Decision provides 'relevant context' for interpreting 'legitimate trade' under Article 41.1 of TRIPS, and in determining whether the shipment containing ANCOP's COVID-19 vaccines, produced under Arion's executive order[21] - issued pursuant to the MC12 Decision - constitute legitimate trade. The Decision allows eligible Members to limit patent rights, "by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to

[19] Appellate Body Report, *China – Auto Parts*, para. 151.
[20] Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.2398; Appellate Body Report, *Australia – Tobacco Plain Packaging*, paras. 6.657.
[21] Case, Annex II.

address the COVID-19 pandemic..."[22] The decision allows any proportion of the goods to be exported to another eligible Member,[23] and there is no requirement for the proposed user to make efforts to obtain an authorization from the right holder to produce the COVID-19 vaccines.[24] However, it is questionable whether the MC12 Decision is 'relevant' context for Article 41.1, as the Decision relates more generally to patent rights under the TRIPS Agreement, but does not mention 'legitimate trade' or Article 41 or enforcement procedures at all.

The legal characterization of the MC12 Decision may have implications for its potential use in treaty interpretation in Issue 1, but also has bearing on Issue 3 (see Section 7.) The MC12 Decision was taken having regard to Articles IX:1, IX:3 and IX:4 of the Marrakesh Agreement. As a waiver under Article IX:3, the MC12 Decision should be limited and its purpose "is not to modify the interpretation or application of existing provisions in the agreements, let alone to add to or amend the obligations under a covered agreement or Schedule."[25] In this regard, the Appellate Body in *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US*) also reversed a finding by the Panel in that case that the waiver at issue qualified as a "subsequent agreement" under Article 31(3)(a) of the Vienna Convention.[26] In that case, the instrument in question was a waiver adopted by the Ministerial Conference permitting the European Communities to provide preferential tariff treatment for products originating in Africa, the Caribbean and the Pacific.[27]

The territorial nature of intellectual property rights, including patents, can also be relevant in interpreting 'legitimate trade' under Article 41.1. The territoriality principle, also known as the principle of independence, is enshrined in Article 4*bis*.1 of the Paris Convention for the Protection of Industrial Property (incorporated into the TRIPS Agreement by Article 2.1, TRIPS Agreement), which provides that "patents applied for in the various countries...shall be independent of patents obtained for the same invention in other countries."[28] Thus, patents are territorial in nature, with each State granting its own patents which are only enforceable in that issuing State. The territoriality principle becomes significant in determining which State's laws, public policies and social norms are relevant for deciding whether shipments containing ANCOP's vaccines constitute 'legitimate trade.'

Finally, on the issue of 'enforcement procedures' under Article 41.1, the Panel in *China - Intellectual Property Rights* has held that they also include 'remedies', such as the authority of judicial authorities

[22] Para. 1, MC12 Decision (emphasis added).
[23] Para. 3 (b), MC12 Decision.
[24] Para. 3 (a), MC12 Decision.
[25] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 389 (emphasis added).
[26] *Ibid* at para. 382.
[27] *Ibid* at para. 10.
[28] Article 4*bis*.1, Paris Convention for the Protection of Industrial Property.

"to make certain orders, such as injunctions, orders to pay damages, orders for the disposal or destruction of infringing goods and provisional measures.[29]

5.2.2 Arguments for Arion

Arion should argue that the shipments containing ANCOP's COVID-19 vaccines constituted 'legitimate trade' and Versania's actions in seizing, and eventually destroying, the shipments created a barrier to legitimate trade.

Arion can argue that the MC12 Decision provides relevant context for interpreting 'legitimate trade under Article 41.1. Since the context of a treaty also includes any other agreement or instrument completed in relation to the treaty,[30] the MC12 Decision can be relevant. The MC12 Decision has been taken by the Ministerial Conference (comprising of all Member States) and allows for limitation of patent rights on COVID-19 vaccines. Although the MC12 Decision does not directly refer to 'legitimate trade' or Article 41, it can be logically concluded that an instrument legitimizing a limitation of patent rights in certain products would be 'pertinent'[31] in interpreting whether trade in those products is 'legitimate' or not.

Arion need not go into details about the legal characterization of the MC12 Decision, instead emphasizing that the fact that the vaccines were produced under the MC12 Decision[32] meant that they did not infringe patent rights in Arion or Boutica. The vaccines were produced in Arion under an Executive Order (pursuant to the MC12 Decision) and were imported in Boutica- the country of final destination- under another Executive Order.[33] Accordingly, the vaccines were "sanctioned or authorized by...law"[34] in both the country of origin, as well as the country of final destination, and thereby constitute 'legitimate trade'.

Further, Arion can use the territoriality principle in demonstrating that ANCOP's vaccines constitute 'legitimate trade'. Since the vaccines were not in Versanian territory, and instead were only transiting through Versania, with the production, consumption and economic effects of trade limited to Arion and Boutica, it is their 'legitimacy' in Arion and Boutica which should be relevant. As the vaccines were authorized by law in both the country of origin, as well as the country of final destination, the claimants can argue the vaccines constitute considered 'legitimate trade'.

[29] Panel Report, *China – Intellectual Property Rights*, para. 7.179
[30] Article 31 (2), Vienna Convention on Law of Treaties.
[31] Appellate Body Report, *China – Auto Parts*, para. 151.
[32] Case, para. 11, Annex II; Paragraph 5(b), MC12 Decision.
[33] Case, paragraph 11, Annex II.
[34] Panel Report, *US – Section 110(5) Copyright Act*, para. 6.224; Panel Report, *Canada – Pharmaceutical Patents*, para. 7.68-69 (citing New Shorter Oxford Dictionary, page 1563).

The characterization of the vaccines as 'legitimate trade' is further strengthened by examining the relevant context[35] of Article 41.1 of TRIPS, namely the objectives and principles enshrined in TRIPS Articles 7 and 8, as well as the Preamble of the TRIPS Agreement, which reflect the key importance given to public health issues.[36] These provisions clarify that the TRIPS Agreement sets out to maintain a balance of rights and obligations,[37] such that the enforcement of intellectual property rights should not become a barrier to legitimate trade.[38]

The vaccines in question were needed to eliminate the risk of COVID-19 cases,[39] and were key for public health purposes. The seizure and destruction of ANCOP's vaccines by the Versanian customs authority not only constitutes a direct barrier to the legitimate trade of goods, but also creates an indirect barrier to trade as it may have a deterrent effect on exporters' choice of transit routes in the future. Such actions have a harmful effect on access to vaccines, and therefore run counter to the protection of public health principles, social welfare as well as the delicate balance of rights and enshrined in the TRIPS Agreement.

Accordingly, Versania's actions in seizing and destroying shipments containing ANCOP's vaccines violate Article 41.1 of the TRIPS Agreement.

5.2.3 Arguments for Versania

Versania can argue that the shipments in question which were seized and subsequently destroyed by the Versanian customs authorities contained patent-infringing goods, and hence do not constitute 'legitimate trade'.

To counter Arion's reliance on MC12 Decision to show the vaccines as legitimate, Versania can first argue that the MC12 Decision does not provide relevant context to interpret the meaning of 'legitimate trade' under Article 41.1. Versania can rely on the Appellate Body Report in *China – Auto Parts* which held that an instrument only provides 'relevant' context when it has "some pertinence to the language being interpreted that renders it capable of helping the interpreter to determine the meaning of such language."[40] In that case, the Appellate Body held that while the Harmonized System may be relevant context for the classification of products, it "does not serve as relevant context for the interpretation of the term "internal charges" in Article III:2" of GATT.[41] The MC12 Decision neither mentions the phrase 'legitimate trade', nor Article 41.1 or enforcement

[35] Article 31, Vienna Convention on Law of Treaties; Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.2398; Appellate Body Report, *Australia – Tobacco Plain Packaging*, paras. 6.657.
[36] Article 8, TRIPS Agreement.
[37] Article 7, TRIPS Agreement
[38] Preamble, TRIPS Agreement.
[39] Case, para. 7.
[40] Appellate Body Report, *China — Auto Parts*, para. 163-164.
[41] Appellate Body Report, *China — Auto Parts*, para. 163-164.

procedures. It can accordingly be argued that MC12 Decision is not 'relevant' context in interpreting "legitimate trade' under Article 41.1. Further, Versania can argue that as a waiver under Article IX:3,[42] the MC12 Decision should be limited and its purpose "is not to modify the interpretation or application of existing provisions in the agreements…"[43]

Even if Versania concedes that the MC12 Decision may provide 'relevant context' in interpreting 'legitimate trade' under Article 41.1, it can still argue that the MC12 Decision is not applicable in the present case. The MC12 Decision only allows for the limitation of patent rights "to the extent necessary to address the COVID-19 pandemic".[44] The text of the MC12 Decision ("Noting the exceptional circumstances of the COVID-19 pandemic.")[45] as well as the 'circumstances of its conclusion'[46] make it clear that the Decision is limited only to cases where it is necessary to address the pandemic. Versania can argue that the vaccines were not 'necessary' to address the COVID-19 pandemic. In doing so, teams may rely on the test of 'necessary' under Article XX GATT. The MC12 Decision is in the nature of a 'waiver'[47], which "is a specific and exceptional instrument subject to strict disciplines" that operates to "relieve a Member, for a specified period of time, from a particular obligation provided for in the covered agreements".[48] Similarly, Article XX GATT is also in the nature of an exception. Accordingly, given the similarities, teams may make reference to the interpretation of the term 'necessary' under Article XX GATT. (Detailed jurisprudence on 'necessary' can be found in Section 6.2.2.1.)

In this regard, Versania can show that ANCOP's vaccines were being sold as booster shots to private distributors for commercial profit, in countries where governments already had sufficient jabs to vaccinate their entire population. Both Arion and Boutica had already secured sufficient supplies of Zancovac to provide two doses to their entire population and an additional booster shot for the immunocompromised population, such that the risk of severe disease was reduced by 95%.[49] The sale of ANCOP's vaccines would only help eliminate the risk of asymptomatic and mildly symptomatic cases, which anyway do not constitute a threat to the public.[50] Thus, Versania can

[42] The MC12 Decision was taken "[h]aving regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing…" Preamble, MC12 Decision.
[43] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 389 (emphasis added).
[44] Paragraph 1, MC12 Decision.
[45] Paragraph 2, Preamble, MC12 Decision.
[46] Article 32, Vienna Convention on the Law of Treaties.
[47] "Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization", paragraph 1, MC12 Decision.
[48] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, paras. 381-382.
[49] Case, para 6, 7 and 9; Clarification Questions, Part X, Ans. 3 [p. 11].
[50] Case, para 7.

argue that the supply of ANCOP's vaccines – especially for private distribution through commercial channels – is not necessary for addressing the COVID-19 pandemic.

Based on the above, Versania can thus argue that Arion cannot rely on the MC12 decision to show that the vaccines were 'legitimate'. As the vaccines were not necessary to address the COVID-19 pandemic, they cannot be said to be produced under the MC12 Decision, and cannot be said to be "sanctioned or authorized by...law".[51] Accordingly, the vaccines were simply patent infringing products, and thus cannot be said to constitute 'legitimate trade' under Article 41.1.

Versania can also rely on the territoriality principle in interpreting 'legitimate trade'. Versania can use this to argue that the laws of Versania would apply when the goods are in the territory of Versania. Patent-infringing goods are illegal under Versanian laws[52] and are hence not legitimate. However, this is not a very strong argument, as the goods were arguably *not in Versanian territory,* and instead were only transiting through Versania, with the production, consumption and economic effects of trade limited to Arion and Boutica.

5.2.4 Questions for teams

Questions for Arion	**Questions for Versania**
What is the scope of the term 'enforcement procedures' under Article 41.1? Do Versania's actions in seizing and destroying the vaccines constitute 'enforcement procedures' under Article 41.1?	What is the scope of the term 'enforcement procedures' under Article 41.1? Do you agree that Versania's actions in seizing and destroying the vaccines constitute 'enforcement procedures' under Article 41.1?
Do you bring an 'as-such' claim against specific provisions of the Versanian legislation, or an *applied* claim against Versania's actions?	
Why are the vaccines in question considered 'legitimate trade'? Does the fact that they are ostensibly produced under the MC12 Decision automatically render them legitimate under Article 41.1? Why?	Considering that the MC12 Decision on TRIPS Agreement was adopted by consensus by the Ministerial Conference, would it not be absurd to consider vaccines produced pursuant to the terms of that Decision as not 'legitimate trade' under Article 41.1 of the TRIPS Agreement?
What is the interpretive value of the MC12 Decision in interpreting 'legitimate trade'	What is the interpretive value of the MC12 Decision in interpreting 'legitimate trade'

[51] Panel Reports, *US – Section 110(5) Copyright Act*, para. 6.224; and *Canada – Pharmaceutical Patents*, para. 7.68 (citing New Shorter Oxford Dictionary, page 1563).
[52] Section 48 and Section 54, Versanian Code on Intellectual Property Protection, 1995.

under Article 41.1, TRIPS Agreement? How would you legally characterize the Decision in terms of WTO and international law?	under Article 41.1, TRIPS Agreement? How would you legally characterize the Decision in terms of WTO and international law?

5.3 ARTICLES 51 AND 52: WHETHER THE SEIZURE OF VACCINES IN TRANSIT VIOLATES ARTICLES 51 AND 52?

5.3.1 Relevant legal provisions and jurisprudence

Article 51 of the TRIPS Agreement provides,

> "*Suspension of Release by Customs Authorities*
>
> *Members shall, in conformity with the provisions set out below, adopt procedures*[13] *to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods*[14] *may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.*" (emphasis added)

Footnote 13 to Article 51 provides: "*It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.*"

Footnote 14 to Article 51 provides, in relevant part: ""*counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;...*"

Article 52 provides,

> "*Application*
>
> *Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder's intellectual property right and to supply*

a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action."

Article 51 is contained within Section 4 of Part III (Enforcement of Intellectual Property Rights) of the TRIPS Agreement, which is titled "Special Requirements Related to Border Measures". Article 51 requires WTO Members to adopt procedures allowing the suspension of release by Customs Authorities in cases of suspected importation of counterfeit trademarks or pirated copyright goods. The second sentence of Article 51 allows for an 'optional extension'[53] (evident from the use of the word 'may') to situations where goods infringe other categories of intellectual property rights, such as patents, subject to the condition that the requirements of Section 4 are met.[54] Footnote 13 to the first sentence of Article 51, clarifies that there is no *obligation* to apply border enforcement measures against goods in transit. Article 52 then imposes certain conditions that must be fulfilled by "any right holder initiating the procedures under Article 51."[55]

Drawing from the text of Articles 51 and 52, as well as the Panel report in *China – Intellectual Property Rights*, Members may apply border measures against goods in transit, provided that the requirements of Section 4 (including Article 52) are met.[56]

Article 52 requires that where right holders are initiating the procedures under Article 51, they must demonstrate a *prima facie* infringement of their intellectual property rights "under the laws of the country of importation." The issue thus hinges on the term "laws of the country of importation", and the question arises whether the 'country of importation' under Article 52 also includes the country of transit or only refers to the country of final destination.

The Versanian Customs Office seized, and subsequently destroyed, the vaccines in transit pursuant to Section 75 of the Versanian Customs Act, 2006. Section 75(3) of the Versanian Customs Act, 2006 provides, "*[a]ny goods against which action is taken pursuant to this section shall be deemed to have been imported into Versania*." Thus, it is clear that Versania considers itself to be the country of importation.

[53] Panel Report, *China – Intellectual Property Rights*, para 7.223.
[54] Article 51, TRIPS Agreement; Panel Report, *China – Intellectual Property Rights*, para 7.223.
[55] Article 52, TRIPS AGreement.
[56] Panel Report, *China – Intellectual Property Rights*, paras 7.223–7.224; *See* Seizing' Pharmaceuticals In Transit: B. Mercurio, "'Seizing' Pharmaceuticals in Transit: Analysing The WTO Dispute That Wasn't" International and Comparative Law Quarterly 61 (2012) 389–426 at 405.

The term 'country of importation' has not been defined in the TRIPS Agreement, or any other Covered Agreement of the WTO, nor has it been previously interpreted by any WTO Panels or Appellate Body.

On previous occasions however, the WTO Appellate Body has taken into account the dictionary meanings of words as a "useful starting point"[57] to interpret treaty terms, although warning that a mechanical application of the dictionary meaning is not conclusive.[58]

In accordance with the customary rules of interpretation, as enshrined in Articles 31 and 32 of the Vienna Convention (see Section 5.2.1), teams may thus seek to rely on the use of the word 'importation' in other provisions of the TRIPS Agreement as well as other Covered Agreements. They may interpret the 'country of importation' accordingly, in a manner consistent with the object and purpose of the treaty. The ambit of 'country' is not at issue here.[59] Such arguments for each party are examined below.

In the context of Article II:1 (b) of GATT, the Panel in *China – Auto Parts* held that "[t]he word "importation" can be defined as: the "bringing of goods into a country from another country";[60] the "action of importing or bringing in something, spec. goods from another country";[61] and "the act of bringing or causing any goods to be brought into a customs territory".[62]

Finally, a string of domestic and regional cases across different jurisdictions have dealt with the application of national intellectual property laws against goods in transit, and the question of when such goods in transit can be considered to be imported into the country. These cases are, of course, not directly relevant for WTO Panels, yet teams may potentially raise them. The question then remains about the persuasive value of domestic judgments before the WTO.

The ILC's Draft Conclusions on subsequent agreements and subsequent practice in relation to the interpretation of treaties[63] have clarified that judgments of domestic courts may constitute 'subsequent practice' under article 31(3)(b) of the Vienna Convention, but these judgments must

[57] Appellate Body Report, *US – Softwood Lumber IV*, para. 59. *See* also Appellate Body Reports, *US – Offset Act (Byrd Amendment)*, para. 248; and, *US – Gambling*, para. 166.
[58] Appellate Body, *EC-Chicken Cuts*, para. 175.
[59] *See* Explanatory Note to Marrakesh Agreement Establishing The World Trade Organization stating "[t] he terms "country" or "countries" as used in this Agreement and the Multilateral Trade Agreements are to be understood to include any separate customs territory Member of the WTO."
[60] Panel report, *China – Auto Parts*, para. 7.155 quoting Black's Law Dictionary, Seventh Edition, 1999, page 759.
[61] Panel report, *China – Auto Parts*, para. 7.155 quoting The Shorter Oxford English Dictionary, 2002 (5th edition), Volume 1, page 1331.
[62] Panel report, *China – Auto Parts*, para. 7.155 quoting WCO, Glossary of International Customs Terms, 2006, page 16.
[63] *See* Official Records of the General Assembly, Seventy-third Session, Supplement No. 10 (A/73/10) (available at: https://legal.un.org/ilc/reports/2018/english/a_73_10_advance.pdf (accessed 18 January 2023)).

relate to the application of the treaty.[64] (The Panel in *US — Origin Marking* relied on these Draft Conclusions of the ILC.[65]) Thus, in relying on any domestic judgments as 'subsequent practice', teams must be able to show that the judgment applies the provisions of the TRIPS Agreement. However, in the present case many of the municipal judgments relating to enforcement of intellectual property rights against goods in transit do not even mention the TRIPS Agreement,[66] and accordingly it will be difficult to show that they relate to the application of the TRIPS Agreement.

The Panel and Appellate Body in *EC-Chicken Cuts* considered whether judgments of a Member's municipal courts could theoretically be considered as supplementary means of interpretation under Article 32 of Vienna Convention. The Appellate Body held that "judgments of domestic courts are not, in principle, excluded from consideration as "circumstances of the conclusion" of a treaty if they would be of assistance in ascertaining the common intentions of the parties for purposes of interpretation under Article 32."[67] However, under Article 32 of Vienna Convention, "recourse may be had to supplementary means of interpretation" either to confirm the ordinary meaning, or were the meaning is "ambiguous or obscure...or leads to a result which is manifestly absurd or unreasonable."[68] Thus, teams must first carry out the interpretive exercise under Article 31, Vienna Convention before turning to domestic judgments as supplementary means of interpretation.

5.3.2 Arguments for Arion

Arion should argue that the 'country of importation' under Article 52 only refers to the country of final destination, i.e. Boutica, and accordingly, in seizing the vaccines pursuant to Section 75 of the Versanian Customs Act, Versania has acted in a manner inconsistent with Article 52 (and consequently Article 51).

In the context of Article II:1 (b) of GATT, the Panel in *China – Auto Parts* held that "[t]he word "importation" can be defined as: the "bringing of goods into a country from another country";[69] the "action of importing or bringing in something, spec. goods from another country";[70] and "the act of

[64] Official Records of the General Assembly, Seventy-third Session, Supplement No. 10 (A/73/10), p. 32, Commentary to Draft Conclusion 4, para. (18).
[65] Panel report, *US - Origin Marking*, para. 7.157.
[66] For instance, *Montex Holdings Ltd. v Diesel* SpA57 (C-281/05) and *Nokia Corporation v Her Majesty's Commissioners of Revenue & Customs*, [2009] EWHC 1903 (Ch) both do not mention the TRIPS Agreement. *Gramophone Company of India Ltd. vs. Birendra Bahadur Pandey and Ors*, AIR 1984 SC 66 predates the TRIPS Agreement.
[67] Appellate Body Report, *EC – Chicken Cuts*, para. 309.
[68] Article 32, Vienna Convention on Law of Treaties.
[69] Panel report, *China – Auto Parts*, para. 7.155 quoting Black's Law Dictionary, Seventh Edition, 1999, page 759.
[70] Panel report, *China – Auto Parts*, para. 7.155 quoting The Shorter Oxford English Dictionary, 2002 (5th edition), Volume 1, page 1331.

bringing or causing any goods to be brought into a customs territory".”[71] Arion could rely on these definitions as the ordinary meaning of the word “importation”.

Arion could further argue that such meaning is confirmed by Article 51 of TRIPS, in particular its footnote 13, which distinguishes between imports and goods in transit. This interpretation is also supported by provisions of other Covered Agreements. Article V of the GATT suggests that goods that are in transit cannot deem to be imported in the territory of the Member through which they are in transit. This follows from the definition of goods in transit in Article V:1 (see Section 6.2.1). Second, the structure of the Agreement on Trade Facilitation (‘TFA’) and in particular, the obligations enshrined in Articles 10 and 11 of TFA,[72] also suggest that there is a conceptual distinction between imported goods and goods in transit, which confirms that importation only happens when the goods are placed in the market of the final destination. Here, it is relevant to note that neither Arion, nor Versania nor Boutica are parties to the TFA. Arion would need to address this if using the TFA as context.

Arion can also argue that ’importation’ only occurs when goods are released for free circulation or placed on the market, and accordingly, Versania cannot constitute the ‘country of importation’. In this regard, Arion could refer to the judgment of the European Court of Justice (ECJ) in *Montex Holdings v Diesel*, where the ECJ held that there could be no infringement of intellectual property rights where the goods were in transit, and were not in free circulation in the European Union.[73] Thus, either release for free circulation, or being put on the market were necessary elements for application of intellectual property rights. Along similar lines, the decision of a UK Court in *Nokia Corporation v Her Majesty’s Commissioners of Revenue & Customs* also held that goods must necessarily be placed on the market in order for there to be an infringement of intellectual property rights.[74]

However, as discussed in Section 5.3.1, it may be difficult to show the relevance of a domestic court’s judgment before a WTO Panel. To constitute ‘subsequent practice’ under Article 31(3)(b) of the Vienna Convention, a municipal judgment must relate to the application of the treaty.[75] Both the

[71] Panel report, *China – Auto Parts*, para. 7.155 quoting WCO, Glossary of International Customs Terms, 2006, p. 16.
[72] Article 10 is titled ‘Formalities connected with Importation, Exportation and Transit’; Article 11.8 specifies that Members should not apply technical regulations and conformity assessment procedures under TBT to goods in transit. Article 11(7) provides that goods in transit should “not be subject to any customs charges nor unnecessary delays or restrictions until they conclude their transit at the point of destination within the Member's territory”. Article 11.4 provides “[e]ach Member shall accord to products which will be in transit through the territory of any other Member treatment no less favourable than that which would be accorded to such products if they were being transported from their place of origin to their destination without going through the territory of such other Member.”
[73] *Montex Holdings Ltd. v Diesel* SpA57 (C-281/05).
[74] *Nokia Corporation v Her Majesty’s Commissioners of Revenue & Customs*, [2009] EWHC 1903 (Ch) at 49.
[75] Official Records of the General Assembly, Seventy-third Session, Supplement No. 10 (A/73/10), p. 32, Commentary to Draft Conclusion 4, para. (18).

Montex case as well as the *Nokia* case do not make any reference to the TRIPS Agreement, and accordingly it would be difficult to claim that these cases relate to the application of the TRIPS Agreement. Teams may further argue that these judgments can be used as a supplementary means of interpretation, but under Article 32 of Vienna Convention teams may either use these judgments to confirm the ordinary meaning, or where the ordinary meaning is "ambiguous or obscure…or leads to a result which is manifestly absurd or unreasonable."[76]

Further, Arion can argue that application of intellectual property rights to goods in transit that were not being put on the market violates the principle of territoriality enshrined in Article 4bis.1 of the Paris Convention, and incorporated by reference into TRIPS Agreement Article 2.1. Since the vaccines were in transit, the production, consumption and economic effects of trade are limited to Arion and Boutica, the laws of Versania should be inapplicable, as their application would otherwise have extraterritorial effects, contrary to the territoriality principle.

Finally, in support of its argument, Arion can rely on Articles 7 and 8 of the TRIPS Agreement as relevant context, arguing that protection of public health, and balance of rights and obligations,[77] are key principles to keep in mind in interpreting the 'country of importation' under Article 52.

Based on the aforementioned grounds, Arion can argue that in seizing, and destroying COVID-19 vaccines in transit, Versania applied its own laws to goods in transit, which is in violation of Article 52 as Versania is not the country of importation. Accordingly, Versania violates Article 52, and consequently Article 51 of the TRIPS Agreement.

5.3.3 Arguments for Versania

Teams should not try to argue that the shipment of ANCOP's COVID-19 vaccines would be placed on the market in Versania, or that there was a danger of this happening, as there are no facts in the case to suggest this. Instead, Versania should argue that the country of transit is included within the ambit of 'country of importation' under Article 52.

Versania may rely on previous WTO jurisprudence to ascertain the ordinary meaning of 'importation'. The Panel in *China – Auto Parts,* in the context of Article II:1 (b) of GATT, relied on World Customs Organization ('WCO') Glossary and dictionary definitions to hold that the ordinary meaning of the word 'importation' implies the "bringing of goods into a country from

[76] Article 32, Vienna Convention on Law of Treaties.
[77] Article 7, TRIPS Agreement

another country";[78] the "action of importing or bringing in something, spec. goods from another country";[79] and "the act of bringing or causing any goods to be brought into a customs territory".[80]

From this definition, it could be argued that the mere act of goods crossing national borders is sufficient for an import to have taken place. This definition does not impose any requirement of placing goods on the market for such an act to be considered an 'import'. Accordingly, Versania as the country of transit would qualify as the 'country of importation'.

Versania may additionally choose to refer to other uses of the word 'import' under the TRIPS Agreement, so as to interpret the meaning of 'country of importation' under Article 52. Article 28(1)(a), dealing with patents, refers to using, offering for sale, selling, or importing. The inclusion of "importing" in this list, suggests that there is a difference between mere importation, and offering for sale or selling. Placing on the market is thus not necessary for importation to occur. Along similar lines, Article 44.1 allows for injunctions to be used to prevent the "entry into the channels of commerce of imported goods" that infringe IPR, alluding that the point of 'importation' has occurred already before the entry into channels of commerce. Thus, placing on the market or entry into channels of commerce are not necessary conditions for 'import' under the TRIPS Agreement. Accordingly, Versania can qualify as the 'country of importation.'

Versania can further support its interpretation with Article 16 of the Berne Convention (incorporated through reference into the TRIPS Agreement[81]) which clarifies that "[i]nfringing copies of a work shall be liable to seizure in any country of the Union where the work enjoys legal protection." [82] Thus, the provision does not limit such seizure only to placing on the market, rather it additionally applies this to seizures of products which have entered from countries even where "the work is not protected, or has ceased to be protected."[83]

Further, the TFA in Article 11.8 prohibits Members from applying technical regulations and conformity assessment procedures under the TBT Agreement to goods in transit. However, TFA does not include any such prohibition on TRIPS enforcement procedures to goods in transit.

To further support its argument, teams may refer to the judgment of the Indian Supreme Court in the *Gramophone* case where the word 'import' was held to mean "bringing into India from outside

[78] Panel report, *China – Auto Parts*, para. 7.155 quoting Black's Law Dictionary, Seventh Edition, 1999, page 759.
[79] Panel report, *China – Auto Parts*, para. 7.155 quoting The Shorter Oxford English Dictionary, 2002 (5th edition), Volume 1, page 1331.
[80] Panel report, *China – Auto Parts*, para. 7.155 quoting WCO, Glossary of International Customs Terms, 2006, page 16.
[81] Article 9.1, TRIPS Agreement; Panel Report, *China – Intellectual Property Rights*, para. 7.173 holding that "Article 9.1 incorporates Articles 1 through 21 of the Berne Convention (1971)".
[82] Article 16, Berne Convention.
[83] Article 16, Berne Convention.

India, that it is not limited to importation for commerce only but includes importation for transit across the country."[84] However, as discussed in Section 5.3.1, it may be difficult to show the relevance of a judgment of a domestic court before a WTO Panel. The Gramophone case cannot constitute 'subsequent practice' as it predates the TRIPS Agreement by more than a decade. The judgment can be used as a supplementary means of interpretation under Article 32 of Vienna Convention only to confirm the ordinary meaning of the provision, or if teams can show that the ordinary meaning is ambiguous or absurd.

5.3.4 Questions for teams

Questions for Arion	Questions for Versania
Under Article 51, in the context of exportation, the Panel in *Canada – Patent Term* held that border measures against export were not subject to the other articles under Section 4, because of the lack of any express words to that effect. Similarly, footnote 13 too does not contain any words to that effect either. Why then should footnote 13 still be subject to the conditions of Article 52? Answer: The Panel, in footnote 214, distinguished between footnote 13, and the optional extension provided for exports. Footnote 13 limits the scope of the obligation in the first sentence of Article 51 rather than providing for an optional extension, as in the case of exports.	If the mere act of crossing a border constitutes 'importation', what would constitute 'goods in transit', in a manner which still gives effect to the words of Article 51?
While in Versanian territory, why should the goods not be subject to Versanian law, consistent with the principle of territoriality of patents?	There is nothing in the facts to suggest that there was a threat of the goods entering your market? Why then would it be WTO consistent for you to impose your legal standards in an extra-territorial manner on goods in transit?
What is the legal and persuasive value of national and regional case law before a WTO Panel?	What is the legal and persuasive value of national and regional case law before a WTO Panel?
	In the midst of the COVID-19 pandemic, with global concerns about vaccine supply and

[84] *Gramophone Company of India Ltd. vs. Birendra Bahadur Pandey and Ors*, AIR 1984 SC 66, para. 39.

	inequity, how do you justify the destruction of the vaccines? Is the destruction not a disproportionate response?

6 WHETHER VERSANIA'S ACTIONS IN SEIZING THE VACCINES IN TRANSIT, VIOLATE ARTICLE V(2) OF THE GATT WHICH PROVIDES FOR FREEDOM OF TRANSIT THROUGH THE TERRITORY OF EACH WTO MEMBER?

6.1 KEY THEMES

The key themes to be addressed within this issue are:

- The scope of Article V:2 and Article V:3, in particular their relationship with each other.
  Article V:2 provides for freedom of transit. Article V:3 further prohibits any unnecessary delays or restrictions for traffic in transit "except in cases of failure to comply with applicable customs laws and regulations" (emphasis added). This issue focuses on whether the exception regarding "applicable customs laws and regulations" in Article V:3 extends to the obligation of granting freedom of transit under Article V:2. If yes, the issue then turns to whether customs enforcement of intellectual property rights can constitute action in furtherance of the 'applicable customs laws and regulations' of a Member taking such action.

- Whether vaccines hastily produced using another company's patented process constitute a danger to human health, and hence justify measures under Article XX(b).
  Arion passed its Executive Order allowing ANCOP to produce vaccines using Zanos' patented process only on 10 July, 2022. Within a month, Arion started manufacturing and exporting its vaccines. Given the timeline, a key issue is thus the safety of the vaccines, and whether Versania can destroy the vaccines in order to protect human health. This also hinges on the question of extra-territoriality, and whether the threat to health must be within the borders of the respondent state.

- Under Article XX(d) of GATT, whether a legislation that is allegedly consistent with the TRIPS Agreement should necessarily be deemed to be "*not inconsistent with the provisions of*" the GATT?
  For Versania's actions to be justified under Article XX(d), Versania must not only be able to show that its actions were necessary to secure compliance with the Versanian Code on Intellectual Property, but also that the Code is "not inconsistent with the provisions of" the GATT. Thus, one key question is whether a legislation that is allegedly consistent with the TRIPS Agreement (as argued by Versania in Issue 1, see Sections 5.2.3 and 5.3.3) is also

necessarily consistent with the GATT. Conversely, if the legislation in its application is considered to be violative of the TRIPS Agreement, can it still be consistent with the GATT?

6.2 LEGAL PROVISIONS AND JURISPRUDENCE

6.2.1 Article V, GATT

Article V of GATT provides for freedom of transit, and reads as follows,

> "1. *Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article "traffic in transit".*
>
> *2. There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.*
>
> *3. Any contracting party may require that traffic in transit through its territory be entered at the proper custom house, but, except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions...*" (emphasis added)

The Panel in *Colombia – Ports of Entry* clarified that Article V:1 provides context to and informs the scope of the substantive obligations found in Article V:2.[85] Thus, drawing from paragraph 1 of Article V, all goods where passage across the territory of a Member is only a portion of a complete journey beginning and terminating beyond the frontier of the Member across whose territory the traffic passes, must be deemed to be 'traffic in transit'.

The first sentence of Article V:2 of GATT is the most significant here. In this context, the Panel in *Russia – Traffic in Transit* held, "to establish inconsistency with the first sentence of Article V:2, it will consequently be sufficient to demonstrate either that a Member has precluded transit through its territory for traffic in transit entering its territory from any other Member, or exiting its territory to any other Member, via the routes most convenient for international transit".[86]

[85] Panel Report, *Colombia – Ports of Entry*, para. 7.396.
[86] Panel Report, *Russia – Traffic in Transit*, para. 7.173.

In *Colombia – Ports of Entry*, the Panel clarified that "Article V:2, first sentence requires extending unrestricted access via the most convenient routes for the passage of goods in international transit whether or not the goods have been trans-shipped, warehoused, break-bulked, or have changed modes of transport. Accordingly, goods in international transit from any Member must be allowed entry whenever destined for the territory of a third country."[87]

The second sentence of Article V:2 of GATT contains a most-favoured nation (MFN) obligation which "is closely related to the obligation to extend freedom of transit, in the first sentence."[88] In *Colombia – Ports of Entry*, the Panel considered that "the second sentence complements and expands upon the obligation to extend freedom of transit, stating additionally that distinctions must not be made based on the nationality, or place of origin, departure, entry, exit or destination of the vessel transporting goods."[89] Thus, the "second sentence requires that goods from all Members must be ensured an identical level of access and equal conditions when proceeding in international transit."[90]

Article V:3 of GATT further prohibits 'unnecessary delays or restrictions' on traffic in transit, except in cases where applicable customs laws and regulations are not complied with.[91] There is no relevant case law on the interpretation or application of Article V:3.

6.2.2 Article XX

Respondents may argue that the measure is justified under Article XX(b) or XX(d) of GATT.

Article XX provides in relevant part:

> "*General Exceptions*
> *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:*
> ...
> *(b) necessary to protect human, animal or plant life or health;*
> ...
> *(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;*"

[87] Panel Report, *Colombia – Ports of Entry*, para 7.401.
[88] Panel Report, *Colombia – Ports of Entry*, para 7.396.
[89] Panel Report, *Colombia – Ports of Entry*, para 7.396.
[90] Panel Report, *Colombia – Ports of Entry*, para 7.402.
[91] Article V:3, GATT.

In order to benefit from the justifying protection of Article XX, a measure must *first* be provisionally justified under one of the sub-paragraphs (a)-(j), and *second*, it must satisfy the conditions of the introductory paragraph (chapeau) of Article XX.[92]

Based on the facts of the case, the most relevant sub-paragraphs are XX(b) and XX(d) of GATT. Theoretically, Versania may choose to bring arguments under Article XX(a), however the facts do not support a strong argument under XX(a). Accordingly, this memorandum focuses on Articles XX(b) and XX(d).

6.2.2.1 Article XX(b)

In order to be provisionally justified under Article XX(b), a measure must be *first* 'designed' to and *second* 'necessary' to protect human, animal or plant life or health.[93] To examine whether a measure is 'taken to' or 'designed to' protect human life or health, panels have, in the past, considered, "(i) whether there was evidence of the existence of the risk to human life or health (health risk) that the measure aimed to reduce; and (ii) if the alleged health risk was found to exist, whether the measure was taken for the purpose of protecting human life or health by reducing that risk, or was instead taken for other reasons."[94] In this examination, a panel must examine all the evidence before it, including "the text of the relevant legal instruments, the legislative history, and other evidence regarding the design, structure and expected operation of the challenged measure."[95] The burden of proof is upon the Member invoking the justification.[96]

If a measure is indeed 'designed to' protect human, animal or plant life or health, a panel then turns to an analysis whether the measure is also 'necessary' to do so. The Appellate Body in *Brazil – Retreaded Tyres* clarified that determining the necessity of the measure requires a 'weighing and balancing' of several factors, including (i) the importance of the objective, (ii) the contribution of the measure to its objective; and (iii) the trade-restrictiveness of the measure.[97] Next, the challenged measure should be compared to potentially less trade-restrictive and equivalent alternative measures. The burden lies on complaining Member to identify possible alternative measures. [98] An alternative measure must be more than "merely theoretical in nature".[99] It should not only allow the respondent

[92] Appellate Body Report, *US – Gasoline*, p. 22.
[93] Panel Reports, *China – Raw Materials*, paras. 7.379-7.380 and *EC- Tariff Preferences*, paras. 7.198-7.199.
[94] Award of the Arbitrators, *Turkey - Pharmaceutical Products*, para 6.76 quoting Panel Report, T*urkey – Pharmaceuticals Products*, 7.134-7.135 and 7.165 et seq.; Panel Report, *EC – Asbestos*, para. 8.170; Appellate Body Reports, *EC – Seal Products*, para. 5.197.
[95] Panel Report, *Turkey – Pharmaceutical Products*, 7.181; Appellate Body Reports, J*apan – Alcoholic Beverages II*, p. 29; *Argentina – Textiles and Apparel*, para. 55; and *US – Shrimp*, para. 137
[96] Panel Report, *US – Gasoline*, para. 6.20.
[97] Appellate Body Report, *Brazil – Retreaded Tyres*, para. 156
[98] *Ibid.*
[99] *Ibid.*

Member to achieve the same level of protection while being less trade-restrictive,[100] but must also be reasonably available to the respondent state, including in terms of cost.[101]

The process of weighing and balancing these factors is "a holistic operation that involves putting all the variables of the equation together and evaluating them in relation to each other after having examined them individually, in order to reach an overall judgment"[102]

6.2.2.2 Article XX(d)

In order to be provisionally justified under sub-paragraph (d), a measure must, *first*, be one designed to secure compliance with laws or regulations that are not themselves inconsistent with some provision of the GATT 1994; and, *second*, the measure must be 'necessary' to secure such compliance."[103]

An analysis of the first element thus requires the state invoking the justification to demonstrate (i) the existence of 'laws or regulations'; (ii) such 'laws or regulations' must not be inconsistent with GATT 1994; and (iii) the measure sought to be justified must be designed 'to secure compliance' with such 'laws or regulations'. [104]

The analysis thus involves an "initial, threshold examination of the relationship between the challenged measure and the 'laws or regulations' that are not GATT-inconsistent so as to determine whether the former is designed to secure compliance with specific requirements of the 'laws or regulations.'"[105] The Appellate Body has clarified that this test is "not ... particularly demanding"[106] as compared to the necessity test – the relevant standard is that an assessment of the design of the measure should reveal that "the measure is *not incapable* of securing compliance with the relevant laws and regulations."[107]

The legal test for the necessity analysis in Article XX(d) has been clarified by the Appellate Body in several cases, including *Korea – Various Measures on Beef*,[108] and is substantially the same[109] as in Article XX(b) (see Section 6.2.2.1). The Appellate Body in *Korea – Various Measures on Beef* has further held in the context of Article XX(d) that the term 'necessary' refers to a "range of degrees of

[100] *Ibid*; Appellate Body Report, *US – Gambling*, paras. 307-308.
[101] Appellate Body Report, *Brazil – Retreaded Tyres*, para. 156; Panel Report, *Turkey – Pharmaceutical Products*, 7.136.
[102] Panel Report, *Turkey – Pharmaceutical Products*, para. 7.137; Appellate Body Report, *Brazil – Retreaded Tyres*, para. 182.
[103] Appellate Body Report, *Korea – Various Measures on Beef,* para. 157.
[104] Appellate Body Report, *India – Solar Cells*, para. 5.58.
[105] Appellate Body Report, *India – Solar Cells*, para. 5.58.
[106] Appellate Body Report, *Colombia – Textiles*, para. 5.70; Panel Report, *Indonesia – Chicken*, para 7.248.
[107] Panel Report, *Indonesia – Chicken*, para 7.248 quoting Appellate Body Report, *Colombia – Textiles*, para. 5.68.
[108] *See* Appellate Body Report, *Korea – Various Measures on Beef*, paras. 152-185.
[109] Appellate Body Report, *China – Publications and Audiovisual Products*, para. 242.

necessity. At one end of this continuum lies 'necessary' understood as 'indispensable'; at the other end, is 'necessary' taken to mean as 'making a contribution to'."[110] The Appellate Body clarified that the meaning of 'necessary' here lies closer to 'indispensable' rather than 'making a contribution to.'[111]

In *Turkey – Pharmaceutical Products*, the Panel considered Turkey's argument under Article XX(d) to be substantially the same as its argument under Article XX(b) – while Turkey attempted to justify its measure under XX(b) on the grounds that it was necessary to ensure access to medicines, under XX(d) it argued that it was necessary to secure compliance with laws requiring Turkey to ensure access to healthcare. Due to this overlap, the Panel applied its assessment (about whether the measure was 'designed to' protect human health) under XX(b) *mutatis mutandis* to XX(d).[112] The award of the arbitrators under Article 25 DSU acknowledged that while it would have been more prudent for the Panel to follow the complete order of analysis, including identifying the specific legal instruments identified by Turkey as a relevant law or regulation as a first step, it did not consider this to be a legal error. It held that the requirements of Article XX(d) are cumulative in nature, and the Panel's analysis was enough to conclude that the measure could not be justified under Article XX(d).[113]

6.2.2.3 Chapeau

Finally, to be justified under Article XX, a measure must also meet the requirements of the chapeau, that is, it must not be applied in a manner that constitutes "arbitrary or unjustifiable discrimination between countries where the same conditions prevail" or act as a "disguised restriction on international trade."[114] The chapeau thus relates to the manner in which that measure is applied.[115]

The analysis must be done on a case-by-case basis[116] and focuses on how the measure is applied. The question of arbitrary or unjustifiable discrimination generally focuses on "whether the discrimination can be reconciled with, or is rationally related to, the policy objective with respect to which the measure has been provisionally justified".[117]

There can be some overlap between 'arbitrary or unjustifiable discrimination' and a 'disguised restriction on international trade'.[118] With respect to the latter, the Panel in *EC-Asbestos* held that it

[110] Appellate Body Report, *Korea – Various Measures on Beef*, paras. 161.
[111] *Ibid.*
[112] Panel Report, *Turkey – Pharmaceutical Products*, paras. 7.217-7.218.
[113] Award of the Arbitrators, *Turkey – Pharmaceutical Products*, paras. 6.160, 6.168.
[114] Article XX, GATT.
[115] Appellate Body Report, *US- Gasoline*, p.20.
[116] Panel Report, *Brazil – Retreaded Tyres*, para. 7.262; Appellate Body Report, *EC – Seal Products*, para. 5.321.
[117] Appellate Body Report, *Brazil – Retreaded Tyres*, para. 230
[118] Appellate Body Report, *US-Gasoline*, p. 23.

entails a measure that can otherwise be provisionally justified under one of the paragraphs of Article XX, but is in fact "a disguise to conceal the pursuit of trade restrictive objects." [119]

6.3 ARGUMENTS FOR ARION

6.3.1 Violation of Article V of GATT

Arion can argue that the shipment of COVID-19 vaccines in question can clearly be held to be 'traffic in transit' under the ambit of Article V, as they were to be transported from Arion to Boutica, with the passage across Versania only being a portion of the complete journey.[120] Thus, Article V:2 is applicable, and provides for freedom of transit via the most convenient routes for international transit.[121]

The strongest argument will be under the first sentence of Article V:2, which provides for freedom of transit "via the routes most convenient".[122] Given Arion and Boutica's geographical location, and the large volumes of doses to be exported, transit through Versania was the most convenient and only economically feasible option.[123] The seizure and destruction of vaccines is a clear violation of the freedom of transit available to Arion. Not only does it directly interfere with the transit of ANCOP's vaccines in the present case, it also creates a deterrent effect on other exporters in the future, thereby also harming potential trade.

Arion may also make an additional argument claiming a violation of the MFN obligation enshrined in Article V:2, second sentence. Arion could argue that the vaccines in question were seized based on 'the ownership of goods' and their 'place of origin', contrary to the requirements of Article V:2, second sentence. No other countries' goods have been seized or destroyed on grounds of IP infringement.[124] In *Colombia – Ports of Entry*, since only goods arriving from Panama or the CFZ were subject to specific requirements of Colombian legislation, the Panel held that the Colombian legislation "makes distinctions based on the place of origin" and was thus in violation of Article V:2, second sentence.[125] However, this may be a difficult argument for Arion, as in *Colombia – Ports of Entry*, the relevant legislation itself had specific reference to Panama, thereby making a *de jure* distinction on the basis of origin. In the present case, arguably the vaccines have been seized on grounds of IP infringement, and not because they were from Arion specifically. The clarifications provide that there were no other vaccines produced with the process patented by Zanos transiting

[119] Panel Report, *EC-Asbestos*, para. 8.236.
[120] Article V:1, GATT.
[121] Panel Report, *Colombia – Ports of Entry*, para 7.401.
[122] Article V:2, GATT.
[123] Case, Annex I, para. 12.
[124] Clarification Questions, Part II, Ans. 21 [p.5]; Part VI, Ans.11 [p.8].
[125] Panel Report, *Colombia – Ports of Entry*, paras. 7.429-430.

through Versania other than the ones produced by ANCOP.[126] Teams should thus not be penalised for instead choosing to focus on arguments under Article V:2, first sentence.

Further, in response to Versania's argument that its interference with freedom of transit under Article V:2 is only due to "failure to comply with applicable customs laws and regulations" under Article V:3 (see Section 6.4.1), Arion can put forward several counter-arguments (either preemptively, or in rebuttals). *First*, Arion should argue that Article V:3 is in the nature of an additional obligation to Article V:2, in that it prohibits 'unnecessary delays or restrictions' on traffic in transit, except in cases where applicable customs laws and regulations are not complied with.[127] There is nothing in the text of Article V to suggest that 'applicable customs laws and regulations' in Article V:3 function as an exception to the obligation under Article V:2 to ensure freedom of transit. *Second*, Arion can point out that the seizures are carried out as a result of alleged inconsistency with the Versanian Code on Intellectual Property Protection, and were carried out by the Customs Office only pursuant to the decision of the Intellectual Property Board.[128] Section 75 of the Customs Act, under which the seizure was carried out, itself refers to the Versanian Code on Intellectual Property Protection.[129] Thus, arguably, the seizure is not a result of failure to comply with applicable customs laws and regulations under Article V:3, but rather a result of an infringement of an IP statute. *Third*, Arion can argue that the seizures are in any case, an "unnecessary...restriction" under Article V:3. Although the term 'unnecessary delays or restrictions" has not been interpreted by panels or the Appellate Body in the context of Article V:3, reference may be had to the interpretation of 'necessary' in the sub-paragraphs of Article XX GATT.

6.3.2 No justification under Article XX of GATT

Arion should also show (either preemptively or in rebuttals) that Versania cannot justify its measures under Article XX(b) or (d).

If Arion choses to put forth arguments pursuant to Article XX(b), it can argue that there is no threat to public health as a result of its export of COVID-19 vaccines. In fact, ANCOP's supply of COVID-19 vaccines is instead beneficial for public health as it helps eliminate the risk of asymptomatic and mildly symptomatic COVID-19 cases.[130] There is nothing in the facts to demonstrate any identified risk accruing to ANCOP's vaccines. Arion should emphasize that it would be a dangerous precedent to treat legitimate vaccines produced under the MC12 Decision as sub-standard and falsified medicines.

[126] Clarification Questions Part II, Ans.4 [p.2].
[127] Article V:3, GATT.
[128] Case, para. 14.
[129] Case, Annex II, Section 73, Versania Customs Act.
[130] Case, para 7.

Under Article XX(d), Arion could argue that Versanian actions were not 'necessary' to secure compliance with the Versanian Code on Intellectual Property Protection. First, there is nothing in the facts to show that there was any risk of the vaccines being diverted into the Versanian market. Second, and in any event, instead of ordering the destruction of the vaccines, the Intellectual Property Board could have authorized the Customs Office to return the shipment to the exporter.

Arion may choose to argue that even if the measures could be justified under one of the sub-paragraphs of Article XX, they do not meet the requirements of the chapeau as they constitute a 'disguised restriction on international trade'. To make this argument, Arion may rely on its arguments under Article 41.1 that Versanian actions created a barrier to legitimate trade (see Section 5.2.2).

6.4 ARGUMENTS FOR VERSANIA

6.4.1 Consistency with Article V of GATT

Versania can argue that the interference with freedom of transit under Article V:2 of GATT is only due to a "failure to comply with applicable customs laws and regulations" under Article V:3. To make this argument, Versania will have to demonstrate that Article V:3 of GATT provides relevant context in interpreting Article V:2 (as per Article 31(2) of the Vienna Convention), and that the provisions of Article V:3 should be taken into account in interpreting Article V:2. This argument is further strengthened by the fact that without such an interpretation there would be an absurd situation where necessary restrictions "in cases of failure to comply with applicable customs laws and regulations" would be permitted by Article V:3, but nonetheless violate Article V:2. This would fail to give effect to the wording of Article V:3 and thus violate the principle of effective treaty interpretation[131]. The seizure and destruction of goods was carried out by the Versanian Customs Authorities, under the power granted to them by Section 75 of the Versanian Customs Act.[132] Thus, the seizure could be considered to be a result of non-compliance with the Customs Act, and is thus justified under Article V:3.

However, it may be difficult for Versania to show that this indeed constitutes an application of its 'customs laws and regulations'. The facts show that this was a case of border enforcement of *intellectual property rights* by customs authorities, rather than application of 'customs laws and regulations.' As Arion should argue, the seizure was carried out by the Customs Office pursuant to the decision by the Intellectual Property Board, and Section 75 of the Versanian Customs Act itself refers to the Versanian Code on Intellectual Property Protection.

[131] See Appellate Body Report, *US – Gasoline*, page. 23.
[132] Case, Annex II, Section 73, Versania Customs Act.

Under Article V:3, Versania will also have to show that the seizures are not an 'unnecessary' restriction as Article V:3 prohibits 'unnecessary restrictions or delays'. For this, reference can be made to the interpretation of 'necessary' under Article XX(b) or (d) (see Sections 6.2.2.1, 6.2.2.2 and 6.4.2).

6.4.2 Justification under Article XX of GATT

In the alternative, Versania may instead concede the violation of Article V:2 and V:3 and in the first instance justify its measures under Article XX(b), or alternatively, Article XX(d) of the GATT.

Under Article XX(d), Versania could argue that its actions in seizing and destroying the shipment of patent-infringing COVID-19 vaccines was necessary to comply with Sections 48, 54 and 61(1) of the Versanian Code on Intellectual Property Protection. Article XX(d) explicitly mentions both customs enforcement as well as protection of patents as examples of laws or regulations which could fall under the ambit of Article XX(d). The Appellate Body has clarified that the term "laws or regulations" in Article XX(d) refers to "rules that form part of the domestic legal system of a WTO Member".[133]

To demonstrate that the identified provisions of Versanian Code on Intellectual Property Protection are not inconsistent with GATT, Versania may rely on its arguments under Issue 1 (see Sections 5.2.3 and 5.3.3 where Versania argued that its *application* of the Versanian Code on Intellectual Property was consistent with TRIPS Agreement). Since the WTO Agreement, including all its annexes, is a 'single undertaking' which must be harmoniously interpreted to give meaning and effect to all provisions across all Covered Agreements,[134] Versania can argue that a law which is consistent with TRIPS Agreement, should also be considered to be GATT- consistent.

Finally, to demonstrate 'necessity' under Article XX(d), Versania can demonstrate that the protection of patent rights, and preventing diversion of patent-infringing rights are of utmost importance (and refer to the text of XX(d) on this point). The Appellate Body in *Korea - Various Measures on Beef* held that the weighing and balancing test to determine 'necessity' should take into account the relative importance of the objective sought to be protected, and that "[t]he more vital or important those common interests or values are, the easier it would be to accept as 'necessary' a measure designed as an enforcement instrument."[135] Versania can argue that the destruction of patent-infringing vaccines was the only way to enforce its citizens' patent rights against goods in

[133] Appellate Body Report, *Mexico – Taxes on Soft Drinks*, para. 69.
[134] Article II:2, Marrakesh Agreement Establishing the World Trade Organization; Appellate Body Report, *Korea – Dairy*, para. 74 quoting Panel Report, *Korea – Dairy*, para. 7.38; Appellate Body Report, *Brazil – Desiccated Coconut*, page 12.
[135] Appellate Body Report, *Korea - Various Measures on Beef*, para. 162.

transit (as required by the Versanian Code on Intellectual Property Protection) and to definitively prevent diversion of the vaccines into its market.

In the alternative, under Article XX(b), a creative line of argumentation can be that Versania needed to protect its pharmaceutical company's intellectual property rights, as failing to do so would disincentivize Zanos as well as other pharmaceutical companies from undertaking research and development of novel vaccines in the future, which would be harmful for public health in Versania as well as outside. The Panel in *Turkey - Pharmaceutical Products* accepted the objective of ensuring access to pharmaceutical products as falling within the ambit of Article XX(b).[136] Furthermore, the parties to that case had also agreed that in the context of Article XX(b), Member States can "take measures to address the risk of future shortages of supplies before such shortages actually arise."[137] Based on this, (although it may seem counter-intuitive at first glance) Versania can argue that the destruction of patent-infringing vaccines in the present is necessary to ensure access to vaccines in the future. Versania can show that its measures were 'necessary' to prevent Zanos and other pharmaceutical companies from being disincentivized to develop novel vaccines in the future, and thus prevent risk of future shortages of vaccines and other pharmaceuticals in the future. This offers a good way out of the condition of territoriality required under Article XX(b) - that the threat to human health must be within the jurisdiction of the respondent state.[138]

Another argument under Article XX(b) could be that vaccines, being highly complex products, are significantly more difficult to develop, and almost impossible to reverse-engineer as compared to generic small molecular drugs that Arion's pharmaceutical industry traditionally has expertise in. Thus, ANCOP's rapid development of vaccines- within only a month of the Executive Order authorizing use of Zanos' patented process- caused alarm about the quality of the vaccines, and thereby posed a threat to human health in both Arion and Boutica. However, this argument is difficult to argue, as the measure seeks to protect human health outside Versanian territory (in Arion and Boutica). There is nothing in the facts to suggest that there was any risk of the vaccines being diverted into, or placed on the market of Versania.

Finally, Versania will also have to demonstrate that the requirements of the chapeau of Article XX are met. To do so, Versania can show that it did not discriminate between the products from Arion and any other products, as there were no other vaccines produced with the process patented by Zanos transiting through Versania other than the ones produced by ANCOP.[139] Versania can further argue that the seizure and the destruction of the vaccines was 'rationally related' to the

[136] Panel Report, *Turkey – Pharmaceutical Products*, paras. 7.158-159.
[137] Panel Report, *Turkey – Pharmaceutical Products*, para. 7.162.
[138] GATT Panel, *United States – Restrictions on Imports of Tuna (Mexico)*, para. 5.26 [unadopted Panel report].
[139] Clarification Questions, Part I, Ans. 4 [p.2].

objectives it aims to pursue (either under XX(b) or XX(d)), and thus the measure was not applied in a manner "to conceal the pursuit of trade restrictive objects."[140]

6.5 QUESTIONS FOR TEAMS

Questions for Arion	Questions for Versania
	If respondent attempts to argue that the seizures were justified under GATT V:3 as an application applicable customs laws and regulations: What is the scope of GATT Articles V:2 and V:3? Do you suggest Article V:3 is an exception to Article V:2? If yes, why?
Since Article V:3 allows Member states to put some restrictions on transit for failure to comply with applicable customs law. This seizure was carried out under the power given to the Customs Authorities by Section 75 of the Customs Act, should it not be considered a valid application of customs law?	*If respondent attempts to argue that the seizures were justified under GATT V:3 as an application applicable customs laws and regulations:* How can the destruction of IP-infringing goods be considered an issue of compliance with customs regulations? Even though the seizure was carried out by the Customs Authorities, they were acting pursuant to the decision of the Intellectual Property Board. Section 75 of the Customs Act also refers to the Code on Intellectual Property Protection. Is this thus not better characterized as an IP measure?
What is the relationship between GATT Article V and TRIPS Article 51 and 52? If a good is imported under Article 52, can it simultaneously be 'in transit' under GATT Article V?	What is the relationship between GATT Article V and TRIPS Article 51 and 52? If a good is imported under Article 52, can it simultaneously be 'in transit' under GATT Article V?
What is the relationship between TRIPS and GATT? If the seizure is considered to be consistent with TRIPS, how can it be inconsistent with GATT?	What is the relationship between TRIPS and GATT? If the seizure is considered to be inconsistent with TRIPS, how can it be consistent with GATT?

[140] Panel Report, *EC-Asbestos*, para. 8.236.

Given the haste with which ANCOP developed its vaccine, concerns about poor quality are legitimate, and pose a serious threat to public health. Do you not agree that Versania is justified in its actions?	Were there any legitimate concerns about the vaccines affecting public health in your territory? If not, how does Article XX(b) also provide a justification for measures such as yours, which aim to protect public health outside your borders?
	How is this measure 'necessary' to protect public health? Even if there were concerns about poor quality vaccines being sent to Boutica, would it not have been better to inform the Boutican authorities, and let them take the decision?

7 WHETHER VERSANIA, BY ALLEGEDLY 'IMPORTING' THE VACCINES IN TRANSIT VIOLATES ITS OBLIGATIONS UNDER PARAGRAPH 3(C) OF THE MC12 DECISION?

7.1 KEY THEMES

The key themes to be addressed within this issue are:

- Whether the MC 12 Decision, and in particular its paragraph 3(c), can be the basis of a claim?

The preliminary question on this issue is whether the MC12 decision can be used by a complainant as the basis of a claim that a respondent state has not fulfilled an obligation, or whether the MC12 Decision - arguably only meant as a waiver from existing obligations - can only be used as a defence. This depends upon the legal characterization of the MC12 Decision, based upon the wording of its provisions, in particular here, paragraph 3(c).

- Whether, by 'importing' COVID-19 vaccines in transit into its territory as per Section 75(3) of the Versanian Customs Act, Versania diverts the vaccines into its territory, in violation of second sentence of paragraph 3(c) of the MC12 Decision?

To the extent that the complainant can demonstrate that paragraph 3(c) of the MC12 Decision can be the basis of a claim, the question then arises if the seizures of the vaccines in transit, coupled with Section 75(3) of the Versanian Customs Act, under which the vaccines in question are "deemed to have been imported into Versania"[141] violate paragraph 3(c) of the MC12 Decision. Paragraph 3(c) of the MC12 Decision requires Member States to "ensure the availability of effective legal means to

[141] *See* Clarification Questions, General Clarification, Section 75(3), Versanian Customs Act, 2006 [p.1].

prevent the importation into…their territories of products manufactured under the authorization in accordance with this Decision".

7.2 RELEVANT LEGAL PROVISIONS AND JURISPRUDENCE

The MC12 Decision provides in relevant part as follows:

> "*Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization*
>
> *Noting the exceptional circumstances of the COVID-19 pandemic;*
>
> …
>
> *1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.*
>
> …
>
> *3. Members agree on the following clarifications and waiver for eligible Members to authorize the use of the subject matter of a patent in accordance with paragraphs 1 and 2:*
>
> …
>
> *(c) Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories under this Decision. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.*" (Emphasis added)

As mentioned previously, the preliminary question would be what the legal nature of the MC12 Decision is, in particular whether it can be the basis of a claim. The text of the MC12 Decision specifies that it has been taken with regard to Article IX:1, IX:3 and IX:4 of the Marrakesh Agreement Establishing the World Trade Organization.[142]

[142] MC12 Decision, Preamble, para. 1.

Article IX:3 of the Marrakesh Agreement allows the Ministerial Conference, "in exceptional circumstances", to "waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements..."[143]

The Appellate Body, in *EC-Bananas III (Article 21.5)* has clarified the scope of a waiver under Article IX:3 of the Marrakesh Agreement, stating that, "the function of a waiver is to relieve a Member, for a specified period of time, from a particular obligation provided for in the covered agreements ... Its purpose is not to modify existing provisions in the agreements, let alone create new law or add to or amend the obligations under a covered agreement..."[144] In the same case, the Appellate Body also reversed a finding by the Panel that the waiver in question qualified as a "subsequent agreement" under Article 31(3)(a) of the Vienna Convention. The Appellate Body held that "multilateral interpretations adopted pursuant to Article IX:2 of the WTO Agreement is most akin to subsequent agreements within the meaning of Article 31(3)(a) of the Vienna Convention, but not waivers adopted pursuant to Articles IX:3 and 4 of the WTO Agreement."[145]

The MC12 Decision, passed in the backdrop of the COVID-19 pandemic, allows Member States to limit patent rights "by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines".[146] Accordingly, it clarifies and waives certain requirements of Article 31. However, further paragraph 1 specifies that this is allowed "to the extent necessary to address the COVID-19 pandemic."[147]

The Decision allows for products manufactured in accordance with the Decision to be exported into other 'eligible Members'. It also contains anti-diversion provisions, and requires all Members (and not just 'eligible Members') to ensure that effective legal means are available to prevent the importation into their territories of products manufactured in accordance with the Decision. To do so, Members shall use "the means already required to be available under the TRIPS Agreement."

7.3 Arguments for Arion

In order to successfully argue this issue, Arion must first be able to demonstrate that the MC12 Decision, in particular its paragraph 3(c) can be a valid basis for a claim. This is tricky, given the

[143] Article IX:3, Marrakesh Agreement Establishing the World Trade Organization.
[144] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 382 (emphasis added).
[145] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 390
[146] MC12 Decison, para. 1
[147] *Ibid.*

Appellate Body's characterization of waivers under Article IX:3 of the Marrakesh Agreement as limited, and not adding new obligations.

To make its argument, Arion's best recourse would be to characterize the MC12 Decision as a 'subsequent agreement' on the application of treaty provisions under Article 31(3)(a) of the Vienna Convention. To do so, Arion would have to argue against the Appellate Body's decision, and instead rely on the reasoning of the Panel in *EC-Bananas III (Article 21.5).* Arion's claim is further supported by the language of paragraph 3 of the Decision which states, "[m]embers agree on the following clarifications and waiver", bolstering the argument that the MC12 Decision is more than just a waiver, instead also creates positive obligations.

The Appellate Body in *US – Clove Cigarettes* has previously held the Doha Ministerial Decision to be a 'subsequent agreement', stating that "[b]ased on the text of Article 31(3)(a) of the Vienna Convention, we consider that a decision adopted by Members may qualify as a 'subsequent agreement between the parties' regarding the interpretation of a covered agreement or the application of its provisions if: (i) the decision is, in a temporal sense, adopted subsequent to the relevant covered agreement; and (ii) the terms and content of the decision express an agreement between Members on the interpretation or application of a provision of WTO law."[148] The Appellate Body further clarified that the "term "agreement" in Article 31(3)(a) of the Vienna Convention refers, fundamentally, to substance rather than to form."[149] It relied on the phrase ""shall be understood to mean" in paragraph 5.2 of the Doha Ministerial Decision which, in its opinion, "clearly expresses a common understanding, and an acceptance of that understanding among Members", and "is not merely hortatory".[150]

Similarly, Arion can argue that the MC12 Decision is a 'subsequent agreement' relating to the application of Article 28.1 and Article 31 of the TRIPS Agreement. It was adopted by consensus on 17 June 2022, subsequent to the relevant Covered Agreement – the TRIPS Agreement.[151] The language of paragraph 3(c), "Members shall ensure the availability of effective legal means to prevent the importation into ... their territories of products manufactured under the authorization in accordance with this Decision" expresses a clear understanding between WTO Members to create a new obligation through the MC12 Decision. The text specifies that this new obligation to prevent importation accrues on *all* Members, and not just 'eligible Members' under the decision. Arion can thus argue that the MC12 Decision acts as a 'subsequent agreement' relating to the application

[148] Appellate Body Report, *US - Clove Cigarettes*, para 262 (original emphasis).
[149] Appellate Body Report, *US - Clove Cigarettes*, para 267.
[150] *Ibid.*
[151] *See* Appellate Body Report, *US - Clove Cigarettes*, para 263.

(rather than the interpretation) of Articles 28.1 and 31 of the TRIPS Agreement, and creates a new obligation for WTO Members.

Arion can then argue that the actions of the Versanian Customs Office in seizing COVID-19 vaccines produced under the MC12 Decision, read with Section 75 (3) of the Versanian Customs Act, 2006 ("*Any goods against which action is taken pursuant to this section shall be deemed to have been imported into Versania*") leads to a violation of the obligation under paragraph 3(c) of the MC12 Decision. The second sentence of paragraph 3(c) requires Member States to "ensure the availability of effective legal means to prevent the importation into" their territories of products manufactured under the Decision. As per Section 73(3) of Versania Customs Act, the vaccines in question are deemed to be imported into Versania.

The seizure and destruction of vaccines clearly shows that Versania did not make available effective legal means to prevent the importation into its territory of COVID-19 vaccines produced in accordance with the MC12 Decision. The Versanian Customs Authority was able, on the application of Zanos to the Intellectual Property Board, to divert COVID-19 vaccines into its own territory. In the hearing before the Intellectual Property Board, ANCOP presented its submissions that its vaccines were produced in accordance with the MC12 Decision. However, the Intellectual Property Board did not accept this claim.[152] Thus, the application of Section 75(3), Versania Customs Act to ANCOP's vaccines violates paragraph 3(c) of the MC12 Decision.

Further, the second sentence of paragraph 3(c) requires Members States to "ensure the availability of effective legal means to prevent the importation into, and sale in, their territories", thus showing that mere importation (as Section 75(3) of Versanian Customs Act deems the present case to be) is sufficient to trigger a violation of paragraph 3(c), even where the vaccines are not then sold in Versanian territory.

7.4 ARGUMENTS FOR VERSANIA

Versania's first response should emphasize that the MC12 Decision, as a waiver under Article IX:3 of the Marrakesh Agreement, cannot be the legal basis of a claim by Arion. To make its argument, it can rely on the Appellate Body's ruling in *EC-Bananas III (Article 21.5*) that a waiver has limited function "to relieve a Member, for a specified period of time, from a particular obligation provided for in the covered agreements". It cannot "create new law or add to or amend the obligations under a covered agreement".[153] As a waiver cannot add to or amend existing obligations, it cannot be the basis of a claim before the WTO Dispute Settlement Body.

[152] Clarification Questions, Part II, Ans. 6 [p.3].
[153] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 382.

Versanias should also highlight that the preamble of the MC12 Decision states that it has been adopted with regards to Articles IX:1, IX:3 and IX:4 of the Marrakesh Agreement. Article IX:2 of the Marrakesh Agreement is conspicuously absent from the text of the MC12 Decision. This strengthens the argument that the MC12 Decision is in the nature of a waiver, and not "akin to" a subsequent agreement under Article 31(3)(a) of the Vienna Convention.[154] The MC12 Decision thus only waives certain obligations of the TRIPS Agreement and is not a 'subsequent agreement' on its application such that it can create new obligations. It thus cannot be the basis of a claim.

Furthermore, Versania can also argue that the MC12 Decision is only limited to authorization of production "to the extent necessary to address the COVID-19 pandemic". On the contrary, Arion's production and supply of unnecessary COVID-19 booster shots on a commercial basis to private distributors, in a country which already had sufficient doses to vaccinate its entire population was not 'necessary' to address the pandemic. Versania can thus argue that the MC12 Decision is not applicable in the present case. Versania can further argue, based on the context and circumstances of its conclusion, the MC12 Decision presumes 'public non-commercial use'. The present factual situation is significantly different from the issues that the MC12 Decision attempts to address, and hence should not be covered within its ambit.

With respect to substantive arguments regarding an alleged violation of paragraph 3(c) of MC12 Decision, Versania can also highlight that the text of paragraph 3(c) requires Member States to "ensure the availability of effective legal means to prevent the importation into...their territories...of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions". Thus, any obligation in paragraph 3(c) is only in the context of goods that have been "diverted to their markets", which is not the case here. Rather, Versania only seeks to destroy the vaccines on grounds of IP infringement and public health concerns.

Finally, Versania can also argue that it did indeed "ensure the availability of effective legal means to prevent the importation" into its territory of COVID-19 vaccines produced in accordance with the MC12 Decision. ANCOP was allowed to participate in the proceedings before the Versanian Intellectual Property Board.[155] After hearing submissions from both Zanos and ANCOP, the Intellectual Property Board concluded that ANCOP was producing vaccines for commercial sale, beyond what is necessary to address the COVID-19 pandemic, and hence the conditions of the 2022 Ministerial Decision were not satisfied.[156] Furthermore, ANCOP had the right to appeal the decision of the Intellectual Property Board before the High Courts in Versania. However, after the

[154] Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 390
[155] Clarification Questions, Part II, Ans. 4 [p.3].
[156] Clarification Questions, Part II, Ans. 6 [p.3].

decision ANCOP informed the Intellectual Property Board that it will not be exercising this right.[157] Moreover, the Versanian Customs Authorities served written notice to ANCOP about the seizure on the very day that the seizure was made. However, ANCOP did not respond to the notice,[158] nor did it make any efforts to retrieve the shipment[159].

The facts in the preceding paragraph demonstrate that there were in fact sufficient effective legal means to prevent the importation into Versania of vaccines produced under the MC12 Decision, and accordingly, Versania does not violate paragraph 3(c) of the MC12 Decision.

7.5 QUESTIONS FOR TEAMS

Questions for Arion	**Questions for Versania**
What is the judicial value of the MC12 Decision? As a 'waiver' the MC12 Decision can only be a defence. How then can it be the legal basis of a claim?	The language of paragraph 3(c) of the MC12 Decision is clear in that It imposes an obligation on Member States. How then can you argue that it cannot be the basis for a substantive claim? Paragraph 3 mentions both 'waiver' and 'clarification' – does this not prove that the MC12 Decision is both a waiver, as well as a source of obligations.
Paragraph 3(c) requires members to prevent importation where the vaccines "are diverted into" its markets. However, in this case, there was no *diversion* of the vaccines into Versanian market. Do you agree that paragraph 3(c) was meant to address issues of diversion for improper use and sale of COVID-19 vaccines? How then do you intend to invoke paragraph 3(c) in a case where a country is merely protecting itself against dual concerns about IP infringement and sub-standard vaccines.	Section 75(3) of the Customs Act provides that the vaccines produced under the MC12 Decision, which you seized, are deemed to have been imported into your territory. What is the meaning of 'import' in paragraph 3(c) in your opinion? How do you reconcile that with the meaning of 'import' in Section 75(3)?
The MC12 Decision represents a limited authorization for restriction on patents. The executive order issued by Arion authorises	The MC12 Decision allows states leeway to address the pandemic, and hence should it not be up to states to decide, for themselves, what

[157] Clarification Questions, Part II, Ans. 8 [p.3].
[158] Clarification Questions, Part II, Ans. 15 [p.4].
[159] Clarification Questions, Part II, Ans. 16 [p.5].

production and sale to private distributors on a commercial basis. How is this justified?	measures are necessary to address the pandemic?
Considering that Boutica already had sufficient doses of vaccines, enough to reduce the risk of severe disease, how is supplying additional doses to them 'necessary to address the COVID-19 pandemic.'? Mildly symptomatic or asymptomatic cases do not threaten public health in the same way and thus cannot justify restrictions on intellectual property.	Even mildly symptomatic and asymptomatic cases also pose threats to public health, as they may result in more serious cases, and spread of the COVID-19 virus. Thus, how were the vaccines not necessary to address the pandemic?