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John H. Jackson Moot Court Competition
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Versania – Seizure of Vaccines In Transit From Arion

Arion
(*Complainant*)

vs

Versania
(*Respondent*)

SUBMISSION OF THE RESPONDENT

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LIST OF REFERENCES

I. TREATIES AND AGREEMENTS

Short Title	Full Title and Citation
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 UNYS 401, 33 ILM 1226 (1994).
GATT	General Agreement on Tariffs and Trade 1994, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 UNTS 187, 33 ILM 1153 (1994).
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS. 299, 33 ILM 1197 (1994).
VCLT	Vienna Convention on the Law of Treaties, 23 May 1969, 1155 UNTS 331.
WTO Agreement	Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 UNTS 154, 33 ILM 1144 (1994).

II. WTO DOCUMENTS

Short Title	Full Title and Citation
Doha Declaration	Declaration on the TRIPS Agreement and Public Health, adopted 14 November 2001, WT/MIN(01)/DEC/2.
2022 Ministerial Decision	Ministerial Decision on the TRIPS Agreement, adopted by the Ministerial Conference since 17 June 2022, WT/L/1141.

III. WTO REPORTS

A. Appellate Body Reports

Short Title	Full Title and Citation
Argentina– Footwear (EC)	Appellate Body Report, Argentina – Safeguard Measures on Imports of Footwear, WT/DS121/AB/R, adopted 2 March 2000.
Brazil – Desiccated Coconut	Appellate Body Report, Brazil – Measures Affecting Desiccated Coconut, WT/DS22, circulated 21 April 1997.

Brazil – Retreaded Tyres	Appellate Body Report, Brazil – Measures Affecting Imports of Retreaded Tyres, WT/DS332, circulated 3 December 2007.
Canada – Patent Term	Appellate Body Report, Canada – Term of Patent Protection, WT/DS170/10/AB/R, circulated 18 September 2000.
Colombia – Textiles	Appellate Body Report, Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear, WT/DS461, circulated 7 June 2016.
EC – Asbestos	Appellate Body Report, European Communities – Measures Affecting Asbestos and Products Containing Asbestos, WT/DS135/AB/R, adopted 05 June 2001.
EC – Bananas III	Appellate Body Report, European Communities – Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/AB/RW2/ECU, WT/DS27/AB/RW2/USA, circulated 26 November 2008.
EC – Seal Products	Appellate Body Report, European Communities – Measures Prohibiting the Importation and Marketing of Seal Products, WT/DS400/AB/R, WT/DS401/AB/R, adopted 16 June 2014.
India – Patents (US)	Appellate Body Report, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R, circulated 19 December 1997.
India – Solar Cells	Appellate Body Report, India – Certain Measures Relating to Solar Cells and Solar Modules, WT/DS456, circulated 16 September 2016.
Japan – Alcoholic Beverages II	Appellate Body Report, Japan – Taxes on Alcoholic Beverages, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, circulated 4 October 1996.
Korea – Dairy	Appellate Body Report, Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products, WT/DS98, circulated 14 December 1999.
Korea – Various Measures on Beef	Appellate Body Report, Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef, WT/DS/161/AB/R, circulated 11 December 2000.
Mexico – Soft Drinks	Appellate Body Report, Mexico – Tax Measures on Soft Drinks and Other Beverages, WT/DS308, circulated 6 March 2006.

US – Continued Zeroing	Appellate Body Report, United States – Continued Existence and Application of Zeroing Methodology, WT/DS350, circulated 4 February 2009.
US – Gambling	Appellate Body Report, United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services, WT/DS285/R, circulated 7 April 2005.
US – Gasoline	Appellate Body Report, United States – Standards for Reformulated and Conventional Gasoline, WT/DS52/AB/R, circulated 29 April 1996.
US – Section 211 Appropriations Act	Appellate Body Report, United States – Section 211 Omnibus Appropriations Act of 1998, WT/176/AB/R, circulated 2 January 2002.
US – Shrimp	Appellate Body Report, United States – Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58, circulated 12 October 1998.
US – Tuna II (Mexico)	Appellate Body Report, United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products - Recourse to Art. 21.5 of the DSU by the United States, WT/DS381/AB/RW/USA, WT/DS381/AB/RW2, circulated 14 December 2018.
US – Upland Cotton	Appellate Body Report, United States – Subsidies on Upland Cotton, WT/DS267/AB/R, adopted 21 March 2005.
US – Wool Shirts and Blouses	Appellate Body Report, United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India, WT/DS33/AB/R, adopted 23 May 1997.

B. Panel Reports

Short Title	Full Title and Citation
Australia – Tobacco Plain Packaging	Panel Report, Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WT/ DS467/R, adopted 27 August 2018.

Canada – Pharmaceutical Patents	Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114, circulated 17 March 2000.
China – Intellectual Property Rights	Panel Report, China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WT/DS362, circulated 26 January 2009.
Colombia – Ports of Entry	Panel Report, Colombia – Indicative Prices and Restrictions on Ports of Entry, WT/DS366/R, circulated 27 April 2009.
Colombia – Textiles	Panel Report, Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear, WT/DS461, circulated 27 November 2015.
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Saudi Arabia – IPRs	Panel Report, Saudi Arabia – Measures concerning the Protection of Intellectual Property Rights, WT/DS567/R, circulated 16 June 2020.
US – Section 211 Appropriations Act	Panel Report, United States – Section 211 Omnibus Appropriations Act of 1998, WT/176/11, circulated 6 August 2001.

IV. ELSA DOCUMENTS

Short Title	**Full Title**
Case	Case, *Versania-Seizure of Vaccines In Transit From Arion*, John H. Jackson Moot Court Competition, 2022/2023, 21st Edition.
Clarification	21st John H. Jackson Moot Court Competition Clarification Questions.

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LIST OF ABBREVIATIONS

Abbreviation	Description
AB	Appellate Body
ABR	Appellate Body Report
Art. / Arts.	Article / Articles
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
COVID-19	Novel Coronavirus Disease 2019
EO 46/22	Executive Order 46/22
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
IP	Intellectual Property
IPR / IPRs	Intellectual Property Right / Intellectual Property Rights
Members	WTO Members
MFN	Most-Favoured Nation
Para. / Paras.	Paragraph / Paragraphs
PR	Panel Report
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property
R&D	Research and Development
s. / ss.	Section / Sections
VCA	Versania Customs Act, 2006
VCIPP	Versanian Code on Intellectual Property Protection, 1995
VIPB	Versanian Intellectual Property Board
VCLT	Vienna Convention on the Law of Treaties
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

SUMMARY OF ARGUMENTS

I. Versania's seizure of vaccines is consistent with TRIPS Arts. 41.1, 51 and 52

- VCIPP s. 61 procedures adopted pursuant to TRIPS Art. 51 is consistent because it enables right holders to lodge written applications for the suspension of release of IPR-infringing goods, including goods in transit allowed under TRIPS Footnote 13.
- VCIPP s. 61 requires Zanos to provide adequate evidence to satisfy the VIPB of a *prima facie* IPR infringement of its patent and is consistent with TRIPS Art. 52.
- The VIPB adjudicates applications under the correct 'laws of the country of importation' and is consistent with TRIPS Art. 52 as 'country of importation' means the 'country in which the application is lodged'.
- Versania's seizure of ANCOP vaccines in transit does not create barriers to legitimate trade because the vaccines were manufactured *not in accordance* with the 2022 Ministerial Decision. The waiver does not apply and ANCOP vaccines were patent-infringing. Trade in IPR-infringing goods is not 'legitimate trade' under TRIPS Art. 41.1, therefore even if seizure creates a barrier to trade it is not a barrier to *legitimate trade* and is consistent with TRIPS Art. 41.1.

II. Versania's seizure of vaccines is consistent with GATT Art. V:2, or if inconsistent the measures are justifiable under GATT Art. XX(d)

- ANCOP vaccines in transit to Boutica are IPR-infringing and constitute 'illegitimate trade' under the TRIPS Agreement. By reading the GATT and TRIPS harmoniously, the GATT V 'freedom of transit' principle does not extend to 'illegitimate traffic in transit' since TRIPS IPR enforcement measures are facilitated through customs laws.
- GATT Art. V:3 is an exception to restrict freedom of transit for 'illegitimate trade' that fails to comply with Versania's customs laws and regulations, which include Special Border Measures in TRIPS Section 4. Patent-infringing vaccines in transit fail to comply with Versania's customs laws. Therefore, Arion's failure to comply with the VCIPP and VCA allows Versanian customs authorities to seize and destroy the ANCOP vaccines in accordance with its TRIPS obligations.
- Alternatively, if seizure and destruction is inconsistent with GATT Art. V:2, the measures are justifiable under GATT Art. XX(d) because measures protecting patent-rights holders against patent-infringing vaccines is provisionally justified as a necessary measure to secure compliance with the VCIPP.

- Seizing and destroying patent-infringing vaccines is also consistent with the *chapeau* under Art. XX as legitimate measures that protect patent rights and do not constitute arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

III. Versania's legal means are consistent with Para. 3(c) of the 2022 Ministerial Decision

- The Panel cannot exercise its jurisdiction over the 2022 Ministerial Decision because it is not a 'covered agreement' under DSU Art.1.1.
- The 2022 Ministerial Decision does not include a dispute settlement provision. Waivers must be read narrowly and with great care in accordance with its 'exceptional' nature under WTO Agreement Arts. IX:3 and IX:4, therefore the Panel should read within the four corners of the waiver's text.
- Waivers cannot modify or create new obligations under the covered agreements, therefore Para. 3(c) does not contain any legal obligation for Versania that can form the basis of the legal claim before the Panel.
- If the Panel does exercise its jurisdiction, Versania ensured its legal means were available and effective pursuant to Para. 3(c) of the 2022 Ministerial Decision. The ANCOP vaccines in transit to Boutica were not manufactured *in accordance* with the Decision and therefore patent-infringing vaccines. Importing and destroying patent-infringing vaccines is consistent with the 2022 Ministerial Decision and the TRIPS Agreement.

STATEMENT OF FACTS

1. Arion, Versania, and Boutica are WTO Members in the same region. Versania is a large, high-income country and hosts several global pharmaceutical companies' headquarters. Versania's pharmaceutical industry is key to its economy and account for 5% of Versania's GDP.
2. Arion is a developing, lower-middle income country, also known for its large pharmaceutical industry that accounts for 25% of total global pharmaceutical exports in volume. Versania's seaports offer Arion a lower cost of sea freight and is convenient access to the high seas to export significant volumes of Arion pharmaceutical products to major destinations. Boutica is a developing country located to the East of Arion and Versania.
3. In March 2020, the WHO declared the COVID-19 pandemic and emphasized the role of "extensive immunization against COVID-19… in order to bring the pandemic to an end". In November 2020, a leading pharmaceutical company in Versania, Zanos, developed the 'Zancovac' vaccine using its established R&D capacity and significant investment from the Versanian Government.
4. Arion and Boutica's pharmaceutical industries also entered the race to develop vaccines. Like Versania, the Arion Government funded the research of Arion's pharmaceutical industry. When Zancovac cleared clinical trials and marketing approval, it was made available for global sale to government around the world at USD 22.5 per dose with capacity to produce 250,000,000 doses per month. Besides Zancovac, four other vaccines have received regulatory approval in Arion and Boutica but are significantly more expensive than Zancovac.
5. Both Arion and Boutica purchased primary vaccine Zancovac doses for their entire population and an additional booster for the immunocompromised. Thanks to Zancovac's efficacy and an intense vaccination campaign, COVID-19 infection levels in Arion significantly reduced by March 2022 and continued to drop since. 2 doses of Zancovac reduced risk of severe disease by 95%.
6. In June 2022, the Arion government and ANCOP Ltd, a major pharmaceutical company in Arion, carried out a study that showed periodic booster shots every six months for the entire population would completely eliminate the risk of asymptomatic and mildly symptomatic cases. The WHO has neither disagreed nor endorsed this study.
7. On 17 June 2022, the WTO Ministerial Conference issued the 2022 Ministerial Decision, allowing developing country Members to authorize the use of process patents to produce

COVID-19 vaccines "to ensure the equitable access of eligible Members to the COVID-19 vaccine". The Decision noted in footnote 1 that "Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged…not to avail themselves of this Decision".

8. Following its own study, ANCOP launched plans to produce COVID-19 vaccines using the 2022 Ministerial Decision for commercial sale at USD 15.5 per dose. Boutican private pharmaceutical distributors in active negotiations with Zanos for private purchase of booster doses, expressed interest in entering into advance purchase agreements with ANCOP instead, pending clinical trials and market authorization of its vaccine.
9. On 10 July 2022, Arion passed EO 46/22 authorizing ANCOP to produce and sell COVID-19 vaccines using the process patented by Zanos, covering 4,000,000 doses for domestic sale in Arion and 3,000,000 doses for export to Boutica – the purchase between Arion and Boutica resulting in a commercial transaction of USD $46.5 million. On 20 July 2022, Boutica passed an EO authorizing the import of ANCOP's vaccines. Following authorization of ANCOP VAX in Boutica, ANCOP decided to ship the doses to Boutica through Versania's sea ports.
10. Zanos raised concerns to the Versanian Ministry of Trade and Industry that the production of ANCOP VAX improperly infringed on its patents held in the territories of all three Members for the Zancovac production process. Zanos filed an application with the IP Commissioner in Versania alleging that ANCOP's production operation infringed the exclusive rights associated with its patents under VCIPP s. 48, requesting that infringing vaccines be seized and destroyed.
11. Zanos submitted adequate evidence of the production and sale of the vaccines. The VIPB accepted Zanos' application and authorized customs authorities to seize and destroy all shipments of ANCOP VAX in transit from Arion to Boutica through Versania. ANCOP had a right to appeal to the Versanian High Courts and notified the VIPB that it would not pursue an appeal to its decision.
12. On August 15, 2022, the Versanian Customs Office at the border with Arion acted pursuant to the decision of the VIPB and under s. 75 of the VCA to confiscate several shipments of ANCOP VAX en route to Boutica. The shipments were destroyed after 15 days.
13. Following Versania's actions, Arion requested consultations which both parties considered unsuccessful, leading to the request to establish this panel pursuant to DSU Arts 4.7 and 6, GATT Art. XXIII, and TRIPS Art 64.1.

IDENTIFICATION OF MEASURES AT ISSUE

I. Whether the VCIPP, which enables the seizure of the IPR infringing vaccines, is consistent with TRIPS Arts. 51 and 52 and whether the seizure creates barriers to legitimate trade under TRIPS Art. 41.1.

II. Whether Versania's seizure of IPR infringing vaccines in transit under the VCIPP is consistent with GATT Art. V:2, or alternatively justified under GATT Art. XX(d).

III. Whether the Panel has jurisdiction to hear matters of the 2022 Ministerial Decision, or whether Versania's importation of vaccines under the VCA is consistent with Para. 3(c).

LEGAL PLEADINGS

I. VERSANIA'S SEIZURE OF VACCINES IS CONSISTENT WITH TRIPS ARTS. 41.1, 51 and 52

[1] The VCIPP is consistent with TRIPS Arts. 41.1, 51 and 52 because IP enforcement procedures adopted pursuant to Arts. 51 and 52 are applied in a manner that impedes *patent-infringing* trade, which is consistent with Art. 41.1 and the object and purpose of the Agreement on *Trade-Related Aspects* of IP. Furthermore, the 2022 Ministerial Decision only authorizes compulsory licenses in addressing the COVID-19 pandemic "to the extent necessary".[1] Arion and Boutica's commercial transaction for 3,000,000 boosters based on Arion's non-WHO reviewed study is unnecessary.[2] Seizing patent-infringing vaccines in transit is a requirement under the *minimum standards* of IP protection and prevents the abuse of TRIPS flexibilities.

A. Versania's seizure of vaccines is consistent with TRIPS Art. 51

[2] TRIPS Art. 51 under Part III forms 'Section 4: Special Requirements Related to Border Measures' that "must be read as a coherent set of procedures and not in isolation".[3] VCIPP s. 61 enable IPR-holders to lodge applications for the 'suspension of release' of alleged patent-infringing goods in transit pursuant to TRIPS Art. 51.

[3] Though TRIPS Art. 51 sentence one only mentions 'counterfeit trademark or pirated copyright goods', Versania can enable applications with respect to suspected goods that infringe other IPRs under TRIPS Art. 51 second sentence. Under TRIPS Art. 1.2, the term 'intellectual property' refers to all IP subject of TRIPS Sections 1 through 7 in Part II. Patents are the subject of Section 5 of Part II. Under Art. 51 third sentence, Members may adopt

[1] 2022 Ministerial Decision, [1].
[2] Clarification, VIII:13.
[3] PR, China – Intellectual Property Rights, [7.218-7.219].

corresponding procedures concerning goods destined for exportation. Lastly, Art. 51 footnote 13 allows Members to making procedures available concerning goods in transit.[4]

[4] To show inconsistency with TRIPS Art. 51, Arion must show that Versania has not enabled right-holders to lodge applications to a competent authority for the suspension of the release of IPR-infringing goods or the procedures do not meet the requirements of TRIPS Section 4. Versania adopted procedures to enable applications for the suspension of release of IPR-infringing goods in transit in conformity with Art. 52.

1. VCIPP s. 61(2) enables right-holders to lodge written applications for the suspension of release of IPR-infringing goods

[5] VCIPP s. 61(2) enables right-holders to make applications to the VIPB to enforce IP protection in Versania. VCIPP s. 61(1) prohibits the "introduction into Versanian customs territory" of any goods infringing an IPR registered in Versania, whether for free circulation or for transhipment to another destination. This procedure provides a domestic mechanism for the procedures required under TRIPS Art. 51. Applications under VCIPP s. 61 are available to right holders concerning imported goods, goods destined for exportation, and goods in transit suspected of infringing an IPR registered in Versania and is consistent with TRIPS Art. 51.

[6] TRIPS Art. 1.1 provides context to interpret the scope of Art. 51. Members must 'give effect to the provisions of this Agreement' but are free to 'determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. VCIPP s. 61 is consistent with this obligation because it meets the requirements under Art. 1.1 to 'give effect' to the provision and is a justified choice of implementation in the Versanian legal system.[5]

2. VCIPP s. 61 application procedures are consistent with TRIPS Art. 51

[7] Footnote 13 to Art. 51 clarifies that 'there shall be no obligation to apply such procedures… to goods in transit'. The footnote lays out an optional extension of Art. 51 procedures to enable applications to be made concerning goods in transit without any "contingent obligation".[6] Where optional, more extensive protection are allowed under TRIPS Art. 1.1 'so long as such protections do not contravene other provisions of the Agreement'. Versania does not contravene any provisions of TRIPS by applying VCIPP s. 61 procedures to goods in transit.

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[4] PR, China – Intellectual Property Rights, [footnote 214].
[5] ABR, India–Patents, [59]; PR, EC–Trademarks and Geographical Indications, [7.766-7.767]; PR, China–Intellectual Property Rights, [7.323].
[6] PR, China–Intellectual Property Rights, [footnote 214].

[8] Under Art. 51., only those procedures concerning imports of IPR-infringing goods must meet the requirements of Section 4. In treating all goods acted on by customs authorities' pursuant to VCIPP s. 61 as *imported* under VCA s. 75(3), Versania ensures that procedural safeguards under the Section are provided to goods destined for exportation and goods in transit, ensuring their compliance with the Agreement.

[9] Under VCIPP s. 61, all goods are afforded the procedural entitlements required under Section 4 of Part III of the TRIPS Agreement, and the procedure enables right holders to assert their private rights by applying for the suspension of release by customs authorities of goods suspected of infringing those rights. The procedure is therefore consistent with the obligation under Art. 51 to 'adopt procedures'.

B. VCIPP s. 61 is adopted and applied consistently with TRIPS Art. 52

[10] Having met its obligation under Art. 51 to adopt procedures to enable applications for suspension of release under VCIPP s. 61, no violation to Art. 51 may be found if the s. 61 procedure meets the requirements of Section 4. The procedure is consistent with the requirements of Art. 52, and no claim is made under other provisions of Section 4. Since Versania has met its obligation under Art. 52, there is no violation of Art. 51.

[11] Under the first sentence of Art. 52, right-holders initiating procedures under Art. 51 must 'provide adequate evidence to satisfy the competent authority that, under the laws of the country of importation there is *prima facie* an infringement of the right holder's intellectual property right,' and 'supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities.' Under the second sentence, customs authorities are required to '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.'

[12] Versania is not in violation of the first sentence of Art. 52 because Zanos was required to provide adequate evidence to satisfy the VIPB of a *prima facie* infringement, and Versania was a 'country of importation' consistent with its meaning under the provision.

1. The VIPB accepted Zanos' adequate evidence of a *prima facie* infringement

[13] The obligation in the first sentence of Art. 52 to require that right-holders provide adequate evidence of a *prima facie* infringement is satisfied by the application of s. 61(2) of the VCIPP, under which a right-holder who makes an application pursuant to s. 61(2) "must provide adequate evidence to satisfy the Intellectual Property Board that, under the provisions of this Code, there is *prima facie* an infringement of the right holder's intellectual property right." In

making its application to the VIPB launched pursuant to VCIPP s. 61(2), Zanos provided adequate evidence to satisfy the VIPB of a *prima facie* infringement.

[14] To make out a *prima facie* infringement, as a "generally-accepted canon of evidence," a claiming party must provide factual evidence "sufficient to raise a presumption that what is claimed is true."[7] To make out a *prima facie* infringement of a patent, a party must only provide preliminary factual evidence to allow the judicial authority to weigh on a balance of probabilities the likelihood that what is claimed may be true. This is reflected in the text of Art 52 that a *prima facie* infringement may be found 'under the laws of the country of importation,' allowing Members to determine the appropriate standard in their legal system.

[15] Recalling that the prohibition under VCIPP s. 61(1) against the introduction of IPR-infringing goods to Versanian customs territory is to be enforced 'as effectively as possible' under s. 61(2), the VIPB sets a low bar regarding adequate evidence to make out *prima facie* cases to prevent any act of infringement to IPR registered in its territory. Zanos met the standard of evidence required by the VIPB by providing Executive Order 46/22 to prove ANCOP's production of vaccines using the process patented by Zanos.[8] Prior to their sale in Boutica, no evidence of harm could exist. Therefore, evidence of production using the process patented by Zanos is sufficient to satisfy the VIPB of a *prima facie* infringement.

C. Versania is the 'country of importation' under TRIPS Art. 52

[16] The complainant may argue that 'country of importation' refers only to the intended country of importation concerning goods in transit. To resolve ambiguity on the interpretation of this term, the ordinary meaning of the words shall be interpreted in their context and in light of the object and purpose of the TRIPS Agreement pursuant to Art. 31 of the VCLT.

[17] The term 'country of importation' is not defined in the TRIPS Agreement. The ordinary meaning of the word 'importation' is "the action of importing or bringing in" or "the bringing in of goods or merchandise from a foreign country, opposite to exportation."[9] 'Country of importation' therefore is any country into which impugned goods are brought. Versania and Boutica are both countries into which the impugned vaccines would be brought in transit.

[18] This interpretation is supported by the context of the term in Art. 51 procedures, which may be made available concerning goods in transit under Footnote 13. The term is used in footnote 14 to Art. 51 to define 'counterfeit trademark goods' and 'pirated copyright goods,' reflecting comparisons between the alleged infringement committed in the country of

[7] ABR, US–Wool Shirts and Blouses, [14].
[8] Clarifications, [II:6].
[9] Oxford English Dictionary. (2011). "Importation",715.

production and a hypothetical making of the impugned goods to determine if they would have infringed IPR had they been produced in that country.[10]

[19] The object and purpose of the TRIPS Agreement under the first Recital of the Preamble to the TRIPS Agreement is 'to promote effective and adequate protection of intellectual property rights.' Arts. 7 and 8 of the Agreement provide "important context for the interpretation" of provisions of TRIPS, and "are to be borne in mind when specific provisions of the Agreement are being interpreted" under Art. 31 of the VCLT.[11] Art. 7 reflects the purpose of promoting and maintaining the societal objectives the Agreement serves, including technological innovation, to the mutual advantage of producers and users of technological knowledge.[12] Art. 8 provides contextual guidance to interpret terms in the Agreement such that WTO Members may pursue certain legitimate societal interests, including public health, so long as measures adopted for such purposes are 'consistent with the provisions of the [TRIPS] Agreement.'[13]

[20] In light of the object and purpose of the Agreement with Arts. 7 and 8 borne in mind, 'country of importation' should be interpreted as the country in which an application for suspension of release pursuant to Art. 51 of the TRIPS Agreement has been lodged, not restricted to the intended country of importation. This interpretation gives effect to the optional extension of Art. 51 procedures to goods in transit, making applications available in the country of transit, and promotes effective protection of IPR by allowing right-holders to lodge an application for the suspension of release of goods infringing their rights in the territory of a Member through whose territory the impugned goods transit. This maintains the internationally agreed minimum standard for IP enforcement Members are bound to under Part III of the TRIPS Agreement and ensures the flexibilities under Art. 8 are not abused by contravening other provisions of the Agreement.[14]

[21] Versania is therefore the proper 'country of importation' under Art. 52 because the application against the vaccines in transit was lodged in Versania. For these reasons, the Versanian customs regime was adopted and applied by the VIPB consistently with Art. 52. Versania has therefore met its obligations under Art. 52 of the Agreement and its actions cannot give rise to a violation of Art. 51.

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[10] Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 616.
[11] PR, Australia–Tobacco Plain Packaging, [6.658, 7.2402].
[12] PR, Australia–Tobacco Plain Packaging, [7.2403].
[13] PR, Australia–Tobacco Plain Packaging, [7.2404].
[14] ABR, US–Section 211 Appropriations Act, [206].

D. Versania's seizure of vaccines is consistent with TRIPS Art. 41.1

[22] Part III of the TRIPS Agreement sets out "an internationally-agreed minimum standard" of procedures that Members are bound to adopt in their domestic law to enforce IPR protections.[15] Versania made enforcement procedures specified in Part III available in order to permit effective action against acts of IPR.[16] Sentence two of Art. 41.1 obligates Members to apply the enforcement procedures specified in Part III 'in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.' Versania did not create barriers to legitimate trade in seizing the vaccines in transit from Arion to Boutica because the vaccines are not within the scope of 'legitimate trade.'

1. Versania's seizure of vaccines does not create 'barriers to legitimate trade'

[23] As shown above, Versania has adopted and applied enforcement procedures specified in Arts. 51 and 52 consistently with the obligations therein. Their application to seize vaccines in transit from Arion to Boutica is consistent with sentence two of Art. 41.1 because the vaccines were not 'legitimate trade,' and creating barriers to illegitimate trade does not violate this obligation. Versania also provided safeguards against the abuse of its enforcement procedures.

2. 'Legitimate trade' does not infringe IPR

[24] The term 'legitimate trade' is not defined in any WTO Agreement. Legitimate interests and objectives have been previously interpreted by Panels, where the ordinary meaning of 'legitimate' was defined as "lawful; justifiable."[17] Distinguishing the Panel's finding in Canada – Patents, "justifiable" is not an apt definition of 'legitimate' in the context of 'legitimate trade.'[18] While Art. 8 of the Agreement allows Members to formulate laws to protect public health and other legitimate social interests, it cannot make IPR-infringing trade legitimate based on the measure's public health purpose.[19] In the context of 'legitimate trade,' 'legitimate' should be interpreted as "lawful." In the TRIPS Agreement, 'legitimate trade' is used in Art. 41.1 and Recital 1 of the Preamble, highlighting that a purpose of the Agreement is 'to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.' Recital 1 informs the object and purpose of the Agreement, and terms under the TRIPS Agreement must be interpreted with Arts. 7 and 8 borne in mind.[20]

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[15] ABR, US–Section 211 Appropriations Act, [206].
[16] PR, Saudi Arabia–IPRs, [7.210].
[17] ABR, US–Tuna II, [313]; PR, Canada–Pharmaceutical Patents, [7.68].
[18] PR, Canada–Pharmaceutical Patents, [7.69].
[19] PR, Canada–Pharmaceutical Patents, [7.25-7.26].
[20] Doha Declaration, [5(a)]; PR, Australia–Tobacco Plain Packaging, [7.2411]; ABR, Canada–Patent Term, [7.26]; PR, US–Section 211 Appropriations Act, [8.57].

[25] The object and purpose of the Agreement is to promote effective and adequate protection of IPR while ensuring that such protections do not themselves become barriers to legitimate trade pursuant to the first Recital of the Preamble. While Art. 8.1 defines public health as a legitimate social interest, trade that infringes IPR under other provisions of the Agreement cannot be legitimate because of their public health purpose. Art. 7 sets the objective of IPR protection under the TRIPS Agreement as the promotion of technological innovation and the dissemination of technology, to the mutual advantage of producers and users of technical knowledge in a manner conducive to socio-economic welfare and to balance rights and obligations.

[26] Interpreted through its ordinary meaning in its context and in light of the object and purpose of the Agreement, 'legitimate trade' may be understood as trade that is lawful and does not infringe IPR under the TRIPS Agreement.

3. ANCOP vaccines sold to private distributors is not 'legitimate trade'

[27] The vaccines produced by ANCOP under a compulsory license authorised pursuant to the 2022 Ministerial Decision are patent-infringing, illegitimate trade because the licence did not meet the conditions of the Decision. As established above, trade in goods that infringe patents are not legitimate trade under Art. 41.1.

[28] The Decision authorizes compulsory licenses for patents to produce COVID-19 vaccines only "to the extent necessary to address the COVID-19 pandemic."[21] ANCOP abused the Decision in using its authorization to produce COVID-19 vaccines using the process patented by Zanos for sale to private pharmaceutical distributors in Boutica of doses that were not necessary to address the pandemic. While seizure is a barrier to trade, Versania created a barrier to illegitimate trade by seizing the patent-infringing vaccines in transit, consistent with sentence two of Art. 41.1.

4. Versania safeguards against the abuse of its enforcement procedures

[29] The obligation in the second sentence of Art 41.1 also requires Members to provide safeguards against abuse of the enforcement procedures specified in Part III of the TRIPS Agreement. Versania provided for safeguards against the abuse of its enforcement procedures by ensuring that all parties to the dispute had access to procedural entitlements including the right to review by a judicial authority.

[30] VCIPP s. 61(3) incorporates the proportionality principle required under Art. 46 of TRIPS, by extending procedural protections through the VIPB to allegedly infringing goods. This

[21] 2022 Ministerial Decision, [1].

prevents the abuse of s. 61 procedures by ensuring that the totality of evidence and third-party interests are considered when the VIPB assesses applications pursuant to VCIPP s. 61(2). Further safeguards were provided by ensuring defendants have a right of appeal to the VIPB.[22] ANCOP did not avail itself of its right of appeal following the decision of the VIPB. Versanian customs authorities waited 15 days after seizing the vaccines to allow ANCOP a reasonable period to launch its right of appeal.

[31] In summary, in seizing vaccines in transit from Arion, Versania adopted and applied its enforcement procedures consistently with Arts. 41.1, 51, and 52 of the TRIPS Agreement. Versania seized the vaccines in transit using enforcement procedures required to be available in its domestic law under Part III of the TRIPS Agreement in a manner that does not create barriers to legitimate trade. Those procedures were adopted in conformity with the obligations under Arts. 51 and 52. The application procedure adopted under VCIPP s. 61 is consistent with Art. 51 obligations and meets the requirements of Art. 52. Finally, Versania provided for safeguards against the abuse of its enforcement procedures.

II. VERSANIA'S SEIZURE OF VACCINES IS CONSISTENT WITH GATT ART. V:2; IF INCONSISTENT SEIZURE IS JUSTIFIABLE UNDER ART. XX(d)

[32] The ANCOP vaccines constitute illegitimate trade, which violates Versania's customs laws made in accordance with its obligations under the TRIPS Agreement. As such, Versania was able to seize and destroy the vaccines due to Arion's 'failure to comply with applicable customs laws and regulations' under the GATT Art. V:3 and Arion's claim must fail.

[33] Alternatively, if Versania violated Art. V:2, seizure and destruction of the vaccines is justifiable as a general exception under Art. XX(d) as it is necessary to secure compliance with the VCIPP. Further, it is not applied in a manner that constitutes 'arbitrary or unjustifiable discrimination between countries where the same conditions prevail' and is not being used as a 'disguised restriction on international trade.'

[34] As outlined in claims I and III, the ANCOP vaccines in transit infringe IPR and therefore constitute illegitimate trade under the TRIPS Agreement. A harmonious reading of the TRIPS and the GATT requires consistency across both agreements.

[35] Under the first sentence of the GATT Art. V:2, Members must provide 'freedom of transit […] for traffic in transit.' 'Traffic in transit' is defined in Art. V:1 as 'Goods […] in transit across the territory of a contracting party when the passage across such territory […] is only a

[22] Clarifications, [II:8].

portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes.' Art. V:1 "informs the scope of Article V:2."[23] Therefore, trade that does not fall within the scope of 'traffic in transit' is not subject to 'freedom of transit' under Art. V:2 of the GATT.

A. Freedom of transit does not extend to 'illegitimate' traffic in transit under GATT Art. V:2

[36] Recital 2(a) of the Preamble to the TRIPS Agreement recognizes 'the applicability of the basic principles of the GATT 1994'. While there is no hierarchy between TRIPS and the GATT,[24] previous jurisprudence affirms that WTO agreements must be interpreted harmoniously.[25] Therefore, to read GATT Art. V harmoniously with the obligations under TRIPS, illegitimate trade must be distinguished from 'traffic in transit' that is guaranteed freedom of transit under the GATT V:2.

1. Compliance with TRIPS is facilitated through Members' customs laws

[37] The TRIPS Agreement necessitates a bridge between domestic IP laws and customs laws since these are the tools available to Members to enable the border measures under Section 4 of Part III of TRIPS. Part III of TRIPS obliges Members to adopt enforcement procedures to address 'acts of infringement', including IPR infringing goods. These procedures are implemented through customs laws required by Section 4, as the provisions in Art. 51 of TRIPS authorize "the suspension by [..] customs authorities" for such goods.[26] Therefore, by trading in goods that fail to comply with customs laws, Members are in violation of TRIPS since every member under the WTO is required to adopt the procedures under Part III. If this were not the case, TRIPS would be ineffective at enforcing the Agreement's obligations and preventing the circulation of IPR infringing goods.

[38] The ANCOP vaccines constitute illegitimate trade in violation of Versania's domestic customs laws and are not guaranteed freedom of transit under the GATT Art. V:2. This allows Versania to seize and destroy the vaccines due to Arion's 'failure to comply with applicable customs laws and regulations' under the GATT V:3.

2. Freedom of transit is not guaranteed for trade that fails to 'comply with applicable customs laws and regulations' under GATT Art. V:3

[23] PR, Russia–Traffic in Transit, [7.169].
[24] PR, EC–Trademarks and Geographical Indications, [7.87].
[25] ABR, Korea–Dairy, [81]; ABR, Argentina–Footwear (EC), [81]; ABR, US–Gasoline, [21-23]; ABR, Japan–Alcoholic Beverages II, [111]; ABR, US–Upland Cotton, [547-549]; ABR, US–Continued Zeroing, [268].
[26] PR, China–Intellectual Property Rights, [7.223-7.224].

[39] Art. V:3 of the GATT addresses 'customs laws and regulations' and actions by Members in relation to their 'customs house'. Read harmoniously, 'freedom of transit' under the GATT Art. V:2 is limited to traffic that complies with 'applicable customs laws and regulations,' and therefore that measures that impede traffic in transit that fails to comply with such measures, adopted pursuant to the TRIPS Agreement, are consistent with the GATT Art. V:2 obligation to ensure freedom of transit for legitimate trade.

[40] The text of Art. V:3 allows Members to prohibit freedom of transit 'in cases of failure to comply with applicable customs laws and regulations.' This clause should be interpreted as a stand-alone exception which qualifies Art. V:2,[27] allowing Members to reconcile their obligations under TRIPS with the GATT Art. V.

[41] Art. V:3 is permissive. A Member 'may require that traffic in transit through its territory be entered at the proper customs house,' but on the condition that 'such traffic […] shall not be subject to any unnecessary delays or restrictions.' However, the paragraph includes an exception for 'cases of failure to comply with applicable customs laws and regulations.' This exception has not been interpreted by a DSB Panel and must be read in accordance with customary international law.

[42] The ordinary meaning of 'failure to comply' is the "omission of expected or required action".[28] As such 'except in cases of failure to comply' relates to required action in accordance with a Member's customs laws and regulations. This exception can also be interpreted as qualifying the statement succeeding it, indicating that the obligation to not subject transiting goods to 'unnecessary delays or restrictions' is only applicable when customs laws and regulations are complied with.[29] This is because a meaningless exception would be redundant. Interpretation must "give meaning and effect to all the terms of a treaty" and must not reduce "whole clauses or paragraphs of a treaty to redundancy or inutility."[30] Art. V:3 should also be read in relation V:2, which is consistent with interpretations of other paragraphs of Art. V.[31] For example, while the second sentence of Art. V:2 extends MFN treatment to traffic in transit passing through a transit state, Art. V:5 extends such protection to "all charges, regulations and formalities in connection with transit."[32] Meanwhile, Art. V:6 extends MFN to "discrimination based on the geographic course of goods" after reaching their destination.[33] Finally, "freedom

[27] Bryan Mercurio, Seizing' Pharmaceuticals in Transit, [421].
[28] Oxford English Dictionary. (2019). "Failure", "Compliance", 293 & 511.
[29] Bryan Mercurio, "'Seizing' Pharmaceuticals in Transit, [421].
[30] ABR, US–Gasoline, [23].
[31] See PR, Colombia–Ports of Entry, [7.456-7.457].
[32] PR, Colombia–Ports of Entry, [7.468].
[33] PR, Colombia–Ports of Entry, [7.467].

of transit is [not] one and the same for all provisions" of Art. V.[34] Therefore, like the other paragraphs which modify or complement Art. V:2, Art. V:3 limits Art. V:2 to balance obligations to comply with domestic customs laws and to provide freedom of transit.

[43] While the object and purpose of Art. V is to ensure 'freedom of transit', it does so in a way that maintains the interests of transit states. This is reflected by V:2 only guaranteeing the most convenient route of transit, as opposed to all routes,[35] and by the reasonableness and necessity standards built into V:3 and V:4 with respect to customs delays and charges.[36]

[44] As such, 'except in cases of failure to comply with applicable customs laws and regulations' should be interpreted as a stand-alone exception. This allows the transit state to act on illegitimate trade, including IPR infringing goods, in violation of domestic customs laws in a way that accords with the obligations under the TRIPS Agreement.

3. Versania is not obligated to provide freedom of transit due to Arion's failure to comply with Versania's 'applicable customs laws and regulations'

[45] The ANCOP vaccines were in violation of Versania's 'applicable customs laws and regulations' under the GATT Art. V:3. Under ss. 54 and 61 of the VCIPP and s. 75 of the VCA, the transit of IPR infringing vaccines is a violation of the respondent's customs laws, adopted in accordance with the TRIPS Agreement.

[46] The Panel should note that "the TRIPS Agreement does not mandate specific forms of legislation."[37] Therefore, if Members comply by implementing laws or regulations that 'give effect' to the provisions of the Agreement, they will meet their obligations.[38] Versania has opted to design its legislation to comply with TRIPS through ss. 54 and 61 of the VCIPP and s. 75 of the VCA. This constitutes Versania's 'applicable customs laws and regulations.'

[47] When the ANCOP vaccines entered Versanian territory, the Versanian Customs Office acted pursuant to the VCIPP and the VCA on trade that failed to comply with Versania's 'applicable customs laws and regulations.' As such, seizing and destroying the vaccines is consistent with the GATT V:2 and Arion's claim must fail.

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[34] PR, Colombia–Ports of Entry, [7.456].
[35] Huarte Melgar, *The Transit of Goods in Public International Law*, [128].
[36] Pogoretskyy, *Freedom of Transit and Access to Gas Pipeline Networks under WTO Law*, [138-139].
[37] PR, China–Intellectual Property Rights, [7.602].
[38] PR, China–Intellectual Property Rights, [7.602]; TRIPS Art. 1.1; ABR, India–Patents (US), [59]; PR, EC–Trademarks and Geographical Indications, [7.766-7.767].

B. Alternatively, seizing and destroying vaccines in transit is justified under GATT Art. XX(d)

[48] If Versania violated the GATT Art. V:2, seizure and destruction are justifiable under Art. XX(d). These measures are necessary to secure compliance with the VCIPP; specifically, s. 61(1), which prohibits the circulation of IPR infringing goods and s. 48, the exclusive rights of patent-holders. Further, they are not being applied contrary to the *chapeau* of Article XX.

[49] Versania qualifies for an exception under Art. XX(d) because the measures applied were designed and necessary to secure compliance with its laws and regulations, which are not themselves inconsistent with the GATT.[39] Further, their application does not constitute 'arbitrary or unjustifiable discrimination between countries where the same conditions prevail' or a 'disguised restriction on international trade'.[40]

1. Seizing vaccines in transit is justified under GATT Art. XX(d)

[50] First the respondent must show that the laws or regulations the measure is intended to secure compliance with, are 'laws or regulations' within the meaning of XX(d).[41] These refer to the rules of a Member's domestic legal system.[42] Versania meets this requirement as 'the protection of patents' is an enumerated ground in XX(d).

2. Seizure and destruction secure compliance with the VCIPP

[51] Next, the respondent must show that the impugned measure is *designed* to secure compliance with the relevant law or regulation.[43] "Securing compliance" refers to the enforcement of obligations.[44] The relationship between the impugned measure and the relevant law or regulation must be sufficiently strong.[45] In this case the seizure and destruction measures were designed exclusively to enforce the prohibition on infringing goods under s. 61(1) and protect the rights of patent holders under s. 48 of the VCIPP.

[52] Finally, the law or regulation itself must not be inconsistent with the GATT.[46] As affirmed by the AB, "a responding Member's law should be treated as WTO-consistent until proven otherwise."[47] Arion has not demonstrated a *prima facie* inconsistency between the VCIPP and the GATT as 'the protection of patents' is enumerated under XX(d).

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[39] Bossche & Zdouc, Law and Policy of the WTO, [613-614]; ABR, Korea–Various Measures on Beef, [157].
[40] Bossche & Zdouc, Law and Policy of the WTO, [646-647]; ABR, Brazil–Retreaded Tyres, [215].
[41] ABR, India–Solar Cells, [5.113].
[42] ABR, Mexico–Soft Drinks, [68-69].
[43] ABR, Mexico–Soft Drinks, [74].
[44] PR, Colombia–Ports of Entry, [7.538]; ABR, Colombia–Textiles, [7.482-7.483].
[45] ABR, Colombia–Textiles, [5.126] and [5.133].
[46] PR, Colombia–Ports of Entry, [7.526].
[47] PR, Colombia–Textiles, [7.511].

3. Seizure and destruction are necessary to secure compliance with the VCIPP

[53] The impugned measure must also be *necessary* to secure compliance with the relevant law or regulation.[48] The seizure and destruction measures are necessary to prevent the importation and sale of ANCOP's COVID-19 vaccine infringing Zanos' patent, thus protecting the patent holder's rights and preventing the circulation of infringing goods.

[54] Necessity is assessed through a holistic balancing of factors.[49] These include (1) the importance of the common interests or values protected by the law or regulation; (2) the trade restrictiveness of the law or regulation; and (3) whether the measure makes a significant contribution to the enforcement of the law or regulation.[50]

[55] The common interests or values protected by the law or regulation are assessed based on their importance to the respondent.[51] As such, their importance enhances their necessity.[52] Given Versania's domestic innovative pharmaceutical market, accounting for 5% of its GDP, including several innovative drug companies, patent protection is extremely important. Weighed against the importance of patent protection, the impact on imports from enforcing the VCIPP and prohibiting infringing goods is not overly restrictive. Goods can enter circulation into Versania so long as they do not infringe IPRs. Meanwhile, protecting IPRs is impossible if infringing goods cannot be seized and prevented from further circulation.

[56] To be necessary, seizure and destruction must make a material contribution to the achievement of their objective.[53] Seizure and destruction prevent infringing goods from being recirculated or copied, which would undermine the patent rights that the VCIPP is designed to protect. Further, in an innovative sector, copying or recirculation undermines the purpose of patent protection given the investment required for R&D. Therefore, given the interests and values that the seizure and destruction measures are designed to protect, as well as their impact on trade and contribution to enforcing the objectives of the VCIPP, seizure and destruction are necessary to ensure its compliance.

[57] Finally, the burden is on the complainant to identify possible alternative measures and there is no alternative consistent with WTO obligations that Versania could reasonably be expected to employ.[54] Members can determine the level of protection that they consider

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[48] ABR, Korea–Various Measures on Beef, [161].
[49] ABR, Korea–Various Measures on Beef, [164]; ABR, US–Gambling, [182].
[50] ABR, Korea–Various Measures on Beef, [164].
[51] ABR, Korea–Various Measures on Beef, [162].
[52] ABR, Korea–Various Measures on Beef, [162].
[53] ABR, Brazil–Retreaded Tyres, [150].
[54] PR, Indonesia–Chicken, [7.153]; ABR, Korea–Various Measures on Beef, [166].

appropriate in each context.[55] Seizure and destruction are the only means to stop infringing goods from entering third-party countries and to prevent their further circulation.

C. Versania's seizure and destruction meets the *chapeau* of the GATT Art. XX

[58] Under the *chapeau* of Art. XX, the application of the impugned measure must not constitute 'arbitrary or unjustifiable discrimination between countries where the same conditions prevail' or 'a disguised restriction on international trade'. The respondent bears the burden of demonstrating that the measure is compliant.[56] Versania's seizure and destruction of the vaccines constitutes neither 'arbitrary or unjustifiable discrimination' nor a 'disguised restriction on international trade'.

1. Seizure and destruction under the VCIPP do not constitute discrimination

[59] For the application of a measure to constitute 'arbitrary or unjustifiable discrimination', discrimination must exist.[57] The VCIPP does not discriminate against Arion. The prohibition on the introduction of IPR infringing goods to Versania under s. 61(1) is applied to goods in transit under s. 54 equally for all WTO Members. Therefore, there is no discrimination within the meaning of the *chapeau*. Alternatively, if the measures do constitute discrimination, it is not arbitrary or unjustifiable and Versania and Arion have different conditions.

[60] Regardless, the *chapeau* does not prohibit discrimination, only discrimination that is arbitrary and unjustifiable.[58] A measure that is not arbitrary or unjustifiably discriminatory should have a rational connection to the objective being advanced.[59] Seizure and destruction are rationally connected to the objective of protecting patent rights by preventing infringing goods from entering free circulation into Versania or third-party countries.

[61] The measures should not be applied rigidly or inflexibly.[60] Versania's measures are not overly rigid because there is sufficient flexibility to consider the conditions prevailing in exporting member countries.[61] Under section 61(3) of the VCIPP, the VIPB must take into consideration the need for proportionality between the seriousness of the infringement and the remedies ordered, as well as the interests of third parties. As such, seizure and destruction are calibrated to and commensurate with the risks arising from a violation of patent rights.[62]

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[55] ABR, Brazil–Retreaded Tyres, [210].
[56] ABR, EC–Seal Products, [5.301].
[57] See ABR, US–Shrimp, [150].
[58] ABR, US–Gasoline; Bossche and Zdouc, *Law and Policy of the WTO*, 649.
[59] ABR, Brazil–Retreaded Tyres, [227].
[60] ABR, US–Shrimp, [164-165, 177]; ABR, EC–Seal Products, [5.305].
[61] ABR, US–Shrimp, [164-165].
[62] ABR, EC–Seal Products, [5.306].

[62] Finally, any discrimination does not occur between countries where the same conditions prevail. Versania has very different conditions from Arion. With 5% of the country's GDP based on novel pharmaceuticals, Versania has a unique interest in ensuring the continuation of its innovative market. R&D in Versania's domestic market will only be maintained if patent-holder rights are protected. Since Arion does not have the same domestic needs, application of the seizure and destruction measure is justifiable.

2. Versania's seizure and destruction of vaccines in transit are not disguised restrictions on international trade

[63] In addition, seizure and destruction were not applied as a 'disguised restriction on international trade'. "Disguised" means an intention to conceal the true purpose of a measure through "deceptive appearances."[63] Seizure and destruction are not being applied under the *guise* of a purpose within the terms of Art. XX(d); their *purpose* is to protect the rights of patent holders in Versania, which is an enumerated ground under XX(d). This is evident from the VCIPP itself, given that the border measures under s. 61(2) are directly tied to enforcing the prohibition on patent-infringing goods in s. 61(1). The application of the seizure and destruction measure is explicitly for the purpose of protecting intellectual property rights of Versanian patent-holders. Therefore, seizure and destruction are justified as a general exception under Art. XX(d) to its violation of Art. V:2, and Arion's claim must fail.

III. VERSANIA'S LEGAL MEANS ARE CONSISTENT WITH PARA. 3(c) OF THE 2022 MINISTERIAL DECISION

[64] The Panel should decline to exercise jurisdiction over this claim because the 2022 Ministerial Decision is not a 'covered agreement' under the DSU and the Decision contains no recourse to dispute settlement. Even if the Panel chooses to hear this matter, Versania's actions taken pursuant to 'effective legal means' were 'available' are therefore consistent with Para. 3(c) of the Decision. Importing vaccines in transit from Arion to Boutica is justified because ANCOP production was authorized *not in accordance* with the Decision and therefore IPR-infringing vaccines that Versania is obligated to seize and destroy.

A. The Panel has no jurisdiction to hear this claim

[65] Ministerial Decisions are not 'covered agreements' under DSU Art. 1.1 because they are not listed under Appendix 1 to the DSU. The 'covered agreements' include the WTO Agreement, the Agreements in Annexes 1 and 2, as well as Plurilateral Trade Agreements in

[63] ABR, EC–Asbestos, [8.236].

Annex 4 where its Committee of signatories has taken a decision to apply the DSU.[64] Declining to exercise jurisdiction of a non-covered agreement is consistent with previous Panel findings.[65]

1. Waivers must be interpreted with 'great care'

[66] Waivers are granted only in "exceptional circumstances" and its terms and conditions must be interpreted narrowly and with great care.[66] This is also affirmed by the history of waiver-making powers between the Contracting Parties of GATT under Art. XXV and the stricter voting requirements under the WTO Agreement Art. IX:3.[67] Furthermore, waivers are closely regulated and subject to the procedures of Art. IX:4 of the WTO Agreement.

[67] Para. 7 of the 2022 Ministerial Decision precludes Members from challenging 'any measures taken in conformity with this Decision' under GATT Arts. XXIII:1(b) and (c) and does not contain a separate dispute settlement provision unlike a number of other waivers granted under WTO Art. IX:3. As Para. 7 of the 2022 Ministerial Decision *explicitly* leaves out recourse to GATT Art. XXIII:1(a), the Panel should reject the prohibition GATT Art. XXIII:1(b) and (c) as *reading in* a provision that is not stated in the waiver text itself: the availability of GATT Art. XXIII:1(a).[68]

[68] Lastly, Para. 3(c) states the 'legal means' are those already available under the TRIPS Agreement. As waivers cannot add to or amend the obligations under the covered agreements.[69] While Versania meets the waiver's terms and conditions, Para. 3(c) does not contain a legally-binding obligation. The Complainant may argue that the *Understanding in Respect of GATT Waivers* may apply to TRIPS Waivers but the Panel should reject this view as other WTO agreement waivers have *expressly* integrated GATT dispute settlement provisions.[70]

2. Arion's rights and obligations are not diminished under DSU Art. 3.2

[69] The Panel declining jurisdiction does not diminish the rights of Arion under DSU Art. 3.2 because the Claim does not concern the rights and obligations provided in the *covered agreements*. Once more, waivers cannot modify existing provisions in the agreements, let alone create new law or add to or amend the obligations under a covered agreement or schedule.[71] Therefore, GATT Art.XXIII:1(a)(b) or (c) does not apply and Arion has no basis to challenge Versania's measures.

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[64] ABR, Brazil–Desiccated Coconut, page 13.
[65] PR, EC and certain member States–Large Civil Aircraft, [7.89].
[66] ABR, EC–Bananas III, [184-187]; PR, US–Sugar Waiver, [5.9].
[67] Feichtner, 61.
[68] ABR, EC–Bananas III, [183].
[69] ABR, EC–Bananas III, [381-382].
[70] Kimberly Waiver, WT/L/518; Cape Verde Decision of 3 May 2011, WT/L/812, [4]; Albania Decision of 17 May 2004, WT/L/567, [3];
[71] ABR, EC–Bananas III, [381-382].

B. If the Panel does exercise jurisdiction, Versania's actions are still in accordance with Para. 3(c) of the Decision

[70] Para. 3(c) of the Decision requires Members to have 'effective legal means' available to prevent the importation, sale, and inconsistent diversion of products manufactured under the authorization in accordance with the Decision to their territories and markets. Versania meets its obligation by having effective legal means available under its customs laws to prevent such inconsistent diversions while maintaining the internationally-agreed minimum standard of IP protection required under the TRIPS Agreement. Versania's seizure is consistent with its obligation under Para. 3(c) because the vaccines were produced under an authorization not in accordance with the Decision and the vaccines were not "necessary to address the COVID-19 pandemic."[72]

[71] By June, 2022, Arion and Boutica had purchased enough Zancovac to provide two primary vaccine doses to their populations, with an additional dose for immunocompromised persons. Using the authorization of the Decision allowed ANCOP to freeload off Zanos' innovations without developing its own vaccine candidate to participate in the market fairly. The decision to provide booster doses every six months was based on a study that found such a campaign would "completely eliminate the risk of asymptomatic and mildly symptomatic cases."[73] The same study found that two doses of Zancovac with an additional dose for immunocompromised persons reduces risk of severe disease by 95%. Completely eliminating the risk of asymptomatic and mildly symptomatic cases in a population that has been doubly vaccinated is not "necessary" as compared to the reduction of severe disease to address the pandemic. For this reason, the vaccines produced under the authorization of Executive Order 46/22 are not in accordance with the Decision and therefore infringe the patent held by Zanos.

1. The ANCOP vaccines were not manufactured under the authorization in accordance with the Decision

[72] If the Panel finds it has jurisdiction to hear claims of a violation to the 2022 Ministerial Decision, Versania acted consistently with its obligation under Para. 3(c) of the Decision in seizing the vaccines in transit from Arion to Boutica because the vaccines were produced under an authorization that was not in accordance with the Decision. Importing products produced not in accordance with the conditions of the Decision to be destroyed serves the purpose of the TRIPS Agreement and is consistent with the obligation under Para. 3(c).

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[72] 2022 Ministerial Decision, [1].
[73] Case, [7].

[73] Under Para. 2 of the Decision, "an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the laws of the Member." Arion authorized the use of the process patented by Zanos under Executive Order 46/22. This authorization was not in accordance with the Decision because it is not in accordance with Paras. 1 and 3(b) of the Decision.

2. Commercial sale of the ANCOP vaccines to Boutica is not "necessary to address the COVID-19 pandemic"

[74] Para. 1 of the Decision allows members to authorize the use of process patents to produce COVID-19 vaccines only "to the extent necessary to address the COVID-19 pandemic." Arion's production of vaccines for commercial sale is beyond what is "necessary" under the terms and conditions of the Decision.

[75] While "necessary" is not defined in the Decision, "necessity" in WTO jurisprudence generally considers whether a measure is truly necessary to meet its objective or if there is another reasonable alternative available.[74] Based on a similar frame of analysis, commercial sale of the ANCOP vaccines for booster doses to Boutica is neither necessary to meet the objective of the 2022 Ministerial Decision nor Boutica's only option to access booster doses.

[76] The objective of the Decision is to ensure that developing countries receive adequate access of COVID-19 vaccines to address the most acute effects of the virus by providing their populations with sufficient vaccination. Booster doses do not fall within this objective as countries that have already had primary doses have sufficient levels of vaccination. Arion's own study found that the two primary doses of the Zancovac COVID-19 vaccine, with a third booster shot for immuno-compromised populations, reduced risk of severe disease by 95%.[75] Further, the WHO has said that the focus of COVID-19 vaccination should be on primary doses as opposed to boosters because true equity issues remain in facilitating access to COVID-19 vaccines in developing countries.[76] Therefore, commercial sale to Boutica for booster doses is not truly necessary to address the COVID-19 pandemic.

[77] Purchasing booster doses of Zancovac was also a reasonable alternative for Boutica to procure more doses. Prior to the sale of the ANCOP vaccines, the Government of Boutica had imported enough Zancovac to administer two doses to its entire population and to provide an additional booster dose to immunocompromised persons, demonstrating that Boutica has the financial means to supply its population with sufficient doses at USD $22.5 per dose price

[74] Du, The Necessity Test in World Trade Law, 818.
[75] Case, [7].
[76] Lacobucci, Covid-19: Focus should be on new vaccines rather than boosters, 376.

point. In addition, Zanos has the capacity to produce 250,000,000 booster doses each month. Therefore, while ANCOP's USD $7 decrease in price point per dose may be fiscally convenient for Boutica, it is not "necessary to address the COVID-19 pandemic."

3. Under Para. 3(b) of the 2022 Ministerial Decision, exportation is limited to vaccines traded 'in accordance with' the Decision

[78] Under Para. 3(b) of the Decision, an Eligible Member may allows products "manufactured under the authorization in accordance with this Decision to be exported to eligible Members." This limits exportation under this compulsory license system to vaccines produced in accordance with the Decision. Further, Para. 3(b) notes allowances for "international and regional joint initiatives" to enable such exports. As waivers should be read narrowly and with great care, the Panel should find that commercial transactions absent state administration is not within the scope of the waiver in Para. 3(b). Due to the lack of procedural safeguards in the compulsory license system pursuant to the Decision as compared to those available under Arts. 31 and 31bis of the TRIPS Agreement, vaccines may be produced under an authorization that is not in accordance with the Decision for exportation to another eligible Member, requiring the Decision be read with great care to avoid abuse.

[79] Where vaccines produced under an authorization that is not in accordance with the Decision are exported to an eligible Member, they become patent-infringing goods because only vaccines produced in accordance with the Decision may be exported under Para. 3(b).

[80] Under Para. 3(c), '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'. The obligation to prevent importation only applies to vaccines produced under an authorization in accordance with the Decision. Importing vaccines produced under an authorization that is not in accordance with the Decision is therefore consistent with this obligation, because no importation of products manufactured under an authorization in accordance with the Decision has occurred.

C. Versania's importation of the ANCOP vaccines was consistent with both the 2022 Ministerial Decision and the TRIPS Agreement

[81] As outlined above, the ANCOP vaccines were not "necessary to address the COVID-19 pandemic". Therefore, they were not in accordance with the Decision and were IPR infringing goods, allowing Versania to act in accordance with its obligations under the TRIPS Agreement. As such, Versania's importation fulfilled the purpose of the TRIPS Agreement and was consistent with the obligation under Para. 3(c) of the 2022 Ministerial Decision.

REQUEST FOR FINDINGS

For the above-mentioned reasons, Versania respectfully requests the Panel to reject Arion's claims and find that:

I. Versania lawfully seized and destroyed the vaccines in accordance with TRIPS Arts. 41.1, 51 and 52.

II. Due to Arion's trade in IPR infringing goods and their failure to comply with Versania's customs laws, Versania did not violate GATT Art. V:2. Alternatively, if a violation is found it is justifiable under Art. XX(d).

III. The Panel lacks jurisdiction to hear a claim pertaining to the terms and conditions of the 2022 Ministerial Decision. Alternatively, if jurisdiction is granted, Versania acted in accordance with Para. 3(c) of the 2022 Decision.