

THE
JOHN H. JACKSON
MOOT COURT COMPETITION



The European Law Students' Association

CASE

**VERSANIA-SEIZURE OF VACCINES
IN TRANSIT FROM ARION**

**THE JOHN H. JACKSON
MOOT COURT COMPETITION**

2022/2023
21st Edition

TECHNICAL SUPPORTER



**WORLD TRADE
ORGANIZATION**

Versania-seizure of Vaccines in Transit

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Background

1. Versania and Arion are neighbouring countries and founding members of the World Trade Organization (WTO). Arion, which designates itself as a developing country within the WTO, is a land-locked, lower-middle income country (as per the World Bank classification) with Gross National Income (GNI) per capita of USD 4,000 in 2021-2022. Arion is known for its large pharmaceutical industry, a significant portion of which has traditionally comprised low-cost generic versions of international branded small-molecule drugs. It is a major exporter of pharmaceuticals, accounting for 25 percent of total global pharmaceutical exports in volume. It exports predominantly to least-developed countries (LDCs) and smaller developing countries. Over the past ten years, Arion has also been seeking to develop vaccine manufacturing capacity within its domestic pharmaceutical industry, to develop affordable bio-similar versions of branded vaccines, as well as novel vaccines for tropical and neglected diseases.
2. Arion is bordered by Versania, a large, high-income country, with the second highest Gross Domestic Product (GDP) globally. Versania hosts the headquarters of several large pharmaceutical companies. Its pharmaceutical industry is key to its economy, accounting for 5% of its GDP. In contrast to Arion, however, Versania largely produces high-priced, novel, small-molecular medication and vaccines. Versania boasts a long coastline of around 7,000 km. Arion being a land-locked country, with a tall chain of mountains straddling its southern borders, is heavily dependent on Versania for its seaports, with the latter providing the only convenient access for Arion to the high seas (see map in Annex I). Due to significant volumes of export and lower cost of sea freight, it is only economically feasible for Arion to export its pharmaceutical products to its major destinations by sea, relying on Versania's ports.
3. In March 2020, as cases of the novel coronavirus disease 2019 (COVID-19) spread around the world, the World Health Organisation (WHO) declared it to be a pandemic. As the death tolls around the world continued to rise, the WHO emphasised the role of vaccines in fighting the pandemic, recognising "*the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the*

pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available."¹

4. As in many other countries, Arion's and Versania's pharmaceutical industries both entered the race to develop vaccines to protect against the novel coronavirus. Versania's pharmaceutical industry, with more established vaccine research and development capacity, and with substantial investments from the Government of Versania, was able to develop a vaccine faster than Arion. In November 2020, Zanos, a leading pharmaceutical company in Versania, filed applications for both process and product patents for its vaccine candidate 'Zancovac' in Versania, as well as in Arion and many other countries. Over the next couple of months, Zancovac cleared clinical trials and subsequently received marketing approval in Versania as well as several other countries, including Arion. It was made available for global sale to governments around the world, at USD 22.5 per dose.
5. 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.
6. Against the backdrop of the COVID-19 pandemic, the Government of Arion publicly emphasised that the most pressing need was to invest in public health, and that access to vaccines was a key priority in fighting the pandemic. It accordingly diverted funds from its disaster-mitigation budget, using that money to import COVID-19 vaccines as well as to invest in its domestic pharmaceutical industry. In January 2021, Arion entered into a purchase agreement with Zanos for supply of sufficient doses of Zancovac to vaccinate its entire population, including booster shots for the immunocompromised population, at USD 22.5 per dose. As a result of an intense vaccination campaign combined with stringent testing and isolation measures, by March 2022, COVID-19 infection levels in Arion had been reduced significantly and have continued to drop since.
7. In June 2022, a study commissioned jointly by the government of Arion and ANCOP Ltd. - a major pharmaceutical company in Arion - showed 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%. In order to completely eliminate the risk of asymptomatic and mildly symptomatic cases, the study concluded that periodic booster shots would be needed every six months for the entire population.

¹ WHO, SEVENTY-THIRD WORLD HEALTH ASSEMBLY, Agenda Item 3, COVID-19 response, WHA73.1 19 May 2020.

8. Based on the study, the Government of Arion released a statement noting 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. Two days after the study was published, ANCOP announced its imminent plans to start producing COVID-19 vaccines. The study as well as the announcements by the Government of Arion and ANCOP garnered significant attention both domestically and internationally.
9. The decision by the Government of Arion to turn over the distribution and sale of COVID-19 vaccines to commercial channels was noted with interest in the Republic of Boutica. Boutica is an upper-middle income WTO member, which also designates itself as a developing country at the WTO. It is located 3,000 kilometres from Arion and, for historical reasons, shares close cultural ties with Arion. Much like in Arion, the government of Boutica managed to import a sufficient supply of Zancovac's COVID-19 vaccines (also patented in Boutica) to provide two primary doses to its entire population and an additional booster shot for the immunocompromised population. The Government of Boutica also announced that, to promote additional access, COVID-19 vaccines would soon be made available for purchase through commercial channels. After this announcement by the Government of Boutica, a number of private pharmaceutical distributors in Boutica entered into talks with both ANCOP and Zanos for private purchase of COVID-19 booster doses.
10. Although ANCOP had yet to start producing vaccines, it promised various distributors in Boutica to deliver COVID-19 vaccine doses at USD 15.5 per dose. Since this was USD 7 cheaper per dose when compared to the price offered by Zanos, many private pharmaceutical distributors in Boutica expressed interest in entering into advance purchase agreements with ANCOP, pending clinical trials and market authorisation.
11. On 10 July 2022, pursuant to paragraph 1 of the 2022 WTO Ministerial Decision on the TRIPS Agreement, Arion passed Executive Order 46/22 (see Annex II) authorising ANCOP to start production and sale of COVID-19 vaccines using the process patented by Zanos. The order authorised production of 4,000,000 doses for domestic sale within Arion, and further production of 3,000,000 doses for export to Boutica. On 20 July 2022, 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 Boutica and Arion subsequently notified their respective executive orders to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), pursuant to paragraph 5 of the 2022 WTO Ministerial Decision on the TRIPS Agreement.

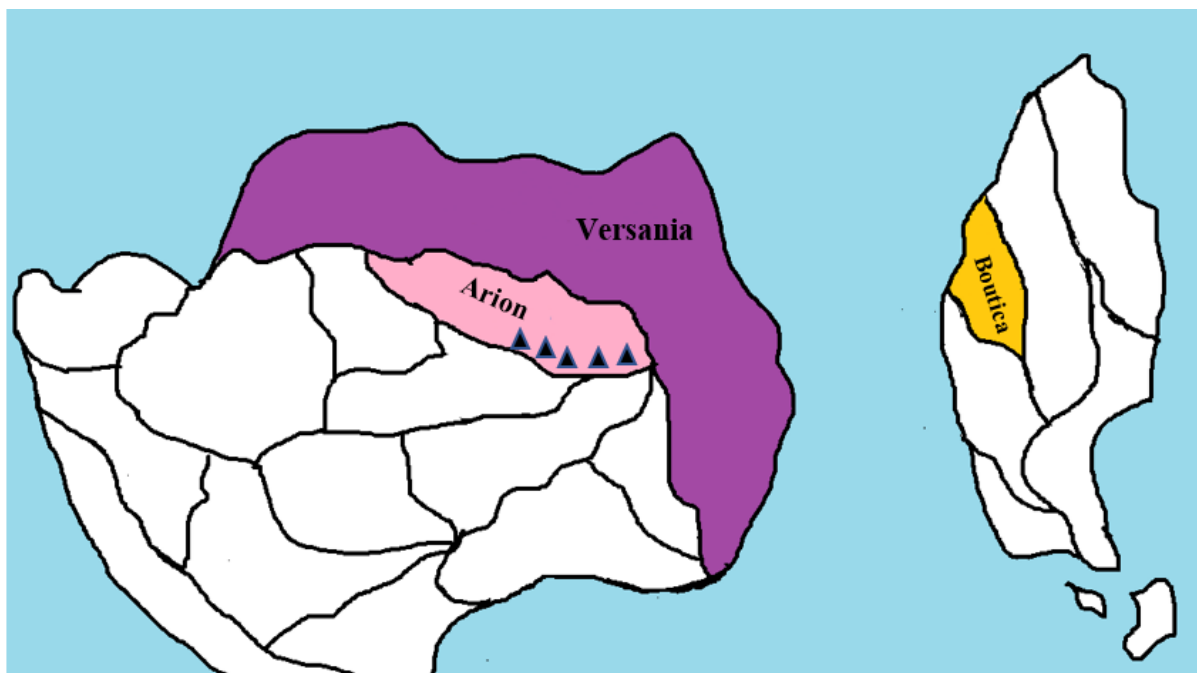
12. Under the authorisation from Executive Order 46/22, ANCOP started the manufacture of vaccines using the process patented by Zanos. It quickly cleared clinical trials and received market authorisation in both Arion and Boutica. Given Arion and Boutica's location (see map in Annex I), and the large volumes of doses to be exported to Boutica, ANCOP decided to ship the vaccine doses to Boutica through Versania's sea ports.
13. However, Zanos expressed concern to the Versanian Ministry of Trade and Industry that the production of ANCOP's vaccines improperly infringed on the patents that it held in Versania as well as in Arion and Boutica for the process of producing Zancovac. Subsequently, the Versanian Minister of Trade issued a press release, stating, "*We are deeply concerned seeing the misuse of the 2022 WTO Ministerial Decision on the TRIPS Agreement for commercial, profit-making reasons. We believe that the aforementioned decision was only intended to facilitate access to COVID-19 vaccines to the extent necessary to address the COVID-19 pandemic, and cannot be used to justify mass sales of patent-infringing booster vaccines on a commercial scale in countries which have already provided the requisite primary vaccines doses to their populations.*"
14. Concerned with ANCOP's imminent sales to Boutica, Zanos filed an application with the IP Commissioner in Versania, alleging that ANCOP's production of COVID-19 vaccines infringed the exclusive rights associated with its patent under Section 48 of the Versanian Code on Intellectual Property Protection, 1995 (see Annex III for relevant provisions of the Versanian Code on Intellectual Property Protection, 1995). Zanos' application further requested that border measures be implemented against any consignment of infringing goods, specifically asking for the seizure and destruction of the infringing goods. After a hearing, the Intellectual Property Board accepted Zanos' application and issued a decision authorising the Versanian Customs Office at the border with Arion to seize and destroy all shipments of ANCOP's vaccines in transit from Arion to Boutica through Versania.
15. In August, ANCOP started sending shipments of its COVID-19 vaccines from its factory in Arion to Boutica through Versania. However, on 15 August, 2022, Versanian Customs Office at the border with Arion, acting pursuant to the Decision of the Intellectual Property Board and under Section 75 of Versania Customs Act, 2006 (see Annex III for relevant provisions of Versania Customs Act, 2006), confiscated several shipments of ANCOP'S COVID-19 vaccines en route to Boutica. These shipments were destroyed by the customs authorities after 15 days.
16. Versania's actions were met with uproar and condemnation from both Arion and Boutica. The Minister of Health from Arion, speaking at a press conference, stated, "*We note with horror the actions of our neighbouring country in destroying shipments of COVID-19 vaccines being sent*

from Arion to Boutica. These vaccines were produced in Arion pursuant to the much-publicised 2022 WTO Ministerial Decision on the TRIPS Agreement in order to increase access to COVID-19 vaccines not just in Arion but also other countries, such as Boutica. Versania's actions go against the very object and purpose of the Ministerial Decision, which was a hard-fought victory necessary to ensure equitable access to COVID-19 vaccines."

17. Troubled by Versania's actions, Arion requested consultations 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 with the government of Versania, with respect to the destruction of the shipments of ANCOP's vaccines in transit from Arion to Boutica via Versania. Arion's representative stated that Versania's actions violated Versania's obligation under the GATT to ensure freedom of transit through its territory. The representative further argued that these measures create barriers to 'legitimate trade' in vaccines, as the vaccines were produced under the 2022 Ministerial Decision on the TRIPS Agreement. Finally, under the 2022 Ministerial Decision on the TRIPS Agreement, Versania has an obligation not to divert COVID-19 vaccines meant for Boutica into its own jurisdiction.
18. In response, Versania's representative claimed that Versania has the right to adopt enforcement procedures against goods infringing intellectual property rights within its territory, including those imported into its territory for purposes of transit. Furthermore, although the representative did not contest that both Arion and Boutica are eligible countries within the meaning of the 2022 Ministerial Decision on the TRIPS Agreement, she argued that the production of vaccines for commercial sale beyond what is necessary to address the COVID-19 pandemic is not covered by the terms of the Ministerial Decision. Finally, Versania's representative argued that Versania's interference with the freedom of transit was only necessary due to Arion's "*failure to comply with applicable customs laws and regulations*", and, in any case, she noted that Versania's enforcement measures could be justified under the General Exceptions clause of the GATT.
19. Both Versania and Arion considered the consultations to be unsuccessful, and consequently, Arion submitted a request for the establishment of a panel to the Dispute Settlement Body (DSB) pursuant to Articles 4.7 and 6 of the DSU, Article XXIII of the GATT and Article 64.1 of the TRIPS Agreement. The request for the establishment of a panel contained the following claims:
 - I. Versania's seizure of vaccines in transit from Arion to Boutica violates Articles 41.1, 51 and 52 of the TRIPS Agreement.

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- 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.

Annex I



Annex II

Executive Order 46/22

The Minister of Health

Recognising the grave risk to public health posed by the COVID-19 pandemic, including the potential risk of repeated waves of the pandemic,

Recognising also that periodic vaccination against COVID-19 is necessary to ensure optimal protection from COVID-19 and a reduced risk of further outbreaks of the disease,

Exercising the powers under the Laws and Constitution of Arion,

Based on the rights and obligations established by the 1995 WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), the 2001 WTO Declaration on the TRIPS Agreement and Public Health as well as the 2022 WTO Ministerial Decision on the TRIPS Agreement,

Pursuant to paragraph 1 of the 2022 WTO Ministerial Decision on the TRIPS Agreement, which allows eligible Members, including Arion, to authorise “*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*”²,

Recalling Article 8 of the TRIPS Agreement which recognises Members’ right to protect public health,

Recalling also paragraph 4 of the 2001 WTO Declaration on the TRIPS Agreement and Public Health which affirms that the TRIPS Agreement “*does not and should not prevent members from taking measures to protect public health ... accordingly ... can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.*”³

1. Hereby authorizes ANCOP Ltd., whose postal address is

77 Ruks Lane
Artinz

² WTO Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022 (WT/MIN(22)/30 WT/L/1141), paragraph 1.

³ WTO Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 (WT/MIN(01)/DEC/2), paragraph 4.

010124 Arion,

to use patented inventions identified in patent numbers 2,071,988 , 2,876,450 and 2,623,230 solely for purposes directly related to the development, production, manufacture and sale, including for export, of COVID-19 vaccines.

2. The quantity of the vaccines authorized to be manufactured by this authorization is 7,000,000 doses, of which:
 - a) 4,000,000 doses shall be for domestic sale within Arion.
 - b) 3,000,000 doses shall be for export to Boutica.
3. This authorization is valid for a period of one year, beginning on the date shown below.

Done in Artinz on 10 July, 2022

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Minister of Health

Annex III

Versanian Code on Intellectual Property Protection, 1995

Chapter III

Patents

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Section 48: Exclusive Rights Conferred by a Patent

A holder of a patent registered in the territory of Versania shall have the exclusive right,

1. where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
2. where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

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Section 54: Application to goods in transit

A holder of a patent registered in the territory of Versania shall be entitled to prevent all third parties from bringing goods, in the course of trade, into the territory of Versania without being released for free circulation there, where such goods infringe upon the exclusive rights conferred upon the patent holder under Section 48.

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Chapter VII

Enforcement

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Section 61: Border measures

1. 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 transshipment to another country of final destination, shall be prohibited.
2. A right-holder shall be entitled to make an application to the Intellectual Property Board to authorize the Customs Authorities to enforce this prohibition as effectively as possible, including through seizure, detention, destruction or disposal of the infringing goods. In making such an application, the right-holder 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.

3. In considering such requests, the Intellectual Property Board shall 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.
4. A decision granting the right-holder's application for action shall immediately be forwarded to the relevant Customs office likely to be concerned by the goods alleged in the application to infringe an intellectual property right.

Versania Customs Act, 2006

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 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.

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