



The European Law Students' Association



Team: 039 R

ELSA MOOT COURT COMPETITION ON WTO LAW

2006/2007

FACTORIL – COMPULSORY LICENSING OF PHARMACEUTICAL PATENT

COSTO

(Complainant)

vs

FACTORIL

(Respondent)

SUBMISSION FOR RESPONDENT

Table of Contents

Table of Contents	I
List of References	III
I. Conventions and Treaties.....	III
II. WTO Reports.....	III
1. Panel Reports.....	III
2. Appellate Body Reports.....	IV
III. GATT Reports	V
IV. Other Cases.....	VI
1. Permanent Court of International Justice	VI
2. International Court of Justice.....	VI
3. International Arbitrations	VI
4. Other Cases	VI
V. WTO Documents	VI
VI. Treatises and Works of Publicists	VII
VII. Domestic Legislation.....	VII
VIII. Contributions, Articles and Other Materials	VIII
List of Abbreviations	X
Summary of Arguments.....	1
Statement of Facts	3
Arguments	4
1: The Panel does not have the jurisdiction to hear this matter due to FTA art 21.....	4
1.1: Jurisdiction is removed by 'legal impediments': <i>Mexico – Soft Drinks</i>	4
1.2: FTA art 21 prevents Costo from seeking redress before this Panel.....	4
1.2.1: The FTA has altered the obligations between Factoril and Costo.....	4
1.2.2: The Panel has no jurisdiction to hear this claim due to the operation of FTA art 21	5
1.3: There is a legal impediment to the Panel's jurisdiction as this matter is <i>res judicata</i>	6
1.3.1: Res judicata is a procedural rule of international law that can apply in the WTO.6	6
1.3.2: The requirements of res judicata are made out in the current matter	7
1.4: Costo is prevented from bringing this claim by the requirements of good faith	8
1.4.1: Costo is estopped (or precluded) by its conduct from bringing this complaint	8
1.4.2: It is an abuse of rights for Costo to bring this complaint.....	8

2: Factoril's Licence B is compliant with TRIPS by operation of art 31	9
2.1: Factoril relies on the exception to art 28.1(a) set out in art 31	9
2.2: The notification requirement in art 31(b) is waived due to a national emergency	9
2.2.1: Factoril relies on Distria's national emergency or circumstance of extreme urgency	9
2.2.2: The Declaration contains an authoritative interpretation of art 31(b)	10
2.2.3: Article 31(b) permits any Member to determine that the authorization requirement is waived	11
2.2.4: The Amblo Virus is a national emergency or other circumstance of extreme urgency	11
2.3: Factoril's art 31(f) 'domestic supply' obligations are waived by the Decision	12
2.3.1: The waiver of article 31(f) and the Decision as a whole is legally binding on Members	12
2.3.2: Distria's determination of insufficient manufacturing capacity is adequate.....	12
2.3.3: The General Council Chairman's Statement is not legally binding	13
2.3.4: Alternatively, Costo has violated the understandings in the Chairman's Statement	14
2.3.5: No further measures need to be taken to prevent trade diversion	14
3: Factoril's Licence C is compliant with TRIPS.....	15
3.1: Licence C falls within TRIPS art 30	16
3.2: Licence C is a limited exception.....	16
3.3: Licence C does not unreasonably conflict with the normal exploitation of the patent	16
3.3.1: Licence C does not conflict with the normal exploitation of the patent	16
3.3.2: If there is a conflict with normal exploitation of the patent it is not unreasonable	17
3.3.3: Legitimate interests of third parties.....	17
3.3.4: Licence C does not unreasonably prejudice Costo Inc's legitimate interests	17
3.4: Licence C falls within TRIPS art 31	18
3.4.1: The conditions of waiver for art 31(b) have been met.....	18
3.4.2: Factoril relies on the Decision waiving art 31(f).....	18
3.4.3: Costo Inc is being paid adequate remuneration under TRIPS art 31(h).....	19
Request for Findings.....	20

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3. *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1C (*Agreement on Trade-Related Aspects of Intellectual Property Rights*) 1869 UNTS 299.
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North Sea Continental Shelf (West Germany v Denmark) (Merits) [1969] ICJ Rep 3 ('North Sea Continental Shelf').

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List of Abbreviations

Chairman's Statement	Statement made by the Chairman of the General Council prior to the Council's agreement to the Decision
Chairman's Statement-Annex I	<i>Minutes of Meeting Held in the Centre William Rappard on 25, 26 and 30 August 2003</i> , WTO Doc WT/GC/M/82 (2003) Annex 1 (Minutes of the General Council Meeting)
covered agreements	The Agreements listed in Annex 1 of the Understanding on Rules and Procedures Governing the Settlement of Disputes
Decision	Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003
Doha Declaration	Declaration on the TRIPS Agreement and Public Health (2001)
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
FTA	Costo-Factoril Free Trade Agreement
GATT 1994	General Agreement on Tariffs and Trade 1994
LDC	Least-developed country
Marrakesh Agreement	Marrakesh Agreement Establishing the World Trade Organization
Multilateral Trade Agreements	The Agreements and associated legal instruments included in Annexes 1, 2 and 3 to the Marrakesh Agreement Establishing the World Trade Organization
NAFTA	North American Free Trade Agreement
Philippines' Statement	Statement made by the Representative for the Philippines at Council for TRIPS meeting held in the Centre William Rappard on 28 August 2003
TRIPS / TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WTO Agreements	The Marrakesh Agreement and the documents contained in its four annexes

Summary of Arguments

Jurisdiction

There is a legal impediment to the Panel's jurisdiction to hear this complaint, by virtue of FTA art 21 or by virtue of the FTA Tribunal already having heard Costo's complaint.

- The FTA operates to alter the obligations between Factoril and Costo such that Costo cannot now bring this claim before the Panel. The mutually agreed modifications satisfy the requirements of the VCLT and should be applied by this Panel.
- The Panel lacks jurisdiction to hear this matter because it is *res judicata*. This doctrine (necessary to ensure finality in litigation) should apply in the WTO dispute settlement system to decisions from other fora, and is substantively made out on the facts of this case.
- Costo is estopped (or precluded) from asserting the jurisdiction of the Panel. Costo represented in FTA art 21 that, if it had a claim that could be brought before both the FTA Tribunal and the WTO Panel, it would only bring a claim before *one* forum. Therefore, Costo is now prevented from bringing the current claim by the good faith requirement of DSU art 3.10. Estoppel (or preclusion) is imported into the WTO system by this requirement. Alternatively, the good faith requirement in DSU art 3.10 precludes an abusive exercise of rights. By bringing the present claim, Costo is using one set of rights – its rights under the DSU – to derogate from another set of rights – Factoril's rights under the FTA. This amounts to an abuse of rights.

Licence B

Licence B is compliant with TRIPS as it falls within art 31.

- Art 31(b) is waived due to the threat of the Amblo Virus in Distria. The Panel should not review Distria's decision that this constitutes a national emergency or circumstance of extreme urgency.
- Objectively assessed, Distria has a factual basis for declaring a national emergency or circumstance of extreme urgency. The Amblo Virus is a grave threat to public health and requires urgent measures to be taken, such as stockpiling M63.

- The Decision waives the TRIPS art 31(f) domestic use requirement. All of the relevant conditions have been met including paras 1(b), 2(a)(ii) and 4 of the Decision. A national emergency exists, Distria has confirmed that it has insufficient manufacturing capacity, and adequate measures have been taken to prevent trade diversion given Distria's limited resources and the low risk of such diversion occurring.

Licence C

Although Licence C is inconsistent with Costo Inc's rights pursuant to TRIPS art 28.1(a), it falls within the exception in TRIPS art 30.

- Licence C is limited as it only narrowly curtails Costo Inc's patent rights. Licence C is limited to a period of twelve months and to the manufacture of 1 million units of M63. Licence C is only being issued in response to the Amblo Virus posing a significant threat to public health in Listria, which is an LDC.
- Licence C does not conflict with Costo Inc's normal exploitation of its M63 patent. Given that Listria is an LDC, Costo Inc would not have anticipated making any significant profit from the sale of M63 to Listria. Furthermore, any profit made from selling M63 to Listria is not derived from exploitation of the patent as M63 is not patented in Listria.
- Even if Licence C does conflict with the normal exploitation of the patent, any conflict is reasonable given the public health interest of ensuring Listria has access to affordable M63.
- Licence C does not unreasonably prejudice the legitimate interests of Costo Inc taking into account the public health interest outlined above.

Alternatively, Licence C falls within the exception in TRIPS art 31.

- Article 31(b) is waived because the threat of the Amblo Virus in Listria is a national emergency or circumstance of extreme urgency.
- The Decision waives TRIPS art 31(f). Subsequent practice by Members demonstrates that the Decision allows export to non-Member LDCs. In accordance with para 4 of the Decision the M63 has been coloured pink to prevent trade diversion.
- Taking into account that Listria is an LDC facing a national emergency, Costo Inc is receiving adequate remuneration that is proportionate to the value of M63 in Listria.

Statement of Facts

1. The Amblo Virus is an infectious and as yet incurable pathogen that is carried by common household pets. Transmission of the virus requires mere contact with animal fur and infection is fatal within days. Although scientists are unsure whether the virus can be spread between humans, it has already been detected in animals in at least two countries, Distria and Listria, presenting an imminent risk of human infection and fatality.
2. M63 is a drug that can extend the life expectancy of Amblo Virus victims by up to 15 years. It is currently protected by patent in most countries, which prevents unauthorised manufacturers from producing cheaper generic versions. Distria and Listria wish urgently to obtain a necessary amount of M63 in order to protect public health, however they have insufficient manufacturing capacity to produce enough M63 domestically.
3. Factoril is a developing WTO Member that has compulsorily licensed M63 in order to meet Distria and Listria's demand at an appropriate price for their markets. Factoril and Distria, as WTO Members, notified the Council for TRIPS of their intentions to use compulsory licences in accordance with TRIPS art 31 and the Decision. Listria was not required to do so as it is not a WTO Member. Under Licence B, Factoril has granted Factoril Inc (a company incorporated in Factoril) the right to make and export 5 million units of pink M63 to Distria while paying a 3% royalty to Costo Inc (a company incorporated in Costo), which holds the M63 patent. M63 is usually green. Factoril has also granted Factoril Inc Licence C, allowing the export of an additional 1 million units of pink M63 to Listria paying a 1.5% royalty. Factoril Inc sells M63 at 30% of market price to Distria and 15% of market price to Listria.
4. Factoril and Costo are parties to a bilateral FTA. FTA art 5 governs the issue of compulsory licences. FTA art 21 requires parties to elect between bringing a claim under the FTA and the WTO, in circumstances that potentially give rise to a dispute under both regimes. Complainants may not pursue remedies under both systems, simultaneously or sequentially. Costo brought a complaint before the FTA Tribunal concerning Licences B and C, whereupon the Tribunal held that Factoril was not in violation of the FTA. Despite this obligation, Costo has brought the current complaint before a WTO Panel.

Arguments

1: The Panel does not have the jurisdiction to hear this matter due to FTA art 21

1.1: Jurisdiction is removed by 'legal impediments': *Mexico – Soft Drinks*

1. Costo is clearly in violation of its agreement not to bring any dispute heard by an FTA Tribunal to a WTO Panel. Costo is bringing its dispute before another forum in an attempt to receive a favourable outcome after the FTA Tribunal decided against it. Such forum shopping severely compromises the objects of the DSU. Articles 3.2 and 3.3 set out the objects as being to promote 'security and predictability [of] the multilateral trading system' through the 'prompt settlement' of disputes.

2. The issue of Terms of Reference generally constitutes a dispute properly before a WTO Panel,¹ and a Panel has no inherent discretion to decline jurisdiction once it is validly established.² *Mexico – Soft Drinks* reaffirmed, however, that Panels have 'the right to determine whether they have jurisdiction in a given case, as well as to determine the scope of their jurisdiction.'³

3. *Mexico – Soft Drinks* plainly contemplated that 'legal impediments' may remove jurisdiction and that these would be rules of international law, such as clauses in bilateral agreements or determination by other international adjudicative bodies of the same dispute.⁴ Factoril submits that legal impediments that remove the jurisdiction of the Panel exist in the present case; namely, FTA art 21, the doctrine of *res judicata* and the principles of good faith.

1.2: FTA art 21 prevents Costo from seeking redress before this Panel

1.2.1: *The FTA has altered the obligations between Factoril and Costo*

4. The operation of VCLT arts 30(3), 30(4)(a) and 30(5) is that where two states make a treaty, it prevails over an earlier treaty to the extent of any inconsistency, provided it complies with art 41. The obligations between Costo and Factoril under DSU art 23.1 have been modified by FTA art 21, such that a dispute may only be brought to the DSB if it has *not* been adjudicated by the FTA Tribunal. As FTA art 21 is not prohibited by the WTO Agreements, does not affect the

¹ Appellate Body, *Mexico – Soft Drinks*, [48]–[49]; Panel, *India – Autos*, [7.65].

² Appellate Body, *Mexico – Soft Drinks*, [53].

³ Appellate Body, *Mexico – Soft Drinks*, [45]; Appellate Body, *US – 1916 Act*, [54] n 30; Appellate Body, *Mexico – Corn Syrup (Article 21.5 – US)*, [53].

⁴ Appellate Body, *Mexico – Soft Drinks*, [54]. See, eg, Panel, *India – Autos*, [7.42].

enjoyment of rights by other parties and would not be incompatible with the object and purpose of the DSU, it is, in accordance with VCLT art 41(1)(b), a valid modification of the DSU. The FTA Tribunal has already heard this matter, thus FTA art 21 applies.

5. The DSU does not expressly prohibit modification of obligations between parties. DSU art 23.1 creates a right for parties to bring a dispute arising from a covered agreement to the WTO, but does not state that this right cannot be modified by parties *inter se*. DSU art 3.2 states that no recommendation of the DSB can diminish Members' rights and obligations under a covered agreement, but this does not prevent Members from voluntarily agreeing to alter their own rights. NAFTA had an exclusive jurisdiction clause in operation when the WTO Agreements were negotiated.⁵ Thus if the DSU was intended to prohibit the creation of exclusive jurisdiction clauses in regional agreements, it would explicitly have done so.

6. Factoril submits that the rights of third parties are not diminished by FTA art 21 in accordance with VCLT art 41(1)(b)(i). A third party can still bring a complaint against Factoril for violation of covered agreements, because the FTA binds only Costo and Factoril.

7. VCLT art 41(1)(b)(ii) requires that any modification of obligations under an agreement does not undermine its object and purpose. The DSU aims to further trade liberalisation by supporting the objectives of the covered agreements and strengthening the multilateral system.⁶ GATT 1994 art XXIV allows the formation of customs unions and free-trade areas, and recognises their importance.⁷ Factoril submits that autonomy to determine dispute settlement procedures within these agreements is critical to their formation and operation. Because these agreements are inexorably intertwined with, and sanctioned by, the covered agreements, dispute settlement procedures under regional agreements are not contrary to the purpose of the DSU.

1.2.2: The Panel has no jurisdiction to hear this claim due to the operation of FTA art 21

8. In WTO dispute settlement, international law applies to the extent that the WTO Agreements do not expressly 'contract out' of its operation.⁸ The DSU is silent on the consequence of *inter se* modifications, and this means that international law should be used to

⁵ NAFTA, art 2005.6.

⁶ DSU, art 23.

⁷ Mathis, 145.

⁸ Panel, *Korea – Government Procurement*, [7.96].

determine the effect of such modifications.⁹ As explained above, the FTA has validly modified Costo and Factoril's obligations under the DSU in accordance with VCLT arts 30 and 41. Factoril therefore submits that FTA art 21 should be applied in this case.

9. Giving effect to exclusive jurisdiction clauses within regional agreements has been entertained by the Appellate Body and Panels. *Mexico – Soft Drinks* stressed that the NAFTA exclusive jurisdiction clause may have impacted upon their decision if it had been invoked.¹⁰ In *Argentina – Poultry*, the Panel implied that the MERCOSUR exclusive jurisdiction clause created legal obligations between the parties, but as the dispute was initiated before the clause took effect, it was not applied.¹¹ If Panels refuse to apply these exclusive jurisdiction clauses, it would contribute to further fragmentation of international obligations, which decreases the stability and integrity of international dispute resolution.¹² Factoril thus submits that FTA art 21 is valid international law that should be applied, and that it creates a legal impediment to the jurisdiction of the Panel.

1.3: There is a legal impediment to the Panel's jurisdiction as this matter is *res judicata*

1.3.1: *Res judicata* is a procedural rule of international law that can apply in the WTO

10. *Mexico – Soft Drinks* contemplated that the Panel's jurisdiction may have been impeded if a NAFTA Panel had actually determined an element of the same dispute.¹³ In *India – Autos*, the Panel suggested that *res judicata* could apply to a complaint identical to one already brought before a Panel, although it was not required to determine this question.¹⁴ *Res judicata* concerns the 'competence of [an] adjudicatory body to address the issue submitted to it'.¹⁵ Factoril submits that if made out, it is a legal impediment to the jurisdiction of the DSB.

11. As outlined above at [8], WTO adjudicative bodies apply international law when the WTO Agreements are silent on an issue. Customary international law has been applied to determine

⁹ Bartels, 514–6; Pauwelyn, 1425.

¹⁰ Appellate Body, *Mexico – Soft Drinks*, [44].

¹¹ Panel, *Argentina – Poultry*, [7.38].

¹² Cassnovas, 229; Koskenniemi and Leino, 556.

¹³ Appellate Body, *Mexico – Soft Drinks*, [44].

¹⁴ Panel, *India – Autos*, [7.55], [7.57]–[7.58], [7.66], [7.103]. See also Appellate Body, *EC – Bed Linen*, [80]; Appellate Body, *US – Shrimp (Article 21.5)*, [92]–[93], [96].

¹⁵ Panel, *India – Autos*, [7.56] n 330.

‘procedural matters’.¹⁶ *Res judicata* is a procedural rule of international law.¹⁷ The DSU has no provision regulating the effect of a matter already having been heard.¹⁸ Factoril thus submits that the Panel should apply *res judicata*. It should make no difference whether the initial claim was brought in a WTO or non-WTO forum, because *res judicata* only operates where the legal claims are ‘essentially the same’.¹⁹

1.3.2: *The requirements of res judicata are made out in the current matter*

12. Factoril submits that this matter is *res judicata* because there has been a final decision between the same parties,²⁰ the specific measures at issue are identical, and the legal basis of the complaint is ‘sufficiently similar’.²¹ Here, the FTA Tribunal’s decision is final as no right of appeal exists. The parties and the measures at issue are identical in both claims.

13. The Panel must examine the specific provisions and determine whether the legal claims are ‘essentially the same’.²² Factoril submits that the obligations in FTA art 5 are substantially similar to those in TRIPS arts 28.1(a), 30 and 31. They are both concerned with the grant of compulsory licences and either party can issue such licences. FTA art 5 and TRIPS art 31(f) both require domestic use. Furthermore, the interpretation of FTA art 5 in the light of the Decision suggests that the obligations in FTA art 5 mirror TRIPS obligations.

14. There are subtle differences between these two agreements, such as the national emergency requirement in FTA art 5. TRIPS art 31(b) does not require a national emergency to issue a compulsory licence; it merely waives the notification requirement in cases of national emergency. *Southern Bluefin Tuna* held that it would be artificial to treat minor substantive differences between treaties as creating different legal bases for claims.²³ Therefore, Factoril submits that the elements of *res judicata* are present in this matter in spite of these small

¹⁶ Panel, *India – Autos*, [7.57]. See, eg, Appellate Body, *US – Shirts and Blouses*, [14] (burden of proof); Appellate Body, *EC – Bananas III*, [132]–[133] (standing).

¹⁷ *Maritime Delimitation*, 364; *Chorzów Factory*, 23; *Awards of Compensation*, 53.

¹⁸ Panel, *India – Autos*, [7.58].

¹⁹ Panel, *India – Autos*, [7.80].

²⁰ Panel, *India – Autos*, [7.62] n 335.

²¹ Panel, *India – Autos*, [7.60]; Appellate Body, *Guatemala – Cement*, [76]; Appellate Body, *US – Shrimp (21.5)*, [78]. See also *Chorzów Factory*, 23; *Trail Smelter Arbitration*, 1952.

²² Panel, *India – Autos*, [7.80].

²³ *Southern Bluefin Tuna*, [54]. See, also, *Glaziou v France*, [7.2]; *Trébutien v France*, [6.3].

distinctions, thereby creating a legal impediment to the jurisdiction of this Panel.

1.4: Costo is prevented from bringing this claim by the requirements of good faith

15. Article 3.10 of the DSU incorporates a ‘good faith’ requirement in the dispute settlement procedure. As the DSU is silent on the meaning of good faith, the content of this requirement must be found in international law.²⁴ Costo is not bringing this complaint in good faith, therefore DSU art 3.10 creates a legal impediment to the Panel’s jurisdiction.

1.4.1: Costo is estopped (or precluded) by its conduct from bringing this complaint

16. At international law estoppel (or preclusion) is grounded in ‘good faith’. The link between estoppel and good faith was accepted in *EC – Sugar*.²⁵ *EC – Sugar* noted that it is unclear whether estoppel applies in WTO dispute settlement, but did not expressly reject previous Panel Reports that implicitly accepted the application of the doctrine in WTO disputes.²⁶ On this basis Factoril submits that the doctrine of estoppel (or preclusion) applies in WTO dispute settlement.

17. Estoppel operates when a ‘party has been induced to act in reliance on the assurances of another party, in such a way that it would be prejudiced were the other party later to change its position.’²⁷ In agreeing to FTA art 21, Costo assured Factoril that it would not, in a situation such as this, bring a dispute before a WTO Panel.

18. For the purposes of estoppel, ‘prejudiced’ can mean either that a party has been disadvantaged or that the other party has been advantaged; the extent of the prejudice is immaterial.²⁸ When a representation or assurance is made through a treaty, the prejudicial reliance ‘lies in the reciprocal exchange of promises’.²⁹ Factoril submits that by agreeing to the FTA, it relied on Costo’s assurance that Costo would comply with its obligations thereunder. By resiling from that assurance, Costo is gaining the advantage of having its complaint reheard. Costo is therefore estopped from bringing this complaint to this Panel.

1.4.2: It is an abuse of rights for Costo to bring this complaint

19. The good faith requirement in DSU art 3.10 also incorporates the prohibition at

²⁴ Appellate Body, *US – Shrimp*, [158].

²⁵ Appellate Body, *EC – Sugar*, [307].

²⁶ Appellate Body, *EC – Sugar*, [310]; Panel, *Guatemala – Cement II*, [8.22]–[8.25]; Panel, *Argentina – Poultry*, [7.38]–[7.39].

²⁷ Panel, *Guatemala – Cement II*, [8.23].

²⁸ *North Sea Continental Shelf*, 26.

²⁹ Bowett, 193.

international law on the abuse of rights (*abus de droit*). The Appellate Body has accepted *abus de droit* as a valid part of WTO dispute settlement, not as an independent rule of law, but as an application of the principle of good faith.³⁰ Factoril does not concede that Costo has the right to bring this complaint to a WTO Panel, but assuming that this right exists, its exercise would be an abuse of rights. *Abus de droit* will operate when a party exercises its rights in a way that impedes another state from enjoying its rights, or where a party's rights are not 'exercised ... reasonably'.³¹

20. Costo has exercised its WTO rights in disregard of Factoril's FTA rights³² – the matter has been finally determined by the FTA Tribunal, yet Costo is seeking an effective rehearing. This defeats Factoril's right under FTA art 21 to have the matter only heard once. It is not reasonable for Costo to assert its rights in this way. Thus this complaint is an abuse of rights by Costo.

2: Factoril's Licence B is compliant with TRIPS by operation of art 31

2.1: Factoril relies on the exception to art 28.1(a) set out in art 31

21. Licence B grants Factoril Inc rights that are normally exclusive to the patent holder under TRIPS art 28.1(a). Factoril submits that it has granted this authorization in full compliance with art 31 and the Decision. Licence A also fully complies with TRIPS, thereby permitting Distria Inc to import the M63 manufactured in Factoril under Licence B.

2.2: The authorization requirement in art 31(b) is waived due to a national emergency

22. TRIPS art 31(b) obliges Members to 'make efforts to obtain authorization from the right holder' before issuing a compulsory licence. Due to exceptional circumstances, no authorization was sought by Factoril Inc. Factoril relies on the art 31(b) requirement being able to be waived 'by a Member in the case of a national emergency or other circumstances of extreme urgency'.

2.2.1: Factoril relies on Distria's national emergency or circumstance of extreme urgency

23. Although there is no emergency in Factoril, Licence B is a response to Distria's national emergency or circumstance of extreme urgency. Nothing in the text of the TRIPS art 31(b) waiver restricts it to a domestic emergency, unlike art 31(f), which requires that the compulsory licence be for domestic use. The Decision waived the domestic use requirement specifically for situations like that currently being faced by Distria. If art 31(b) were intended to act as a restriction on licensing for export, it would have been addressed in the Decision.

³⁰ Appellate Body, *US – Shrimp*, [158].

³¹ Appellate Body, *US – Shrimp*, [158].

³² Appellate Body, *US – Gasoline*, 22.

24. To determine the conditions of the art 31(b) waiver, it must be interpreted in line with the rules in VCLT arts 31 and 32. Under DSU art 3.2, all covered agreements must be interpreted in accordance with the ‘customary rules of interpretation of public international law’. It is well established that VCLT arts 31 and 32 embody customary principles of treaty interpretation.³³ The following analysis will draw on these principles.

2.2.2: *The Declaration contains an authoritative interpretation of art 31(b)*

25. Although para 5 of the Declaration does not give rise to rights and obligations in and of itself, it can and should be used to interpret the meaning and scope of TRIPS art 31(b). The Ministerial Conference has the exclusive authority to adopt authoritative interpretations of the Multilateral Trade Agreements, including TRIPS,³⁴ and a WTO Panel is *bound* to follow these interpretations.³⁵ In this case, the use of this power has two requirements. First, the Ministerial Conference must have made this interpretation following a recommendation by the Council for TRIPS. Second, the Ministerial Conference must have decided to adopt the interpretation by at least a three-fourths majority of Members. The Ministerial Conference negotiated and adopted the Declaration following a recommendation of the April 2001 meeting of the Council for TRIPS.³⁶

26. Declarations are often the major product of Ministerial Conferences, and the Declaration was put to and approved unanimously by a vote of a plenary session of the Ministerial Conference. Moreover, paras 4 and 5(a) of the Declaration clearly state that it expresses the intention of the parties regarding how TRIPS ‘should be interpreted’ and how it ‘shall be read’. On this basis, the Declaration could also be considered a ‘subsequent agreement between the parties regarding the interpretation of the treaty’.³⁷ For these reasons, the Declaration should be considered a key text when interpreting TRIPS arts 30 and 31.

27. In the alternative, should the Declaration not be considered by this Panel to be a subsequent agreement on interpretation of TRIPS, Factoril submits that it is a supplementary means of interpretation under VCLT art 32. Supplementary means of interpretation are

³³ Appellate Body, *US – Gasoline*, [16]–[17]. See also Appellate Body, *US – Gambling*.

³⁴ Marrakesh Agreement, art IX:2.

³⁵ Ehlerman and Ehring, 807.

³⁶ Vandoren, 6.

³⁷ VCLT, art 31(3)(a).

generally circumstances relating to a treaty's conclusion or preparatory works,³⁸ but can also include documents published after the conclusion of a treaty that indicate the parties' intentions at the time of entering into a treaty.³⁹ The Declaration is a statement agreed to by all parties that reaffirms their original intentions in respect of TRIPS. The Declaration does not purport to add new rights or obligations to TRIPS, it simply 'affirms' that its provisions should be read in a way that protects public health;⁴⁰ a principle already stated in TRIPS art 8.

2.2.3: Article 31(b) permits any Member to determine that the authorization requirement is waived

28. The text of art 31(b) states that '[the authorization] requirement may be waived *by a Member*'. This wording indicates that if a Member determines that the conditions for waiver are met, the affected Member has the ability and the right to waive the requirement with no external consultation or review being required. The meaning of these words is reinforced by para 5(c) of the Declaration, which reaffirmed the flexibility embodied in art 31(b), recognizing that '[e]ach Member has the right to determine what constitutes [an emergency], it being understood that public health crises ... can represent a national emergency or other circumstance of extreme urgency'.⁴¹

29. The broad interpretation of art 31(b) set out in para 5(c) of the Declaration is consistent with the established purpose of the provisions set out in TRIPS arts 7 and 8.⁴² If the DSB were to adopt an interpretation of the art 31(b) waiver that did not give full deference to the sovereignty of individual Members to respond to health crises as contemplated by para 5(c), the art 31(b) waiver would be severely limited and the careful balance established between art 28.1(a) and arts 30 and 31 would be lost.⁴³

2.2.4: The Amblo Virus is a national emergency or other circumstance of extreme urgency

30. Even if Members' declarations of emergency may be reviewed by a Panel, Distria is clearly facing a national emergency. The Amblo Virus, a deadly disease that is transmitted by contact

³⁸ VCLT, art 32. See also Sinclair, 141.

³⁹ Appellate Body, *EC – Chicken Cuts*, [303]–[305].

⁴⁰ Declaration, para 4.

⁴¹ Declaration, para 5(c).

⁴² VCLT, art 31(1).

⁴³ See Appellate Body, *US – Gasoline*, 16–17.

with animal fur and fatal within days, has been discovered in Distria. The threat is sufficiently grave that the Distrian Government has ordered 5 million units of M63 over the short period of 12 months. While some scientific uncertainty currently exists in relation to the Amblo Virus, these unknown factors add to the risk and justify the sense of urgency in seeking an appropriate level of preparedness for the possibly devastating consequences. With no known method of curing or preventing the disease and insufficient manufacturing capacity to produce a sufficient amount of M63 domestically, Distria's situation can only be described as a national emergency or circumstance of extreme urgency, of a kind to which the flexibility of TRIPS art 31 was designed to respond.

31. The notice requirements of art 31(b) (that in situations of national emergency the patent holder should nevertheless be notified as soon as reasonably practicable) have been satisfied, as Factoril promptly gave formal notification of Licence B to the Council for TRIPS on 20 February 2006. Notice was made freely available via the website created in accordance with the Decision.

2.3: Factoril's art 31(f) 'domestic supply' obligations are waived by the Decision

2.3.1: The Decision is legally binding on Members and waives art 31(f)

32. The Decision is a validly made binding waiver of art 31(f),⁴⁴ and Licence B complies with the conditions of waiver. Costo has not complained about the majority of those requirements. As discussed above, Distria is experiencing a national emergency and has therefore fulfilled the requirements of its notification.⁴⁵ The following submissions will therefore focus on the issues of manufacturing capacity and trade diversion.

2.3.2: Distria's determination of insufficient manufacturing capacity is adequate

33. Paragraph 2(a)(ii) of the Decision states that one of the terms of the waiver of art 31(f) is that the eligible importing Member (Distria) should confirm that it 'has established that it has insufficient ... manufacturing capacities in the pharmaceutical sector for the product(s) in question.' The Annex to the Decision provides that, for Distria to establish insufficient manufacturing capacity, it must have 'examined this capacity and found that ... it is currently insufficient for the purposes of meeting its needs.' Distria's notification to the Council for TRIPS on 1 February 2006 states it has done so. There are cogent policy reasons for allowing sovereign governments to determine the state of their own manufacturing capacity. Indeed, a developing country with sufficient manufacturing capacity would have little reason to resort to importation,

⁴⁴ *Marrakesh Agreement*, art IX:3.

⁴⁵ Decision, para 1(b).

especially after issuing a compulsory licence of its own. The object of the art 31(f) waiver would be severely undermined if any party other than the Member in question were to be given authority over this determination.

2.3.3: The Chairman's Statement is not legally binding

34. The Chairman's Statement made at the adoption of the Decision suggests an additional requirement, that 'notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities'.⁴⁶ However, the Chairman did not suggest that failing to provide this additional information would result in breach of the waiver. Moreover, the General Council has shown an intention to exclude the Chairman's Statement from having any binding legal force. The Decision indicates that it was made '*in light of the Chairman's Statement*'.⁴⁷ On 29 July 2005 a correction was issued which states that this reference was provided for information purposes only, and is 'without prejudice to Members' legal rights and obligations'.⁴⁸ On this basis, the Chairman's Statement should not be seen as creating binding rights and obligations.

35. Moreover, the Chairman's Statement should not be considered 'context' under VCLT art 31. The Chairman's Statement is not an agreement of the parties to TRIPS within VCLT art 31(2)(a). It is also not an instrument relating to the conclusion of a treaty under VCLT art 31(2)(b), as it was drafted by the General Council Chairman and not by one of the parties. The Appellate Body in *US – Gambling* adopted this literal approach to the scope of the term 'context' under the VCLT art 31. They held that guidelines drafted by the GATT Secretariat, in spite of being relied upon by many parties in drafting schedules, could not be considered context.⁴⁹ This was because those guidelines had not been accepted by all parties as an agreement that related to the treaty.⁵⁰

36. Before the Council for TRIPS approved the Chairman's Statement and forwarded it to the

⁴⁶ Chairman's Statement.

⁴⁷ Decision, n 1 (emphasis added).

⁴⁸ *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003: Corrigendum*, WTO Doc WT/L/540/Corr.1 (2005) (Correction issued by the General Council).

⁴⁹ Appellate Body, *US – Gambling*, [174]–[175].

⁵⁰ Appellate Body, *US – Gambling*, [174]–[175].

General Council, the representative from the Philippines made it clear that it remained the prerogative of the notifying Member to provide ‘as much or as little information as it deemed relevant’, and that no other Member nor the Council for TRIPS has a right to reject a notification on the basis of the information provided about manufacturing capacity.⁵¹ Other states have also emphasised that there was no agreement that the Chairman’s Statement affected the operation of the Decision.⁵² Therefore, there was no agreement among all Members that the Chairman’s Statement created a binding obligation to provide information about how a Member established its insufficient manufacturing capacity.

37. Consequently, the Chairman’s Statement can only be considered as a supplementary means of interpretation under VCLT art 32. Factoril concedes that the Chairman’s Statement is part of the ‘circumstances of [the Decision’s] conclusion’,⁵³ as this provision of the VCLT has been interpreted to include unilateral instruments.⁵⁴ However, the Chairman’s Statement *may* be considered as a supplementary means of interpretation where there is ambiguity.⁵⁵ Here there is no such ambiguity.

2.3.4: Alternatively, Costo has violated the understandings in the Chairman’s Statement

38. Alternatively, if Costo asserts that the Chairman’s Statement creates substantive obligations, Costo’s action in bringing this complaint before this Panel has ignored the understanding that issues arising from the use of the Decision should be resolved expeditiously and amicably by seeking review by the Council for TRIPS or a mutually acceptable solution.⁵⁶ If Costo gives weight to the Chairman’s Statement, this complaint violates the understandings in that Statement and cannot be said to be in good faith.⁵⁷

2.3.5: No further measures need to be taken to prevent trade diversion

39. Factoril Inc’s M63 pill has been manufactured with a distinctive pink colouring, which

⁵¹Philippines’ Statement, [4].

⁵² *Minutes of Meeting held in the William Rappard Centre on 8–9 and 31 March 2005*, WTO Doc IP/C/M/47 (2005) [194] (Comments by the Representative for Zambia).

⁵³ VCLT, art 32.

⁵⁴ Appellate Body, *EC – Chicken Cuts*, [287]–[289].

⁵⁵ VCLT, art 32. See also Sinclair, 141.

⁵⁶ Chairman’s Statement.

⁵⁷ DSU, art 3.10.

instantly identifies it as having been manufactured under Factoril's compulsory licences. The purpose of this distinctiveness is to prevent trade diversion, where the goods intended for the citizens of Distria are diverted or resold in more lucrative developed world markets. Trade diversion is already occurring on an extremely small scale to Lister Inc. However, this is unlikely to have a negative effect on the goals of Licence B. Several hundred units of M63 is a relatively insignificant amount and it is unreasonable to expect that *substantial* trade diversion to Listria will ever occur, due to Licence C and Listria's more price elastic market conditions.

40. Paragraph 4 of the Decision states that 'eligible importing Members shall take reasonable measures *within their means*, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation'. The Chairman's Statement includes a number of 'best practice' suggestions for achieving this objective;⁵⁸ however, the requirement to take reasonable measures to prevent trade diversion operates 'strictly on a "best endeavour basis"'.⁵⁹

41. The Amblo Virus falls into the WHO's definition of a Type III disease, because it is not materially present in the developed world.⁶⁰ As most developing countries and LDCs will have similar or less favourable market conditions to Distria, there is far less incentive for traders to engage in trade diversion than for Type I and II diseases such as HIV/AIDS. Furthermore, the Amblo Virus is present in very few countries and no instances of human infection have been reported. There are therefore very few possible markets to which pink M63 could be diverted. The alteration of colour to minimise trade diversion is identified in the Chairman's Statement's 'best practice' guidelines.⁶¹ Such measures are proportionate to the relatively low risk of trade diversion and to Distria's limited means. Further measures would unnecessarily increase production time and costs, which would have a far more detrimental effect on the achievement of the policy goals of the Decision than any minor instances of trade diversion that may occur.

42. For the above reasons, Licence B fulfills the requirements of art 31 and the Decision, making it in full conformity with TRIPS.

3: Factoril's Licence C is compliant with TRIPS

43. Factoril acknowledges that Licence C is inconsistent with Costo Inc's rights pursuant to TRIPS art 28.1(a), but submits that Licence C falls within an exception: either TRIPS art 30 or

⁵⁸ Chairman's Statement – Annex I.

⁵⁹ Philippines' Statement, [4].

⁶⁰ Commission on Intellectual Property Rights, Innovation and Public Health, 25.

⁶¹ Chairman's Statement – Annex I.

art 31.

3.1: Licence C falls within TRIPS art 30

44. In *Canada – Pharmaceuticals*, the Panel interpreted some key terms within art 30 but did not interpret aspects of the provision unnecessary to decide that case. Those aspects that were undecided must be interpreted in accordance with VCLT arts 31 and 32.

45. Factoril submits that Licence C is a limited exception to art 28.1(a). Taking into account the legitimate interests of public health in Lustria, Licence C does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice Costo Inc's legitimate interests.

3.2: Licence C is a limited exception

46. In *Canada – Pharmaceuticals*, the Panel said that a 'limited exception' is a small or narrow exception that only makes a small diminution of the patent holder's rights.⁶² 'Limited' should be measured by the extent to which Costo Inc's legal rights are curtailed.⁶³

47. Licence C only slightly curtails Costo Inc's rights. Licence C is geographically limited and all units of M63 that are exported to Lustria are coloured pink to prevent trade diversion. Licence C is limited to a period of twelve months and to the manufacture of 1 million units of M63. Moreover, the licence is only being issued in response to the Amblo Virus posing a significant threat to public health in Lustria, which is an LDC with no patent laws. Factoril therefore submits that Licence C can be distinguished from the stockpiling provisions disallowed in *Canada – Pharmaceuticals*, as it amounts to only a minor incursion upon Costo Inc's rights.

3.3: Licence C does not unreasonably conflict with the normal exploitation of the patent

3.3.1: Licence C does not conflict with the normal exploitation of the patent

48. In *Canada – Pharmaceuticals*, the Panel explained that 'exploitation' refers to the commercial activity by which a patent owner employs their exclusive patent rights to extract economic value from their patent.⁶⁴ The Panel held that 'normal' means both an empirical conclusion about what common practice is and a normative standard of entitlement.⁶⁵

49. Costo Inc would not anticipate being able to profitably market M63 in Lustria. As an LDC, Lustria's domestic market would be unable to sustain monopoly pricing of M63 as Costo Inc sells

⁶² Panel, *Canada – Pharmaceuticals*, [7.30].

⁶³ Panel, *Canada – Pharmaceuticals*, [7.31].

⁶⁴ Panel, *Canada – Pharmaceuticals*, [7.54].

⁶⁵ Panel, *Canada – Pharmaceuticals*, [7.54].

it at over six times Factoril Inc's price.

50. Even if Costo Inc were able to sell M63 to Listria, it would not be profiting from the *exploitation* of its patent because the commercial value is being extracted in Listria, where Costo Inc has no patent. Similarly, although Licence C allows production of M63 in Factoril, where Costo Inc has a patent, exploitation occurs in the country in which profit is being derived, namely Listria. As Costo Inc has no M63 patent in Listria, sale to Listria cannot conflict with the normal exploitation of Costo Inc's legal rights.

3.3.2: *If there is a conflict with normal exploitation of the patent it is not unreasonable*

51. In *Canada – Pharmaceuticals* it was unnecessary to decide when an exception would *unreasonably* conflict with the normal exploitation of the patent. Factoril submits that whether a conflict is unreasonable should be assessed in relation to the legitimate interests of third parties. This gives the provision its ordinary meaning, which is affirmed by looking to the object and purpose of TRIPS. In particular, art 7 emphasises the need for a balanced approach to interpreting TRIPS.

52. Factoril submits that, even if the extent of a conflict should be assessed relative to its economic consequences, as Costo Inc would not have anticipated profiting from the sale of M63 in Listria, any conflict would not be unreasonable.

3.3.3: *Legitimate interests of third parties*

53. Licence C is essential for protecting public health and promoting access to M63 in Listria. Such an interest is recognised in TRIPS art 8 and the Declaration – both emphasise that Members may adopt measures necessary to protect public health. Factoril submits that any conflict with the normal exploitation of Costo's patent is legitimate given the impending health crisis in Listria. Ensuring that Listria's citizens can access life-saving medicine is a paramount interest, justifying conflict with the normal exploitation of the patent.

3.3.4: *Licence C does not unreasonably prejudice Costo Inc's legitimate interests*

54. In *Canada – Pharmaceuticals*, the Panel said that a 'legitimate interest' was an interest justified by public policy or other social norm.⁶⁶ However, the Panel did not need to assess whether a measure unreasonably prejudiced the legitimate interests of the patent holder, taking account of the legitimate interests of third parties. Factoril submits that to determine whether any prejudice to Costo Inc's interests is unreasonable, Costo Inc's legitimate interests must be weighed against the legitimate interests of third parties. Factoril submits that for the reasons stated above at [53], Listria's interests outweigh any interests of Costo Inc.

⁶⁶ Panel, *Canada – Pharmaceuticals*, [7.69].

3.4: Licence C falls within TRIPS art 31

55. Article 31 allows a Member to authorize a licence for use other than that permitted under art 30. If Licence C does not fall within art 30, Factoril submits that the Licence C was granted in compliance with the art 31 exception and the Decision.

3.4.1: The conditions of the waiver in art 31(b) have been met

56. As noted above at [22], art 31(b) requires the proposed user to make efforts to obtain authorization from the patent holder. Factoril relies on this requirement being waived due to a national emergency. For the same reasons discussed above at [23]–[24] in respect of Licence B, Factoril submits that it grants Licence C relying on Listria’s national emergency.

3.4.2: Factoril relies on the Decision waiving art 31(f)

57. Factoril submits that its art 31(f) domestic supply obligations are waived by operation of the Decision. The VCLT mandates that when interpreting a treaty such as the Decision, its context is to be taken into account, which includes subsequent practice of the parties. In accordance with VCLT art 31(3)(b), Factoril submits that subsequent practice establishes agreement that the Decision may be used to export to non-Member LDCs, such as Listria. Moreover, Factoril submits that such an interpretation is consistent with para 4 of the Declaration, which provides that TRIPS should be interpreted and implemented in a manner supportive of a Member’s right to promote access to medicines for *all*.

58. The Appellate Body has noted that subsequent practice constitutes objective evidence of the parties’ understanding as to the meaning of a treaty.⁶⁷ To establish ‘subsequent practice’ within the meaning of VCLT art 31(3)(b), there must be a ‘common, consistent and discernible pattern of acts or pronouncements’ and ‘those acts or pronouncement must imply agreement on the interpretation of the relevant provision’.⁶⁸

59. Factoril submits that there is a clear pattern of using the Decision to allow export to non-Member LDCs. All countries that have implemented the Decision have made provision for compulsory licences to be issued for export to non-Member LDCs.⁶⁹

⁶⁷ Appellate Body, *Japan – Alcoholic Beverages II*, 13; Appellate Body, *EC – Chicken Cuts*, [255].

⁶⁸ Appellate Body, *US – Gambling*, [192]. See also Appellate Body, *EC – Chicken Cuts*, [257]; *Japan – Alcoholic Beverages II*, 13.

⁶⁹ *Patent Act*, RSC 1985, c 23, ss 21.01–21.2 (Canada); *Commission Regulation (EC) No 816/2006 of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems* [2006] OJ L 157/1; *Kingdom Act on Patents of 1995* (Netherlands) art 57(1); *Act No 9 of December 1967 Relating to Patents* (Norway) §§ 49, 69; *Regulation No 1162 of 20 December 1996* (Norway) §§106–109a;

60. *EC – Chicken Cuts* held that not every party has to have engaged in a particular practice for it to qualify as ‘common’ or ‘concordant’ practice.⁷⁰ Factoril submits that the lack of adverse reaction from other Members should be understood as acceptance that Members may export to non-Member LDCs under the Decision. In *EC – Chicken Cuts* the Appellate Body noted that lack of protest may amount to agreement in specific situations, such as where parties have been made aware of the practice.⁷¹ TRIPS art 63.2 requires Members to notify the Council for TRIPS of laws and regulations pertaining to the subject matter of TRIPS. All Members would therefore be aware that the Decision is being used to allow export to non-Member LDCs. Factoril submits that the clear pattern of either exporting generic drugs to non-Member LDCs or accepting such practice implies agreement that the Decision permits such conduct.

61. The Decision imposes conditions on both ‘eligible importing Members’ and exporting Members. As Listria is not a Member, it is not strictly bound by these requirements. Although the Council for TRIPS was not notified in accordance with art 2(c) of the Decision, given that such notifications need not be approved by a WTO body, Factoril submits that such a minor procedural error should not invalidate Licence C. For the same reasons as for Licence B (see [39]), adequate steps have been taken to prevent trade diversion in accordance with art 5 of the Decision. Factoril therefore submits that it may rely on the Decision to waive TRIPS art 31(f).

3.4.3: *Costo Inc is being paid adequate remuneration under TRIPS art 31(h)*

62. Factoril submits that, by paying Costo Inc royalties of 1.5% of the price Lister Inc pays for generic M63, Factoril Inc is paying adequate remuneration in the circumstances, in accordance with TRIPS art 31(h). Article 3 of the Decision provides that adequate remuneration should be calculated relative to the value of M63 in Listria. M63 is not patented in Listria, and as an LDC, Listria’s purchasing power is weak, thus remuneration is understandably low to reflect a significantly lower market value. Factoril submits that the royalties being paid thus constitute adequate remuneration.

Patents Act (India) (No 39 of 1970) s 92A; Government of Canada, Canada’s Access to Medicines Regime (Consultation Paper, 24 November 2006).

⁷⁰ Appellate Body, *EC – Chicken Cuts*, [259].

⁷¹ Appellate Body, *EC – Chicken Cuts*, [272].

Request for Findings

Factoril requests that the Panel hold that there are legal impediments to its jurisdiction to hear Costo's substantive complaints. In the alternative, Factoril requests that the Panel recommend to the DSB that Licence B and Licence C are in full conformity with TRIPS arts 28.1(a), 30 and 31 and with the Decision.