

ELSA MOOT COURT COMPETITION ON WTO LAW  
2006/2007

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*FACTORIL – COMPULSORY LICENSING OF PHARMACEUTICAL PATENT*

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COSTO  
*(Complainant)*

vs

FACTORIL  
*(Respondent)*

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SUBMISSION FOR COMPLAINANT

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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.
4. *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 2 (*Understanding on Rules and Procedures Governing the Settlement of Disputes*) 1869 UNTS 401.
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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.
covered agreements	The Agreements listed in Annex 1 to 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
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	General Agreement on Tariffs and Trade
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
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 Agreement / TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
VCLT	Vienna Convention on the Law of Treaties
WTO Agreements	The Marrakesh Agreement and the documents contained in its four Annexes

*Summary of Arguments***Jurisdiction:***There is no impediment to the Panel's jurisdiction to hear this complaint*

- On the facts of this case, there is no legal impediment to the Panel's jurisdiction.
- The FTA does not alter Costo's ability to bring a claim under the DSU. FTA art 21 does not alter the obligations between Costo and Factoril at international law. Alternatively, obligations under the FTA are not enforceable before the Panel.
- Estoppel (or preclusion) does not apply in the WTO dispute settlement system.
- *Res judicata* does not apply in the WTO dispute settlement system to decisions from other fora and, in any case, its elements cannot be made out because the legal claims before the FTA and the Panel are different.

**Licence B:***Licence B is inconsistent with TRIPS arts 28.1(a), and does not fulfill the requirements of art 31 and the Decision*

- Licence B is inconsistent with TRIPS art 28.1(a) as it permits Factoril Inc to manufacture and export M63 to Distria, which is an exercise of Costo Inc's exclusive rights.
- Licence B is inconsistent with TRIPS art 31(b), because Factoril Inc did not seek a voluntary licence from Costo Inc. Factoril may not rely on the art 31(b) waiver as neither Distria nor Factoril is experiencing a national emergency or other circumstance of extreme urgency. The Amblo Virus represents a risk, but it does not have the requisite 'urgency' to justify recourse to the art 31(b) waiver.
- Licence B is inconsistent with art 31(f) as it is not predominantly for domestic supply. The Decision, which waives art 31(f), does not apply as the requirements in paras 1(b), 2(a)(ii) and 4 have not been met: Distria has not complied with its notification that it would only use the Decision in a national emergency; Distria has not adequately established that it has insufficient manufacturing capacity as it has not supplied the Council for TRIPS with any information to demonstrate the basis for its determination; and both Distria and Factoril have not taken reasonable measures to prevent trade diversion as the pink colouring is inadequate in light of the real risk of re-exportation.

**Licence C:*****Licence C is inconsistent with TRIPS art 28.1(a), 30 and 31***

- Licence C is inconsistent with TRIPS arts 28.1(a), 30 and 31 as it permits Factoril Inc to manufacture and export M63 to Listria, contrary to the rights of Costo Inc.
- Licence C does not fall within art 31 as it is not predominantly for domestic supply (art 31(f)). Listria cannot rely on the Decision as it is not a WTO Member.
- Licence C is not limited within the meaning of art 30. A limited exception is one that makes only a small diminution of a patent holder's legal rights. Licence C impedes Costo Inc's rights to make, use and sell M63. One million units of M63 are being produced in Factoril over a 12 month period, and sold to Listria for stockpiling purposes. Therefore Licence C is not limited.
- Licence C unreasonably conflicts with the normal exploitation of Costo Inc's M63 patent. Licence C conflicts with Costo Inc's rights to make and sell M63. The normal practice of Costo Inc would be to preserve its monopoly over M63, so that it would be the exclusive manufacturer and supplier to as many countries as possible. Costo Inc will suffer financial detriment due to Licence C conflicting with its normal patent rights. This financial detriment is neither proportionate nor fair. Licence C therefore unreasonably conflicts with the normal exploitation of Costo Inc's M63 patent.
- Licence C unreasonably prejudices Costo Inc's legitimate interests. Without patent protection Costo Inc will be unable to recover the costs of researching and developing M63 which will reduce its incentive to develop new life saving drugs in the future. The needs of Listria are not sufficiently urgent to outweigh the strong policy in favour of maintaining a sustainable pharmaceutical research sector and Costo Inc's legitimate patent rights.

*Statement of Facts*

1. Factoril and Distria are developing country WTO Members. Pursuant to TRIPS, Factoril and Distria have domestic intellectual property regimes that protect exclusive patent rights. Costo is a developed WTO Member in which Costo Inc, a pharmaceutical innovator, is incorporated. Listria, a least-developed country that is not a WTO Member, has no patent laws.
2. The Amblo Virus is a newly discovered disease, carried by certain household pets, which is believed to be transmittable to humans on contact with animal fur. It is unknown whether transmission between humans is possible. Both Distria and Listria have reported cases of the Amblo Virus.
3. Costo Inc developed and patented M63, a potentially life-saving drug that is believed to suppress the symptoms of the Amblo Virus for up to 15 years. M63 is patented in most countries including Costo, Factoril and Distria. The governments of Distria and Listria have decided to stockpile M63 as a precautionary measure. Despite the existence of the M63 patent, both decided not to negotiate with Costo Inc, preferring to seek a cheaper, generic version.
4. Factoril and Costo agreed in an FTA (formed in 2000) to issue compulsory licences for pharmaceutical patents only to respond to a national emergency and only to supply the domestic market (art 5). Despite this, Factoril granted Factoril Inc (incorporated in Factoril) Licence B, allowing it to manufacture 5 million units of M63 for sale to Distria. Factoril Inc also chose not to first approach Costo Inc for a voluntary licence.
5. Under Licence B, Factoril Inc will colour its M63 pink, rather than the usual green. Factoril Inc will pay Costo Inc 3% of the wholesale price, which Factoril Inc has set at 30% of market price. Although Distria has followed some requirements of TRIPS and the Decision, it did not explain how it determined that it had insufficient manufacturing capacity. Further, despite hundreds of units of pink M63 are being diverted from Distria to Listria, Distria has decided not to take further steps to prevent re-exportation. Factoril has also granted Licence C to Factoril Inc to make and export 1 million units of pink M63 to Listria. Under Licence C, Costo Inc will receive only 1.5% of Factoril Inc's price (15% of market price).
6. Costo brought a claim against Factoril to the FTA Tribunal, which incorrectly applied the Decision and misinterpreted Factoril's FTA obligations. The FTA art 21 purports to prevent Costo from disputing its WTO rights before a Panel. Costo commenced consultations with Factoril with regard to Factoril's failure to comply with its TRIPS obligations. Consultations failed, and Costo requested the establishment of a Panel. No Member objected to this at the relevant meeting of the DSB and a Panel was duly established.

### *Identification of WTO Measures at Issue*

**Measure 1:** Licence B, issued by Factoril to Factoril Inc, which grants it the right to manufacture 5 million units of pink M63 for export to Distria.

**Measure 2:** Licence C, issued by Factoril to Factoril Inc, which grants it the right to manufacture 1 million units of pink M63 for export to Listria.

### *Arguments*

#### **1: The Panel has jurisdiction to hear this matter**

##### **1.1: Prima facie the Panel has jurisdiction and Factoril must establish any deficiency**

1. Together, Costo's complaint, DSU arts 3.2, 7.1, 7.2, 11, 19.2 and 23 and the Panel's Terms of Reference establish the jurisdiction of the Panel to hear this matter.<sup>1</sup> *Mexico – Soft Drinks* held that the Panel cannot 'decline to exercise validly established jurisdiction [absent a] legal impediment'.<sup>2</sup> Factoril bears the burden of establishing a legal impediment.<sup>3</sup> Costo submits that in this case no legal impediment exists.

2. Costo submits that the claim it brought against Factoril before the FTA Tribunal is fundamentally different from this complaint. The complaints are based on legally independent instruments that involve substantively different obligations that operate alongside one another.

##### **1.2: The FTA is irrelevant to WTO dispute settlement**

###### ***1.2.1: FTA art 21 does not alter obligations under the DSU***

3. *Mexico – Soft Drinks* held that DSU arts 23.1 and 3.3 create an 'entitle[ment] to a ruling'.<sup>4</sup> FTA art 21 cannot qualify this right. It does not meet the requirements of VCLT art 41<sup>5</sup> because provisions of the WTO Agreements implicitly prohibit modification of this right,<sup>6</sup> or alternatively, because the alteration is 'incompatible with [an]...object and purpose'<sup>7</sup> of the WTO Agreements; the creation of a single procedure for dispute settlement.

4. Marrakesh Agreement art II:2 states that the Multilateral Trade Agreements (including the

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

<sup>2</sup> Appellate Body, *Mexico – Soft Drinks*, [54].

<sup>3</sup> Appellate Body, *US – Wool Shirts and Blouses*, 14.

<sup>4</sup> Appellate Body, *Mexico – Soft Drinks*, [52] (emphasis in original).

<sup>5</sup> VCLT art 30(5).

<sup>6</sup> VCLT art 41(1)(b).

<sup>7</sup> VCLT art 41(1)(b)(ii).

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DSU) are ‘integral’ and ‘binding on all Members’. Article X:8 makes no provision for amendments as between states, demonstrating an intention to prohibit bilateral alterations to the DSU. Article XVI:4 requires ‘[e]ach Member’ to conform to the WTO Agreements, and reservations are only permitted under art XVI:5 if those agreements provide for it – which the DSU does not.

5. DSU art 23.1 mandates that parties ‘shall have recourse to, and abide by ... this Understanding’.<sup>8</sup> DSU art 3.2 states that the ‘dispute settlement system of the WTO’ is a ‘central element’ in providing ‘security and predictability’ to WTO dispute resolution. Further, an explicit purpose of the WTO was to create ‘an integrated, more viable and durable multilateral trading system’.<sup>9</sup> The WTO Agreements thus aim to create a single undertaking, with non-derogable rights to bring complaints. The objective of centralised and standardised decision-making is further demonstrated by Members’ broad right to intervene in disputes as third parties,<sup>10</sup> and the requirement that when resolving an issue the Panel ‘fully take ... into account’<sup>11</sup> the rights of Members who are not necessarily parties to a dispute.

**1.2.2: Alternatively, the Panel should not enforce obligations arising under the FTA**

6. Panels may apply those norms of international law that are compatible with the WTO system.<sup>12</sup> *Mexico – Soft Drinks* held, however, that the DSU cannot be used to ‘determine rights and obligations outside the covered agreements.’<sup>13</sup> This was a response to Mexico’s request for a finding that ‘the [US] ... acted ... inconsistently with its NAFTA obligations’.<sup>14</sup> The right to bring a claim is ‘comprehensive’<sup>15</sup> and substantive. Costo submits that to apply FTA art 21 would be to determine obligations outside the covered agreements, which *Mexico – Soft Drinks* precludes.

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<sup>8</sup> DSU art 23.1 (emphasis added).

<sup>9</sup> Marrakesh Agreement, Preamble.

<sup>10</sup> DSU art 10.2; Appellate Body, *EC – Bananas III*, [132]–[133].

<sup>11</sup> DSU art 10.1.

<sup>12</sup> Panel, *Korea – Government Procurement*, [7.96]; Appellate Body, *Mexico – Soft Drinks*, [56]. See, eg, Appellate Body, *US – Shrimp*, [158] (good faith); Panel, *Indonesia – Autos*, [14.28] (presumption against conflict). See also Bartels, 513-15.

<sup>13</sup> Appellate Body, *Mexico – Soft Drinks*, [56] (emphasis added).

<sup>14</sup> Appellate Body, *Mexico – Soft Drinks*, [56].

<sup>15</sup> Appellate Body, *US – Corrosion-Resistant Steel Sunset Review*, [89]; Appellate Body, *Mexico – Soft Drinks*, [52].



7. Further, DSU arts 3.1 and 19.1 state that panels cannot ‘add to or diminish’ rights in the covered agreements. By applying FTA art 21, the panel would “diminish” the right of a complaining Member ... to bring a dispute’.<sup>16</sup> It should therefore decline to do so.

8. There is a clear distinction between customary international law (applicable to all Members) and bilateral treaty obligations. While it may sometimes be appropriate to apply *procedural* customary international law under the DSU,<sup>17</sup> it is not appropriate to enforce bilateral agreements to which all Members are not party. The Panel in *EC – Biotech* refused to do so,<sup>18</sup> and this Panel should not take the large and unprecedented step of applying such agreements. To do so would be contrary to the language and objects of the Marrakesh Agreement and DSU. A Panel’s terms of reference in DSU art 7.1 ‘require’ it to ‘examine...covered agreement(s)’ and no others.<sup>19</sup> DSU art 11 outlines the function of the Panels, which again extends only to the *covered agreements*. The Panel cannot discharge its function if it does not adjudicate complaints about the violation of WTO obligations.<sup>20</sup> If the Panel were to allow FTA art 21 to take precedence over its stated function, it would be failing to discharge its responsibilities under the DSU.

9. By applying FTA art 21, this Panel would render Marrakesh Agreement art X:8 (regulating amendment of the DSU) effectively otiose; which the Appellate Body has described as ‘abhorrent’.<sup>21</sup> Instead of using the deliberately burdensome method of amendment, private amendments between states will spring up where perceived to be politically expedient.

### **1.3: Estoppel and preclusion are not applicable in the WTO system**

10. Costo submits that it cannot be estopped from making this complaint to the Panel, as estoppel and preclusion do not apply in WTO dispute settlement. ‘[E]stoppel has never been applied by the Appellate Body’ and it is ‘far from clear’ whether it should apply.<sup>22</sup> Its application in this case (to deny jurisdiction) would ‘diminish’ the right to make a complaint.<sup>23</sup>

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<sup>16</sup> Appellate Body, *Mexico – Soft Drinks*, [53]; Bartels, 514.

<sup>17</sup> Panel, *India – Autos*, [7.57].

<sup>18</sup> Panel, *EC – Biotech*, [7.92].

<sup>19</sup> Appellate Body, *Mexico – Soft Drinks*, [49].

<sup>20</sup> Appellate Body, *Mexico – Soft Drinks*, [51].

<sup>21</sup> Appellate Body, *US – Shrimp*, [121]; Appellate Body, *US – Shrimp (21.5)* [137]-[138].

<sup>22</sup> Appellate Body, *EC – Sugar*, [312], [310]. See also Panel, *EC – Sugar*, [7.63].

<sup>23</sup> Bartels, 518.

11. To this extent, the DSU should be regarded as altering the international law (including estoppel (or preclusion)) that might otherwise apply. Even if estoppel were imported into the WTO system by the 'good faith' requirement in DSU art 3.10,<sup>24</sup> it could only operate on a party 'engaged' in dispute resolution, based on conduct occurring since 'the...initiation of a case'.<sup>25</sup> *EC – Sugar* thus prevents estoppel being used to 'inhibit the ability of WTO Members to *initiate*' a claim.<sup>26</sup>

**1.4: *Res judicata* is inapplicable in the WTO, or alternatively is not made out**

**1.4.1: *Res judicata* should not be applied in WTO Panel proceedings in respect of decisions from other fora**

12. *India – Autos* noted that whether *res judicata* applies in the WTO was an open question,<sup>27</sup> but any suggestion that it does was exclusively in the context of previous WTO decisions and grounded not on *res judicata* at international law, but on sections of the DSU.<sup>28</sup> The DSU does *not* require that WTO Panels treat decisions from other fora as being determinative of issues.

13. The Panel must enforce the covered agreements,<sup>29</sup> but cannot do so if it is bound in the exercise of its jurisdiction by decisions under non-covered agreements.<sup>30</sup> Further, a significant purpose of the DSU is to ensure predictability in dispute settlement.<sup>31</sup> If *res judicata* applied in the WTO, whether or not the WTO had jurisdiction to hear a claim would be dependent on a comparison of rights under the relevant agreements, which would be inherently uncertain.<sup>32</sup>

14. Even if the obligations in the FTA were identical to those under TRIPS, DSU art 23.1 (mandating 'recourse to' the DSU) and Marrakesh Agreement art IX:2 (reserving to the 'exclusive authority' to adopt interpretations of covered agreements to the Ministerial

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<sup>24</sup> Appellate Body, *EC – Sugar*, [307]. See also Mitchell, 'Good Faith in WTO Dispute Settlement', 362.

<sup>25</sup> Appellate Body, *EC – Sugar*, [312].

<sup>26</sup> Appellate Body, *EC – Sugar*, [312] (emphasis added).

<sup>27</sup> Panel, *India – Autos*, [7.57]–[7.58].

<sup>28</sup> Panel, *India – Autos*, [7.58]. See also Appellate Body, *US – Shrimp (21.5)* [97]; Appellate Body, *EC – Bed Linen*, [93]–[94], [98].

<sup>29</sup> Marrakesh Agreement, art III:2; DSU, arts 1.1, 1.2.

<sup>30</sup> Panel, *Argentina – Poultry*, [7.40].

<sup>31</sup> Appellate Body, *EC – Bed Linen*, [94]; DSU, arts 3.2, 3.3.

<sup>32</sup> See, eg, *Southern Bluefin Tuna*, [54]–[59].

Conference or General Council) manifest an intention that adjudication of disputes under WTO Agreements be conducted solely by the DSB.<sup>33</sup> This intention precludes matters that have been decided by other fora being *res judicata*; in such circumstances it would be appropriate for a Panel to determine the claim *de novo* to ensure correct interpretation of WTO Agreements. *Res judicata* should not apply in the WTO.

**1.4.2: In any case, the matter is not *res judicata* because Costo's legal claims are different**

15. *Res judicata* requires 'a final decision, on a given issue, between the same parties'.<sup>34</sup> The 'given issue' consists of 'the specific measures at issue and the legal basis of the complaint'.<sup>35</sup> Here, the legal bases are not 'essentially the same'.<sup>36</sup> The agreements are separate;<sup>37</sup> FTA art 5 concerns only 'pharmaceutical patent[s]', whereas TRIPS arts 30 and 31 concern patents generally. FTA art 5 has an absolute requirement of national emergency, whereas compulsory licences may be issued in a range of circumstances under TRIPS (for example, public non-commercial use, anti-competitive practices, failure of negotiation).<sup>38</sup> The obligations under FTA art 5 do not require any attempt at negotiation before the issue of a compulsory licence, whereas this is *prima facie* required under TRIPS art 31(b). Lastly, use under a TRIPS licence need only be *predominantly* for the supply of a domestic market (art 30(f)), not exclusively for that market (as in FTA art 5).

**2: Factoril's Licence B is inconsistent with TRIPS arts 28.1(a), 31(b) and 31(f)**

**2.1: The rights granted under Licence B are exclusive rights under art 28.1(a)**

16. By granting Licence B, Factoril has violated Costo Inc's exclusive rights to make, offer and sell M63, mandated under TRIPS art 28.1(a). Article 31 is an exception to art 28.1(a) rather than an exclusion of its operation.<sup>39</sup> Factoril bears the burden of proof in establishing an exception under art 31.<sup>40</sup>

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<sup>33</sup> Panel, *EC – Commercial Vessels*, [7.194].

<sup>34</sup> Panel, *India – Autos*, [7.62] n 335; *Chorzów Factory*, 23; *Trail Smelter Arbitration*, 1952.

<sup>35</sup> Panel, *India – Autos*, [7.65]; Appellate Body, *Guatemala – Cement*, [76].

<sup>36</sup> Panel, *India – Autos*, [7.80].

<sup>37</sup> Pauwelyn, 'Spaghetti Bowl', 201.

<sup>38</sup> TRIPS Agreement, art 31.

<sup>39</sup> See Appellate Body, *EC – Tariff Preferences*, [100]–[103].

<sup>40</sup> Panel, *Canada – Pharmaceuticals*, [7.16].

**2.2: Licence B violates TRIPS art 31(b)**

17. Before curtailing the legitimate interests of patent owners, Members must negotiate for a reasonable period of time with the object of executing a voluntary licence.<sup>41</sup> Factoril has not attempted to do so. This vital process grants patent owners and Members the opportunity to come to a mutually beneficial agreement.<sup>42</sup> As Factoril Inc made no attempt to negotiate or directly notify Costo Inc, Factoril bears the burden of establishing the ‘national emergency’ requirement in the art 31(b) waiver.

**2.2.1: The art 31(b) waiver requires an emergency in the territory of the producing Member**

18. Article 31(b) protects Members that do not have the time, resources or bargaining power to negotiate due to the urgency of their circumstances. These conditions are not present in Factoril, where there is no state of emergency and where M63 is being produced for profit.

**2.2.2: Article 31(b) does not allow Members to unilaterally deem that an emergency exists**

19. Factoril cannot rely on Distria’s declaration of national emergency because, on a proper construction of art 31(b), Distria does not have the right to deem any situation a national emergency without a reasonable factual basis. Although the Amblo Virus presents a risk, it does not constitute a national emergency or circumstance of extreme urgency.

20. It is necessary to apply VCLT arts 31 and 32 to interpret the meaning of the national emergency waiver in art 31(b). Under the DSU art 3.2, all covered agreements must be interpreted in accordance with the ‘customary rules of interpretation of public international law’. The Appellate Body has recognised that VCLT arts 31 and 32 are declaratory of such rules.<sup>43</sup>

21. The ordinary meaning of art 31(b) must be the starting point for its interpretation.<sup>44</sup> The phrase ‘may be waived by a Member’ is qualified by ‘in the case of’ which implies that a case of emergency must *actually* exist in order for the negotiation requirement to be waived.

22. This interpretation is reinforced by other provisions of TRIPS, which form part of the ‘context’ when interpreting TRIPS art 31(b) under the VCLT.<sup>45</sup> TRIPS art 21 provides that ‘Members may determine conditions on the licensing and assignment of trademarks’, which grants Members the prerogative to establish such conditions without external review. If art 31(b)

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<sup>41</sup> TRIPS Agreement, art 31(b).

<sup>42</sup> Matthews, 73, 78–81.

<sup>43</sup> Appellate Body, *US – Gasoline*, 16–17.

<sup>44</sup> VCLT, art 31(1).

<sup>45</sup> VCLT, art 31(2). See Appellate Body, *US – Gambling*, [164]–[169].

had intended to grant a right to deem any situation to be an emergency, it would have been framed in comparable language to art 21.

23. Moreover, the Ministerial Conference clearly considered that a declaration of national emergency was subject to an objective standard, which is why it explicitly addressed concerns as to whether epidemics such as HIV and malaria met this standard in para 5(c) of the Declaration. Such an understanding would have no meaning if Members' art 31(b) waivers could not be challenged.

24. In light of the above, art 31(b) should not be interpreted in a way that grants Members the incontestable right to waive the obligation to seek a voluntary licence without an objective determination of a relevant emergency. Such an interpretation would render art 31(b) obligations inutile, which in turn would unduly encroach on art 28.1(a) rights.

***2.2.3: The Declaration should not be used to interpret art 31 of TRIPS***

25. The Declaration states at para 5(c) that Members have the right to determine what constitutes a national emergency or circumstance of extreme urgency. The Declaration should not be considered any more than a political statement.

26. The Ministerial Conference has the authority to adopt interpretations of TRIPS.<sup>46</sup> However para 5(c) is not framed as an interpretation of TRIPS art 31(b). Therefore the Declaration should not be considered to be a 'subsequent agreement ... regarding interpretation' within VCLT art 31(3)(a).

27. Only an amendment can give rise to new rights and obligations under a treaty.<sup>47</sup> Thus, no interpretative tool could possibly give rise to a non-judiciable right to declare an emergency as this right has no basis in the text of art 31(b). Any interpretation purporting to do so is invalid.<sup>48</sup> Accordingly, para 5(c) of the Declaration cannot create such a right.

***2.2.4: The Amblo Virus does not fall within the art 31(b) waiver***

28. Costo does not deny that the Amblo Virus could represent a serious health risk and reaffirms that TRIPS does not prevent Members from taking reasonable precautions to protect public health. However, the Amblo Virus is not an emergency or circumstance of extreme urgency within the meaning of art 31(b).

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<sup>46</sup> Marrakesh Agreement, art IX:2

<sup>47</sup> Sinclair, *The Vienna Convention on the Law of Treaties*, 130.

<sup>48</sup> Marrakesh Agreement, art IX:2.

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29. There is no entrenched concept of emergency at international law,<sup>49</sup> and there exists limited WTO jurisprudence on point. In *US – Line Pipe Safeguards*, the Appellate Body considered that a safeguard measure<sup>50</sup> could only be taken in ‘emergency situations’, to the extent ‘necessary to provide extraordinary and temporary relief’.<sup>51</sup> In the context of art 31(b) as a whole, national emergency is grouped with ‘other circumstances of extreme urgency’, which strongly suggests that ‘emergency’ is a subset of ‘circumstances of extreme urgency’. This interpretation accords with the concept of necessitating extraordinary and temporary relief.<sup>52</sup> Further, interpretation must be performed in context of the obligation – to seek a voluntary licence – that is waived if the waiver is validly made. Therefore, circumstances must manifest imminent and extraordinary urgency that necessitates temporary relief in the form of a compulsory licence.

30. There is no evidence that justifies considering the Amblo Virus as a threat that creates a situation of extreme urgency or national emergency. Despite the short incubation and mortality period of the Amblo Virus, a number of facts demonstrate that the situation is not urgent: the lack of animal to human transmission; the uncertainty as to the possibility of human to human transmission; the lack of an epidemic in the animal population of Distria; and that there is no shortage of M63. While this does not mitigate the risk that an emergency may occur in future, there is no ‘extreme urgency’ arising from the present facts.

31. If the mere presence of a virus in a country is grounds for a national emergency, even where that virus is not present in the human population, it is difficult to envisage a situation that would not be considered an emergency. Such a broad interpretation would render article 31(b) inutile, acting as a de facto waiver of the obligation to seek a voluntary licence.<sup>53</sup> Members are only free to determine what constitutes a national emergency *within reason*.<sup>54</sup>

32. It is not Costo’s submission that nothing should be done unless the Amblo Virus threat escalates. Distria and other Members are entitled to take precautionary measures to prevent the spread of the disease and educate their population as to the risk. However, M63 is not a

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<sup>49</sup> Schloemann and Ohlhoff, 445.

<sup>50</sup> GATT, art XXIV.

<sup>51</sup> Appellate Body, *US – Line Pipe Safeguards*, [80], [83].

<sup>52</sup> Appellate Body, *US – Line Pipe Safeguards*, [83].

<sup>53</sup> Appellate Body, *US – Gasoline*, 23.

<sup>54</sup> Gervais, 251.

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preventative drug; it merely suppresses the symptoms of the virus once caught. In any event, adherence to article 31(b) does not prevent access to M63 in Distria, but rather appropriately balances the protection of public health with the recognition of Costo Inc's exclusive rights.

### **2.3: Licence B is in violation of TRIPS art 31(f)**

#### ***2.3.1: Licence B is clearly not for domestic use and Factoril must rely on the Decision***

33. Licence B provides for the manufacture of M63 solely for export purposes. It is therefore prima facie in breach of the art 31(f) 'domestic use' provision of TRIPS. Factoril bears the burden of proving that it meets the grounds for a waiver of article 31(f) under the Decision. Costo recognises that the Decision was made in accordance with art IX:3 of the Marrakesh Agreement and is a valid waiver. However, Costo submits that the waiver does not apply to Licence B as paragraphs 1(b), 2(a)(ii) and 4 of the Decision are not satisfied. These paragraphs require Distria to abide by its notification to use the Decision only in cases of national emergency, to establish its manufacturing capacity as insufficient and to prevent trade diversion. As it has already been submitted that no national emergency exists in Distria,<sup>55</sup> the following submissions will focus on the latter points.

#### ***2.3.2: The Chairman's Statement has substantial interpretive weight as context***

34. At the adoption of the Decision, which waived the requirements of TRIPS art 31(f), the Chairman of the General Council made a statement that revealed several understandings on which the Decision was based. One of these shared understandings was the 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 to the Chairman's Statement, that it has insufficient or no manufacturing capacities'.<sup>56</sup>

35. The Chairman's Statement is part of the 'context' of the Decision under VCLT art 31(2)(b). It is an instrument made in connection with the conclusion of the Decision that was accepted by the parties to the Decision (through the members of the General Council).<sup>57</sup> In *EC – Chicken Cuts*, the Appellate Body considered that the Harmonized System was 'context'. The Harmonized System was binding on some members of the WTO and was not mentioned in the GATT itself; however, it was generally observed and referred to in the course of negotiations.<sup>58</sup> Arguably in

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<sup>55</sup> See above [28]–[30].

<sup>56</sup> Chairman's Statement.

<sup>57</sup> See Sinclair, *The Vienna Convention on the Law of Treaties*, 130 n 59.

<sup>58</sup> Appellate Body, *EC – Chicken Cuts*, [194]–[199].

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closer connection than the Harmonized System and the GATT, the Decision itself states that it was adopted ‘in light of the Chairman’s Statement’,<sup>59</sup> and there was general acceptance of the Statement in the relevant minutes of the General Council.<sup>60</sup> As a part of its ‘context’, the Chairman’s Statement *must* be considered when interpreting the requirements imposed by the Decision.<sup>61</sup>

**2.3.3: Alternatively, the Chairman’s Statement is a supplementary means of interpretation**

36. If the Statement is not considered part of the context of the Decision, it is part of the supplementary means of interpretation.<sup>62</sup> Without the Chairman’s Statement, the requirements of the Decision regarding the determination of domestic manufacturing capacity and the use of ‘reasonable measures’ to prevent trade diversion are ambiguous. Therefore recourse to supplementary materials can be justified to clarify this ambiguity or to confirm any interpretation made following the general rule in VCLT art 31.<sup>63</sup>

37. Factors that determine the relevance of a supplementary means of interpretation include the temporal relationship of the instrument or document to the treaty, how much knowledge parties could have about the instrument or document and its role in the negotiating process of the treaty.<sup>64</sup> Following these criteria, the Chairman’s Statement is highly relevant to interpreting the Decision. The Chairman’s Statement was read out immediately preceding the adoption of the Decision and articulates shared understandings of the Members arising from negotiations in the Council for TRIPS and the General Council. Further, the substantive provisions of the Chairman’s Statement were reiterated prior to the adoption of the art 31*bis* amendment to TRIPS.<sup>65</sup>

38. Similarly, in *US – Gambling* it was held that Scheduling Guidelines, which ‘provided a

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<sup>59</sup> Decision, fn 1. See also *Minutes of Meeting Held in the Centre William Rappard of 25, 26 and 30 August 2003*, WTO Doc WT/GC/M/82 (2003) (Minutes of the General Council Meeting).

<sup>60</sup> *Minutes of Meeting Held in the Centre William Rappard of 25, 26 and 30 August 2003*, WTO Doc WT/GC/M/82 (2003) [31]-[88] (Minutes of the General Council Meeting).

<sup>61</sup> VCLT, art 31.

<sup>62</sup> VCLT, art 32.

<sup>63</sup> VCLT, art 32.

<sup>64</sup> Appellate Body, *EC – Chicken Cuts*, [290]-[291].

<sup>65</sup> *Amendment to the TRIPS Agreement*, WTO Doc WT/L/641 (2005) (Amendment made by the General Council).



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common language and structure that although not obligatory, [were] widely used and relied upon', should inform the interpretation of a related treaty provision.<sup>66</sup> Even though the Appellate Body considered these documents to be a supplementary means of interpretation, the fact that they reflected the shared understandings of the parties during the negotiation of the treaty gave them a high level of significance when interpreting the treaty.<sup>67</sup> *Mexico – Telecoms* similarly accorded 'substantial interpretive weight'<sup>68</sup> to guidelines issued by the Chairman that were generally accepted by the Members, even where the guidelines and accompanying Chairman's note explicitly stated that they were not 'authoritative' or 'legal' interpretations.<sup>69</sup> In light of the above reasons, the requirements of the waiver in the Decision should be interpreted in accordance with the understandings expressed in the Chairman's Statement.

#### **2.3.4: *Distria has not established that it has insufficient manufacturing capacity***

39. To establish insufficient manufacturing capacity, the importing member needs to *confirm* that it has insufficient capacity. The Decision's Annex requires the importing Member to *establish* that it has insufficient capacity by examining its own capacity and finding it to be insufficient. This requires a principled and empirical evaluation of manufacturing capacity in order to establish that art 31(f) may be waived.

40. The Chairman's Statement indicates that, 'to promote transparency and avoid controversy' the notification required by para 2 should include information as to the way in which this assessment was made. This substantive requirement, which was supported by the Council for TRIPS, plays an important role in allowing Members to 'seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably'.<sup>70</sup> It is integral to ensuring that the Decision is used in good faith and by Members who have genuine need.

41. The complete lack of any information proffered by Distria or Factoril that insufficient manufacturing capacity exists means that the burden of proof to establish eligibility for the waiver has not been satisfied and therefore, the waiver does not apply.

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<sup>66</sup> Appellate Body, *US – Gambling*, [204].

<sup>67</sup> *Ortino*, 127–8.

<sup>68</sup> Panel, *Mexico – Telecoms*, [7.67]–[7.68].

<sup>69</sup> Panel, *Mexico – Telecoms*, [7.43]–[7.44].

<sup>70</sup> Chairman's Statement.

**2.3.5: Factoril and Distria have not taken reasonable steps to prevent trade diversion**

42. Trade diversion is a very real threat to access to medicines in developing countries.<sup>71</sup> Unscrupulous traders may seek to take advantage of the differentially priced drugs imported under compulsory licence. Indeed, such diversion is already occurring as Lister Inc has begun to import pink M63 from various companies in Distria, indicating that the controls on trade diversion in Distria are insufficient, if not non-existent.

43. Many measures can be taken to minimise the threat of trade diversion, including changing the packaging, name, shape and colour of the drug or perhaps even engaging in agreements with local distributors to ensure that the medications are being delivered to the desired end users. Should Distria experience difficulty in taking adequate steps, para 4 of the Decision provides that they should seek technical and financial cooperation in order to implement reasonable measures. The Chairman's Statement also includes some best practice guidelines. For the reasons outlined above, this statement should be followed when interpreting the Decision.<sup>72</sup>

44. Factoril Inc has changed the colour of their generic M63 to pink in an attempt to prevent trade diversion. This token effort is hardly satisfactory to fulfil the requirements of para 4 of the Decision, which requires that Distria itself 'take reasonable measures ... proportionate to ... the risk of trade diversion'. As mentioned above, trade diversion of pink M63 is not merely a risk, but a reality, as M63 from Distria is already being diverted to Listria. Most users will not know what colour the pill is meant to be without further markings or packaging. Although this complaint is against Factoril, as the exporting Member it is reliant on Distria's status as an *eligible* importing Member to maintain the validity of Licence B. In order to export M63 to Distria under Licence B, Factoril needs to ensure that reasonable measures are being taken in Distria to prevent trade diversion. The failure of Factoril and Distria to take reasonable steps undermines the purpose of Licence B and, until remedied, should invalidate Licence B.

**3: Licence C is inconsistent with TRIPS art 28.1(a) and does not fall into arts 30 or 31**

45. Licence C allows Factoril Inc to manufacture and sell M63 without the consent of Costo Inc, the patent holder. Costo submits that Licence C violates TRIPS as it is inconsistent with art 28.1(a) and does not fall within the exceptions stipulated in art 31 or 30.

**3.1: Licence C does not meet the requirements of TRIPS art 31**

46. Costo submits that Licence C does not meet the requirement of TRIPS art 31(f) that supply be predominantly for the domestic market. Factoril cannot rely on the Decision as Listria is not a

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<sup>71</sup> Chairman's Statement.

<sup>72</sup> See above [34]-[38].

WTO Member and therefore cannot be an 'eligible importing Member'.

### **3.2: Licence C does not fall within TRIPS art 30**

47. Article 30 establishes three criteria that must be met in order to qualify for an exception to TRIPS art 28.1(a): the exception must be limited, it must not unreasonably conflict with the normal exploitation of the patent and it must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

48. The three conditions are cumulative, each being a separate and independent requirement that Factoril must satisfy in order to establish that Licence C falls within art 30.<sup>73</sup>

#### **3.2.1: Interpretation of art 30**

49. Costo submits that in *Canada – Pharmaceuticals* the Panel correctly interpreted key terms within art 30 and the Panel's decision should be applied. In regard to aspects of art 30 that did not require a determination in *Canada – Pharmaceuticals*, Costo emphasises that art 30 must be interpreted according to arts 31 and 32 of the VCLT; in particular looking to the ordinary meaning of the terms, taking into account the context and object and purpose of the treaty.

50. In accordance with the analysis above,<sup>74</sup> the Declaration is a political statement rather than an official interpretation and it cannot alter the rights of Members under TRIPS. Moreover, Costo submits that the Declaration merely affirms the approach taken in *Canada – Pharmaceuticals* and the general principles of interpretation outlined in the VCLT.

51. Articles 7 and 8 evince the object and purpose of TRIPS. In *Canada – Pharmaceuticals* the Panel noted that arts 7 and 8 do not give rise to rights and obligations in and of themselves, but provide the context in which the balance was struck by articles such as 30 and 31. Articles 7 and 8 are relevant to interpreting the terms of TRIPS, but the use of these provisions cannot renegotiate the substantive provisions of the agreement.<sup>75</sup> TRIPS was fiercely negotiated. In regards to pharmaceuticals patents, it was recognised that the rights of inventors and owners needed to be delicately balanced with the needs of end users and licensees.<sup>76</sup>

52. Furthermore, arts 7 and 8 themselves qualify the extent to which they may influence the interpretation of TRIPS. Article 8 provides that measures may be taken to protect public health only where the measures are 'necessary,' and art 7 emphasises the importance of the interests of

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<sup>73</sup> Panel, *Canada – Pharmaceuticals*, [7.20].

<sup>74</sup> See above [25]-[27].

<sup>75</sup> Panel, *Canada – Pharmaceuticals*, [7.24]-[7.26].

<sup>76</sup> Gervais, 14.

the patent holder.

**3.2.2: Article 30 must be construed in the context of art 31**

53. Costo submits that compulsory licences such as Licence C were intended to be governed by art 31, and not art 30 of TRIPS. Article 31 applies to uses of a patent other than those allowed under art 30.<sup>77</sup> If a compulsory licence could be granted under art 30, legal certainty would be severely undermined in respect of determining which is the appropriate provision that Members should use when authorising a compulsory licence.

54. A draft version of art 30 demonstrates that the provision was designed to address situations such as non-commercial experimental use, and prior user rights.<sup>78</sup> Even though these indicia were removed from the final version, the draft shows that it was not envisaged that art 30 would be used to issue compulsory licences. By contrast, this is the clear purpose of art 31.

55. In any case, if art 30 can apply to compulsory licences, Licence C does not meet the requirements set out in art 30, and it is therefore inconsistent with art 28.1(a).

**3.2.3: Licence C is not a 'limited exception'**

56. In *Canada – Pharmaceuticals*, the Panel said that 'limited exception' means a small or narrow exception that only makes a small diminution of the patent holder's legal rights.<sup>79</sup>

57. Licence C impedes Costo Inc's rights to make, use and sell M63. One million units of M63 are being produced in Factoril over a 12 month period, and sold to Listria for stockpiling purposes. In *Canada – Pharmaceuticals* the Panel found that the stockpiling of patented pharmaceuticals for sale once the patent had expired was not 'limited'. Licence C goes even further than Canada's impugned law; the right to manufacture under Licence C is 12 rather than 6 months, and Licence C permits the actual sale of M63 *during* the patent period.

**3.2.4: Licence C unreasonably conflicts with the normal exploitation of the patent**

58. In *Canada – Pharmaceuticals* the Panel explained that the normal practice of patent owners 'is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.<sup>80</sup>

59. Licence C conflicts with Costo Inc's rights to make and sell M63. The normal practice of

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<sup>77</sup> TRIPS Agreement, art 31 n 7.

<sup>78</sup> Special Distribution Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Draft of TRIPS, July 23, 1990*, WTO Doc MTN.GNG/NG11/W/76 (1990).

<sup>79</sup> Panel, *Canada – Pharmaceuticals*, [7.30]–[7.31].

<sup>80</sup> Panel, *Canada – Pharmaceuticals*, [7.55].

Costo Inc would be to preserve its monopoly over M63, so that it would be the exclusive manufacturer and supplier of M63 to as many countries as possible. Costo Inc has gone to some lengths to protect its monopoly, having registered a patent over M63 in most countries. Costo Inc's M63 patent entitles it to exclude all forms of competition in the M63 market in Factoril. Thus Licence C conflicts with the way in which Costo Inc would normally exploit its patent.

60. In *Canada – Pharmaceuticals* it was unnecessary to determine when a conflict with normal exploitation rights would be unreasonable. Costo submits that as this aspect of art 30 is concerned with commercial exploitation, an assessment as to whether the conflict is unreasonable should be made in relation to the commercial detriment arising from the conflict.

61. In *US – Copyright*, the Panel interpreted the meaning of the words 'not unreasonable' in relation to TRIPS Agreement art 13, which is similar but not identical to art 30.<sup>81</sup> Applying the Panel's interpretation, Costo submits that Licence C unreasonably conflicts with the normal exploitation of the patent because Costo Inc suffers financial detriment that is not 'proportionate', is 'more than might be thought likely or appropriate' and is not of 'fair ... amount or size'.<sup>82</sup> Costo Inc will suffer financial detriment as a result of Factoril Inc manufacturing and exporting generic M63 to Lustria. Costo Inc is only receiving 0.225% (1.5% of 15%) of the normal sale price of M63. Licence C will also have a detrimental impact on Costo Inc's ability to profit from the sale of M63 in markets outside Lustria and Factoril. The effect of Licence C is to disclose to the public that the cost of manufacturing M63 is much less than the price at which Costo Inc sells the drug. The dissemination of this knowledge will impair Costo Inc's bargaining position with importers and consumers outside of Factoril and Lustria.

### ***3.2.5: Costo Inc's legitimate interests have been unreasonably prejudiced***

62. Licence C unreasonably prejudices the legitimate interests of Costo Inc, taking account of the legitimate interests of third parties. *Canada – Pharmaceuticals* defines 'legitimate interest' as an interest that is justified by public policy or other social norm.<sup>83</sup> Costo submits that 'unreasonable' should have the same meaning as discussed above at [60]–[61].

63. Protection of patent rights is essential for promoting and supporting vital research into life saving medications such as M63, which may never have been developed without the patent system. This interest is expressly recognised in TRIPS art 7, which sets out the promotion of

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<sup>81</sup> Panel, *US – Copyright*, [6.227].

<sup>82</sup> Panel, *US – Copyright*, [6.225].

<sup>83</sup> Panel, *Canada – Pharmaceuticals*, [7.69].

technological innovation as an object of TRIPS. Costo Inc's ability to recoup a reasonable proportion of its development costs through the exercise of its exclusive rights under the M63 patent therefore has a strong basis in both law and public policy. Further, the protection of private property rights is a social norm that should only be curtailed in exceptional circumstances. In the long term the legitimate interests of third parties, even Listria, are aligned with maintaining the integrity of the patent system and encouraging inventors to develop new treatments to address future threats.

64. Although Costo recognises the importance of ensuring that people in Listria have access to M63, Licence C unreasonably prejudices Costo Inc's legitimate interests because alternatives to a compulsory licence were not considered. Even if art 8 supports the proposition that public health could be considered as a legitimate third-party interest, the article provides that where a Member take measures to protect public health it may do so *only* if such measures are *necessary*. In *US – Gambling* the Appellate Body said that a measure would not be 'necessary' if reasonable WTO-consistent alternatives had not been considered.<sup>84</sup> For instance, Factoril could have tried to negotiate with Costo Inc to supply M63 to Listria. Negotiations for differential pricing are common in the pharmaceutical sector and Costo Inc would have no commercial incentive to refuse to cooperate due to the risk that a compulsory licence could subsequently be issued.<sup>85</sup>

65. Given the importance of maintaining economic incentives for pharmaceutical companies to develop new drugs, Costo submits that even taking into account public health considerations, the curtailment of Costo Inc's rights is not 'appropriate', 'proportionate' or 'fair' because Factoril did not first negotiate with Costo Inc.<sup>86</sup>

66. Costo submits that Licence C is not sufficiently limited, that it unreasonably conflicts with Costo Inc's normal exploitation of the M63 patent, and that it unreasonably prejudices Costo Inc's interests, which are legitimate and justified by public policy and social norms. Infringement of any one of these limbs of art 30 is sufficient to render Licence C inconsistent with Factoril's TRIPS obligations.

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<sup>84</sup> Appellate Body, *US – Gambling*, [306]-[307].

<sup>85</sup> See Matthews, 99; Bale, 644; Rozek and Rainey, 477; Subramaniam, 330.

<sup>86</sup> Panel, *US – Copyright*, [6.225].

*Request for Findings*

Costo requests the Panel exercise its jurisdiction in this matter and find that:

- Licence B is inconsistent with TRIPS art 28.1(a) and 31, as well as the Decision;  
and
- Licence C is inconsistent with TRIPS art 28.1(a), 30 and 31.

Costo therefore requests that the Panel recommend to the DSB that Factoril be requested to bring Licences B and C into conformity with its obligations under TRIPS.