

ANNEX IX TO THE HANDBOOK FOR EMC² PANELLIST

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ELSA MOOT COURT COMPETITION (EMC²) ON WTO LAW
2006-2007

THE BENCH MEMORANDUM

Factoril – Compulsory Licensing of Pharmaceutical Patent

by

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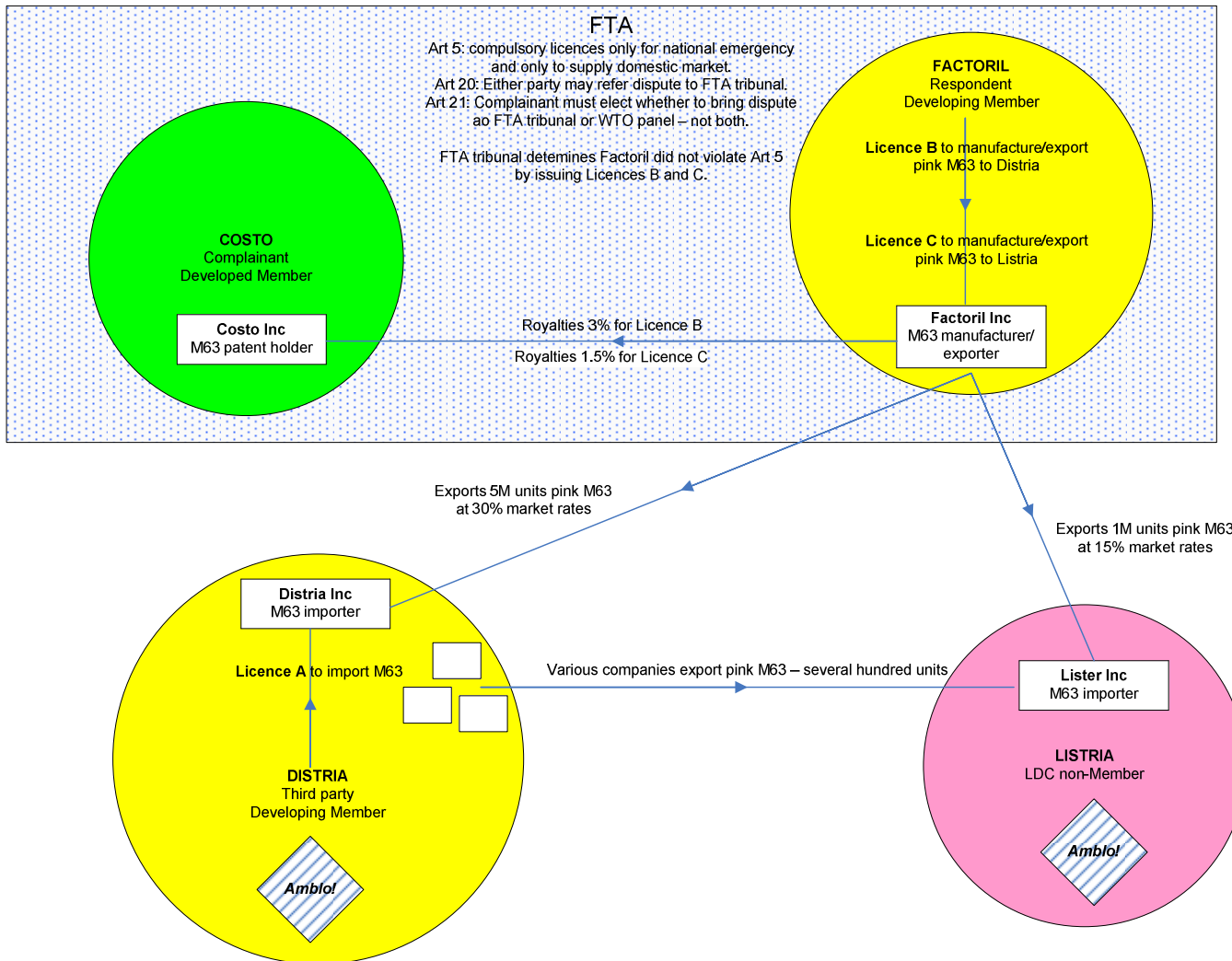
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1. Overview of Key Facts



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2. Timeline of the Case

2000	Factoril enters FTA with Costo.
5 January 2005	Distria notifies Council for TRIPS that it intends to use the Decision as an importer in a national emergency (pursuant to para 1(b) of the Decision).
5 January 2006	Amblo Virus discovered in Distria and Listria.
1 February 2006	Distria notifies Council for TRIPS of Licence A (pursuant to para 2(a) of the Decision).
20 February 2006	Factoril notifies the Council for TRIPS of Licence B (pursuant to para 2(c) of the Decision).
?	Factoril Inc enters contract for export to Distria Inc pursuant to Licence B.
?	Factoril grants Licence C .
?	Factoril Inc enters contract for export to Lister Inc pursuant to Licence C.
March 2006	Costo brings unsuccessful claim to FTA tribunal against Factoril regarding Licences B and C.
?	Costo and Factoril hold unsuccessful consultations pursuant to the DSU.
15 July 2006	Costo requests and DSB establishes panel. Distria reserves third party rights.

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3. Background Documents

a) Agreements and Treaties

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Articles 7-8, 28, 30-31.

Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement), Articles IX-X.

- Teams may wish to refer to these provisions, for example, in assessing the legal status of various documents relating to TRIPS and public health, as listed below.

Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU).

- Teams may wish to rely on various provisions in the DSU in relation to Factoril's jurisdictional defence.

Vienna Convention on the Law of Treaties (VCLT), Articles 30-32, 41.

- All teams will need to be conversant with these provisions, as well as their application by WTO panels and the Appellate Body in cases such as *EC - Chicken Cuts* (WT/DS269, WT/DS286) and *US - Gambling* (WT/DS285).

b) Documents regarding TRIPS and public health

General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003', WT/L/540 (**Decision**), especially paras 1(a), 1(b), 2(a)(ii), 4, 9, 11, and the Annex.

- Much of this problem is about the meaning of the Decision, which creates a temporary waiver from paragraphs 31(f) and (h) of the TRIPS Agreement.

General Council, 'Amendment of the TRIPS Agreement: Decision of 6 December 2005', WT/L/641 (**Amendment**), especially para 2.

- The Decision has now been converted into a formal amendment of the TRIPS Agreement. The Decision remains in force pending the Amendment's entry into force (para 11).
- The Amendment might have interpretative value in connection with the Decision. Perhaps it represents a subsequent agreement or (since it has not yet entered into force) subsequent practice under Article 31(3)(a) or (b) of the VCLT respectively.
- Given the similarity between the Amendment and the Decision, it is most likely that Factoril would use the Amendment to confirm the significance or meaning of the Decision.
- However, Costo might also wish to use the Amendment in this way, eg to confirm the importance of the Chairman's Statement (since the Chairman's Statement was also read out upon the adoption of the Amendment).

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Ministerial Conference, 'Declaration on the TRIPS Agreement and Public Health Adopted on 14 November 2001', WT/MIN(01)/DEC/2 (**Declaration**), especially paras 5-6.

- Paragraph 6 of the Declaration provided the basis for the subsequent work in the WTO leading to the Decision and the Amendment.

General Council, 'Minutes of Meeting Held in the Centre William Rappard on 25, 26 and 30 August 2003', WT/GC/M/82 (**Chairman's Statement**), paras 29-31 and Annex I (in relation to 'colouring').

- Before the Members adopted the Decision, the then Chairman of the General Council, Mr Carlos Pérez del Castillo of Uruguay read out a statement forwarded by the Chairman of the Council for TRIPS on approval from the TRIPS Council (para 29).
- After reading the statement, the Chairman proposed that the General Council, 'in the light of the Chairman's Statement he had just read out', adopt the Decision (which it did) (paras 30-31).

Council for Trade-Related Aspects of Intellectual Property Rights, 'Minutes of Meeting Held in the Centre William Rappard on 28 August 2003', IP/C/M/41, especially the **Philippines' Statement** in paras 4 and 8.

- The Philippines queried certain parts of the Chairman's Statement before the General Council adopted the Decision.

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4. Costo's claim against Licence B

a) TRIPS Agreement Art 28.1(a) – right to prevent making and offering for sale

- Factoril should concede that Licence B is *prima facie* inconsistent with Costo Inc's rights under Article 28.1(a).
- However, Factoril claims that Licence B comprises 'other use without authorization' under Article 31.

b) TRIPS Agreement Art 31(b) – efforts to obtain authorization

- Factoril should concede that Factorial Inc did not try to obtain from Costo Inc authorization to manufacture and export M63 on reasonable commercial terms (Case para 10).
- However, Factoril should claim that it waived this requirement because this is a 'case of a national emergency or other circumstances of extreme urgency or ... public non-commercial use'. (Costo Inc must nevertheless be notified promptly – can assume this occurred eg through the website or the notification to the TRIPS Council: Case paras 8-9).
- Costo may argue that the 'national emergency' or other relevant circumstance must be in the country of export (ie in Factoril, not Distria).
- Factoril should respond that this is inconsistent with the whole point of the Decision.¹ This interpretation would mean that use justified under the Decision would still violate Article 31(b) unless efforts were made to obtain authorization (which could cause unwarranted delays in an emergency). Accordingly, Factoril might argue that either:
 - (i) Article 31(b), read in accordance with Article 31(1) of the *Vienna Convention on the Law of Treaties* (VCLT) (including TRIPS Arts 7-8 as context or object and purpose), does not require the national emergency to be in the exporting country; or (perhaps in the alternative)
 - (ii) the Decision implicitly affects the interpretation of Article 31(b), pursuant to Article 31(3)(a) or 32 of the VCLT, such that the 'national emergency' may be in the importing country.
- In relation to point (ii) above, Costo may respond by referring to paragraph 9 of the Decision, which suggests that it 'is without prejudice to the ... interpretation' of Article 31(b).
- Costo could also argue that the circumstances surrounding the Amblo virus in Distria do not constitute a national emergency or other circumstance falling within Article 31(b) of the TRIPS Agreement. This suggestion is discussed further below in relation to the Decision para 1(b).

c) TRIPS Agreement Art 31(f) – supply of the domestic market

- Factoril should concede that Licence B is *prima facie* inconsistent with Article 31(f).

¹ See Frederick Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99(2) *American Journal of International Law* 317, 342.

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- However, Factoril claims that Licence B meets the conditions of the waiver from Article 31(f) in paragraph 2 of the Decision.
 - Factoril needs to explain why it can rely on the Decision as a defence: eg, because it is a ‘subsequent agreement’ under VCLT Art 31(3)(a), a waiver under WTO Agreement Art IX:3 (see also Art IX:4), or a binding ‘other decision’ under WTO Agreement Art IV:1 (and Art IX:1).²
 - Costo could contend that the Decision is not binding and Factoril cannot rely on it as a defence, but it has the weaker case here.

d) Decision para 1(b) – national emergency

- Distria has notified the Council for TRIPS that it intends to use the Decision as an importer, ‘but only in a national emergency’ (Case para 1).
 - Paragraph 1(b) of the Decision anticipates that eligible importing Members may limit notifications in this way.
 - Paragraph 5(b) of the Declaration states that ‘Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted’. This suggests that use under Article 31 is not restricted to the circumstances expressly mentioned in that provision, such as ‘national emergency’. However, Distria’s notification to the Council for TRIPS seems to render this irrelevant.
- Costo should argue that the circumstances surrounding the Amblo Virus in Distria do not amount to a ‘national emergency’ because:
 - ✗ The Amblo Virus has only been discovered in certain house pets in Distria and Listria (Case para 2).
 - ✗ Scientists don’t know yet whether the Amblo Virus can be transferred from one human to another (Case para 3).
 - ✗ The Case facts do not contain any evidence that humans have actually been infected with the Amblo Virus or suffered any adverse consequences from it.
- Factoril should respond that the circumstances are serious enough to constitute a national emergency because:
 - ✓ Tests show that the Amblo Virus may be transmitted to humans through contact with animal fur, with fatal results within days (Case para 3).
 - ✓ Both Distria and Listria consider that the Amblo Virus threatens the population not only of both countries but also potentially the world (Case para 3).
- Factoril should also point out that the Decision does not limit the circumstances in which it may be required or, specifically, the types of

² See Hunter Nottage and Thomas Sebastian, ‘Giving Legal Effect to the Results of WTO Trade Negotiations: An Analysis of the Methods of Changing WTO Law’ (2006) 9(4) *Journal of International Economic Law* 989, 1003-9.

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diseases covered. Therefore, the fact that the Amblo Virus is not mentioned does not mean that it cannot create a national emergency.

- Paragraph 1(a) of the Decision defines 'pharmaceutical product' by reference to 'the public health problems as recognized in paragraph 1 of the Declaration'.
- Paragraph 1 of the Declaration refers to 'public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'. The word 'especially' suggests that other diseases or 'public health problems' covered by the Declaration and Decision may arise.
- Paragraph 1 of the Declaration is arguably incorporated into the Decision by the reference in paragraph 1(a). Alternatively, it might amount to a 'subsequent agreement' under VCLT Art 31(3)(a)³ or an authoritative interpretation of the TRIPS Agreement under WTO Agreement Art IX:2.
- The negotiating history of the Decision (including the rest of the Declaration) arguably confirms this interpretation.⁴ This history could arguably be examined pursuant to Article 31(1) (context or object and purpose), 31(2)(a), or 32 of the VCLT.
- For example, paragraph 5(c) of the Declaration is in similar terms to paragraph 1, stating that 'Each Member has the right to determine what constitutes a national emergency ..., it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency'.

- Costo may concede or argue this point, although it probably has the weaker side here.
 - Costo's best argument might be that, although the reference to 'HIV/AIDS, tuberculosis, malaria and other epidemics' in paragraph 1 of the Declaration does not restrict the types of diseases that may be covered, it does indicate the kinds of problems that the drafters envisaged, and they are arguably of a scale and seriousness far greater than the Amblo Virus (at least to date).
 - Costo could also dispute the relevance of various items of negotiating history other than paragraph 1 of the Declaration.

e) Decision para 2(a)(ii) – insufficient manufacturing capacity

- Costo should argue that Distria's notification of 1 February 2006 to the Council for TRIPS is inconsistent with paragraph 2(a)(ii) of the Decision because Distria did not explain how it determined that it had insufficient manufacturing capacity (Case para 6). Consequently, the M63 exports from Factoril to Distria do not comply with the Decision.

³ See below n 22.

⁴ Abbott, above n 1, 332.

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- Costo needs to rely on the Chairman's Statement to explain why Distria's notification did not comply with paragraph 2(a)(ii).
- The Chairman's statement says: 'To promote transparency and avoid controversy, 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 in the pharmaceutical sector'.⁵
- Factoril should respond that the Decision merely requires the eligible importing Member to confirm that it has established that it has insufficient capacity 'in one of the ways set out in the Annex'. Distria did confirm that it had established that it had insufficient capacity in the way set out in paragraph (ii) of the Annex (Case para 5(b)).
 - Accordingly, in suggesting a requirement that the eligible importing Member indicate 'how' it established that it had insufficient capacity, the Chairman's Statement was merely referring to the requirement to identify which of the two ways set out in the Annex the Member had used.
 - Alternatively, if the Chairman's Statement means more than this, it should not be taken to override the text of the Decision because:
 - (i) it is improper to interpret the Decision in the light of the Chairmans' Statement under either Article 31(2) or Article 32 of the VCLT; or
 - (ii) if the Chairman's Statement carries interpretative weight, so does the Philippines' Statement, which raises doubts about the Members' agreement with the statement. It maintains that '[t]he sole prerogative for establishing insufficient manufacturing capacity was with the notifying Member. ... A Member could, therefore, provide as much or as little information as it deemed relevant' (para 8).
- If the panel decides to take the Chairman's Statement into account in interpreting the Decision, and if it decides that Distria did not explain how it determined that it had insufficient manufacturing capacity, Factoril could argue that this is merely a breach of a transparency requirement.⁶
 - Accordingly, it can be rectified by Distria providing details at the hearing. It does not mean that Costo may challenge Distria's determination that it has insufficient manufacturing capacity and the consequential exports under Licence B.
- Costo could respond that the Chairman's Statement in fact imposes a substantive requirement to explain how the eligible importing Member established insufficient manufacturing capacity, allowing other Members to

⁵ Chairman's Statement, para 29 (top of p 7).

⁶ Abbott, above n 1, 336.

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challenge the basis on which it did so⁷ (contrary to the Philippines' Statement).

- Factoril could argue, as a last resort, that even if Distria has failed to comply with its obligations under the Decision, Factoril has complied with its obligations, and if Costo wishes to pursue the matter it will need to request the establishment of a new panel with Distria as a respondent.
- Costo could respond that the waiver in paragraph 2 of the Decision is available on condition that the 'terms set out below in this paragraph' are all met, including those imposed regarding the eligible importing Member.

⁷ Michael Trebilcock and Robert Howse, *The Regulation of International Trade* (3rd ed, 2005) 431; Carlos Correa, 'Access to Drugs under TRIPS: A not so expeditious solution' (2004) 8(1) *Bridges* 21, 22 <<http://www.ictsd.org/monthly/bridges/BRIDGES8-1.pdf>>.

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f) Decision para 4 – reasonable measures to prevent re-exportation

- Costo should argue that Distria did not take reasonable measures to prevent re-exportation as required by paragraph 4 of the Decision because it decided ‘that it need not take any additional steps to prevent re-exportation of the imported M63’ (Case para 11).
- Factoril should emphasize that Distria decided not to take *additional* steps, keeping in mind that the different colour was one measure already in place that would help prevent re-exportation.
- Factoril should also point out that Distria had regard to ‘the urgent need for M63 within Distria, and Distria’s limited resources’ (Case para 11).
 - Paragraph 4 of the Decision specifically states that eligible importing Members are to take reasonable measures ‘within their means, proportionate to their administrative capacities and to the risk of trade diversion’.
 - The Philippines’ Statement sets out the Members’ ‘shared understanding’ that ‘the undertaking assumed by eligible importing countries in the Decision to take reasonable measures within their means to prevent trade diversion of products imported under the system was strictly on a “best endeavour basis”’.
- Costo could respond that the ‘risk of trade diversion’ was high, given the occurrence of the Amblo Virus in Listeria and the fact that it was not a WTO Member and therefore might have trouble securing alternative supply.
 - This is evidenced by the facts – the risk of trade diversion was actually realised, as Lister Inc imported several hundred units of pink M63 from Distria (Case para 13).
- Costo should add that paragraph 4 of the Decision states that if an eligible importing Member ‘experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation’.
 - Hence, the appropriate response was for Distria to request cooperation from Costo or other developed country Members in taking measures to prevent trade diversion.
- Finally, Costo should point out that the ‘shared understanding’ alleged in the Philippines’ Statement does not appear in the Decision itself or in the Chairman’s Statement, which has more interpretative force. Costo may contend that it is improper to interpret the Decision in the light of the Philippines’ Statement, under either Article 31(2) or Article 32 of the VCLT.

5. Costo’s claim against Licence C

a) TRIPS Agreement Art 28.1(a) – right to prevent making and offering for sale

- Factoril should concede that Licence C is *prima facie* inconsistent with Costo Inc’s rights under Article 28.1(a).
- However, Factoril should claim that Licence B comprises one of the ‘limited exceptions’ allowed under Article 30.

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b) TRIPS Agreement Art 30 – limited exceptions

- In arguing this issue, both teams should take into account the Panel Report in *Canada – Pharmaceuticals*.⁸ Article 30 imposes three requirements, according to its text as interpreted by the panel:
 - (i) The exception must be 'limited' – this is a separate requirement.⁹ This means 'a narrow exception – one which makes only a small diminution of the rights in question'.¹⁰ The 'economic impact' of the exception is not relevant in assessing whether an exception is 'limited'.¹¹
 - Canada's stockpiling exception was not limited because, '[w]ith no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term'.¹²
 - In contrast, Canada's regulatory review exception was limited because, '[a]s long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded'.¹³
 - (ii) The exception must 'not unreasonably conflict with a normal exploitation of the patent'. Such normal exploitation 'is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.¹⁴
 - Canada's regulatory review exception did not conflict with a normal exploitation of the patent because 'the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization ... is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws'.¹⁵
 - (iii) The exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'.
 - The panel in *Canada – Pharmaceutical Patents* did not need to decide whether the qualification regarding legitimate interests of

⁸ Panel Report, *Canada – Patent Protection of Pharmaceutical Products* ('*Canada – Pharmaceutical Products*'), WT/DS114/R, circulated 17 March 2000, adopted 7 April 2000 without appeal.

⁹ *Ibid*, paras 7.20-7.21.

¹⁰ *Ibid*, para 7.30.

¹¹ *Ibid*, para 7.49.

¹² *Ibid*, paras 7.34, 7.36.

¹³ *Ibid*, para 7.45.

¹⁴ *Ibid*, para 7.55.

¹⁵ *Ibid*, para 7.57.

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third parties might also apply to the second requirement of Article 30.¹⁶

- A ‘legitimate interest’ is not a ‘legal’ interest or right¹⁷ but a ‘normative claim calling for protection of interests that are “justifiable” in the sense that they are supported by relevant public policies or other social norms’.¹⁸
 - For example, some contend that scientific experimentation without consent during the term of the patent falls within this exception because ‘both society and the scientist have a “legitimate interest” in using the patent disclosure to support the advance of science and technology’.¹⁹
 - Canada’s regulatory review exception did not unreasonably prejudice the legitimate interests of the patent owner contrary to Article 30.
- Costo should argue that Licence C does not fall under Article 30 because:
 - ✗ Using Article 30 to allow licences like Licence C would involve an unlimited exception, dependent solely on Members’ unilateral decision-making as to which non-Members to export to and what conditions to impose.
 - ✗ Licence C conflicts with a normal exploitation of the M63 patent because, in its absence, Listria would have to purchase M63 from Costo Inc.
 - ✗ The royalty rate of 1.5% is less than that applicable under Licence B (3%) and the price is only 15% of market rates. Therefore, Costo Inc is missing out on significant royalties.
 - ✗ Licence C unreasonably prejudices the legitimate interests of the patent owner (Costo Inc). These kinds of licences diminish incentives to research and innovate, to the detriment of global health.
 - Factoril should respond that Licence C does fall under Article 30 because:
 - ✓ Licence C is limited in terms similar to those required by the Decision (eg pink M63, maximum 1M units, 12 months only, non-renewable).
 - ✓ The amount of revenue forgone is likely to be small.²⁰
 - ✓ Licence C includes provision for payment of royalties (1.5%).
 - ✓ Legitimate interests of third parties include the health of potential sufferers of the Amblo Virus in Listria, and the interests of global society in preventing public health crises and their proliferation.

¹⁶ Ibid, para 7.59.

¹⁷ Ibid, paras 7.68, 7.73.

¹⁸ Ibid, para 7.69.

¹⁹ Ibid.

²⁰ Cf Trebilcock and Howse, above n 7, 430-31 (discussing the use of Article 30 to allow exports under compulsory licence to a WTO Member lacking sufficient manufacturing capacity to take advantage of Article 31).

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- ✓ Countries such as Canada allow exports under compulsory licence to least developed or other non-WTO Members (often subject to stringent conditions similar to those in the Decision).²¹ (Perhaps this could constitute ‘subsequent practice’ under Article 31(3)(b) of the VCLT, although it is likely to meet the high standard required.)
- ✓ Some commentators suggest this approach is justified under Article 30.²²
- Factoril should support its arguments by reference to relevant context, object and purpose, and negotiating history (pursuant to the relevant provisions of the VCLT), including:
 - ✓ Declaration para 5(a), which emphasizes that ‘each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles’.
 - ✓ The ‘Objectives’ and ‘Principles’ of the TRIPS Agreement are arguably found in Articles 7 and 8 respectively, which include reference to ‘social and economic welfare’, ‘a balance of rights and obligations’ (Art 7), and ‘measures necessary to protect public health and nutrition’ (Art 8.1).
 - ✓ Declaration para 4, which states, ‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, ... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines *for all*’ (emphasis added).²³
 - ✓ Decision para 1(b), which highlights the particular circumstances of least-developed countries (or at least LDC Members). More generally, the plight of LDCs and the importance of development is reflected in the Doha Development Agenda and various parts of the TRIPS Agreement.
 - ✓ Decision para 6(i), which allows some flexibility in relation to LDCs even where they are non-Members.
- Costo may dispute the interpretative relevance of these provisions, their legal status, or their significance for Factoril’s argument.

²¹ See eg Matthew Rimmer, ‘The Jean Chrétien Pledge to Africa Act: patent law and humanitarian aid’ (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889, 894.

²² See eg Abbott, above n 1, 337-38, 340. But see Sandra Bartelt, ‘Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health’ (2003) 6(2) *Journal of World Intellectual Property* 283, 300.

²³ This paragraph, at least, is arguably a ‘decision’ of the Members under Article IX:1 of the WTO Agreement and a ‘subsequent agreement’ pursuant to Article 31(3)(a) of the VCLT: Frederick Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’ (2002) 5(2) *Journal of International Economic Law* 469, 491-92.

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- Factoril could also refer to the call for a ‘human rights approach’ to interpretation of WTO provisions, including the TRIPS Agreement.²⁴ It might rely on a range of human rights documents to support Licence C.
- c) **TRIPS Agreement Art 31 – other use without authorization**
 - Costo should point out that Licence C does not fall within Article 31, primarily because it is inconsistent with Article 31(f), which allows other use without authorization ‘predominantly for the supply of the domestic market of the Member authorizing such use’.
 - Although the word ‘predominantly’ may provide some flexibility, the facts suggest that Licence C is not even predominantly for the supply of Factoril’s market.
 - Factoril should probably focus on Article 30 and concede that Licence C does not meet the requirements of Article 31.
 - If Factoril does argue that Licence C falls within Article 31, this should be in the alternative, because ‘other use’ pursuant to Article 31 ‘refers to use other than that allowed under Article 30’ (footnote 7 to Article 31).

²⁴ See eg Sub-Commission on the Promotion and Protection of Human Rights, UN, *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner*, E/CN.4/Sub.2/2001/13 (27 June 2001).

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d) Decision – waiver of Art 31(f)

- Costo should point out that paragraph 2 of the Decision provides a waiver from Article 31(f) for an exporting Member exporting to an ‘eligible importing Member’, which is exhaustively defined in paragraph 1(b) to include last-developed country Members as well as other Members that have notified the Council for TRIPS of their intention to use the system as an importer.
 - The Decision does not contemplate the possibility of a non-Member (such as Listria under Licence C) being an ‘eligible importing Member’.
- Factoril should probably focus on Article 30 and concede that Licence C does not meet the requirements of the Decision.

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6. Factoril's jurisdictional defence

a) General

- Teams have significant flexibility in approaching this issue, given the limited amount of WTO jurisprudence on it. They should attempt to provide some structure to their arguments.
- Teams must pay particular attention to the VCLT and show a good understanding of the place of the WTO within public international law, including contested matters concerning its jurisdiction and applicable law.
- Teams will also need a good understanding of the case *Mexico – Taxes on Soft Drinks*.²⁵

b) Mexico – Taxes on Soft Drinks

- Mexico asked the panel to decline jurisdiction in favour of an Arbitral Panel under Chapter Twenty of the North American Free Trade Agreement (NAFTA). The panel rejected this request, holding that it had no discretion to decline jurisdiction in this case.²⁶ The Appellate Body upheld the panel's conclusion.²⁷
 - In contrast, here Factoril is claiming that the panel lacks jurisdiction altogether (Case para 18). This may be a harder argument to make but it may mean Factoril does not have to argue that *Mexico – Taxes on Soft Drinks* was incorrectly decided.
 - The panel emphasized that it was not deciding 'whether there may be other cases where a panel's jurisdiction might be legally constrained'.²⁸
 - Similarly, the Appellate Body 'express[ed] no view as to whether there may be other circumstances in which legal impediments could exist that would preclude a panel from ruling on the merits of the claims that are before it'.²⁹
- The panel noted that 'there was nothing in the NAFTA that would prevent the United States from bringing the present case to the WTO dispute settlement system'.³⁰ The Appellate Body reiterated this feature of the case.³¹
 - In contrast, here Article 21 of the FTA indicates that Costo cannot bring the dispute to the WTO because it has already brought it to the FTA tribunal (Case para 14). This may support Factoril's argument.
- The panel noted that, '[i]n the present case, the complaining party is the United States and the measures in dispute are allegedly imposed by Mexico.

²⁵ Appellate Body Report, *Mexico – Tax Measures on Soft Drinks and Other Beverages*, ('*Mexico – Taxes on Soft Drinks*'), WT/DS308/AB/R, circulated 6 March 2006, adopted 24 March 2006; Panel Report, *Mexico – Taxes on Soft Drinks*, WT/DS308/R, circulated 7 October 2005, adopted 24 March 2006 as modified by the Appellate Body Report.

²⁶ Panel Report, *Mexico – Taxes on Soft Drinks*, para 7.18.

²⁷ Appellate Body Report, *Mexico – Taxes on Soft Drinks*, para 57.

²⁸ Panel Report, *Mexico – Taxes on Soft Drinks*, para 7.10.

²⁹ Appellate Body Report, *Mexico – Taxes on Soft Drinks*, para 54 (see also para 44).

³⁰ Panel Report, *Mexico – Taxes on Soft Drinks*, para 7.13.

³¹ Appellate Body Report, *Mexico – Taxes on Soft Drinks*, para 44.

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In the NAFTA case, the situation appears to be the reverse: the complaining party is Mexico and the measures in dispute are allegedly imposed by the United States.³²

- In contrast, here the measures in dispute are the same – Licences B and C (Case paras 15, 17). This may support Factoril’s argument.
- However, Costo alleged violation of Article 5 of the FTA before the FTA tribunal and alleges violation of WTO provisions before the WTO panel (Case paras 15, 17). Moreover, the FTA and WTO provisions are quite different. This may support Costo’s argument.
- The panel based its decision in part on DSU Arts 3.2, 11, 19.2 and 23.³³ The Appellate Body also relied on DSU Arts 3.2, 3.3, 7.1, 7.2, 11, 19.2 and 23.³⁴
 - Based on these interpretations, the provisions seem to support Costo’s case. However, Factoril could also argue that aspects of these provisions support its position.
- The Appellate Body stated, ‘we see no basis in the DSU for panels and the Appellate Body to adjudicate non-WTO disputes’.³⁵
 - Factoril could argue that it is not asking the Appellate Body to adjudicate a non-WTO dispute. On the contrary, the FTA tribunal has already adjudicated this matter under Article 5 of the FTA.
 - Costo could respond that Factoril is requesting the Appellate Body to rule on the meaning of Article 21 of the FTA.
 - Factoril could also contest or attempt to restrict the Appellate Body’s statement, keeping in mind that WTO panels and the Appellate Body frequently interpret Members’ domestic legislation, and that the WTO is not ‘clinically isolated’ from public international law.³⁶

c) **Conflict between DSU and FTA Art 21**

- Factoril could argue that no conflict arises between the DSU and FTA Art 21. Rather, the DSU should simply be interpreted with regard to FTA Art 21 to conclude that the panel lacks jurisdiction in this case.
 - Factoril could maintain that no conflict arises because it is possible to comply with both the DSU and FTA at the same time.³⁷

³² Panel Report, *Mexico – Taxes on Soft Drinks*, para 7.14. See also Appellate Body Report, *Mexico – Taxes on Soft Drinks*, para 54.

³³ Panel Report, *Mexico – Taxes on Soft Drinks*, paras 7.6-7.9.

³⁴ Appellate Body Report, *Mexico – Taxes on Soft Drinks*, paras 47-53.

³⁵ *Ibid* para 56.

³⁶ Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline* (‘US – Gasoline’), WT/DS2/AB/R, circulated 29 April 1996, adopted 20 May 1996, 17. (The Appellate Body stated that ‘the *General Agreement* is not to be read in clinical isolation from public international law’).

³⁷ See eg Panel Report, *Indonesia – Certain Measures Affecting the Automobile Industry* (‘Indonesia – Autos’), WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R and Corr.1, 2, 3, 4, circulated 2 July 1998, adopted 23 July 1998 without appeal, n 649; Gabrielle Marceau, ‘Conflicts of Norms and Conflicts of Jurisdictions: The Relationship between the WTO Agreement and MEAs and other Treaties’ (2001) 35(6) *Journal of World Trade* 1081, 1084.

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- Factoril would need to explain why the FTA is relevant to the interpretation of the DSU – eg, pursuant to VCLT Art 31(3)(c).
- Costo could agree that no conflict arises but dispute that the FTA is relevant to the interpretation of the DSU or dispute the interpretative effect Factoril is claiming.
 - Costo could argue that the FTA does not fall within VCLT Art 31(3)(c) because not all WTO Members are party to it.³⁸
- Alternatively, Costo could argue that a conflict does arise between the DSU and FTA Art 21, and that this conflict should be resolved in favour of the DSU.
 - Costo could maintain that a conflict arises where an obligation in one agreement (FTA Art 21) prevents a party from exercising a right under another agreement (using the dispute settlement system under the DSU).³⁹
 - Costo could argue that the DSU is about enforcing WTO rules and therefore the DSU overrides the FTA in the context of the WTO dispute settlement system,⁴⁰ perhaps because DSU Arts 3.2 and 19.2 operate as a ‘conflicts rule’ in favour of the WTO agreements.⁴¹
- Factoril could respond that, even if a conflict arises here, FTA Art 21 should prevail.
 - Factoril should argue that the general rules on treaty formation and successive treaties apply to the WTO.⁴²
 - Factoril could contend that the FTA modified the WTO agreements between Factoril and Costo, in accordance with VCLT Art 41 (some commentators agree that such *inter se* modifications are possible).⁴³ Therefore, the FTA prevails pursuant to VCLT Art 30(4)(a) (see also Art 30(5)).
- Costo should respond that *inter se* modifications to the WTO agreements are not possible pursuant to VCLT Art 41,⁴⁴ based on an interpretation of that provision and perhaps the WTO Agreement.

³⁸ See eg Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, circulated 29 September 2006, para 7.68 (not appealed).

³⁹ See eg Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to other Rules of International Law* (2003) 329; ILC, UN, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law – Report of the Study Group (Martti Koskenniemi)*, A/CN.4/L.682 (4 April 2006) [25].

⁴⁰ See Martti Koskenniemi and Päivi Leino, ‘Fragmentation of International Law? Postmodern Anxieties’ (2002) 15(3) *Leiden Journal of International Law* 553, 572.

⁴¹ Lorand Bartels, ‘Applicable Law in WTO Dispute Settlement Proceedings’ (2001) 35(3) *Journal of World Trade* 499, 507.

⁴² Panel Report, *Korea – Measures Affecting Government Procurement* (‘Korea – Procurement’), WT/DS163/R, circulated 1 May 2000, adopted 19 June 2000 without appeal, para 7.96.

⁴³ See eg Pauwelyn, above n 39, 475; ILC, above n 39, [306].

⁴⁴ See eg Marceau, above n 37, 1105; Joel Trachtman, ‘Review of Joost Pauwelyn, Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law’ (2004) 98 *American Journal of International Law* 855, 858-59. See also Panel Report, Panel Report, *Turkey –*

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d) *Res judicata*

- Factoril could argue that the *res judicata* rule⁴⁵ precludes the panel from accepting jurisdiction.
 - Factoril would need to show that *res judicata* forms part of customary international law or is a general principle of law and is therefore part of international law⁴⁶ and applicable in WTO disputes.
 - This requires the parties to the FTA and WTO disputes to be the same, which they are (Costo and Factoril).
 - It also requires the issues to be the same. Although, as noted above, the legal claims are different in both form and substance (FTA Art 5 vs TRIPS Agreement), the same issues will need to be relitigated eg whether there is a national emergency, significance of the Declaration etc. A risk of inconsistent rulings exists.
- Costo could respond that *res judicata* is not part of customary international law or a general principle of law, or that it does not apply in WTO disputes.⁴⁷
 - Costo could also argue that even if *res judicata* applies in WTO disputes, it is not applicable here, eg because Costo's legal claims are different, the FTA tribunal did not decide any issues that the WTO panel needs to decide, or (perhaps) the potential parties to the WTO dispute include non-parties to the FTA dispute (such as Distria).
- Even if *res judicata* is not strictly applicable, Factoril could argue that Costo is estopped from raising this matter in the WTO, having agreed to the FTA terms and chosen to bring a dispute in the FTA. This argument might even be valid in the absence of FTA Art 21.⁴⁸
 - Factoril would need to show that estoppel forms part of customary international law or is a general principle of law and is therefore part of international law⁴⁹ and applicable in WTO disputes.
- Costo could respond that estoppel is not part of customary international law or a general principle of law, or that estoppel does not apply in WTO disputes.⁵⁰

Restrictions on Imports of Textile and Clothing Products ('Turkey - Textiles'), WT/DS34/R, circulated 31 May 1999, adopted 19 November 1999 as modified by the Appellate Body Report, paras 9.181-9.182; Chios Carmody, 'WTO Obligations as Collective' (2006) 17(2) *European Journal of International Law* 419, 441-42.

⁴⁵ In connection with overlaps in international jurisdiction, see Yuval Shany, *The Competing Jurisdictions of International Courts and Tribunals* (2003) 21-28.

⁴⁶ See ICJ Statute Arts 38(1)(b) and (c); Shany, above n 45, 245-46.

⁴⁷ The Panel did not decide this issue in Panel Report, *Indonesia - Autos*, paras 7.57-7.66, 7.103.

⁴⁸ See the discussion of the *electa una via* rule (or the 'principle of election') in Shany, above n 45, 23.

⁴⁹ See ICJ Statute Arts 38(1)(b) and (c).

⁵⁰ The Appellate Body raised some doubts about whether estoppel applied to WTO disputes but did not decide the issue in Appellate Body Report, *European Communities - Export Subsidies on Sugar ('EC - Export Subsidies on Sugar')*, WT/DS265/AB/R, WT/DS266/AB/R, WT/DS283/AB/R, circulated 28 April 2005, adopted 19 May 2005, paras 310, 312.

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- Costo could also argue that even if estoppel applies in WTO disputes, it is not applicable here based on the facts.
- Finally, Factoril could argue that even if *res judicata* and estoppel do not apply, in the interests of judicial comity and coherence in international law the panel should have regard to the FTA tribunal's decision and FTA Art 21 in declining to hear or in deciding the case.

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7. Summary of Arguments

a) Licence B

Issue	Costo's arguments	Factoril's arguments
TRIPS Art 28.1(a)	Licence B violates Costo Inc's patent rights.	Concede, but exempt under Art 31.
TRIPS Art 31(b)	Factoril Inc did not seek authorisation from Costo Inc.	Concede, but requirement waived because this is a national emergency or other circumstance of extreme urgency or public non-commercial use.
	National emergency etc must be in Factoril, not Distria.	This reading of Article 31(b) is incorrect, particularly having regard to Articles 7 and 8 and the Decision.
	Decision para 9 makes clear that it does not affect the interpretation of Art 31(b).	
	In any case, this is not a national emergency (note facts).	Yes it is (note facts).
TRIPS Art 31(f)	Licence B is not predominantly for supply of Factoril's own market.	Concede, but requirement waived under Decision, which is binding and can be relied on as a defence.
Decision para 1(b)	This is not a national emergency (note facts).	Yes it is (note facts).
	Reference to HIV etc in para 1(a) (via Declaration para 1) indicates the types of things that may be a national emergency or public health problem.	This list is not exhaustive, as demonstrated by the negotiating history and the word 'especially' in Declaration para 1.
Decision para 2(a)(ii)	Distria did not explain how it established that it had insufficient capacity, as required by Chairman's Statement.	Distria explained what it needed to in connection with the Annex. Chairman's Statement is disputed by Philippines' Statement and cannot affect the words of the Decision.
	The Chairman's Statement imposes a substantive obligation. Costo can challenge Distria's determination of insufficient capacity.	If anything, the Chairman's Statement imposes merely a transparency obligation. Costo cannot challenge Distria's determination of insufficient capacity.
	As Distria breached this obligation, Licence C is inconsistent with the Decision.	If Distria breached this obligation, it does not affect the validity of Licence C. Factoril complied with its obligations.
Decision para 4	Distria did not take reasonable measures to protect re-exportation,	Distria did not take <i>additional</i> steps - colour already prevented re-

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	even though the 'risk of trade diversion' was high and was realised.	exportation.
	If Distria had trouble taking reasonable measures it should have requested assistance as described in para 4.	Para 4 requires Members to take reasonable measures 'within their means'.
	The Philippines' Statement is not reflected in the Chairman's Statement and cannot affect the interpretation of para 4.	Philippines' Statement confirms this is merely a 'best endeavour' obligation.

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b) Licence C

Issue	Costo's arguments	Factoril's arguments
TRIPS Art 28.1(a)	Licence C violates Costo Inc's patent rights.	Concede, but exception under Art 30.
TRIPS Art 30	An exception for Licence C would not be 'limited'.	Licence C is limited in terms similar to those required by the Decision.
	Licence C conflicts with a normal exploitation of the M63 patent because, in its absence, Listria would have to purchase M63 from Costo Inc.	The amount of revenue forgone is small.
	Licence C unreasonably prejudices the legitimate interests of the patent owner (Costo Inc). These kinds of licences diminish incentives to research and innovate, to the detriment of global health.	Legitimate interests of third parties include the health of potential sufferers of the Amblo Virus in Listria, and the interests of global society in preventing public health crises and their proliferation.
	These provisions do not carry interpretative weight, or do not help Factoril's argument.	These arguments are supported by the Declaration paras 4-5(a), TRIPS Arts 7-8, Decision paras 1(b), 6(i), and the call for a 'human rights approach' to interpreting the TRIPS Agreement.
TRIPS Art 31	Licence C is not predominantly for supply of Factoril's own market.	Concede.
Decision	Listria is not an eligible importing Member, so Licence C is not covered by the Decision.	Concede.

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c) Jurisdictional Defence

Issue	Costo's arguments	Factoril's arguments
Soft Drinks	<i>Soft Drinks</i> suggests panels cannot decline jurisdiction.	This case is different because FTA Art 21 precludes the panel hearing the case, and the question is not discretion to exercise jurisdiction but lack of jurisdiction altogether.
	DSU provisions support the existence of panel jurisdiction.	DSU provisions support the absence of panel jurisdiction.
	Factoril is asking the panel to rule on a non-WTO issue ie the meaning of FTA Art 21.	Panels frequently interpret non-WTO laws.
	The claims and issues in the FTA and WTO disputes are different.	The parties and measures in dispute are the same in the FTA and WTO disputes.
Conflict	No conflict arises between the DSU and FTA Art 21. The FTA does not fall within VCLT Art 31(3)(c) because not all WTO Members are parties to it.	Concede, but FTA Art 21 is relevant (under VCLT Art 31(3)(c)) in interpreting the DSU to conclude that the panel lacks jurisdiction.
	In the alternative, a conflict arises and the DSU prevails over FTA Art 21, because <i>inter se</i> modifications to the WTO agreements are not permitted.	If a conflict arises, FTA Art 21 prevails under VCLT Art 30(4)(a) and 41 because the FTA is an <i>inter se</i> modification to the WTO agreements (between Costo and Factoril).
Res judicata	<i>Res judicata</i> does not apply to WTO disputes, or it does not apply in this instance.	<i>Res judicata</i> is part of customary international law or a general principle of law. It applies here because the parties and issues are the same.
Estoppel	Estoppel does not apply to WTO disputes, or it does not apply in this instance.	Estoppel is part of customary international law or a general principle of law and applies in the circumstances of this case.
Judicial comity	Judicial comity does not require the panel to refuse to hear the case.	Judicial comity and coherence in international law mean the panel should not hear the case.

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8. Suggestions for further reading

a) TRIPS and public health

Frederick Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5(2) *Journal of International Economic Law* 469.

Frederick Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99(2) *American Journal of International Law* 317.

James Gathii, 'The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties' (2002) 15(2) *Harvard Journal of Law and Technology* 291.

Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) *Journal of International Economic Law* 73.

Médecins Sans Frontières, 'Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable', prepared for the XVI International AIDS Conference, Toronto, August 2006 <<http://www.accessmed-msf.org/>>.

Matthew Rimmer, 'The Jean Chrétien Pledge to Africa Act: patent law and humanitarian aid' (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889.

FM Scherer and Jayashree Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Nations' (2002) 5(4) *Journal of International Economic Law* 913.

Haochen Sun, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health' (2004) 15(1) *European Journal of International Law* 123.

b) WTO, public international law, and FTAs

International Law Commission, UN, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law – Report of the Study Group (Martti Koskenniemi)*, A/CN.4/L.682 (4 April 2006).

Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) *Journal of International Economic Law* 17.

Federico Ortino, 'Treaty Interpretation and the WTO Appellate Body Report in *US - Gambling: A Critique*' (2006) 9(1) *Journal of International Economic Law* 117.

Campbell McLachlan, 'The Principle of Systemic Integration and Article 31(3)(c) of the Vienna Convention' (2005) 54 *International & Comparative Law Quarterly* 279.

Joost Pauwelyn, 'Adding Sweeteners to Softwood Lumber: the WTO-NAFTA "Spaghetti Bowl" is Cooking' (2006) 9(1) *Journal of International Economic Law* 197.

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Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (2003).

Joost Pauwelyn, 'The Jurisdiction of the World Trade Organization' (2004) 98 *American Society of International Law Proceedings* 135.

Yuval Shany, *The Competing Jurisdictions of International Courts and Tribunals* (2003).

Joel Trachtman, 'The Jurisdiction of the World Trade Organization' (2004) 98 *American Society of International Law Proceedings* 139.