'SEIZING' PHARMACEUTICALS IN TRANSIT: ANALYSING THE WTO DISPUTE THAT WASN'T

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Abstract Several recent detentions of generic pharmaceutical products transiting through the European Union (EU) for suspected infringements of intellectual property rights raised serious concerns for public health advocates and threatened to expose systemic problems existing in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The detentions not only garnered international attention, but India and Brazil formally began WTO dispute settlement proceedings against the EU. The parties recently reached a mutually agreed solution to the matter and the proceedings have been halted, leaving unanswered the complex legal and technical questions raised by the detentions of pharmaceuticals in transit. Despite a solution being reached in this dispute, the matter will undoubtedly resurface in the near future for a number of reasons. For instance, the EU is attempting to export its laws to its trading partners through the negotiation of free trade agreements and in other forums such as the recently concluded Anti-Counterfeiting Trade Agreement which increases the likelihood that similar detentions will occur at some point in the future. Moreover, recent trends in international intellectual property law indicate a move towards increased protection and enforcement in at least the short and medium term. The issue therefore offers the opportunity for rich legal analysis into an underexplored, yet increasingly important, aspect of WTO law.

I. INTRODUCTION

In early December 2008, Dutch customs officials acting in response to complaints from the patent rights owner confiscated for suspected patent infringement 570 kilograms of the drug losartan potassium[1] (used to treat high blood pressure) that were docked in Rotterdam while in transit from India to Brazil.[2] After delaying the shipment for 36 days, Dutch authorities released the

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[1] The Dutch patent for losartan is held by US-based DuPont under the branded name of 'Cozaar'. Merck Sharp & Dohme possess the Dutch marketing rights for the drug. The generic drug at issue is manufactured by Dr. Reddy's and is imported into Brazil by EMS.

[2] India, Brazil and the EC made interventions at the WTO General Council Meeting held on 3 February 2009 under agenda item 'Other Business'. For the complete statements, see <http://indiainthewto.wordpress.com/2009/03/11/text-of-indian-statement-on-generics-seizure-before-trips-council/> (India); <http://keionline.org/blogs/2009/02/03/intervention-by-brazil-at-wto-general-council-on-seizure-of-500-kilos-of-generic-medicines-by-dutch-customs-aut> (Brazil); and

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goods to the exporter, who promptly shipped the drugs back to India, the country of manufacture. The drug at issue is patented neither in the country of export or in the country of final destination. Nor is the drug subject to a compulsory licence. The drug is, however, patented in the Netherlands, the country of transit. There was no suggestion that the generic medicines at issue were of substandard quality.

So began the controversy that saw several additional 'seizures',[3] numerous heated exchanges between European, Brazilian and Indian diplomats and impassioned and angry statements from non-governmental organizations (NGOs) and public health activists.[4] Following a year of fruitless negotiations and repeated threats, India and Brazil filed complaints at the WTO over the matter. After delaying the establishment of a panel for several months, the parties reached a temporary settlement to the issue and proceedings halted (ie a panel was never established).[5] A final settlement was reached in July 2011.[6]

While a diplomatic solution is always preferable to having recourse to a dispute settlement process, the resolution leaves unanswered the complex legal and technical questions raised by the detentions of pharmaceuticals in transit.

<http://keionline.org/blogs/2009/02/05/ec-intervention-at-wto> (EC). Interventions were also made at the WTO TRIPS Council Meeting held on 3 March 2009 under agenda item M 'Other Business'. For their complete statements, see <http://keionline.org/node/309> (India); <http://keionline.org/blogs/2009/03/04/brazilian-intervention-at-trips-council> (Brazil); and <http://lists.essential.org/pipermail/a2k/2009-March/003983.html> (EC). See also Bridges Weekly Trade News, 'Dutch Seizure of Generic Drugs Sparks Controversy' (Intellectual Property Programme 13 (3), 28 January 2009) <http://ictsd.net/i/news/bridgesweekly/38841/>.

[3] The EU contest the terminology 'seizures' and instead uses the term 'temporal detentions'. Regulation 1383/2003 likewise uses the terms 'detention' and 'suspension' as opposed to 'seizure'. See Council Regulation (EC) No 1383/2003 of 22 July 2003, concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, OJ (2003) L 196/7, third recital and arts 4, 9.1 and 11.

[4] For instance, activist Brook Baker expressed 'outrage' at the detentions and Indian Commerce Secretary GK Pillai stated that the detentions were 'an act of piracy … This is a dangerous thing happening, which is totally uncalled for. It is part of the strategy by these countries to target generic drugs from India.' Brook Baker, 'Pointing the finger at Big Pharma – Dutch seizure of generic medicines' (12 February 2009) European Aids Treatment Group <http://www.eatg.org/eatg/Global-HIV-News/EU-Policy/Pointing-the-finger-at-Big-Pharma-Dutch-seizure-of-generic-medicines>; Radhieka Pandeya, 'Dr Reddy's consignment of drugs to Brazil seized' (*Live Mint*, 15 January 2009) <http://www.livemint.com/2009/01/14220926/dr-reddy8217s-consignment-o.html>. See also Bridges (n 2). In a more levelled response, Médecins Sans Frontières (MSF) expressed concern that the Regulation could be used to impede access to essential medicines and even affect its own procurement activities. 'MSF letter to EC over Dutch generics seizure' (18 February 2009) <http://www.msfaccess.org/>.

[5] On the initial settlement, see Kaitlin Mara, 'Minister: India Anticipates European Fix to Law Delaying Generics Shipments' (Intellectual Property Watch, 20 October 2010) <http://www.ip-watch.org/weblog/2010/10/20/ambassador-india-anticipates-european-fix-to-law-delaying-generics-shipments/>.

[6] On the final settlement, see India's Ministry of Commerce and Industry, 'India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit' (Press Release, 28 July 2011) <http://pib.nic.in/newsite/erelease.aspx?relid=73554>.

Most prominent among the unresolved issues is a more definitive understanding of the limits to increasing intellectual property (IP) protection beyond the minimum standards set out in the TRIPS Agreement and correspondingly the limits to reducing the explicit flexibilities contained in the Agreement. Other issues, such as how transiting goods fit within the territorial nature of intellectual property rights (IPRs) and what effect increased IPRs have on third country markets are also left unanswered. More generally, a formal decision discussing (or at least recognizing) the inherent tension between liberalized trade and IPRs would have been a welcome addition to the burgeoning literature in the area of international IP law.[7]

Despite the diplomatic solution, the issue of goods in transit retains currency for two main reasons. First, the EU is exporting its laws to its trading partners through the negotiation of free trade agreements (FTAs)[8] and in other forums such as the recently concluded Anti-Counterfeiting Trade Agreement (ACTA)[9] which increases the likelihood that similar detentions/seizures will occur at some point in the future. Second, recent trends in international IP law strongly indicate a move towards increased protection and enforcement in at least the short and medium term. The issue therefore offers the opportunity for rich legal analysis into an underexplored, yet increasingly important, aspect of the TRIPS Agreement and the GATT. Additionally, despite EU assurances that it would cease the detentions, reports surfaced in early-2012 that the EU had again detained an Indian shipment of generic pharmaceuticals destined for South America.[10]

Unfortunately, most commentary and analysis on this issue has focused on the public policy aspects of encouraging access to low-cost medicines in the developing world. This article is novel in that it avoids the policy aspects of the detentions/seizures and instead legally analyses the relevant issues in order to determine the likely outcome of the now abandoned WTO complaint.

[7] In providing for minimum standards of IP protection and enforcement in a manner which some would see as trade restrictive the TRIPS Agreement is unlike any other WTO covered agreement, which liberalizes and encourages reductions of trade barriers. Historically, proponents of patent protection were protectionists whereas opponents of patents were free traders. See Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 Journal of Economic History 1. It must be recognized, however, that the ability to produce and export 'illegitimate' goods is much greater now than when the historical debate took place.

[8] See, eg EU–Colombia-Peru FTA, art 241 (concluded in 2010 and initialled in March 2011 but not yet ratified and in force); EU–CARIFORUM Economic Partnership Agreement, art 163. See also, European Commission, Directorate General for Trade, 'Strategy for the Enforcement of Intellectual Property Rights in Third Countries' (2004) <http://trade.ec.europa.eu/doclib/html/122636.htm>.

[9] See European Union, 'Joint statement on the Anti-Counterfeiting Trade Agreement (ACTA) from all the negotiating partners of the agreement' Reference: IP/10/1504 (15 November 2010) <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1504&format=HTML&aged=0&language=EN&guiLanguage=en>.

[10] Joe C Mathew, 'Dutch customs seize Indian drugs in transit, industry frets' (*Business Standard*, 23 January 2012) <http://www.business-standard.com/india/news/dutch-customs-seize-indian-drugs-in-transit-industry-frets-/462590/>.

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More specifically, the article will assess the legal issues involved and make determinations on the compatibility of the EU measure with the yet to be interpreted border enforcement measures contained in the TRIPS Agreement. For the sake of completeness, this article will also analyse the actions under the freedom of transit provision of Article V of the GATT. The WTO provisions at issue are complex, vaguely drafted and subject to differing interpretations. The provisions could also be accused of being contradictory in places. For this reason, context plays an important role in interpreting the treaty and therefore the role of other relevant WTO actions including, *inter alia*, the Doha Declaration on the TRIPS Agreement Public Health (2001)[11] and the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003 ('Implementation Decision'),[12] will be discussed.

Part II provides a contextual overview to the current dispute by briefly reviewing the relevant historical basis for the TRIPS Agreement as well as the important events and activities which have shaped the protection and enforcement of international IP since the advent of the WTO. Part III forms the substantive portion of this article in that it analyses and evaluates the substantive claims addressed by India and Brazil in the respective Requests for Consultation with the EU and the Netherlands over the detentions of pharmaceuticals in transit.[13] Part III is split into two sections: the first section addresses the substantive claims made under the TRIPS Agreement and the second section addresses the claim under the GATT. Part IV concludes that the consistency of the EU measures with the TRIPS Agreement and GATT depends heavily upon the interpretive techniques adopted by the panel/Appellate Body and the amount of weight given to the 'context' of trade and public health.

II. THE TRIPS AGREEMENT AND BEYOND: A CONTEXTUAL OVERVIEW

In order to provide context to the issue of detentions/seizures of pharmaceuticals in transit, it is necessary to briefly review the recent history of international IP law as it relates to public health and access to medicines. For the purposes of this article, this begins with the negotiation of the TRIPS

[11] WTO, Doha Declaration on the TRIPS Agreement Public Health' WT/MIN(01)/DEC/2 (20 November 2001).

[12] WTO General Council, 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003' WT/L/540 and Corr.1 (1 September 2003).

[13] The article will therefore not discuss the procedural and administrative nuances of the EU Regulation. It should be noted, however, that both complainants claimed violations of several provisions in the TRIPS Agreement relating to the procedural timing and application of the EU law (so called 'as applied' inconsistencies with the TRIPS Agreement). See, for instance, Brazil's claims regarding arts 50 (provisional visions), 55 (duration of suspension) and 59 (remedies) of the TRIPS Agreement.

Agreement, continues with the ascent of the access to medicines movement in the early-2000s and concludes with the recent efforts by larger developed countries to maximize IPRs in FTAs and elsewhere, most notably in the recently concluded ACTA.

The story behind the negotiation of the TRIPS Agreement[14] is well known—the United States (US), European Community (EC), Japan, Switzerland and other proponents of strong IPRs overcame initial developing-country resistance to incorporating IPRs directly into the international trading regime by trading off access to their potentially lucrative textile and agricultural markets.[15] Developing countries were also granted several important TRIPS-related concessions, most notably deferred implementation of substantial provisions of the agreement and promises of technology transfer and technical assistance.[16] With these concessions, developing country objections waned and attention turned to negotiating the agreement.[17]

The TRIPS Agreement is comprehensive in coverage and includes seven sectors of IPRs (ie copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs of integrated circuits; and protection of undisclosed information).[18] Like other covered agreements, the basis of TRIPS is the principles of most favoured nation (MFN) and national treatment. The TRIPS also establishes minimum levels of protection and enforcement provisions. In formulating minimum standards, TRIPS

[14] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 December 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol 31, 33 ILM 81 (1994).

[15] See GATT Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, 20 September 1986, 25 ILM 1623 (1986); *United States Proposal for Negotiations on Trade Related Aspects of Intellectual Property Rights*, GATT Doc MTN. GNG/NG11/W/14 (20 October 1987); *Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights*, GATT Doc. MTN.GNG/NG11/W/16 (20 November 1987). See generally, Susan K Sell, *Private Power, Public Law: The Globalisation of Intellectual Property Rights* (CUP, 2003); Graeme B Dinwoodie and Rochelle C Dreyfuss, 'TRIPS and the Dynamics of Intellectual Property Lawmaking', (2004) 36 CaseWResJIntlL 95; Laurence R. Helfer, 'Mediating Interactions in an Expanding International Intellectual Property Regime' (2004) 36 CaseWResJIntlL 123; Laurence R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking (2004) 29 YaleJIntlL 21.

[16] The benefits of the concessions are still debated. See, for instance, Duncan Matthews and Viviana Munoz-Tellez, 'Bilateral Technical Assistance and TRIPS: the United States, Japan and the European Communities in Comparative Perspective' (2006) 9 Journal of World Intellectual Property 629; Timothy P Trainer, 'Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation)?' (2008) 8 John Marshall Review of Intellectual Property Law 47.

[17] For a succinct history of the origins of the TRIPS Agreement and its negotiating process, see Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge, 2002), ch 1 (origins) and 2 (negotiations). For more detailed background on the TRIPS Agreement, see Susan K Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of New York Press, 1998).

[18] TRIPS also requires Members to provide for the protection of plant varieties, either by patent or an effective sui generis system such as the plant breeder's rights established in the International Union for the Protection of New Varieties of Plants Convention.

incorporates the substantive obligations of the Paris and Berne Conventions and certain provisions of the Treaty on Intellectual Property in Respect of Integrated Circuits and the Rome Convention. In addition, TRIPS also sets standards in areas which were either not addressed in or, according to Members, were not sufficiently covered in the WIPO Agreements. Thus, the Agreement goes beyond existing treaties in both topical coverage and scope. As part of the 'global package deal'[19] of agreements that make up the WTO, the TRIPS Agreement is subject to binding and enforceable dispute settlement.[20]

As previously mentioned, the TRIPS Agreement contains several flexibilities which allow for such things as longer implementation periods and reduced commitments for developing country Members. Other flexibilities include exceptions to exclusive owner rights, the most prominent of which is the compulsory licence, which permits a government to allow someone other than the rights holder to utilize or produce the patented product or process without the consent of the patent owner.[21] The trade issues surrounding compulsory licenses gained worldwide attention in 2000, when several pharmaceutical companies challenged the legality of the South African Medical and Related Substances Control Act of 1997, which allowed for compulsory licensing of patented pharmaceuticals.[22] The lawsuit, filed in the domestic courts of South Africa, brought the issue of access to medicines to the forefront and evoked passionate reactions and extremely unfavourable publicity for the pharmaceutical companies. At the same time, the US not only supported the litigation in South Africa but also filed a WTO complaint challenging the consistency of Brazil's compulsory licensing provisions in Brazilian industrial property law, which contained a 'local working' requirement, with the TRIPS Agreement.[23]

[19] Ernst-Ulrich Petersmann, 'Constitutionalism and International Organisations' (1996–1997) 17 Northwestern Journal of International Law & Business 442.

[20] Although the WIPO administered Paris and Berne Conventions contemplated dispute settlement recourse to the ICJ, such recourse required the consent of both parties and was never utilized. See Harold C Wegner, 'Injunctive Relief: A Charming Betsy Boomerang' (2006) 4 Northwestern Journal of Technology & Intellectual Property 170 ('The enforceability of the TRIPS Agreement through the WTO DSB has breathed new vitality into the old WIPO conventions, including the Paris Convention.'). For more on WTO dispute settlement, see Simon Lester and Bryan Mercurio, *World Trade Law: Text, Commentary and Materials* (Hart Publishing, 2008) ch 5; Thomas Zimmermann, *Negotiating the Review of the WTO Dispute Settlement Understanding* (Cameron May, 2006).

[21] For identification and analysis of additional flexibilities, see Bryan Mercurio, 'Reconceptualising the Debate on Intellectual Property Rights and Economic Development' (2010) 3 The Law and Development Review 65.

[22] See Sarah Boseley, 'At the Mercy of Drug Giants: Millions Struggle with Disease as Pharmaceutical Firms Go to Court to Protect Profits' *The Guardian* (12 February 2001) (reporting that approximately 40 pharmaceutical companies were challenging art 15c of South Africa's 1997 Medicines Act) <http://www.guardian.co.uk/society/2001/feb/12/aids.wto>.

[23] See *Brazil – Measures Affecting Patent Protection*, Request for the Establishment of a Panel by the United States, WT/DS199/3 (9 January 2001); art 68 of Brazil's industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997); art 27.1 of the TRIPS Agreement.

With the negative publicity showing no signs of abating, the pharmaceutical companies relented and abandoned their challenge to the South African legislation.[24] The US also backtracked, negotiating a settlement to its WTO complaint whereby Brazil agreed to consult with the US before invoking any domestic compulsory licensing provisions (but did not agree to amend its legislation).[25] In September 2001, the US position shifted when it threatened to issue a compulsory license for the antibiotic ciprofloxacin ('Cipro') unless the patent owner (Bayer AG Corporation) reduced its price so that the US could stockpile the drug in the event of large-scale anthrax attacks.[26] This made it difficult for the US to maintain its position on compulsory licences at the WTO. Thus the time was ripe for developing countries to push for a shift in stance from developed countries towards access to medicines.

In November 2001, developing country efforts were rewarded when WTO Members confirmed, reiterated and clarified the flexibilities existing in the TRIPS Agreement in the Doha Ministerial Declaration on TRIPS and Public Health.[27] Even more, on 30 August 2003 Members resolved the remaining issue left unsettled in the Doha Declaration—that countries with insufficient or no pharmaceutical manufacturing capabilities could not make use of the provision due to Article 31(f), which requires that compulsory licences must be granted 'predominantly for the supply of the domestic market'—through a waiver which allows generic pharmaceuticals made under compulsory licence to be exported to countries that lack sufficient production capacity, provided certain conditions and procedures are followed.[28] In 2005, Members agreed to

[24] See Karen DeYoung, 'Makers of AIDS Drugs Drop S. Africa Suit' *Washington Post* (19 April 2001) A13 (reporting that the pharmaceutical companies were dropping their suit against the South African government due to the 'public relations nightmare').

[25] See Office of the United States Trade Representative, 'United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute' Press Release (25 June 2001) (reporting that the US and Brazil mutually agreed to transfer the dispute to a consultative forum and stating that the US would continue its policy of not raising objections to compulsory licensing provisions in developing countries' laws if aimed at addressing HIV/AIDS) <http://www.ustr.gov/releases/2001/06/01-46.htm>. For analysis of the underlying issue of 'working requirements', see Bryan Mercurio and Mitali Tyagi, 'Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements' (2010) 19 Minnesota Journal of International Law 275.

[26] At the same time, Canada briefly issued a compulsory licence for Cipro. For a compilation of newspaper stories and other information pertaining to this issue see <http://www.cptech.org/ip/health/cl/cipro/>.

[27] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (20 November 2001). For analysis, see Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 JIEL 469.

[28] See Implementation Decision (n 12). For discussion, analysis and criticism, see Paul Vandoren and Jean Charles Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health: Making it Work' (2003) 6 Journal of World Intellectual Property 779; 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 JIEL 73.

make the waiver permanent as the first ever amendment of the TRIPS Agreement.[29]

The recognition and strengthening of the flexibilities in the area of public health could have led to a significant rebalancing of interests between IP exporting and importing Members. But the prevailing mood at the multilateral negotiations was not matched by the larger developed country Members, which continued to unilaterally increase IPRs, protection and enforcement standards. Moreover, despite the fact that the TRIPS Agreement is often viewed as a one-sided agreement favouring developed countries,[30] it is now clear that developed countries did not achieve all that they sought in the Uruguay Round[31] and certain countries are now attempting to raise standards and erode flexibilities through bilateral or regional FTAs or through regime shifting (and forum shopping) at the multilateral level.

The US and EU are the most prominent and important catalysts of this movement, with both actively negotiating FTAs with TRIPS-Plus provisions providing for increased coverage and standards and reduced TRIPS-based flexibilities. In this regard, numerous commentators have predicted the forum from the multilateral level to the bilateral and regional level will lead to a 'ratcheting up' of the multilateral standards.[32] Moreover, the forum shift goes beyond traditional trade agreements and includes other international agreements. Most controversial among these are the efforts to reduce trade in counterfeits and increase IP enforcement standards through the ACTA,[33] which critics claim not only increases the scope IPRs and their enforcement but also threatens human rights,[34] and the less prominent but perhaps more

[29] See WTO General Council, 'Amendment of the TRIPS Agreement, Decision of 6 December 2005' WT/L/641, 8 December 2005; WTO General Council, 'Chairperson's statement, December 2005' (6 December 2005) <http://www.wto.org/english/news_e/news05_e/trips_319_e.htm>. This will take effect when two-thirds of the membership formally accepts the amendment.

[30] See, eg Jerome H Reichman, 'Securing Compliance with the TRIPS Agreement after U.S. v India' (1998) 1 JIEL 586 (stating that TRIPS represents 'the standards of protection on which the industrial countries could agree among themselves'). For economic analysis, see Phillip McCalman, 'Who Enjoys TRIPS Abroad: An Empirical Analysis of Intellectual Property Rights in the Uruguay Round' (2005) 38 Canadian Journal of Economics 574. See also World Bank, *World Development Report 1998/99: Knowledge for Development*, suggesting developed countries would benefit more from TRIPS, with the US receiving the biggest gains ($19 bn and Korea incurring the biggest losses ($15 bn).

[31] This realization was not readily apparent during or immediately following the implementation of the TRIPS Agreement. See, eg Susan K Sell, 'The Origins of a Trade-Based Approach to Intellectual Property Protection: the Role of Industry Associations' (1995) 17 Science Communication 163 (arguing that industry interests succeeded in getting most if not all of what they desired included into the TRIPS Agreement).

[32] See Peter Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property' (2001) 4 Journal of World Intellectual Property 791; Laurence R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' 29 YaleJIntlL 1 (2004).

[33] See 'Joint statement on the ACTA' (n 9).

[34] See, eg the website <http://freeknowledge.eu/acta-a-global-threat-to-freedoms-open-letter>; and <http://www.publicknowledge.org/anti-counterfeiting-trade-agreement>. For a compilation of articles and comments on the ACTA, see <http://www.michaelgeist.ca/tags/anti-counterfeiting+trade+agreement>.

significant proposed Substantive Patent Law Treaty (SPLT), which aims to harmonize substantive requirements of patent law and in so doing remove some of the interpretive flexibilities of the TRIPS Agreement.[35]

The MFN clause contained in Article 4 of the TRIPS Agreement further assists the 'ratchet' process of recalculating and resetting international standards in that it provides that a Member which grants 'any advantage, favour, privilege or immunity' to the nationals of *any* other country (regardless of whether that country is a Member of the WTO) must accord the same treatment to the nationals of other Members of TRIPS. The clause is relatively unqualified and TRIPS does not contain a provision similar to Article XXIV of the GATT, which may serve to exempt FTAs from the operation of MFN. To illustrate, if Country A and Country B negotiate an FTA (or agree to TRIPS-Plus provisions in another multilateral agreement), the MFN provision of Article 4 will operate to force both countries to make the same IP concessions and commitments in the FTA available to all nations. The MFN provision therefore applies to FTAs and the TRIPS-plus provisions have the potential to become the new minimum standard from which any future WTO trade round will proceed.

While some believe that MFN essentially provides IP exporting countries carte blanche to raise standards and reduce existing flexibilities, the TRIPS Agreement contains built-in safeguards which limit the extent of the erosion. In other words, Members can only act within the bounds of TRIPS. Part III discusses and evaluates these limitations in the context of the detentions/seizures dispute.

III. THE LEGALITY OF THE DETENTIONS: TRIPS AND THE GATT

The Dutch detention of losartan potassium in December 2008 is but one of a number of similar incidents which regularly took place in the EU throughout 2008 and 2009[36] under the authority of Council Regulation (EC) 1383/2003

[35] For instance, the TRIPS Agreement and WIPO administered Patent Law Treaty allow Members and signatories wide scope in defining such terms as novelty, inventive step and non-obviousness, industrial applicability and utility. The SPLT would remove the flexibilities. For commentary, see Jerome H Reichman and Rochelle Cooper Dreyfuss, 'Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty' (2007) 57 DukeLJ 85.

[36] India's request for consultations specifically mentions only five 'seizures' of drugs originating from India: (1) a consignment of clopidogrel destined for Colombia (October 2008); (2) a consignment of abacavir, purchased on behalf of UNITAID and destined for Nigeria (November 2008); (3) a consignment of olanzapine destined for Peru (November 2008); (4) a consignment of rivastigmine destined for Peru (November 2008); and (5) a consignment of losartan destined for Brazil (December 2008). *European Union and a Member State – Seizure of Generic Drugs in Transit*, Request for Consultations by India, WT/DS408/1 (19 May 2010). Other detentions effecting multiple Indian manufacturers are reported to have occurred. See Rupali Mukherjee, 'Generics face patent barrier' *The Times of India* (11 February 2009) <http://articles.timesofindia.indiatimes.com/2009-02-11/india-business/28009863_1_generic-versions-eu-customs-customs-action>; Pandeya (n 4); Lison Joseph, 'Shipments seizure: India's drug makers may avoid EU route' (*Live Mint*, 12 December 2008).

('Regulation 1383/2003'), which allows customs officials to take certain measures (including suspension or detention) against goods suspected of infringing IPRs.[37] While the drugs at issue and country of final destination changed with every detention, India claims that Dutch customs officials 'seized' 19 consignments of generic drugs transiting through The Netherlands in 2008 and 2009, all but three of which originated in India.[38] Reports indicate that detentions also occurred in France, Germany, Spain and the United Kingdom.

Regulation 1383/2003 recognizes the seriousness of the issues relating to cross-border trade of suspect goods as well as the risk that goods in transit could rather easily be diverted to the local market.[39] The Regulation is extremely broad in scope in that it allows customs to take action against goods suspected of infringing IPRs (1) to be released into free circulation in the EU; (2) to be exported or re-exported; (3) under customs authority or supervision; and (4) under suspensive status. Thus, Regulation 1383/2003 applies both to goods which require customs clearance and to those goods which do not require customs clearance. The third recital of Regulation 1383/2003 makes clear that transhipment of goods through the EU is included as a situation covered by the Regulation. Moreover, the Regulation provides that the law of the Member State where the goods are discovered or detained is the law to be applied to determine whether there is an infringement of IPRs.

The detention/seizure of generic pharmaceuticals in transit touches not only upon the principles of free trade and the rights of IP owners, but is also an important public health issue. The detention/seizure of pharmaceuticals can seriously impede and obstruct the international trade in generic drugs, many of which are destined for developing country markets that rely on cheaper, more cost-effective generic versions of pharmaceuticals.[40] As India noted in its

[37] See (n 3). See also Marius Schneider and Olivier Vrins, 'Regulation (EC) 1383/2003' in Marius Schneider and Olivier Vrins (eds), *Enforcement of Intellectual Property Rights Through Border* Measures, (OUP, 2006) 95, 3.116; *Netherlands, Report Q208, Border Measures and other means of custom Intervention against Infringers*, in the name of the Dutch Group of the AIPPI by Gertjan Kuipers (Chariman), Manon Rieger-Jansen, Bas Pinckaers, Fisal Van Vesel, Jef Vandeckerckhove (2009) <www.aippi.nl/uploads//Q208%20NL%201.PDF>.

[38] Request for Consultations by India, (n 36) 1–2. For this reason, the Indian industry feared for the long-term viability of European transit points. See Pandeya (n 4) (quoting DG Shah, Secretary General of the Indian Pharmaceutical Alliance (IPA), an industry lobbyist group: 'We are concerned that all our exports of generic medicines to South America and Africa passing through Europe will come to standstill unless the government were to challenge the EU Council Regulation of 22 July 2003 and seek its amendment.').

[39] According to the EU, nearly 60 per cent of suspect goods intercepted by customs were in transit or simply being warehoused in the EU. European Commission, Taxation and Customs Union, 'Report of EU Customs Enforcement of Intellectual Property Rights: Results at the European Border – 2008' (2009) 20 <http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf>.

[40] See Pandeya (n 4) (quoting Leena Menghaney, India project manager for the Campaign for Access to Essential Medicines, an initiative of Médecins Sans Frontières, as stating: 'The EC regulations that have led to the seizure of Indian generic drugs in transit to Brazil have created

intervention at the WTO General Council Meeting held on 3 February 2009, 'the importance of generic drugs and their essentiality may vary in inverse proportion to the level of development of a country.'[41] Moreover, due to its location many of the drugs exported from generic producers will transit through Europe. More worryingly, the EU is strategically exporting Regulation 1383/2003 to its developing country trading partners through the negotiation of FTAs, the ACTA and other international agreements, which increase the likelihood of such detentions/seizures by other countries in the future.[42] Finally, it is entirely possible that the detentions could 'undermine the ability of Members to address public health needs by means of cross-licensing arrangements' to assist countries with insufficient or no manufacturing capacity to import medicines from other Members, as permitted by the Implementation Decision regarding paragraph 6 of the Doha Declaration on TRIPS and Public Health.[43]

While it would be in overstatement to conclude that the EU measures and FTA negotiating objectives threaten the very nature of trade in generic pharmaceuticals,[44] the actions do have a deterrent effect on the trade. For instance, the detentions/seizures have already caused several Indian generic pharmaceutical manufacturers to consider using alternative (more expensive) transportation routes.[45] Given the important role that generic pharmaceuticals play in reducing the costs of medicines (and thereby facilitating access to such medicines) the widespread concern does not seem entirely misplaced.

In the months following the December 2008 detentions, the issue was debated in the TRIPS Council at the WTO and at the World Health

barriers to the export of affordable, quality, low-cost generic drugs from India to other developing countries . . . The fallout will be on patients' lives in the developing world who will not be able to access affordable life-saving drugs from India.'). Activist Brook Baker insinuates that this was the very purpose of the measure when stating that the Regulation is the result of 'backroom, closed door lobbying by Big Pharma'. Baker (n 4).

[41] WTO General Council Meeting (India, 3 February 2009) (n 2). For instance, India stated that the EU measures will impair efforts of MSF, Clinton Foundation, Bill and Melinda Gates Foundation in providing medicines to the developing world. ibid.

[42] See, eg text fn 10. For instance, the EU pushed the issue of detentions for in transit counterfeit goods so strongly in the ACTA that the negotiations almost collapsed. Moreover, at the EU's insistence leaked early-drafts of the ACTA negotiating text provided for the possibility of mandatory injunctions for IPR infringements of in transit goods. The final text makes such injunctions optional. See draft text leaked in July 2010 <http://publicintelligence.net/anti-counterfeiting-trade-agreement-acta-july-2010-draft/>; 'De Gucht Lashes Out at US over *ACTA*, Geographical Indications' 28(28) *Inside U.S. Trade* (16 July 2010).

[43] See WTO General Council Meeting (Statement of Brazil) (n 2) para 9.

[44] Both complainants have consistently decried the EU and others (including the WHO) for conflating generic pharmaceuticals with the issue of counterfeit pharmaceuticals. See, eg (n 2).

[45] See Joseph (n 36) (claiming that Indian manufacturers were investigating alternatives such as transporting their goods to storage facilities in non-European countries and quoting NR Munjal, vice-chairman of the generic manufacturer Ind-Swift, as stating: 'We are already pursuing possibilities of sending consignments through routes where it doesn't touch European ports while in transit. Another alternative we are looking at is having a storage facility in a non-European country, from where we can serve our markets.').

Organization. For instance, the issue was the subject of a 'highly emotional debate'[46] at the 3–4 February meeting of the WTO General Council, with Brazil and India fervently arguing that the detentions violate several provisions of the TRIPS Agreement and the GATT.[47] For instance, India's statement centred on the public health aspect of the detentions/seizures:

> Such instances [of seizures] cause us great concern due to their systemic and far reaching implications. In addition to going against the spirit of a rule based trading system and impeding free trade, such acts represent a distorted use of the international IP system and circumscribe TRIPS flexibilities. Repeat of such actions may have an impact on exporters' choice of transit routes, which may affect the economics of trade of pharmaceutical products and consequently, have a deleterious effect on access to essential drugs and public health budgets of recipient countries.[48]

Brazil also made an impassioned statement against the detentions/seizures, which included the following:

> The decision to impede the transit of a cargo of generic medicines – which was not headed for the Dutch market – is unacceptable and sets a dangerous precedent. . . . The protection of intellectual property cannot supersede the protection of more fundamental values, such as the protection of life and the right to promote public health.[49]

The issue was also raised at the WHO's Executive Board meeting, where a joint statement by Brazil's Foreign Minister, Celso Amorim, and Health Minister, Dr Jose Gomes Temporao, stated:

> The Brazilian Government considers that the decision by the Dutch authorities to detain an input which is strategic to public health in a developing country, and exported in conformity with the existing international norms, represents a grave drawback in the treatment of the issue of the universal access to medicines . . . [the Dutch decision to seize generic drugs is] distorted use of the international intellectual property system, supposedly upheld by European Union legislation, and contrary to the spirit and provisions of the Doha Declaration on TRIPS and Public Health.[50]

In defending the detentions, EU Ambassador Eckart Guth argued that Regulation 1383/2003 is compliant with the TRIPS Agreement[51] and stressed

[46] WTO General Council Meeting (Statement of the EC) (n 2).

[47] Sixteen developing country Members supported the statements. See Bridges Weekly Trade News, 'Brazil Slams EU for Seizure of Generic Drugs' Intellectual Property Programme 13(4) (4 February 2009) <http://ictsd.org/i/news/bridgesweekly/39772/>.

[48] WTO General Council Meeting (Statement of India) (n 2). See also WTO General Council Meeting (Statement of Brazil) (n 2) para 6.

[49] WTO General Council Meeting (Statement of Brazil) (n 2) paras 4, 11.

[50] See Bridges ('Dutch Seizure of Generic Drugs Sparks Controversy') (n 2).

[51] Even scholars and practitioners in India initially sided with the EU on the legality of the detentions. For instance, Professor Shamnad Basheer of the National University of Juridical

that the EU 'has absolutely no intention to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries, nor have our measures had this effect. We are absolutely committed to all the efforts that are being made to facilitate access to medicines.'[52]

On 11 May 2010, following a year of unsuccessful negotiations, India formally brought a complaint to the WTO against the EU and The Netherlands. In its request for consultations, India claimed violations of Articles 2, 7, 8, 28, 31, 41 and 42 of the TRIPS Agreement and Articles V:2, V:3, V:4, V:5, V:7 and X of the GATT.[53] Brazil subsequently filed its own request for consultations, claiming violations of Articles 1.1, 2, 28, 31, 41.1, 41.2, 42, 49, 50.3, 50.7, 50.8, 51, 52, 53.1, 53.2, 54, 55, 58 and 59 of the TRIPS Agreement, Articles V:1, V:2, V:3, V:4, V:5, V:7 and X:3 of the GATT and Article XVI:4 of the Agreement Establishing the WTO.[54]

Sciences, stated: 'If the consignment does infringe a patent, then you cannot question the EU for seizing it under their patent laws,' and Rajeshwari Hariharan, a partner at law firm K&S Partners, concluded: 'There are cases where a product is in transit and is seized at a transit point. If this [drug] product was in transit via the Netherlands, and was seized there due to patent infringement, it is a valid argument for the EU . . . In fact, India takes the same stance.' Radhieka Pandeya, 'Dr Reddy's consignment of drugs to Brazil seized' (*Live Mint*, 15 January 2009). Basheer subsequently amended his views; for several blog postings see <http://spicyipindia.blogspot.com/>.

[52] WTO General Council Meeting (Statement of the EC) (n 2). Likewise, European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and Access to Medicines (paras 1 and 2) '[s]tresses that access to affordable pharmaceutical products in poor developing countries and LDCs is essential to attain the proposed EU development goals and would contribute to poverty reduction, increase human security, and promote human rights and sustainable development'; and '[b]elieves that EU policy should aim at maximizing the availability of pharmaceutical products at affordable prices in the developing world'.

[53] In addition to EC Regulation 1383/2003, India identified the following laws, rules, regulations, guidelines and administrative practices of the EU and of the Netherlands relevant to the dispute: Commission Regulation (EC) No. 1891/2004 of 21 October 2004; Council Regulation (EEC) No 2913/92 of 12 October 1992; Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004; Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006; Relevant provisions of the Patents Act of the Kingdom of the Netherlands, 1995 (*Rijksoctrooiwet 1995*) (the 'Patents Act'), as amended, including, without limitation, the provisions of Chapter IV thereof, especially arts 53 and 79, and relevant rules, regulations, guidelines and administrative practices; Relevant provisions of the General Customs Act of the Netherlands (*de Algemene douanewet (Adw))* (the 'Customs Act'), as amended, including, without limitation, arts 5 and 11 and relevant rules, regulations, guidelines and administrative practices; Customs Manual VGEM (30.05.00 Intellectual Property Rights, Version 3.1) (*Douane Handboek VGEM, 30.05.00 Intellectuele eigendomsrechten, 6 April 2009, Versie 3.1*) including, without limitation, the provisions of ch 6 and of other relevant chapters; The Public Prosecutor's Office Guide to Intellectual Property Fraud 20005A022 of 1 February 2006 (*Aanwijzing intellectueleeignendomsfraude 2005A022*) and the Public Prosecutor's Office Directive (2005R013); Relevant provisions of the Criminal Code of the Netherlands (*Het Nederlandse Wetboek van Strafrecht*) including, without limitation, the provisions of art 337, and relevant rules, regulations, guidelines and administrative practices; and Relevant provisions of the Criminal Procedure Code of the Netherlands and relevant rules, regulations, guidelines and administrative practices. Request for Consultations by India, (n 36) 2–3.

[54] *European Union and a Member State – Seizure of Generic Drugs in Transit*, Request for Consultations by Brazil, WT/DS409/1, IP/D/29, G/L/922 (19 May 2010). Canada, China, Ecuador, India, Japan and Turkey joined the consultations as third parties.

The following subsections analyse the most important aspects of the complaints made against the EU and the Netherlands. In accordance with the panel in *EC—Trademarks and GIs*, which found that when there are claims under two WTO agreements, there is 'no hierarchy between these two agreements, which appear in separate annexes to the WTO Agreement' and that '[o]ne logical approach would be to begin in each instance with the TRIPS Agreement',[55] this article likewise follows this approach and analyses the legal issues under the TRIPS Agreement prior to turning to the issues under the GATT.

A. TRIPS Agreement

This subsection will analyse the more substantive claims made in the now-dormant dispute settlement proceeding, notably Article 41, Article 51 and 52 (together with Article 28), Article 53 and Article 58. In this regard, this subsection will not analyse claims which were dependent upon the finding of an inconsistency with a substantive claim. To further illustrate, Brazil's claim that Regulation 1383/2003 violates Article 1.1—which sets out certain minimum standards in the area of IP protection and enforcement and offers Members the discretion to provide higher protection and enforcement standards if they so desire—is entirely dependent upon the success of other TRIPS-based claims. This is the case as the often overlooked and under-appreciated second sentence of Article 1.1 only grants Members the right to implement more extensive protection than the TRIPS Agreement requires 'provided that such protection does not contravene the provisions of this Agreement'.[56] Brazil's argument would have been that the EU provides more extensive protection in a manner which contravenes certain provisions of the TRIPS Agreement.[57] That is, the EU measures violate the binding limitations on additional IP protection allowed for in Article 1.1. In order to be successful, Brazil would have had to have demonstrated that the EU's measures actually violate another provision of the TRIPS Agreement (ie provisions which contain binding language setting out general principles, procedural guarantees or limitations on enforcement measures).[58] The claim of an inconsistency with

[55] Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS290/R (15 March 20) para 7.87. Interestingly, the panel offered no explanation or justification for its determination.

[56] See contra, Paris Convention, art 19, stating that a subsequent agreement between parties cannot contravene the Convention.

[57] Moreover, the World Health Assembly cautioned Member states to 'take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights' *World Health Assembly*, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA61.21 (24 May 2008).

[58] See also arts 41(1)–(4); 42 sentence 2; 43(2); 46 sentence 3; 47; 48(1); 50(3), (4) and (6) of the TRIPS Agreement.

Article 1.1 of the TRIPS Agreement is therefore entirely dependent upon the success of other TRIPS-based claims. For this reason, such claims will not be further addressed. The remaining part of this subsection will now analyse the substantive claims in turn.

1. Article 41

Both complainants claimed a violation of Article 41, which requires Members to 'avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse' and that procedures concerning the enforcement of IPRs 'shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays'.[59] The complainants would likely have argued that the EU measures—that is, the detentions/seizures—created 'barriers' to 'legitimate trade' in generic pharmaceutical products. The EU would have likely defended its measures by attempting to demonstrate that 'barriers' are only 'created' against goods suspected of infringing IPRs as opposed to legitimate goods.

At first glance, this claim appears much like the claim under Article 1.1, with the consistency of EU measures with Article 41.1 dependent upon the findings on another TRIPS-based issue subject to the complaint. The situation is however more complicated as, if the goods in question turn out not to infringe any IPRs, the EU would have had a difficult time persuading the panel that its enforcement measures did not create barriers to legitimate goods. Likewise, if used against legitimate goods not infringing any IPR the detentions/seizures could also violate Article 41.2, which provides that enforcement procedures 'shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays'. Quite simply, the use of enforcement procedures against non-infringing goods could be deemed to be an 'unwarranted delay'.

The broader question which the panel and/or Appellate Body would have faced is the potential conflict between the legitimate trade in generic pharmaceuticals and the protection of legitimate IPRs as mandated in by the TRIPS Agreement.[60] Interestingly, here even the European Federation of Pharmaceutical Industries and Associations (EFPIA) prioritizes public health and trade in generic pharmaceuticals over IPRs:

> [I]t is neither the policy nor practice of our members to encourage Member States to use the powers of detention available to them to prevent the flow of legitimate

[59] In its Request for Consultations, Brazil specifically claimed violations of art 41.1 and 41.2 while India made the more general claim of a violation of art 41

[60] The panel in *Canada–Pharmaceuticals* discussed the meaning of 'legitimate' within the context of art 30 of the TRIPS Agreement, stating: ['Legitimate'] must be defined in the way that it is often used in legal discourse—as 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. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (7 April 2000) para 7.69.

> generic products from manufacturer to customer outside the EU. This applies even where goods transit through EU countries where intellectual property legislation could be applied . . . Where the product is not counterfeit and it is ascertained that no intellectual property rights apply at either country of origin or destination, the customs authorities should allow the product to be released, irrespective of the intellectual property status of the product in the EU.[61]

While it would be possible for a panel or the Appellate Body to resolve the Article 41 claim by interpreting and attempting to balance the 'legitimate' interests in trade in pharmaceuticals against the legitimate interests of IPRs holders, it is more likely that determination of this claim would be dependent upon the findings in the other substantive claims, most notably Articles 51 and 52.

2. Article 51 and Article 52

Perhaps the most important claim the complainants raised is Article 51.[62] The first sentence of Article 51 requires Members to adopt procedures allowing trademark and copyright owners to apply for the suspension by the customs authorities of release of counterfeit or pirated goods into circulation into the commerce of the country/territory.[63] Footnote 13 to Article 51 further provides that there is 'no obligation to apply such procedures . . . to goods in transit'.

Article 51, second sentence, then permits Members to extend border measures to: 'goods which involve *other infringements of intellectual property rights, provided that the requirements of this Section are met*.'[64] Thus, Members may—but are not obliged to—adopt procedures allowing patent owners to apply for the suspension by the customs authorities of release of infringing goods into circulation into the commerce of the country/territory. Again, in accordance with footnote 13 to Article 51 Members may also apply such measures to goods in transit.

While some point to the title of the section 'suspension of release by customs authorities' and argue that the section only applies to situations where customs must actually 'release' goods—ie import, export and re-export—and

[61] EFPIA, 'EFPIA Statement: Customs seizures of in-transit medicines' (13 March 2009) <http://www.efpia.eu/content/default.asp?PageID=559&DocID=6574>.

[62] Oddly, India did not claim a violation of art 51 or 52 in its request for consultations. Brazil claimed a violation of both articles.

[63] The first sentence of art 51 reads: '(Members must adopt procedures) to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods.' Members are also allowed to provide for similar procedures relating to goods destined to be exported.

[64] Emphasis added. The reference to 'this Section' refers to 'Section 4: special requirements related to border measures' of the TRIPS Agreement. The reason that patents are not included in the first sentence of art 51 is likely due to the difficulties associated with determining whether a product infringes a patent, which sometimes require lengthy procedures and complex testing.

not to situations where the goods do not actually need to be released by customs,[65] such an argument cannot be sustained for a number of reasons. First, such an interpretation would actually prohibit customs from seizing counterfeits under all circumstances—even if deceptive or harmful to the public—including when there is a high risk of diversion to the local market. Furthermore, footnote 13 to Article 51 explicitly provides that measures may be applied to goods in transit. Article 51, therefore, does not prohibit the possibility of the procedures being utilized by patent owners and applied to goods in transit, but does subject any TRIPS-plus border enforcement measures (ie those involving alleged patent-infringing goods) to the requirements of Section 4 of the Agreement, namely Articles 52–60.[66]

Importantly, Article 52 then requires rights holders initiating the procedures under Article 51 to provide 'adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right' (emphasis added) and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. Similarly, footnote 14 to Article 51 refers to the 'law of the country of importation' to determine goods containing counterfeit trademarks or copyright piracy.

In the present situation, the EU allows patent owners to apply for the suspension of release of allegedly infringing goods destined for circulation in the EU and to goods in transit.[67] In this regard, the EU measure is a twin-expansion of Article 51 in that it applies to patents and to goods in transit, neither of which are mandated by the Article. The important question thus becomes whether Brazil or the EU is the 'country of importation', for the purpose of determining consistency with Article 52 (and by extension Article 51). It seems clear that if the country of final destination (ie Brazil) is deemed to be the country of final importation then the EU measures are inconsistent with Article 52 of TRIPS. If, however, the country of transit (ie EU) is deemed to be the country of importation, then the EU measures are consistent with Article 52 of TRIPS.

In order to be consistent with Article 51 (footnote 13), the complainants would argue that the EU must demonstrate a *prima facie* infringement of the right holder's IPRs in the country of final importation. Support for this interpretation of Articles 51 and 52 is based not only on the territoriality

[65] For such an argument, see Xavier Seuba, 'Free Trade in Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border' (March 2010) ICTSD Issue Paper No 27, 14.

[66] For recent jurisprudence, see Panel Report, *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (20 March 2009) paras 7.223–7.224.

[67] Article 2.1(c)(i) of Regulation 1383/2003 requires customs to take action if goods 'in the Member State in which application for customs action is made, infringe: (i) a patent under that Member State's law.' See also, art 10 ('The law in force in the Member State within the territory of which the goods are placed in one of the situations referred to in Article 1(1) shall apply when deciding whether an intellectual property right has been infringed under national law.').

principle of IPRs (based on Article 4 of the Paris Convention) but also on a contextually based reading of the provisions—including footnote 13, which distinguishes between imports and goods in transit (implying that the terms have different meanings) and footnote 14 to Article 51. As the EU is using its own laws to determine the basis of the seizures, the complainants would assert its measures are inconsistent with Article 51.

In response, the EU would counter that its measure is consistent with Articles 51 and 52, and more specifically that the term 'country of importation' can be read so as to include the transiting country.[68] Moreover, while certain provisions in the TRIPS Agreement support the complainants argument that imports and goods in transit are treated differently (ie footnote 14 of Article 52, Article 44 and Article 51.1), other provisions in which there is no differentiation (ie Articles 28(a) and 36).

Unfortunately, the term 'country of final importation' is not defined anywhere in the TRIPS Agreement, nor is the term defined in Article V of the GATT. In order to interpret the relevant clause, a panel would need to first define the term 'import'. The Merriam-Webster dictionary defines 'import' as 'to bring from a foreign or external source: as . . . to bring (as merchandise) into a place or country from another country'.[69] Under this definition, the simple act of a good crossing the border would mean that an import has taken place and that, in fact, a transiting country could qualify as the 'country of importation'.

The fundamental concept of 'territoriality' also fails to definitively resolve the issue, as the EU would argue that the goods have entered into its territory for the purposes of customs law and thus its IP laws and regulations are applicable while Brazil and India would argue (and in fact have argued that) seizing/detaining the goods violates territoriality as the goods were not meant for sale and distribution in the EU market.[70] Likewise, India and Brazil both challenge the assertion that Article 28 of the TRIPS Agreement has been breached since no exploitation has taken place,[71] and furthermore argue that

[68] The EU could also attempt to argue that the reference to 'country of importation' in art 52 only refers to the mandatory requirements of art 51; that is the suspension of imported counterfeit and pirated goods. Under such an interpretation, art 52 is inapplicable to other situations, including exportation and transiting goods. This argument would have been unlikely to succeed for a host of reasons, and it does not seem likely that the EU would have made such an argument. For analysis, see Seuba (n 65) 12–13 and more generally 16–21.

[69] See <http://www.merriam-webster.com/dictionary/import>.

[70] WTO General Council Meeting (Statement of India) (n 2); also, WTO General Council Meeting (Statement of Brazil) (n 2) para 7: 'Brazil is gravely concerned with the setting of a precedent for extraterritorial enforcement of IP rights. Attempts to extend the rights granted by patents beyond national borders have critical systemic implications. They affront fundamental canons of the multilateral trade system, in particular the well-established principle of territoriality, a fundamental pillar of the international intellectual property regime.'

[71] See Seuba (n 65) 12. Article 28(1) states that patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of:

when Article 28 is read cumulatively together with Article 2 of the TRIPS Agreement, Article 4*bis* of the Paris Convention and the last sentence of paragraph 6(i) of the Implementation Decision, 'the rights conferred on the owner of a patent cannot be extended to interfere with the freedom of transit of generic drugs lawfully manufactured within, and exported from, India'.[72]

It thus seems unclear and ambiguous on its face whether the term 'country of importation' as used in Article 52 refers to the transiting country or country of final destination. In such a circumstance, Articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT) become relevant to the enquiry as both Articles have attained the status of customary or general international law.[73] Article 31 requires that a treaty be interpreted in good faith, according to the purpose, object, and context of the treaty, with resort to supplementary means of interpretation (including negotiating history) under Article 32 applicable only if the preliminary interpretation results in ambiguity or absurdity. It is also beyond doubt that treaty interpretation under the VCLT must follow a textual approach.[74]

Although the Appellate Body initially introduced a kind of sequencing for the contextual aspects of Article 31 of the VCLT that resembled the use of supplementary materials in Article 32 of the VCLT, the Appellate Body later amended its reasoning to endorse a holistic and integrated approach to the interpretive elements in Article 31 of the VCLT. The Appellate Body unambiguously made this clear in the recent *US–Zeroing* dispute:

> The principles of interpretation that are set out in Articles 31 and 32 are to be followed in a holistic fashion. The interpretative exercise is engaged so as to yield an interpretation that is harmonious and coherent and fits comfortably in the treaty as a whole so as to render the treaty provision legally effective. . . . [A] treaty interpreter is required to have recourse to context and object and purpose to elucidate the relevant meaning of the word or term. . . . This logical progression

using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

[72] Request for Consultations by India (n 36) para 3.

[73] See Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, 29 April 1996, 17: '[Article 31 of the VCLT] has attained the status of a rule of customary or general international law.' Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996) 10: '[Article 32 of the VCLT], dealing with the role of supplementary means of interpretation, has also attained the same status [of customary or general international law].' See also, Appellate Body Report, *United States – Continued Existence and Application of Zeroing Methodology*, WT/DS350/AB/R (4 February 2009) paras 267–8.

[74] See ibid (Appellate Body Report, *Japan–Alcohol*) 17 ('[T]he words actually used in the Article provide the basis for an interpretation that must give meaning and effect to all its terms. The proper interpretation of the Article is, first of all, a textual interpretation'). See also Summary Records of the 876th Meeting, (1966) 1 *Yearbook* of the *International Law Commission* 219, U.N. Doc. A/CN.4/SER.A/1966; Ian Sinclair, *The Vienna Convention on the Law of Treaties*, 130–5 (2nd edn, Manchester University Press, 1984); Gerald Fitzmaurice, 'The Law and Procedure of the International Court of Justice: Treaty Interpretation and Certain Other Treaty Points' (1951) 28 British Yearbook of International Law 1.

> provides a framework for proper interpretative analysis . . . . At the same time, it should be kept in mind that treaty interpretation is an integrated operation, where interpretative rules or principles must be understood and applied as connected and mutually reinforcing components of a holistic exercise. . . . [R]ules and principles of the Vienna Convention cannot contemplate interpretations with mutually contradictory results. Instead, the enterprise of interpretation is intended to ascertain the proper meaning of a provision; one that fits harmoniously with the terms, context, and object and purpose of the treaty. The purpose of such an exercise is therefore to narrow the range of interpretations, not to generate conflicting, competing interpretations. Interpretative tools cannot be applied selectively or in isolation from one another. It would be a subversion of the interpretative disciplines of the Vienna Convention if application of those disciplines yielded contradiction instead of coherence and harmony among, and effect to, all relevant treaty provisions.[75]

With this statement, the Appellate Body resolutely clarified the exact objective of the enterprise of interpretation: one interpretation which is at harmony with the entire treaty and thus integrates all of the contextual elements set out in VCLT Article 31.

In determining 'ordinary meaning' of 'country of importation', it is necessary to examine the 'context and in the light of its object and purpose' of the treaty. The Panel in *Canada–Pharmaceuticals* reiterated and clarified relevant context when stating:

> The context to which the Panel may have recourse for purposes of interpretation of specific TRIPS provisions . . . is not restricted to the text, Preamble and Annexes of the TRIPS Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement, as well as any agreement between the parties relating to these agreements within the meaning of Article 31(2) of the Vienna Convention on the Law of Treaties.[76]

Accordingly, included in the 'ordinary meaning' of 'country of importation' as used in Article 52 are other relevant provisions in the TRIPS Agreement as well as related agreements made by the parties within the meaning of Article 31(2) of the VCLT.

The Doha Declaration on the TRIPS Agreement and Public Health and the later Implementation Decision are thus relevant and the obvious starting point to add context to this dispute. Adopted during the WTO Ministerial Conference in Qatar in November 2001, the Declaration addressed the impact international IP was having on the public health of Members. The Declaration

[75] Appellate Body Report, *US – Zeroing Methodology* (n 73) paras 268–73.

[76] Panel Report, *Canada–Pharmaceutical Products* (n 60) para 7.14. The Appellate Body has subsequently held that 'a treaty interpreter *is required to have recourse to context* and object and purpose to elucidate the relevant meaning of the word or term.' Appellate Body Report, *US – Zeroing Methodology* (n 73) para 268 (emphasis added). This is compatible with the use of the word 'shall' in art 31(1) and (2) of the VCLT.

clarified and reiterated the space available to Members suffering a public health crisis and re-enforced the flexibilities existing in the TRIPS Agreement.

Despite the fact that the legal weight of the Doha Declaration is unclear,[77] it is more than likely that the Doha Declaration is more than merely persuasive and would affect the way a panel or the Appellate Body decides such a case. Thus, while it is unlikely that the Declaration could be viewed as an authoritative interpretation under Article IX(2) of the Marrakesh Agreement Establishing the WTO,[78] it has the *look* and *effect* of an authoritative interpretation.[79] Moreover, the Doha Declaration was delivered by the body with the *exclusive* authority to issue such interpretations.

Even if the Declaration is to be viewed merely as a diplomatic statement carrying no legal weight, a panel or the Appellate Body would undoubtedly find it necessary to consider and discuss the impact of the Declaration. Moreover, even if such discussion is limited to the Declaration forming part of the *context* in which the enforcement obligations exists, it would demonstrate that Article 52 (and more broadly the enforcement obligations of Part IV of the TRIPS Agreement) is a mere part of a 'balanced' and flexible agreement. Thus,

[77] Some Members, notably the US, believe that the Declaration has no legal authority as it is a merely a 'diplomatic step'. USTR Fact Sheet Summarising Results from WTO Doha Meeting, 15 November 2001 <http://www.usembassy.it/file2001_11/alia/a1111516.htm>. Academic commentary is divided, with some arguing the Doha Declaration has little definitive legal value. See, ie Alan O Sykes, 'TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution"' (2002) 3 ChiJIntlL 54 : 'It should be noted that ministerial declarations within the WTO are not legally binding in the dispute resolution process, and in the event of a dispute the language of the treaties as approved by national governments would prevail over any contradictory declaration by the ministers. But the Doha Declaration is primarily interpretive of imprecise obligations in TRIPS, and does not appear to contradict any textual provision. As such, it is likely to be persuasive authority in the interpretation of TRIPS in the event of a dispute.'

[78] See contra, Andrew D Mitchell and Tania Voon, 'Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law' (2009) 43 JWT 573.

[79] For further discussion, see Carlos Correa, *Implications of the Doha Declaration on the Trips Agreement and Public Health* (World Health Organization, 2002): 'given the content and mode of approval of the Doha Declaration, it can be argued that it has the same *effects* as an authoritative interpretation. In particular, in providing an agreed understanding on certain aspects of the TRIPS Agreement in paragraph 5, Members have created a binding precedent for future panels and Appellate Body reports.' See also, Claus-Dieter Ehlermann and Lothar Ehring, 'The Authoritative Interpretation Under art IX:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements' 8 JIEL 803. Ehlermann and Ehring point out that 'an authoritative interpretation would not have been suitable, given that this Declaration contained statements of a political nature, confirmed (or even merely referred to) existing provisions, and gave a *mandate* for legislative action.' However, for an argument supporting the position that the Declaration is an interpretation under art IX(2), see Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP, 2007) 279–82. For more detailed discussion on the legal status of the Doha Declaration, see 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 Harvard Journal of Law & Technology 291. To date, no panel or Appellate Body has had the opportunity to discuss the status of the Doha Declaration; however, previous panels and the Appellate Body have confirmed the exclusive ability of the Ministerial Conference and the General Council to adopt interpretations. See Appellate Body Report, *Japan–Alcohol* (n 73) 13; Appellate Body Report, *United States – Measure Affecting Imports Of Woven Wool Shirts And Blouses From India*, WT/DS33/AB/R (25 April 1997) 19–20.

it is beyond doubt that the Doha Declaration would provide context to this dispute and influence any reading of Article 52 of the TRIPS Agreement.[80]

In relevant part, the Doha Declaration states that the TRIPS Agreement 'can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and . . . to promote access to medicines for all'. The complainants have used this clearly unambiguous statement in support of their position against the detentions of generic pharmaceuticals in transit. For instance, Brazil asserts that '[e]xtraterritorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration'.[81] The complainants also point to the Implementation Decision negotiated between Members in 2003 as further context to the dispute and as evidence of both the need to balance IPRs with public health and the legitimacy of trade in generic pharmaceuticals.

Regardless of whether one completely agrees with the complainants' conclusions, it is clear that the VCLT mandates the enforcement obligations contained in the TRIPS Agreement be viewed in the light of the other provisions of the treaty, the preamble, and any instrument completed in relation to the treaty. In this regard, all of the other provisions and instruments indicate that the operation of any provision in the TRIPS Agreement must be sympathetic to the kind of concerns addressed by trade in generic pharmaceuticals.

Furthermore, it is clear that 'object and purpose' is a necessary consideration in interpretation under the VCLT[82] and that the 'object and purpose' to be considered in an interpretation under the VCLT is that of the *entire* treaty and not just the 'object and purpose' of a particular provision. The Appellate Body in *EC–Chicken Cuts* stated:

> '[W]e caution against interpreting WTO law in the light of the purported 'object and purpose' of specific provisions, paragraphs or subparagraphs of the WTO agreements, or tariff headings in Schedules, in isolation from the object and purpose of the treaty on the whole. Even if, *arguendo*, one could rely on the specific 'object and purpose' of heading 02.10 of the EC Schedule in isolation, we would share the Panel's view that 'one Member's unilateral object and purpose for the conclusion of a tariff commitment cannot form the basis' for an interpretation of that commitment, because interpretation in the light of Articles 31 and 32 of the [VCLT] must focus on ascertaining the common intentions of the parties.'[83]

[80] WTO General Council Meeting (Statement of India) (n 2) (stressed 'balance between public health concerns and protection and enforcement of IPRs. The decisions on Public Heath are a valuable part of the WTO acquis and need to be adhered to in letter and spirit.').

[81] WTO General Council Meeting (Statement of Brazil) (n 2) para 8.

[82] Appellate Body Report, *US – Zeroing Methodology* (n 73) para 268: '[A] treaty interpreter is required to have recourse to context and object and purpose to elucidate the relevant meaning of the word or term.'

[83] Appellate Body Report *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WT/DS269/AB/R, WT/DS286/AB/R (12 September 2005) para 239.

While the Preamble to an Agreement is the usual starting point when attempting to ascertain the object and purpose of an agreement, the Preamble to the TRIPS Agreement is of little assistance as it is difficult to reconcile certain statements. For instance, the Preamble calls upon Members to 'ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade', but this follows the call to 'tak[e] into account the need to promote effective and adequate protection of intellectual property rights'.

The more relevant provisions relating to the 'object and purpose' of the Agreement are Articles 7 and 8, which respectively provide the 'objectives' and 'principles' of the protection and enforcement of IPRs and the TRIPS Agreement.[84] Articles 7 and 8 read, in relevant part:

> Article 7: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.
> Article 8(1): Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Given the emphasis on balancing rights and obligations as well as explicitly allowing Members to 'adopt measures necessary to protect public health' it is appropriate to read Article 52 within the context of Article 7 and 8 and the greater dispute at issue. In this regard, Brazil accurately recalled that 'protection of public health and the promotion of the public interest are still part of TRIPS fundamental principles.'[85]

It could also be argued that Article 41 of the TRIPS Agreement—discussed earlier as a potential claim in its own right—supplement Articles 7 and 8 in establishing the objectives and purpose of the Agreement. Recalling that Article 41 prohibits barriers to legitimate trade and unwarranted delays the complainants could seek to include Article 41 as relevant for the purposes of demonstrating the legality of trade in generic pharmaceuticals.

According to Article 32 of the VCLT, the place of the supplementary materials is strictly secondary and limited to circumstances where applying Article 31 yields an interpretation where terms remain ambiguous or obscure, or the result reached is manifestly absurd or unreasonable. Thus, drafting history and other supplementary material would only become relevant if a proper interpretation could not be reached under Article 31. In any event, it is doubtful that such information would assist in this matter as at the time of

[84] It should also be noted that India claimed violations of arts 7 and 8 in their own right.
[85] WTO General Council Meeting (Statement of Brazil) (n 2) para 8.

negotiation, seizing/detaining goods in transit for suspected patent infringement was not the norm or even contemplated.[86]

Finally, it is appropriate to briefly mention that in any WTO dispute both India and the EU would be arguing for the exact opposite position of their domestic law. Thus, while India is arguing at the WTO that an importation cannot take place while the goods are merely in transit such a position is contrary to the Supreme Court of India decision in *Gramophone Company of India v Birendra Bahadur Pandey*,[87] which held that the term 'import' means 'bringing into India from outside India, that it is not limited to importation for commerce only but *includes importation for transit across the country*.'[88] India could perhaps argue that the facts of *Gramophone* can be distinguished from the present situation. *Gramophone* involved the seizure by Indian customs of a shipment of pirated cassettes transiting through India on their way from Singapore to Nepal. At the time, and still today, international treaties provide for the absolute seizure of materials violating copyright. In contrast, the present case involves patent infringement and trade in generic medicines and both public opinion and international law/treaties may indeed view the actions completely differently. In this regard, India could argue that the context of the situation would be as important as the definition itself. In fact, the Court in *Gramophone* did perhaps provide for such a contextual argument when stating that 'the word 'import' . . . cannot bear the narrow interpretation sought to be placed upon it to limit it to import for commerce. *It must be interpreted in a sense which will fit the Copyright Act into the setting of the international conventions*.'[89]

The situation in the EU has only recently been clarified by a decision of the European Court of Justice (ECJ) finding that in most circumstances detentions of transiting pharmaceuticals from one non-EU member state to another to violate EU law. Prior to this decision, the legality of detentions of in transit goods remained uncertain despite the previous ECJ decision in *Montex v Diesel*,[90] which held that there was no infringement of IPRs by virtue of goods

[86] Frederick M Abbott, 'Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: a threat to international trade, development and public welfare' (2009) 1 WIPO Journal 47.

[87] AIR 1984 SC 66. This decision overruled the decision in *The Central India Spinning and Weaving and Manufacturing Company, Limited, The Empress Mills, Nagpur v The Municipal Committee, Wardha* [1958] 1SCR 1102, see in particular para 47.

[88] ibid para 39. Emphasis added.

[89] ibid para 29. Emphasis added.

[90] *Montex Holdings Ltd. v Diesel* SpA57 (C-281/05). See also *Class International BV v Beecham Group PLC* (C-405/03) (holding that a rights owner can oppose the offering for sale of goods even when the goods are under the external transit procedure if there is a risk of diversion of the goods to the EU market). Such decisions expand upon the reasoning in *Polo v Lauren* (C-383/1998) (holding the predecessor to the current regulation is 'expressly designed to apply to goods passing through Community territory from a non-member country destined for another non-member country' and that 'the external transit of non-Community goods is not completely devoid of effect on the internal market [. . .] as there is a risk that counterfeit goods placed under the external transit procedure may be fraudulently brought on to the Community market').

merely passing through a Member State if the goods are not in free circulation in the EU.[91] In *Montex*, the Court also held that the rights holder had the burden of proof to establish that there was a sufficient risk of fraudulent diversion to the EU market 'by establishing either the existence of a release for free circulation [. . .] in a Member State in which the [right] is protected, or of another act necessarily entailing their being put on the market in such a Member State'.[92]

In the subsequent years, application of the principles set out in *Montex* differed in national courts with some closely following the decision and others applying a legal 'production fiction' in order to treat the in transit goods as if they had been manufactured in the Member State concerned. An example of the former is the UK court in *Nokia Corporation v Her Majesty's Commissioners of Revenue & Customs*, which nicely summarized and begrudgingly followed the state of the law when it dismissed Nokia's application for judicial review of HMRC's refusal to detain a consignment of 400 counterfeit Nokia phones and accessories transiting through the UK on their way from Hong Kong to Colombia. The Court held:

> 49. . . . First, infringement of registered trade mark requires goods to be placed on the market and that goods in transit and subject to suspensive customs procedures do not, without more, satisfy this requirement. . . .
>
> 50. Second, the position is different if the goods in the transit procedure are subject to the act of a third party which necessarily entails their being put on the market ('the *Montex* exception'). But the burden of establishing this rests on the trade mark proprietor.
>
> 51. Third, a mere risk that the goods may be diverted is not sufficient to justify a conclusion that the goods have been or will be put on the market.
>
> 52. Fourth, the Counterfeit Goods Regulation has not introduced a new criterion for the purposes of ascertaining the existence of an infringement of a registered trade mark or to determine whether there is a use of the mark which is liable to be prohibited.
>
> 80. . . . I recognise that this result is not satisfactory. I can only hope it provokes a review of the adequacy of the measures available to combat the international trade in fake goods by preventing their transhipment through Member States.[93]

[91] The decision is at <http://www.ippt.eu/files/2006/IPPT20061109_ECJ_Montex_v_Diesel.pdf>. See contra, *Re Montres Rolex SA* (C-60/02), which held that Regulation 1383/2003 required Member States to prohibit the processing of goods transiting through the EU.

[92] *Montex Holdings Ltd. v Diesel* SpA57 (C-281/05) para 26.

[93] '[2009] EWHC 1903 (Ch)'. Other jurisdictions, such as South Africa, also prohibit border measures extending to transiting goods. See *A M Moolla Group Ltd. v The GAP, Inc.*, Supreme Court of Appeal of South Africa, 543/03, 2004.

Thus, the Court held that because the goods were 'in transit' and there was no risk that the goods would be released onto the market in the UK or within the EU, there was no trade mark infringement in the EU.[94] In other words, because the goods were not being released onto the UK or EU market the goods could not be deemed counterfeit goods within the meaning of Regulation 1383/2003 and therefore could not be seized. The Court of Appeal in *Nokia* referred the case to the ECJ by asking the following question:

> Are non-Community goods bearing a Community trade mark which are subject to customs supervision in a Member State and in transit from a non-Member State to another non-Member State capable of constituting "counterfeit goods" within the meaning of Article 2(1)(a) of Regulation 1383/2003/EC if there is no evidence to suggest that those goods will be put on the market in the EC, either in conformity with a customs procedure or by means of an illicit diversion.[95]

In contrast, the District Court of the Hague in *Sisvel v Sosecal* held that in order to determine whether the detained goods—MPEG Audio products exported from China and destined for Brazil—infringed IPRs within the meaning of Article 2 of the Anti-Counterfeit Regulation, the court must apply a legal 'production fiction' treating transiting goods as if they had been manufactured in the Member State concerned.[96] In so doing, the Dutch court based its decision on Article 6(2)(b) of the former Anti-Counterfeit Regulation (3295/94) and the decision of the Dutch Supreme Court in *Philips v Princo* (NJ 2007/85, 19 March 2004). Furthermore, the Dutch court in *Sisvel* distinguished its case from that of *Montex* by pointing out that the court in that case examined the measure solely under the Trademark Directive, and thus did not consider the production fiction allowed under Article 6(2)(b) of the Regulation. Finally, the court argued that application of the ruling in *Montex* would essentially deprive the Anti-Counterfeit Regulation of its purpose.

[94] In fact, the laws of several EU Member States deem in transit counterfeit goods as a trademark infringement. See, eg art 337 of the Dutch Criminal Code; art 4(1) of the Finnish Trade Marks Act; and art L.716–9 of the French Intellectual Property Code.

[95] *Nokia Corporation v Her Majesty's Commissioners of Revenue & Customs and the International Trade Mark Association* (as proposed intervener), Manufacturing Fiction/Referral to the Court of Justice, Court of Appeal England and Wales, London, UK, 9 November 2009 <http://www.eplawpatentblog.com/2010/January/Court%20of%20Appeal%20Order%20Nokia.pdf>.

[96] District Court The Hague, 18 July 2008. See also, *Cybergun S.A. v Koninklijke Luchtvaart Maatschappij N.V, and Wargaim LLC*, January 20 2010 (decision stayed pending ECJ determination of *Nokia* and *Phillips*). See also *The Polo Lauren Company v PT Dwidua Langgeng Pratama International Freight Forwarders*, (C-383/98), stating para 34: 'After all, the external transit of non-Community goods is not completely devoid of effect on the internal market. It is, in fact, based on a legal fiction. Goods placed under this procedure are subject neither to the corresponding import duties nor to the other measures of commercial policy; it is as if they had not entered Community territory. In reality, they are imported from a non-member country and pass through one or more Member States before being exported to another non-member country. This operation is all the more liable to have direct effect on the internal market as there is a risk that counterfeit goods placed under the external transit procedure may be fraudulently brought on to the Community market, as several Governments pointed out in their written observations and at the hearing.'

Belgian customs authorities similarly relied on Article 6(2)(b) of the former Anti-Counterfeit Regulation in a matter involving a consignment of electric shavers exported from China transiting through Belgium to an unstated and uncertain final destination. In *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company, the Belgian* court submitted a preliminary question to the ECJ, asking whether Article 6(2)(b) of the former Anti-Counterfeit Regulation is harmonized community law; that is, must a national court must apply the production fiction when assessing whether goods in transit infringe national IPRs?[97]

As both the *Nokia* and *Phillips* disputes involved 'transit' procedures, the ECJ joined the cases.[98] The ECJ decision, issued on 2 December 2011 determined that in normal circumstances, EU IPRs do not apply to goods in transit. In this regard, the Court ruled that the domestic authorities of Member States cannot apply a legal 'production fiction' to goods in transit. However, the Court left open the possibility of applying EU IPRs in some cases—for example, the destination of goods is not declared, false information has been submitted, the importer refuses to cooperate with customs or there is a proven risk of a counterfeit product being diverted to the EU market. In leaving the possibility of applying EU IPRs, the Court has allowed for the application suspensive measures where EU IPRs are deemed to be applicable.[99] The importance of providing such leeway cannot be understated; leaving open the possibility to apply WU IPRs and apply suspensive procedures is clearly intended to enable a domestic court in the Member-concerned to conduct a proper examination of whether there is sufficient evidence of infringement of an IPR.[100] Thus, while the ECJ has limited the use of EU IPRs in the case of transiting goods it has not entirely prohibited their relevance or use.

[97] Opinion of Advocate General Cruz Villalón, delivered on 3 February 2011 in the joined cases of C-446/09 and C-495/09, paras 17–22.

[98] *Nokia Corporation v Her Majesty's Commissioners of Revenue and Customs* (C-495/09); *Koninklijke Philips Electronics NV v Lucheung Meijing Industrial Company Ltd* (C-446/09).

[99] The opinion of the Advocate General (AG) of the ECJ, issued in February 2011, similarly found that EU IPRs could not be used to automatically detain and consider as 'counterfeit' goods in transit or temporary storage 'without sufficient grounds for suspecting' that the goods are to be put on the EU market. Opinion of Advocate General Cruz Villalón (n 97) para 112. While the AG did not approve of the use of a legal 'production fiction' to goods in transit, he did concede that 'suspicions' that the goods will be placed on the EU market based on circumstantial evidence and a lack of detail in customs declarations may be sufficient to allow detention and seizure. Ibid paras 54–79, 97, 101–12. For a useful summary of the issues and the AG's opinion, see David Wilson and Rachel Montagnon, 'AG's Opinion: "sufficient grounds for suspecting" danger of fraudulent entry of goods into the EU required for seizure by Customs of goods in transit' Herbert Smith IP News Flash (8 February 2011) <http://www.herbertsmith.com/NR/rdonlyres/0B4A4F6D-374C-440C-A41A-2FEBA3CC00A5/0/20110207AGsOpinionDavidWilsonandRachelMontagnon.html>.

[100] Judgment in Joined Cases C-446/09 *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company Ltd and others* and C-495/09 *Nokia Corporation v Her Majesty's Commissioners of Revenue and Customs* <http://www.eulaws.eu/?p=1165>. For a useful summary of the EU measures/events and proposed amendments, see Olivier Vrins, "The

Taking all of this information into account, the panel/Appellate Body would face the unenviable task of determining this complicated and important issue. Given the complexities and extensive contextual background of this issue it is impossible to accurately predict a result. However, certain facts would seem to weigh in favour of the complainants. First, it is unquestionable that trade in generic pharmaceuticals is legitimate trade. Given this, it would be implausible (and potentially violate Article V of the GATT, as discussed below) to assert that legitimate trade in a particular good must circumvent the EU in order to avoid WTO-consistent detention/seizure for infringement of EU IPRs. Second, public health has attained a position of prominence at the WTO and a decision allowing for the detention of in transit generic pharmaceuticals would seem to undercut the intention and spirit of the Doha Declaration and Implementation Decision.

That being the case, this author is slightly uncomfortable with this analysis and conclusion as it would result in the customs authorities of one jurisdiction attempting to apply the laws of another jurisdiction. For example, customs authorities in the EU determining whether the goods infringe upon the IPRs of Brazil, the 'country of importation'. This result could not have been intended by the drafters of the text nor desired by the Members. Moreover, such a result is simply not practical, feasible or realistic. Another systemic issue with a decision finding for the complainants on this issue is that it seems fair and reasonable given the importance of public health—in fact, the above analysis hinges on the public-health related 'context' in accordance with Article 31 of the VCLT. Extending this reasoning to non-health related goods is extremely problematic. Therefore, any panel/Appellate Body decision finding in favour of the complainants would need to be narrowly crafted and limited to public-health related goods or provide for the possibility of exceptions (perhaps in a manner similar to the ECJ decision in the joined cases of *Nokia* and *Philips*). Unfortunately, it is simply not possible to predict whether a panel/Appellate Body would be able or willing to make what would be a bold and highly controversial decision.

3. Article 53

In its request for consultations, Brazil claimed a violation of Article 53.1 and 53.2; Article 53, entitled 'Security or Equivalent Assurance' provides:

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

European Commission's proposal for a regulation concerning customs enforcement of IP rights" (2011) 6 Journal of Intellectual Property and Practice 774.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

The claim relating to Article 53.1 is of interest as it is unclear whether the provision requires customs officials to demand security or equivalent assurance in order to safeguard and 'protect' the interests of importers and other traders and to 'prevent abuse' or whether it is merely optional. This is relevant as Article 6(1) of Regulation 1383/2003 merely demands a written acceptance of liability in the right holder's application for action. This acceptance, however, is required under Article 56 of the TRIPS Agreement. It would appear that the requirement in Article 53.1—that is, the provision of a security—is an additional demand on top of the requirement contained in Article 56. Moreover, the addition of the phrase '... sufficient to protect the defendant and the competent authorities and to prevent abuse' would seem rather pointless if the security or equivalent assurance were merely optional. On the other hand, the language of Article 53.1 merely grants the authority to Members to require competent authorities to have the authority to require an applicant to provide a security, but does not appear to mandate such a requirement ('shall have the authority to require').

More generally, it is also unclear whether the 'competent authority' is customs or the government. For instance, it is unclear whether legislation providing that only written acceptance of liability is taking the 'authority' away from customs or whether the government is in fact the 'competent authority'.

Debating the finer points of Article 53 may at first instance seem trivial or overly pedantic, but when Article 51, second sentence, permits Members extending border measures to patents on the condition that 'the requirements of [Section 4] are met' one realizes that such finer points may in fact determine the legality of the EU transit measures.

On balance it would appear that a panel/Appellate Body would favour the EU position. Despite the second phrase of Article 53.1, the language used in the first phrase of the article is not written in a manner which demands that customs authorities require a security or equivalent assurance. Importantly, provisions in the TRIPS Agreement and other WTO covered agreements which

are mandatory are not written in a similar fashion; that is, where provisions of the WTO agreement require mandatory action the language is clear and almost always beyond doubt. Thus, it is likely that if Article 53.1 was intended to require action the language used in the article would have been more precisely drafted.

4. Article 58

Brazil also claimed a violation of Article 58 of the TRIPS Agreement, which requires officials when acting *ex officio* to acquire 'prima facie evidence that an intellectual property right is being infringed'. The interesting aspect to Article 58 is that it does not explicitly state or even hint at the jurisdiction of the infringing IPR. Thus, in order for Brazil's claim to succeed, it would have had to prove that the evidence of IPR being infringed must be of the 'country of importation', and in line with its arguments under Article 51 and 52, that the 'country of importation' must be interpreted to be the country of final destination.

The EU would have defended its measures against this claim by stating that Article 58 merely states 'prima facie evidence that an intellectual property right is being infringed', not that the IPR must be in the country of importation. Article 58 does not state or even allude to the jurisdiction of the infringement and the most sensible reading of the Article would be that the goods be infringing an IPR in the jurisdiction of the customs officials. If however 'country of importation' is implicitly read into Article 58, the EU would repeat its arguments under Article 51 and 52, arguing that the term 'country of importation' should be deemed to be the country of transit.

The resolution of this claim is thus likely to be dependent upon the findings relating to Articles 51 and 52. The interesting aspect of this claim, however, is the apparent obliviousness of the drafters of the TRIPS Agreement to issues involving in transit goods. Forethought regarding goods in transit relating to IPRs should have alerted the drafters to the inadequacy of a provision which fails to indicate the appropriate jurisdiction. On the other hand, perhaps one could infer from the lack of guidance that the drafters assumed that customs authorities would only apply the laws and regulations of their own jurisdiction. Of course, such an interpretation would not only favour the EU in terms of Article 58 but also the interpretation of Articles 51 and 52.

B. GATT: Freedom of Transit

In addition to the provisions of the TRIPS Agreement analysed in the preceding subsection, Articles V and XX of the GATT are also relevant to the detention of pharmaceuticals. Article V provides the legal framework of the freedom of transit principle while Article XX may serve as a possible exception to the principle. Both India and Brazil claimed violations of Article V. India's

statement to the WTO General Council meeting of 3 February 2009 succinctly summarizes the complainants position in this regard: 'The WTO rule based system provides for freedom of transit by the most economical and convenient routes and without unnecessary delays and restrictions. The act of seizure by the Dutch authorities is therefore, a denial of the rule based system which we seek to build and strengthen in the WTO.'[101]

The relevant portions of Article V provide:

1. Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a Member when the passage across such territory, with or without transshipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article 'traffic in transit.
2. There shall be freedom of transit through the territory of each Member, via the routes most convenient for international transit, for traffic in transit to or from the territory of other Members. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.
3. Any contracting party may require that traffic in transit through its territory be entered at the proper custom house, but, except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions and shall be exempt from customs duties and from all transit duties or other charges imposed in respect of transit, except charges for transportation or those commensurate with administrative expenses entailed by transit or with the cost of services rendered.[102]

Thus, while Article V:1 provides the definition of goods in transit, Article V:2 lays down the fundamental principle of freedom of transit. In April 2009, the panel in *Colombia–Ports of Entry* agreed with the parties in the dispute that Article V:1 provides context to and informs the scope of the substantive obligations found in Article V:2.[103] Furthermore, the panel held that 'freedom of transit', when applied to Article V:2 'must . . . be extended to all traffic in

[101] WTO General Council Meeting (Statement of India) (n 2).

[102] The complainants also claimed violations of subparagraphs 4, 5 and 7. Cumulatively, the complaints allege the EU 'measures at issue, *inter alia*, are unreasonable, discriminatory and interfere with, and impose unnecessary delays and restrictions on, the freedom of transit of generic drugs lawfully manufactured within, and exported from, India by the routes most convenient for international transit.' Request for Consultations by India (n 36).

[103] *Colombia – Indicative Prices and Restrictions on Ports of Entry*, WT/DS366/R (20 May 2009). The panel found that the definition of 'traffic in transit' provided in art V:1 'seems sufficiently clear on its face.' ibid para 7.396.

transit when the goods' passage across the territory of a Member is a only a portion of a complete journey beginning and terminating beyond the frontier of the Member across whose territory the traffic passes. Freedom of transit must additionally be guaranteed with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport.'

The panel also clarified the meaning and relationship between the first and second sentence of Article V:2. According to the panel, Article V:2, first sentence, '*requires* extending unrestricted access via the most convenient routes for the passage of goods in international transit whether or not the goods have been trans-shipped, warehoused, breakbulked, or have changed modes of transport.' Therefore, goods in international transit from a Member must be allowed entry whenever destined for the territory of a third country. The panel also added that transit must be provided for the 'most convenient' routes for transport through the territory.[104] The obligation in Article V:2, second sentence, is patently clear: Members cannot 'make distinctions between goods which are 'traffic in transit' based on the flag of vessels; the place of origin, departure, entry, exit or destination of the vessel; or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.'[105] Therefore, Article V:2, second sentence, requires that 'goods from all Members must be ensured an identical level of access and equal conditions when proceeding in international transit.'

While the paragraphs 2 and 3 of Article V appear to prohibit interference with goods in transit, Article V.3 potentially significantly alters the situation. While recognizing that goods in transit shall 'not be subject to any unnecessary delays or restrictions and shall be exempt from customs duties', the paragraph also contains an important qualifier, 'except in cases of failure to comply with applicable customs laws and regulations'.

Thus, despite Brazil's assertion that '[t]he measure taken by the Dutch authorities clearly violates the freedom of transit, which is a right enshrined in GATT Article V',[106] the issue is more complicated and deserving of proper legal analysis. For instance, the EU could have attempted to defend the measure by arguing that it is acting under the authority provided for in Article V:3 to apply its 'customs laws and regulations'. The complainants would, of course, challenge the assertion that Regulation 1383/2003 is an IP law, not a customs law, and thus falls outside the scope of Article V. The EU has the stronger position on this issue for at least two reasons. First, Regulation 1383/2003 explicitly refers to the EC Customs Code and it is reasonably clear that the regulation promotes the stated goals of European customs authorities to support IPRs and fight counterfeit and pirated goods. Second, in its execution, Regulation 1383/2003 provides that surveillance is to be maintained by the Customs Policy Division of the DG for Taxation and the Customs Union.

[104] ibid para 7.401.
[105] ibid para 4.402.
[106] WTO General Council Meeting (Statement of Brazil) (n 2) para 3.

Another potentially strong argument the EU could have made concerns the fact that it is clear that all goods transiting through a territory may be subjected to some delays in order to, *inter alia*, determine whether the goods infringe any IPRs. Article 55 of the TRIPS Agreement requires that customs officials release suspended goods if, within 10 working days after the applicant has been served notice of the suspension, the applicant fails to notify customs that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods (provided that all other conditions for importation or exportation have been complied with). The Article also provides for a 10-working-day extension of the timeline, 'in appropriate cases'. In line with this provision, Article 13 of Regulation 1383/2003 provides the right holder only 10 working days to inspect the goods and determine whether further action should be instigated. This makes an 'as such' challenge of Regulation 1383/2003 unlikely to succeed. On the other hand, given that in some cases the suspension exceeded 80 working days,[107] the application of the EU procedures could be subject to an 'as applied' challenge.[108]

Another interesting argument the EU could have made is that while Article V:3 of the GATT prohibits. 'unnecessary delays or restrictions', the text limits the prohibition (and thus allows such delays and restrictions) to situations where customs laws and regulations are complied with. Therefore, it could be argued that the limitation confines the applicability of the 'necessity test' to situations where customs laws and regulations have been fully complied with but nevertheless the goods in transit have been subjected to 'unnecessary delays or restrictions'. In situations where customs laws and regulations have not been complied with, it could be argued that the prohibition on unnecessary delays or restrictions is inapplicable.

It is therefore debatable whether Regulation 1383/2003 is, 'as such', inconsistent with Article V of the GATT. If any part of the Regulation or its application were deemed to be inconsistent with Article V of the GATT, the issue then would become whether any GATT inconsistency can be justified through successful invocation of Article XX(d) of the GATT. Article XX provides, in relevant part:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between

[107] In the case of abacavir, the shipment was seized on 12 November 2008 and released on 12 March 2009, to which the Dutch government admitted '[t]he customs authorities did not respect the time limits for detention and disposal of this case'. See 'Formal response Dutch government on seizures and border measures in FTAs (to parliamentary questions), posted by Health Action International on its list-serv and <http://lists.essential.org/pipermail/ip-health/2009-April/013674.html>.

[108] As noted (n 13), this article will not fully analyse the procedural and administrative nuances of the EC Regulation or its application.

> countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> . . .
>
> (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices.

It is well established in WTO jurisprudence that an inconsistency with GATT can only be justified when the requirements of both the specific Article XX exception and the chapeau (introductory clause) are met.[109] At first instance, the respondent (in other words, the party asserting the affirmative defence) must identify the relevant exception and demonstrate that its measures fit within the scope of the exception.[110] In the case of detentions/seizures of pharmaceuticals, the relevant exception would be Article XX(d)) and the EU would need to demonstrate both that the measure is (1) designed to 'secure compliance' with laws or regulations that are not themselves inconsistent with some provision of the *GATT 1994*; and is (2) 'necessary' to secure such compliance.[111]

To satisfy the first condition, the EU would have to identify the laws or regulations for which it seeks to secure compliance, establish that those laws or regulations are not themselves WTO-inconsistent, and demonstrate that the particular measure at issue is itself designed to secure compliance with the relevant laws or regulations.[112] If Regulation 1383/2003 is found to be

[109] Appellate Body Report, *US–Gasoline* (n 73) 22. The Appellate Body has on several occasions declined to authoritatively decide whether art XX of the GATT is available to other covered agreements, but noting that the chapeau to art XX states that 'nothing in *this Agreement*' shall prevent measures for the non-trade purposes set out therein' the weight of the evidence suggests that the article is only applicable to the GATT. See *China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, WT/DS363/AB/R (19 January 2010) paras 7.743–7.745, 7.914. See also Fernando Piérola, 'The Availability of a GATT Article XX Defence with Respect to a Non-GATT Claim: Changing the Rules of the Game?' (2010) 5 Global Trade and Customs Journal 172.

[110] On burden of proof, see Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef,* DS161/AB/R (10 January 2001) para 157; Appellate Body Report, *United States – Measures Affecting Imports of Woven Shirts and Blouses*, WT/DS33/AB/R (23 March 1997) 14.

[111] See Appellate Body Report, *Korea–Beef* ibid para 157.

[112] For illustration, see Panel Report, *United States – Measures Relating to Shrimp from Thailand*, WT/DS343/R/, paras 7.174–7.183. It is worth noting that the Appellate Body in *Mexico–Soft Drinks* held that 'a measure can be said to be designed "to secure compliance" even if the measure cannot be guaranteed to achieve its result with absolute certainty'. Appellate Body Report, *Mexico – Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/AB/R (24 March 2006) para 74.

inconsistent with the TRIPS Agreement then almost certainly the invocation of the Article XX(d) would fall at the first hurdle. If, on the other hand, the EU could demonstrate that its measures are designed to secure compliance with the TRIPS Agreement it would still have to demonstrate that such measures were 'necessary'.[113] If this can be accomplished, it seems clear that any law or regulation which is necessary for the implementation of the TRIPS Agreement would not be regarded as being inconsistent with GATT (within the meaning of article XX(d)). To conclude otherwise would result in a measure necessary to implement one agreement actually violating another agreement. This would counter the rule of effective treaty interpretation requiring a harmonious interpretation of the WTO Agreement (including annexes). Moreover, the well-established presumption against conflict implies a preference for an interpretation that avoids such conflict.

Presumably, the EU would argue that the importance of IPRs to the global economy and the need to protect communities from substandard and counterfeit pharmaceutical products (both separately and cumulatively) provide a sound basis on which to determine the 'necessity' of certain enhanced border measures. Jurisprudence on the 'necessity test' is well developed. The Appellate Body in the *Korea–Beef* first established the 'necessity test' for Article XX(d) (the standard test was later applied to other provisions in Article XX).[114] In that case, the Appellate Body held that 'necessary' does not necessarily mean 'indispensable' and could even resemble 'making a contribution to':

> We believe that, as used in the context of Article XX(d), the reach of the word 'necessary' is not limited to that which is 'indispensable' or of absolute necessity or inevitable to secure compliance certainly fulfil the requirements of Article XX (d). But other measures, too, may fall within the ambit of this exception. A used in Article XX(d), the term 'necessary' refers, in our view to a range of degrees of necessity. At one end of this continuum lies 'necessary' understood as 'indispensable'; at the other end, is 'necessary' taken to mean as 'making a contribution to'. We consider that a 'necessary' measure is, in this continuum, located significantly closer to the pole of 'indispensable' than to the opposite pole of simply 'making a contribution to'.[115]

The Appellate Body in *Korea–Beef* also noted three additional factors should be 'weighed and balanced' in order to determine if a measure is 'necessary': (i) the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect; (ii) the extent to which the measure contributes to the realization of the end pursued, the securing of compliance with the law or regulation at issue; and, (iii) the restrictive impact

[113] For illustration, see ibid paras 7.184–7.191.
[114] See *EC–Asbestos*, WT/DS135/AB/R (5 April 2001) para 172.
[115] Appellate Body Report, *Korea–Beef* (n 110) para 161.

of the measure on imported goods. In this regard, it is worth quoting from the Appellate Body Report:

> 162. . . . It seems to us that a treaty interpreter assessing a measure claimed to be necessary to secure compliance of a WTO consistent law or regulation may, in appropriate cases, take into account the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect. The more vital or important those common interests or values are, the easier it would be to accept as 'necessary' a measure designed as an enforcement instrument.
>
> 163. There are other aspects of the enforcement measure to be considered in evaluating that measure as 'necessary'. One is the extent to which the measure contributes to the *realization of the end pursued*, the securing of compliance with the law or regulation at issue. The greater the contribution, the more easily a measure might be considered to be 'necessary'. . . .
>
> 164. In sum, determination of whether a measure, which is not 'indispensable', may nevertheless be 'necessary' within the contemplation of Article XX(d), involves in every case a process of weighing and balancing a series of factors which prominently include the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports.[116]

Thus, in order to resolve whether a measure is 'necessary', panels and the Appellate Body weighs and balances a series of factors to determine whether a WTO-consistent alternative measure or even a less WTO-inconsistent measure exists which the Member concerned could 'reasonably be expected to employ'.[117] Given that other WTO Members effectively deal with the exact same issues which Regulation 1383/2003 purports to address in different ways is relevant in determining the existence of reasonable available alternative measures which are either WTO-consistent or less inconsistent than Regulation 1383/2003.[118] The EU could defend its regime as offering a greater level of protection against the risk of diversion into the EU common market and/or an enhanced level of consumer protection. As with other issues in this dispute, forecasting a panel/Appellate Body is difficult. That being said, one would expect that if the panel/Appellate Body considered Regulation 1383/2003 to not be inconsistent with any of the challenged provisions of the TRIPS Agreement, it would also find that the EU measure meets the requirements of this section and thus deem it 'necessary'.

If the EU can demonstrate that its measures are both designed to 'secure compliance' with laws or regulations that are not themselves inconsistent with

[116] See also Panel Report, *US – Shrimp from Thailand* (n 112) paras 7.187–7.189.
[117] Appellate Body Report, *Korea–Beef* (n 110) para 166.
[118] See Seuba (n 65) 28–9.

any provision of the GATT and 'necessary' to secure such compliance, it still must conform to the requirements of the chapeau—in other words, the EU would have to demonstrate that its measures are not applied in a manner which constitutes arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. Again, if the panel/Appellate Body considered Regulation 1383/2003 to not to be inconsistent with any of the challenged provisions of the TRIPS Agreement, then it is likely that the EU measure would not be deemed to be arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

IV. CONCLUSION

The amicable resolution of this dispute leaves many questions unanswered and several important issues of the TRIPS Agreement unresolved. Likewise, the dispute provided an opportunity to clarify the relationship between the TRIPS Agreement and the 'freedom of transit' provisions under the GATT. This article attempted to fill some of the gaps left by the mutually agreeable solution to the dispute. While it did not attempt to resolve every issue, it did endeavour to provide an overview and initial legal analysis to some of the more interesting and important issues presented in the dispute. Given that provisions relating to IP and the transit of goods remain part of EU law and that numerous other jurisdictions provide for similar treatment of transiting goods it is likely that a similar dispute will arise in the future.

If such a dispute does reach the adjudicative stage of the WTO dispute settlement process, the panel/Appellate Body would be tasked with determining complex legal issues in the context of impacting upon important public health related issues. If past precedent is used as a guide, one would expect the panel to craft a narrow decision focusing on a few issues rather than attempting to create a sound body of jurisprudence. For example, the panel could focus on the 'as applied' claims in order to find a violation in an attempt to avoid analysing the more complex and controversial 'as such' claims. However, such an interpretive strategy would not avoid all issues. For instance, an interpretation of the 'country of importation' under Article 52 of the TRIPS Agreement seems unavoidable. Thus, the ultimate resolution to this dispute would seem to hinge on willingness of the panel/Appellate Body to focus on trade in generic pharmaceuticals and rely on 'context' in its interpretation of the TRIPS Agreement. This article demonstrates that a contextually based interpretation of a claim involving trade in generic pharmaceuticals would likely lead to the EU measure being deemed to be inconsistent with Article 52. In turn, this would result in the EU measure also being deemed to be inconsistent with Article 41 and perhaps even Article 58. The measure would thus also be inconsistent with Article V of the GATT and highly unlikely to be saved by Article XX(d).

On the other hand, if the panel/Appellate Body takes a broader view of transiting goods as opposed to focusing on the subset of trade in generic pharmaceuticals it is entirely possible (if not likely) that the 'country of importation' would be interpreted to include the transiting country. In such a circumstance, the EU measures 'as such' would be consistent not only with Article 52 but also with Articles 41 and 58. Moreover, the EU measures would also be consistent with Article V of the GATT since it is clear this provision is not meant to apply to trade in illicit goods—including goods that infringe IPRs protected under the TRIPS Agreement. If, however, the panel/Appellate Body did find an inconsistency with Article V of the GATT it is likely that the measures would fall under Article XX(d) of the GATT as necessary to secure compliance with laws or regulations which are not inconsistent with the relevant IPRs protected in the TRIPS Agreement.

Perhaps as important as any decision would be the fact that this dispute has revealed the inadequacies of the provisions in the TRIPS Agreement relating to in transit trade of goods. Simply stated, it is clear that the drafters did not foresee the complex issues resulting from the protection and enforcement of IPRs when applied to goods in transit. While it would be naive to call upon WTO Members to amend the agreement to provide increased certainty and perhaps better reflect the views of Members some increased predictability would be welcome to both traders and customs authorities.