American University International Law Review

Volume 26
Issue 3 *Focus Issue: Intellectual Property Law Enforcement and the Anti-Counterfeiting Trade Agreement (ACTA)*

Article 5

2011

A Trade Agreement Creating Barriers to International Trade?: ACTA Border Measures and Goods in Transit

Henning Grosse Ruse - Khan

A TRADE AGREEMENT CREATING BARRIERS TO INTERNATIONAL TRADE?: ACTA BORDER MEASURES AND GOODS IN TRANSIT

HENNING GROSSE RUSE - KHAN*

INTRODUCTION 646
I. SEIZURES OF GENERIC DRUGS IN TRANSIT THROUGH E.U. PORTS 648
II. WTO COMPLAINTS BY INDIA AND BRAZIL 651
A. ALLEGED INCONSISTENCIES WITH WTO/TRIPS PROVISIONS 652
B. TRIPS AS A BENCHMARK CONSTRAINING ADDITIONAL IP PROTECTION 654
III. ACTA PROVISIONS ON BORDER MEASURES 660
A. SCOPE OF ACTA BORDER MEASURES 663
1. Patent Infringements 664
2. In-Transit Goods 669
3. Other Forms of IP Infringements 673
4. Options to Limit the Scope of Border Measures 677
B. APPLICABLE LAW AND DETERMINATION OF INFRINGEMENT 681
1. The Applicable Law in IP Border Enforcement Cases 681
2. Determination of Infringement 686
C. ACTA SAFEGUARDS FOR PUBLIC HEALTH AND AGAINST TRADE BARRIERS 689
1. Interpretation Based on TRIPS Articles 7 and 8 690
2. Obligation to Avoid the Creation of Barriers to

* Senior Research Fellow, Max Planck Institute on Intellectual Property, Competition and Tax Law, Munich (Germany); Email: henning.gr-khan@ip.mpg.de. This is an edited version of a paper presented at PIJIP conference on "Public Interest Implications of the ACTA Draft," American University, Washington College of Law (Washington DC, 14-16 June 2010) and at the Society of International Economic Law (SIEL) Second Biennial Global Conference (Barcelona, July 8–10, 2010).

Legitimate Trade.....695
IV. ACTA VERSUS PUBLIC HEALTH AND FREE TRADE SAFEGUARDS UNDER TRIPS 703
A. THE CONFLICT POTENTIAL BETWEEN TRIPS AND ACTA 705
1. Scope of Border Measures.....707
2. Applicable Law.....708
3. Safeguards for Traders and Goods Owners.....708
4. Implementing the Article 31(f) TRIPS Waiver.....709
5. A General Shift in the IP Enforcement System?.....710
6. The Role of TRIPS Articles 7 and 8 in Interpreting ACTA 712
B. COHERENCE, NORM CONFLICT, AND CONFLICT RESOLUTION.....714
1. The Principle of Harmonious Interpretation and Systemic Integration.....714
2. Defining Norm Conflicts.....715
3. Conflict Resolution Tools in TRIPS and ACTA.....719
4. Conflict Rules in General International Law.....722
CONCLUSION 724

INTRODUCTION

In recent times, the relation between international trade and intellectual property ("IP") enforcement has become a controversial topic in international law. On one hand, most IP exporting countries point to increasing trade in counterfeits and fake goods as the primary factor which destroys markets for the originals and deceives consumers into buying fake and sometimes even dangerous products. The lack of adequate IP enforcement at home, and especially in markets abroad, is identified as a key obstacle to international trade in IP protected goods. New and ambitious international rules on civil, criminal, border, and internet IP enforcement are therefore viewed as the main remedy to restore fair global competition and facilitate trade in legitimate goods and services worldwide.

Most developing countries, on the other hand, take a different view: as their goods and services are becoming increasingly competitive with those of developed country producers, new and more stringent international IP enforcement rules seek to introduce a

new set of non-tariff barriers to trade that will preponderantly hinder developing country exporters. Even if agreements such as the Anti-Counterfeiting Trade Agreement ("ACTA") do not directly bind developing countries that are not parties to the treaty, implementing the new IP enforcement rules in the ACTA negotiating countries affects the majority of all goods traded internationally. IP enforcement at the border has the potential to create barriers to trade in goods not even destined to the markets of future ACTA countries. For example, when applied to goods in transit, the IP protection and enforcement standards in the transit country can cause detention and seizures—even if there is no IP infringement in the country of production or destination. Some developing countries consider such enforcement measures as protectionist and their trade restrictive effects as contrary to the main principle of trade liberalization in the World Trade Organization ("WTO").

This article examines these arguments on the trade restrictive effects of the new international "gold standards" in IP enforcement. Parts I and II describe the seizures of generic medicines in transit through E.U. ports. This has led India and Brazil to challenge the consistency of the seizures with obligations under WTO Agreements on trade and IP protection. A key insight is that this dispute is based on the notion that the WTO TRIPS Agreement contains not only minimum, but also maximum standards for IP enforcement. In Part III, the ACTA provisions on border measures are examined as to whether they do create trade barriers, in particular whether they mandate or allow seizures of generic medicines in transit. The analysis not only takes a close look at various provisions affecting the scope of border measures, but further scrutinizes the impact of the applicable law rule in ACTA and the safeguards it foresees against IP enforcement functioning as a trade barrier. Part IV builds on the analysis by examining whether there exists any conflict between the ACTA TRIPS-plus enforcement standards and the free trade and access to medicines safeguards in the TRIPS Agreement. This analysis leads to the conclusion that, while the principle of harmonious interpretation minimizes direct conflict with TRIPS as a matter of international law, the policy choices underlying ACTA raise systemic concerns. Instead of including a few general checks and balances for the defendant, ACTA should give as much attention to specific safeguards for all interested parties affected by its

enforcement rules as it gives to concise and comprehensive new remedies for right holders.

I. SEIZURES OF GENERIC DRUGS IN TRANSIT THROUGH E.U. PORTS

Starting in 2008, Dutch authorities decided to seize, delay, and return several shipments of generic drugs transiting E.U. ports en route to destinations in South America and Africa on account of suspected patent infringements.[1] The shipments predominantly originated in India and were all destined for developing countries such as Brazil, Venezuela, Colombia, Peru, or Nigeria. The drugs at issue were protected in the E.U., but apparently not in the countries of origin or destination. Citing complaints of suspected infringement from alleged owners of patents or supplementary protection certificates, customs authorities in the Netherlands have detained a substantial amount of generic medicines in transit through the Netherlands.[2] These consignments were initially detained and subsequently destroyed, returned to the country of origin, or, in a few cases, permitted to proceed to the destination country after considerable delay.[3]

1. *See* Reese Ewing, *Brazil to Object to Dutch Seizure of Generic Drug*, REUTERS (Jan. 23, 2009), http://www.reuters.com/article/idUSN2327254420090123 (discussing Brazil's frustration with Dutch authorities for seizing a shipment of Losartan, a generic high blood pressure medicine, because of an IP rights claim by a Netherlands-based company); *see also* Int'l Ctr. for Trade & Sustainable Dev. [ICTSD], *Dutch Seizure of Generic Drugs Sparks Controversy*, 13 BRIDGES WKLY. TRADE NEWS DIG., no. 3, Jan. 28, 2009, at 5, *available at* http://www.ictsd.org/downloads/bridgesweekly13-3.pdf (stating that Brazil believes the Netherlands' actions represent a "distorted use of the international intellectual property system" and present a setback to universal access to medicine); William New, *Alarm Escalates Over Delayed Generic Drug Shipments as Action Sought*, INTELL. PROP. WATCH (Mar. 6, 2009, 5:13 PM), http://www.ip-watch.org/weblog/ 2009/03/06 /alarm-escalates-over-delayed-generic-drug-shipments-as-action-sought/ (noting a statement from health professionals, including Oxfam International and Health Action International, condemning the Dutch seizure as a risk to the "critical treatment" of HIV-positive Nigerian patients).

2. *See* Request for Consultations by India, *European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS408/1 (May 19, 2010) [hereinafter India Consultation Request].

3. *See id.* at 1 ("Available evidence confirms that the customs authorities seized at least 19 consignments of generic drugs in 2008 and 2009 while in transit

One example is the hypertension drug losartan potassium, manufactured as a generic in India by Dr. Reddy's Laboratories and patented for the E.U. territory by DuPont and Merck Sharp & Dohme. In December 2008, Dutch custom authorities detained a consignment of losartan medication in transit to Brazil at Schipol Airport in Amsterdam.[4] Due to threats of destruction by the right holder, the consignment was subsequently returned to India. Similar action was taken as regards, for example, generics for the drugs clopidogrel, abacavir, olanzapine, and rivastigmine.[5] In all cases, the Dutch authorities acted pursuant to the European Communities Council Regulation No. 1383/2003 on border measures ("BMR").[6]

The public health dimension of the transit seizures is probably best demonstrated by the following incident: about three months after the controversial losartan detention occurred, an UNITAID[7] funded shipment consisting of forty-nine kilograms of abacavir sulfate tablets was confiscated at Schiphol Airport by Dutch customs authorities under the claim that it contained counterfeit goods.[8] The medicines, manufactured by the Indian company Aurobindo, are used in second-line treatment of HIV/AIDS in Nigeria for a program implemented by the Clinton Foundation on behalf of UNITAID. UNITAID protested sharply, insisting that the shipment did not contain counterfeit drugs or any other goods infringing on IP rights, and that the medication was prequalified by the World Health

through the Netherlands, 16 of which originated in India.").

4. *See id.* at 4.

5. *See id.*

6. *See* Council Regulation 1383/2003, 2003 O.J. (L 196) 7, 9 (EC) (stating that customs authorities are permitted to detain or suspend the release of goods for a period of three working days if they suspect infringement of an intellectual property right to allow a "right-holder" to submit an application for customs action).

7. UNITAID is an international drug purchase facility established in 2006 to provide long-term, sustainable, and predictable funding to increase access and reduce prices of diagnostics and quality drugs for the treatment of HIV/AIDS, malaria, and tuberculosis in developing countries. It was founded by France, Brazil, Chile, Norway, and the United Kingdom, and it is hosted and administered by the World Health Organization ("WHO"). *See How UNITAID Came About*, UNITAID, http://www.unitaid.eu/en/about/-background-mainmenu-18/159.html (last visited Mar. 1, 2011).

8. *See UNITAID Statement on Dutch Confiscation of Medicines Shipment*, UNITAID, http://www.unitaid.eu/en/resources/news/156-unitaid-statement-on-dutch-confiscation-of-medicines-shipment.html (last visited Mar. 1, 2011).

Organization ("WHO") and had received tentative approval by the United States Food and Drug Administration.[9]

The incident occurred shortly before a TRIPS Council Meeting on March 3-4, 2009 where India and Brazil issued strong statements against the European Communities ("EC") border measures and threatened legal action under the WTO dispute settlement system as a last resort.[10] Responding to an earlier EC statement in the WTO General Council that downplayed the Lortasan seizure,[11] Brazil pointed out that the amount temporarily seized would have been enough to treat 300,000 patients suffering from hypertension for a full month.[12] It further alleged that some of the earlier seizures in the Netherlands led to the destruction of the consignments concerned.[13] Brazil finally argued that these actions severely hamper medicine distribution to needy populations, given the risk that on key transit routes supplies may be regularly intercepted based on the assertion of patent infringement in the transit country.[14]

Apart from India and Brazil, several NGOs and some commentators view the EC border measures as "contrary to the letter and spirit of the Doha Declaration on TRIPS and Public Health," as

9. *See id.*

10. *See* Statement by Brazil, TRIPS Council, Agenda Item 'M' (Other Business) Public Health Dimension of TRIPS Agreement (Feb. 3-4, 2009), http://www.ip-watch.org/weblog/wp-content/uploads/2009/03/intervention-by-brazil.pdf, 1, ¶¶ 11, 16 [hereinafter Statement by Brazil] (claiming that the Dutch actions violated WTO principles because the medicine detained was not patent-protected in either the exporting countries or the importing country); *see also* Intervention by India, TRIPS Council, Agenda item 'M' (Other Business) Public Health Dimension of the TRIPS Agreement (Feb. 3-4, 2009), http://www.ip-watch.org/weblog/wp-content/uploads/2009/03/ intervention-by-india.doc [hereinafter Intervention by India] (claiming that the confiscation of the generic medicines by the Dutch has a direct and negative impact on the legitimate trade of generic medicines, public health, and universal access to medicine).

11. *See* WTO General Council, Any Other Business (Feb. 3, 2009), http://www.ip-watch.org/files/WTO_GENERAL_COUNCIL.doc (asserting that the Dutch authorities only temporarily detained the medicine to control it as allowed by TRIPS and E.U. customs law and that the authorities were under no obligation to return the medicine to India).

12. *See* Statement by Brazil, *supra* note 10, ¶ 6 (noting that even though the shipment's size is not relevant in ascertaining the gravity of the Dutch seizure, the potential benefits of the medications in question were extensive).

13. *See id.* ¶ 8.

14. *See id.* ¶ 9.

potentially countering efforts under the WTO's so-called "paragraph six mechanism" to export drugs produced under a compulsory license into countries with insufficient pharmaceutical manufacturing capacity, and as inconsistent with resolutions issued by the WHO and the EC Parliament.[15]

II. WTO COMPLAINTS BY INDIA AND BRAZIL

On May 12, 2010, India and Brazil initiated separate WTO dispute settlement proceedings against the E.U. and the Netherlands by requesting consultations over the seizures of generic medicines in transit.[16] These requests for consultations are the first step under the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU").[17] Since the consultations failed to settle the dispute within sixty days after the date of receipt of the request for consultations, India or Brazil may request the establishment of a panel,[18] which would then issue a report on the consistency with obligations under the WTO Agreements of the seizures of generics, the BMR as such, and its application in the cases described above in Part I.[19] Later, in May 2010, Canada, Ecuador, China, Japan, and Turkey requested to join the

15. *See* Frederick M. Abbott, *Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil*, 13 BRIDGES, no. 1, Feb.-Mar. 2009, at 13, *available at* http://ictsd.org/i/news/bridges/ 44192/ (claiming that the confiscations are an exaggerated approach to intellectual property law and raising concerns that legitimate trade may fall under attack as well); Letter from Christian Wagner-Ahlfs, BUKO Pharma-Kampagne et al., to Pascal Lamy, Dir. Gen., World Trade Org. (Feb. 18, 2009), *available at* http://keionline.org/misc-docs/seizures/ WTO_seizures_18feb.pdf (noting that intellectual property right claims conflict with the ability to provide "access to medicine for all" and with the ability of organizations to properly address public health issues).

16. *See* India Consultation Request, *supra* note 2; Request for Consultations by Brazil, *European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS409/1 (May 19, 2010) [hereinafter Brazil Consultation Request].

17. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes art. 4(2), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU] (stating that each member must allow sufficient opportunity for consultation on any complaints made by another member regarding any activity affecting an agreement in the first member's territory).

18. *See id.* art. 4(7).

19. *See* India Consultation Request, *supra* note 2, at 1-2; Brazil Consultation Request, *supra* note 16, at 2-3.

consultations in accordance with DSU Article 4(11).[20] The "substantial trade interests" required by DSU Article 4(11) were, inter alia, based on exports of generic drugs to a large number of countries worldwide, on issues of public health and access to medicines, and on the fact that drugs destined to the requesting country had been seized in the E.U.[21] All these requests were subsequently accepted by the E.U.[22] At the time of writing, neither Brazil nor India has requested the establishment of a panel or notified the WTO Dispute Settlement Body ("DSB") of a mutually agreed solution.

A. ALLEGED INCONSISTENCIES WITH WTO/TRIPS PROVISIONS

Brazil considers the above-mentioned measures as inconsistent, inter alia, with the following WTO provisions:

1. Articles V:1, V:2, V:3, V:4, V:5, V:7 and X:3 of the GATT 1994;
2. 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(b), and 59 of the TRIPS Agreement, and Article 4*bis* of the Paris Convention of 1967;

20. *See Dispute Settlement DS409: European Union and a Member State Seizure of Generic Drugs in Transit (Brazil)*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm (last updated June 22, 2010) [hereinafter *Brazil WTO Dispute*]; *see also Dispute Settlement DS408: European Union and a Member State Seizure of Generic Drugs in Transit (India)*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm (last updated June 22, 2010) [hereinafter *India WTO Dispute*].

21. *See, e.g.*, Request to Join Consultations by Canada, *European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS409/2 (June 1, 2010) (stating that Canada exports forty percent of its generic drugs to other countries because Canada supports and is active on the issues of public health and access to medicine); Request to Join Consultations by China, *European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS409/6 (June 3, 2010) (noting that China produces a large quantity of generic drugs and is a bilateral trade partner of the E.U. and the Netherlands); Request to Join Consultations by Ecuador, *European Union and a Member State Seizure of Generic Drugs in Transit*, WT/DS409/3 (June 2, 2010) (explaining that generic drugs shipped to Ecuador were seized in the E.U.'s territory, causing Ecuador to believe that shipments of drugs to Ecuador may be intercepted in the future).

22. *See Brazil WTO Dispute*, *supra* note 20; *India WTO Dispute*, *supra* note 20 (reporting that the E.U. had accepted the requests of Canada, China, Ecuador, India, Japan, and Turkey to join the consultations).

3. Article XVI:4 of the WTO Agreement[23]

India in turn provides more concrete arguments on inconsistencies of the measures with some specific provisions of WTO law, including:

> 1. Paragraphs 2, 3, 4, 5 and 7 of Article V of the GATT 1994 because the 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;
>
> 2. Article X of the GATT 1994, including, without limitation, Article X:3, because the measures at issue, *inter alia*, are not administered in a uniform, impartial and reasonable manner;
>
> 3. Article 28 read together with Article 2 of the TRIPS Agreement, Article 4*bis* of the Paris Convention, 1967 and the last sentence of paragraph 6(i) of the Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "August 30, 2003 Decision") because a cumulative reading of these provisions confirms, *inter alia*, that 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;
>
> 4. Articles 41 and 42 of the TRIPS Agreement because the measures at issue, *inter alia*, create barriers to legitimate trade, permit abuse of the rights conferred on the owner of a patent, are unfair and inequitable, unnecessarily burdensome and complicated and create unwarranted delays; and
>
> 5. Article 31 of the TRIPS Agreement read together with the provisions of the August 30, 2003 Decision because the measures at issue, *inter alia*, authorise interference with the freedom of transit of drugs that may be produced in, and exported from, India to Members of the World Trade Organization with insufficient or no capacity in the pharmaceutical sector that seek to obtain supplies of such products needed to address their public health problems by making effective use of compulsory licensing.[24]

23. *See* Brazil Consultation Request, *supra* note 16, at 4.
24. *See* India Consultation Request, *supra* note 2, at 2-3.

India considers further:

> [T]hat the measures at issue also have a serious adverse impact on the ability of developing and least-developed country members of the World Trade Organization to protect public health and to provide access to medicines for all. Accordingly, the provisions of the TRIPS Agreement referred to above must be interpreted and implemented in light of the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 and in the light of Article 12(1) of the International Covenant on Economic, Social and Cultural Rights, which recognizes the right of all persons to the enjoyment of the highest attainable standard of physical and mental health.[25]

This article does not purport to offer a comprehensive analysis of all the alleged inconsistencies between the seizures of generic medicines in transit and WTO law.[26] Instead, it shall be limited to some thoughts on potential violations of TRIPS provisions as these may effectively serve as an important international law benchmark to assess the border measure provisions in ACTA.

B. TRIPS AS A BENCHMARK CONSTRAINING ADDITIONAL IP PROTECTION

Interestingly, both India and Brazil argue that the E.U. and Dutch measures at issue not only infringe on obligations under the WTO/GATT rules on trade in goods,[27] but also are inconsistent with

25. *Id.* at 3.

26. For an analysis of some of the IP, trade, and public health issues under WTO law, see generally XAVIER SEUBA, FREE TRADE OF PHARMACEUTICAL PRODUCTS: THE LIMITS OF INTELLECTUAL PROPERTY ENFORCEMENT AT THE BORDER 1-42 (2010), *available at* http://ictsd.org/downloads/2010/04/seuba_web_10.pdf; Shashank P. Kumar, *Border Enforcement of Intellectual Property Rights Against In-Transit Generic Pharmaceuticals: An Analysis of Character and Consistency*, 32 EUR. INTELL. PROP. L. REV. 506, 511-518 (2010).

27. Here, the potential of border measures against goods in transit to serve as a barrier to international trade and the freedom of transit makes an infringement of GATT Article V a possible scenario: the "Freedom of Transit" clause in GATT Article V(2) stipulates that "[t]here shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties." *See* General Agreement on Tariffs and Trade art. V(2), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]. This is, however, subject to compliance "with applicable customs laws and regulations" and the potential invocation of a general

several provisions of the TRIPS Agreement. In at least one aspect, this is a novel type of dispute. For the first time in WTO dispute settlement history, TRIPS is used as a benchmark for *constraining* additional ("TRIPS-plus") IP protection. According to both India's and Brazil's consultation requests, the E.U. and Dutch measures are argued to be inconsistent with, inter alia, TRIPS Article 1(1), Article 41, and other norms from the TRIPS section on border measures (Articles 51-60). The crucial point is that these alleged infringements do not result from failure to meet the TRIPS minimum standards of IP protection and enforcement.

Instead, it is the TRIPS-plus nature that caused the seizure of generics in transit. The legal basis for the transit seizures, the BMR, goes beyond the TRIPS minimum standards in several aspects. For one, the BMR covers not only "trademark counterfeit goods" and "pirated copyright goods" as defined in TRIPS;[28] it covers infringements of other IP rights such as patents.[29] The BMR further mandates border measures against goods in transit[30] and those destined for exportation under BMR Article 1(1). TRIPS, on the other hand, demands such measures only against imports.[31] In addition to alleging inconsistency of the BMR as such, the consultation requests also argue that its application to generic drugs in transit by the Dutch custom authorities violates TRIPS obligations.[32]

These complaints challenge one of the central elements of international IP law: the notion of minimum standards.[33] Generally,

exception clause, which, under Article XX(d), allows exceptions for measures "necessary to secure compliance with laws or regulations relating to the protection of patents." *Id.* arts. V(3), XX(d).

28. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 51, n.13, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

29. *See* Council Regulation 1383/2003, *supra* note 6, art. 2(1).

30. Technically, the BMR does not use the term transit but instead refers in Article 1(1) to specific customs procedures defined in the E.U. Uniform Customs Code. *See id.* art. 1(1)(a) (referring to Articles 61, 37, and 183 of the E.U. Uniform Customs Code).

31. *See* TRIPS Agreement art. 51.

32. *See* India Consultation Request, *supra* note 2, at 2-3; Brazil Consultation Request, *supra* note 16, at 2-4.

33. The concept of minimum standards finds expression especially in Articles

international treaties on IP protection create a "floor," setting a minimum level of protection that must be available in all national laws of the contracting parties without any apparent limitation as to the further extension of IP protection.[34] This notion of minimum standards is a central feature in the long history of international IP protection whose development has primarily been a one-way route towards ever-increasing levels of protection.[35]

However, some provisions in existing treaty law from the Berne and Paris Conventions as well as the TRIPS Agreement may function as a door-opener for maximum standards, or "ceilings,"[36] to international IP protection. Relevant in this context, TRIPS Article 1(1) expressly allows WTO Members to grant more extensive protection than what is prescribed in the Agreement but only

19 and 20 of the revised Berne Convention as well as Article 19 of the Paris Convention. The wording of Article 20 of the Berne Convention in this regard is quite instructive when it requires further agreements to "grant to authors *more extensive rights* than those granted by the Convention." *See* Berne Convention for the Protection of Literary and Artistic Works arts. 19-20, Sept. 9, 1886, *as amended on* Sept. 28, 1979, 25 U.S.T. 1341, 1161 U.N.T.S. 30 [hereinafter Berne Convention] (emphasis added); *accord* Paris Convention for the Protection of Industrial Property art. 19, Mar. 20, 1883, (as last revised at Stockholm, July 14, 1967), 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

34. *See* Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 944 (2008) (noting that in addition to offering minimum levels of protection, TRIPS also attempts to control discriminatory practices); *see also* Kal Raustiala, *Density and Conflict in International Intellectual Property Law*, 40 U.C. DAVIS L. REV. 1021, 1028 (2007) (claiming that TRIPS was intentionally created to set minimum, rather than maximum, standards of protection).

35. "[O]nce rights have been inscribed into the text of an IP convention, they basically become sacrosanct for now and the future. Revision conferences (with only a few remarkable exceptions) have regularly served the purpose of further strengthening the position of right holders; hardly ever was an effort undertaken to question or curtail incumbent rules." *See* Annette Kur & Henning Grosse Ruse - Khan, *Enough is Enough The Notion of Binding Ceilings in International Intellectual Property Protection* 8-9 (Max Planck Inst. for Intellectual Prop., Competition & Tax Law Research Paper Series, Paper No. 09-01, 2008), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1326429. One exception is the Revision of the Berne Convention 1971, where an Annex addresses the option for developing countries to grant compulsory licenses mainly for translation purposes and the proposed amendment of the TRIPS Agreement in the course of the Doha process. *See* WTO General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005) [hereinafter *TRIPS Amendment*].

36. For a general analysis of this concept in international IP law, *see* Kur & Grosse Ruse - Khan, *supra* note 35.

"provided that such protection does not *contravene* the provisions of this Agreement."[37] One justification for such a "ceiling" function comes from the incorporation of TRIPS into the WTO multilateral trading system: as several TRIPS provisions indicate, minimal, but also excessive or abusive reliance on IP protection, can distort and create barriers to international trade.[38] Especially for border measures against IP infringements, the strong link to global trade and the traditional WTO/GATT approach towards further trade liberalization provide a rationale which explains binding language safeguarding the

37. In full, Article 1(1) states: "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, *provided that such protection does not contravene the provisions of this Agreement.* Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." TRIPS Agreement art. 1(1) (emphasis added). In the June 2010 TRIPS Council meeting, the delegate of India emphasized the "non-contravention" requirement and pointed to maximum standards, or ceilings, in TRIPS that may stand against certain TRIPS-plus measures in national laws and in international agreements such as ACTA. *See* Intervention by India, to WTO TRIPS Council, on Agenda Item M: TRIPS-plus Enforcement Trends 1 (June 2009) [hereinafter TRIPS-plus Enforcement India], *available at* http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/intervention-by-india-seizure-of-generic-drug-consignments-at-ec-ports.pdf. In the same vein, the delegate of China stressed that TRIPS-plus protection and enforcement "shall not contravene the provisions of [TRIPS]." *See* Intervention by China, to WTO TRIPS Council, on Agenda Item M: TRIPS-plus Enforcement Trends (June 8-9, 2009) [hereinafter TRIPS-plus Enforcement China], *available at* http://keionline.org/node/883.

38. *See, e.g.*, TRIPS Agreement pmbl. (emphasizing the need to "ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade"); *id.* art. 41 (stating that IP enforcement procedures must protect against infringement of intellectual property rights without blocking legitimate trade); *id.* art. 8(2), 40(1) (noting that measures may be necessary to prevent "practices which unreasonably restrain trade" and that some practices may adversely affect trade); *see also* CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 25 (2007) (suggesting that the higher the level of protection for intellectual property rights, the more likely the protections will create barriers for legitimate trade); ICTSD & UNCTAD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT 75 (2005), *available at* http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm; Klaus Elfring, *Allgemeine Bestimmungen und Grundprinzpien* [*General Provisions and Basic Principles*], *in* TRIPS: INTERNATIONALES UND EUROPÄISCHES RECHT GEISTIGEN EIGENTUMS [TRIPS: INTERNATIONAL AND EUROPEAN INTELLECTUAL PROPERTY LAW] 79, 84 (Jan Busche & Peter-Tobias Stoll eds., 2007).

interests of traders.[39]

In order to review the consistency of the TRIPS-plus elements of the BMR and its application to generics in transit with TRIPS, one therefore needs to assess which form of additional IP protection has the potential to "contravene" TRIPS.[40] Without excluding other arguments for findings of contravention,[41] instances where this qualification of TRIPS Article 1(1) applies are most likely cases where one can point to conflicts with a *mandatory* TRIPS provision instead of an *optional* one. However, mandatory rules that impose an obligation on states to limit IP protection are rare in international law.[42] Instead, most limitations take the form of optional provisions, for example the so-called "TRIPS flexibilities," which allow a country to freely decide on which grounds it allows for compulsory licenses to be issued in its national IP regime.[43] In relation to the TRIPS provisions on IP enforcement, however, things are different: several provisions contain binding language which set out general principles upholding procedural guarantees for the defendant or preventing the creation of trade barriers as well as specific obligations limiting enforcement measures.[44]

Since TRIPS integrates safeguards for both free trade[45] and public health considerations,[46] and balances these with its provisions on IP

39. *Cf.* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 474 (3d ed. 2008) (describing TRIPS Articles 51-60 on border measures as the most "trade-related" section of the TRIPS Agreement).

40. For a more detailed analysis of this term, see generally Henning Grosse Ruse - Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1 TRADE L. & DEV. 56 (2009).

41. *See* ICTSD & UNCTAD, *supra* note 38, at 24 (explaining that the pressure to accept TRIPS-plus standards in FTA negotiations might contravene the objective and purpose of the WTO Agreement and TRIPS to provide a secure framework for the conduct of international trade relations).

42. For a useful overview, see generally P. BERNT HUGENHOLTZ & RUTH L. OKEDIJI, CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT 55 (2008), *available at* http://www.ivir.nl/publications/hugenholtz/finalreport2008.pdf.

43. *See* World Trade Organization, Ministerial Declaration of 14 November 2001, ¶¶ 4, 5 WT/MIN(01)/DEC/2 (2001) [hereinafter Doha Declaration].

44. *See* TRIPS Agreement arts. 41(1-4), 42, 43(2), 46, 47, 48(1), 50(3, 4, 6), 52, 53, 55, 56, 58(b-c).

45. *See id.* pmbl., art. 41(1).

46. *See id.* arts. 8(1), 31*bis*.

protection under TRIPS Article 7,[47] the TRIPS-plus character of the E.U. and Dutch measures may be inconsistent with TRIPS. One concrete example from the list of TRIPS provisions claimed in Brazil's and India's consultations is the idea that seizing goods merely in transit based on alleged IP infringements according to the law of the transit country may run counter to the agreement's obligation to make border measures dependant on prima facie evidence for IP infringements based on the "law of the country of importation".[48] While such a finding depends on a narrow interpretation of the term "country of importation," which does not include transit countries,[49] the case provides one practical example where a TRIPS provision could serve as a ceiling rather than a floor in international IP protection.

TRIPS Article 52 is one of the provisions Brazil alleges to be infringed by the seizure of generics in transit.[50] This allegation may go even further since the TRIPS preamble expresses an aim "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[51] Furthermore, Article 41(1) contains a general obligation that IP enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for

47. *Id.* art. 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.").

48. TRIPS Agreement art. 52; *see* Henning Grosse Ruse - Khan & Thomas Jaeger, *Policing Patents Worldwide? EC Border Measures Against Transiting Generic Drugs Under EC and WTO Intellectual Property Regimes*, 40 INT'L REV. INTELL. PROP. & COMPETITION L. 502, 533-34 (2009) (arguing that seizing goods in transit according to the law of the transit country is only consistent with TRIPS if the term "country of importation" is interpreted to include transit countries).

49. *See id.* at 534-36 (maintaining that the TRIPS agreement does not include countries of transit in the definition of "country of importation" because it could restrict countries' access to medicines, which does not encourage social and economic welfare); Kumar, *supra* note 26, at 512-13 (concluding that "importation" must be read to include only the destination country in order to prevent measures that create barriers to legitimate trade); *see also* discussion *infra* Part III(B)(1) (comparing Article 7(1) of the ACTA text with Article 52 of the TRIPS Agreement and discussing the difference in how goods in transit are affected under each regulation).

50. *See* Brazil Consultation Request, *supra* note 16.

51. *See* TRIPS Agreement pmbl.

safeguards against their abuse." India and Brazil have both also claimed a violation of TRIPS Article 41(1).[52] A key issue here would be a Panel's approach to interpreting ambiguous terms such as "legitimate trade" and "abuse." If the Panel would take the TRIPS balancing objectives in Article 7 and its public interest principles in Article 8 seriously, public health and access to medicines considerations should play an important role.[53] Indeed, all WTO Members—including the E.U. and its member states—emphasized in the Doha Declaration the importance of such an interpretation based on Articles 7 and 8, especially in the public health context.[54] Nevertheless, it remains to be seen whether India or Brazil will continue their challenge of the E.U. and Dutch border measures as TRIPS violations under the WTO dispute settlement system continue.[55]

III. ACTA PROVISIONS ON BORDER MEASURES

Forced by various leaks after years of secrecy,[56] the negotiating parties to ACTA, the European Union, the United States, Japan, Australia, New Zealand, Canada, South Korea, Singapore, Morocco, Mexico and Switzerland, finally released an official draft text in April 2010.[57] Subsequent to this release, the July round of negotiations in Lucerne, Switzerland produced a revised ACTA draft which again leaked in the middle of the month.[58] Another ACTA

52. *See* India Consultation Request, *supra* note 2, at 3; Brazil Consultation Request, *supra* note 16, at 4.

53. *See* TRIPS Agreement arts. 7-8.

54. *See* Doha Declaration, *supra* note 43, ¶¶ 4-5.

55. Alternatively, the WTO complaint may serve as a bargaining chip—especially for India in its FTA negotiations with the E.U. *See generally India Plans Front to Nip New Piracy Law*, THE ECON. TIMES (India), May 29, 2010, http://economictimes.indiatimes.com/news/ economy/policy/India-plans-front-to-nip-new-piracy-law/articleshow/5986902.cms.

56. *See* Anti-Counterfeiting Trade Agreement: Informal Predecisonal/ Deliberative Draft, Jan 18, 2010 [hereinafter ACTA Draft—Jan. 18, 2010], *available at* https://sites.google.com/site/iipenforcement/acta (follow "Full Leaked Text Dated January 18, 2010").

57. *See* Anti-Counterfeiting Trade Agreement: Public Predecisonal/ Deliberative Draft, Apr. 21, 2010 [hereinafter ACTA Draft—Apr. 21, 2010], *available at* http://trade.ec.europa.eu/doclib/docs/2010/april/tradoc _146029.pdf.

58. *See* Anti-Counterfeiting Trade Agreement: Informal Predecisonal/ Deliberative Draft, July 1, 2010, [hereinafter ACTA Draft—July 1, 2010], *available at* https://sites.google.com/site/iipenforcement/acta (follow

draft leaked after the Washington round of negotiations in August 2010.[59] On October 2, 2010, the negotiating parties finally released a new consolidated text reflecting the "outcome of the 11th and final round of negotiations," which is almost identical to the final ACTA version, which the negotiating parties made available in early December 2010.[60] The following analysis is largely based on the December 2010 final text, with specific references to earlier versions contained in the October and April 2010 official drafts, the July text, and the August ACTA draft.

In a press release after the first official release, the E.U. Commission emphasized that "the overall objective of ACTA is to address large-scale infringements of intellectual property rights which have a significant economic impact," and stressed that "ACTA will by no means lead to a limitation of civil liberties or to 'harassment' of consumers."[61] The Commission also points out that ACTA "will not hamper access to generic medicines."[62] A subsequent press release after the Lucerne round of negotiations in July 2010 went further, asserting that "ACTA will not hinder the cross-border transit of legitimate generic medicines."[63] Nevertheless, amongst the various concerns expressed by NGOs and academics about the impact of ACTA was its potential impact on the free transit

"Consolidated ACTA Text, July 1, 2010").

59. *See* Anti-Counterfeiting Trade Agreement: Informal Predecisonal/ Deliberative Draft, Aug. 25, 2010 [hereinafter ACTA Draft—Aug. 25, 2010], *available at* https://sites.google.com/site/iipenforcement/acta (follow "Full Leaked Text Dated August 25, 2010").

60. For the October text, see Anti-Counterfeiting Trade Agreement: Informal Predecisonal/Deliberative Draft, Oct. 2, 2010 [hereinafter ACTA Draft—Oct. 2, 2010], *available at* http://trade.ec.europa.eu/doclib/docs/2010/october/tradoc_146699.pdf. For the final ACTA text, see Anti-Counterfeiting Trade Agreement, Dec. 3, 2010 [hereinafter ACTA Text—Dec. 3, 2010], *available at* http://www.dfat.gov.au/trade/acta/Final-ACTA-text-following-legal-verification.pdf.

61. *See* Press Release, Eur. Comm'n, Anti-Counterfeiting Trade Agreement: European Commission Welcomes Release of Negotiation Documents (Apr. 21, 2010), http://trade.ec.europa.eu/doclib/press/index.cfm?id=552 (stressing that ACTA will not modify IP law, but will create rules for enforcing IP rights in "courts, at borders, and over the internet").

62. *Id.*

63. *See* Press Release, Eur. Comm'n, Anti-Counterfeiting Trade Agreement, Report on the 9th Round of Negotiations (July 2, 2010), http://trade.ec.europa.eu/doclib/press/index.cfm?id=588&serie=352&langId=en.

of goods and, hence, on international trade.[64] There were allegations that ACTA would oblige countries to introduce border measures against goods in transit along the lines of the BMR, which had led to the highly controversial seizures of generic drugs in transit from India to the various developing countries discussed above.[65] In response, the E.U., among others, stated after the release of the October 2010 text that "ACTA provides a balanced Agreement, which replies to concerns expressed by Members of the European Parliament, Non Governmental Organisations and other stake-holders regarding issues such as [t]he safeguard of access to medicines."[66]

Now with the final round of negotiations concluded and the resulting final text available, does ACTA indeed mandate seizures against goods in transit? And does it extend to goods allegedly infringing patents (instead of merely applying to pirated copyright and counterfeit trademark goods, as is the case with TRIPS)? Before the October 2010 ACTA text, the relevant ACTA provisions were complex and often heavily bracketed, indicating that the negotiating parties had not reached consensus and that different options were still on the table.[67] In the October version, however, there seems to have been widespread agreement over most controversial issues as only a few reservations of some negotiating parties remained,[68] which

64. *See, e.g.*, *Text of Urgent ACTA Communique: International Experts Find that Pending Anti-Counterfeiting Trade Agreement Threatens Public Interests*, AM. U. WASH. C. L. PROGRAM INFO. JUST. & INTELL. PROP. (June 23, 2010), http://www.wcl.american.edu/pijip/go/acta-communique [hereinafter *Urgent ACTA Communique*] (stating that ninety academics, practitioners, and public interest organizations concluded that ACTA is also harmful to fundamental rights, internet regulation, access to medicine, IP law, international law, and democracy).

65. *See id.*

66. Press Release, Eur. Comm'n, All You Want to Know About the Anti-Counterfeiting Trade Agreement (ACTA) (Oct. 20, 2010), http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/508&format=HTML&aged=0&language=EN&guiLanguage=en (noting that ACTA even references the Doha Declaration, TRIPS Article 7, and "the exclusion of patent infringements from the section on border control and penal enforcement.").

67. *See* ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 2.X; ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X; ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X.

68. As Bridges reports, "an EU official close to the negotiations said that the October text was over 99 percent agreed, and that officials would be able to iron out remaining differences 'through e-mail contact' in the weeks to come. No more

apparently have been resolved in the December 2010 final text. In the following Sections A-C, the main provisions of the December 2010 ACTA text relevant for border measures are reproduced and analyzed for their potential to mandate or allow seizures of generic drugs in transit.

A. SCOPE OF ACTA BORDER MEASURES

The ACTA provisions on border measures extend the existing minimum standards under TRIPS, which obliges WTO members to provide border measures only against "importation of counterfeit trademark or pirated copyright goods."[69] Based on the final December 2010 ACTA text, Section 3 contains the following main provision on the scope of border measures:

> Section 3: Border Measures
> ARTICLE 13: SCOPE OF THE BORDER MEASURES
> In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of intellectual property rights, a Party should do so in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade.[70]

Further, Article 16 is decisive for determining the scope of obligations for border measures in ACTA:

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rounds of negotiations would be needed, the official said, describing the process as 'really at the final stage, about to cross the finishing line.'" *See* ICTSD, *Anti-Counterfeiting Trade Pact '99 Percent' Complete*, 14 BRIDGES WKLY. TRADE NEWS DIG., no. 34, Oct. 6, 2010, at 1, *available at* http://ictsd.org/downloads/bridgesweekly/bridgesweekly14-34.pdf.

69. *See* TRIPS Agreement art. 51. The border measures obligations under TRIPS cover easily detectable forms of copyright and trademark infringements, which custom authorities should be able to identify without the need for technical expertise. *Id.* art. 51, n.14.

70. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13. Footnote 4 to Article 13 states: "Where a Party has dismantled substantially all controls over movement of goods across its border with another Party with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border." Footnote 5 provides: "It is understood that there shall be no obligation to apply the procedures set forth in this section to goods put on the market in another country by or with the consent of the right holder." Finally, footnote 6 says: "The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section."

> ARTICLE 16: BORDER MEASURES
> 1. Each Party shall adopt or maintain procedures for import and export shipments under which:
> (a) its customs authorities may act upon their own initiative, to suspend the release of suspect goods; and
> (b) where appropriate, a right holder may request its competent authorities to suspend the release of suspect goods.
> 2. A Party may adopt and maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under Customs control under which:
> (a) its customs authorities may act upon their own initiative, to suspend the release of, or to detain, suspect goods; and
> (b) where appropriate, a right holder may request the competent authorities to suspend the release of, or to detain, suspect goods.[71]

Together, these provisions determine the types of IP infringements and the trade activities for which future ACTA parties must provide border measures in their national laws. To determine whether ACTA mandates or allows seizures of generic drugs in transit, several aspects pertaining to the scope of border measures under ACTA are particularly relevant. The first subsection answers the question of how ACTA border measures apply to goods suspected of patent infringement.[72] The second subsection examines how ACTA addresses goods in transit.[73] The third subsection then looks at other forms of alleged infringements that might affect international trade in generic medicines.[74] The final subsection scrutinizes the *chapeau* of ACTA Article 13 to determine which options exist so as to allow countries to exclude from the scope of border measures those forms of IP infringements which may pose a significant threat to generics in transit.[75]

1. Patent Infringements

The ACTA provision on the scope of border measures has been one of the most contentious among the negotiating parties. This provision concerns primarily the types of IP-infringing goods to be covered, but also addresses what form of trade activities fall under

71. *See id.* art. 16.
72. *See* discussion *infra* Part III(A)(1).
73. *See* discussion *infra* Part III(A)(2).
74. *See* discussion *infra* Part III(A)(3).
75. *See* discussion *infra* Part III(A)(4).

ACTA border measures. Some earlier drafts would have obliged contracting parties to impose border measures against goods "in transit" and in relation to any goods "suspected of infringing intellectual property rights."[76] The latter phrase was defined in the April ACTA draft as "goods infringing any of the intellectual property rights covered by TRIP," in principle including patents.[77] As some of the earlier leaked ACTA drafts indicate, the E.U. favored this approach.[78] It pushed for ACTA's provisions to be broadly defined so as to ensure that infringements of geographical indications ("GIs") fall under its provisions.[79]

76. *See* ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X:1-2.

77. *Id.* Its application to patents was, however, unclear. Article 2.X:2 continued by allowing to exclude certain types of IP infringements if the rights concerned were inter alia "[protected by [non-product- or sector-specific] [registration] *sui generis* systems]." The heavily bracketed text indicated that goods infringing certain (registration) sui generis rights may be excluded from the scope of ACTA's border measures. The relevant question then was whether this optional exception would cover goods infringing patents. While patent rights under TRIPS Article 27(1) must be granted without discrimination to the field of technology and hence arguably are non-product and non-sector specific, they would normally not be considered a sui generis system of protection. The term refers to an IP protection mechanism "of its own kind." It is commonly used for rights in investment bearing databases outside copyright (for example, see Council Directive 96/9, arts. 7-11, 1996 O.J. (L 77) 20, 21 (EC)) or to systems of plant variety protection outside patent law. *See* TRIPS Agreement art. 27.3(b). More recently, certain mechanisms to protect traditional knowledge and/or related genetic resources have been referred to as sui generis. *See Traditional Knowledge*, WORLD INTELL. PROP. ORG., http://www.wipo.int/tk/en/tk/ (last visited Mar. 1, 2011). It therefore seems unlikely that the negotiating parties had patent rights in mind when they allowed excluding rights protected by certain sui generis systems.

78. *See* Anti-Counterfeiting Trade Agreement: Informal Predecisional/ Deliberative Draft art. 2.X:2, Mar. 18, 2010 [hereinafter ACTA Draft—Mar. 18, 2010], *available at* https://sites.google.com/site/iipenforcement/ acta (follow "Full Leaked Text Dated Mar. 18, 2010"). The approach chosen also strongly resembles Article 1 of the BMR. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X:1.

79. *See EU, U.S. to Discuss Differences Over ACTA Scope in Bilateral Meeting*, 28 INSIDE U.S. TRADE, no. 30, July 30, 2010, http://insidetrade.com/ Inside-US-Trade/Inside-U.S.-Trade-07/30/2010/eu-us-to-discuss-differences-over-acta-scope-in-bilateral-meeting/menu-id-710.html (discussing the E.U.'s desire to broaden the scope of ACTA to protect any infringement of GIs in the same manner as infringements of trademarks and copyrights). This report notes that the "scope of the agreement is expected to be a main issue of discussion since both [the United States and the E.U.] have reached a deadlock on whether products with geographic indications ("GIs") should be included in the agreement." *Id. See generally* Jimmy Koo, *Comparing ACTA Texts April 2010 v. July 2010*, AM. U. WASH. C. L. PROGRAM ON INFO. JUST. & INTELL. PROP. (Aug. 12, 2010),

For most commentators, however, the crucial issue was the threat that border measures aimed at alleged patent infringement pose to the free transit of medicines.[80] ACTA negotiators, including the E.U., responded by declaring publicly that "patents will not be covered in the Section on Border Measures."[81] But even on the basis of the subsequently leaked ACTA texts, there was no clear expression that goods in transit allegedly infringing patent rights were to be excluded from the general scope of border measures under the ACTA draft.[82] In the December 2010 ACTA text reproduced above, the matter has finally been addressed: it clarifies that "[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section."[83] This derogates from the general ACTA definition of the term "intellectual property" as comprising "all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement"[84] and hence from the general obligation under ACTA Article 6(1) to foresee enforcement procedures against "any act of infringement of intellectual property rights covered by this Agreement." It excludes patents and the protection of undisclosed information from the ACTA border measure obligations without the need to resort to the ambiguous provision in Article 13 and its conditions for limiting the scope of border measures to certain types of IP infringements.[85] As a result, no future ACTA party will be obliged to introduce or maintain a system of border measures that applies to suspected patent infringing goods. From the perspective of international trade and access to medicines,

http://www.wcl.american.edu/pijip/ go/koo08122010 (discussing the issues surrounding GIs as a potential deal-breaker).

80. *See Urgent ACTA Communique*, *supra* note 64.

81. *See* Press Release, Eur. Comm'n, *supra* note 63.

82. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X (stating that parties may exclude "certain rights other than trademarks, copyrights and GIs" from the definition of "goods infringing an intellectual property right."). In the ACTA draft that leaked after the Washington, D.C. round of negotiations, the text remains unchanged from the July text version. *See* ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 2.X.

83. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13, n.6. The October 2010 version already contained similar language stating "for the purpose of this Agreement, Parties agree that patents do not fall within the scope of this Section." *See* ACTA Draft—Oct. 2, 2010, *supra* note 60, art. 2.X n.6.

84. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 5(h).

85. *See id.* art. 13; *see also* discussion *infra* Part III(A)(4) (providing a more detailed analysis of this provision).

this is certainly an improvement from earlier drafts. As the subsequent analysis will show, however, it is by no means a sufficient safeguard to ensure that transit seizures of generic medicines do not occur.

While ACTA does not mandate border measures for suspected patent infringement, a further question is whether ACTA allows its future contracting parties to introduce or maintain such a system. This concerns not only the E.U., where the BMR covers both patents and transits,[86] but given the dynamics of international IP law and policy, one must expect the trend of a continuous increase in protection and enforcement standards to continue.[87] It is probably not too farfetched that in the near to medium future, some countries might consider ACTA standards as insufficient and strive for "ACTA-plus" standards in their own laws and/or in international agreements. The question then is whether, and to what extent, ACTA would allow its future contracting parties to have additional, stronger IP enforcement laws such as border enforcement against allegedly patent infringing goods. Here, the general rule in Article 2(1) of the December 2010 ACTA text allows "more extensive protection and enforcement of intellectual property rights than is required by this Agreement, provided that such protection and enforcement does not contravene the provisions of this Agreement."[88]

Future ACTA parties therefore can extend border measures to cover goods suspected of patent infringement, unless this can be argued to "contravene" ACTA provisions. Would such extended coverage amount to contravening the negotiating parties' agreement expressed in Footnote 6 to the Border Measures Section that "patents do not fall within the scope of this Section"? This appears not to be the case: by agreeing to exclude inter alia patent rights from the section on border measures, the negotiating parties primarily wanted to ensure that ACTA does not contain an obligation to foresee border

86. *See* discussion *supra* Part I.

87. *See* Kur & Grosse Ruse - Khan, *supra* note 35, at 8-14 (explaining that typically, once rights have become part of a convention, they remain part of the convention while new rules and rights are added on top of them, strengthening rights and protections).

88. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 2(1) (emphasis added). This provision mirrors TRIPS Article 1(1), which is discussed in detail in Part II(B) above and Part IV below.

measures against goods suspected of patent infringements. In response to fears that ACTA might require seizures of generics in transit, negotiating parties announced that "patents will not be covered in the Section on Border Measures."[89] Excluding patent infringements from the scope of Section 3 thus means that section's obligations do not apply to national border measures that extend to goods suspected of patent infringements. For example, the obligation under Article 13 that future ACTA parties should not unjustifiably discriminate between IP rights in defining the scope of their national border enforcement systems does not apply to patents.[90] Hence, an extension to cover patent infringements is not contravening Footnote 6 to the Border Measures Section.

However, this conclusion does not rule out the possibility that extending border measures to patent infringements contravenes other ACTA provisions, particularly in light of some of the free trade and public health safeguards which ACTA negotiators borrowed from TRIPS to alleviate public health concerns. In this context, ACTA Article 6 is relevant: it is a verbatim copy of TRIPS Article 41(1) and serves as an important safeguard against the creation of trade barriers and against abusive reliance on IP enforcement measures in TRIPS.[91] While Footnote 6 prevents the application of ACTA Section 3 obligations to patent rights, national border enforcement measures which address patent infringement are not immune from the general obligations ACTA imposes with respect to IP enforcement. For example, the text of Article 6(1) refers to all IP enforcement procedures available in national law and demands that "[t]hese procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."[92] Since this horizontal safeguard applies across the board and so affects all ACTA obligations, its operation in the context of transit seizures will be discussed separately in Part III(C)(2).

89. Press Release, Eur. Comm'n, *supra* note 63.

90. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13.

91. *See* discussion *supra* Part II; *see also* discussion *infra* Part IV (discussing the trade interests in generic drugs and Article 41(1) of the TRIPS Agreement).

92. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(1).

2. In-Transit Goods

The second controversy regarding the scope of border measures under ACTA concerns the treatment of goods in transit, or in-transit goods as they are now defined in the December 2010 final text.[93] While ACTA Article 16 now contains a fairly clear rule, [94] earlier drafts indicate the range of options that had been on the table among the negotiating parties.[95] This shows that anything beyond the treatment of allegedly infringing imports was equally subject to disagreement. Interestingly, certain combinations of a narrow scope (covering only "suspected counterfeit trademark goods" and "suspected pirated copyright goods") and mere optional provisions on transits and exports would arguably have resulted in a treaty without a direct threat to generics in transit.[96]

In Article 16 of the December 2010 ACTA text, the negotiating parties agreed that procedures must be available for customs authorities, and right holders where appropriate, to suspend the

93. This version defines "in-transit" goods as those under "customs transit," defined as the "procedure under which goods are transported under customs control from one customs office to another," or "transshipment," defined as the "procedure under which goods are transferred from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation." *Id.* art. 5(f), (i), (n).

94. *See id.* art. 16 ("A Party may adopt or maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under customs union control.").

95. *See*, *e.g.*, ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X (extending to goods "imported, exported, in-transit or in other situations where the goods are under customs supervision."); *see also id.* art. 2.6, ¶ 1 (revealing other permutations of similar draft language).

96. *Compare id.* ("1. Each Party shall provide procedures for import [and in-transit] shipments and [may] [shall] provide procedures for export shipments, by which right holders may request the competent authorities to suspend release of suspected counterfeit trademark goods and suspected pirated copyright goods [goods suspected of infringing an intellectual property right] into free circulation."), *with id.* art. 2.X, ¶ 3 ("[Parties shall provide for the provisions related to border measures to be applied [at least]in cases of trade mark counterfeiting and copyright piracy. [Parties may provide for such provisions to be applied in other cases of infringement of intellectual property rights.]]"). In the July ACTA text, however, the brackets around the term "in-transit" under Option 1 are removed. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.6, ¶ 1 (citing option 1). The July text contains a new Option 2, favored by the majority of the negotiating parties, which is limited to counterfeit trademark and pirated copyright goods, but applies to transit. *Id.*

release of "import and export shipments."[97] On the other hand, the second paragraph of this provision states that "[a] Party *may* adopt or maintain procedures for suspect in-transit goods or in other situations where the goods are under Customs control."[98] Based on the permissive language of these provisions, ACTA does not obligate contracting parties to introduce or maintain border measures against any form of goods in transit. This again appears to be a significant improvement from most of the options that were earlier on the table—especially from the perspective of international trade in generic medicines. Given that patents are completely excluded from ACTA's border measure section, and measures against transits are merely optional rather than mandatory, one has to ask whether ACTA still threatens in-transit generics. Before this question is addressed in further detail below, the ACTA definitions pertaining to transits must be assessed.

Article 5 in the December 2010 ACTA text contains three definitions that are relevant here. First, the definition of the term "in-transit goods" in Article 5(i) distinguishes between two modes of transit: goods under "customs transit" and those under "transshipment."[99] According to Article 5(f), "customs transit" is "the customs procedure under which goods are transported under customs control from one customs office to another."[100] "Transshipment" is in turn defined in Article 5(n) as "the customs procedure under which goods are transferred under customs control from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation."[101] The leaked ACTA draft of January 2010 reveals that these terms and their definitions are based

97. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 16(1)(a)-(b).

98. *Id.* art.16(2) (emphasis added).

99. *Id.* art. 5(i). The current definition of "in-transit goods" appeared first in the publicly released April 2010 ACTA draft text. *See* ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.6, n.23 (referring to the bracketed inclusion of "in-transit" goods under Option 1 of draft Article 2.6). This definition of "in-transit goods" also appeared in the July ACTA draft text and the leaked draft text following the Washington, D.C. round of negotiations. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.6 (defining "in-transit" goods in footnote 18); ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 1.X (placing the definition of "in-transit" goods in Article 1.X: Definitions, located in Chapter One, Section B).

100. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 5(f).

101. *Id.* art. 5(n).

on the International Convention on the Simplification and Harmonization of Customs Procedures ("Kyoto Convention").[102] Until the final draft, it was questionable whether analyzing these terms could provide any valuable insights on the general scope of the notion of "transit" in ACTA, as it was not clear that all negotiating parties favor such technical customs definitions.[103] However, the decision to move the definitions into a "General Definitions" section implies consensus amongst the negotiating parties on their relevance to the whole agreement.[104]

The implementation of technical customs law terms in ACTA should be helpful to those authorities responsible for implementing border measures, as they should be familiar with these terms. If one applies the Kyoto Convention's definitions to the case of transiting generics, it appears that the second alternative definition of "transshipment" in ACTA Article 5(n) is relevant: generic medicines produced in one country and in transit through another on the way to a third country of final destination are, after arrival in the transit country, "transferred under customs control from the importing means of transport to the exporting means of transport within the area of one customs office."[105] The technical customs definitions thus cover the typical scenarios that have led to the seizure of generics in transit. Nevertheless, since it is not mandatory to extend border measures to transits under the final December 2010 text, does ACTA

102. *See* ACTA Draft—Jan. 18, 2010, *supra* note 56, art. 2.6 n.10 (revealing that Canada, New Zealand, and the United States proposed the inclusion of "customs transit" and "transshipment" as defined by the Kyoto Convention).

103. It was doubtful whether all negotiating parties who used the term "in-transit" or referred to goods in transit in more general terms—as the E.U. did in Art.2.X:1-2 of the April 2010 ACTA Draft—relied on the same definition of transit *in their proposals*. *See, .e.g.*, ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 1.X:1-2.

104. *See* ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 1.X. However, a careful reading of the October 2010 ACTA text reveals that the definitions of "in-transit goods," "Customs transit," and "transshipment," contained in Article 1.X, General Definitions, are not exactly the definitions used in the agreement itself. *See* ACTA Draft—Oct. 2, 2010 *supra* note 60, art. 1.X. Instead, the draft language in Article 2.X:2 regarding Border Measures uses the phrase "*goods in transit* or in other situations where the goods are under Customs control." *Id*. art. 2.X, ¶ 2 (emphasis added). The December draft addresses the discrepancy, which was most likely the result of poor legal drafting, by aligning the terminology in Article 16 to the definitions in Article 5. ACTA Text—Dec. 3, 2010, *supra* note 60, arts. 5, 16.

105. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 5(n).

really continue to pose a significant threat for trade in generics?

The typical juridical answer is particularly apt in this case: it depends. Distinct from TRIPS, ACTA explicitly allows parties to provide "procedures for suspect goods in transit or in other situations where the goods are under customs control."[106] Further, as mentioned above, Article 2(1) of the December 2010 ACTA text generally allows parties to implement more extensive protection, "provided that such enforcement does not contravene the provisions of this Agreement."[107] In relation to extending border measures to cover patent infringing goods, section 1 concludes that such "ACTA-plus" enforcement procedures may contravene the agreement's provisions, particularly the safeguards against trade barriers and abuse set out in the "General Obligations" Section.[108] The same conclusion applies to extending border measures to goods in transit, unless the explicit allowance in ACTA Article 16(2) warrants a different result.[109]

One might argue that this explicit permission implies that making use of this right (i.e. extending border measures to cover transits) cannot be considered "contravening" ACTA. In principle, this is a logically sound argument. However, while providing enforcement procedures against goods in transit cannot be viewed as contravening ACTA norms, certain methods of doing so certainly may nevertheless contravene ACTA. The general obligation in ACTA Article 6(1) that all enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" also applies to cases where ACTA explicitly allows certain measures. If a future ACTA party decides to make use of this allowance, it must still ensure that it

106. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 16(2). TRIPS, on the other hand, states: "It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit." TRIPS Agreement art. 51 n.13; *see also* Grosse Ruse - Khan & Jaeger, *supra* note 48, at 534-35 (opining that while this may be viewed as some form of implicit allowance to extend border measures to goods in transit, this view is contested); Kumar, *supra* note 26, at 515-17 (discussing the conflicting scholarly interpretation of footnote 13 to TRIPS Article 51).

107. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 2(1).

108. *Id.* art. 6(1); *see also* discussion *infra* Part III(A)(3) (discussing the operation of Article 6(1)).

109. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 16(2).

is doing so in a way that does not create trade barriers or allow abuse. Hence, the option to provide border measures against goods in transit is subject to the general obligation to do so in a manner that does not create barriers to legitimate trade.[110] An attempt to give a more concrete meaning to the ambiguous terms used in the general obligation provision can be found in Part III(C)(1).

3. Other Forms of IP Infringements

Another reason why the December 2010 ACTA text may still pose a threat to international trade, particularly with respect to generic medicines, is the fact that border measures apply not only to counterfeit trademark and pirated copyright goods,[111] but in principle to all goods suspected of any other infringement of IP rights, except patents and the protection of undisclosed information. This follows from ACTA Article 6(1), which states that "[a] Party shall ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of *intellectual property rights covered by this Agreement* ."[112] The term "intellectual property" is understood as comprising "all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the

110. This may be especially relevant wherever procedures against transits are combined with extending the IP-infringing goods covered, such as patent infringing goods. The transit seizures subject to the WTO dispute brought by India and Brazil indicate the trade distorting potential of such extended IP enforcement regimes. *See*, *e.g.*, India Consultation Request, *supra* note 2, at 2.

111. *See* TRIPS Agreement art. 51 (stating that members may adopt procedures to allow right holders to file claims in respect of goods "which involve other infringements of intellectual property rights" in conformity with the rest of the agreement's provisions). Earlier ACTA drafts contained proposals which similarly mandated border measures "[at least] in cases of trademark counterfeiting and copyright piracy." ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X, ("Scope of the Border Measures") ¶ 3. The July 2010 ACTA text reveals that this provision was the counter-proposal by the United States, Singapore, Australia, New Zealand, Japan and Canada. ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X ("Scope of the Border Measures") ¶ 3. The provision further clarified that "[p]arties may provide for such provisions to be applied in other cases of infringement of intellectual property rights." *Id.* In essence, the substance of the proposed Article 2.X:3 was identical with the scope of border measures as defined in the first sentence of TRIPS Article 51. *See* TRIPS Agreement art. 51. It therefore would not have obliged contracting parties to provide border measures against goods suspected of infringing patents, but explicitly allowed parties to do so.

112. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(1) (emphasis added).

TRIPS Agreement."[113] Therefore, in general, border enforcement procedures must extend to infringements of any IP rights provided in the TRIPS Agreement. As discussed above, however, this is subject to the exclusion of patent and test data rights by virtue of footnote 6 to the Border Measures Section.[114] The remaining types of IP infringements for which future ACTA parties must provide border enforcement procedures thus cover, inter alia, all forms of trademark infringements and infringing uses of geographical indications. Such a broad scope of border measures permitted under ACTA had been highly contentious amongst the negotiating parties, particularly with respect to GIs.[115]

While extending border measures to goods suspected of infringing GIs offers supporters of strong GI protection the opportunity to impose their law on any goods transiting through their territory,[116] for trade in generic medicines this extension to all forms of trademark infringements is particularly problematic. In earlier ACTA drafts, this extension was explicitly addressed in a bracketed footnote, which provided that:

> [The provisions of this section shall also apply to confusingly similar trademark goods [which means any goods, including packaging, bearing without authorization a trademark that is similar to the trademark validly registered in respect of such or similar goods where there exists a likelihood of confusion on the part of the public between the trademark borne and the trademark validly registered, and that thereby infringes the rights of the owner of the trademark in question under the law of the

113. *Id.* art. 5(h).

114. Discussion *supra* Part III(A)(1).

115. *See, e.g.*, Press Release, Office of the U.S. Trade Representative, USTR Releases Statement Regarding Recent ACTA Negotiations in New Zealand (Apr. 2010), http://www.ustr.gov/about-us/press-office/press-releases/2010/april/ustr-releases-statement-regarding-recent-acta-negoti (stating that while the E.U. and Switzerland favor a wide scope which covers goods protected by geographical indications due to a perceived comparative advantage in the production and sale of premium food and agricultural products associated with well known regions in Europe, the United States and other "new world" countries desire a more limited scope and advocate that GIs should be excluded).

116. If the substantive system of protection for GIs in the transit country considers the mere transit as sufficient for infringement, without a threat of trade diversion onto the domestic market, any in-transit good that uses similar or identical terms may be subject to seizure.

country in which the procedures set out in this Section are invoked.][117]

Commentators have rightly pointed to the threat this poses to transiting generic medicines: by relying on the same or similar words identifying the active ingredient, the labels used to identify generics often may be to some extent similar or close to the trademarks of the original manufacturer.[118] While a manufacturer may be expected to take into account the scope of trademark protection in the country of final destination, combining such a broad scope of border measures with their optional extension to goods in transit imposes another significant barrier to international trade. The generic producer would need to distinguish its labeling from all protected trademarks in all transit countries in order to ensure that the medicines are not seized in transit. This in turn will increase transaction costs and may prevent traders from using the most efficient transit routes. It hence adds further barriers to the global trade in generics and the cheap provision of medicines to populations in need.

Another troubling point is that custom authorities are not well-placed to act against "confusingly similar trademark goods" in general.[119] Findings of likelihood of confusion based on the degree of similarity of both the labels and the goods require a comprehensive legal analysis which is much less straightforward than determining whether goods are counterfeit.[120] Such an assessment is typically performed by courts or trademark offices, which have the necessary

117. ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X, ¶ 2 n. 22; *see also* ACTA Draft—Mar. 18, 2010, *supra* note 78, art. 2.X, ¶ 2 (revealing in footnote 9 that the extension of border measures to basically all forms of trademark infringements was proposed by the E.U.); ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X, ¶ 2 (indicating support from Australia, South Korea, Switzerland, and Japan in footnote 16 that this provision apply to "confusingly similar trademark goods").

118. *See* Sean Flynn, *Note on ACTA and Access to Medicines*, AM. U. WASH. C. L. PROGRAM ON INFO. JUST. & INTELL. PROP., http://www.wcl.american.edu/pijip/go/blog-post/note-on-acta-and-access-to-medicines (last visited Mar. 1, 2011) ("Extending border suspensions and goods destructions to mere trademark infringements should be particularly worrying for generic medicines manufacturers.").

119. *See* Kimberlee Weatherall, ACTA Australian Section-by-Section Analysis (April Public Draft), 28 (Apr. 30, 2010), *available at* http://works.bepress.com/cgi/viewcontent.cgi?article=1020&context=kimweatherall (expressing a concern that a determination of whether a trademark is "confusingly similar" is difficult).

120. *See id.*

legal expertise, case law, and experience to rely upon. Imposing this task on customs officers is likely to result in a considerable increase in seizures and temporary detentions based on right holder allegations that transiting generics are confusingly similar. Until the generic producer or subsequent owner of the goods is able to show that no likelihood of confusion exists or that the goods do not pose any threat of being diverted into domestic markets,[121] the goods will be detained for the time being because ACTA Article 17 allows initial detentions based on evidence for prima facie trademark infringement, judged by "the law of the Party providing the procedures."[122] ACTA Article 19 then requires contracting parties, acting through competent authorities, to initiate proceedings to determine the existence of an infringement "within a reasonable period of time."[123] Even though there is a good chance that in-transit generics will subsequently be found by a court not to infringe trademarks in the transit country,[124] ACTA does not generally allow the goods to be released against provision of a security.[125] In general, the goods will therefore remain detained until a court has decided on the infringement issue. Given the duration of court proceedings, such detention periods will likely pose another considerable obstacle to international trade in generic medicines.[126]

121. *See* discussion *infra* Part III(B)(2) (discussing the situation in countries where such a requirement in the substantive trademark law may provide a ground for releasing the goods due to the absence of substantive infringement).

122. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(1); *see* discussion *infra* Part III(B)(2) (analyzing the "choice of law" rule).

123. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 19. ACTA does not contain any provision similar to Article 55 of TRIPS which limits the initial detention period to 10 days. TRIPS Agreement art. 55; *see also* discussion *infra* Part IV(A)(3) (discussing ACTA Article 19's consistency with the TRIPS Agreement).

124. *See* discussion *infra* Part III(B)(1) (discussing the decisive question of whether goods merely in transit are likely to be considered as infringing based on the law of the transit country).

125. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 18 ("A Party may, only in exceptional circumstances or pursuant to a judicial order, permit a defendant to post a bond or other security to obtain possession of suspect goods ."). In comparison, Article 53(2) of the TRIPS Agreement in turn explicitly requires that, for certain forms of alleged IP infringements, the owner/importer of the goods must have the option of posting a security in order to have the goods released. TRIPS Agreement art. 53; *see also* discussion *infra* Part IV(A)(3) (discussing the TRIPS consistency of ACTA Article 18).

126. *See* discussion *infra* Part III(C)(2) (discussing whether such trade barriers may be tackled under the new proposal in the General Obligations section of

Finally, another form of IP rights contained in the TRIPS Agreement that is related to pharmaceutical products is the protection of test data under Article 39(3).[127] Although footnote 6 to the Border Measures Section generally excludes the protection of undisclosed information from its scope,[128] the arguments above show that ACTA parties nevertheless *may* provide for enforcement measures against goods that are suspected of infringing their domestic test data protection system.[129] In case they also extend their border measures to goods in transit, the question then arises whether generics may run the risk of being considered as infringing test data protection in the transit country. If so, this form of protection could be argued as functioning as a trade barrier for generics in transit. However, the protection of test data against unfair commercial use concerns data submitted to regulatory authorities in order to obtain marketing approval for pharmaceutical or agricultural chemical products—not the goods produced as a consequence of using this data.[130] Even TRIPS-plus test data exclusivity regimes in national laws are highly unlikely to extend protection to generics from abroad: while the test data relevant to the marketing approval may be protected in the country of transit, generics produced elsewhere do not aim for marketing approval in the transit country even if the production occurred in reliance on this data. Hence, extending border measures to test data protection does not seem to pose a threat to international trade in generics.

4. Options to Limit the Scope of Border Measures

As previous sections have demonstrated, ACTA's negotiating parties have tried to alleviate concerns over transit seizures and

ACTA, which includes the text of TRIPS Article 41 verbatim).

127. *See* TRIPS Agreement art. 39(3) (stating that Members must protect test data against disclosure, unless necessary to protect the public or unless steps are taken to avoid unfair commercial use).

128. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13, n.6.

129. *See* discussion *supra* Part III(A)(1)-(2).

130. The subject matter of the protection under TRIPS is undisclosed information contained in written material which details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal and plant health, impact on the environment, and efficacy of use. TRIPS Agreement art. 39(3). *See generally* CORREA, *supra* note 38, at 32; G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 1, 7 (2003).

access to medicines in the final December 2010 ACTA text. Nevertheless, some problems remain. ACTA generally allows parties to provide border measures against goods in transit and it requires future contracting parties to extend border enforcement to types of suspected IP infringements which carry the potential to create barriers to the trade in generic medicines. This raises the question of whether the *chapeau* provision in ACTA Article 13 may be utilized to limit this potential. It states:

> In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of intellectual property rights, a Party should do so in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade.[131]

In particular, Article 13 might be applied to exclude those ordinary forms of trademark infringement that have been identified in section c above as tools to temporarily detain goods in transit until a court in the transit country has ruled on the matter.

ACTA Article 13 has neither a 'predecessor' in earlier drafts, nor a counterpart in the TRIPS Agreement. Subject to certain conditions, the provision allows ACTA parties to exclude IP infringement from the scope of domestic border enforcement systems.[132] It appears to primarily serve as a compromise tool bridging the differences between the E.U. and the United States over covering infringements of GIs and other IP rights beyond the minimum standards contained in TRIPS Article 51.[133] The provision contains several open and ambiguous terms and conditions,[134] which in sum create a form of

131. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13.

132. *See id.* (stipulating that a party can effect policies regarding border enforcement and IP rights so long as they are consistent with its domestic IP rights regime and is consistent with the TRIPS Agreement).

133. *Compare id.* art. 13 (stating that a party should promulgate border measures that do not "unjustifiably" discriminate), *with* ACTA Draft—Oct. 2, 2010, *supra* note 60, art. 2.X (stating that a party should promulgate border measures that do not "unreasonably" discriminate). The fact that, in the October 2010 text version, the equivalent provision contained one of the very few remaining terms which were still disputed amongst the parties ("unreasonably" rather than the current "unjustifiably") supports the view that this provision was part of a compromise between the United States and the E.U.

134. Ambiguous terms in Article 13 include "discriminate unjustifiably," "as

constructive ambiguity that disguises the remaining differences amongst the parties over the treaty text.[135] Instead, each party will be able justify its own understanding by relying on a favorable interpretation of one or more of these terms. While this constructive ambiguity may have been primarily created to allow the negotiating parties to take different approaches to address infringements of geographical indications, it may equally serve as an appropriate tool to exclude ordinary trademark infringements from a national system of border measures.

The basic obligation which Article 13 repeats is to provide "for effective border enforcement of intellectual property rights,"[136] subject to several requirements. For instance, a Party's acts must be "consistent with [its] domestic system of intellectual property rights protection" and "without prejudice to the requirements of the TRIPS Agreement."[137] The first phrase clarifies that enforcement measures apply only insofar as the ACTA party's domestic system of substantive IP protection considers the goods potentially infringing.[138] Hence, for ordinary trademark infringements, border measures must, in principle, be available. The second phrase ensures that future ACTA parties are bound by the minimum standards of border enforcement prescribed in the TRIPS Agreement.[139] It equally

appropriate," "legitimate trade," "and "consistent with a parties domestic system of intellectual property rights protection." ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13.

135. *See* Henning M. Grosse Ruse - Khan, *The Role of Chairman's Statements in the WTO*, 41 J. WORLD TRADE 475, 491-92 (2007) (positing that "constructive ambiguity" allowed all sides to come to an agreement at the cost of specificity).

136. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13. This basic obligation is already contained in Article 6. *See id.* art. 6(1) ("Each Party shall ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement"); *see also* discussion *supra* Part (II)(A)(3).

137. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13.

138. *See* discussion *infra* Part III(B)(2) (discussing the relationship of ACTA with domestic IP protection laws). *Compare* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13 ("In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection ."), *with id.* art. 3(1) ("This Agreement shall be without prejudice to provisions in a Party's law governing the availability, acquisition, scope, and maintenance of intellectual property rights.").

139. *See id.* art. 13. In applying this provision, for example, a future party may not, exclude border measures against counterfeit trademark and pirated copyright goods as demanded by TRIPS Article 51 when introducing limits to the types of IP infringements covered.

upholds all minimum requirements that safeguard the interests of traders and owners of the goods potentially subject to border measures.[140] This condition does not prevent future parties from excluding ordinary trademark infringements from its border IP enforcement system as long as counterfeit trademark goods are still covered, as defined in footnote 13 to TRIPS Article 51.

The main discretionary element of Article 13, then, is that a party can provide for such effective border measures "as appropriate." Within the boundaries mentioned above, this seems to offer ample flexibility to limit the types of infringements covered.[141] This discretion is further limited only slightly by the call that parties "should do so in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade."[142] Here, the use of the permissive "should" instead of the mandatory "shall" is a decisive factor in that it does not create a new obligation under international law.[143] The second element concerning the avoidance of trade barriers would actually militate in favor of limiting border measures in a way that does not threaten trade in generic medicines.[144] Under the first element, unjustifiable discrimination should be avoided but justifiable distinctions between types of infringements where good faith reasons validate a different treatment are certainly allowed. Here, access to medicines and international trade in generic medicines and other goods can serve as justifications to exclude

140. *Id.* In application, this provision would uphold TRIPS Articles 41, 55, and 56. *See* TRIPS Agreement arts. 41, 53, 55, 56; *see also* discussion *infra* Part IV(A)(3) (discussing potential conflicts between ACTA and the TRIPS Agreement).

141. The notion of effectiveness does not preclude such findings. In the preamble to the TRIPS Agreement, the negotiating parties expressed their intention "[to provide] effective and appropriate means for the enforcement of trade-related intellectual property rights, *taking into account differences in their respective legal systems and practices*." ACTA Text—Dec. 3, 2010, *supra* note 60, pmbl. (emphasis added). This strongly indicates that the notion of effectiveness must nevertheless give deference to variances among the national enforcement systems.

142. *See id.* art. 13.

143. *See* GERVAIS, *supra* note 39, at 203 (discussing the use of the word "should" in TRIPS Article 7 and stating that it should not be viewed as reducing the scope of "shall").

144. *See* discussion *infra* Part III(C)(2) (analyzing TRIPS Article 41(1)). TRIPS Article 41(1) is the equivalent provision of Article 13 in ACTA, even though the former is phrased as a "shall" obligation.

ordinary trademark infringements, especially if the country has introduced border measures against goods in transit. The *chapeau* provision in ACTA Article 13 therefore allows for the exclusion of those types of infringements from a domestic system of border measures that are particularly problematic for generic drugs in transit. The general obligation to create such measures for ordinary trademark infringements is therefore also waived so long as such exclusion can be justified on public health grounds.

In sum, the scope of the ACTA border measures section allows parties to prevent the seizure of generic medicines. However, countries have to implement the agreement with all of these options in mind in order to take public health issues into account.

B. APPLICABLE LAW AND DETERMINATION OF INFRINGEMENT

This section assesses two related general aspects of the December 2010 ACTA text that may affect international trade in generics. The border measures section in ACTA contains rules on the applicable law governing the determination of the IP-infringing character of goods subject to border measures. Section 1 below contrasts the relevant ACTA provision with that of the TRIPS Agreement and highlights its impact on international trade in generics. Furthermore, ACTA, as an agreement on the enforcement of IP rights, claims not to set its own standards of IP protection and does not prescribe which acts contracting parties shall treat as infringements of their national laws. It contains a general rule, however, on the relationship between the applicable national IP infringement standards and the IP enforcement obligations under ACTA. Section 2 examines the operation of this rule for cases of generics in transit.

1. The Applicable Law in IP Border Enforcement Cases

In principle, a system for the enforcement of IP rights such as border measures is a system of procedural law as distinguished from substantive law. However, the international character of global trade and its natural connection to the territories and markets of several countries makes it useful, if not necessary, to include a rule on which a nation's substantive law shall apply. The applicable law then primarily determines whether the goods in question infringe on IP

rights.[145] As the Dutch transit seizure cases have shown, the national laws of the country of production, of transit, and of destination certainly may have different answers here.[146] A choice of law rule that decides which substantive law is relevant will therefore be crucial for determining the existence of an IP infringement.

Under TRIPS, the choice of law rule obliges WTO Members to require from right holders applying for the seizure of goods "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."[147] Thus, the relevant law determining whether the goods in question are prima facie infringing is that of the country of importation.[148] This choice is arguably driven by two considerations. First, since TRIPS merely obliges WTO members to provide border measures against imports, the authorities and courts charged to rule on the infringing nature of goods will likely be those of the importing country. Of course, applying one's own law to judge IP infringements will make things much easier. In principle, however, the application of a foreign law is always a possible alternative, both under general doctrines of private international law as well as under the generally accepted choice of law rule for IP rights.[149] Second, since the goods

145. *See* discussion *infra* Part III(B)(2) (discussing the problem of determining infringement and establishing the role of the scope of the applicable substantive IP law).

146. *See* discussion *supra* Part I (discussing the seizure by the Dutch of generic drugs in transit and the conflict among several substantive IP regimes).

147. *See* TRIPS Agreement art. 52.

148. *Id.* In addition, TRIPS refers to the law of the importing country to determine goods that contain counterfeit trademarks or copyright piracy. *See id.* art. 51 n.14.

149. One common theory in private international law calls for the application of the law of the country which has the strongest territorial link or connection to the legal issue to be decided. Other theories examine all potentially applicable norms and ask which has the strongest and most valid interest to be applied (government interest analysis). In both instances, this may be a foreign territory and a foreign rule. The application of the principle of *lex loci protectionis* to determine the law applicable to the protection of a certain subject matter by IP rights can also lead to the application of a foreign law as soon as IP protection for a foreign territory is sought. Article 5(2) of the Revised Berne Convention on the Protection of Literary and Artistic Works confirms this for the area of copyright law by determining that ''the extent of protection, as well as the means of redress afforded to the author to protect his rights, shall be governed exclusively by the *laws of the country where protection is claimed*.'' Berne Convention, *supra* note 33, art. 5(2) (emphasis

are to be sold or otherwise commercialized on the market of the importing country, understood as the country of final destination,[150] there is generally a strong link to that country, justifying the application of its law.[151]

The December 2010 ACTA text contains a provision equivalent to TRIPS Article 52, which states:

> Each Party shall provide that its competent authorities shall require a right holder that requests the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures) to provide adequate evidence to satisfy the competent authorities that, under the law of the Party providing the procedures, there is prima facie an infringement of the right holder's intellectual property right.[152]

Despite its similarly to TRIPS, the applicable law rule is different in ACTA: instead of the country of importation, the relevant benchmark for judging whether goods are IP-infringing is "the law of the Party providing the procedures,"[153] meaning the domestic IP law

added). For the question of applicable law in the context of private international law, this rule is frequently cited to justify the application of the law of the country where an act conflicts with IP rights granted by the domestic law and on this basis protection is sought (lex loci protections). For the area of patent law, one can refer to Article 4*bis* (1) of the Paris Convention for the Protection of Industrial Property: ''Patents applied for in the various countries of the Union by national of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.'' Paris Convention, *supra* note 33, art. 4(1); *see* CORREA, *supra* note 38, at 81 (expressing that this principle of independence of patents builds on and presupposes the principle of territoriality).

150. *See* Kumar, *supra* note 26, at 510-17 (discussing the relation of the term "country of importation" in the context of other relevant articles of TRIPS); Grosse Ruse - Khan & Jaeger, *supra* note 48, at 534-36 (interpreting the meaning of the term "country of importation").

151. Kumar, *supra* note 26, at 512-17 (indicating that other provisions in TRIPS suggest that an essential element of importation into a country is the likelihood and possibility of the goods entering the channels of commerce in [the] country.).

152. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(1).

153. The definitions of "counterfeit trademark goods" and "pirated copyright goods" in the definitions section of ACTA further confirm this applicable law rule. *See id.* art. 5(d), (k) (stating that whether goods are counterfeit or pirated is to be judged "under the law of the country in which the procedures set forth in Chapter II (Legal Framework for Enforcement of Intellectual Property Rights) are invoked."). These differ in the same aspect from the otherwise identical provisions in footnote 14 to TRIPS Article 51. TRIPS Agreement art. 51 n.14 (announcing only that counterfeit or pirated goods are to be judged under the law of the country

of the authorities adopting the border measures. For measures taken against imported goods, nothing changes: they are still judged by the law of the importing country since the relevant authorities are those of the importing country. For goods in transit, however, the applicable law is no longer that of the country of importation or final destination, but instead that of the country where the goods are seized by customs in transit, namely the transit country.[154]

As the Dutch transit seizure cases illustrate, this change in the choice of law rule can have severe consequences.[155] In those cases, the law of the transit country was applied to determine whether the drugs in transit are IP-infringing even though there was no IP infringement in the countries of origin and production or the countries of importation and final destination.[156] Although some have argued otherwise,[157] this rule is, at least formally, consistent with the notion that IP rights are territorial in nature.[158] A broad definition of

of importation).

154. *See* Grosse Ruse - Khan & Jaeger, *supra* note 48, at 534-36 (addressing the question of whether the TRIPS Agreement takes a more specific approach by defining the "laws of the country of importation" as applying only to the country of final destination); discussion *infra* Part IV(B) (discussing whether the transit country rule is consistent with the TRIPS Agreement).

155. *See* discussion *supra* Part I (describing how the Dutch seizure of generic medicines to treat hypertension and HIV/AIDS, among other diseases, prevented the medicines from reaching their destination in developing countries in South America and Africa).

156. *See* discussion *supra* Part II(B) (explaining that Dutch authorities seized the generic medicines under E.U. and Dutch border measures, a choice of law rule which arguably contradicts the TRIPS approach of making border measures dependent on evidence of IP infringements based on the law of the country of importation).

157. *See, e.g.*, India Consultation Request, *supra* note 2, ¶ 3 (reading the TRIPS Agreement and Doha Declaration to mean that "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"); Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WIPO J. 43, 49 (2009) (arguing that the decision of the E.U. to apply European laws to goods in transit constitutes a denial of "the sovereign rights of foreign WTO Members" to grant their own patents).

158. *See* L. BENTLY & B. SHERMAN, INTELLECTUAL PROPERTY LAW 929 (2d ed. 2004) (stating that under the principle of territoriality, the existence and scope of IP protection in relation to acts committed on domestic territory depends on the domestic law); CHRISTOPHER ARUP, THE NEW WORLD TRADE ORGANIZATION AGREEMENTS: GLOBALIZING LAW THROUGH SERVICES AND INTELLECTUAL

territoriality may allow minimal territorial linkages, such as the transit of goods through a country, to be treated as a sufficient expression of territoriality by the law of the transit country. Thus, such minimal territorial connections can be used as the relevant connecting factor for a choice of law rule, even though the goods may have a much stronger connection to the territory of another country, for example, the country in which the goods will be sold or otherwise commercialized.[159] Notwithstanding the consistency of the choice of law rule with the territorial nature of IP laws, the existence of these comparably stronger territorial linkages have sparked many scholars to criticize laws with a minimal link as "extraterritorial" in reach.[160]

PROPERTY 30 (2000); INTERNATIONAL ENCYCLOPEDIA OF INTELLECTUAL PROPERTY TREATIES 3 (Alfredo Ilardi & Michael Blakeney eds., 2004) (explaining that while international IP law heavily influences domestic legislation, global IP rights are nevertheless "a bundle of nationally enforceable rights"); Paul Katzenberger & Annette Kur, *TRIPS and Intellectual Property, in* 18 IIC STUDIES IN INDUSTRIAL PROPERTY AND COPYRIGHT LAW: FROM GATT TO TRIPS 1, 3-5 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996) (asserting that the domestic nature of the protection of IP rights effectively constitutes a non-tariff restriction on trade and illustrating how this type of restriction operates in the context of pirated goods). *But see* Annette Kur, *A New Framework for Intellectual Property Rights Horizontal Issues*, 35 INT'L REV. INTELL. PROP. & COMPETITION L. 1, 7 (2004) (discussing the "erosion of the territoriality principle" in light of the global dimension of IP rights, and calling for the development of new mechanisms to resolve cross-border IP disputes).

159. Unless international harmonization via multilateral treaties on conflict of law rules has circumscribed national autonomy to determine which connecting factors trigger the applicable law, countries enjoy freedom to decide how to define the notion of territoriality and the necessary linkages of conducts or persons to its territory.

160. *See* Abbott, *supra* note 15 (noting that transit of goods through EU airports "involves minimal jurisdictional contract with EU territory," and arguing that "[i]t is an extreme concept of trade regulation to suggest that goods in transit must comply with ordinary local regulatory requirements in order to avoid confiscation by local customs authorities"); *see also* Josef Drexl, *Lex Americana ante portas Zur Extraterritorialen Anwendung nationalen* [*Lex Americana ante portas The Extraterritorial Application of National Law*], *in* URHEBERRECHT IM INFORMATIONSZEITALTER [COPYRIGHT IN THE INFORMATION AGE] 429 (Ulrich Loewenheim ed., 1999); Henning Grosse Ruse - Khan, *A Pirate of the Caribbean? The Attractions of Suspending TRIPS Obligations*, 11 J. INT'L ECON. L. 313, 349-50 (2008) (discussing the recent trend in the extraterritorial application of domestic IP laws by countries that "fear insufficient IP protection for the intellectual assets of their companies abroad" in lieu of working towards harmonization of IP laws through international agreements).

For generics in transit, the applicable law rule in ACTA allows the transit country to apply its own law to determine whether goods in transit infringe on IP rights. While not all transit countries may consider the mere transit of goods as IP infringing,[161] the applicable law rule nonetheless creates uncertainty and legal insecurity for all international trade in goods: the owners and traders in generic medicines now have to consider the choice of law rules and substantive laws of all transit countries in order to find out whether it is "safe" to use a specific transit route.

2. Determination of Infringement

Given ACTA's applicable law rule, the question arises how to determine an infringement of IP rights under ACTA. In this regard, the December 2010 ACTA text provides:

> ARTICLE 19: DETERMINATION AS TO INFRINGEMENT
> Each Party shall adopt or maintain *procedures by which its competent authorities may determine*, within a reasonable period of time after the initiation of the procedures described under Article 16 (Border Measures), *whether the suspect goods infringe an intellectual property right*.[162]

Whether one of the remedies specified in ACTA is available first depends on the finding that the goods are infringing in accordance with the procedures adopted pursuant to Article 19.[163] However, as a treaty concerned with the enforcement of IP rights, ACTA does not set its own substantive standards in regards to the infringement of IP rights.[164] Instead, Article 3(2) provides the general rule on the

161. *See* discussion *infra* Part III(B)(2) (elaborating on the determination of infringement).

162. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 19 (emphasis added).

163. *Id.* art. 20(1), (3) (providing that competent authorities may destroy goods or impose administrative penalties "*following a determination referred to in Article 19 that the goods are infringing*") (emphasis added).

164. *Id.* art. 3(1) (confirming that ACTA's provisions shall not be understood as setting new or distinct standards of substantive IP protection, other than those available under the domestic laws of future ACTA parties). Apart from specific instances in which ACTA enforcement obligations arguably set de facto new standards of substantive IP enforcement, for example, regarding copyright protection on the internet, this is a crucial difference between ACTA and the TRIPS Agreement. In the latter, the general obligation in IP enforcement requires "that enforcement procedures are available so as to permit effective action *against any act of infringement of intellectual property rights covered by this Agreement.*"

relationship between the procedural rules mandated under ACTA and the substantive standards of IP protection under which states determine infringements—"[ACTA] does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under its laws and regulations."[165] The decisive question of whether goods are IP infringing thus depends on the substantive IP protection standards in domestic law.[166] In situations where no substantive IP protection exists according to domestic law, there is per se no obligation to establish IP enforcement measures. Put another way, ACTA does not require contracting parties to enforce border measures against goods that do not infringe domestic IP rights. Countries that do not consider transit as an act infringing a patent, trademark, or copyright protected under their national IP systems would therefore not be obliged to seize these goods, even if their systems of IP border enforcement would generally extend to patent infringements as well as goods in transit.[167]

Thus, the final fate of allegedly infringing goods in transit depends on whether the substantive scope of IP protection in the transit country actually covers transit as an infringing act. In other words, would the domestic IP law consider acts with a marginal territorial link to the transit country as infringements or does it demand a real and proven threat of trade diversion in the market of the transit country? A recent decision of the English Court of Appeals raised precisely this question, analyzing whether the BMR encompasses

TRIPS Agreement art. 41(1) (emphasis added). The verbatim copying of this provision into ACTA Article 6(1) is apparently the result of poor legal drafting since this provision is directly contradicted by Article 3. ACTA Text—Dec. 3, 2010, *supra* note 60, arts. 3, 6(1).

165. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 3(2). The development of Article 3(2) is traceable to the April 21, 2010 draft. *See* ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X n.21 (Scope of the Border Measures) ("No Party shall be obliged to apply this section to any goods that do not infringe an intellectual property right held within the territory of that Party. [*Negotiator's note*: Study moving to General Provisions section.]").

166. As the previous section has shown, it is the law of the contracting party that governs the applicable procedures. The question discussed in this section is related, but a distinct one since it deals with the scope of ACTA and whether it sets out new standards of IP infringement.

167. One can further argue that this follows as a general rule also from the requirement for prima facie evidence for an "*infringement* of the right holder's intellectual property right." ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(1) (emphasis added).

goods in transit.[168] On this question, the European Court of Justice ("ECJ") has previously held that trademark ownership in the country of transit did not justify interference with the transit procedure unless the "goods are subject to the act of a third party while they are placed under the external transit procedure which necessarily entails their being put on the market in the Member State of transit."[169] The ECJ also clarified that the risk of deviance to the transit market must be manifest, stating specifically that the possibility that "they could theoretically be marketed fraudulently" is insufficient to support the trademark owner's application under the BMR.[170] In sum, the right-holder must offer concrete evidence for a substantiated threat of trade diversion in order to show the infringement of trademarks in the transit country (which in turn triggers the application of border measures).[171]

Other ACTA parties, however, may certainly take a different position here. Often the substantive scope of protection will vary according to type of IP right in question: while a country may demand a concrete threat of trade diversion for trademark infringement, it may consider any form of transit sufficient for the infringement of other IP rights, or may not view any transiting goods as potentially infringing in other cases. For generic drugs in transit, the availability of potential remedies, such as seizure and destruction of goods under ACTA,[172] depends on whether, and under what conditions, the domestic IP law of the country providing the border measures considers transits as potentially infringing. On one hand, this seems to reduce the risk for border measure remedies against transiting generics as patent or trademark infringing goods since few countries are likely to apply such a broad notion of protection for an

168. Case C-495/09, Nokia Corp. v. HM Comm'rs of Revenue & Customs, 2010 O.J. (C 37) 22, 22; Nokia Corp. v. HM Comm'rs of Revenue & Customs, [2009] EWHC (Ch) 1903 (Eng.).

169. Case C-281/05, Montex Holdings Ltd v. Diesel SpA, 2006 E.C.R. I-10897, ¶ 23. The ECJ made similar judgments in other cases. *See*, *e.g.*, Case C-405/03, Class Int'l BV v. Colgate-Palmolive Co., 2005 E.C.R. I-8761, ¶ 50; Case C-383/98, Polo/Lauren Co. v. PT. Dwidua Langgeng Pratama Int'l Freight Forwarders, 2000 E.C.R. I-2531, ¶ 34.

170. *Montex Holdings Ltd*, 2006 E.C.R. ¶ 24.

171. For a detailed discussion of the ECJ's case law in the context of E.U. seizures of generics in transit, see Grosse Ruse - Khan & Jaeger, *supra* note 48, at 510-19.

172. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 20.

IP right to transit cases that lack any real link to their territory. On the other hand, under ACTA, authorities in the transit country may detain generics merely "suspected" of infringing domestic IP rights until a court decision on that question has been issued.[173] This is because ACTA allows right holders to request the suspension of goods if they can provide prima facie evidence of infringements of their rights.[174] Until customs have clarified whether an alleged threat of trade diversion really exists, goods are unlikely to be released.[175] Moreover, if the right-holder and the owner of the goods dispute the facts underlying the case for trade diversion, the goods may not be released until the matter has been resolved in a court.[176] The E.U. and Dutch seizures demonstrate the likelihood of such scenarios arising. Even if goods are released after a certain period of time, this temporary detention poses a significant obstacle to free transit and the international trade in generic medicines. This result further introduces great legal insecurity and uncertainty for traders and users of generic medicines. In sum, ACTA Article 3(2) does not provide sufficient safeguards against seizures of generics in transit.

C. ACTA SAFEGUARDS FOR PUBLIC HEALTH AND AGAINST TRADE BARRIERS

Sections III(A) and (B) above have analyzed the potential threat that the ACTA border measures pose for international trade for generics in transit in particular. While negotiators have taken some important steps to address the matter, the December 2010 ACTA text still seems to allow seizures of goods in transit suspected of "ordinary" trademark infringement in the transit country. This section now examines the efficacy of relevant safeguards incorporated into the December 2010 ACTA text. Do the mandated border measures prevent trade barriers and protect public health

173. *See id.* arts. 16, 19. Article 19 specifies that this determination must be made within a "reasonable period." Earlier drafts contained specific maximum periods for initial detentions until determination of infringement. *See, e.g.*, ACTA Draft—July 1, 2010, *supra* note 58, art. 2.6, ¶ 3 (showing that the negotiating parties favored a maximum detention period of one year, with the exception of Singapore, who favored a maximum period of sixty days).

174. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(1).

175. Note, however, that detained goods may be released against posting of a bond or other security. *Id.* art. 18.

176. *Id.* art. 19.

concerns? In particular, do the safeguards prevent seizures of generics in transit from (re-)occurring?

1. Interpretation Based on TRIPS Articles 7 and 8

The July draft text of ACTA offers opportunities for a public interest focused interpretation of the ACTA treaty terms.[177] Initially, the text of Article 1.X was a verbatim copy of Articles 7 and 8 of the TRIPS Agreement, provisions that have been identified as key TRIPS flexibilities affecting the interpretation and implementation of all TRIPS provisions.[178] Then, in the August 2010 ACTA draft, the newly inserted preamble contained a verbatim copy of the TRIPS text in brackets and also provided that the contracting parties are "[d]etermined to implement this Agreement in a manner consistent with the objectives and principles set out in the TRIPS Agreement ."[179]

Now, the final December 2010 ACTA text provides: "The objectives and principles set forth in Part I of the TRIPS Agreement, in particular in Articles 7 and 8 shall apply, *mutatis mutandis*, to this Agreement."[180] In addition, in the relevant part of the December 2010 text of the ACTA preamble the negotiating parties agree to ACTA:

177. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 1.X (text proposed by Australia, New Zealand, Singapore, and Canada) (stating that IP rights should be enforced in a manner consistent with "the promotion of technological innovation," and that parties may "adopt measures necessary to protect public health and nutrition" and other sectors in the public interest). *But see id.* art. 1.X, ¶ 3 (revealing that Japan, Mexico, South Korea, and the United States requested the deletion of language regarding the abuse of IP rights while the E.U. wished to incorporate the principles of the provision into the ACTA preamble).

178. *See generally* Henning Grosse Ruse - Khan, *Proportionality and Balancing Within the Objectives for Intellectual Property Protection*, *in* 18 INTELLECTUAL PROPERTY AND HUMAN RIGHTS 161, 185 (Paul L.C. Torremans ed., 2008) (noting that "one of the TRIPS flexibilities is the right of individual WTO Members to interpret TRIPS in light of its purpose" as expressed in Articles 7 and 8); Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979, 1018-46 (2009) (discussing the ways in which Articles 7 and 8 guide interpretation of the TRIPS Agreement, can also be used to challenge the aggressive expansion and enforcement of IP rights, and spark development of new international IP norms).

179. ACTA Draft—Aug. 25, 2010, *supra* note 59, pmbl.

180. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 2(3).

> *Recognizing* the principles set out in the Doha Declaration on the TRIPS Agreement and Public Health, adopted on November 14, 2001, by the WTO at the Fourth WTO Ministerial Conference, held in Doha, Qatar;[181]

The TRIPS provisions incorporated in ACTA state:

> Article 7 Objectives
> 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 Principles
> 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.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.[182]

Against the background of their interpretative role,[183] the question arises whether the incorporation of these provisions by reference can have the same impact on ACTA treaty interpretation. One way to shed light on this question is by analyzing an ACTA provision that, if interpreted widely, may be pertinent in the context of transit seizures. In relevant part, Article 18 states that "a Party may, only in *exceptional circumstances* or pursuant to a judicial order, permit a defendant to post a bond or other security to obtain possession of suspect goods."[184] The question then is what would constitute

181. *Id.* pmbl.

182. TRIPS Agreement arts. 7-8.

183. For a general discussion on the role of Article 7 and 8 in TRIPS, see Henning Grosse Ruse - Khan, *A Comparative Analysis of Policy Space in WTO Law* 2 (Max Planck Inst. for Intellectual Prop., Competition & Tax Law Research Paper Series, Paper No. 08-02, 2008), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1309526.

184. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 18 (emphasis added). The provision stems from a bracketed footnote in an earlier draft stating that "where the competent authorities suspend the release of suspected counterfeit trademark or

"exceptional circumstances?" Could this provision function as a public health safeguard that allows the release of generics in transit against posting of a security, for example, if the traders or recipients of the medicines can make a case for a good faith public health use of the drugs?

On one hand, in the likely event that the term "exceptional circumstances" is interpreted narrowly, this would only allow for a marginal scope of application in general. On the other hand, an interpretation based on TRIPS Articles 7 and 8 may lead to different results. Therefore, the central question hence is whether the incorporation of these TRIPS provisions can perform a similar interpretative function in ACTA. In that case, any open and ambiguous terms in ACTA, including "exceptional circumstances," would have to be interpreted in light of the balancing objectives and public interest principles expressed in the TRIPS provisions. Such an interpretation then can assume the existence of exceptional circumstances whenever public health and access to medicines concerns speak for the release of goods in transit, even if they are IP infringing in the transit country.[185]

As mentioned above, ACTA's negotiating parties recognized the principles set out in the Doha Declaration on TRIPS and Public Health in the preamble to the December draft,[186] which provides a strong argument that these principles should control interpretation of ACTA provisions. The Doha Declaration indicates that TRIPS

pirated copyright goods, the authorities shall not permit the goods to be released into free circulation, exported, or subject to other customs procedures, except in exceptional circumstances." ACTA Draft—Apr. 21, 2010, *supra* note 57, n.24. The July ACTA text reveals that United States and Japan were the main supporters of this provision. ACTA Draft—July 1, 2010, *supra* note 58, n.19. In the ACTA draft that leaked after the Washington, D.C. round of negotiations, the language was moved to the provision dealing with remedies. ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 2.11. The next iteration of the provision appeared in what would be close to its final form. ACTA Draft—Oct. 2, 2010, *supra* note 60, art. 2.9.

185. A similar result may be obtained by a public health motivated interpretation of the term "due cause." ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(4). That provision concerns certain options to deny right holder applications for seizures of allegedly infringing goods and states "a Party may provide that, where the applicant has abused the process, or where there is *due cause*, its competent authorities have the authority to deny, suspend, or void an application." *Id.* (emphasis added).

186. *See id.* pmbl.

should be interpreted and implemented "in a manner supportive of WTO members' right to protect public health."[187] WTO members recognized that the expressed "objectives and principles" guide interpretation of the Agreement, in accordance with "customary rules of interpretation of public international law."[188] The recognition of these principles of treaty interpretation in ACTA, therefore, indicates that the drafters intended to give TRIPS Articles 7 and 8 the same interpretative weight as WTO members agreed to in the Doha Declaration.

Further support for such a result comes from the customary rules of treaty interpretation in international law. Under the general rules of treaty interpretation embodied in the Vienna Convention on the Law of Treaties ("VCLT"), a treaty's object and purpose is one main element for understanding its provisions.[189] ACTA does not contain a provision explicitly entitled "Objectives;" therefore, ACTA's object and purpose is arguably defined through ACTA's incorporation of TRIPS Articles 7 and 8. In other words, the balancing objectives and public interest principles embodied in Articles 7 and 8 function as the main objectives of ACTA, which strongly support a broad interpretation of the term "exceptional circumstances" oriented towards public health.

Another aspect of the principles on treaty interpretation offers additional arguments for taking public health perspectives into account. The VCLT provides that treaty interpretation may also be guided by any relevant international law that applies to the parties.[190] This could be a basis for taking access to medicine considerations into account, flowing from the right to health as embodied in the

187. Doha Declaration, *supra* note 43, ¶ 4.

188. *Id.* ¶ 5(a).

189. Vienna Convention on the Law of Treaties art. 31(3), May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT]; *see also* Henning Grosse Ruse - Khan, *A Real Partnership for Development? Sustainable Development as Treaty Objective in European Economic Partnership Agreements and Beyond*, 13 J. INT'L ECON. L. 139, 163-66 (2010) (explaining the role of "object and purpose" when interpreting treaties in international economic law).

190. VCLT, *supra* note 189, art. 31(3)(c); *see also* Campbell McLachlan, *The Principle of Systemic Integration and Article 31(3)(C) of the Vienna Convention*, 54 INT'L & COMP. L.Q. 279, 280 (2005) (proposing that Article 31(3)(c) expresses a value of "systemic integration" in international law).

International Covenant on Economic, Social and Cultural Rights.[191] Such an "integrative" interpretation, however, should be seen as a safeguard of last resort.[192] Here, the incorporation of Articles 7 and 8 of the TRIPS Agreement offer sufficient means to take public health considerations into account when interpreting open and ambiguous ACTA terms such as "exceptional circumstances."[193]

The example therefore proves the point that the same balancing objectives and public interest principles which guide treaty interpretation in relation to the TRIPS Agreement apply in the ACTA context. At the same time, treaty interpretation is equally affected by the ordinary meaning and the context of the treaty provision at issue.[194] While TRIPS Articles 7 and 8 play a role, for most of the concrete ACTA obligations with concise treaty language, the ordinary meaning of the terms in their context will be the starting point and primary elements for interpretation.[195] Still, there are other provisions not discussed here which contain open and ambiguous treaty terms such as "legitimate trade" and "proportionality."[196] The interpretation of those provisions, like "exceptional circumstances,"

191. International Covenant on Economic, Social and Cultural Rights art. 12, Jan. 3, 1976, 993 U.N.T.S. 3.

192. *See* Henning Grosse Ruse - Khan, *Policy Space for Domestic Public Interest Measures Under TRIPS* (South Centre Research Paper No. 22, 2009), *available at* http://www.southcentre.org/index.php?option=com_content&view=article&id=1039%3Apolicy-space-for-domestic-public-interest-measures-under-trips&Itemid=248&lang=en (explaining the integrative approach as it applies to TRIPS and the Doha Declaration).

193. Nevertheless, the exceptional character of the release option in Article 18 limits its potential role in the context of transiting generics. Traders and recipients of generics would depend on the willingness of customs and courts to rely on this exception. Contracting parties might also take different positions here so that, again, security and predictability in international trade with generics suffers. In sum, even if this exception is applied in the context of transiting generics, it is unlikely to provide a solution that serves as comprehensive safeguard against seizures such as those by Dutch authorities.

194. *See* VCLT, *supra* note 189, art. 31(1); *see generally* Grosse Ruse - Khan, *supra* note 178, at 162-81 (applying VCLT rules of treaty interpretation to TRIPS Articles 7 and 8)

195. *See, e.g.*, Rep. of the Int'l Law Comm'n, 17th Sess., U.N. Doc. A/CN.4/189, *reprinted in* 1966 Y.B. INT'L L. COMM'N 169, 220, 221 [hereinafter Int'l Law Comm'n Rep] (stressing a "textual approach" where the "starting point of interpretation is the elucidation of the meaning of the text, not an investigation *ab initio* into the intentions of the parties").

196. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(1), (3).

will be ripe for guidance from ACTA's object and purpose, which is arguably embodied in TRIPS Articles 7 and 8.

2. Obligation to Avoid the Creation of Barriers to Legitimate Trade

Since the July 2010 draft, the ACTA text contains a new provision that may function as an additional safeguard against the use of IP enforcement procedures as barriers to trade and against abusive reliance on such procedures.[197] In the final December 2010 ACTA version, the relevant text provides:

> ARTICLE 6: GENERAL OBLIGATIONS WITH RESPECT TO ENFORCEMENT
> 1. Each Party shall ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.[198]

As indicated above, the new provision is a verbatim copy of TRIPS Article 41(1).[199] The second sentence builds on similar language in ACTA's preamble,[200] and in Article 13.[201] The provision

197. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X, ¶ 1 (General Obligations with Respect to Enforcement). In the July ACTA text, the whole provision, which stemmed from a U.S. proposal, is still in brackets. *See id.* n.8. The ACTA draft that leaked after the subsequent Washington, D.C. round of negotiations, however, does not contain any brackets or other indications of dissent amongst the negotiating parties. *See* ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 2.X, ¶ 1 (General Obligations with Respect to Enforcement). While there have been changes in the other paragraphs of the provision on General Obligations, this text remained the same in the subsequent October draft. ACTA Draft—Oct. 2, 2010, *supra* note 60, art. 2.X, ¶ 1.

198. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6.

199. *See* discussion *supra* Part III(A)(1)-(2).

200. *Compare* ACTA Text—Dec. 3, 2010, *supra* note 60, pmbl. ("*Desiring* to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."), *with* TRIPS Agreement pmbl. ("*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.").

201. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13 ("In providing for effective border enforcement of intellectual property rights, a Party should do so in

contains a binding obligation, horizontally applicable to all enforcement measures under ACTA. It can be particularly relevant for border measures under ACTA and their potential to mandate seizures of generic medicines and other goods in transit in light of the language "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."[202] Since this provision contains a binding prohibition against applying enforcement procedures as to create barriers to legitimate trade, it is not surprising that India and Brazil claim that the E.U. transit seizures violate the TRIPS Article 41(1) version of this provision.[203]

In order to assess the operation of the new Article 6(1) of ACTA in relation to the ACTA provisions which may mandate or allow transit seizures, the decisive question is when the detention and seizure of goods in transit amounts to "barriers to legitimate trade." Such detentions and seizures arguably create barriers to international trade by temporarily preventing the free movement of goods in transit via detention in the transit country, and, when goods are permanently seized and subsequently destroyed, by inhibiting the free movement of goods from the country of origin towards the country of destination. Under WTO law, the principle of freedom of transit stipulates that "[t]here shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties."[204] A contextual interpretation of the term "barriers to legitimate trade" in TRIPS Article 41(1) thus arguably includes measures that inhibit the international transit of goods as a central element to global trade. ACTA Article 6(1) is a verbatim copy of this TRIPS provision and should be interpreted identically given that all ACTA negotiating parties are WTO members, and that, presumably, the negotiating parties want to introduce provisions consistent with WTO law, especially the TRIPS Agreement.[205]

a manner that avoids the creation of barriers to legitimate trade."); *see also* discussion *supra* Part III(A)(4) (analyzing the elements of Article 13).

202. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(1). *But see id.* art. 13 (providing that ACTA parties "should," rather than "shall," enforce border measures in a manner that "avoids the creation of barriers to legitimate trade").

203. *See supra* Part II.

204. GATT art. 5(2).

205. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 1 (emphasizing that

Whereas detentions and seizures of goods in transit are creating barriers to international trade, difficulties arise especially in relation to the interpretation of the term "legitimate trade." For example, how does one determine the legitimacy of the trade inhibited or prevented by the operation of IP enforcement procedures—in this case border measures against goods in transit? In order to address this question it is useful to first look at the understanding of the identical term in TRIPS Article 41(1).

In the WTO/TRIPS context, so far no Panel or Appellate Body report has addressed the interpretation of the relevant part of TRIPS Article 41(1).[206] However, the term "legitimate" as part of the phrase "legitimate interests"[207] has been interpreted by a WTO Panel. In *Canada-Pharmaceutical Products*, a WTO Panel defined "legitimate" 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."[208] Determining legitimacy therefore requires a normative assessment of the relevant action, conduct, or measure based on justifiable public interests and policies. Such a normative approach finds support in the literature, which views TRIPS Article 41(1) as an expression of the need for balancing the interest of title-holders, alleged infringers, and the public interest.[209]

Based on this reasoning, "legitimate trade" under TRIPS Article 41(1) means any trade for which a justifiable public policy or interest exists or which is supported by other social norms. Thus, trade in generic drugs is legitimate because of the public policy of promoting cheaper access to medicines and the interest in promoting public

ACTA respects obligations under existing agreements, "including the TRIPS Agreement").

206. *See generally WTO Analytical Index: TRIPS*, WORLD TRADE ORG., http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_e.htm#article41 (last visited Mar. 1, 2011).

207. *See* TRIPS Agreement art. 30 ("Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the *legitimate* interests of the patent owner, taking account of the legitimate interests of third parties.") (emphasis added).

208. Panel Report, *Canada Patent Protections of Pharmaceutical Products*, ¶ 7.69, WT/DS114/R (Mar. 17, 2000) [hereinafter Canada Panel Report].

209. *See, e.g.*, ICTSD & UNCTAD, *supra* note 38, at 581.

health. In comparison, trade in fake drugs, which contain the wrong dosage of active ingredients, is not legitimate because no interest is served in promoting access to ineffective or dangerous drugs. Under such a normative assessment, the barriers to trade created by seizing and detaining generic drugs in transit are arguably barriers to legitimate trade and thus inconsistent with TRIPS Article 41(1).

In addition to the normative approach, legitimacy can also be understood in a positivist sense to mean anything authorized by law.[210] Under such a legalistic approach, any trade which is in conformity with the law is legitimate trade. Determining legality is the obvious problem with this approach, in particular, which body of law should control.[211] For the interpretation of "legitimate" in TRIPS Article 41(1), WTO law is the primary source of guidance, including the substantive standards of IP protection in the TRIPS Agreement. The international obligations in TRIPS, however, would not provide a sufficient answer since internationally traded goods may be infringing the TRIPS-mandated IP protection in one WTO Member country but not in another. Based on the concept of territoriality, these goods may be non-infringing in the country of origin and destination, but maybe infringing in the country of transit. It is precisely this scenario that led to the current dispute over transit seizures between the European Union, India, and Brazil. The territorial nature of IP rights (and hence of IP legality) is what makes such a determination of legitimacy inconclusive and somewhat meaningless. Since ACTA does not affect the fundamental territorial nature of IP rights, a positivist understanding of the term legitimacy in Article 6(1) is equally unavailing.

The above arguments speak for a normative, rather than positivist, understanding of "legitimate trade" under ACTA Article 6(1). Thus,

210. Canada Panel Report, *supra* note 208, ¶ 7.68 (noting the ordinary meaning of the term is "conformable to, sanctioned or authorized by, law or principle" or "[n]ormal, regular, conformable to a recognized type");. *see also* Panel Report, *United States Section 110(5) of the US Copyright Act*, ¶ 6.224, WT/DS160/R (June 15, 2000) (recognizing a positivist definition of legitimacy).

211. One option is that international rules, notably international trade and IP treaty rules, determine legality. Another option is that domestic law determines legality. The latter approach raises a second question: which domestic law? Applying the laws of the countries of origin, transit, and destination may produce variable results. *See infra* Part III(B)(1) (discussing applicable law in IP border enforcement cases in light of the principle of territoriality).

any enforcement procedures that create barriers to trade for which a justifiable public policy exists or which are supported by other social norms would be considered as "barriers to legitimate trade." The only question remaining is what type of public policy or social norms are relevant? Although ACTA does not contain a comprehensive set of normative values which could guide the understanding of legitimacy, the reference to TRIPS Articles 7 and 8 as discussed above indicate that, inter alia, public health concerns must be taken into account in the interpretation of ACTA provisions.[212] This finds further support in the preamble to ACTA, which references "the principles set out in the Doha Declaration on the TRIPS Agreement and Public Health."[213] This confirms that public health concerns are relevant social norms in determining the legitimacy of trade under a normative framework.

A more difficult question is which normative considerations and public policies are decisive, those of the country of production, the country of transit, or the country of final destination? Here, the specific free trade rationale of Article 6(1) comes into play.[214] If safeguarding free trade is indeed the rationale for Article 6(1), then requiring *cumulative* normative legitimacy based on the public interests and social norms in *all* countries involved is too narrow of an approach. To explain, there may be instances where trade would not be considered legitimate simply because one country does not recognize the normative considerations held by others. This would be problematic if the non-recognizing country is one which has minimal

212. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 2(3) ("The objectives and principles set forth in Part I of the TRIPS Agreement, in particular in Articles 7 and 8 shall apply, *mutatis mutandis*, to this Agreement."); *see also* discussion *supra* Part III(C)(1) (arguing that Articles 7 and 8 of the TRIPS Agreement supply the object and purpose of ACTA by reference).

213. ACTA Text—Dec. 3, 2010, *supra* note 60, pmbl. Under the Doha Declaration, *supra* note 43, ¶ 5 (a), the importance of the object and purpose of a treaty, as embodied in TRIPS Agreement arts. 7-8, is highlighted as a principle of treaty interpretation which guides the understanding of all TRIPS provisions. Recognizing this principle in ACTA means that Article 7 and 8 TRIPS—incorporated into ACTA by reference in Article 2(3)—equally guide the interpretation of all ACTA provisions. For further details, see discussion *supra* Part III(A)(1).

214. This is supported by the preamble to ACTA which also expresses the intention of the negotiating parties to avoid the creation of trade barriers. ACTA Text—Dec. 3, 2010, *supra* note 60, pmbl.

territorial link to the goods traded. In light of the international and cross-border nature of trade, justifiable public interests and social norms may originate from *any* country directly affected by the trade and would certainly include the country of origin and the country of destination. Whether the public policy concerns of the country of transit are equally relevant, however, should depend on whether the traded goods have a substantial connection to the transit country.[215] This would mean that seizures of goods in transit amount to the creation of barriers to legitimate trade whenever the trade in these goods can be justified primarily by a public policy in the country of origin or the country of destination.

Such a result, however, must be examined for consistency with the specific border measure provisions in ACTA. In order to achieve an overall coherent interpretation, the understanding of different provisions within the same agreement cannot conflict.[216] In other words, the operation of the prohibition to create barriers to legitimate trade cannot be understood in a way which prohibits border measures against goods in transit that ACTA explicitly allows or even mandates. If ACTA would have included a binding obligation to introduce border measures against IP infringing goods in transit, there would be little room left for arguing that national seizures of allegedly patent infringing generics in transit per se violate the free trade safeguard in Article 6(1). Since the border measure obligations in the final December 2010 ACTA text exclude patents; since they allow but do not mandate enforcement against goods in transit; and since they further can be limited to certain types of IP infringements under Article 13 on the scope of border measures (such as trademark

215. Similar to questions of the applicable law in private international law, a substantial connection test could ask whether, for example, the threat of trade diversion onto the domestic market or other factors establish a sufficient connection to the territory of the transit country which justifies the application of that country's normative values to affect the determination of "legitimate trade." For a similar argument that generics in transit constitute legitimate trade when there is no threat of diversion onto the domestic market of the transit country, see also Kumar, *supra* note 26, at 513.

216. This follows from the principle of good faith in treaty interpretation (as embodied in the VCLT, *supra* note 189, art. 31 (1)) which is, inter alia, an expression of the principle of *pacta sunt servanda* that in turn embodies the principle of effectiveness. *See* Int'l Law Comm'n Rep., *supra* note 195, at 221; IAN SINCLAIR, THE VIENNA CONVENTION ON THE LAW OF TREATIES 119-120 (2d ed. 1984).

counterfeiting and copyright piracy),[217] there is more room for applying Article 6(1). As discussed above, the right to introduce additional enforcement measures is limited by contravening ACTA provisions.[218] Thus, the prohibition to create barriers to legitimate trade can still function to limit "ACTA-plus" border measures. Not even the explicit allowance to extend border measures to goods in transit is immune from this general obligation in Article 6(1). If an ACTA party decides to make use of this allowance, it must still ensure that it is doing so in a way which does not create trade barriers.[219]

If this insight is applied to the understanding of "legitimate trade" advocated here, ACTA Article 6(1) will prohibit seizures of goods in transit as a barrier to legitimate trade whenever the trade in these goods can be justified by a public policy in the country of origin or the country of destination. Since the transit and trade in generic drugs will almost always be justified by public health concerns in the country of destination, any ACTA contracting party must ensure that its system of border measures does not create barriers to such trade. The best option for doing so is to exclude transit from the scope of the domestic border IP enforcement system altogether. If, however, a country chooses to extend border measures to transits, it must comply with Article 6(1) and ensure that the free transit of generics is not affected. This can be done by addressing the main threat to generics in transit, namely by eliminating border measures against ordinary forms of trademark infringements.[220] Other mechanisms may also be an option—such as the applicable law approach in the Swiss border measure system, which requires that goods in transit infringe both Swiss IP law and the law of the country of destination.[221]

217. *See* discussion *supra* Part III(A)(1)-(4).

218. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 2(1); *see also* discussion *supra* Part III(A)(2).

219. *Cf.* discussion *supra* Part III(A)(2).

220. *See* discussion *supra* Part III(A)(3).

221. For a general explanation on the Swiss approach to border enforcement, see *Ab 1. Juli 2008 in der Schweiz mit neuer rechtlicher Grundlage gegan Fälschung und Piraterie*, STAATSSEKRETARIAT FÜR WIRTSCHAFT SECO (July 1, 2008), https://www.ige.ch/index.php?eID=tx_cabaghtml2pdf&URL=/juristische-infos/rechtsgebiete/faelschung-und-piraterie/rechtslage-ab-1-juli-2008.html%3Fpdf%3D1&page_uid=362.

An alternative to border measures against goods in transit is enforcement in the country of destination. The December 2010 ACTA text is devoid of this alternative, though earlier ACTA drafts contained a provision to this effect.[222] While alternative enforcement in the country of destination would seem to address the problem of seizures in the transit country, the operation of such a provision would have a rather limited effect because it would apply only in cases where exports or transits are destined to another ACTA party.[223] Further, it remains doubtful that any provision similar to the proposed Article 2.X offers enforcement in the country of destination as a reliable alternative. Instead, the proposal seemed to refer only to situations where an ACTA party requests such information in a specific instance of transit or export.[224] It therefore does not allow generally excluding right holder applications or *ex officio* measures *a priori* for cases of exportation and transit. Nevertheless, the general idea of enforcement in the country of final destination as an alternative to border measures against goods in transit may be another option to pursue further.[225] It certainly would not have

222. One draft stated:

> [As an alternative to procedures in Article 2.6.1 and 2.7.1 relating to export or in-transit shipments, each Party shall provide that where shipments are exported from that Party, or shipments are in-transit through that Party, it shall cooperate to provide all available information to the destination Party, upon request of the destination Party, to enable effective enforcement against shipments of infringing goods.]

ACTA Draft—Apr. 21, 2010, *supra* note 57, art. 2.X (preceding art. 2.9). In the subsequent July and August ACTA drafts, the provision appeared in slightly modified forms and was supported only by Australia, New Zealand, and Canada. *See* ACTA Draft—July 1, 2010, *supra* note 58, art. 2.X (preceding art. 2.9); ACTA Draft—Aug. 25, 2010, *supra* note 59, art. 2.X (preceding article 2.9).

223. Given that in most seizure cases the transiting generics were destined for developing countries, which are not currently negotiating parties of ACTA and are unlikely to accede to ACTA in the foreseeable future, enforcement in these destination countries would not be an option under the draft Article 2.X.

224. Alternatively, the proposed Article 2.X may be understood that in cases of exports and transits, countries are allowed to waive obligations under Articles 2.6.1 and 2.7.1 (now Article 16) if they "provide all available information to the destination Party, upon request of the destination Party, to enable effective enforcement against shipments of infringing goods." But such a reading hinges on a wide interpretation of "as an alternative to procedures in Articles 2.6.1 and 2.7.1." *Id.*

225. For this to be a viable alternative to border measures for goods in transit, options for communication and cooperation between the relevant authorities in transit and destination country must be improved, especially in relation to goods

equivalent potential to create barriers to legitimate trade.

In sum, ACTA Article 6(1) prohibits ACTA parties from applying their border measures in a way that creates barriers to the trade in generics. Especially when these countries go beyond ACTA to extend border measures to goods in transit, they are under an international obligation to ensure that their domestic border enforcement systems allow the free transit of generics. In addition, other ACTA provisions, such as those on civil enforcement regarding injunctive relief and damages, must be implemented in a way that does not affect legitimate trade in generics.[226] Article 6(1) therefore functions as a horizontal safeguard against trade barriers and IP enforcement abuse.

IV. ACTA VERSUS PUBLIC HEALTH AND FREE TRADE SAFEGUARDS UNDER TRIPS

In a joint statement shortly before the first public release of the ACTA draft in April 2010, the negotiating parties declared: "ACTA will not interfere with a signatory's ability to respect its citizens' fundamental rights and liberties, and will be consistent with the TRIPS Agreement and will respect the Declaration on TRIPS and Public Health."[227] As mentioned above, a subsequent press release after the Lucerne round of negotiations in July 2010 went further, asserting that "ACTA will not hinder the cross-border transit of legitimate generic medicines," and assuring that "patents will not be covered in the Section on Border Measures."[228]

This analysis, however, calls into question the consistency of certain ACTA provisions with the TRIPS Agreement. As Part III demonstrates, the most recent ACTA text still allows seizures of

which the transit country considers as being IP infringing on their face.

226. In this manner, ACTA Article 6(1) can also be applied to address concerns over the impact other IP enforcement obligations, such as those concerning injunctions, may have on the transit of generic medicines. For an overview of other concerns related to ACTA, see *Concerns raised over ACTA at TRIPS Council*, THIRD WORLD NETWORK (Nov. 1, 2010), http://www.twnside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.101102.htm.

227. Press Release, Eur. Comm'n, Joint Statement on Anti-Counterfeiting Trade Agreement (ACTA) (Apr. 16, 2010), http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/437.

228. Press Release, Eur. Comm'n, *supra* note 63.

generics in transit based on alleged patent or trademark infringements in the transit country. And in some instances, the ACTA rules only allow the release of generics after a considerable period of detention.[229] In other cases, ACTA mandates their destruction.[230] While some ACTA provisions, in particular the general obligation under Article 6(1), can be applied to limit the negative impact of ACTA rules to transiting generics, no provision explicitly prohibits transit seizures. Instead, Article 6(1)'s function to safeguard trade in generics hinges on the correct interpretation of ambiguous and open treaty terms like "legitimate trade."[231]

Part II pointed to several TRIPS provisions that may constrain the ability of WTO members to extend border measures to allegedly patent infringing goods in transit. In their consultation requests, India and Brazil also relied on TRIPS provisions, which they argue are infringed by the Dutch transit seizures. They are thereby invoking TRIPS as an agreement that contains a ceiling on the introduction of additional IP protection measures.[232] As a benchmark constraining additional protection beyond TRIPS under certain conditions, TRIPS may also affect the ability of WTO Members, under international law, to negotiate obligations for such additional protection in ACTA provisions.[233] This section looks at the potential for TRIPS to legally constrain the TRIPS-plus options under ACTA. The section focuses on certain ACTA provisions that have the potential to conflict with TRIPS, and on the general international law parameters that may be invoked to resolve any conflicts between TRIPS and ACTA.

229. The goods suspected of IP infringement will in principle be released only once a court or other relevant authority has decided on the infringing character of the goods. *See* ACTA Draft Text—Dec. 3, 2010, *supra* note 60, art. 19.

230. Once goods are found to IP infringing, the principle remedy is the destruction or disposal outside the channels of commerce. *See id.* art. 20(1).

231. *See* discussion *supra* Part III(C)(2).

232. *See* India Consultation Request, *supra* note 2; Brazil Consultation Request, *supra* note 16.

233. In a response to Members of the European Parliament demanding a WTO inquiry into ACTA, the WTO Director General Pascal Lamy noted that while TRIPS does not preclude its members from introducing additional measures to protect IP rights, as the negotiating parties to ACTA are doing, such protection cannot contravene TRIPS provisions. *See* Letter from Pascal Lamy, Dir.-Gen., World Trade Org., to EU Parliament Members (May 4, 2010), *available at* http://keionline.org/sites/default/files/WTO-Lamy_Answer-to-MEP-letter.pdf.

A. THE CONFLICT POTENTIAL BETWEEN TRIPS AND ACTA

The tension, if not direct conflict, between TRIPS and TRIPS-plus free trade agreements ("FTAs") as well as ACTA are evident in the perceptions of WTO Members. For example, the Indian and Chinese delegates expressed such concerns in the TRIPS Council Meeting on June 8-9, 2010.[234] On the relation between TRIPS and TRIPS-plus FTAs such as ACTA the Indian delegate stated:

> Although TRIPS Agreement is usually considered to be a minimum levels agreement, enforcement levels cannot be raised to the extent that they contravene TRIPS Agreement. TRIPS plus measures cannot be justified on the basis of Art 1:1 since the same provision also states that more extensive protection may only be granted "provided that such protection does not contravene the provisions of this Agreement". In addition to laying certain minimum standards, TRIPS Agreement also provides 'ceilings', some of which are mandatory and clearly specified in the TRIPS Agreement.[235]

The delegate further emphasized the potential effects of the additional enforcement obligations in ACTA on the TRIPS Agreement: "In view of the recent seizures of generic drug consignments, [ACTA] provisions relating to 'in-transit' in all likelihood would create barriers to access to essential generic medicines, as well as access to critical climate change technologies."[236]

Similarly, the Chinese delegate stressed that while TRIPS generally establishes "only minimum standards of IP protection," it also constrains the ability of WTO Members to foresee more extensive protection by requiring, inter alia, that "such protection shall not contravene the provisions of this agreement."[237] These views were shared by delegates from Peru, South Africa, Egypt, Bolivia, Ecuador, and other developing countries.[238] At the subsequent TRIPS Council Meeting, China threatened to pursue

234. ICTSD, *Animated TRIPS Council Meeting Tackles Public Health, ACTA, Biodiversity*, 14 BRIDGES WKLY. TRADE NEWS DIG., June 16, 2010, *available at* http://ictsd.org/i/news/bridgesweekly/78201/.

235. TRIPS-plus Enforcement India, *supra* note 37.

236. *Id.*

237. TRIPS-plus Enforcement China, *supra* note 37 (quoting Article 1(1) of TRIPS).

238. ICTSD, *supra* note 234.

dispute settlement in the WTO as a result of "any negative spill-over effects" from ACTA.[239] China argued that ACTA should be evaluated to determine whether it is consistent and compatible with the existing WTO legal framework, whether it impinges on the rights of WTO members, and whether it creates additional obligations for WTO members.[240]

Given many countries' concerns about conflicts between TRIPS and subsequent TRIPS-plus FTAs, the conflict potential between TRIPS and ACTA, in relation to border measures against goods in transit, must be critically assessed. Specifically, a potential conflict exists between TRIPS provisions that integrate public health concerns and free trade aspects and ACTA rules allowing seizures of transiting generics. As discussed in Part II, examples of TRIPS provisions that such seizures may violate include Articles 41(1) and 52.[241] Other norms may also be relevant, especially from the border measures section which contains binding safeguards for the interests of traders.[242] Any meaningful analysis here depends on the exact wording of the final ACTA provisions and their application to transiting generics. While such a scrutiny was premature in relation to the earlier, still heavily bracketed ACTA drafts, the December 2010 ACTA text contains the outcome of the final round of negotiations. The following thus offers an overview of ACTA provisions potentially conflicting with TRIPS, and sets out some guidelines for understanding the relevant ACTA and TRIPS provisions in a mutually consistent manner. In order to frame the discussion on what constitutes a conflict between TRIPS and ACTA, the subsections briefly survey the instances in which ACTA border measures extend beyond TRIPS standards.[243]

239. *See China Slams Nearly Completed ACTA, Questions its WTO Compatibility*, INSIDE U.S. TRADE, Nov. 2, 2010, http://insidetrade.com/201011022343572/WTO-Daily-News/Daily-News/china-slams-nearly-completed-acta-questions-its-wto-compatibility/menu-id-173.html.

240. *Id.*

241. Recall that, under TRIPS, additional IP protection may not contravene TRIPS provisions. *See* TRIPS Agreement art. 1(1).

242. *Id.* arts. 53.1, 2; 55; 56, 58(b). For an in-depth analysis of these sections, *see also* Grosse Ruse - Khan & Jaeger, *supra* note 48.

243. ACTA may directly conflict with TRIPS so that compliance with both agreements is impossible, or ACTA provisions may indirectly undermine the exercise of a right under TRIPS, such as a TRIPS flexibility. *See* discussion *infra* Part IV(B).

1. Scope of Border Measures

While TRIPS requires border measures only against the importation of counterfeit trademark goods or pirated copyright goods,[244] in principle, future ACTA parties must provide border enforcement against imports and exports of goods infringing *any* IP right covered in TRIPS, with the exception of patent rights.[245]

The rather ambiguous provision on the scope of border measures offers ways to limit enforcement to certain IP infringements if done "in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade."[246] For example, based on the arguments above, it can be applied to exclude ordinary trademark infringements from the scope of border measures.

Further, ACTA requires *ex officio* actions in relation to imports and exports,[247] whereas TRIPS merely allows *ex officio* measures if certain conditions are fulfilled.[248] Finally, like TRIPS, ACTA allows the extension of border measures to goods in transit.[249]

In sum, the scope of ACTA border measures differs from TRIPS in that more types of IP infringements and exports must be included. TRIPS allows the extension of border measures to other IP infringements and to goods in transit, provided the parties adhere to the relevant safeguards for traders and good owners.[250] In the ACTA context, where extension of border measures to goods in transit is also allowed, the crucial question becomes whether these safeguards are properly integrated into the ACTA framework.

244. *See* TRIPS Agreement art. 51. These terms are further defined in Article 51, note 14.

245. *See* discussion *supra* Part III(A)(1)-(3).

246. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 13.

247. *Id.* art. 16(1).

248. TRIPS Agreement art. 58.

249. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 16(2).

250. TRIPS Articles 1(1) and 51 allow these forms of TRIPS-plus protection if the further requirements of the TRIPS border measure section are met (such as those in Articles 52-55) and in so far as these forms do not contravene TRIPS provisions. *See* TRIPS Agreement arts. 1(1), 51; *see also* Grosse Ruse - Khan & Jaeger, *supra* note 48, at 524.

2. Applicable Law

While TRIPS requires adequate evidence of infringement "under the laws of the country of importation,"[251] ACTA demands such evidence based on the "laws of the Party providing the procedures."[252] For imported goods subject to border measures, the two rules both lead to the law of the importing country being decisive for showing prima facie infringement.

For transit cases, the assessment of IP infringement must now be based on the law of the transit country.[253] Here, ACTA takes a different position than TRIPS. Whether this difference actually amounts to "facial conflict with the WTO TRIPS Agreement,"[254] however, depends on the notion of conflict in international law and possible ways to reconcile the diverging provisions.[255]

3. Safeguards for Traders and Goods Owners

ACTA creates more opportunities for right holders to provide securities,[256] but unlike TRIPS, it does not mandate the release of goods upon provision of a security by the "owner, importer, or consignee."[257] Instead, under ACTA, goods owners, importers, or other defendants may only provide securities to obtain possession of the goods "in exceptional circumstances or pursuant to judicial

251. TRIPS Agreement art. 52.

252. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 17(1).

253. This question of applicable law, however, does not prejudice the question of whether that country's substantive IP law actually considers transit of the goods as an act of infringement. *See id.* art. 3(2*); see also* discussion *supra* Part III(B).

254. Sean Flynn, *Amend ACTA: Defining Terms by Country of Importation*, AM. U. WASH. C.. L. PROGRAM ON INFO. JUST. & INTELL. PROP. (Sept. 9, 2010), http://www.wcl.american.edu/pijip/go/blog-post/amend-acta-defining-terms-by-country-of-importation.

255. *See* discussion *infra* Part IV(B).

256. In addition to the options provided in TRIPS, see TRIPS Agreement art. 53(1), ACTA contains an additional option which allows rights holders to provide the security "in the form of a bond conditioned to hold the defendant harmless from any loss or damage resulting from any suspension of the release of, or detention of, the goods in the event the competent authorities determine that the goods are not infringing." *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 18.

257. *See* TRIPS Agreement arts. 53(2), 55 (providing for the release of goods after ten days of detention upon "the posting of a security in an amount sufficient to protect the right holder for any infringement").

order."[258]

Further, while TRIPS has an indemnification provision to protect importers and owners of goods in the event of wrongful detention of goods,[259] ACTA has no equivalent provision, other than the general obligation to provide fair and equitable procedures and to provide "appropriate" protection for "the rights of all participants subject to procedures."[260]

Third, TRIPS contains mandatory limits on the duration of the initial detention of goods suspected of infringement.[261] Although ACTA does not contain an equivalent rule, the general obligation to protect the rights of all participants to the procedures in an appropriate manner may have the same effect.[262]

Finally, ACTA grants rights to obtain information to right holders which go beyond those in TRIPS.[263] These rights however are subject to a general privacy safeguard.[264]

4. Implementing the Article 31(f) TRIPS Waiver

It has been argued that an effective implementation of the TRIPS "paragraph six mechanism"[265] could also be at risk whenever

258. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 18.

259. *See* TRIPS Agreement art. 56.

260. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(2). As an extended version of TRIPS Article 41(2), ACTA Article 6(2) arguably covers the specific rights of traders foreseen under TRIPS Article 56, even though ACTA does not explicitly mention indemnification.

261. *See* TRIPS Agreement art. 55 (providing that proceedings must be initiated, or the goods released, within ten days with a possible extension of another ten days "in appropriate cases").

262. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(2).

263. *Compare id.* art. 22, *with* TRIPS Agreement art. 57.

264. Article 22 begins with the *chapeau* clause—"[w]ithout prejudice to a Party's laws pertaining to the privacy or confidentiality of information"—indicating that such laws may override the specific duties to provide authorities with powers to disclose information. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 22.

265. For similar allegations in the European Union Transit case, see WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003) and *TRIPS Amendment*, *supra* note 35. The "paragraph six mechanism," so termed due to its original mandate in the Doha Declaration, see Doha Declaration, *supra* note 43, ¶ 6, which this General Council decision implements, allows exports of medicines produced under a compulsory license into countries with insufficient

medication produced under a compulsory license for export to a country with insufficient manufacturing capacity transits through ports of ACTA parties.[266] Also, in this scenario the ACTA provisions relevant for border measures against generics in transit offer no explicit safeguard against seizures solely based on transit jurisdiction: depending on the scope of IP infringements covered by domestic border measures of future ACTA parties, any medication that is patent or trademark protected in domestic law could be subject to seizure and destruction.[267]

However, by seizing drugs produced under the paragraph six mechanism, the future ACTA parties would directly contradict the efforts undertaken by the WTO and its members to promote access to medicines in these cases. On one hand, seizures of goods in transit may inhibit the supply of drugs under the paragraph six mechanism to countries with no sufficient pharmaceutical manufacturing capacities. On the other hand, ACTA's general obligation not to create barriers to legitimate trade may constitute a safeguard which ensures the free transit of medicines produced under the paragraph six mechanism.[268]

5. A General Shift in the IP Enforcement System?

Apart from these specific differences between ACTA and TRIPS border measure standards, some are concerned about the general tendency of ACTA to enlarge remedies for right holders, without retaining the necessary checks and balances to secure the rights of

manufacturing capacities.

266. *See* Intervention by India, *supra* note 10; Statement of Brazil, *supra* note 10; India Consultation Request, *supra* note 2. Under Parliament & Council Regulation 816/2006, art. 13(1), 2006 O.J. (L 157) 1, 6 (EC) the E.U.'s implementation legislation regarding the "paragraph six mechanism," the importation, re-exportation, or transit of drugs produced under a compulsory license, granted pursuant to the paragraph six mechanism, is generally prohibited and custom authorities must detain these drugs in accordance with Article 14 of the Regulation 816/2006. Drugs re-exported or in transit to an importing country that lacks manufacturing capacity are exempted from this prohibition, and the importing country is thus eligible to receive drugs produced under a compulsory license abroad in accordance with the paragraph six mechanism. *Id.* art. 13(2). It is nevertheless unclear whether this exemption would cover potential seizures based on the BMR instead of Article 13(1).

267. *Cf.* Abbott, *supra* note 15.

268. For details, see discussion *supra* Part III(C)(2).

defendants. The concerns raised by India in the October 2010 TRIPS Council meeting offer a good summary of the potential conflict between ACTA and TRIPS in this regard:

> The draft ACTA limits the protection otherwise available to accused infringers under the TRIPS Agreement by potentially lowering knowledge thresholds, limiting due process requirements (e.g., requirements to act within particular time frames), limiting evidentiary requirements, and by not specifying the type of authority empowered to make critical decisions. This shift to summary administrative action may curtail the rights of accused infringers to defend patent infringement claims, ordinary trademark and copyright infringement claims. This represents a substantial transformation from the original concept of enforcement under the TRIPS Agreement.[269]

This article cannot offer a comprehensive analysis of whether all enforcement provisions in ACTA contain appropriate checks and balances to secure the rights of the defendant. It is worth mentioning, however, that ACTA contains a general rule providing that "each Party shall take into account the need for proportionality between the seriousness of the infringement, the interests of third parties, and the applicable measures, remedies and penalties."[270] Therefore, ACTA basically adopts TRIPS's proportionality rule regarding the final fate of IP-infringing goods, but here as a general obligation for all enforcement procedures.[271] This in itself is certainly a positive development. As a general principle, the effective functioning of ACTA's proportionality rule depends on ACTA parties' willingness and ability to recognize concrete and specific defenses and other relevant safeguards for the rights of the defendants, such as those contained in TRIPS Article 42 on civil enforcement and in Articles 53 through 56 on border measures, which are absent from ACTA.

This discrepancy places a heavy burden on the proportionality rule and its domestic implementation by ACTA parties. It creates uncertainty and legal insecurity for those bold enough to implement these general principles by establishing concrete and specific defenses tailored to the new and strengthened remedies for right holders. The ambiguity of the so-called "three-step test," which

269. *Concerns raised over ACTA at TRIPS Council*, *supra* note 226.
270. ACTA Text—Dec. 3, 2010, *supra* note 60, art. 6(3).
271. *Compare id.*, *with* TRIPS Agreement art. 46.

limits the ability of WTO members to introduce tailored exceptions and limitations to most IP rights in TRIPS, serves as a cautionary tale here.[272] While it certainly can be interpreted in a balanced manner, the three-step test has often served as a pretext for arguing that new exceptions and limitations in national laws would be inconsistent with TRIPS.[273]

Unfortunately, developing countries and small economies are among those most likely to be threatened with dispute settlement or even unilateral sanctions if they dare to implement these general principles in ACTA Article 6. This assumes, of course, that they have accepted the "irresistible" offer to comply with ACTA as part of an FTA-deal. The asymmetry between concrete and concise remedies and general checks and balances is, therefore, a systemic concern with ACTA. While this concern can be addressed by an interpretation and implementation of Article 6 that takes seriously the incorporation of TRIPS Articles 7 and 8, this outcome relies on the ability and willingness of ACTA parties to do so.

6. The Role of TRIPS Articles 7 and 8 in Interpreting ACTA

Before moving to the conflict analysis, it is worth reiterating some general observations on the appropriate interpretation of the substantive provisions in TRIPS and ACTA. In general, the relevant TRIPS and ACTA provisions are interpreted in light of their ordinary meaning, context, and the treaty's object and purpose.[274] As discussed above, Articles 7 and 8 define the object and purpose of TRIPS.[275] All WTO members, including all ACTA negotiating parties, have confirmed the importance of TRIPS Articles 7 and 8 for

272. *See* TRIPS Agreement arts. 13, 17, 26(2), 30. In essence, these different versions of the test require domestic exceptions to IP exclusivity to be (1) limited, (2) without conflict with the normal exploitation of IP, and (3) without prejudice to the legitimate interests of the rightholder, taking into account legitimate interests of third parties.

273. *See, e.g.*, Christophe Geiger et al., *Declaration: A Balanced Interpretation of the "Three-Step Test" in Copyright Law* 1 J. INTELL. PROP. INFO. TECH. & ELEC. COM. L. 119, 119 (2010), *available at* http://www.jipitec.eu/issues/jipitec-1-2-2010/2621/Declaration-Balanced-Interpretation-Of-The-Three-Step-Test.pdf.

274. VCLT, *supra* note 189, art. 31.

275. *See* discussion *supra* Part III(C)(1).

the interpretation of all TRIPS provisions.[276] Further, WTO members specifically affirm that TRIPS "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[277]

Through treaty interpretation, the public health dimension of the TRIPS Agreement and the Doha Declaration can therefore exercise an important influence on the appropriate understanding of open treaty terms such as "legitimate trade," "abuse," or "country of importation."[278] Further, the object and purpose of TRIPS, as embodied in Articles 7 and 8, arguably has an impact on the understanding of the term "contravene" in TRIPS Article 1(2). Thus, the question of whether additional IP enforcement in ACTA "contravenes" TRIPS provisions is also guided by the balancing objectives and public interest principles in TRIPS Articles 7 and 8.[279] This may also result in findings of contravention in cases in which TRIPS-plus measures frustrate other WTO members' abilities to promote social welfare, protect public health, and facilitate access to medicines. As this author has argued elsewhere, there is generally no room for such findings when additional IP protection or enforcement curtails an optional flexibility under TRIPS as opposed to a mandatory rule such as in TRIPS Articles 41(1) or 52.[280]

To the extent that TRIPS Articles 7 and 8 influence the understanding of TRIPS, the same can be argued for ACTA since Article 2(3) incorporates these flexibilities by reference.[281] Hence,

276. *See* Doha Declaration, *supra* note 43, ¶ 5(a) (emphasizing as one of the key flexibilities under TRIPS that "[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles").

277. *Id.* ¶ 4.

278. On the importance of TRIPS's object and purpose as compared to the other main elements of treaty interpretation, see Grosse Ruse - Khan, *supra* note 178, at 162.

279. On the meaning of the term "contravene" in light of the debate on conflict of norms in international law, see Grosse Ruse - Khan, *supra* note 38, at 67-70.

280. *Id.* at 70-73. On the similar issue of the appropriate understanding of the notion of "conflict" between different norms in international law, see discussion *infra* Part IV(B).

281. *See* discussion *infra* Part III(C)(2) (discussing how TRIPS Articles 7 and 8 influence ACTA's interpretation through their incorporation via ACTA Article

Article 2(3) both reduces the conflict potential by mandating a public health supportive interpretation of ACTA and increases the likelihood for coherence between TRIPS and ACTA.

B. COHERENCE, NORM CONFLICT, AND CONFLICT RESOLUTION

Given the potential for norm conflicts between TRIPS and ACTA, described above, this section examines how these potential conflicts would be resolved under the rules and principles of public international law.[282]

1. The Principle of Harmonious Interpretation and Systemic Integration

Resolution of norm conflicts in international law is foremost achieved by the principle of harmonious interpretation and systemic integration, which operates as a presumption against conflict.[283] As embodied in VCLT Articles 31 through 33, a harmonious treaty interpretation is not possible when the ordinary meaning and context of the two relevant terms, understood in light of the object and purpose of the treaties, do not permit a mutually consistent understanding.[284]

The fact that TRIPS and ACTA essentially share the same object and purpose, as embodied in TRIPS Articles 7 and 8, makes a harmonious interpretation much easier. Several, if not most, of the differences mentioned above lend themselves to an integrative approach. For example, with regard to the ACTA options for defendants to post a bond or other security as a means to obtain the release of seized goods,[285] public health considerations may

2(3) and ACTA's recognition of the principles embodied in the Doha Declaration).

282. *See* Joost Pauwelyn, *The Role of Public International Law in the WTO: How Far Can We Go?* 95 AM. J. INT'L L. 535, 535-78 (2001). *See generally* Rep. of the Int'l Law Comm'n, Conclusions of the Work of the Study Group on the Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, U.N. Doc. A/61/10 (2006) [hereinafter ILC Conclusions] (outlining techniques of interpretation and rules of conflict resolution in international law).

283. ILC Conclusions, *supra* note 282, ¶¶ 4, 17-19. *See generally* McLachlan, *supra* note 190, at 309-19 (proposing an interpretive process to account for systemic integration as embodied in VCLT Article 31(3)(c)).

284. VCLT, *supra* note 189, arts. 31-33.

285. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 18.

constitute an "exceptional circumstance" given ACTA's object and purpose, in which case the provision is consistent with the mandatory cases for such securities covered in TRIPS Article 53(2).[286]

In the same vein, the general obligation in ACTA Article 6(2) to protect the rights of all participants in enforcement procedures can be understood to include the more specific obligation under TRIPS Article 56 to foresee right holder liability for any injury caused to defendants through the wrongful detention of goods. ACTA Article 6(2) can equally facilitate a harmonious interpretation that includes the maximum period of initial detention set forth under TRIPS Article 55.

Finally, the proportionality rule in ACTA Article 6(3) arguably applies in all those cases in which ACTA lacks a specific defense or safeguard for the defendant, but where one is present in TRIPS.[287] While this certainly does not remove the asymmetry in ACTA between concrete and concise remedies on the one hand and mere general checks and balances on the other, such asymmetry is to some extent mitigated by the relationship between ACTA and TRIPS. Thus, the absence of comprehensive and specific checks and balances in ACTA does not amount to a conflict of norms with TRIPS in light of the principles of integration and harmonious interpretation.

2. Defining Norm Conflicts

Resolving norm conflicts also involves defining what constitutes a true "conflict" of norms.[288] In the strictest sense, a conflict exists only where there is a direct incompatibility such that complying with one rule necessitates the violation of another.[289] The WTO Appellate Body seems to follow this view.[290] Still, this is not the only

286. On the interpretation of this and other ambiguous terms in ACTA in light of TRIPS Articles 7 and 8, see discussion *supra* Part III(C)(1).

287. On the role of the general proportionality rule, see discussion *supra* Part IV(A)(5).

288. *See generally* JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW (2003).

289. *See id.* at 167 (discussing the "technical approach" to conflict in international law).

290. *See, e.g.*, Appellate Body Report, *Guatemala Anti-Dumping Investigation Regarding Portland Cement from Mexico*, ¶ 65, WT/DS60/AB/R (Nov. 2, 1998)

perspective on norm conflict: a broader view finds conflicts when a treaty obligation limits or prevents the exercise of a right provided by another treaty.[291]

In the TRIPS context, if this broader definition of conflict prevails, a TRIPS-plus rule in ACTA may be in conflict with an optional TRIPS provision as soon as it limits the ability of a WTO member to exercise a right or flexibility provided by TRIPS. Whenever such a conflict then is decided in favor of the TRIPS provision, this approach could be argued as making TRIPS flexibilities inviolable and untouchable. Some support for such a position comes from the Doha Declaration in which WTO members "reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility" for the purpose of public health protection.[292]

On the other hand, such a far reaching effect may appear to contradict the overall notion of optional flexibilities in TRIPS. Since WTO members implement optional flexibilities through domestic law, if a WTO member thus decides to waive its right to use a certain flexibility allowed under TRIPS, this is equally a way of exercising its right and part of the flexibility TRIPS provides. Thus, applying a wide notion of norm conflict so as to prevent a WTO member from making such a decision could be viewed as turning an optional rule into a mandatory one.

However, one must bear in mind that a broad understanding of what constitutes a norm conflict in international law does not pre-determine the answer to the question which of the conflicting norms prevails. This is a separate analysis governed by the applicable conflict *resolution* tools in either of the conflicting bodies of norms or in general international law.[293] Hence, adopting a wide understanding of norm conflict does not imply TRIPS flexibilities prevailing over TRIPS-plus provisions in subsequent international IP treaties such as ACTA. It merely widens the scope of conflict

(defining conflict as "a situation where adherence to the one provision will lead to the violation of the other provision").

291. *See Pauwelyn*, *supra* note 282, at 551. For an overview on various different approaches to conflicts or inconsistencies, see ILC Conclusions, *supra* note 282; PAUWELYN, *supra* note 288, at 167-174.

292. Doha Declaration, *supra* note 43, ¶ 4.

293. *See* discussion *infra* Part IV(B)(3).

resolution analysis to include the relationship between optional rights under TRIPS and subsequent curtailments of these rights in TRIPS-plus rules.

In the context of the ACTA-TRIPS relationship, some of the arguments above speak in favor of adopting a narrow definition of norm conflict, which means that a conflict only exists when compliance with one rule necessitates the violation of another rule.[294] This approach also aligns with the understanding of the term "contravene" in TRIPS Article 1(1).[295] However, the resolution of norm conflicts becomes more limited and technical under this approach. The narrow definition of conflict would not eradicate the conflict potential between TRIPS and ACTA, as long as it is based on the operation of mandatory TRIPS limits to additional IP protection and a corresponding obligation for such an additional protection in ACTA. For example, if the final ACTA text would have mandated the seizure of generics in transit, as discussed above, TRIPS obligations would be violated by complying with such an ACTA obligation.[296] But a narrow definition excludes an important part of potential conflicts, namely the relation between TRIPS flexibilities and subsequent TRIPS-plus rules, from its scope. A wider understanding of norm conflict avoids that and appears more apt to address the need for policy coherence between TRIPS and ACTA.[297] In the end, the main argument in favor of a wider understanding is that it does not conflate conflict *definition* and conflict *resolution*. As a conflict resolution tool, Article 1(1) TRIPS and its notion of "contravening" also have no bearing on what should constitute a norm conflict between TRIPS and ACTA. Instead, it is only relevant in the resolution of conflicts discussed below.

Among the ACTA–TRIPS differences discussed in Part IV(A) above, those pertaining to the scope of border measures under ACTA fall inside the wide definition of conflict. In particular the mandatory extension of the types of IP infringements to be covered by border

294. On the operation of the specific ACTA conflict clause, see discussion *supra* Part IV(B)(2).

295. *See* discussion *supra* Part II(B).

296. *See* discussion *supra* Part III(A)(2).

297. Such coherence is increasingly claimed between the ability to exercise TRIPS flexibilities and TRIPS-plus IP provisions in FTAs. *See* TRIPS-plus Enforcement China, *supra* note 37; TRIPS-plus Enforcement India, *supra* note 37.

measures under ACTA curtails the flexibilities TRIPS foresees in this regard.[298] Another norm conflict may exist if one finds that ACTA does not adhere to the relevant safeguards for traders and goods owners in TRIPS. As explained above, however, the specific safeguards contained in TRIPS Articles 53-56 can be encompassed by the general checks and balances rules in ACTA Article 6.[299] Here, a harmonious interpretation mitigates any potential conflict.

This also applies to the safeguard against IP enforcement functioning as a barrier to legitimate trade under TRIPS Article 41(1). Given that ACTA contains a verbatim copy of this rule in its Article 6(1), any implementation of ACTA that creates barriers to legitimate trade equally conflicts with ACTA Article 6(1).[300] ACTA and TRIPS therefore both prohibit the application of border IP enforcement in a way that inhibits international trade and especially the free transit of generic medicines. This result also speaks against findings of norm conflict in the implementation of the "paragraph six mechanism" on the exportation of medicines to countries with insufficient manufacturing capacities. Implementing ACTA in a way that inhibits the trade and transfer of medicines produced under this mechanism would already amount to a violation of Article 6(1).

However, a norm conflict—even in its narrow meaning—may exist in relation to the different applicable law rules. While TRIPS Article 52 requires adequate evidence of infringement "under the laws of the country of importation," ACTA Article 17(1) demands such evidence based on the "laws of the Party providing the procedures." Does adherence with one rule hence lead to inconsistency with the other? For allegedly infringing imported goods, the applicable law is that of the importing country under both TRIPS and ACTA. For goods in transit, however, the distinct rules lead to the law of the importing country under TRIPS, and to the law of the transit country under ACTA. A broad interpretation of "country of importation," under TRIPS Article 52, to include the transit country may be a way to harmonize the provisions. In applying the VCLT interpretative rules, however, the object and

298. *Cf.* discussion *supra* Part IV(A)(5).
299. *See* discussion *supra* Part IV(B)(1).
300. *See* discussion *supra* Part III(C)(2).

purpose of TRIPS work against such broad interpretation.[301] Since the VCLT rules of interpretation delineate the limits of the concept of harmonious interpretation to prevent norm conflicts, ACTA Article 17(1) is therefore in conflict with TRIPS Article 52.

3. Conflict Resolution Tools in TRIPS and ACTA

Conflict resolution depends on the applicable conflict resolution rules, which may derive from either of the two treaties or from general international law.[302] Although TRIPS Article 1(1) does not directly address the consistency of additional IP protection in international treaties, but instead refers to additional protection in domestic law, it should be understood as the relevant TRIPS conflict norm in relation to additional IP protection in general.[303] As discussed above, Article 1(1) prohibits additional IP protection that contravenes TRIPS provisions and hence only upholds a *binding* TRIPS norm constraining additional IP protection over subsequent contrary obligations in relations between WTO members.[304] From the WTO/TRIPS perspective, the obligations under TRIPS Article 52 constrain the ability of WTO members to set contravening standards in ACTA. The flexibilities under TRIPS Article 51 on the other hand allow extending border measures beyond the minimum scope of imports of trademark counterfeits and pirated copyright goods. Doing so constitutes an optional right which a WTO member may choose to exercise. The ACTA obligations which mandate a wider scope affect this right, but do not "contravene" TRIPS in the sense of Article 1(1). As argued above, finding a TRIPS-plus rule to contravene a TRIPS flexibility in effect turns an optional provision into a mandatory one.[305]

The relevant conflict resolution rule in ACTA sets out as a central

301. *See* Grosse Ruse - Khan & Jaeger, *supra* note 48, at 534-36; discussion *supra* Part II.

302. *Cf.* Pauwelyn, *supra* note 282, at 544-45.

303. *Cf.* Letter from Pascal Lamy, *supra* note 233. For a more detailed discussion, see Henning Grosse Ruse - Khan, *The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, 18 J. INTELL. PROP. L. (forthcoming 2011).

304. *See* discussion *supra* Part IV(A).

305. *See* discussion *supra* Part IV(B)(2). For further details, see also Grosse Ruse - Khan, *supra* note 303.

tenet its intention to respect existing agreements, including TRIPS.[306] Thus, ACTA expresses the intention of the negotiating parties not to derogate from any WTO/TRIPS obligations. The final ACTA text uses only the term "obligations," as opposed to the use of "rights and obligations" in the conflicts clauses of some FTAs. This suggests that the negotiating parties believe the future ACTA may prevail over optional TRIPS flexibilities. But as far as TRIPS obligations are concerned, namely binding limits to additional IP protection, those would prevail in the event of a conflict in the narrow sense defined above. Thus, the two conflict norms in TRIPS and ACTA lead to equivalent and consistent results: TRIPS would prevail over ACTA only in case of a conflict with a mandatory TRIPS limit on additional IP protection.

Therefore, in relation to the conflict between TRIPS Article 52 and ACTA Article 17(1), the binding obligation in TRIPS prevails over ACTA. While ACTA Article 1 mandates this result, Article 16(2) explicitly allows border measures against goods in transit.[307] The applicable law rule in ACTA Article 17(1) leads to the application of the law of the transit country, which conflicts with TRIPS despite the intention in ACTA Article 1 not to derogate from TRIPS. The best way to resolve this problem is to redraft ACTA's applicable law rule. If this does not happen, the most appropriate solution is to apply TRIPS Article 52 to cases where the ACTA rule leads to conflicting results. Thus, if a future ACTA party decides to extend border measures to goods in transit, their IP-infringing character must nevertheless be decided on the basis of the law of the country of importation, understood as the country of final destination, and not the law of the transit country.

Interestingly, in the July ACTA text, some negotiating parties proposed a different version of Article 1 which would have ensured that ACTA would not derogate from existing *rights* and obligations that the ACTA parties owe one another under TRIPS—"Nothing in this Agreement shall derogate from [EU/NZ/Sing: any existing rights and] any obligation of a Party with respect to another Party under existing agreements, including [TRIPS]."[308] The bracketed addition,

306. *See* ACTA Text—Dec. 3, 2010, *supra* note 60, art. 1.
307. *Id.* art. 16(2).
308. ACTA Draft—July 1, 2010, *supra* note 58, art. 1.1.

proposed by the E.U., New Zealand, and Singapore, would have also ensured that ACTA would not derogate from existing rights the ACTA parties owe one another under TRIPS. In the subsequent ACTA draft leaked in August 2010, however, the text referred only to "obligations."[309] Still, the question arises whether language along the lines of the July ACTA text might function to safeguard TRIPS flexibilities insofar as their operation is undermined by ACTA provisions.

This seems unlikely, however, for many reasons. First, the negotiating parties may understand "rights and obligations" with respect to each other as describing a treaty obligation in international law from a dual perspective where the obligation of one party is the right of another party. If so, the term would still only apply to obligations in international law and not as a safeguard for TRIPS flexibilities as optional treaty rights. Second, even if one assumes that the bracketed text applies to TRIPS flexibilities, it is limited to rights that future ACTA parties owe to each other. If these countries decide to waive rights by not exercising certain TRIPS flexibilities, then any ACTA provision that undermines the use of such a flexibility would arguably not derogate from such a right within the meaning of the July draft of Article 1. Finally, because ACTA contains specific TRIPS-plus rules, the only interpretation of which undermines the exercise of TRIPS flexibilities, the operation of Article 1 cannot lead to a result which renders the specific TRIPS-plus provision inutile or ineffective.[310] In sum, it remains rather doubtful that the bracketed addition in the July version of Article 1 would operate to prevent specific TRIPS-plus rules in ACTA from undermining TRIPS flexibilities. Only where such rules in ACTA are open-textured or ambiguous in their impact on TRIPS would such a version of Article 1 safeguard TRIPS flexibilities.[311]

309. *See* ACTA Draft—Aug. 25, 2010, supra note 59, art. 1.1 ("Nothing in this Agreement shall derogate from any obligation [NZ/US/Kor/J/CH/Mex/Can/Sing: of a Party with respect to any other Party] under existing agreements, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.").

310. As explained in *supra* note 216, this follows from the application of the principle of good faith in treaty interpretation as embodied in VCLT, *supra* note 189, art. 31 (1).

311. This result would however already follow from the principle of harmonious interpretation as discussed *supra* Part IV(B)(1).

4. Conflict Rules in General International Law

General international law conflict norms support the findings of the previous section. VCLT Article 30 concerns the application of successive treaties on the same subject matter.[312] According to VCLT Article 30(2), TRIPS should prevail in the event of an incompatibility, given ACTA's intent not to derogate expressed in Article 1.[313]

In addition, ACTA may also be subject to VCLT Article 41, which concerns *inter-se* agreements to modify multilateral treaties between certain of the parties.[314] In relation to the WTO/TRIPS Agreement, ACTA constitutes an *inter-se* agreement since it would be concluded amongst some members of the WTO and modify the TRIPS enforcement obligations as between themselves, mainly by adopting stronger standards. This would make ACTA's applicability in relation to TRIPS subject to the requirements of VCLT Article 41. One issue that arises is whether TRIPS Article 1(1) can be viewed as a "possibility for modification" under VCLT Article 41(1). If so, the qualification not to contravene TRIPS would be decisive for the ACTA-TRIPS relationship.

If one does not view TRIPS Article 1(1) as such a clause conditionally allowing subsequent *inter-se* treaties, then ACTA is a valid *inter-se* modification of TRIPS enforcement standards so long as the requirements of VCLT Article 41(1)(b) are met.[315] The main issue here would be whether any modification, namely stronger IP enforcement standards, relates to a TRIPS provision, "derogation

312. On the operation of Article 30 of the Vienna Convention as a conflict norm, see ILC Conclusions, *supra* note 282, ¶ 24; Grosse Ruse - Khan, *supra* note 303.

313. VCLT, *supra* note 189, art. 30(2) ("When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of the other treaty prevail" in the event of an incompatibility).

314. *Id.* art. 41. The conditions set out by Article 41 do not necessarily lead to the invalidity of the relevant *inter-se* treaty norm; rather, the consequences depend on an interpretation of the original treaty. *See* ILC Conclusions, *supra* note 282, ¶ 29. In relation to the original multilateral treaty, one might generally assume mere inapplicability, instead of invalidity, of the of the relevant *inter-se* treaty norm.

315. VCLT, *supra* note 189, art. 41(1)(b) (providing that parties to a multilateral treaty may alter the treaty as to themselves if "the modification in question is not prohibited by the treaty and (i) does not affect the enjoyment by the other parties of their rights under the treaty or the performance of their obligations; (ii) does not relate to a provision, derogation from which is incompatible with the effective execution of the object and purpose of the treaty as a whole").

from which is incompatible with the effective execution of the object and purpose of the treaty as a whole."[316] Specifically, the question is whether any ACTA TRIPS-plus standard derogates from a TRIPS rule in a way that is incompatible with the TRIPS objectives expressed in Articles 7 and 8.[317] ACTA fails to meet the requirements of VCLT Article 41(1)(b), therefore, only in situations where ACTA rules cannot be cured of their incompatibility with TRIPS through the incorporation of TRIPS Articles 7 and 8 by reference, mainly where ACTA uses precise treaty language that is immune to an interpretation in light of Article 7 and 8.[318]

Given the very general terms used in the balancing objectives and public interest principles of TRIPS, this standard seems difficult to apply. Since the effect of *inter-se* modifications is generally confined to the national IP regimes of the modifying parties, the *inter-se* derogation from TRIPS flexibilities, as such, cannot be viewed as incompatible with the "effective execution of the object and purpose of the treaty as a whole."[319] Instead, the operation of VCLT Article 41 should require an effect on other WTO members and their ability to implement the TRIPS objectives.[320] If a TRIPS-plus *inter-se* treaty inhibits the ability of other WTO members to exercise their rights under TRIPS, i.e., to use the TRIPS flexibilities effectively, then such a modification also violates VCLT Article 41(1)(b)(ii). That means, would ACTA mandate the seizures of generics in transit in any way, the negative impact on other WTO members' right to rely on TRIPS flexibilities, such as the Doha "paragraph six mechanism," would violate VCLT Article 41(1)(b). However, as argued above, the prohibition on the creation of trade barriers under ACTA Article 6(1) should serve as a safeguard against such a negative impact on the "paragraph six mechanism."

Finally, ACTA may also pose a problem under VCLT Article

316. On the application of VCLT Article 41 in relation to TRIPS and FTAs in general, see Andrew D. Mitchell & Tania Voon, *Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law*, 43 WORLD J. TRADE 571, 571-601 (2009); Grosse Ruse - Khan, *supra* note 303.

317. On the role of Articles 7 and 8 as the object and purpose of TRIPS, see Doha Declaration, *supra* note 43, ¶ 5.

318. On the operation and limits of TRIPS Articles 7 and 8 as ACTA treaty objectives, see discussion *supra* Part III(C)(1).

319. VCLT, *supra* note 189, art. 41(1)(b)(ii).

320. This is also consistent with VCLT Article 41(1)(b)(i). *See supra* note 315.

41(2).[321] Unless the ACTA negotiating parties have discharged their notification duty in respect of all other WTO members, they are acting in violation of the VCLT.[322] That said, it is doubtful that a violation of VCLT Article 41(2) will have any practical effect.

In sum, the general international law conflict rules, especially those contained in VCLT Articles 30 and 41, support the results found under the specific conflict clauses in TRIPS Article 1(1) and ACTA Article 1. To the extent that TRIPS contains a binding limit on additional IP protection and enforcement, it will prevail over ACTA. On the other hand, optional TRIPS flexibilities are unlikely to prevail over TRIPS-plus obligations under ACTA, unless ACTA violates requirements established in VLCT Article 41(1)(b) by affecting the rights of other WTO members to exercise these flexibilities.[323]

CONCLUSION

This article has reviewed the ACTA provisions on border measures against the backdrop of Dutch seizures of generics in transit, and the resulting initiation of dispute settlement proceedings by India and Brazil against both the E.U. and the Netherlands. According to both India and Brazil, the E.U. and Dutch measures are inconsistent with TRIPS Articles 1(1) and 41 and other TRIPS norms from the section on border measures (Articles 51-60). These alleged infringements do not result from a failure to meet the TRIPS minimum standards of IP protection and enforcement; rather, it is the TRIPS-plus character of the measures that led to the seizure of generics in transit. Thus, for the first time in WTO dispute settlement, TRIPS has been used as a benchmark for constraining additional IP protection. Given this new perspective on TRIPS, the

321. VCLT, *supra* note 189, art. 41(2) (requiring the modifying parties to notify any other parties to the agreement of their intent to modify and the proposed modification).

322. The WTO notification mechanism with respect to Regional Trade Agreements under Article XXIV of GATT or Article V of GATS apparently has not been used by the ACTA negotiating parties. *See Regional Trade Agreements Information System*, WORLD TRADE ORG., http://rtais.wto.org/UI/Public Maintain RTAHome.aspx (last visited Mar. 1, 2011).

323. Note that this would also violate the general principle that "[a] treaty does not create either obligations or rights for a third State without its consent." VLCT, *supra* note 189, art. 34.

TRIPS-plus elements contained in ACTA, which relate to IP enforcement at the border, warrant close scrutiny.

While the final ACTA text does not mandate the extension of border measures against goods in transit, it certainly allows the detention of goods suspected of infringing trademarks and patents in the transit country. This can easily lead to the seizure of transiting generics, similar to the Dutch seizures previously mentioned. ACTA parties have the option to avoid this threat because the enforcement mechanisms threatening the international trade in generic drugs are not mandatory. Moreover, future ACTA parties have a general obligation to prevent IP enforcement procedures from creating barriers to legitimate trade. As argued above, this obligation acts to prohibit future ACTA parties from implementing ACTA in a way that inhibits the international trade and transit in generic medicines. This understanding of ACTA's safeguards against trade barriers finds support in its incorporation of TRIPS Article 7 and 8, which play a strong interpretative role in the understanding of ACTA norms.

Although ACTA contains a general obligation to protect the rights of defendants and third parties, ACTA provides comprehensive and concise provisions on remedies that asymmetrically protect rights holders. This imbalance raises systemic concerns because it places the burden of a proportional, fair, and equitable enforcement system primarily on ACTA parties. Therefore, future ACTA parties must take these general obligations seriously and draft concrete defenses and other safeguards for all those affected by the new extended remedies. It remains to be seen whether the uncertainty inherent in the general obligations will prevent developing countries, in particular, from doing so.

In acknowledging that TRIPS contains both minimum and maximum standards for IP protection and enforcement, it follows that TRIPS can constrain the ability of WTO members to enter into TRIPS-plus agreements like ACTA. In the case of ACTA, however, most TRIPS-plus border measure obligations do not amount to contravention of TRIPS provisions. First, ACTA's general obligations can be interpreted harmoniously with the specific safeguards for free trade in TRIPS Article 53 through 56. Second, a contravention of TRIPS provisions does not exist when merely

optional TRIPS flexibilities are undermined by more stringent IP enforcement under ACTA. The TRIPS and ACTA rules on the applicable law for judging the IP infringing character of goods in transit are the only provisions truly in contravention. Here, conflict resolution provisions in ACTA, TRIPS, and general international law operate to prioritize the application of TRIPS Article 52 over ACTA Article 17(1) to the extent of conflict. This example highlights the need to redraft certain of ACTA's provisions to create consistency with the TRIPS Agreement.

Finally, if ACTA's negotiating parties were to truly take seriously their pledge for TRIPS consistency, they should also have strived for policy coherence. Rather than including a few general checks and balances for the defendant, the negotiating parties should have crafted specific safeguards for all interested parties affected by the ACTA enforcement rules in order to counterbalance the comprehensive new remedies created for rights holders. It is this asymmetry that creates the gravest systemic concerns with ACTA.