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IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment

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Abstract
This article critically examines the dynamics between public health, intellectual property, and international trade in the context of the TRIPS Amendment and its theoretical implications in international law. The article suggests that international efforts in the TRIPS 2003 Waiver and 2005 Amendment addressing public health concerns have not been very successful due to the birth defect of TRIPS, i.e., hoping a private-rights-in-nature regime could accommodate public interests in health concerns. TRIPS' birth defect further reveals itself in post-TRIPS development and contributed to the failure of the TRIPS Waiver and Amendment due to the resulting practice fragmentation and procedural hurdles in domestic compulsory licensing administration. Moreover, the TRIPS Amendment raised a fundamental theoretical issue, i.e., how the WTO as an international organization in public international law can regulate compulsory licensing of intellectual property rights as private rights – in particular the proprietary right to remuneration – while recognizing that TRIPS grants no positive rights. The paper suggests that the key to the issue is the treatment of private rights in public international law. It is submitted that the TRIPS Amendment has no legal basis in international law due to its unwarranted intrusion into members' domestic affairs and individuals' private proprietary rights. The article thus calls for alternative thinking about the TRIPS Amendment, in particular to leave administration of compulsory licensing fully with domestic authorities as it is in the Paris Convention.

Keywords
WTO; TRIPS amendment; public health; private rights; compulsory licensing

1. Introduction

The unfortunate Ebola outbreak in West Africa in 2014 clearly remains a 'public health emergency of international concern' in 2015.[1] As part of the global effort tackling the situation, the European Medicines Agency (EMA) classified Ebola as an orphan disease in late 2014, which incentivizes development of Ebola cure through

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1 UN General Assembly, 'Letter dated 12 January 2015 from the Secretary-General addressed to the President of the General Assembly' (A/69/720), 19.

preferential market exclusivity for medicines with orphan designation.[2] As the West African countries suffering in the epidemic are least-developed countries with insufficient or no pharmaceutical manufacturing capacities, their access to the Ebola cure, once developed, will need to rely on The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Paragraph 6 System in the framework of the World Trade Organization (WTO).[3] However, the 2005 TRIPS Amendment that attempted to legalize the Paragraph 6 System is reaching its tenth year of pending status in 2015, and there is no sign of it coming into effect in the near future.[4] Should the Ebola epidemic get worse, will the current TRIPS mechanism be sufficient to handle global health emergencies of public concern? Within the current global context, it is meaningful to re-examine the issue of public health concerns in the international trading framework, and in particular the success or failure of the TRIPS Amendment for public health.

TRIPS is certainly a breakthrough of the Uruguay Round negotiation establishing the WTO.[5] However, as TRIPS negotiations 'were highly contentious', and intellectual property protection perspectives are segmented between developed and less-developed countries, the TRIPS Agreement 'is one of the more controversial international intellectual property agreements that have entered into force'.[6] One of the key issues of debate and controversy is the tension between TRIPS and public health concerns, which has generated a great deal of literature, in particular around the turn of the millennium.[7] On the one hand, upon the conclusion of

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2 See EMA News, 'Speeding up development of Ebola treatments and vaccines (20/10/2014)', available at www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002190.jsp&mid=WC0b01ac058004d5c1 (accessed 10 March 2015). Human Ebola virus species, compositions and methods thereof have been patented by the US Government in 2009 (US20120251502, PCT/US2009/062079). All Ebola therapies and vaccines, however, are still in various stages of development, and none of them have been approved for human use so far.

3 The WTO's Paragraph 6 System refers to the 'waiver' allowing generic medicines to be made through compulsory licenses exclusively for exporting to countries that have no capacity in producing the medicines themselves. The system is developed under Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health by removing the exportation limit under compulsory licenses in Art. 31(f) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

4 The Amendment refers to the WTO's amendment to TRIPS proposed in December 2005. See General Council, 'Amendment of the TRIPS Agreement', WT/L/641, Decision of 6 December 2005 (hereafter the TRIPS Amendment). The TRIPS Amendment is an attempt to legalize the 2003 TRIPS Waiver, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', which offers temporary suspension of certain TRIPS compulsory licensing obligations as a solution to public health crises. For details of the TRIPS Waiver and Amendment, see discussion in Section 2.2.

5 R.C. Dreyfuss and A.F. Lowenfeld, 'Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together', (1997) 37 *Virginia Journal of International Law* 275, at 276–7.

6 P.K. Yu, 'The Objectives and Principles of the TRIPS Agreement', (2009) 46 *Houston Law Review* 979, at 980; see also, G.B. Dinwoodie and R.C. Dreyfuss, 'Designing A Global Intellectual Property System Responsive to Change: the WTO, WIPO, and Beyond', (2009) 46 *Houston Law Review* 1187, at 1188.

7 See, e.g., R. Weissman, 'Long Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries', (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069; S.M. Ford, 'Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents', (2000) 15 *American University International Law Review* 941; F.M. Abbott, 'The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis', (2001) 7 *Widener Law Symposium Journal* 71; J. Rein, 'International Governance Through Trade Agreements: Patent Protection for Essential Medicines', (2001) 21 *Northwestern Journal of International Law and Business* 379; C.O. Garcia-Castrillón, 'An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health', (2002) 5 *Journal of International Economic Law* 212; D. Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A

the TRIPS Agreement, international pharmaceutical companies' active lobbying has seen great success in obtaining a high level of patent protection in relation to pharmaceutical products in the trading framework.[8] On the other hand, many countries 'are distressed by the costs arguably imposed by TRIPS intellectual property norms on drugs which are crucial to many government health plans and insurance provisions'.[9] Therefore, 'poor countries affected by the AIDS pandemic and international health organizations actively have sought to preserve state regulatory powers within the confines of the TRIPS agreement'.[10] The 1999 WHA Resolution, for example, urges member states to 'ensure that public health interests are paramount in pharmaceutical and health policies', and to 'explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs'.[11] Some critiques against TRIPS' impact on public health go even further. As '[c]learly the rules sought by the pharmaceutical companies are unnecessarily harmful to the poor countries', Bhagwati suggests that 'TRIPs should not be in the WTO at all'.[12] These controversies around the tension between public health and pharmaceutical patent protection lead us to the issue of TRIPS' response to public health concerns and its implications.

This article offers a critical examination of the legitimacy issue of TRIPS' compulsory licensing mechanism, the 2003 TRIPS Waiver and 2005 TRIPS Amendment in particular, and its relevant implications for public health. Section 2 introduces TRIPS' framework on the public health issue and the development of the compulsory licensing regime in relation to public health concerns. Section 3 provides a critical analysis of the nature of compulsory licensing and the paradox of TRIPS' intellectual property philosophy in relation to the tension between public health and pharmaceutical patent protection in the context of TRIPS-development dynamics. The article suggests that the unfortunate incorporation of intellectual property rights into international trade, without first reconciling development and intellectual property rights protection, creates TRIPS' birth defect. Further jurisprudential examination in Section 4 reveals that this 'birth defect' not only causes the failure of the compulsory licensing amendment, but also causes the Waiver and Amendment to lose their legitimate basis in international law. The article suggests that the TRIPS Amendment raises an important question: how can TRIPS, as a public international law regime, handle the proprietary right to remuneration in compulsory licensing while recognizing that IPRs are private rights and TRIPS grants no positive rights? To answer this question, the paper further looks at private rights' treatment in international law and the dynamics between government and private rights in

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Solution to the Access to Essential Medicines Problem?', (2004) 7 *Journal of International Economic Law* 73; G. Shaffer, 'Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection', (2004) 7 *Journal of International Economic Law* 459; F.M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', (2005) 99 *The American Journal of International Law* 317.

8 See Weissman, *supra* note 7, 1075–85; see also, Rein, *supra* note 7, at 381.

9 J.H. Jackson, *Sovereignty, The WTO, and Changing Fundamentals of International Law* (2006) 247

10 Rein, *supra* note 7, at 381.

11 The 52nd World Health Assembly (WHA), Revised Drug Strategy (WHA52.19, 24 May 1999), 1.(2) and 1.(3).

12 J.N. Bhagwati, *In Defense of Globalization: With a New Afterword by the* Author (2007) 185.

international trade. Building on this critical examination, the article concludes in Section 5 with a call for alternative thinking about the TRIPS compulsory licensing mechanism for promoting public health in the international trading framework.

2. WTO TO PROMOTE PUBLIC HEALTH THROUGH INTERNATIONAL TRADE

2.1. WTO/TRIPS for public health

Although public health might not appear to be one of its key concerns, the WTO has kept it in focus. Setting 'to raise standards of living' as one of its objectives, the WTO regime must be concerned with public health as a core aspect of this goal.[13] '[W]ith its competence well established over trade in products and services', as Jackson suggests, the WTO indeed 'has considerable relevance to health issues'.[14] Through dealing with 'product safety and health related to foodstuffs and animal health' in the Sanitary and Phytosanitary (SPS) Agreement and by 'creat[ing] norms relating to product standards in other types of goods' in the text on Technical Barriers to Trade (TBT), the WTO's role in health is evident.[15] According to GATT 1994, WTO members are free to adopt or enforce measures 'necessary to protect human, animal or plant life or health' in a manner consistent with WTO requirements.[16] Therefore, promoting public health is indeed one of the WTO's imperatives.

Among other WTO agreements, the TRIPS Agreement is institutionally structured to play a prominent role in relation to public health under the WTO framework. TRIPS' Preamble states that members desire 'to establish a mutually supportive relationship' between the WTO and the World Intellectual Property Organization (WIPO), and other relevant international organizations.[17] This was considered to include 'urging greater cooperation with UNCTAD, the World Health Organization (WHO) and other institutions that pursue broad developmental interests'.[18] The TRIPS' 'greater cooperation' with the WHO of course provides a significant international framework for addressing public health issues.

Indeed, the TRIPS Agreement makes indirect or direct references to public health in the provisions illustrating exhaustion, compulsory licensing, and TRIPS principles. As to exhaustion of rights, the TRIPS Agreement states that nothing in the TRIPS Agreement 'shall be used to address the issue of the exhaustion of intellectual property rights'.[19] The purpose of this provision, according to the 2001 Doha Declaration, 'is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4'.[20] Parallel imports under this doctrine 'may prevent market segmentation

13 First recital of the Preamble, Agreement Establishing the World Trade Organization.
14 Jackson, *supra* note 9, at 247.
15 Ibid.
16 Art. XX(b), General Agreement on Tariffs and Trade 1994 (GATT 1994).
17 Last recital of the Preamble, the TRIPS Agreement.
18 UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (2005) 13–14.
19 Art. 6, the TRIPS Agreement.
20 Para. 5(d), the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2, adopted at the Fourth WTO Ministerial Conference in Doha, Qatar on 14 November 2001, the 2001 Doha Declaration).

and price discrimination by titleholders on a regional or international scale', which is 'of particular importance in the health sector'.[21] TRIPS' liberal perspective towards exhaustion therefore gives flexibility to national governments to establish relevant mechanisms to address public health concerns.

Moreover, the TRIPS Agreement implicitly touches the issue of public health in its regulation of the compulsory licensing practice. According to the Agreement, members are free to authorize any third parties or to permit government the 'use of the subject matter of a patent without the authorization of the right holder' if certain conditions are met.[22] The conditions include limiting it to domestic use and adequate remuneration paid.[23] Commonly known as the compulsory licensing clause, this provision clarifies the conditions for the grant of compulsory licenses and allows members to address public health concerns through restraining the exercise of those private rights residing in the grants of patents.[24]

In addition to the indirect reference, the TRIPS Agreement makes direct reference to public health when it identifies its principles. Intellectual property protection and enforcement, as the TRIPS Agreement indicates, 'should contribute to … the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare'.[25] Under this objective, the TRIPS Agreement states:

> 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.[26]

In this provision, the TRIPS Agreement clearly sets protection of 'public health and nutrition' as one of the fundamental principles of the regime. Similar to the way the General Exception provision Article XX functions in relation to the rest of the GATT 1994, Article 8.1 is about external exceptions and limitations 'that concern the use of rights, not the rights themselves' throughout the TRIPS Agreement.[27] As the Panel in *EC – Trademarks and Geographical Indications* suggested, TRIPS' negative, instead of positive, rights granting feature 'inherently grants Members freedom to pursue legitimate public policy objectives' and many of such measures to attain those public policy objectives 'do not require an exception under the TRIPS Agreement'.[28]

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21 C.M. Correa, *Integrating Public Health Concepts into Patent Legislation in Developing Countries* (2000), 72–3; See also S.F. Musungu et al., *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks* (2004) 13–14.

22 Art. 31, the TRIPS Agreement.

23 Ibid.

24 UNCTAD-ICTSD, *supra* note 18, 461–2.

25 Art. 7, the TRIPS Agreement.

26 Art. 8.1, the TRIPS Agreement. Emphasis added.

27 N. Pires de Carvalho, *The TRIPS Regime of Patent Rights* (2010), 223. Carvalho suggests (at 225) that Art. XX(a) of the GATT 1994 is a provision 'of relevance to the understanding and application of Article 8.1 [of the TRIPS Agreement]'.

28 *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (*EC - Trademarks and Geographical Indications (Australia)*), Panel report (WT/DS290/R, 15 March 2005), para. 7.210.

Accordingly, to 'protect public health' would be one of the justifications of general exceptions to intellectual property rights as long as it was in a manner consistent with the TRIPS Agreement. For the issue of patentable subject matter for example, the TRIPS Agreement thus allows members to exclude certain inventions from patentability for the purpose of offering protection to 'human, animal or plant life or health'.[29] Therefore, the objectives and principles as expressed in Articles 7 and 8.1 of the TRIPS Agreement clearly accommodate the interests of public health and should not be interpreted lightly.[30] In fact, it has also been similarly reiterated in the Doha Declaration, that 'each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles'.[31] The WTO panel's practice too confirmed this. In its discussion of the limiting conditions of adopting the patent right exceptions prescribed in Article 30 of the TRIPS Agreement, the Panel in *Canada – Pharmaceutical Patents* states that, when examining the limiting conditions, '[b]oth the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind'.[32]

However, the WTO in general or the TRIPS in particular may care about public health, yet might not provide enough assurance to promoting public health. There thus exists a tension between the international trading framework and domestic mechanism addressing public health concerns. As seen in the SPS Agreement revealed by Jackson for example, there is a tension in the WTO framework between reconciling 'international goals of liberalizing trade and thus requiring scientific evidence of potential harm (to avoid barriers that are really due to protectionist motives)' with each member's 'sovereign right to determine the level of risk which should be tolerated in its society'.[33] Similarly as pointed out by the Appellate Body in *Brazil – Retreaded Tyres*, the general exception for health protection under GATT 1994 'illustrates the tensions that may exist between, on the one hand, international trade and, on the other hand, public health and environmental concerns'.[34] The tension between international trade and public health is particularly relevant to the debates surrounding the compulsory licensing issue in the TRIPS framework.

2.2. The TRIPS Amendment's public health 'flexibility'

Although there were some disagreements between developed and developing members in regards to bringing intellectual property rights into the trading regime in the Uruguay Round Negotiation, TRIPS' conclusion indicated the success of the 'US-led

29 Art. 27.2, the TRIPS Agreement.

30 The WTO Ministerial Conference suggests that the TRIPS Council's work 'shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.' See para. 19, Ministerial Declaration, adopted at the Fourth Session of the Ministerial Conference at Doha on 14 November 2001, WT/MIN(01)/DEC/1.

31 Para. 5(a), the 2001 Doha Declaration.

32 *Canada–Patent Protection of Pharmaceutical Products (Canada–Pharmaceutical Patents)*, Panel Report (WT/DS114/R, 17 March 2000), para. 7.26.

33 Jackson, *supra* note 9, at 247.

34 *Brazil – Measures Affecting Imports of Retreaded Tyres* (*Brazil – Retreaded Tyres*), Appellate Body Report (WT/DS332/AB/R, 3 December 2007), para. 210.

effort' in overcoming developing members' concerns over public health.[35] However, during TRIPS' post-Uruguay implementation, developing countries' concerns in the Uruguay Round were soon being realized, and '[t]he TRIPS Agreement would in fact be invoked to prevent them from addressing their public health needs'.[36] Developing countries' concerns evolved over the years and Zimbabwe's request on behalf of the African Group at a TRIPS Council meeting in 2001 triggered discussion on access to medicines, which eventually led to the 2001 Doha Declaration.[37]

The 2001 Doha Declaration is 'a significant milestone' addressing developing country concerns regarding access to medicines and TRIPS.[38] According to the Declaration, the TRIPS Agreement 'does not and should not prevent members from taking measures to protect public health', rather 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.[39] Most importantly, the Declaration states:

> We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[40]

TRIPS' perspective towards compulsory licensing as reflected in the Doha Declaration remains quite 'conservative'. According to the Doha Declaration, each WTO member 'has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'.[41] This seems to indicate that the compulsory licensing domain falls completely within the domestic government's authority. Similarly, as to what constitutes national emergency or extreme urgency, the Doha Declaration states that each member has the complete right of determination.[42] So far there remains a delicate international-domestic balance: while members' right of resorting to compulsory licensing is justified under international framework, how intellectual property rights are treated for public health considerations and under what circumstances remain issues of domestic law. This international-domestic balance as to compulsory licensing is consistent with the Paris Convention that permits compulsory licensing yet neither limits the grant of compulsory licenses nor establishes any right to remuneration on behalf of patent right holders, rather leaves them solely to domestic authorities.[43]

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35 F.M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO', (2002) 5 *Journal of International Economic Law* 469, at 470.
36 Ibid., 471–2.
37 Ibid., 480–1.
38 Ibid., 470.
39 Para. 4, the 2001 Doha Declaration.
40 Ibid., para. 6.
41 Ibid., para. 5(b).
42 Ibid., para. 5(c).
43 Art. 5A, Paris Convention for the Protection of Industrial Property (Paris Convention), as amended on 28 September 1979. For more details on the compulsory licensing mechanism in the Paris Convention, see Section 3.3.

The delicate balance soon came to an end when the international trading regime details treatments of intellectual property rights under TRIPS' 2003 Waiver and then the 2005 Amendment. In August 2003, the WTO General Council came to a decision on the implementation of this instruction of the Ministerial Conference, the TRIPS Waiver.[44] Under the TRIPS Waiver, if any member grants a compulsory license to produce pharmaceutical products for the purpose of exporting to any least-developed country member or any other member 'has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question', the TRIPS obligation of limiting compulsory licensing products to domestic use will be waived.[45] Under this TRIPS Waiver system, the 'adequate remuneration' that the exporting member paid will need to 'tak[e] into account the economic value to the importing member of the use that has been authorized in the exporting member'.[46] At the same time, the TRIPS obligation of the importing member to pay the right holders adequate remuneration will be waived.[47] By shifting remuneration claim from both importing and exporting members to exporting member only, the TRIPS Waiver therefore steps into the domestic realm of private rights treatment. While the Declaration bears significant 'interpretative value' yet does not change the TRIPS Agreement, the Waiver 'necessitated a far more "drastic" legal solution that would allow members to do something that was not allowed under the TRIPS Agreement'.[48] The delicate international-domestic balance in the Doha Declaration is thus broken.

The TRIPS Waiver establishes a detailed and complex mechanism to 'facilitate' public health flexibility. First of all, the Waiver has a limited scope of application as it, in general, applies only to patented pharmaceutical products 'needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration'.[49] This text is actually a compromise after going through fierce debates between developing and developed countries – the US in particular – as to the scope-of-diseases issue, i.e., whether the Waiver should only be applicable to a list of diseases or not.[50] Although it has now been generally recognized that the disease scope of the Waiver is flexible,[51] Canada, as the first developed country to use this Waiver for export, prescribed a list of limited pharmaceutical products eligible for export under license in its legislation to implement the Waiver.[52] Secondly, the Waiver limits the

44 WTO General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', WT/L/540 and Corr.1, 1 September 2003 (hereafter the TRIPS Waiver).
45 Para. 2, the TRIPS Waiver. For the TRIPS obligation, see Art. 31(f), the TRIPS Agreement.
46 Para. 3, the TRIPS Waiver.
47 Ibid. For the TRIPS obligation, see Art. 31(h), the TRIPS Agreement.
48 P. Vandoren and J.C. Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work', (2003) 6 *The Journal of World Intellectual Property* 779, at 780.
49 Para. 1(a), the TRIPS Waiver.
50 Abbott, *supra* note 7 (2005), 327–32. According to Abbott, countries like the US, Japan, and Switzerland supported the limited view of the scope of diseases for the purpose of 'limit[ing] the number of patented technologies subject to compulsory licensing for export.' Ibid., 329.
51 Vandoren & Eeckhaute, *supra* note 48, at 785.
52 Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act* (*The Jean Chrétien Pledge to Africa*), passed at the 3rd Session of the 37th Parliament of Canada, assented to 14 May 2004. Under section 21.02 of the Act, pharmaceutical products under the TRIPS Waiver system are limited to those 56 patented pharmaceutical products listed in Schedule 1 of the Act. For the debates on the legislation in Canada, see Abbott, *supra* note 7 (2005), 332–3.

scope of benefited countries as it confines eligible importing countries to least developed countries and any other country that 'has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question'.[53] It is worth mentioning here that the limited country scope of importing members was to 'compensate' for the failure to limit the scope of diseases and 'interest in limiting the prospective importing countries was consistent with a general interest in limiting the use of the [waiver] system'.[54] Thirdly, the Waiver established a detailed procedure to regulate any member's use of the system as an importer. A member must satisfy certain procedural requirements, including submitting a one-time notification to the TRIPS Council of its interest, and the 'insufficient or no manufacturing capacity' determination made.[55] Moreover, the assessment on manufacturing capacity must be based on 'a product-by-product' basis rather than on a sectoral basis.[56] Fourthly, the use of the waiver system is subject to good faith and transparency checks. According to the statement of the Chairman of the Council for TRIPS, the waiver system 'should be used in good faith to protect public health and, without prejudice to paragraph 6 of the [Doha] Decision, not be an instrument to pursue industrial or commercial policy objectives'.[57]

Undoubtedly, the TRIPS Waiver attempted to offer a solution to public health crises. As Abbott suggests, the TRIPS Waiver 'represents a success for developing countries in the pursuit of their public health agenda at the WTO'.[58] Later on in December 2005, the WTO General Council agreed to make health flexibility permanent by incorporating the TRIPS Waiver into the TRIPS regime through an amendment.[59] According to this decision, the Protocol Amending the TRIPS Agreement will insert Article 31 *bis* after Article 31 and insert an explanatory Annex to the TRIPS Agreement after Article 73.[60] The Protocol prohibits reservations and originally was open for acceptance by members until 1 December 2007.[61] The deadline for member acceptance was extended five times and the latest General Council decision of 30 November 2015 extended the acceptance deadline to 31 December 2017.[62] So far

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53 Paras. 1(b) and 2(a)(ii), the TRIPS Waiver. Of course, this limitation makes sense theoretically as those countries with sufficient manufacturing capacity do not need the waiver. However, singling out those countries with insufficient or no manufacturing capacity together with the procedural and good faith limitations (discussed next in the same paragraph) clearly reflects the TRIPS Waiver's intention of limiting the use of the waiver system as much as possible.

54 Abbott, *supra* note 7 (2005), at 331, 335.

55 Para. 2(a), the TRIPS Waiver.

56 Vandoren and Eeckhaute, *supra* note 48, 785–6.

57 WTO General Council, Minutes of Meeting held in the Centre William Rappard on 25, 26, and 30 August 2003 (WT/GC/M/82, 13 November 2003), para. 29. The Chairman's statement also makes a clear reference to transparency (Ibid., para. 29) that:

> To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

58 Abbott, *supra* note 7 (2005), 343; See also, Vandoren and Eeckhaute, *supra* note 48, at 780.

59 WTO General Council, Amendment of the TRIPS Agreement.

60 Para. 1, Protocol Amending the TRIPS Agreement.

61 Ibid., paras. 2, 3.

62 WTO General Council, 'Amendment of the TRIPS Agreement – Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement' (WT/L/965, Decision of 30 November 2015).

there are 93 – including 28 EU member states – out of 162 WTO members that have accepted the Protocol.[63] As the current acceptance is still far below the two-thirds majority as required under the WTO Agreement to bring an amendment into effect in the absence of a consensus, the Protocol is still not in effect.[64]

The public health flexibilities reflected in the TRIPS Waiver and Amendment were warmly welcomed at the very beginning. More recent assessments, however, 'have been more equivocal'.[65] The TRIPS Waiver 'has not been as successful as the WTO had hoped'.[66] There is actually only one successful case under the TRIPS Waiver system by Rwanda in importing TriAvir, a combination AIDS drug from Canada around 2007.[67] Some suggest that the TRIPS Waiver system is far from adequate to tackle current public health crisis of the Ebola epidemic outbreak.[68] The ineffectiveness or even failure of the TRIPS Waiver and Amendment leads us to the issue of the dynamics between compulsory licensing and public health, in particular the nature of TRIPS' compulsory licensing system. Moreover, breaking the international-domestic balance by allowing the WTO regime to handle 'private' intellectual property rights as to compulsory licensing that originally regulated solely by domestic regime, the TRIPS Amendment faces theoretical challenges in international law.[69]

3. Public health caught in TRIPS' birth defect

3.1. The private rights dilemma and TRIPS' philosophical paradox

As the analysis above indicates, TRIPS' treatment of intellectual property rights in compulsory licensing shifts over time. From Doha Declaration to TRIPS Amendment, the classic international-domestic balance was transcended as TRIPS' international compulsory licensing mechanism steps into issues of procedure, condition and remuneration of pharmaceutical patents that were solely regulated within domestic realm before. We are thus led to the question as to the nature of intellectual property rights under the TRIPS framework.

The TRIPS Agreement indeed spells out its intellectual property philosophy clearly. As to the nature of intellectual property rights, the Preamble of the TRIPS Agreement states that WTO members recognize that 'intellectual property rights are

63 WTO, 'Members Accepting Amendment of the TRIPS Agreement', available on the WTO official site: www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 20 February 2016).

64 Art. X.1, Marrakesh Agreement Establishing the World Trade Organization (the WTO Agreement).

65 L.R. Helfer and G.W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (2011), 124.

66 R. Thapa, 'Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement', (2011) 16 *Journal of Intellectual Property Rights* 470, at 472.

67 By July 2014, only Rwanda notified the Council for TRIPS as the importer and Canada notified the Council for TRIPS as the exporter under the paragraph 6 system. See Rwanda, 'Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (IP/N/9/RWA/1, 19 July 2007); Canada, 'Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (IP/N/10/CAN/1, 8 October 2007).

68 G. Moretti, 'Better be safe than sorry: should the regulation on patent compulsory licensing for exportation be reconsidered?' *Queen Mary Journal of Intellectual Property* online posts, 23 December 2014. Available at qmjip.wordpress.com/2014/12/ (accessed 10 March 2015).

69 See discussion in Section 4.

private rights'.[70] TRIPS' reference to 'private rights' was incorporated into the Agreement at the insistence of the Hong Kong delegation during the TRIPS Agreement negotiations.[71] Indeed, in as early as the 1989 submission to the Group of Negotiation on Goods (GATT), the Hong Kong delegation suggested that 'emphasis should be placed on civil remedies (as distinct from criminal and administrative remedies) on the grounds that intellectual property rights are primarily *private rights*'.[72] As to the question of the types of procedures to be provided, Hong Kong suggested:

> While participants should be free to decide to protect IPRs by means of civil, criminal, or administrative procedures or a combination of these, in accordance with their national legal systems, Hong Kong considers that emphasis should rest primarily on civil procedures, as they appear the most appropriate to protect *private rights.*[73]

Undoubtedly, the Hong Kong delegation's purpose of referencing to private rights was to clarify that the enforcement of intellectual property rights is the responsibility of private rights holders rather than of governments. Moreover, this enforcement responsibility shifting effect is well reflected in the TRIPS Agreement. The 'common feature' of the Sections in Part III of the TRIPS Agreement in resting the responsibility of initiating various protection procedures on private right holders, for example, indicates well 'the nature of intellectual property rights as private rights'.[74]

Recognizing intellectual property rights as private rights not only shifts the responsibility of enforcement to private rights holders from the governments, but also at the same time creates a barring effect against unwanted government actions. This is because the private right nature means that limits are set on third parties and even public authorities, preventing them from engaging in illegitimate infringement, which also reveals the negative right nature of intellectual property rights. In its examination of the nature of exclusive right conferred under Article 16.1 in *EC – Trademarks and Geographical Indications*, the Panel suggested that it is an exclusive right that 'belongs to the owner of the registered trademark alone, who may exercise it to prevent certain uses by "all third parties" not having the owner's consent'.[75] The Panel further confirmed that Article 16.1 'only provides for a *negative right* to prevent all third parties from using signs in certain circumstances'.[76] Therefore, the

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70 Fourth Recital of the Preamble, the TRIPS Agreement.

71 F.M. Abbott, 'Technology and State Enterprise in the WTO', in *World Trade Forum: State Trading in the Twenty-First Century* (1998), at 144, footnote 11.

72 Enforcement of Intellectual Property Rights, Hong Kong Submission to Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (MTN.GNG/NG11/W/54, 7 December 1989), para. 6 (p. 2). Emphasis added.

73 Ibid., at para. 9 (p. 2). Emphasis added.

74 *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (*China – Intellectual Property Rights*), Panel Report (WT/DS362/R, 26 January 2009), para. 7.247. According to the Panel:

> The Panel also observes that a common feature of Sections 2, 3 and 4 of Part III of the TRIPS Agreement is that the initiation of procedures under these Sections is generally the responsibility of private right holders… This is consistent with the nature of intellectual property rights as private rights, as recognized in the fourth recital of the preamble of the TRIPS Agreement. Acquisition procedures for substantive rights and civil enforcement procedures generally have to be initiated by the right holder and not *ex officio.*

75 *EC - Trademarks and Geographical Indications (Australia)*, Panel report, para. 7.602.

76 Ibid., para. 7.611, footnote 558. Emphasis added.

Panel suggested that 'the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of *negative rights* to prevent certain acts'.[77] The private right barring effect, however, has been eroded as TRIPS' 2003 Waiver and 2005 Amendment stepped into detailing compulsory licensing treatments of private-rights-natured pharmaceuticals that originally fall into the domestic law domain.[78] This erosion further creates a legitimacy issue of the TRIPS Waiver and Amendment in international law.[79]

The erosion of private right's barring effect further reveals the paradox of TRIPS' intellectual property philosophy. In addition to its recognition of intellectual property rights as private and negative rights, the TRIPS Agreement also emphasizes intellectual property rights' public implications. Indeed, TRIPS' philosophy is to achieve a balance between rights and obligations in intellectual property rights protection. The TRIPS Agreement states its objective clearly:

> 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.[80]

For this purpose of balancing rights and obligations, the TRIPS Agreement allows members to 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', and measures to prevent right holders' intellectual property rights abuse or anti-competition practices, as long as these measures are TRIPS consistent.[81] It is for this purpose of balancing rights with obligations that the TRIPS Agreement provides various exceptions and limitations to the exclusive rights conferred by a copyright, trademark, industrial design, or patent respectively.[82]

However, intellectual property rights' private right nature and public interest implications do not necessarily reconcile well. Research has shown that the TRIPS is always caught in a paradoxical tension between the protection of private rights and the accommodation of public interests.[83] In fact, the private right nature might put intellectual property right protection in conflict with third party interests or even public interests. When this kind of situation arises, where to draw the line of balance between the private right holders' interests and interests of others becomes a significant issue. In *China – Intellectual Property Rights*, when China invoked the sovereign exception under Article 17 of the Berne Convention to justify its denial of copyright protection to illegal and unconstitutional publications, the Panel rejected China's claim. The Panel suggested:

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77 Ibid., para. 7.210. Emphasis added.
78 See discussion in Section 2.2.
79 See discussion in Section 4.2 in particular.
80 Art. 7, TRIPS Agreement. Emphasis added.
81 Arts. 8(1) and 8(2), TRIPS Agreement.
82 For TRIPS' exceptions to intellectual property rights and the nature of compulsory licensing, see discussion in Section 3.2.
83 W. Guan, 'The Poverty of Intellectual Property Philosophy', (2008) 38 *Hong Kong Law Journal* 359, at 393–6.

> ... that copyright and government censorship address different rights and interests. Copyright protects private rights, as reflected in the fourth recital of the preamble to the TRIPS Agreement, whilst government censorship addresses public interests.[84]

As the only case touching on the tension between private rights and public interests in the context of the TRIPS Agreement, this case carries significant weight in the WTO's jurisprudence as to TRIPS' objectives and principles, the balance of rights and obligations in particular. By emphasizing the private rights recital of the TRIPS preamble over the Berne Convention's sovereign exception (incorporated into TRIPS through Art. 9), the WTO Panel shows preference to private rights considerations in the tension between private rights and public interests. Tipping the balance towards private rights may overshadow TRIPS' objectives and principles in Articles 7 and 8 that are supposed to guide the reading of each provision of the TRIPS Agreement.[85] This tipping of the balance in favour of private rights is as problematic as the 2005 Amendment's breaking private right's barring effect, as both fail to maintain the balance of rights and obligations. It might be more desirable if the Panel could exercise its judicial self-restraint on the issue, as how to limit private rights for public interest within a given country is a constitutional issue that falls into domestic law. Further examination next on the nature and context of compulsory licensing indicates that TRIPS' philosophy paradox reveals itself in the confusion of taking account of the legitimate interests of third parties in exceptions to various intellectual property rights. While exceptions to trademarks, patents, and industrial designs should take into account the legitimate interests of third parties, exceptions to copyrights are not required to do so in the TRIPS Agreement. TRIPS' intellectual property philosophy paradox, as will be revealed in the sections next, developed at TRIPS' founding moment, is indeed its birth defect.

3.2. The nature and context of TRIPS compulsory licensing

While intellectual property rights are recognized as private rights, compulsory licensing is incorporated into the TRIPS regime as one of the exceptions and limitations to intellectual property rights. According to Article 30 of the TRIPS Agreement, members may balance a patent's exclusive rights with certain exceptions. However, TRIPS requires that these 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'.[86] Within this context, compulsory licensing is permitted – though not directly mentioned – under Article 31 of the TRIPS Agreement. The TRIPS Agreement itself does not spell out 'compulsory licensing' exactly. Rather, it states, if a member 'allows for other use of the subject matter of a patent without the authorization of the right holder', requirements like limiting to domestic use and paying adequate remuneration to the right holder should be observed.[87] According to the Panel in

84 *China – Intellectual Property Rights*, Panel Report, para. 7.135.
85 Para. 5(a), the 2001 Doha Declaration.
86 Art. 30, the TRIPS Agreement.
87 Art. 31, the TRIPS Agreement.

Canada – Pharmaceutical Patents, Articles 30 and 31 'are linked together' and 'both provisions permit exceptions to patent rights subject to certain mandatory conditions'.[88]

Compulsory licensing being one of the exceptions and limitations to patent rights provides us with a fundamental framework to examine the nature and boundary of the compulsory licensing regime in TRIPS. The jurisprudence of the exceptions and limitations to various intellectual property rights under TRIPS, and the origin of the patent exceptions in TRIPS in particular, sheds light on the issue. Similar to exceptions to patent rights provided in Article 30, TRIPS regime also provides exceptions to copyrights in Article 13, exceptions to trademark rights in Article 17, and exceptions to industrial designs in Article 26(2) of the TRIPS Agreement. According to the Panel in *Canada – Pharmaceutical Patents*, the general provision of Article 30 of the TRIPS Agreement 'was obviously based on the text of Article 9(2) of the Berne Convention' that deals with copyright exceptions in reproduction of copyright work without permission.[89] The text of the Berne Convention, on which Article 30 was modeled, reads as follows:

> It shall be a matter for legislation in the countries of the Union to permit the reproduction of [literary and artistic] works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.[90]

Most importantly, as the Panel in *Canada – Pharmaceutical Patents* rightly pointed out, other exceptions to copyright, trademark, and industrial design in the TRIPS Agreement share the same origin of Article 9(2) of the Berne Convention.[91] Moreover, the Panel also noticed that the Berne text was incorporated into Article 30 of the TRIPS Agreement with certain changes.[92] In addition to the final condition of the 'legitimate interests' of right holder in Berne text, the TRIPS' text added that account must also be taken of 'the legitimate interests of third parties'.[93] As in exceptions to patent rights, exceptions to trademark rights and industrial designs both added a requirement of account being taken of 'the legitimate interests of third parties' in addition to legitimate interests of right holders.[94] In the context of TRIPS, legitimate

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88 *Canada – Pharmaceutical Patents*, Panel Report, para. 7.91. However, it should be made clear that Art. 30 and Art. 31 are distinct from one another. Although the three conditions set forth by Art. 30 define the kind and scope of the permissible exceptions, Art. 30 itself does not list the specific acts that might be exempted. Art. 31 then deals with 'other use' – i.e., use other than that allowed under Art. 30 – that requires no authorization from the right holders. This formulation indicates the drafters' intension of distinguishing the 'limited exceptions' that are authorized under Art. 30 from compulsory licensing authorized under Art. 31.

89 Ibid., at para. 7.71.

90 Art. 9(2), Berne Convention.

91 The Panel in *Canada – Pharmaceutical Patents* (Original footnote 420 to para. 7.71) states:

> The text of Berne Article 9(2) also served as the model for three other exceptions clauses in the TRIPS Agreement - Articles 13, 17 and 26.2, providing respectively for similar exceptions from obligations on copyright, trademarks and industrial designs. Article 13 is a nearly identical copy of Berne Article 9(2). Like Article 30, both Articles 17 and 26.2 made small changes to the text of Berne Article 9(2).

92 *Canada – Pharmaceutical Patents*, Panel Report, para. 7.71.

93 Art. 30, the TRIPS Agreement.

94 Arts. 17 and 26(2), the TRIPS Agreement.

interests are 'used to help define the scope of an intellectual property right or rights by helping to ascertain the nature of the rights and carve out the exceptions to what is expressly stated to be a right or rights'.[95] As for the exceptions to trademark rights for example, the TRIPS Agreement states:

> Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.[96]

However, as for the exceptions to copyright, the TRIPS Agreement closely adopts the text of the Article 9(2) of the Berne Convention and makes no reference to any account of the legitimate interests of third parties.[97] The absence of the reference to the account of legitimate interests of third parties makes it distinctive from the trademark, industrial design and patent exceptions in TRIPS regime. Absent any documentation of the TRIPS negotiations or any WTO jurisprudence to explain the distinction, it is almost impossible to understand what significant implications WTO negotiators intended to attach to this distinction. However, this distinction cannot be a mistake and must mean something, as has been emphasized by the Appellate Body in *US – Gasoline* stating that any 'interpretation must give meaning and effect to all the terms of a treaty'.[98] A reasonable interpretation of this distinction would at least mean that there are different limitations and exception to copyright and patent rights, and that the legitimate interests of third parties are present as a limitation to right holder's exclusive rights in patent rights but not copyrights.

According to the Panel in *Canada – Pharmaceutical Patents*, 'legitimate interests' are different from 'legal interests' as third parties 'are by definition parties who have no legal rights at all' in being able to accomplish the tasks excluded by patent rights.[99] The term 'legitimate interests' therefore 'must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms'.[100] The Panel thus suggests that the reference to 'legitimate interests of third parties' indicates that the term 'legitimate interests' should be 'construed as a concept broader than legal interests'.[101] As for 'third parties', unfortunately, there is not much jurisprudence in this context. The available interpretation can only be found in relation to trademark exceptions. In

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95 M. Davison and P. Emerton, 'Rights, Privileges, Legitimate Interests, and Justifiability: Article 20 of TRIPS and Plain Packaging of Tobacco', (2014) 29(3) *American University International Law Review*, 505, at 528. According to the authors (at 530), '[t]he legitimate interests of the third parties are a basis for considering whether there exists a right to exclude others from using copyrighted or patented subject-matter, designs, and trademarks.'

96 Art. 17, the TRIPS Agreement.

97 Art. 13 of the TRIPS Agreement reads as follows:

> Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

98 *United States – Standards for Reformulated and Conventional Gasoline* (*US – Gasoline*), Appellate Body report (WT/DS2/AB/R, 29 April 1996), at 23.

99 *Canada – Pharmaceutical Patents*, Panel Report, para. 7.68.

100 Ibid., at para. 7.69.

101 Ibid., at para. 7.71.

EC — *Trademarks and Geographical Indications*, the Panel considered that 'third parties' include consumers:

> The parties to this dispute agree that "third parties" for the purposes of Article 17 include consumers. The function of a trademark is to distinguish goods and services of undertakings in the course of trade. That function is served not only for the owner, but also for consumers. Accordingly, the relevant third parties include consumers. Consumers have a legitimate interest in being able to distinguish the goods and services of one undertaking from those of another, and to avoid confusion.[102]

In the same context, 'third parties' in the context of Article 17 of the TRIPS Agreement include persons using a geographical indication (GI) in accordance with a GI registration.[103]

The above search for the origin of TRIPS' patent exceptions carries several significant implications. First, there is an important discrepancy as to TRIPS' intellectual property exception regime. The legitimate interests of third parties should be taken into account in exceptions to trademarks, patents, and industrial designs but not in exceptions to copyrights. Second, the legitimate interests – normative claims which are not of legal interest yet broader than legal interests justifiable by 'relevant public policies or other social norms' – of third parties can serve as a limitation to check and balance with the legal interests of right holders. Moreover, third parties could be consumers or users of relevant intellectual property rights. Third, although compulsory licensing as exception justifies legitimate interests of third parties to limit private rights, TRIPS Agreement says nothing about how to limit these private rights. Essentially, limitation of private rights is a constitutional issue falling into the domain of domestic law.

As the legitimate interests of third parties serving as the foundation of exceptions to intellectual property rights are claims justifiable by 'relevant public policies or other social norms', the legitimate interests of third parties and public concerns should at least be consistent if not identical with each other. As the Panel pointed out in *Canada – Pharmaceutical Patents*, the scope and conditions of the patent exceptions 'must be examined with particular care', and '[b]oth the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind'.[104] In the same way public concerns check and balance with private intellectual property rights as prescribed in Articles 7 and 8.1, the legitimate interests of third parties serve as exceptions to various intellectual property rights. It is therefore not surprising to see that confusion as to the jurisprudence of the legitimate third party interests

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102 *EC - Trademarks and Geographical Indications (Australia)*, Panel report, para. 7.675.

103 Ibid., at para. 7.679, the Panel states:

> The European Communities submits that "third parties" for the purposes of Article 17 include persons using a GI in accordance with a GI registration. The Panel agrees. Article 17 permits an exception to the rights conferred by a trademark which include, according to Article 16.1, a right to prevent "all third parties" from using certain signs. The basis of the complainant's claim is that those third parties include GI users. It is logical that, if GI users are included in the third parties subject to the trademark owner's right, they are also included in the third parties taken into account in assessing the availability of an exception to that right.

104 *Canada – Pharmaceutical Patents*, Panel Report, para. 7.26.

in compulsory licensing clearly reveals TRIPS' private right philosophy paradox. Indeed, as the section next will indicates, they are sharing the same root of TRIPS' birth defect.

3.3 The birth defect of the TRIPS agreement

The root of TRIPS' philosophy paradox and compulsory licensing's jurisprudential confusion as to third party interests can be traced back to the founding moment of the TRIPS regime. Before the introduction of intellectual property rights into the international trading framework through the TRIPS Agreement, intellectual property was still the domain of specialists and intellectual property right producers.[105] TRIPS' incorporation of intellectual property into the international trading framework 'elicited great concern over its pervasive role in people's lives and in society in general'.[106] This incorporation reveals serious international contentions and divides regarding protection between the developed and developing countries. The intellectual property rights divide between the North and the South is evident in TRIPS negotiation, in particular during the process of the formulation of the Preamble and the Objectives and Principles provisions of the TRIPS Agreement.

TRIPS negotiation started at the GATT Ministerial Conference at Punta del Este, Uruguay in September 1986, a critical moment 'when the negotiations between developed and less-developed countries over the revision of the Paris Convention were deadlocked at WIPO'.[107] Before the Uruguay Round, in the 1970s in particular, developing countries focused very much on establishing new rules on a New International Economic Order (NIEO) that depended on greater access to technology protected by intellectual property rights in developed countries. Developed countries, however, have been very much concerned with the WIPO system's failure to provide effective protections to the interests of their technology-based and expressive industries.[108] As one of the principle 'new area' negotiations in the Uruguay Round, the incorporation of intellectual property rights into international trade was quite controversial and opinions were divided between developing and developed countries.[109]

The negotiation process of the TRIPS clearly indicates the contentions around intellectual property rights protection between the developed and developing countries. While the draft legal text from developed countries including the EC, the US, Japan, Switzerland, and Australia – the "A" text – emphasizes the domestic enforcement and the applicability of GATT dispute settlement mechanism to TRIPS disputes, a dozen developing countries proposed another legal text – the "B" text – with a focus on maintaining flexibility to implement economic and social development objectives.[110] At the very beginning of the negotiation, developed countries

105 R. Ricupero and R. Melendez Ortiz, 'Preface', in UNCTAD and ICTSD eds., *Resource Book on TRIPS and Development* (2005) vii.
106 Ibid.
107 Yu, *supra* note 6, at 982.
108 UNCTAD-ICTSD, *supra* note 18, at 3.
109 Ibid., 3–4. The other 'new area' negotiation in the Uruguay Round concerned trade in services which resulted in the General Agreement on Trade in Services (GATS); See also, Yu, *supra* note 6, at 983–4.
110 D.J. Gervais, 'Intellectual Property, Trade & Development: The State of Play', (2005) 74 *Fordham Law Review* 505, at 507–8.

and a few developing countries were only expecting a Tokyo Round type 'code' to be incorporated into the GATT framework. The US proposal submitted to the Group of Negotiation on Goods (GATT) in 1988 for example, suggests as one of the objectives to '[e]ncourage non-signatory governments to adopt and enforce the agreed standards for protection of intellectual property and join the [GATT] agreement'.[111] In relation to revision and amendment of the GATT, the US proposed an open mechanism that is able to accommodate future consensus on improved protection for new forms of technology and creativity.[112]

India, however, submitted a detailed paper indicating a developing country perspective in sharp contrast with US proposal.[113] India suggested that only the restrictive and anti-competitive practices of the intellectual property right owners 'can be considered to be trade-related because they alone distort or impede international trade'.[114] India therefore suggested that, according to the mandates from the Trade Negotiation Committee, the negotiation on trade-related aspects of intellectual property rights:

> ... should be governed by the concerns and public policy objectives underlying the national systems for the protection of intellectual property, including developmental and technological objectives. This is particularly important for developing countries because the intellectual property system has wide ranging implications for their economic and social development. Any principle or standard relating to intellectual property rights should be carefully tested against the touchstone of the socio-economic, developmental, technological and public interest needs of developing countries.[115]

Therefore, India concluded that '[i]t would ... not be appropriate to establish within the framework of the General Agreement on Tariffs and Trade any new rules and disciplines pertaining to standards and principles concerning the availability, scope and use of intellectual property rights'.[116] However, due to the threats of sanctions and implicit dismantling of the GATT, as well as concessions offered by developed countries in other areas like agriculture and textiles, 'the resistance of developing countries was overcome'.[117] The final result of the Uruguay Round mirrored the A text and 'embodied norms that had been accepted by industrialized countries', and developing countries' concerns 'were reflected in large part in two provisions—Articles 7 and 8 [of the TRIPS Agreement]'.[118]

The negotiating process of the compulsory licensing provision Article 31 in TRIPS perfectly reflects this dynamics. Prior to TRIPS, compulsory licensing was

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111 US submission, 'Suggestion by the United States for Achieving the Negotiating Objective (Revision)' (MTN.GNG/NG11/W/14/Rev.1, 17 October 1988), Communication from the US to, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, 3.
112 Ibid., 18.
113 Indian submission, 'Standards and Principles concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights' (MTN.GNG/NG11/W/37, 10 July 1989), Communication from India to Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods.
114 Ibid., 2.
115 Ibid.
116 Ibid., 19–20.
117 UNCTAD-ICTSD, *supra* note 18, at 4.
118 Gervais, *supra* note 110, at 508.

indeed a common practice internationally.[119] The Paris Convention, for example, explicitly states that each country 'shall have the right to take legislative measures providing for the grant of compulsory licenses'.[120] The negotiation revising the Paris Convention broke down in 1982, 'in significant part because of competing demands concerning compulsory licensing' between developing countries' NIEO demands for technology sharing and developed countries' demands for stronger protection of proprietary interests of patents.[121] India's submission in 1989, for example, proposed a compulsory licensing regime that covers licensing for non-working, and licenses of rights relating to food, medicine, and agricultural chemicals.[122] It is worth mentioning that the Paris Convention expressly allows compulsory licensing if patents fail to work locally.[123] However, the final result of the compulsory licensing negotiation reflected developed countries' interests and the compulsory licensing on grounds of non-working was taken out.[124]

Similar dynamics can also be found in the process of negotiating the enforcement principles of the TRIPS Agreement. During the Uruguay Round, the establishment of detailed rules enforcing intellectual property rights was led by the EC and the US.[125] The EC and the US texts 'reflected the view of the business community', and the US and the EC 'largely imposed their own conception of the subject'.[126] The Indian delegation expressed concerns as to the enforcement obligations' institutional implications, in particularly to developing countries.[127] Based on the Indian proposal, developing countries' concerns were only reflected in Article 41.5, which allow members 'to avoid any obligation to establish a special judicial system to enforce IPRs or to assign specific resources, but did not influence otherwise very much the outcome of the negotiations'.[128]

The successful incorporation of intellectual property rights into the WTO through the conclusion of the TRIPS Agreement to some extent recognizes the power asymmetry and legalizes the fragmentation between the developed and developing countries. This unfortunate intellectual property rights divide between the North and the South in this regard is the birth defect of the TRIPS regime within

119 UNCTAD-ICTSD, *supra* note 18, at 462.
120 Art. 5.A(2), Paris Convention.
121 UNCTAD-ICTSD, *supra* note 18, at 463.
122 Indian submission, 'Standards and Principles concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights'.
123 Arts. 5.A(2) and (4), the Paris Convention.
124 The issue of licensing on grounds of non-working was addressed indirectly by Arts. 27.1 and 70.6 of the Agreement. See UNCTAD-ICTSD, *supra* note 18, at 467.
125 For the EC's submission, see 'Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights,' (MTN.GNG/NG11/W/16, 20 November 1987), Communication from the EC to Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods; for US's submission, see 'Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights: Communication from the United States' (MTN.GNG/NG11/W70, 11 May 1990), Communication from the US to Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods.
126 UNCTAD-ICTSD, *supra* note 18, at 578–9.
127 For the Indian delegation's submission, see 'Enforcement of Trade-Related Intellectual Property Rights: Communication from India' (MTN.GNG/NG11/W/40, 5 September 1989), Communication from India to Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods.
128 UNCTAD-ICTSD, *supra* note 18, at 579, 585.

the WTO framework.[129] Moreover, the negative implications of TRIPS' birth defect travel beyond the intellectual property rights framework and affect the entire WTO framework. Developing countries adopted new commitments regarding intellectual property rights protection in the Uruguay Round in the expectation of getting better market access in agriculture, textiles, and other sectors.[130] When these benefits failed to materialize, developing countries' dissatisfaction has become one of the key factors causing the deadlock of the Doha Round negotiation.[131]

The birth defect of TRIPS and the deadlock of the Doha Round negotiation have indeed been key to the failure of the 2003 TRIPS Waiver and 2005 TRIPS Amendment. As not much account of public interests and development has been taken in the TRIPS regime due to its birth defect, it is not surprising to see TRIPS' confusion as to taking account or not of the legitimate interests of third parties in exceptions to various intellectual property rights.[132] TRIPS Amendment's breaking the international-domestic balance worsens compulsory licensing mechanism's ability addressing public health concerns. Expecting TRIPS to address public health concerns in the 2003 Waiver and 2005 Amendment is therefore squaring a circle in vain. This further leads us to the question of the legitimacy of the TRIPS Waiver and Amendment. As rightly pointed out by the Appellate Body in *US – Gasoline* that WTO agreements are 'not to be read in clinical isolation from public international law',[133] the following examination will focus on the Waiver and Amendment's implications as to the dynamics between the WTO, members, and private rights from public international law perspective. It is submitted that the TRIPS Waiver or Amendment encounters legitimacy deficit in international law due to its unnecessary 'disrespect' to members' sovereign authority in managing public health and its intrusion into affairs of private parties that should originally be domestically regulated.

4. Public health, IPRs and trade: the private right dilemma in international law

4.1. Implications for members' trade autonomy in international law

Much research attributes the failure of the 2003 Waiver and the 2005 Amendment to strong pharmaceutical lobbying against the domestic legislative change accommodating public health flexibility and to the complexity of the cumbersome procedure.[134] Our above analysis on TRIPS' birth defect, however, indicates that the failure might be because of the paradox of sovereign management of private rights in

129 For more discussion on TRIPS' 'birth defect', see W. Guan, *Intellectual Property Theory and Practice: A Critical Examination of China's TRIPS Compliance and Beyond* (2014), 5–7.

130 United Nations Industrial Development Organization (UNIDO), *Public Goods for Economic Development* (2008), 80.

131 See for example, the coalition of developing countries known as the Like Minded Group (LMG)'s attempt to challenge the launch of the Doha Round negotiation. A. Narlikar, *World Trade Organization: A Very Short Introduction* (2005) 54–5; see also, Dinwoodie and Dreyfuss, *supra* note 6, 1188–9.

132 As to TRIPS' consideration of the legitimate interests of third parties in intellectual property exceptions, see discussion in Section 3.2.

133 *US – Gasoline*, Appellate Body report, 17.

134 See discussion in Section 2.2.

international trade.[135] Indeed, in the same way the Uruguay negotiation's incorporation of intellectual property rights into GATT creates TRIPS' birth defect, the establishment of TRIPS' authority of compulsory licensing over private-rights-natured pharmaceutical patents inevitably leads to the Waiver's failure. The Amendment raises an important question: how can TRIPS, as a public international law regime, handle the proprietary right to remuneration in compulsory licensing while recognizing that IPRs are private rights and TRIPS grants no positive rights? The key, as has been shown in the SPS Agreement for example, is the tension between the international free trade regime and members' sovereign rights to manage public health issues.[136] This tension indeed reflects the basic theme of international trade law – a tension between 'the necessity for legal rules conducive to stability and predictability, and the human need for solutions to short-term and ad hoc problems', or simply the 'dilemma of rule versus discretion'.[137] To answer this question, the paper in next two sections further looks at the dynamics between government and private rights in international trade and private rights' treatment in international law.

The balanced dynamics between the rigidity of the international regime versus the flexibility demanded from member states' sovereign autonomy situates at the center of the tension between rule versus discretion. Therefore, checks and balances the rigidity of international rules and commitments with flexibility accommodating members' domestic political needs is of fundamental importance to the legitimacy of international trade law.[138] WTO rules thus 'must strike a balance between commitments and flexibility'.[139] The TRIPS Agreement indeed provides certain flexibility. As we mentioned above, compulsory licensing was introduced as exceptions and limitations to patent rights.[140] Moreover, the TRIPS' 'general exceptions' mechanism as defined in Article 8.1 provides members flexibility in intellectual property enforcement for purposes of protecting public health and facilitating social development.[141] By leaving members the freedom to determine the grounds for compulsory licenses and to define situations of national emergency and extreme urgency, the Doha Declaration indeed recognizes this flexibility.[142] The recognition of the flexibility was well reflected throughout TRIPS' negotiation process. During TRIPS negotiation, the strong resistance from developing countries to the strict limits proposed by

135 See discussion in Sections 3.1 and 3.2, in particular Section 3.1.
136 Jackson, *supra* note 9, at 247; see main text associated with *supra* note 33.
137 J.H. Jackson, *The World Trading System: Law and Policy of International Economic Relations* (1997), at 10, 29.
138 See P. Sutherland et al., *The Future of the WTO: Addressing Institutional Challenges in the New Millennium* (2004), para. 39. According to the Report (para. 39), both GATT and the WTO have been 'intended to provide a structured and functionally effective way to harness the value of open trade to principle and fairness'; and their rules 'provide checks and balances including mechanisms that reflect political realism as well as free trade doctrine.'
139 WTO Secretariat, *World Trade Report 2009: Trade Policy Commitments and Contingency Measures* (2009), xiii. The Report (at xiii) states:

> Trade agreements define rules for the conduct of trade policy. These rules must strike a balance between commitments and flexibility. Too much flexibility may undermine the value of commitments, but too little flexibility may render the rules unsustainable.

140 For compulsory licensing as exceptions to patent rights, see discussion in Section 3.2.
141 For TRIPS' principles in Art. 8.1 as the 'general exceptions' mechanism, see discussion in Section 2.1.
142 See discussion in Section 2.2.

developed countries was the key reason leading to 'any enumeration of permissible grounds' for compulsory licensing in early negotiation text to be removed in order to give members more flexibility.[143]

However, the 2003 Waiver, as later on adopted in the 2005 Amendment, creates segmentation of compulsory licensing practice by defining 'eligible importing Member' and 'exporting Member'.[144] Detailed rules and procedures complicated the practicality of compulsory licensing; and waivers of the domestic use limitation and the remuneration requirement reallocated compulsory licensing administration among members.[145] Members, in particular importing members, are under obligations to 'take reasonable measures within their means' ensuring that the use of imported products is consistent with the Waiver.[146] In his comments on The US and EU viewpoints in TRIPS Waiver negotiation, Abbott suggests that there is 'a general interest in limiting the use of the [TRIPS Waiver] system'.[147] The 2003 Waiver and the 2005 Amendment, intending to provide more policy choice, turned out to significantly undermine the compulsory licensing flexibility in TRIPS and the Doha Declaration.

By undermining compulsory licensing flexibility, the 2003 Waiver and 2005 Amendment indeed go against the nature and scope of TRIPS' obligations under international law. According to the TRIPS Agreement, members on the one hand 'shall give effect to' TRIPS' provisions, yet on the other hand are 'free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'.[148] Similarly, when it comes to members' obligations regarding enforcement, the TRIPS Agreement states that members are under no obligation to change their institutions, capacity or resources distribution to law enforcement in their judicial systems.[149] Under international law, while states are required to fulfil their international obligations, generally they are also 'free as to the manner in which, domestically, they put themselves in the position to meet their international obligations'.[150] The TRIPS Agreement by its nature should pay deference to national authorities' sovereign freedom in managing critical situations of public health.

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143 UNCTAD-ICTSD, *supra* note 18, at 465.
144 Para. 1, 2003 TRIPS Waiver.
145 Paras. 2–3, 2003 TRIPS Waiver.
146 Paras. 4–5, 2003 TRIPS Waiver.
147 Abbott, *supra* note 7 (2005), at 335. According to Abbott (at 318.) the US considered the TRIPS Waiver as 'a problematic compromise', and 'has since sought to limit its scope of application' through bilateral or limited multilateral frameworks.
148 Art. 1.1, the TRIPS Agreement.
149 Art. 41.5 of the TRIPS Agreement states:

> It is understood that this Part [Part III – Enforcement of Intellectual Property Rights] does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

150 R. Jennings and A. Watts, *Oppenheim's International Law* (1992), at 82 § 1.

Not only they are inconsistent with the nature and scope of TRIPS' obligations, but also the Waiver and Amendment encounter legitimacy deficit in international law. As revealed above, the disturbing difference of the Waiver and Amendment from previous TRIPS Agreement lies in detailing domestic limitation of private-rights-natured pharmaceuticals, which essentially creates a 'direct effect' of international law over domestic issues. The nature and scope of the TRIPS obligations as defined in Article 1 of the Agreement have been well elaborated in the rich deliberation regarding the issue of the WTO Agreement's 'direct effect'. During the Uruguay round negotiation, the question of whether the WTO Agreement should be given direct effect attracted a great deal of attention among leading trade scholars.[151] Despite that, however, 'the question of direct effect was not a subject that drew the express attention of the TRIPS negotiators, at least as reflected in the minutes of the negotiating sessions'.[152] Members' practice varies on this issue. While Argentina accepts the direct effect, the US rejects the practice.[153] Under US law, for example, no person 'shall have any cause of action or defense' under WTO covered agreements, nor can they challenge 'any action or inaction' by any government authorities on the ground that such action or inaction is WTO inconsistent.[154] The European Union (EU) too states that the WTO Agreement, including its Annexes, by nature 'is not susceptible to being directly invoked in Community or Member State courts'.[155] It is therefore suggested that '[t]he most reasonable interpretation' of TRIPS' perspective on this issue 'would appear to be that each Member is free to determine whether it will apply the Agreement directly, and that this will depend on its legal system and practice'.[156] It in fact has been a well-established jurisprudence in international law that choices between giving international law direct effect and implementing them through transformation into national law 'are matters for each state to determine for itself according to its own constitutional practices'.[157] The nature of the WTO's direct effect jurisprudence prescribes the international regime's deference to national sovereign autonomy in international compliance.

From the jurisprudence of TRIPS's 'general exceptions' mechanism, to the scope and nature of the TRIPS obligation, to the WTO's direct effect jurisprudence, all appear to be calling for TRIPS' respect to national authorities in public health management as a way of balancing the rigidity of the trading regime. Intending to provide more policy choice tackling public health crisis, TRIPS' 2003 Waiver and 2005 Amendment conversely create segmentation of the compulsory licensing mechanism and significantly undermine the flexibility of the regime. The rigidity of the current compulsory licensing regime reflected in the 2003 Waiver and 2005 Amendment created more barriers to members' exercise of freedom in granting

151 M. Hilf and E. Petersmann, *National Constitutions and International Economic Law* (1993).
152 UNCTAD-ICTSD, *supra* note 18, at 23.
153 Ibid., at 31–5.
154 Section 102(c)(1)(A) and (B), Uruguay Round Agreements Act, Pub. L. 103-465, 108 Stat. 4818 (1994).
155 See, 94/800/EC: Council Decision (of 22 December 1994) concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986–1994).
156 UNCTAD-ICTSD, *supra* note 18, at 26.
157 Jennings and Watts, *supra* note 150, at 82–3.

compulsory licenses, and led to the failure of the Waiver's application and the Amendment's ratification. This has much to do with the birth defect of the TRIPS regime and certainly casts doubts on the legitimacy of 2003 TRIPS Waiver and 2005 TRIPS Amendment.

Further analysis below will indicate that the intrusive compulsory licensing regime as reflected in the Waiver and Amendment also intervenes in the private rights sphere that has been shielded from international intrusion in traditional international law. This intrusion into private-rights-natured pharmaceutical patents further undermines the legitimacy of TRIPS' current compulsory licensing regime.

4.2 Implications for private rights' treatment in international law

The Waiver and Amendment not only erode members' trade autonomy via limiting the compulsory licensing flexibility, but also intrude into individuals' rights by limiting a patent proprietor's right to adequate remuneration. The disrespect to members' sovereign rights in managing public health undermines the legitimacy of TRIPS Waiver and Amendment, as it is inconsistent with the nature and scope of the TRIPS obligation and the general jurisprudence of direct effect in international law. This indeed further creates another undesirable consequence in their intrusion into proprietary rights of individuals that originally should be domestically regulated.

As the name 'waiver' indicates, the TRIPS Amendment waives certain original compulsory licensing requirements on both exporting and importing countries for the purpose of providing more flexibility to address public health concerns. On the one hand, the Amendment waives Article 31(f)'s requirement that exporting countries limit compulsory licensing to be used predominantly for the supply of the domestic market. On the other hand, the Amendment waives Article 31(h)'s requirement on importing countries to pay adequate remuneration to proprietors. The key of the waivers then is the shift of the proprietors' right to remuneration from both exporting and importing countries to exporting countries only. The other provisions of the Waiver on limitation of the application scope, benefited countries, procedural requirement and good faith limitation are to facilitate this shift towards more flexibility. As the proprietor's remuneration arguably remains the same and the Waiver's impact on international trade is probably minimal. However, TRIPS' direct regulation of private parties' proprietor rights is highly unusual, as TRIPS exceptions should concern the use of rights only rather than the rights themselves.[158] Moreover, the remuneration right shifting effect indicates that the TRIPS Amendment touches the 'positive rights' aspect of intellectual property,[159] which runs at odds with the established jurisprudence that the negative right natured TRIPS regime does not give positive rights to use.[160] The TRIPS Amendment thus raises a fundamental question:

158 Carvalho, *supra* note 27, at 223.

159 While positive rights entitle a person 'to have another do some act for the benefit of the person entitled', negative rights 'entitl[e] a person to have another refrain from doing an act that might harm the person entitled'. See B.A. Garner, *Black's Law Dictionary* (2009).

160 *EC - Trademarks and Geographical Indications (Australia)*, Panel report, para. 7.210. For detailed discussion of the negative rights jurisprudence, see Section 3.1.

how would international law regulate private rights and could TRIPS directly touch private rights?

As the natural consequence of the direct effect jurisprudence, international regimes should refrain from intervening in individual rights within domestic affairs. This is well-established in GATT/WTO jurisprudence on the doctrine of direct effect. For example, the Panel in *US – Section 301 Trade Act* states:

> Under the doctrine of direct effect, which has been found to exist most notably in the legal order of the EC but also in certain free trade area agreements, obligations addressed to States are construed as creating legally enforceable rights and obligations for individuals. Neither the GATT nor the WTO has so far been interpreted by GATT/WTO institutions as a legal order producing direct effect. Following this approach, the GATT/WTO did *not* create a new legal order the subjects of which comprise both contracting parties or Members and their nationals.[161] (original footnote omitted)

Therefore, the GATT/WTO in general has no direct effect and consequently creates neither rights nor obligations on members' nationals.[162] Contracting parties of GATT or members of the WTO are not in the same legal order as their nationals.

It is thus a well-established jurisprudence that the WTO in particular or international law in general neither adds nor diminishes private rights of individuals. In fact, individuals are not subjects of international law, and consequently derive no rights nor bear any obligations under international law.[163] Long after the Westphalia era, the individual has not been the subject of international law,[164] and states have been traditionally been the only subjects of international law.[165] Individuals such as Heads of State or diplomatic envoys of course can enjoy certain rights and obligations according to international law, yet have not therefore become subjects of international law.[166] As Jennings and Watts suggest, 'the rights in question are

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161 *United States – Sections 301-310 of the Trade Act 1974* (*US – Section 301 Trade Act*), Panel report (WT/DS152/R, 22 December 1999), para. 7.72.

162 Of course, the Panel also emphasized that the statement was made as a matter of fact, and that (Ibid., para. 7.72, footnote 661):

> The fact that WTO institutions have not to date construed any obligations as producing direct effect does not necessarily preclude that in the legal system of any given Member, following internal constitutional principles, some obligations will be found to give rights to individuals. Our statement of fact does not prejudge any decisions by national courts on this issue.

163 Of course, international law protects human rights and individuals are ultimately the beneficiaries of international human rights protection. Recent developments in international criminal law, as Crawford points out, have made it 'no longer possible to deny that individuals may have rights and duties in international law': J. Crawford, *Brownlie's Principles of Public International Law* (2012), 17. However, this does not directly make individuals 'subjects' of international law who can directly bear rights and liabilities under international law. As Crawford suggested, 'to classify the individuals as a 'subject' of international law is unhelpful,' as individuals do not have the same capacities as other types of subjects of international law, and international human rights norms 'are not yet regarded as applying horizontally between individuals, in parallel to or substitution for the applicable national law,' and neither are there any means for their enforcement in international law. Therefore, Crawford points out that human rights and other obligations assumed for the benefit of individuals 'arise against the state, which so far has a virtual monopoly of responsibility': Ibid., 121.

164 I. Brownlie, *The Rule of Law in International Affairs: International Law at the Fiftieth Anniversary of the United Nations* (1998), 48.

165 L. Henkin, *International Law: Politics and Values* (1995), 7–8.

166 Jennings and Watts, *supra* note 150, at 846.

enjoyed by the individuals concerned not as rights in international law but as rights derived from national law'.[167] Only under national law instead of international law would individuals derive legal rights and assume legal liabilities.

Nationality jurisprudence in international law too suggests that international regime has no legitimate base of handling individual rights. Under traditional international law, nationality is the only way to link individuals into international law, and thus all the relations of individuals from different countries are summed up in the relations of countries.[168] International law thus applies in relation to a natural person via his nationality of certain states through the same way that international law attributes the nationality of a state to a private company or other legal person.[169] In international law, therefore, it is argued that there is a 'doctrine of the freedom of states in matters of nationality'.[170] In the Advisory Opinion of the Permanent Court concerning the *Tunis and Morocco Nationality Decrees*, the Court insisted that, 'in the present state of international law, questions of nationality are, in opinion of this Court, in principle within this reserved domain'.[171] Serving both as the bridge and boundary between international law and domestic law, nationality not only connects individuals to international law, but also works as an important shield for individuals from international intervention. Individuals' connection with international law through nationality is for the purpose of realizing domestic protection of individual rights in the international arena rather than establishing an international regime's domestic reach over individuals.

It has thus been well established that nationality is 'very important for international law'.[172] Nationality not only limits international regime's intrusion into states' sovereignty over domestic affairs, but also shields individuals from international intervention. This carries fundamental significance to our analysis, as it clearly explains why the WTO in general or the TRIPS Agreement in particular has no direct effect and creates no obligations to individuals. Home states exclusively have the right as well the obligation to protect the exercise of individual rights. In his discussion of the relationship of individuals to the state under the framework of sovereignty in the international legal system, Brand suggests that the international legal framework is a 'two-tiered social contract', 'under which the individual relates to the state in domestic law, and only the state relates to the international legal order in international law'.[173] Similarly, as the WTO is considered to be a member-driven organization, Hudec suggests that there is no basis for 'asking the WTO to meet the

167 Ibid., 847.
168 Brownlie, *supra* note 164, at 48. Brownlie argues that 'the principal connection between the individual and the system of international law is still *via* the status of nationality'. See also Jennings and Watts, *supra* note 150, at 857. Jennings and Watts state that 'nationality is the principal link between individuals and international law.'
169 Jennings and Watts, *supra* note 150, at 859.
170 I. Brownlie, *Principles of Public International Law* (2008), 383.
171 PCIJ, Ser. B, no. 4 (1923), 24, as cited ibid.
172 Jennings and Watts, *supra* note 150, at 849.
173 R.A. Brand, 'Sovereignty: The State, the Individual, and the International Legal System in the Twenty First Century', (2002) 25 *Hastings International and Comparative Law Review* 279, at 286–7.

legitimacy standards of an institution with powers of governance'.[174] There is no justification to legitimize the international regime's directly intervening with individuals and private rights. Through detailing compulsory licensing treatments of the private-rights-natured pharmaceuticals, however, the TRIPS Waiver and Amendment contradict this jurisprudent in international law. It is in this sense, compulsory licensing or issue of TRIPS' direct effect will need to and have to be left in the hands of national authorities.

Therefore, there is no justification for any international regime's intrusion into matters within the domestic jurisdiction of national authorities. This indeed has been one of the core doctrines of the contemporary international legal order. Under the current international legal order, countries are both the subjects and law-makers of international law at the same time. In general, there is no more superior authority above the countries.[175] Therefore, 'state consent is the foundation of international law' and that 'that law is binding on a state only by its consent remains an axiom of the political system, an implication of state autonomy'.[176] Nonintervention therefore has become a cornerstone of international law and has been enshrined in the UN Charter:

> Nothing contained in the present Charter shall authorize the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any state or shall require the Members to submit such matters to settlement under the present Charter.[177]

The above reference to the jurisprudence of individuals' status in international law bears fundamental significance to our examination of TRIPS Waiver and Amendment's legitimacy. No matter how much the WTO cares about promoting public health, TRIPS should confer no rights and create no obligations on individual right holders as to their patent rights. This confirms the fundamental nature of intellectual property rights as private and negative rights as recognized in TRIPS.[178] The Paris Convention permits compulsory licensing yet neither limits the grant of compulsory licenses nor establishes any right to remuneration on behalf of patent right holders.[179] The total freedom of compulsory licensing remains in the hands of domestic authorities. The TRIPS Agreement, however, establishes the right to adequate remuneration on behalf of the right holders and detailed procedural requirements for granting compulsory licenses.[180] The establishment of a right to remuneration on behalf of the right holders of course runs against the established jurisprudence that

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174 See R.E. Hudec, 'Comment on "The Club Model of Multilateral Cooperation and Problems of Democratic Legitimacy"', in R.B. Porter et al. (eds), *Efficiency, Equity, and Legitimacy: the Multilateral Trading System at the Millennium* (2001) 297–8.

175 See E.U. Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International Organizations and Dispute Settlement* (1997), 54. In his discussion on consensus decision-making, Petersmann suggests that it is the general principle underlying WTO decision-making that 'the WTO does not have the power to impose new trade policy obligations.'

176 Henkin, *supra* note 165, at 27.

177 Art. 2.7, Charter of the United Nations (UN Charter).

178 For intellectual property rights as private and negative rights, in particular the barring effect thereof, see discussion in Section 3.1.

179 Art. 5A, Paris Convention.

180 For the right to adequate remuneration, see Art. 31(h) of the TRIPS Agreement.

the TRIPS Agreement generally confers negative rights instead of positive rights.[181] To make things worse, the TRIPS Waiver and Amendment, in particular the waiver of the adequate remuneration that reallocated the compensation remedy available to patent right holders,[182] crossed the line and stepped into 'matters of domestic jurisdiction' of national authority. TRIPS Waiver and Amendment penetrated the nationality shield safeguarding the right holders from international intervention, which undermines their legitimacy under international law.

Moreover, the compulsory licensing amendment's disrespect to members' sovereign management of public health and intrusion into member's nationals' proprietary rights of patents are mutually intertwined and share the same problematic heritage of TRIPS' birth defect. The amendment's penetration into matters of domestic jurisdictions limits members' freedom in compulsory licensing administration and disturbs individuals' proprietary rights without much legitimate basis. The legitimacy of the compulsory licensing amendment is therefore in serious doubt, as it contradicts the nature of TRIPS obligations, the jurisprudence of the WTO Agreement's direct effect, and the jurisprudence of individuals' status in international law.

5. Conclusion: the dynamics between public health, IPRs, and trade

It is unfortunate that the TRIPS Waiver is largely ineffective and the TRIPS Amendment approval remains stagnant. Views over the contribution of the TRIPS to public health are very diverse. Often, the failure is attributed to strong pharmaceutical lobbying in exporting countries against amending their patent legislation accordingly, and to the complexity of the procedure turning the system to a burdensome one that 'is largely symbolic and is unlikely to lead to any significant increase in the supply of medicines for the poor'.[183] NGOs and others criticize that the TRIPS Waiver and Amendment 'impos[e] unnecessary obstacles to the effective use of compulsory licensing by countries with inadequate production capacity'.[184] Abbott and Reichman consider that the Amendment is unfortunately 'saddled with unnecessary administrative hurdles', and the TRIPS Waiver and Amendment are indeed 'not the optimal solution for stakeholders seeking the most administratively simple or expeditious mechanism for permitting exports under compulsory license'.[185] Some

181 *EC - Trademarks and Geographical Indications (Australia)*, Panel report, para. 7.210. For detailed discussion of the negative right jurisprudence, see discussion in Section 3.1. Of course, it would not be unusual if the TRIPS Agreement concerned the use of right rather than the right itself. The TRIPS Waiver, however, directly touches and reallocates the right to remuneration.

182 Para. 3, the TRIPS Waiver.

183 Thapa, *supra* note 66, 472–3.

184 F.M. Abbott and J.H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions', (2007) 10 *Journal of International Economic Law* 921, at 932.

185 Ibid., 921, at 932.

even consider the TRIPS rules to be harmful to the poor and suggest that 'TRIPs should not be in the WTO at all'.[186]

Our analysis above, however, suggests that the failure of the TRIPS Waiver and Amendment goes beyond the procedural and institutional issues to the jurisprudential deficit stemming from TRIPS' birth defect. As intellectual property rights are private rights and the TRIPS regime grants only negative rights instead of positive rights, the issue of the TRIPS Waiver is a question of how the WTO as an intergovernmental organization in public international law regulates private rights that supposedly fall only within the purview of domestic authorities. The Paris Convention allows compulsory licensing and leaves total freedom of regulating compulsory licensing in the hands of domestic authorities. The Convention does not limit the grant of compulsory licenses nor establish a right to remuneration on behalf of patent right holders.[187] The delicate international-domestic balance is maintained, and the dynamics between public health, private rights and international trade is consistent with the direct effect doctrine and jurisprudence of individuals' status in international law. Should the Ebola epidemic get worse, national authorities should have enough flexibility to address public health concerns.

The TRIPS Agreement, however, establishes the right to adequate remuneration on behalf of the right holders and develops detailed procedural requirements for granting compulsory licenses.[188] The birth defect of the TRIPS Agreement reveals the jurisprudential paradox of TRIPS' intellectual property philosophy. While TRIPS recognizes intellectual property rights as private and negative rights, it also attempts to provide a check and balance through a general exception mechanism accommodating public health and economic development interests. Account of third parties' legitimate interests must be taken in relation to exceptions to patents, trademarks and industrial designs, yet not to exceptions to copyrights. Yet, the TRIPS Agreement at least still recognizes members' freedom in determining the grounds for compulsory licensing and situations of national emergency or extreme urgency. The TRIPS Waiver and Amendment, however, turn into the last straw breaking the already fragile equilibrium of the compulsory licensing practice. By establishing a complex procedure and limiting the scope of the application and benefiting countries, the Amendment creates segmentation of the compulsory licensing practice and limits its positive contribution to public health. Further jurisprudential analysis shows that the compulsory licensing amendment in the TRIPS Waiver and Amendment challenges the nature and scope of the TRIPS obligations and penetrates international and domestic affairs without legal basis. Through the TRIPS Amendment, the WTO as a public international law regime goes beyond touching the use of private rights to touching private rights themselves, in particular in shifting and reallocating the proprietary right to remuneration in compulsory licensing. The TRIPS Waiver and Amendment lacks legitimacy in international law.

186 Bhagwati, *supra* note 12, at 185.
187 Art. 5A, Paris Convention.
188 Art. 31(h), the TRIPS Agreement.

It is of course very noble for TRIPS to think of public health. However, the TRIPS Waiver and Amendment have disturbed the balance between private rights, governments, and trade for public health. The time has not yet arrived to use the international trading framework to interfere in domestic governance of the private-rights-natured pharmaceutical patents. Neither is the international institutional structure and political reality ready for this interference. Administration of compulsory licensing for public health should be left solely within the hands of domestic authorities as it is in the Paris Convention. Domestic policy makers should bear more responsibility and be more active through domestic instead of international framework in promoting public health. Solutions to public health crisis for the benefit of the least developed and developing countries can be provided elsewhere instead of within the TRIPS framework.