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INTERPRETING THE DOCTRINE OF LEGITIMATE EXPECTATIONS IN WTO JURISPRUDENCE IN ITS APPLICATION TO COMPULSORY LICENCES

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This paper attempts a critical examination of the doctrine of legitimate expectations in relation to non-violation complaints with a view to underlining its doctrinal significance for developing countries to justify the use of TRIPS flexibilities, such as compulsory licences, for public health considerations. Consequently, the author briefly traces some failed promises during the negotiation of TRIPS, and argues that the principle of good faith interpretation under World Trade Organisation law is more supportive of the contention that developing countries, which are generally the ones faced with complex public health issues require as a matter of fairness, greater flexibility to use compulsory licences in order to obtain affordable medicines to protect their legitimate public health expectations. This argument rests on the presumption that TRIPS allows for the substantive protection of legitimate expectations based on the balance of rights and obligations, and presently the agreement overly protects patents on essential medicines. Therefore, by implication the legitimate expectations of only the home governments of the pharmaceutical industry are protected at the expense of developing countries.

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I. INTRODUCTION

The doctrine that protects legitimate expectations remains an emerging principle and is mentioned in various settings in World Trade Organization (WTO)[1] law.[2] In the context of the general principles of international law, it is commonly used in determining the consistency of domestic measures taken by a party to a treaty as part of a balance of rights and obligations or to observe a duty by not damaging the fundamental interests of another party to the agreement.[3] It is largely an accepted axiom that promises, practices, and policies form the basis of this doctrine.[4] Relevant case law of the International Court of Justice and writings of key legal scholars show that a party can be said to have legitimate expectations within the meaning of the general principle of international law when all of the following two elements are present.

First, pursuant to conduct - when those expectations are justifiable (and thus legitimate) in the light of the nature of that conduct and other relevant circumstances; and second, when the first party acts in reliance on the conduct of the second party and for the second party not to continue to honour those

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[1] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15. 1994, 1867 U.N.T.S. 154 [hereinafter MARRAKESH AGREEMENT].

[2] Appellate Body Report, *Japan – Alcoholic Beverages II*, ¶ 13, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996). [hereinafter JAPAN – ALCOHOLIC BEVERAGES II]. Panel Report, Japan - Measures Affecting Consumer Photographic Film and Paper, ¶ 1050, WT/DS44/R (March 31, 1998). [hereinafter JAPAN-FILM CASE]. *See also* 1 WTO ANALYTICAL INDEX: GUIDE TO WTO LAW AND PRACTICE 283 (Cambridge: Cambridge University Press, 2nd ed. 2007).

[3] Laurent Ruessmann, *The Place of Legitimate Expectations in the General Interpretation of the WTO Agreements* (Institute for International Law, Working Paper No 36: Leuven, December, 2002) footnote 5, explaining that legitimate expectation falls under good faith interpretation. *See also* IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 640-642 (Oxford: Clarendon Press, 1990).

[4] Joseph Raz, *Promises and Obligations, in* LAW, MORALITY AND SOCIETY: ESSAYS IN HONOUR OF HLA HART 219 (Peter Hacker et Joseph Raz eds., Oxford, New York: Oxford University Press, 1977). [hereinafter RAZ]

legitimate expectations (i.e. to change its conduct) would result in damage to the interests of the first party.[5] Remarkably, panels and the Appellate Body (AB) have consistently invoked this doctrine within the canons of WTO treaty interpretation to help resolve international trade disputes.[6] According to international law the notion of expectation can be divided into two subgroups: "legitimate expectations" and "reasonable expectations".[7] In some sense, the panel in *Japan – Film* case emerged the concept of "legitimate expectation" with that of "reasonable expectation".[8]

Subsequently, a WTO panel has accepted the usage of both terms interchangeably.[9] However, in *European Commission (EC) - LAN*, the AB reversed the panel's findings in light of the interpretation of "legitimate expectations" of the parties, as the panel had confused the concept legitimate expectations with that of reasonable legitimate expectations.[10] By that interpretation, it can be reasoned as a matter of WTO jurisprudence that the non-violation nullification and impairment provisions protect "legitimate expectations" as opposed to the "reasonable legitimate expectation.[11] In *India - Patent Products*, the panel stated that one of the precepts developed under the General Agreement on Tariffs and Trade (GATT

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[5] *Id.* explaining that this rule is variously referred to as "justified reliance", "estoppel", "deemed (implicit) agreement", etc. Regardless of what it is called, legal commentators agree that it falls under the broader heading of "good faith interpretation and/or application" of a treaty. *See* International Court of Justice decision in the El Salvador - Honduras Land, Island and Maritime Frontier Case, [1990] I.C.J. Rep., 92, 118 *in* 1 ROBERT JENNINGS AND ARTHUR WATTS, OPPENHEIM'S INTERNATIONAL LAW 527 (Peace, Harlow-UK: Longman, 1992).

[6] *See* JAPAN – ALCOHOLIC BEVERAGES, *supra* note 2; JAPAN – FILM, *supra* note 2.

[7] DAE-WON KIM, NON-VIOLATION COMPLAINTS IN WTO LAW: THEORY AND PRACTICE 286 (Berne, Peter Lang, 2006).

[8] JAPAN-FILM CASE, para. 10.70.

[9] The Panel in *Korea – Measures Affecting Government Procurement*, ¶ 7.75, WT/ DS163/R (May 1, 2000) [hereinafter KOREA-PROCUREMENT CASE].

[10] The Appellate Body Report in *EC – Customs Classification of Certain Computer Equipment*, ¶¶ 80-111, WT/DS62/AB/R (Jun. 5, 1998) [hereinafter EC-LAN].

[11] The Panel Report, *EC — Measures Affecting Asbestos and Products Containing Asbestos*, ¶ 8.285, WT/DS135/R (Sept. 18, 2000). [hereinafter EC-ASBECTOS]. The Panel Report, *EC - Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-feed Proteins,* ¶¶ 80-88, DS28/R (31 Mar. 31, 1992). [hereinafter EC-OILSEED]. EC – LAN, *supra* note 10, paras. 83–84. The Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶¶ 45-62, WT/DS50/R (Sept. 5, 1997). [hereinafter INDIA-PATENT]. The Appellate Body Report, *Korea – Taxes on Alcoholic Beverages,* ¶¶ 125-127, WT/ DS75/AB/R (Jan. 18, 1999), paras. 125–127. [hereinafter KOREA ALCOHOLIC BEVERAGES] KOREA –PROCUREMENT, *supra* note 9, para. 7.9ff and 7.75.

1947)[12] is that rules and disciplines governing the multilateral trading system serve to protect legitimate expectations of members.'[13]

Similarly, in *EC – LAN*, the AB affirmed that the doctrine of legitimate expectations is based on the mutual consent of members in the international agreement.[14] Assuming that this frame of reference is correct, then the notion of legitimate expectations remains a significant doctrine that could operate to reinforce a balance of rights and obligations in the WTO system pursuant to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - which similar to all other covered agreements, must protect the legitimate expectations of all members.[15] Advocates of patent rights often overlook the importance of any impartial evaluation of TRIPS in ascertaining its rigidity; however, some scholars have tended towards persuasive evidence, by focusing on the belief that the complex patent standards under the agreement are too harsh in their current form for developing countries.[16]

For example, access to essential medicines for developing countries was not a major issue before the inception of TRIPS into the international trading system given that several leading developing countries, such as India, were technically able to manufacture low-cost generic medicines for export.[17] However, this is no longer possible the case following the conclusion of the TRIPS agreement, and India

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[12] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT 1947].

[13] INDIA – PATENT, para. 7.20.

[14] EC-LAN, para. 45.

[15] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS AGREEMENT].

[16] PETER DRAHOS AND JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?121 (LONDON, STERLING VA: EARTHSCAN, 2002), explaining that the existing IP regime is excessively tilted towards the interests of developed countries rather than developing countries. [hereinafter DRAHOS AND BRAITHWAITE]. To explain why this is so, Drahos claims that it is because developing countries do not set standards and in fact, the international movement of IP standards has been exported mainly form developed to developing countries. *See* PETER DRAHOS, DEVELOPING COUNTRIES AND INTERNATIONAL INTELLECTUAL PROPERTY STANDARD-SETTING 7 (STUDY PAPER 8: COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, 2002).

[17] Frederick Abbott and Jerome Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions, 10 J. Int. Econ. Law 4, 928 (2007). [hereinafter ABBOTT AND REICHMAN].

having to assume its full obligation to protect pharmaceutical patents in 2005.[18] TRIPS has created unnecessary tension between WTO member states, and has greatly threatened access to affordable medicines in these countries,[19] although one of the stated goals of the TRIPS agreement was 'to reduce tensions arising from IP protection'.[20] This defeats the central purpose of TRIPS, which per its "objectives" provision under Article 7 is to promote technological innovation and to disseminate and transfer the same.

In fact, it is not a mistake, neither was it an accident that the WTO members included technology transfer under the objectives of the TRIPS Agreement, as this was in absolute satisfaction of developing countries' concerns, many of whom saw technology transfer as part of the bargain in which they have agreed to protect intellectual property (IP) rights.[21] It is rather unfortunate and inconsistent with the overriding objectives of TRIPS that many developing countries complain that access to technology is still an issue.[22] Although, the doctrine of legitimate expectation could be interpreted to overcome several trade issues facing

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[18] Gail Evans, Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries 34 AJLM 2, 180 (2008). *See also* Peter Drahos, Securing the Future of Intellectual Property: Intellectual Property Owners and Their Nodally Coordinated Enforcement Pyramid, 36 Case W. Res. J. Int'l L. 1, 76 (2004), observing that India's success in building a strong pharmaceutical industry was based in large measure upon its recognition of patents for pharmaceutical processes, but not for pharmaceutical products. Cicero Gontijo, CHANGING THE PATENT SYSTEM FROM THE PARIS CONVENTION TO THE TRIPS AGREEMENT 6 (Rio de Janeiro, Brazil, published by Heinrich Boll Foundation: Global Issue Papers No. 96, 2005), examining the legislative freedom for member states before the TRIPS Agreement. *Ibid.* p. 13, and the consequences of TRIPS on developing countries.

[19] MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY: A CONCISE GUIDE TO THE TRIPS AGREEMENT 3-6 (London, Sweet & Maxwell, 1996), noting disagreements over pharmaceutical patents between the US and Korea, India, Thailand and Brazil from 1987 through 1992.

[20] CARLOS CORREA AND DUNCAN MATTHEWS, THE DOHA DECLARATION TEN YEARS ON AND ITS IMPACT ON ACCESS TO MEDICINES AND THE RIGHT TO HEALTH 7 (Discussion Paper, United Nations Development Programme, Bureau of Development Policy, December 2011).

[21] Frederick Abbot, The WTO Trips Agreement and Global Economic Development - The New Global Technology Regime, 72 Chi.-Kent L. Rev. 2, 387 (1996).

[22] Request for an Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members by Zambia on behalf of the Least-Developed Country Members, ¶6, IP/C/W/457 (Oct. 21, 2005). NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF TRADEMARKS AND DESIGNS 580, ¶ 66.5 (Alphen aan den Rijn: Kluwer Law International, 2011). [hereinafter CARVALHO]

developing countries under the ambiance of WTO regime, including favourable trade terms and market access, in the context of TRIPS, this analysis focuses on the lack of pharmaceutical technology specifically to promote access to medicines for public health protection.[23]

This is relevant, as during the negotiation of TRIPS, the issue of potential inadequate access to pharmaceutical technology was placed on the negotiation agenda,[24] and developing countries have formed legitimate expectations that they will have access to these technologies to promote affordable medicines, and this followed the assurance given by developed countries.[25]Consequently, with the lack of pharmaceutical technology in mind, the common understanding is that per its objectives, TRIPS is clearly not working for developing countries, whose legitimate expectations reside in access to medicines and public health protection.[26] In fact, no one disagrees that TRIPS has conferred massive benefits on the members with large IP portfolios; particularly, the United States (US) and the EC, both of which are home to the world's leading pharmaceutical and chemical industries.[27]

This highlights the difference in the protection granted by TRIPS which unduly favours the interests of the pharmaceutical industry, and thereby also the legitimate expectations of their home governments. The rest, in particular developing countries, are in a position of being importers, gaining nothing substantial from agreeing to the terms of trade for IP that often serves to the comparative advantage of key developed countries.[28] A question that arises from the abovementioned shortcomings is whether the imbalance created by TRIPS is capable of being resolved by widening the doctrine of legitimate expectations and ensuring that the legitimate expectations of all parties are met. This question has become significant and requires a definite answer. However, in the absence of one,

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[23] Gail Evans, A Preliminary Excursion into TRIPS and Non-Violation Complaints, 3 JWIP 6, 871-972 (2000) [hereinafter EVANS].

[24] Swaraj Barooah, India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs, 5 TL&D 1, 158 (2013), noting that developing countries were beginning to demand access to technology. DRAHOS AND BRAITHWAITE, *supra* note 16, at 10, noting that the Indian generics industry warned of dramatic price increases in essential medicines that would follow from the obligation in TRIPS to grant twenty-year patents on pharmaceutical products.

[25] Thirukodikaval Nilakanta Srinivasan, *Doha Round of Multilateral Negotiations and Development* 6 (Stanford, CA: Stanford Centre for International Development Working Paper No. 252, 2005) [hereinafter SRINIVASAN].

[26] *Id.*

[27] *Ibid.* at 11.

[28] *Id.*

the legitimacy of TRIPS, and the whole WTO landscape, particularly its Dispute Settlement Understanding (DSU)[29], stand threatened.

Here, governments differ in terms of their unique expectations and they should be able to pursue their legitimate expectations individually, notwithstanding this, the jurisprudential position taken by the AB to diminish any legal basis for pursuing subjective and unilaterally determined expectations of one of the parties to a treaty is at odds with the spirit of WTO system which in hindsight protect legitimate expectation of its members.[30] Cottier puts this in a proper perspective by arguing that 'instead of generalising the recognition of the existence of legitimate expectation throughout WTO law, the Appellate Body has recognised it only in the realm of non-violation, denying its applicability elsewhere'.[31] This argument is evidenced by doubts often raised by the developing country members concerning the failure of the international trading system to protect their interests.

The reason behind this distrust is the proliferation of patent rights which disproportionately favours developed countries and weakens the legitimate expectations of developing countries as they end up struggling with high costs and shortages of essential medicines.[32] Notably, one important legal concept to achieve a balance of reasonable legitimate expectations is the doctrine of non-violation complaints (NVCs) under TRIPS.[33] This doctrine is consistent with the good faith approach in interpreting WTO law, which is also guided by the

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[29] Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes. Marrakesh Agreement Establishing World Trade Organization, Annex 2, Apr. 15, 1994. THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS, 1869 U.N.T.S. 401, 33 I.L.M. 1226. [hereinafter DSU].

[30] EC – LAN, *supra* note 10, para. 84.

[31] THOMAS COTTIER, THE CHALLENGE OF WTO LAW: COLLECTED ESSAYS 137 (LONDON, CAMERON MAY, 2007) [hereinafter COTTIER].

[32] Peter Yu, *International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia,* 1 MICH. ST. L. REV. 1, 27 (2007), calling for developing countries to fine-tune their IP systems in an effort to better reflect their different needs, interests, and goals [hereinafter YU].

[33] Non-Violation Nullification of Benefits claims are directly referred to in Article 26 of the WTO/DSU [*supra* note 29], Article XXIII of the GATT 1994. Replaced General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187. [hereinafter GATT 1994], Article XXIII.3 of the GATS. General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 284 (1999), 1869 U.N.T.S. 183, 33 I.L.M. 1167. [hereinafter GATS 1994), and TRIPS AGREEMENT, Article 64, *supra* note 15.

principles of legal certainty, transparency, and normative legitimacy; all of which characterise the corpus of public international law.[34] This doctrine effectively amounts to a complaint that a country has violated the spirit but not the letter of WTO law.[35]

Traditionally, NVCs were closely tied to tariff concessions (trade in goods) and subsequent legitimate expectations flowing from such concessions.[36] These complaints have been under a *moratorium* since the creation of TRIPS. Many scholars fear that if the *moratorium* of NVCs were to expire, any measure, such as a compulsory licence, allegedly viewed by key developed countries as often nullifying or impairing benefits under TRIPS may practically be subject to non-violation claims under certain conditions, in particular claims involving a breach of legitimate expectations.[37] Although a relatively simple concept, as a matter of legal reasoning enforcing NVCs in practice can give rise to a number of problems. For instance, in the *Japan - Film*, the WTO confirmed that the principle of NVC in itself is an exceptional remedy which should be approached with caution.[38]

It is on this basis that this paper attempts a critical examination of the doctrine of reasonable legitimate expectations in relation to NVCs with a view to underline its doctrinal significance for developing countries to justify the use of TRIPS flexibilities, such as compulsory licences, for public health considerations. Consequently, the author briefly traces some failed promises during the negotiation of TRIPS and argues that the principle of good faith interpretation under WTO law is more supportive of the contention that developing countries, require as a matter of fairness greater flexibility to use compulsory licences in order to obtain affordable medicines to protect their legitimate public health expectations due to the reason that they are generally the ones faced with complex public health issues. This argument rests on the presumption that TRIPS allows for the substantive protection of legitimate expectations based on the balance of rights and obligations, and presently the agreement overly protects patents on essential medicines.

This reasonably leads to the unbalanced protection of the legitimate expectations of the home governments of the pharmaceutical industry at the expense of developing countries. Further, the paper examines the legal precepts of NVCs

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[34] Nathan Miller, An International Jurisprudence? The Operation of 'Precedent' Across International Tribunals,15 L.J.I.L. 3, 499 (2002).
[35] *Id.*
[36] *Id.*
[37] COTTIER, *supra* note 31, at 137, noting that non-violation complaints functions within the WTO system like the good faith function in general international law.
[38] JAPAN – FILM CASE, *supra* note 2, para. 10.37.

under the concept of reasonable legitimate expectations in relation to its application to the context of WTO law, which is also firmly built on the principle of good faith consideration under the Vienna Convention of the Law of Treaties (VCLT).[39] This is done in the hope that the author will be able to vindicate and strengthen the significance of the spirit of law as well as the necessity of interpreting the doctrine of legitimate expectations from a fundamental fairness perspective, in order to make the invocation of compulsory licences under TRIPS justifiable for legitimate public health protection in developing countries.

II. THE LEGAL BASIS FOR NON-VIOLATION COMPLAINTS WITHIN THE WTO FRAMEWORK

Resolving trade disputes is one of the core functions of the WTO.[40] The WTO DSU mandates member states to submit their complaints under the procedure and mechanism delineated in the Marrakesh Agreement.[41] That is, WTO agreements on goods and services allow countries to bring cases against each other on the ground that a country has violated an agreement or broken a commitment that has deprived it of an expected benefit.[42] Article 3.2 of the DSU in part stipulates that:
The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law.

In *Japan - Alcoholic Beverages II*, the AB examined the concept of "security and predictability" in WTO law and made the following statement:
WTO rules are reliable, comprehensible and enforceable. WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind. In that way, we will achieve the 'security and predictability' sought for the multilateral trading system by the Members of the WTO through the establishment of the dispute settlement system.[43]

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[39] The Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679 (entered into force Jan. 27 1980) [hereinafter VCLT].
[40] MARRAKESH AGREEMENT, *supra* note 1, Article III, Section 3, which stipulates that one of the functions of the WTO is to administer the dispute settlement body.
[41] DSU, *supra* note 29.
[42] ELIMMA EZEANI, THE WTO AND ITS DEVELOPMENT OBLIGATION: PROSPECTS FOR GLOBAL TRADE 120 (New York, Anthem Press, 2011).
[43] JAPAN – ALCOHOLIC BEVERAGES II, at 31.

In *EC - LAN,* the AB referred to "security and predictability" as an object and purpose of the WTO Agreement generally, stating that 'the security and predictability of the reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other trade barriers to trade' is an object and purpose of the WTO Agreement, generally, as well as of the GATT 1994'.[44] In *US — Section 301 Trade Act*, the panel examined the importance of the concept of "security and predictability" and stated: 'Providing security and predictability to the multilateral trading system is another central object and purpose of the system which could be instrumental to achieving the broad objectives of the Preamble'.[45]

With a view to preserving the basic principles and to further the objectives underlying the multilateral trading system, the Preamble to the WTO agreement recognises that 'there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development'.[46] In the *US - Shrimp* case the AB noted that: 'preambular language reflects the intentions of negotiators of the WTO Agreement, we believe it must add colour, texture and shading to our interpretation of the agreements annexed to the WTO Agreement'.[47]

So, where any WTO member adopts a trade policy measure or takes some action that are inconsistent with the obligations of that member, or contrary to the overriding objectives of the WTO agreements, and its principles members are free to initiate proceedings after consultations.[48] Therefore, in WTO jurisprudence, it is allowed if one government can show that it has been deprived of an expected benefit because of another government's action, or because of any other situation that exists.[49] As a prescriptive matter, there are two types of complaints which play a practical role in the WTO dispute settlement process. These are the violation complaint and, far less frequently, the NVC.[50] One might

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[44] EC-LAN, para. 82.

[45] The Panel Report, *US - Sections 301–310 of the Trade Act 1974,* ¶ 7.75, WT/DS152/R (Dec. 2, 1999). [hereinafter US-SECTION 301].

[46] *See* MARRAKESH AGREEMENT, *supra* note 1, Preamble.

[47] The Appellate Body Report, *US - Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 153, WT/DS58/AB/R (Oct. 12, 1998). [hereinafter US-SHRIMPS].

[48] GATT 1994, *supra* note 33, Article XXII. *See also DSU, supra* note 29, Article 4.

[49] COTTIER, *supra* note 31, para. 10.32. *See* Susy Frankel, Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes,12 J. Int'l. Econ. Law. 4, 1029 (2009). [hereinafter FRANKEL]

[50] WORLD TRADE ORGANISATION SECRETARIAT. A HANDBOOK ON THE WTO DISPUTE SETTLEMENT SYSTEM 35 (Cambridge, Cambridge University Press, 2004). [hereinafter HANDBOOK ON THE WTO DSU].

wonder about the legitimacy of the NVC, given that the WTO agreement contains all the rights and obligations on which the members agreed in their negotiations. Why should there be a remedy against actions that are not inconsistent with these rights and obligations, in other words, measures that the WTO agreement does not preclude?

The reason is that an international trade treaty such as the WTO agreement can never be a complete set of rules without gaps.[51] As a result, it is possible for WTO member to take measures that comply with the letter of the agreement, but nevertheless frustrate one of its objectives or undermine trade commitments contained in the agreement.[52] More technically speaking, the benefit a member legitimately expects from another member's commitment under the WTO agreement can be frustrated both by measures proscribed in the WTO agreement and even by measures consistent with it.[53] If one member frustrates another member's benefit by taking a measure otherwise consistent with the WTO agreement, this impairs the balance between the mutual trade commitments of the two members. The NVC provides for a means to redress this imbalance.[54]

There are three main WTO provisions of relevance to NVCs and the TRIPS agreement: 1) Article XXIII of GATT 1994; 2) Article 64 of the TRIPS agreement; and 3) Article 26 of the DSU. The basic rules on "non-violation" and "situation" complaints are established in Article XXIII of GATT 1994. In GATT jurisprudence, NVCs appear to have originally been designed to counter the capacity of members to avoid relatively simple obligations and specific tariff concessions in multilateral trade agreements by making ambiguous domestic regulatory arrangements.[55] The aim of NVCs is very simple: to generally preserve the balance of benefits struck during multilateral negotiations; this was confirmed in the *Japan – Film* case.[56] Article 64.1 of the TRIPS agreement incorporates by reference Article XXIII of the GATT 1994 as the general dispute settlement provision governing the TRIPS agreement.[57]

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[51] *Ibid.* at 32.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Non-Violation Nullification or Impairment Under the TRIPS Agreement. Communication from Canada to the Council for TRIPS, 1, IP/C/W/127 (Feb. 10, 1999). *See* ROBERT HUDEC, ENFORCING INTERNATIONAL TRADE LAW: THE EVOLUTION OF THE MODERN GATT LEGAL SYSTEM, 7 (Salem, New Hampshire, Butterworth Legal Publishers, 1993).
[56] *See* EC-OILSEED, *supra* note 11, para. 144. *See also* JAPAN – FILM CASE, *supra* note 2, para. 10.50.
[57] TRIPS AGREEMENT, *supra* note 15, Article 64(1) reads:

Article XXIII of the GATT 1994 sets out the specific circumstances in which a WTO member is entitled to a remedy. Under "Nullification or Impairment, Article XXIII:1 specifies that:

> If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of (a) the failure of another contracting party to carry out its obligations under this Agreement, or (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or (c) the existence of any other situation, the contracting party may, with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it.

Despite these GATT provisions referred to in Article 64 of TRIPS, the agreement establishes a *moratorium* on the application of the non-violation remedy to the agreement, and commits WTO members to examine how the concept might apply in the context of the TRIPS agreement. Article 64 provides:

> (2) Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement. (3) During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

While the foregoing provision flows inescapably from the operation of Article XXIII, the manner in which NVCs will be applied in WTO disputes – including

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> The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

any under the TRIPS agreement – is established in Article 26 of the DSU. Article 26.1 of the DSU specifically addresses NVCs in the sense of Article XXIII:1(b) of GATT 1994 and requires the complainant to 'present a detailed justification in support of any complaint relating to a measure which does not conflict with the relevant covered agreement'.[58] No presumption applies in non-violation cases as regards nullification or impairment. The text of Article XXIII:1(b), combined with the concept of nullification or impairment of a benefit[59] gives rise to three conditions whose existence a complainant must establish, in order to be successful with a NVC.[60]

These three conditions are: (1) the application of a measure by a member of the WTO; (2) the existence of a benefit accruing under the applicable agreement; and (3) the nullification or impairment of a benefit as a result of the application of the measure.[61] While some WTO members have in the past relied on the principle of legitimate expectation as the basis of claiming a nullification or impairment of a benefit as a result of the application of a measure,[62] the WTO suggests that it would be wrong to believe that the NVC has a wide scope of application and is suitable to address all sorts of measures otherwise consistent with GATT 1994 and the other covered agreements.[63] Panels and the AB have stated that the remedy in Article XXIII:1(b) 'should be approached with caution and should remain an exceptional remedy',[64] since otherwise the trading world would be plunged into a state of precariousness and uncertainty.[65]

One panel has added: 'The reason for this caution is straightforward. Members negotiate the rules that they agree to follow and only exceptionally would expect to be challenged for actions not in contravention of those rules'.[66] Significantly, the

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[58] HANDBOOK ON THE WTO DSU, *supra* note 50, at 33.

[59] Note that Article 26(1) of the DSU also covers the other kind of non-violation complaint, which combines the "measure applied by a Member" with the impeded "attainment of any objective" of GATT 1994, instead of combining the non-violating measure with "nullification or impairment of a benefit", as it typically happens in non-violation complaints.

[60] *See* "Burden of proof". DSU, *supra* note 29, Article 26.1(A). *See also* JAPAN-FILM CASE, para. 10.32.

[61] *Ibid.* para. 10.41. *See also* KOREA-PROCUREMENT, *supra* note 9, para. 7.85. EC-ASBESTOS, *supra* note 11, para. 8.283.

[62] INDIA –PATENT, *supra* note 11, paras. 42, 45 and 48. EC-LAN, *supra* note 10, paras. 84 and 97.

[63] HANDBOOK ON THE WTO DSU, *supra* note 50, at 33.

[64] EC-ASBESTOS, *supra* note 11, para. 186. *See also* JAPAN-FILM CASE, *supra* note 2, para. 10.37.

[65] EC-OILSEED, *supra* note 11, para. 113.

[66] JAPAN-FILM CASE, *supra* note 2, para. 10.36.

delay in the entry into force of the NVC provision in Article 64 reflects the intense controversy surrounding this concept during the TRIPS negotiations.[67] The members have agreed not to use non-violation claims under the TRIPS regime, although such claims remain consistent with the WTO law.[68] Pursuant to Article 64(2), this *moratorium* was initially intended to last for the first five years of the WTO (i.e. 1995–99), but has since been extended.[69] Significantly, Paragraph 11(1) of the Doha Decision on Implementation-Related Issues and Concerns instructed the TRIPS Council to make a recommendation to the Cancun Ministerial Conference, and until then the members agreed not to file NVCs under TRIPS.[70]

The *moratorium* has been extended from one ministerial conference to the next, the latest being the 2015 Nairobi Ministerial Conference.[71] It should be noted prior to the Nairobi Ministerial Conference, the 9th WTO Ministerial Conference held in Bali, Indonesia in 2013 issued the following declaration on TRIPS Non-Violation and Situation Complaints:

> We take note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to our Decision of 17 December 2011 on "TRIPS Non-Violation and Situation Complaints" (WT/L/842), and direct it to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to our next Session, which we have decided to hold in 2015. It is agreed that, in the

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[67] THOMAS FAUNCE, WARWICK NEVILLE AND ANTON WASSON, NON-VIOLATION NULLIFICATION OF BENEFIT CLAIMS: OPPORTUNITIES AND DILEMMAS FOR AUSTRALIA IN THE WTO DISPUTE SETTLEMENT SYSTEM 128 (Canberra: Commonwealth of Australia, the Office of Trade Negotiations of the Department of Foreign Affairs and Trade, 2006). [hereinafter FAUNCE, ET AL.]. *See* Negotiating History of GATT Article XXIII:2. Secretariat Notes (Jul. 14, 1989). Available at: http://www.worldtradelaw.net/document.php?id=history/urdsu/W31.pdf [Accessed Apr. 7, 2017].

[68] EVANS, *supra* note 23, at 868.

[69] Thomas Cottier, and Krista Schefer, *Good Faith and the Protection of Legitimate Expectations in the WTO*, *in* NEW DIRECTIONS IN INTERNATIONAL ECONOMIC LAW 49 (Marco Bronckers and Reinhard Quick eds., The Hague: Kluwer Law, 2000), noting that with the considerable growth of international trade regulation in terms of scope and subject matter, the potential role of the non-violation complaint has been considerably reduced. It will be further reduced as general principles of law are applied in the process of interpreting WTO law.

[70] Sixth WTO Ministerial Conference. Draft Ministerial Declaration of the Doha Programme, ¶ 46, WT/MIN(05)/W/3/Rev.2 (Hong Kong, Dec. 18, 2005).

[71] WTO Nairobi Ministerial Declaration. TRIPS and Non-Violation and Situation Complaints. WT/MIN(15)/41 – WT/L/976 (Dec. 19, 2015).

> meantime, Members will not initiate such complaints under the TRIPS Agreement.[72]

Nevertheless, just as the concept of NVCs has lost much of its legal efficacy, at least two members (the US and Switzerland) recently advanced the argument that NVCs should be allowed in order to discourage members from engaging in "creative legislative activity" that would allow them to get around their TRIPS commitments.[73] This reveals how determined certain developed country members were to ensure its inclusion (and still remain so) despite the fact that there was little in TRIPS that would have justified any NVC claim consistent with the objectives on which the concept was originally developed.[74]

III. REASONABLE LEGITIMATE EXPECTATIONS UNDER THE CANNONS OF INTERNATIONAL TREATY INTERPRETATION IN THE WTO/DSU

Over the last century there has been a major transformation in the international trading regime. This necessitated a regulatory mechanism that would also include settling disputes among members.[75] As indicated already, significantly, with the WTO establishing a framework for trade policies,[76] dispute settlement has been

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[72] Ninth WTO Ministerial Conference. TRIPS Non-violation and Situation Complaints. Ministerial Decision, WTO Doc. WT/MIN(13)/31/WT/L/906 (Bali, Dec. 11, 2013) [hereinafter NINTH WTO MINISTERIAL].

[73] Council for TRIPS. Non-Violation Complaints under the TRIPS Agreement. Communication from the US, ¶ 4.9, IP/C/W/599 (Jun. 10, 2014). Communication from the United States, Scope and Modalities of Non-Violation Complaints Under the TRIPS Agreement, IP/C/W/194 (July 17, 2000) at 7, Appendix, under the subheading 'Legal Basis for the Position of the US Regarding Expiration of the "Moratorium" on Non-Violation Cases'. *see* Minutes of the Council for TRIPS Meeting (Geneva, meeting held on Mar. 8-9 and 31, 2005) IP/C/M/47, para. 238; IP/C/M/49, para. 230; IP/C/M/64 - Meeting held on Oct. 26-27, 2010, para. 312; IP/C/M/67 - Meeting held on Oct. 26-27 and Nov. 17 2011, para. 252. *See also* Frederick Abbott, *Non-Violation Nullification or Impairment Causes of Action Under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder* (Quaker United Nations Office, Occasional Paper 11, 2003), *available at:* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2364991.

[74] FAUNCE ET AL., *supra* note 67, at 128.

[75] DSU, *supra* note 29.

[76] Bernard Hoekman, *The WTO: Functions and Basic Principles in* DEVELOPMENT, TRADE AND THE WTO: A HANDBOOK 42 (Bernard et al., eds., World Bank, 2002), noting that the WTO is concerned with setting the rules of the trade policy games.

one of the key functions of the organisation.[77] Interpretation of WTO agreements is at the centre of dispute settlement since most disputes involve questions of law relating to clarification of the relevant rules governing relationships between members'.[78] Notably, the VCLT[79] is an important covenant that has guided WTO panels and the AB in a number of disputes.[80] Article 3.2 of the DSU recognises that interpretative issues that arise in WTO dispute settlements should be resolved through the application of customary rules of interpretation of public international law.[81]

The panel in *Korea – Procurement* held that the customary rules of international law apply to WTO treaties, and to the process of treaty formation under the international trading regime in defining the economic relations between members.[82] This reflects a measure of recognition that the general agreements embodied under the WTO are not to be read in clinical isolation from public international law.[83] It is therefore the assumption that this reasoning will help accommodate the practical doctrine that aims to protect reasonable legitimate expectations. Further, the doctrine has already been applied in international law and many trade disputes.[84]

In other words, the concept of legitimate expectation is not new to WTO law and had long entered into mainstream cannons of international treaty interpretation.[85]Thus, for the sake of consistency and legitimacy, the doctrine of protection of legitimate expectations is considered to be a dominant element[86] or

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[77] Fabien Gelinas, Dispute Resolution as Institutionalization in International Trade and Information Technology, 74 FORDHAM L. REV. 2, 503 (2005), stating that by all accounts, the success of the WTO is largely due to the success of its dispute settlement system.
[78] Andrew Guzman and Beth Simmons, Power Plays & Capacity Constraints: The Selection of Defendants in WTO Disputes, 34 J. Legal Stud. 2, 558 (2005).
[79] VCLT, *supra* note 39.
[80] *Id.*
[81] Appellate Body Report, *US - Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, ¶ 61, 62 WT/DS213/AB/R, WT/DS213/AB/R/Corr.1 (Nov. 28, 2002) [hereinafter US-CARBON STEEL].
[82] KOREA-PROCUREMENT, *supra* note 9, para. 7.96.
[83] Appellate Body Report, *US - Standards for Reformulated and Conventional Gasoline*, ¶ 16, WT/DS2/AB/R (Apr. 29, 1996) [hereinafter US – GASOLINE].
[84] See *supra* note 2.
[85] International Thunderbird Gaming Corporation v. Mexico, at 147-148 (NAFTA/UNCITRAL, Award, Jan. 26, 2006).
[86] Saluka Investments BV v. The Czech Republic, ¶ 302, UNCITRAL-PCA (Partial Award, Mar. 17, 2006) .

one of the major components[87] of the standards of fair and equitable treatment of a treaty.[88] More significantly, it is well settled in WTO case law that the principles codified in Articles 31 and 32 of the VCLT make up such customary rules,[89] and must be respected and applied in interpreting the TRIPS agreement.[90] Nevertheless, evidence shows that the implementation of strict standards of patents under TRIPS has already challenged the very constitution of the trade regime; additionally, as a matter of pragmatic consideration, the inception of TRIPS into the international trading system means that the value of IP has become a highly contested area of private law.[91]

Subsequently, the changes brought by TRIPS pursuant to strict patent protection have pushed the trading system into new and difficult directions to the detriment of developing countries.[92] Therefore, it is important to consider some decisions of the WTO/DSU and the question of whether the doctrine of legitimate expectations can be interpreted in a way that might operate to justifiably limit the rigidity of IP law to privilege the interests of developing country members over developed countries, or at least balance their mutual legitimate expectations.

A. Reasonable Legitimate Expectations in Japan – Film

On 13 June 1996, the US requested consultations with Japan concerning Japan's laws, regulations and requirements affecting the distribution, offering for sale and internal sale of imported consumer photographic film and paper. The US alleged that the measure at issue - the Japanese Government treated imported film and paper less favourably through these measures, in violation of GATT Articles III and X, and that these measures nullify or impair benefits accruing to the US (a non-violation claim) within the meaning of Article XXIII:1(b) of GATT.[93] In response, Japan contested the foregoing allegation under the following: first, Japan contended that any interpretation of GATT should be in accordance with

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[87] EDF (Services) Limited v. Romania, ¶ 216 (ICSID Case No. ARB/05/13, Award, Oct. 8, 2009).

[88] Generation Ukraine, Inc. v. Ukraine, ¶ 20.37 (ICSID Case No. ARB/00/9, Award, Sept. 16, 2003), noting that protection of legitimate expectations is 'a major concern of the minimum standards… of treaties'.

[89] Appellate Body Report, *US - Continued Existence and Application of Zeroing Methodology*, ¶ 268, WT/DS350/AB/R (Feb. 4, 2009) [hereinafter US-ZEROING METHODOLOGY].

[90] INDIA - PATENTS CASE, *supra* note 11, para. 46.

[91] EVANS, *supra* note 23, at 882. Note that the Preamble to the TRIPS Agreement recognises 'that intellectual property rights are private rights'. *See*, TRIPS AGREEMENT, *supra* note 15.

[92] *Id.*

[93] JAPAN —FILM CASE, *supra* note 2.

customary rules under Article 3.2 of the DSU, which refers to the general principles of interpreting WTO agreements as part of public international law.

Japan was of the view that Article 31 on the general rules of interpretation and Article 32 on the supplementary means of interpretation of the VCLT represent such customary rules of interpretation of public international law.[94] Second, Japan urged the panel to take a cautious approach and refrain from adding to or diminishing the rights and obligations of members under WTO agreements in accordance with Articles 3.2,[95] and 19.2 of the DSU that provides for the same principle with respect to the findings and recommendations of panels and the AB.[96] Furthermore, Japan submitted that the scope of Article XXIII:1(b) in the GATT jurisprudence is well defined, and may be discerned by reference to key expressions in the text of the provision taking into account that there must be a "benefit" accruing under the agreement.

This "benefit" consists of the legitimate expectations of opportunities arising out of relevant concessions. For expectations to be legitimate, they must take into account all measures that a party making the concession could impose subject to being reasonably anticipated at the time of the concession.[97] Third, there must be the application of a "measure" by another WTO member,[98] wherein the term "measure" refers to a government policy or action, but not every such policy or action constitutes a measure for the purposes of Article XXIII:1(b) "Measures" under the abovementioned Article must either provide "benefits" or impose obligations. As for the latter, a "measure" for non-violation purposes must be a government policy or action, which imposes legally binding obligations or the substantive equivalent.

Moreover, the complaining party must show that the "benefit" in question is being "nullified or impaired" as the result of the application of the "measure". To meet this requirement, the complaining party must demonstrate that the relevant

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[94] *For example*, US – GASOLINE, *supra* note 83. *See also* JAPAN - ALCOHOLIC BEVERAGES, *supra* note 2.

[95] John Jackson, *The WTO Dispute Settlement Procedures: A Preliminary Appraisal in* THE WORLD TRADING SYSTEM: CHALLENGES AHEAD 163 (Jeffrey Schott ed., Washington D.C., Peterson Institute for International Economics, 1996), mentioning that Japan wanted to caution the Panel to interpret nullification or impairment and to use judicial restraint and avoid being too activist in making changes to the rights and obligations of the nation states.

[96] *Supra* note 2. Japan argued that Article 19:2 of the DSU stipulates: '... in their findings and recommendations, the panel and AB cannot add to or diminish the rights and obligations provided in the covered agreements'.

[97] *Id.* para 6.15

[98] *Id.* para 6.16.

measure is upsetting the competitive position of the imported products subject to the relevant tariff concession.[99] In other words, measures reasonably anticipated at the time of the concession cannot frustrate legitimate expectations. Thus, such measures cannot nullify or impair a benefit accruing under the agreement. For Japan, given the addition of other multilateral agreements to the GATT, any restraint in application of the non-violation remedy was more appropriate than ever before.[100] It contended that the non-violation claims put forth by the US in the proceedings urged for a dramatic expansion of the non-violation remedy because, in Japan's view, the US asked that this exceptional remedy be applied beyond recognised and appropriate limits.[101]

Japan further argued that all of the policies in question were enacted and known to the US long before the relevant concessions, i.e., those made in 1994 with respect to black and white, and colour film and paper.[102] Since virtually every government action in this case occurred before 1979, it is inconceivable that these policies could not have been reasonably anticipated at the time of the 1979 tariff concessions. Accordingly, in Japan's view, all of the alleged measures could have been reasonably anticipated by the US at the time of those tariff concessions.[103] Notwithstanding the logic of the foregoing argument, the panel had to practically test the elements of a non-violation claim pursuant to the requirement that there be application of a measure by a WTO member.[104] The Panel analysed whether the application of a measure amounted to a non-violation case.

The Panel examined that giving a broad definition to measure does not expand the scope of the Article XXIII:1(b) remedy, and should not be defined in an unduly restrictive manner.[105] Furthermore, it was noted that the term "measure" in Article XXIII:1(b) and Article 26.1 of the DSU 'refers only to policies or actions of governments, not those of private parties'.[106] In this context, the panel made it clear that 'we do not *a priori* consider it inappropriate to apply the Article XXIII:1(b) remedy to other governmental actions, such as those designed to strengthen the competitiveness of certain distribution or industrial sectors through non-financial assistance.[107] Importantly, pursuant to Article XXIII:1(b) of the GATT (non-violation claim), the Panel found that the US failed to demonstrate

[99] *Id.* para 6.17.
[100] *Id.* para 6.34.
[101] *Id.* para 6.36.
[102] *Id.* para 6.20.
[103] *Id.*
[104] JAPAN – FILM, *supra* note 2, para. 10.42.
[105] *Ibid.* para. 10.50.
[106] *Ibid.* para. 10.52.
[107] *Ibid.* para. 10.38.

that the measures at issue nullified or impaired benefits accruing to the US within the meaning of Article XXIII:1(b).

Moreover, providing the correct interpretation of Article III:4 of the GATT (national treatment – domestic laws and regulations), the panel found that the distribution measures were generally origin-neutral and did not have a disparate impact on imported film or paper. The Panel therefore found that the US had not proved that the distribution measures were inconsistent with Article III:4 of the GATT. Also, the panel examined the legal merit of the US argument in relation to Article X:1 of the GATT (trade regulations – prompt publication). The panel considered that the publication requirement in Article X:1 extends to two types of administrative rulings: (i) administrative rulings of "general application"; and (ii) "administrative rulings addressed to specific individuals or entities" that establish or revise principles or criteria applicable in future cases.

Based on this legal standard, the panel found that Japan was not in violation of Article X:1 because the US failed to demonstrate that Japan's administrative rulings at issue in the case amounted to either of these administrative rulings in respect of which the publication requirement under Article X:1 should be applied. In the end, the panel rejected the US complaint on the ground that it had failed to demonstrate that the contended Japanese measures "nullified or impaired", either individually or collectively, the "benefits" accruing to the US within the meaning of GATT Article XXIII:1(b). The panel also based this finding on the fact that that the US had not established that the Japanese "measures" cited by the US accorded less favourable treatment to imported photographic film and paper within the meaning of GATT Article III:4.

The Panel's analysis of the foregoing elements underscores the link between the legitimacy of any expected benefit and whether any measure thereof would have been reasonably anticipated. According to the panel, in order for the expectations of a benefit to be legitimate the challenged measures must not have been reasonably anticipated at the time the concession was negotiated. If the measures were anticipated, a member could not have had a legitimate expectation of improved market access to the extent of the impairment caused by these measures.[108] Therefore, the broad interpretation given the term "measure" is not determinative of the scope of the non-violation action as a whole.

It is, in fact, the concepts of "benefit" and "nullification or impairment" that play the decisive role in determining the outcome of a claim.[109] It is clear from the

[108] *Ibid.* para. 10.76.
[109] EVAN, *supra* note 23, at 879.

above analysis that the panel applied the law judiciously in its proper scope when interpreting measures that potentially may nullify or impair benefits accruing in the context of WTO law, and this interpretative principle created security and predictability as to the correct application of WTO jurisprudence on the protection of legitimate expectation.

B. Reasonable Legitimate Expectations in India - Patent Protection

Prior to the *India – Patent*,[110] certain GATT practices such as conditions of competition, internal measures on quantitative restrictions, tariff commitments, and concessions had all helped to establish broadly two concepts to protect legitimate expectations: the protection of competitive relationship expectations in the context of violation complaints (under Article XXIII:1(a) of GATT) involving Articles III and XI of GATT; and the protection of legitimate expectations relating to market access concessions in the context of NVCs (under Article XXIII:1(b) of GATT) (to protect reciprocal Article II tariff concessions).[111] The panel dealt with the provisions of TRIPS in a situation outside the scope of the two specific concepts developed earlier.

The measure at issue: (i) India's "mailbox rule" – under which patent applications for pharmaceutical and agricultural chemical products could be filed; and (ii) the mechanism for granting exclusive marketing rights to such products. IP at issue was Patent protection for pharmaceutical and agricultural chemical products, as provided under Article 27 of TRIPS. It was alleged that the measure does not make patent protection available for inventions concerning pharmaceutical and agricultural chemical products as provided in Article 27 of the TRIPS agreement, nor does it provide rules that conform to obligations of the TRIPS agreement regarding the acceptance of applications and the grant of exclusive marketing rights.

As a consequence, it was alleged that India's legal regime or measure remains inconsistent with its obligations under the TRIPS agreement, including but not limited to Articles 27, 65 and 70 of the TRIPS agreement. To interpret the TRIPS provisions at issue, the panel sought to protect legitimate expectations on the basis of customary rules of public international law- specifically, the rule of interpreting international instruments in "good faith", stating that "good faith interpretation requires the protection of legitimate expectations derived from the protection of intellectual property rights provided for in the Agreement."[112]

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[110] INDIA – PATENT CASE, *supra* note 11.
[111] GATT 1947, *supra* note 12. [Replaced GATT 1994*, supra* note 33].
[112] INDIA – PATENTS CASE, *supra* note 11, para. 7.18.

The panel reasoned that India has not complied with its obligations under Article 70.8(a) and, in the alternative, paragraphs 1 and 2 of Article 63 of the TRIPS agreement,[113] because it has failed to establish a mechanism or "means" that adequately preserves novelty and priority in respect of applications for pharmaceutical and agricultural chemical product patents under Article 65 of the agreement, and to publish and notify adequately information about such a mechanism;[114] and that India has not complied with its obligations under Article 70.9 of the TRIPS agreement,[115] because it has failed to establish a system for the grant of exclusive marketing rights.[116]

The panel on that basis concluded that India's mailbox application system for patents was in violation of the TRIPS rules. One of the reasons for that finding was that the Indian system did not protect the legitimate expectations of other WTO members. Citing GATT 1947 Panel reports as authority for the principle of legitimate expectations,[117] the panel held that the concept of the protection of legitimate expectations in relation to the TRIPS agreement applies to the competitive conditions in the domestic economies of other members.[118] The panel interpreted the doctrine of protection of legitimate expectations in line with the right of patentees. Thus, its interpretation is consistent with the letter as opposed to the spirit of law as this account truly rejects the legitimate expectations of the public on the basis of good faith application of the law.

Although India lost on the substance claim, on appeal, the AB overturned one of the panel's core reasoning on a matter of law. The AB rejected the panel's use of a legitimate expectations (of members and private right holders) standard, which derives from the non-violation concept, as a principle of interpretation for the TRIPS agreement.[119] It was proclaimed that protection of legitimate expectations

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[113] *Ibid.* para. 7.59

[114] *Ibid.* paras. 6.34 and 7.60.

[115] *Ibid.* para. 6.16.

[116] *Ibid.* para 6.67.

[117] The Panel Report, *Italian Discrimination Against Imported Agricultural Machinery*, ¶¶ 12-13, BISD 7S/60 (23 Oct. 23, 1958). The Panel Report, *US - Taxes on Petroleum and Certain Imported Substances*, ¶5.22, BISD 34S/136, (Jun. 17, 1987). The Panel Report, in US - Section 337 of the Tariff Act of 1930, ¶ 5.13, BISD 36S/345 (Nov. 7, 1989).

[118] INDIA-PATENT CASE, *supra* note 11, para. 7.21.

[119] Appellate Body Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products,* ¶ 48, WT/DS50/AB/R (Dec. 19, 1997). [hereinafter AB INDIA-PATENT].*See* Ruth Okediji, Rules of Power in an Age of Law: Process Opportunism and TRIPS Dispute, in HANDBOOK OF INTERNATIONAL TRADE: ECONOMIC AND LEGAL ANALYSES OF TRADE POLICY AND INSTITUTIONS 49 (Kwan Choi and James Hartigan, eds., Oxford, UK, Blackwell, 2004).

of members is a well-established GATT principle.[120] The AB based its conclusion on the following: (i) the protection of legitimate expectations is not something that was used in GATT practice as a principle of interpretation; and (ii) the panel's reliance on the Article 31 of the VCLT for its legitimate expectations interpretation was not correct because the 'legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself'.

Pointing to Articles 3.2 and 19.23 of the DSU,[121] the AB clarified that the process of treaty interpretation should not include the 'imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended'.[122] Here, it is evident that the AB attempted to ignore the reliance or invocation of the spirit of law but concentrated on the letter alone. For added clarity, the AB reasoned that the DSB must be guided by the rules of treaty interpretation set out in the VCLT, and must not add to or diminish the rights and obligations provided in the WTO agreement.[123] However, more significantly, the decision of the AB leaves intact the possibility of deploying customary rules of international law to claim legitimate expectations, which can also favour the protection of public interests or their legitimate protection.

From a developing country perspective, the AB's decision is particularly interesting because it limits the scope of TRIPS obligations, thus pre-empting possible policy freedom available to India to determine the appropriate method of implementing its obligations under the TRIPS agreement within the context of its own legal system[124] to promote the public interest, which remains a central principle underpinning the Indian patent system. For example, Section 83(d) of the Indian Patent Act 1970[125] holds a fundamental principle on which patents are granted in India and this is governed by the reasonable requirement of the public that also echoes the entire "principles" (Article 8) on which the TRIPS agreement is built upon.[126]

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[120] INDIA-PATENT CASE, *supra* note 11, para 7.20.
[121] DSU. Articles 3(2) and 19(2) make clear that panels and the Appellate Body "cannot add to or diminish the rights and obligations provided in the covered agreements".
[122] AB INDIA-PATENT, *supra* note 119, para. 45.
[123] *Ibid.* paras. 40, 43. *See* CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 235 (Oxford, Oxford University Press, 2007).
[124] AB INDIA-PATENT, *supra* note 119, para. 59.
[125] The Indian Patents Act, 1970 [Act 39 of 1970 amended].
[126] Thaddeus Manu, Examining the Legality of Affordability Requirements as a Substantive Condition for Granting Compulsory Licences Pursuant to the TRIPS Agreement, 18 JWIP 6, 313 (2015).

It provides that: 'patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interests especially in sectors of vital importance for socio-economic and technological development of India'. Consistent with the goal of public health protection, the relevant provision of the Indian Patent Act provides that 'patents granted do not in any way prohibit Central Government in taking measures to protect public health'.[127] Therefore, if the Indian measure could have helped to promote public health objectives then this interpretative understanding ought to be valid, as the country had formed a convincing legitimate expectation that public health remained a significant public policy goal right from the negotiation of TRIPS.[128]

The interesting aspect of the legal logic enumerated in the India - Patent case is that although in substance the legal question before the panel was whether India holds any legitimate expectation, as to the implementation of TRIPS obligations, in contrast, the legal position of the AB in its application of the doctrine of legitimate expectation deviates in from the Japan – Film's case. We therefore learn immediately that although in the Japan – Film's case WTO does permit use of customary international law and thus, legitimate expectations must be respected if they are a result of mutual intention and if they also satisfy other requirements this is not quite the case from a developing country position.

C. Reasonable Legitimate Expectations in the EC – LAN

EC - LAN involved the general customary rule of legitimate expectations in yet another context — an alleged violation of Article II of GATT 1994 that prohibits members from applying tariffs inconsistent with their schedule of concessions. The AB approved of the panel's examination of the context of the object and purpose of the WTO agreement; of which the legitimate expectations are an integral part.[129] The report of the AB reversed the findings of the panel that the US was entitled to legitimate expectations.[130] This is when the EC had argued that the existence of a common intention forms the basis for the mutual consent of the signatories to be bound by an international agreement. Therefore, this common intention finds its authentic expression in the text of the treaty, not in the subjective expectations of one or other of the parties to the agreement.

Moreover, in the view of the EC, the balance of mutual concessions among members, which is the result of the successive rounds of negotiations in the framework of the GATT/WTO, would be severely upset if the legitimate

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[127] *Ibid. see*, Section 83(e).
[128] DRAHOS AND BRAITHWAITE, *supra* note 24 and the accompanying text.
[129] EC-LAN, *supra* note 10, para. 88.
[130] *Id.*

expectations of one member would, through the principle of Most Favoured Nation, apply to all other members whose balance of reciprocal concessions was based on substantially different and variable legitimate expectations.[131] Consistently, the legitimate expectation according to the AB of members is consistent with the principle of good faith under Article 31 of the VCLT.[132] The reasoning of the AB, consistent with EC's argument, was that the purpose of treaty interpretation under Article 31 of the VCLT is to ascertain the common intention of the parties, which cannot be ascertained on the basis of the subjective and unilaterally determined expectations of one of the parties to a treaty.[133]

In other words, the AB characterised legitimate expectations to be beyond the realm of the principle of good faith if such expectations were unilaterally based on the subjective interpretations of one party to a treaty, rather than an objective, ascertainable conduct of parties.[134] This understanding persuasively questions the validity of subjective expectation of the US, which in particular, consistently attempts to put pressure on developing countries to abandon the use of compulsory licences to obtain affordable medicines for public health protection.[135] For example, the US has threatened South Africa,[136] Thailand and later India. The US threatened to impose sanctions on Thailand if it went ahead to issue a compulsory licence to obtain affordable medicines.[137] Moreover, following India's use of compulsory licensing in Bayer v Natco[138], evidence suggests that the country has come under intense bilateral pressure from the US.[139]

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[131] *Ibid.* para 16.
[132] *Id.* para 83.
[133] *Id.* para 84.
[134] *Id.*
[135] Thaddeus Manu, *Essential Medicines and the Complexity of Implementing Nationally Based Compulsory Licensing: On the Need for a Regional System of Compulsory Licensing in Sub-Sahara African*, 36 E.I.P.R 1, 47 (2014) [hereinafter MANU].
[136] The US threatened to respond forcefully in accordance with appropriate trade remedy if South Africa does not repeal, suspend, or terminate the amendment of Section 15(c). Available at: http://www.cptech.org/ip/health/sa/stdept-feb51999.html [Accessed Mar. 12, 2017]. Jerome Reichman, Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 J. Law Med. Ethics 2, 256 (2009). [hereinafter REICHMAN]. Michelle Nerozzi, The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being TRIPped by Developed Countries, 47 Vill. L. Rev. 3, 616 (2002), noting that the US has threatened to curtail economic aid programs and to impose trade sanctions on the governments of South Africa.
[137] ABBOTT AND REICHMAN, supra note 17, at 953. SUZANNE MULLIGAN, CONFRONTING THE CHALLENGE: POVERTY, GENDER, AND HIV IN SOUTH AFRICA 62 (Peter Laing Academic Publishers, Vol. 4, 2010).
[138] The Controller General of Patents and the Order: Mumbai-India [CLA No. 1 of 2011, Decision on Mar. 12, 2012] Available at:

IV. TRIPS AND THE ISSUE OF "BENEFITS" DERIVED FROM MARKET ACCESS

As emerged from the above discussion, Article XXIII:l(b) of the GATT simply refers to any "benefit" accruing, directly or indirectly, under the agreement. Nevertheless, it does not further define or explain what "benefits" are referred to.[140] Significantly, WTO law considers that such "benefits" constitute those that a member may reasonably or legitimately expect to obtain from a negotiated concession on market access.[141] Despite its simplicity in legal construction, the term "benefit" has generated much philosophical debate and conceptually it lacks a common understanding, as there are profoundly different views as to what is meant by a "benefit" or what will amount to "benefits" given the different levels of development among WTO members. Remarkably, while existing decisions on the non-violation remedy in the GATT context provide a useful framework for the overall analysis, nevertheless, they are of limited use in defining "benefits" in the context of TRIPS.[142]

In hindsight, the notion of a "benefit" as envisaged in TRIPS appears to be quite different from that in the GATT perspective,[143] as the idea of "benefits" is less clear in TRIPS than in GATT, — which embodies specific market access commitments. More significantly, TRIPS principally provided no commitment to market access as the agreement only sets out basic rules for IP protection, and this

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http://www.gnaipr.com/CaseLaws/Controller%20Order%20-%2012032012.pdf [Accessed Mar. 19, 2017]. *See,* Thaddeus Manu, Building National Initiative of Compulsory Licences: Reflecting on the Indian Jurisprudence as s Model for Developing Countries, 14 JITLP 1, 26-35 (2015).

139 A Timeline of US Attacks on India's Patent Law & Generic Competition (Access Campaign and Medecins sans Frontieres, January 2015). Available at: <https://www.msfaccess.org/sites/default/files/MSF_assets/IP/Docs/IP_factsheet_TimelineUSPressureIndia_ENG_2014.pdf> [Accessed Mar. 14, 2017]. Peter Roderick and Allyson Pollock, India's Patent Laws under Pressure, 380 *The Lancet* 9846, e2 (2012).

140 CHARLES FRIED, CONTRACT AS PROMISE: A THEORY OF CONTRACTUAL OBLIGATION 87 (BOSTON, MA: HARVARD UNIVERSITY PRESS, 1981) [hereinafter FRIED].

141 The Panel Report, *EEC - Tariff Treatment on Imports of Citrus Products from Certain Countries in the Mediterranean Region (EEC – Citrus)*, ¶ 4.27, 4.34, L/5776 (Feb. 7, 1985 [not adopted]. *See* EVANS, *supra* note 23, at 881.

142 *See* Further Consideration of Non-Violation Nullification or Impairment Under the Agreement on Trade-Related Aspects of Intellectual Property Rights. Communication from Canada. Council for TRIPS, ¶ II(B), IP/C/W/249 (Geneva, Mar. 29, 2001).

143 *See,* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 223, IP/C/M/29 (Geneva, meeting held on Nov. 27-30 and Dec. 6 Dec. 2000) [Restricted].

may structurally damage the concept of benefit – a basis that would help claim for legitimate expectations under the agreement.[144] As a *sui-generis* agreement that establishes minimum standards of IP protection,[145] TRIPS facilitates IP rights, and thus it can be argued that the agreement is not a market access arrangement as such, as it is concerned with rights associated with products and not products *per se*.[146]

Nonetheless, it is essential to note that IP rights have the potential to impact market access, when relevant markets are not supplied or are under supplied. Consequently, it can be argued that TRIPS is a market access agreement because it helps reduce market distortions that existed prior to its negotiation by establishing adequate minimum standards regarding the availability, scope and use of trade-related IP rights,[147] and by ensuring effective and appropriate means for the enforcement of those rights.[148] This fundamental claim is enhanced by the fact that the Preamble of the agreement is intended 'to reduce distortions and impediments to international trade … and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade'.[149]

Pointedly, market access obligations are condensed in the respective GATT and General Agreement on Trade in Service (GATS)[150] schedules of WTO members,

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[144] *See*, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 60 IP/C/M/62 (Geneva, meeting held on Mar. 2-3, 2010) [Restricted].

[145] Non-Violation and Situation Nullification or Impairment Under the TRIPS Agreement. Communication from Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela. Council for the TRIPS. ¶ 31, IP/C/W/385 (Oct. 30, 2002).

[146] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 280, IP/CM/37/Add.1 (Geneva, meeting held on Nov. 17-19, 2002). *See also* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 62, IP/C/M/62 (Geneva, Meeting held Mar. 2-3, 2010) [Restricted].

[147] *See,* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 204, IP/C/M/65 (Geneva, Meeting held on Mar. 1, 2011). *See also* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 270, IP/C/M/67 (Geneva, Meeting held on Oct. 26-27 and Nov. 17, 2011).

[148] Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, 2, IP/C/W/194 (Geneva, Meeting held on Jul. 17, 2000), *see* subheading: "The TRIPS Agreement is a Market Access Agreement".

[149] *See* TRIPS AGREEMENT, *supra* note 15, Preamble.

[150] GATS 1994, *supra* note 33.

and have been negotiated in successive GATT/WTO Rounds.[151] Notably, the results of WTO market access negotiations were recorded in national schedules of concessions annexed to the Uruguay Round Protocol, which formed an integral part of the Final Act.[152] The perception of differences between the agreements exists because the rights under TRIPS are granted to persons rather than applied to goods.[153] However, like any other WTO agreement, the rules set forth in TRIPS determine the way in which a WTO member's goods and services should be treated in the territories of other members, making the agreements more alike than different in their application and purpose.[154]

Such a perception is also held by developed countries like the US that sees no substantial difference between the GATT, GATS and TRIPS agreement as they all are part of a single undertaking.[155] In fact, it is argued that the "benefits" accruing to members under TRIPS are just as clear logically as those deriving from the GATT and other WTO agreements. This understanding would consistently vindicate the common view that TRIPS is a market access agreement since the agreement is not designed to protect market access, but to establish standards of IP protection, which, if abused (inadequate supply), may even undermine market access (impair benefits).[156]

The alternative proposition is that TRIPS is a market access agreement, but of a distinctive character;[157] and that from a typical developing country perspective additional measures are more or less needed in order to accrue "benefits" from the agreement. With this premise in mind, nothing should stop developing countries from circumventing the rigidity of the enforcement provisions under TRIPS pursuant to pharmaceutical patents with a view to demanding "benefit" from the agreement, which seems to have already eroded their legitimate expectation on access to medicines for public health protection. It is significant that the TRIPS agreement allows for the use of compulsory licensing to protect the public interest.

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[151] MARRAKESH AGREEMENT, *supra* note 1. *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 159, IP/C/M/27 (Geneva, Meeting held on 26-29 June 2000, para 159.

[152] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 1867 U.N.T.S. 14.

[153] Council for TRIPS. Non-Violation and Situation Complaints, Summary Note by the Secretariat, ¶ 34, IP/C/W/349/Rev.2, (Oct. 19, 2012).

[154] *Id.*

[155] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 41 IP/C/W/349/Rev.2 (Geneva, Meeting held on Jun. 19, 2002).

[156] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 126, IP/C/M/75/Add.1 (Geneva, Meeting held on Feb. 25-26, 2014).

[157] *See generally,* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 27, IP/C/W/349/Rev.2 (Geneva, Meeting held on Jun. 19, 2002).

V. COMPULSORY LICENCES AS GOOD FAITH "MEASURES" FOR PUBLIC HEALTH PROTECTION

While the conceptual understanding of the NVC provision is inherently straightforward in legal terms, there is persisting ambiguity surrounding its practical use to achieve fairness, as it still remains confusing and unresolved.[158] In this regard, the doctrine of "good faith" challenges the sufficiency of the text of the WTO agreement from a fundamental fairness standpoint because it implies that the letter of law, if required by good faith, may nonetheless impose duties that are not explicitly mentioned in the agreement.[159] Significantly, the notion of damage, loss or detriment without some express infringement of rights is largely unfamiliar to the fundamental principle of law.[160]

However as a matter of customary international law, states have always been required to carry out their treaty obligations in good faith.[161] Analogously, the private law of obligations requires the promisor to carry out its obligations in good faith, and quite consistently, it may be argued that the real basis of non-violation claims is the doctrine of "good faith".[162] Consequently, it appears clear that even where there is an explicit agreement, it is not the agreement, but judgments of fundamental fairness or the spirit of law that must define how states should act towards each other.[163]

With the foregoing view in mind, nothing in the operation of the doctrine of legitimate expectation compels the conclusion that the letter of law would generally undermine the members' autonomy in the nature of performance of their TRIPS obligations. In fact, this supports the contentious view that the application of good

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[158] Non-Violation and Situation Nullification or Impairment Under the TRIPS Agreement. Communication from Argentina, Plurinational State of Bolivia, Brazil, China, Colombia, Cuba, Ecuador, Egypt, India, Indonesia, Kenya, Malaysia, Pakistan, Peru, Russian Federation, Sri Lanka and Bolivarian Republic of Venezuela to the Council for TRIPS, 2, IP/C/W/385/Rev.1, 3 (May 27, 2015), arguing that application of non-violation and situation complaints is unnecessary, raises systemic concerns and shall not apply to the settlement of disputes under the TRIPS Agreement.

[159] FRIED, *supra* note 140, *see,* footnote 43, at 75. *See also* EVANS, *supra* note 23, at 881.

[160] *Ibid.* Evans, at 880.

[161] VCLT, *supra* note 39, Article 26. GATT 1994, *supra* note 33. Article XX, Chapeau. Appellate Body Report, *EC – Trade Description of Sardines,* ¶ 278, WT/DS231/AB/R, Sept. 26, 2002). Appellate Body Report, US - Continued Dumping and Subsidy Offset Act of 2000, ¶¶ 296–298, WT/DS217/AB/R, WT/DS234/AB/R (Jan. 16, 2003). US-SHRIPS, *supra* note 47, para. 158. *See also* EVANS, *supra* note 23, at 880.

[162] *Id.* at 881, observing that NVC jurisprudence is based on the principle of "Good Faith".

[163] *Id.*

faith depends on the fundamental principle of fairness, and it appears that the spirit of law will defeat any interpretation of TRIPS based on the letter. Therefore, the right of developing countries to grant compulsory licensing for public health protection along the lines of legitimate expectations is justified on the ground of principles of good faith.

By this, it is assumed that a compulsory licensing mechanism is permitted under WTO law.[164] After all, this doctrine reinforces the idea that, subject to certain conditions, a member that in the spirit of TRIPS adopts a policy meant to protect public interests should be required to follow and apply that policy in cases subject to it without being forced to depart from it. This argument is made bearing in mind that many developing countries that have attempted to implement compulsory licences for public health interests have been forced to forego such efforts,[165] even though every state has the right to protect the fundamental interest of its people.[166]

A. Inadequacy of Compulsory Licensing to Serve the Interests of Developing Countries

Taking the view that the TRIPS agreement allows the use of compulsory licensing contingent upon where the law of a member state provides for it, thus, legally WTO members have the right to grant compulsory licences or threaten it usage as a means to promote affordable medicines.[167] Nevertheless, it seems that only developed countries are able to utilise the compulsory licensing regime without any legal questions being raised about the consistency of such measures with TRIPS.[168]

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[164] TRIPS AGREEMENT, *supra* note 15, Article 31. GERVAIS, *supra* note 170, at 165, commenting that that the fact that the grounds for issuing a compulsory licence was left open means that compulsory licensing is permitted.

[165] Myles Getlan, TRIPS and the Future of Section 301: A Comparative Study in Trade Dispute Resolution, 34 COLUM. J. TRANSNAT'L L. 1, 173 (1995), for more details regarding Brazilian, South African, and Thai Section 301 cases.

[166] *See generally*, Felipe Romero-Moreno, The Digital Economy Act 2010: Subscriber Monitoring and the Right to Privacy under Article 8 of the ECHR, 30 Int'l. Rev. Law, Comp. & Tech. 3, 7 (2016), discussing generally the responsibility of the state to protect the public interest.

[167] Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement ¶ 2.135 (Geneva, UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, Cambridge. Cambridge University Press, 2005), stating that compulsory licences are generally a matter of national law.

[168] James Love, Research Note: Recent European Union Compulsory Licenses. (Geneva, Knowledge Ecology International, Mar. 17, 2014). Annex B, Special 301 comments, citing Italy, Germany and the UK. Available at: http://keionline.org/sites/default/files/Annex_B_European_Union_Compulsory_Licenses_1Mar2014_8_5x11_0.pdf [Accessed Apr. 6, 2017. Divya Murthy, The Future of

As a matter of empirical logic, the compulsory licensing instrument was an area of intense negotiations leading up to the conclusion of TRIPS.[169]

Negotiation history suggests that developed countries generally sought stronger protection of patented technologies.[170] On the contrary developing countries wanted TRIPS to provide easier access to patented technology, primarily through compulsory licences.[171] Gervais narrates that the US was concerned with how TRIPS would affect the pharmaceutical industry, whereas India had general reservations about restrictions on compulsory licences for patents.[172] In the end, Article 31 of TRIPS, as adopted by the GATT Director General Dunkel endorsed a draft TRIPS agreement, which was not strictly arbitrated by the negotiating parties.[173]

Titled: "Other Use Without Authorization of the Right Holder", in as much as members law permit Article 31 only conditions the use of compulsory licences based on certain procedural requirements that must be satisfied by members, and the grounds on which to do so are not limited.[174] The controversy surrounding the

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Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health, 17 Am. U. Int'l L. Rev. 6, 1314-1315 (2002), citing the US threat to grant a compulsory licence for Bayer's antibiotic Ciprofloxacin.

[169] Donald Harris, TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing, 18 J. Intell. Prop. L. 2, 383 (2011) [hereinafter HARRIS].

[170] DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, 15 (London, Sweet & Maxwell, 1st ed. 1998) [hereinafter GERVAIS].

[171] *Ibid.* at 16, providing examples that Brazil and Korea, for example, argued for allowing compulsory licensing, while Austria and Hong Kong requested more restrictive measures.

[172] *Ibid.* at 27.

[173] *Ibid.* at 26-27, describing the continuing disagreements among member states in the negotiating rounds regarding compulsory licences.

[174] Arguably, countries also might justify compulsory licences based on a public interest exception under Article 8(1) of TRIPS to prevent abuses by IPRs holders pursuant to Article 8(2). Compulsory licences based on these principles still must be consistent with Article 31. Note that although TRIPS contains numerous conditions key among them are: (1) an effort should be made to negotiate a voluntary licence on reasonable commercial terms, but this requirement may be waived in case of "national emergency" or "other circumstances of extreme urgency" or "in cases of public non-commercial use", Article 31(b) This exception allows a government to bypass the step of negotiating compensation with the patent holder in the interests of expediency; (2) the government must provide for "adequate remuneration" to the right holder, Article 31(h); (3) the licence use must be "predominantly for the supply of the domestic market", Article 31(f). Other conditions include: authorisation of such use shall be considered on its individual merits, Article 31(a); the scope and duration of the licence must be limited to the purpose of the authorisation Article 31(c); the licence is non-exclusive, Article 31(d), and is generally non-transferable Article 31(e); the licence is terminated when the circumstances which led to it cease to exist

negotiation of compulsory licensing regime under TRIPS manifested soon after the inception of TRIPS, and even before several developing country members assume their full obligation to protect pharmaceutical patents. This is when South Africa attempted to use compulsory licensing to mitigate the high costs and shortages of HIV medicines by enacting the South African Medicines and Related Substances Control Amendment Act of 1997.[175]

In a resistance move, thirty-nine pharmaceutical companies, mostly multinational corporations, instituted a lawsuit in the High Court claiming an infringement of the enforcement provision of patent, in particular, pleading whether the proposed Section 15(c), which allowed for compulsory licensing, was compatible with South Africa's obligation under Articles 27(1) and 28 of TRIPS.[176] The matter was never determined before a court; under mounting pressure, the companies eventually dropped their challenge in April 2001.[177]

B. Towards the Doha Declaration on TRIPS and Public Health

The foregoing controversy led to the extraordinary meeting held by the TRIPS Council in 2001, on IP and access to medicines, at the request of African members of the WTO.[178] The Africa Group maintained that the flexibilities particularly, compulsory licensing contained in TRIPS required clarification and that the

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and are unlikely to recur, Article 31(g), and the government's decision is subject to independent judicial review, Article 31(i). *See* HARRIS, *supra* note 169, 18.

[175] The Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18,505, Dec. 12, 1997 [amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991].

[175] Sara Ford, Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents, 15 Am. U. Int'l L. Rev. 4, 952 (1999) [hereinafter FORD]. *See also* Matthew Leis, Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and The Agreement on Trade Related Aspects of Intellectual Property Rights, 3 B.U. Int'l L.J. 1, 222 (2004).

[176] Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa [Case No 4183/98, filed Feb 18, 1998].

[177] Grace Avedissian, Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of Super-Terrorism, 18 Am. U. Int'l L. Rev 1, 256 (2002), stating the US contested South Africa's compulsory licensing law for two years before capitulating to public and interest group pressure.

[178] Informal Session of TRIPS Council for the Special Discussion on IP and Access to Medicines, WTO Doc. IP/C/W/296 (Jun. 20, 2001). Available at: https://www.wto.org/english/tratop_e/trips_e/counciljun01_e.htm [Accessed Apr. 5, 2017].

agreement itself may possibly need an amendment.[179] They argued that, 'Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health'.[180] On 14 November 2001, the 4th Ministerial Conference adopted the Doha Declaration on TRIPS and Public Health, which clarified that, 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.[181]

The Doha Declaration also identified a conspicuous weakness of the compulsory licensing provision under TRIPS regarding the inability of certain WTO members that lacked sufficient manufacturing capacity to take advantage of compulsory licences to promote local manufacture of generic medicines.[182] The members further instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[183] This resulted in the 30 August 2003 Decision on the Implementation of the Doha Paragraph 6 Programme, which sought to remedy the complex legal environment that prevents developing countries from obtaining affordable medicines. This decision initially waived the obligation set out in Article 31 Paragraphs (f) and (h),[184] and eventually led to the Amendment of Article 31(f), which provided that any such use shall be authorised predominantly for the supply of the domestic market of the member authorising such use.[185] The permanent amendment was

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[179] *Ibid.* para. 29.

[180] *See*, Draft Ministerial Declaration: Proposal from a Group of Developing Countries, ¶ 1, WTO Docs. IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001), this argument was one of the main points of contention during the preparatory work for the Doha Ministerial Council Meeting. Available at: http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm#Top [Accessed Apr. 2, 2017].

[181] Full Texts of the World Trade Organisation, Declaration on the TRIPS Agreement and Public Health, ¶ 5(b) WT/MIN(01)/DEC/2, 41 I.L.M. 755. (Nov. 14, 2001) [hereinafter DOHA DECLARATION]. *See,* Bryan Mercurio, TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World, 8 Marq. Intell. Prop. L. Rev. 2, 244 (2004), observing that the Doha Declaration sought to clarify the interpretation of TRIPS and emphasised the flexibilities already written into the agreement.

[182] *Ibid.* para. 6.

[183] *Ibid.* at para. 6.

[184] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003 ¶ 3, WT/L/540 and Corr. 1 (Sept. 1, 2003).

[185] TRIPS General Council on the Amendment of the TRIPS Agreement, WT/L/641 (Decision of Dec. 6, 2005).

intended to give legal certainty that would make it easier developing countries to use compulsory licensing.[186]

Mike Moore, the then WTO Director-General, observed that: 'The settlement shows that the WTO's Agreements, such as TRIPS, contain the necessary flexibility to meet the health needs of developing countries and can be used as a basis for resolving difficult issues concerning access to essential drugs'.[187] The EC also adopted a series but comparable resolution and regulation aimed to promote the spirit of the Doha solution.[188] In fact, the general expectation following the Doha Declaration was that developing countries facing the outbreak of diseases will use compulsory licences to mitigate the high costs and shortages of essential medicines.[189] However, the reality departs from that expectation, as relatively few developing countries have issued compulsory licences and even those countries that were successful did so under repressive bilateral conditions.[190] The argument against the use of compulsory licences is based on a broad consensus that patents on pharmaceutical medicines provide a very strong economic incentive for research.[191] Hence, their usage may potentially reduce the incentive to invest in

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[186] Thaddeus Manu, Assessing the Potential Impact of Intellectual Property Standards in EU and US Bilateral Trade Agreements on Compulsory Licensing for Essential Medicines in West African States, 23 Afr. J. Int'l & Comp. Law 2, 227 (2015), stating that the WTO seeks to address the legal complexity set out in Article 31(f)

[187] Mike Moore, "Moore Welcomes News of Settlement of South Africa Drug Lawsuit" (Apr. 19, 2001). Available at: http://www.wto.org/english/news_e/spmm_e/spmm58_e.htm [Accessed Jun. 11, 2015]. *See also* James Thuo Gathii, *Approaches to Assessing Essential Medicines and the TRIPS Agreement,* in INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE 400 (Peter Yu, ed., Westport Connecticut, Praeger, Vol. 4, 2007).

[188] European Parliament Resolution on Access to Drugs for HIV/AIDS Victims in the Third World, 2001 OJ (C 343) 300.37 *See also,* Regulation (EC) No 816/2006, OJ L 157 of 9.6.2006.

[189] HARRIS, *supra* note 169, at 387.

[190] Note that Switzerland in 2015 puts a bilateral pressure on Colombia's Ministry of Health and Social Protection to deny the granting of a compulsory licence for Imatinib, a leukaemia medicine owned by Novartis. Ambassador Livia Leu, the Swiss Head of Bilateral Economic Relations and Delegate of the Federal Council for Trade Agreements. Available at:
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closing-arguments.pdf> [Accessed Mar. 19, 2017].

[191] Henry Grabowski, Patents, Innovation and Access to New Pharmaceuticals, 5 J. Int'l Econ. L.
4, 850 (2002).

research and development.[192] It is on this basis that the pharmaceutical industry often fight the use of compulsory licences.[193] Notably, while some believe that the procedural requirements appear under Article 31 of TRIPS are technically vague and complex, and thus, prohibits developing countries use of compulsory licensing,[194] others also provide that some countries fear retaliation from key developed countries.[195] This is further compounded by bilateral IP and investment agreements, which often contains TRIPS-plus provisions.[196]

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[192] Richard Epstein and Scott Kieff, Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents, 78 U. Chi. L. Rev. 2, 92 (2011), claiming that efforts to justify compulsory licensing for pharmaceutical patents are simply not tenable because defenders fail, first, to understand the power of the background presumption against it.

[193] Stephanie Skees, Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?, 17 Pace Int'l L. Rev. 2, 242. Richard Castellano, Note, Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent 46 IDEA: The Intell. Prop. L. Rev. 2, 289 (2006). Cole Fauver, 'Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come, 8 Nw. J. Int'l L. & Bus.3, 676 (1987), explaining that compulsory licences reduce the inventor's incentive to develop new technology. [hereinafter FAUVER].

[194] Cynthia Ho, Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS, 34 N.C. J. Int'l L.& Com. Reg. 2, 462 (2009). Jennifer Andrew, Swine Flu, Bird Flu, Sars, Oh My! Applying the Precautionary Principle to Compulsory Licensing of Pharmaceuticals Under Article 31 of TRIPS, 2011 Mich. St. Law Rev. 2, 416 (2011).

[195] HARRIS, *supra* note 169, at 387.

[196] The non-technical term TRIPS-Plus refers to provisions for the protection of IPRs that go beyond the WTO/TRIPS standards. Peter Drahos, 'BITs and BIPs: Bilateralism in Intellectual Property' (2001) 4 *The Journal of World Intellectual Property* 6, 798, stating that the two actors responsible for this process are the US and the EU. Frederick Abbott, Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health, 12 (Geneva, Quaker United Nations Office, Occasional Paper 9, 2002), noting that they appear designed to negate the effective use of compulsory licensing, which contravenes the letter and spirit of the Doha Declaration. Mohammed El Said, Public Health related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region, 46 (Cairo, World Health Organisation and International Centre for Trade and Sustainable Development, 2010). Sisule Musungu and Graham Dutfield, Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organisation, 2 (Geneva, Ottawa, Quaker United Nations Office and Quaker International Affairs Programme, TRIPS Issues Papers 3, 2003), explaining that the TRIPS-plus concept covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions.

VI. APPLICATION OF THE DOCTRINE OF LEGITIMATE EXPECTATION FOR PUBLIC HEALTH PROTECTION

On the basis of the preceding analysis, it is important to appreciate the significance of trust to the doctrine of good faith, which provides guidance about the scope of the doctrine of customary rules of interpretation of public international law, and how the doctrine could interact, or how it ought to be applied consistently, in meeting the legitimate expectations of developing countries that seek essential medicines for public health protection. Notably, while maintaining their commitments in the TRIPS agreement, the WTO members recognised that the Doha Declaration solution should be used in good faith to protect public health.[197]

At the very least, this logically implies an unconditional acceptance rather than a total rejection of the principle of reasonable legitimate expectations under the TRIPS and within the WTO law. The reason behind the same is that the WTO requires trust from developing countries to redeem its image, which by a unanimous assumption from the standpoint of developing countries is being damaged due to the perception that TRIPS only meets the unilateral expectations of developed countries.[198] Often, stronger protection of patents is sought for and the use of compulsory licences is discounted on the basis that these safeguards instruments are inconsistent with TRIPS.[199]

Importantly, only the right to prevent third parties from taking certain actions is given to patentees under TRIPS.[200] The agreement does not allow the patentees to exploit their rights if other provisions of law, otherwise consistent with the WTO agreements, prohibit that exploitation.[201] Essentially, while TRIPS requires that adequate remedial measures should be provided, in most cases it gives substantial discretion to members to determine the level of appropriate remedies.[202] Pursuant

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[197] The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Excerpt from the General Council Minutes, Statement Read Out by the Chairman of the General Council, ¶ 29, WT/GC/M/82 – Meeting of Aug. 25, 26 and 30, 2003.

[198] DRAHOS AND BRAITHWAITE, *supra* note 16 and the accompanying text. *See also* WILLIAM CLINE, TRADE POLICY AND GLOBAL POVERTY 264 (Washington DC., Peterson Institute, 2004), accusing the WTO of widening the social gap between rich and poor.

[199] MANU, *supra* note 135.

[200] TRIPS AGREEMENT, *supra* note 15, Article 28.

[201] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, 3, IP/C/W/194 (Geneva, Meeting held on Jul. 17, 2000) *see* subheading: "The TRIPS Agreement is One Part of a Coherent System of Agreements".

[202] TRIPS AGREEMENT, *supra* note 15, Preamble of Article 31.

to this, non-violation causes of action might also be foreseen in the area of use of flexibilities, such as compulsory licensing, for public interest protection.

This leaves open the question of whether or not domestic policy orientation, meant to protect public health, could be regarded as an actionable benefit for the purposes of a NVC claim. Accordingly, members' responsibility to regulate important matters should not be undermined by actual or threatened NVC claims under TRIPS. Therefore, the non-violation remedy should not constrain members from implementing public health policies.[203] In other words, a member should consider whether the measure being contemplated could have been foreseen during the Uruguay Round negotiations in case a proposed national measure appears to have an adverse effect on the owners of IP rights.[204]

From a law and economics perspective, the question is whether per the theory of efficient breach any adoption of pro-health measures in order to obtain any pharmaceutical technology may lead to an efficient breach of WTO/TRIPS.[205] The answer lies in the fact that WTO law is not closed, self-contained system, isolated from the rest of public international law.[206] Therefore, there is a solid basis that the general rules of treaty interpretation as set out in the VCLT, which also guide the interpretation of WTO can be deployed as an interpretative tool to clarify the consistency of pro-public health measures with TRIPS.[207]

Logically, the starting to frame any discussion regarding the consistency of pro-public health measure with TRIPS is to understand that the principal aim of the

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[203] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 176, IP/C/M/27 (Geneva, Meeting held on June, 26-29, 2000)

[204] Ministerial Declaration of Punta del Este Sept. 20, 1986, Sept. 20, 1986, MIN(86)/W/19, 25 I.L.M. 1623 (1986) (Punta del Este Declaration, launching the Uruguay Round GATT Doc. Min. Dec. No. 86 – 1572, 1986-1994) [hereinafter PUNTA DEL DECLARATION}. For a detailed negotiation history *see* TERENCE STEWART, THE GATT-URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1992) ((The Hague, Kluwer Law International, 1993).

[205] Joost Pauwelyn, WTO Dispute Settlement: Of Sovereign Interests, Private Rights and Public Goods, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALISED INTELLECTUAL PROPERTY REGIME 823 (Keith Maskus and Jerome Reichman, eds., Cambridge, Cambridge University Press, 2005), describing the efficient breach as a 'safety valve that may, in the long run, serve to legitimise WTO obligations, rather than to undermine them'.

[206] The Report of the Appellate Body in US - Standards for Reformulated and Conventional Gasoline, 17, WT/DS2/AB/R (Apr. 29, 1996). PETER VAN DEN BOSSCHE AND WERNER ZDOUC, THE LAW AND POLICY OF THE WORLD TRADE ORGANIZATION 61 (New York, Cambridge University Press, 3rd edn. 2013).

[207] AB INDIA-PATENT, *supra* note 199, para 46.

WTO agreement is to protect expectations, particularly, those formed by its members or governments.[208] The AB in *Turkey – Restrictions on Imports of Textiles and Clothing Products* case, accepted a statement in legal principle that WTO system of rights and obligations provides, in certain instances, flexibility to meet the specific circumstances of members or for governments to respond to specific realities.[209] In this perspective of things, the AB in *Japan – Alcoholic Beverages II* indicated that the rules of the WTO are not so rigid or so inflexible and that they will served the multilateral trading system best if they are interpreted with that in mind.[210]

Therefore, it is presumed that members to a treaty will refrain from imposing unreasonable burdens on one another,[211] or specifically, to refrain from acts calculated to frustrate the principles of the treaty, which in the context of TRIPS is to promote the public interests.[212] As the AB in the *EC – Hormones* case noted: 'We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation'.[213] Importantly, Article 60 of the VCLT raises the presumption that any reasonable measures adopted by a party in accomplishing the object and purpose of any agreement would not generally constitute a material breach. Article 60.5 even permits for a material breach of a treaty for the purposes of protecting the human person and this includes public health interests.[214]

Remarkably, the theory of efficient breach takes the position that, from an economic perspective, breach is acceptable, and indeed should be encouraged by law if such an action results in an outcome that benefits the breaching party and

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[208] Chios Carmody, WTO Obligations as Collective, 17 Eur. J. Int. Law 2, 422 (2006).

[209] For instance, Appellate Body Report, *Turkey – Restrictions on Imports of Textiles and Clothing Products,* ¶ 9.184, WT/DS34/R (May 31, 1999).

[210] JAPAN – ALCOHOLIC BEVERAGES, *supra* note 2, para. 34.

[211] United Nations Commission on International Trade Law Yearbook 150 (New York, United Nations Publication No. A/CN.9/SER.A/2000, Vol. 31, 2000), finding that many legal systems generally recognise that a party that fails to perform its obligation because of the occurrence of certain types of events may be exempted from the consequences of any such failure to perform.

[212] Jerome Reichman, From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement, 29 New York Univ. J. Int.'l L. & Pol. 1-2, 35 (1997), arguing that if the principles in Article 8 of TRIPS were interpreted properly it would legitimise ad hoc exceptions required by overriding national needs, such as compulsory licensing for public health protection.

[213] Report of the Appellate Body in EC - Measures Concerning Meat and Meat Products (Hormones), (US) ¶ 165, footnote 154, WT/DS26/ARB (Jul. 12, 1999).

[214] David Jonas and Thomas Saunders, The Object and Purpose of a Treaty (2010) 43 VAND. J. TRANSNAT'L L. 3, 576 (2010).

society as a whole.[215] As Reichman puts it, 'compulsory licensing converts exclusive property rights into *de facto* liability rules', and argues that so long as liability rules provide innovators with truly adequate compensation they will be justified.[216] Thus, from a legal perspective, the preferable view would be considering compulsory licensing as a special norm provided by international IP regime. According to this line of argument, issuing compulsory licences would not amount to breach of treaty law, but to inherent limitations of pharmaceutical patents. [217]

VII. TRIPS NEGOTIATIONS AND THE PROMISE OF MARKET ACCESS AND TECHNOLOGY TRANSFER

So far, the foregoing discussion has established that the WTO does permit use of customary international law and thus, legitimate expectations must be respected if they are a result of mutual intention and if they also satisfy other requirements as seen in *Japan-Film* and *EC-LAN*. However, in light of the conclusion reached in the analysis of *India-Patent,* it seems that the DSB respected legitimate expectations but that of developed countries. What can thereupon tilt the balance in favour of developing countries would be the use of negotiating history to bring out promises unfulfilled by the developed countries and thus, make already present flexibilities such as compulsory licensing even broader.

It is important to note that if a party was misled about the extent of their obligations and benefits due to opposing positions, the negotiation history of TRIPS can be adduced to protect legitimate expectations.[218] Significantly, the use of *travaux préparatoires*, has become a constant interpretative tool in resolving disputes over the interpretation of treaties.[219]The DSB has persuasively stressed

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[215] Valentina Vadi, Access to Essential Medicines and International Investment Law: The Road Ahead, 8 JWIT 4, 520 (2005). [hereinafter VADI].

[216] Jerome Reichman and Catherine Hasenzhal, Non-Voluntary Licensing of Patented Inventions 24 (Geneva, ICTSD and UNCTAD Issue Paper No. 5, 2003).

[217] VADI, *supra* note 215, at 521.

[218] ANTHONY AUST, MODERN TREATY LAW AND PRACTICE 197 (Cambridge: Cambridge University Press, 2000), stating that the negotiation history can be used as a supplementary means of TRIPS interpretation.

[219] *Travaux priparatoires* is a term referring to the preparatory work of the treaty negotiations, including documents such as proposals, drafts, statements, and reports of negotiation meetings. *See,* Lord McNair, *The Law of Treaties*, 411 (Oxford, Oxford University Press,1961). Pursuant to Article 32 of the VCLT, *travaux preparatoires* can be used as a "supplementary means of interpretation". *See,* Draft Articles on the Law of Treaties with Commentaries, 218 (Text adopted by the International Law Commission at its eighteenth session, in 1966, and submitted to the General Assembly as a part of the Commission's

that the correct approach towards interpretation of any of the WTO agreements is to focus on the intention of the parties to the agreement.[220] More importantly, the negotiating history of a treaty falls within the category of "Supplementary Means of Interpretation", as given under Article 32 of the VCLT.[221]

Notably, in *Japan - Alcoholic Beverages,* the AB announced that: 'There can be no doubt that Article 32 of the Vienna Convention, dealing with the role of supplementary means of interpretation, has attained the status of customary or general international law'.[222] The place of supplementary materials, according to Article 32 of the VCLT, is strictly secondary and limited to circumstances where applying Article 31 of the VCLT yields an interpretation where terms remain ambiguous or obscure, or the result reached is manifestly absurd or unreasonable.[223]As already indicated one of the potentially difficult subjects for negotiation was compulsory licensing. In fact, while differences existed some agreements were reached and well documented or written down.[224]

At the onset, developing countries asserted in negotiation of their right to use compulsory licences.[225] While the EC argued that compulsory licensing should be a

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report covering the work of that session, Yearbook of the International Law Commission, vol. II, 1966).

[220] US-SHRIMPS, *supra* note 47, paras. 114-117.

[221] Article 32 of the VCLT reads:

> Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31(a) of the VCLT leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.

[222] JAPAN – ALCOHOLIC BEVERAGES, SUPRA note 2, at 9.

[223] EC-LAN, *supra* note 10, paras. 86 and 92.

[224] There were two major working drafts developed in 1990. Chairman's Report to the GNG on the Status of Work in the Negotiating Group (GATT Doe. MTN.GNG/NG11/W/76, Jul. 18, 1990) and the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (GATT Doc. MTN.TNCIW/35/Rev.1, Dec. 3, 1990). Gervais (n 260) comparing these two working drafts article by article with the final TRIPS Agreement. Terence Stewart (ed.), *The GATT-Uruguay Round: A Negotiating History (1986-1992)* (Kluwer Law International, Volume 1, 1993) 2286-2289.

[225] Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay, and Pakistan (GATT Doc. MTN.GNG/NG ll/W/71, May 14, 1990) part HI, chap. II, Article. *See,* Champ and Attaran (n 40) 369. This document is still officially restricted and unavailable on the WTO website; however, it is published in

permissible exception to patent rights,[226] the US was almost alone at the other end of the spectrum, seeking to bar any possible use of compulsory licences.[227] Despite the US using coercion during negotiations,[228] none of these negotiation positions show that the parties will exclude compulsory licensing on any grounds.[229] If it really were the parties' intention after such a protracted debate to eliminate compulsory licensing, one would at least expect to find that remarkable consensus reflected in clear, unambiguous treaty language but this is not the case.[230]

As evidenced in the minutes of the negotiations up to December 1991, nothing indicated that the parties were entertaining the complete prohibition of

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Intellectual Property and International Trade: The TRIPS Agreement, Carlos Correa and Abdulqawi Yusuf (eds.) (Kluwer Law International, 1998) 441.

[226] *See* Draft Agreement on Trade-Related Aspects of Intellectual Property, Communication from the European Communities (GATT Doc. MTN.GNG/NG1lW/68, Mar. 29, 1990) Article 26.

[227] Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States (GATT Doc. MTN.GNG/NG11/W/70, May 11, 1990) Article 27. Paul Champ and Amir Attaran, Patent Right and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S. - Brazil Patent Dispute, 27 Yale J. Int. Law 2, 369 (2002), *see* footnote 25, stating that the US proposal restricted compulsory licensing to national emergencies and anti-competitive abuses. [hereinafter CHAMP AND ATTARAN].

[228] Ana Maria Pacon, *What Will TRIPS Do for Developing Countries?*, in FROM GATT TO TRIPS – THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 332 (Friedrich-Karl Beier and Gerhard Schicker, eds., Munich, Germany, Max Plank Institute of Foreign and International Patent, Copyright and Competition Law, 1996), noting that developing countries were forced to negotiate after the United States began imposing unilateral trade sanctions pursuant to the now infamous "Special 301" law, which authorises the USTR to impose unilateral trade sanctions on countries it declares to be insufficiently protecting IP rights. *See* FORD, supra note 175, Ford, *supra* note 175, at 947, mentioning that this coercion was used during the negotiations in an arbitrary manner that suggests its primary purpose was to influence developing countries in the Uruguay Round negotiations. *See also See also* Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 U. PA. J. INT'L L. 4, 1078 (1996) mentioning that according to the minutes of a June 1991 negotiating meeting, several developing countries expressed frustration with the way the US used the law throughout the negotiations, claiming that it violated the commitments under the Punta del Este Declaration to not take any measures that would improve negotiating positions. *See, importantly*, Negotiating Group on TRIPS, Meeting of Negotiating Group of Jun. 27 and 28, 1991, ¶¶ 4-5. GATT Doc. MTN.GNG/TRIPS/1, (Jul. 25, 1991).

[229] CHAMP AND ATTARAN, *supra* note 226, at 378, citing local working.

[230] *Id.* 370.

compulsory licensing,[231] except remarkably, for the final draft, which was not negotiated but instead determined by the GATT Secretariat.[232] Given that the GATT Secretariat determined the final draft, which fell outside the negotiated or agreed draft, the actual intentions of the parties at the conclusion of the TRIPS agreement are difficult to understand.[233] Thus, the wording in the final TRIPS agreement cannot indicate anything about the negotiators' intentions, and certainly not in the way that a genuine consensus would have done.[234]

Notwithstanding this development, the arbitrated draft allowed for compulsory licensing without regard to any grounds, thus repudiating any conflicting position that sought to allow compulsory licences only for national emergencies or anti-competition violations (the latter limitation resurfaced in the final TRIPS agreement, but only for semi-conductor technology).[235] Notably, in the broader interests of equity and good faith, if developing countries are unable to implement their national policies to, for instance, protect public health then the legitimate expectations can be used to correct concessions agreed on after a potential deliberate misrepresentation by a developed country pursuant to the availability of flexibilities.

With respect to the idea of maximum flexibility for developing country members most of the WTO Ministerial Declarations have recognised that even though developing countries have undertaken significant new commitments, both substantive and procedural, key promises made by developed country members pursuant to market access and technology transfer objectives are yet to be met.[236] Srininavasan's account of the negotiation history of TRIPS has shown that the developing countries knew about the extent to which TRIPS would affect their capacity to protect public health interests, and hence objected to it.[237] However, these countries were promised real benefits including market access and

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[231] *Id.* 378.
[232] *Id.*
[233] *Id.*
[234] *Id.*
[235] Article 31(c) of TRIPS.
[236] Fourth WTO Ministerial Conference. Ministerial Declaration, ¶¶ 4, 6, 13, 16, 17, 37 and 38, WT/MIN(01)/DEC/1 (Doha, Nov. 20, 2001) [hereinafter FOURTH WTO MINISTERIAL DECLARATION]. Sixth WTO Ministerial Conference. Ministerial Declaration, ¶¶ 6, 11, 12, 13, 40, 43, 47 and 52., WT/MIN(05)/DEC (Hong Kong, Dec. 22, 2005) [hereinafter SIXTH WTO MINISTERIAL DECLARATION]. First WTO Ministerial Conference. Ministerial Declaration, ¶¶ 13, 15, 18, WT/MIN(96)/DEC/ (Singapore, Dec. 18, 1996). Second WTO Ministerial Conference. Ministerial Declaration, ¶¶ 5 and 6, WT/MIN(98)/DEC/ (Geneva, May, 20, 1998).
[237] SRINIVASAN, *supra* note 25, at 6. *See also* CARVALHO, *supra* note 22, at 134.

technology transfer that they expected as *quid pro quo* for the opening of farm and textiles markets.[238]

Moreover, Drahos and Braithwaite demonstrate that the developing countries were anxious that higher standards of IP would lead to adverse changes in their national patent laws, which would subsequently take away the flexibility required to obtain essential medicines and these concerns were known to developed countries.[239] Nevertheless, the fact is that TRIPS was carefully negotiated to be sufficiently flexible to accommodate different legal regimes and members' needs to achieve different policy objectives.[240] Furthermore, to interpret the significance of the foregoing viewpoint would mean that pro-health-related measures could fall within such provisions, in rare circumstances, where such a measure was not impliedly or expressly addressed by either party during the negotiations.

This explicitly leaves open the question of whether a party could have expectations for NVC purposes in relation to continued shortages and high costs or relatively lesser market access for certain products, (for example, essential medicines) whose absence is shown to pose a serious risk to human life or health.[241] This understanding, if taken to its natural conclusion, would suggest that the developing countries have no inherent obligation to seek clarification when there is a basis to expect that actual flexibility or fairer treatment will be maintained under TRIPS. This view is based on the contention that developing countries knew during the TRIPS negotiations that they were required to concede so much, and had also reasonably formed a correct idea of the consistency of the compulsory licensing practice.

Thus, the developed country members rightfully, but in good faith, believed that developing countries had legitimate expectations of flexibility and fairer treatment in the international trading system. This calls for TRIPS to be interpreted along the lines of the authentic principle of a good faith. Hence, for the purpose of consistency, the requirement to interpret TRIPS to satisfy the notion of good faith would not be a departure from the practical understanding of developing countries' legitimate expectations of the continuation of the actual benefits that were to accrue, at the time of the TRIPS negotiations. Significantly, the legitimate expectations of developing countries in TRIPS are substantially different from that of developed countries.

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[238] *Id.*

[239] DRAHOS AND BRAITHWAITE, *supra* note 24 and the accompanying text.

[240] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, ¶ 114, IP/C/M/23 (Geneva, Meeting held on Apr. 21-22, 1999).

[241] EC-ASBESTOS, *supra* note 11, para. 190.

This subject is reflected in the fact that while the latter prefer to use TRIPS in its conventional form as a means of rent-seeking to defend their commercial interests, the former prefer to use the flexibilities to obtain access to (technology transfer) essential medicines as promised prior to the inception of the agreement into the international trading system.[242] Consequently, it is fundamental to TRIPS that public policy and technology transfer are adequate — a well-founded notion under the agreement. More significantly, the common intention of the parties as stated in the Preamble of TRIPS is to protect uniform IP standards, while recognising public policy exception, and technology transfer as significant in meeting the reasonable expectations of all members.

Hence, if a compulsory licensing instrument could be used to realise technology transfer and development objectives consistent with TRIPS in meeting the legitimate expectations of any member, then any national action thereof could not be held to nullify or impair a benefit to another member. This view does not dispute the fact that TRIPS intends to make the protection and enforcement of patents a medium to promote technological innovation, transfer, and dissemination at the heart of its objectives in order to improve the socio-economic welfare of everyone.[243] Consequently, the so-called good faith interpretation would allow members to adopt any necessary measures in circumventing what the TRIPS Preamble recognises as only private rights, if those measures were to protect public interests in pursuance of Articles 7 and 8 of TRIPS.[244]

VIII. LEARNING FROM PRACTICE AND EXPERIENCE: COMPULSORY LICENSING FOR PUBLIC INTERESTS

As a matter of empirical analysis, in the past, standards of patent regulation have been territorial standards,[245] granted by governments to encourage scientific progress and the dissemination of information.[246] The standards of patents and their regulatory scope were notions founded territorially under the remit of national law.[247] The principle that shaped this was genuinely based on equal

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[242] Peter Yu, *Toward a Nonzero-sum Approach to Resolving Global Intellectual Property Disputes: What We Can Learn from Mediators, Business Strategists, and International Relations Theorists*, 70 U. Cin. L. Rev. 2, 569,635 (2002), reviewing and presenting an argument that ignores the claim that IPRs under TRIPS were to attract facilitate technology transfer.

[243] TRIPS AGREEMENT, *supra* note 15, Article 7.

[244] *See* Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, 2, IP/C/W/249 (Geneva, Meeting held on Mar. 29, 2001) *see* Section II.

[245] Peter Drahos, Thinking Strategically About Intellectual Property Rights, 21 Telecom. Pol. 3, 202 (1997).

[246] *Id.*

[247] *Id.*

treatment but not on equal standards, given the difference in the socio-economic conditions of countries.[248] An attempt to shift these territorial standards to a global system formed a significant part of the Uruguay Round of the GATT negotiations,[249] and the creation of the WTO.[250]

Nevertheless, the outcome of the negotiations did not alter the fundamental rationale on which countries grant patents - which is to stimulate domestic socio-economic welfare through the industrial application of technological inventions, as opposed to enhancing the welfare gains of foreign countries,[251] and neither did it render the use of compulsory licensing to promote the public interest inconsistent with TRIPS.[252] It is worth noting that before TRIPS, the right of WTO members to grant compulsory licences on any grounds was rarely questioned or rejected.[253] Notably, the concept and practice of compulsory licences are not new, even in developed countries.[254]

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[248] *Ibid.* at 203.

[249] PUNTA DEL DECLARATION, *supra* note 204.

[250] Peter Drahos, Global Property Rights in Information: The Story of TRIPS at the GATT, 13 *Prometheus* 1, 13 (1995).

[251] Michael Halewood, Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law, 35 Osgoode Hall L.J. 2, 245 (1997), arguing that patents are granted in the interest of domestic economy and this serves to promote a number of the policy goals of less developed economies: employment creation, industrial and technological capacity building, national balance of payments, and economic independence. *See* GEORG BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, AS REVISED AT STOCKHOLM IN 1967 71 (Geneva, WIPO Publication No. 611(E) BIRPI, 1969, WIPO Reprinted, 1991). *See also* WIPO: REFUSALS TO LICENCE IP RIGHTS – A COMPARATIVE NOTE ON POSSIBLE APPROACHES 9 (Geneva, WIPO Publication, August 2013) *see,* Box 2. John Michel, *Introduction to the Principal National Patent Systems* (Volume 1, New York, 1936) 15, cited in Justice Rajagopala Ayyangar, Report on the Review of the Patents Law ¶ 21 (New Delhi, September 1959). Available at: http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report [Accessed Apr. 12, 2017], noting that 'Patent systems are not created in the interest of the inventor but in the interest of national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy'.

[252] Chapter 37 of the US Code of Federal Regulations Section 1.56(a) Duty to Disclose Information Material to Patentability, states that 'A patent by its very nature is affected with a public interest'.

[253] Brian Mercurio and Mitali Tyagi, Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements, 12 Minn. J. Int. Law 2, 283 (2010).

[254] FAUVER, *supra* note 193, at 672, citing Canada, Germany, Japan, Sweden, Switzerland and the United Kingdom.

This instrument has a long history and has remained a prominent feature of the general philosophy of patent regimes for over a century.[255] Notably, Article XVI:1 of the Marrakesh Agreement, establishing the WTO reads:

> Except as otherwise provided under this Agreement or the Multilateral Trade Agreements, the WTO shall be guided by the decisions, procedures and customary practices followed by the CONTRACTING PARTIES to GATT 1947 and the bodies established in the framework of GATT 1947.[256]

Importantly, Article 31 of the VCLT, which several WTO panels and the AB agree as attaining the status of 'customary rules of interpretation of public international law'[257] indicates that any subsequent practice in the application of the treaty that establishes the agreement of the parties regarding its interpretation should also be considered.[258] This is consistent with WTO jurisprudence. The AB in India – Patent case recognises that these rules must be respected and applied in interpreting the TRIPS agreement or any other covered agreement.[259]

Significantly, in the *EC - Chicken Cuts* case the AB noted that: 'We observe that "subsequent practice" in the application of a treaty may be an important element in treaty interpretation because it constitutes objective evidence of the understanding of the parties as to the meaning of the treaty'.[260] Notably, Sir Gerald Fitzmaurice argued that:

> The way in which the parties have actually conducted themselves in relation to the treaty affords legitimate evidence as to its correct interpretation ... Conduct usually forms a more reliable guide to intention and purpose than anything to be found for instance in the preparatory work of the treaty,

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[255] Friedrich-Karl Beier, Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law, 30 Int. Rev. Ind. Prop. Copyr. Law 3, 259-260 (1999), finding that most patent laws in developed countries permit compulsory licences, but stressing that actual grants of such licences remain rare.

[256] The Panel Report, *EC - Customs Classification of Frozen Boneless Chicken Cuts,* ¶¶ 265-266, WT/DS269/AB/R, WT/DS286/AB/R, WT/DS269/AB/R/Corr.1, WT/DS286/AB/R/Corr.1 (Sept. 12, 2005) [hereinafter US-CHICKEN CUTS].

[257] For example, US-GASOLINE, *supra* note 83, para. 17. US-CARBON STEEL, supra note 81, paras. 61-62.

[258] VCLT, *supra* note 39, Article 31(3)(b).

[259] AB INDIA-PATENT, s*upra* note 119, para. 46.

[260] US-CHICKEN CUTS, *supra* note 256, paras. ¶¶ 255, 259.

> simply because it has taken concrete and active, and not merely verbal or paper form.[261]

It is significant that the AB acknowledged in *Japan - Alcoholic Beverages II* that:

> Article XVI:1 of the WTO Agreement and paragraph (1)(b)(iv) of the language of Annex 1A incorporating the GATT 1994 into the WTO Agreement bring the legal history and experience under the GATT 1947 into the new realm of the WTO in a way that ensures continuity and consistency in a smooth transition from the GATT 1947 system.[262]

Arguably, the practice and experience of several members in regard to using compulsory licensing has been carried over into WTO jurisprudence, and thus has ensured continuity and consistency in a smooth transition from the GATT to the WTO.[263] According to the foregoing continuity and consistency argument, which underlines the legal basis of a smooth transition from the GATT 1947 to the WTO legal system makes compulsory licensing permissible under TRIPS.[264] Remarkably, in the *Canada - Patent Term* case the AB noted that: 'A treaty applies to existing rights, even when those rights result from 'acts which occurred before the treaty entered into force'.[265]

IX. FUNDAMENTAL FAIRNESS JUSTIFICATION FOR PROTECTING THE LEGITIMATE EXPECTATIONS OF DEVELOPING COUNTRIES UNDER TRIPS

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[261] GERALD FITZMAURICE, THE LAW AND PROCEDURE OF THE INTERNATIONAL COURT OF JUSTICE, 357 (Cambridge, Cambridge University Press, Vol. 1, 1986).

[262] JAPAN – ALCOHOLIC BEVERAGES II, *supra* note 2, para. 35.

[263] BERND HANSEN AND FRITJOFF HIRSCH, PROTECTING INVENTIONS IN CHEMISTRY: COMMENTARY ON CHEMICAL CASE LAW UNDER THE EUROPEAN PATENT CONVENTION AND THE GERMAN PATENT LAW 407 (Berlin, Wiley-Vch: Weinheim, 1997), providing evidence that at least nine of twelve Western European countries permit compulsory licensing on public interest grounds.

[264] The landmark case concerning "The Right of Passage over Indian Territory" (Portugal v. India) [Merits, I.C.J. Reports 1960] 44, para. 6. The Court held that:

> Where therefore the Court finds a practice clearly established…. the Court must attribute decisive effect to that practice for the purpose of determining their specific rights and obligations. Such a particular practice must prevail.

[265] Appellate Body Report, Canada - Term of Patent Protection (US Complaint), ¶ 70, WT/DS170/AB/R (Sept. 18, 2000).

As emerged from the above analysis, scholarly accounts have clearly pinned down the doctrine of protection of legitimate expectations under WTO law as a norm that fits well within the principle of fundamental fairness. Accordingly, several legal scholars regard fundamental fairness as one of the fundamental pillars of law; and it is recognised internationally as a central pedestal or a requirement on which the general principles of law sit.[266] This requires decisions to be made in accordance with the spirit of legal rules and be strongly linked to that of individual autonomy in national jurisdictions to protect national interests, as a significant part of the protection of legitimate expectations.

Significantly, Barak-Erez is of the view that respecting other people's humanity also mandates respect for their legitimate expectations.[267] More significantly, the European Court of Justice has considered the legitimate expectation doctrine vis-à-vis cases where violation of the general principle of law was alleged.[268] A balanced view along these lines would suggest that developing countries deserve fairer treatment, and that, ultimately, fairness is the normative concept most closely associated with the doctrine of legitimate expectations. As a result, Lord Bingham stated that the doctrine of legitimate expectations is "rooted in fairness".[269]

This sentiment is also echoed by Allan, who endorsed fundamental fairness as the logical disposition that underlies the rationale for the doctrine of legitimate expectations.[270] Remarkably, Raz also stated that there is a moral rule that requires promises to be kept, and this doctrine is based on the idea that promises, practices and policies generate legitimate expectations because of their relationship to fairness.[271] Moreover, Reynolds asserts that: 'If all people failed to keep promises then no one would be able to rely on promises and the essential social mechanism of promise would dissolve'.[272] He further contends that: 'The very idea of making a

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[266] James Maxeiner, Some Realism about Legal Certainty in Globalization of the Rule of Law, 31 Houst. J. Int. Law 1, 27, 30 (2008), emphasising the necessity of establishing a rule-based society in the interest of legal certainty and predictability.

[267] Daphne Barak-Erez, The Doctrine of Legitimate Expectations and the Distinction between the Reliance and Expectation Interests, 11 EUR PUB L. 4, 588 (2005).

[268] Mulder v Minister van Landbouw en Visserij, 1988 E.C.R. 2321 in DAMIEN CHALMERS, EUROPEAN UNION LAW: TEXT AND MATERIALS 455 (New York, Cambridge University Press, 2006).

[269] R. v IRC *ex parte* MFK Underwriting [1990] 1 All ER 91, 111.

[270] TREVOR ALLAN, LAW, LIBERTY, AND JUSTICE: THE LEGAL FOUNDATIONS OF BRITISH CONSTITUTIONALISM 197 (Oxford, Clarendon Press, 1994), noting that it is inevitable that the doctrine is explained with reference to fairness since the doctrine largely restates the general principle of fairness in a more technical form.

[271] RAZ, *supra* note 4, 219.

[272] Paul Reynolds, Legitimate Expectations and the Protection of Trust in Public Officials, 2011 J. Pub. L. 2, para, 520 (2010), pointing out that there is an inevitable connection

false promise in a world where false promises are universalised is incoherent', noting that the gratuitous breaking of promises destroys trust.[273]

In addition, he reiterates the possibility of the existence of trust and that any protection of legitimate expectations would demand the same thing: that promises are kept.[274] It is pertinent to note that during the negotiations on TRIPS, developed countries made it clear that the protection of patents would increase the transfer of technology to developing countries, promising a balance of rights and obligations.[275] Also, in fairness to them this promise was culminated with the inclusion of Article 7 of TRIPS,[276] and is also reflected in several provisions of TRIPS, in particular Articles 62 and 67.[277] It is important to note that the Doha Declaration also refers to the as-yet unfulfilled commitment of developed country members to provide incentives to their enterprises and institutions to promote technology transfer to developing countries pursuant to Article 66(2).[278]

The fact that access to essential medicines pertinent to public health protection is lacking in developing countries despite it being over twenty years since the introduction of TRIPS into the international trading system undoubtedly shows that the promise is already a failed one.[279] Given the rationale for the recognition

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between trust and legitimate expectations [hereinafter REYNOLDS]. *See also* ONORA, O'NEILL, TOWARDS JUSTICE AND VIRTUE: A CONSTRUCTIVE ACCOUNT OF PRACTICAL REASONING 174-175 (Cambridge, New York: University Press, 1996).

[273] *Ibid.* REYNOLDS, para. 530.

[274] REYNOLDS, *supra* note 268, para 555.

[275] YU, *supra* note 242, and the accompanying text.

[276] Matthjis Geuze, Effectively Enforcing Your Intellectual Property Rights: Understanding the Full Implications of TRIPS for the Pharmaceutical Industry, Maximizing Patent Protection in the Pharmaceutical Industry 7 (London: Institute for International Research Conference, January 1998).

[277] Note that within the framework of the PREABLE TO THE TRIPS AGREEMENT and Articles 62 and 67 together creates the basis for the desirability of improving technical cooperation and technology transfer to developing countries. See, NINTH WTO MINISTERIAL, *supra* note 72, para. 37. *See also* FOURTH MINISTERIAL WTO DECLARATION, *supra* note 236, para. 37., WT/MIN(01)/DEC/1 (Doha, Nov. 20, 2001). SIXTH WTO MINISTERIAL DECLARATION, *supra* note 236, para. 43. Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* 98 (Alphen aan den Rijn, Netherlands, 3rd edn., Kluwer Law International, 2010). CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 179 (Oxford, Oxford University Press, 2009).

[278] DOHA DECLARATION, *supra* note 181, para. 7.

[279] Thaddeus Manu, *Locally Working Patents and the Grant of Compulsory Licences: The Need for Stronger Statutory Provisions in Africa,*3 *Global Journal of Comparative Law* 2, 203,206 (2014),

that legitimate expectations are grounded in fairness, as a manifestation of law, it is important to achieve legal certainty over the reconciliation between this principle and matters of public health protection. Significantly, the complexities surrounding public health protection in developing countries are well documented in the empirical literature.[280] In most situations, fairness requires a consideration of all the conditions by allowing some margin of flexibility to TRIPS.

In this case, the extent to which countries confronted by the spread of diseases could use compulsory licences to circumvent the strict enforcement of patents to deal with the high costs and shortages of essential medicines continues to challenge public authorities in developing countries.[281] This contention is illustrated by the view that people in developing countries are unable to enjoy the fruits of patented inventions as well as achieve the socio-economic welfare that should, under normal circumstances, accompany the granting of patents.[282] This premise alone implies that developing countries have reasonably acquired the legitimate expectations to exercise their discretion to use compulsory licences to defend their public health interests.

More importantly, essential medicines are classified as part of the human right to health and treated as such within the tenets of international law,[283] and

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observing that the TRIPS Agreement has failed to keep up with its normative promise in view of its inability to deliver key affordable medicines for public health protection in line with the object and purpose of Article 7.

[280] WORLD HEALTH ORGNISATION, THE WORLD MEDICINES SITUATION 61 (Geneva, World Health Organisation, 2004), estimating over 1.7 billion people have little or no access to essential medicines.

[281] UNITED NATIONS, THE MILLENNIUM DEVELOPMENT GOAL 8 -THE GLOBAL PARTNERSHIP FOR DEVELOPMENT: MAKING RHETORIC A REALITY 61 (United Nations MDG Gap Task Force Report, New York, 2012), explaining that the poor continue to face difficulties in obtaining essential medicines because of scarce availability and high prices.

[282] Mark Lemley, Peter Menell and Robert Merges, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 13 (4th Revised ed., New York, Aspen Law, 2007), stating that because IPRs impose social costs on the public, the IP laws can be justified by the public good argument only to the extent that they do, on balance, encourage enough creation and dissemination of new works to offset those costs.

[283] Article 12(1), The International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force Jan. 3, 1976 [hereinafter ICESCRs] maintains that:

> The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

constitutional law of several countries.[284] In line with the principle of universal integration of good faith standards along the customary rules of treaty interpretation governed by the VLCT, WTO law can authentically be read consistent with human rights norms, and more specifically within the framework of TRIPS to promote access to essential medicines which is now a matter of international law.[285] It is important that the AB confirmed that WTO law cannot be read in clinical isolation from public international law and that WTO law should be interpreted according to customary rules of treaty interpretation.[286]

Taking public international law into account, access to essential medicines has been affirmed as an indicator for the fulfilment of the right to health.[287] It is therefore of

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See also Article 35 of the Charter of Fundamental Rights of the European Union [O.J. (2000/C 364/01) provides that:

> Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices…

See also Article 25(1) of the Universal Declaration on Human Rights, G.A. Res. 217(III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948):

> Everyone has the right to a standard of living adequate for the health and well-being …. including …. medical care … in circumstances beyond his control.

For a description of the sources and scope of the right to health, *see* Report of the Special Rapporteur [Paul Hunt] of the Commission on Human Rights on THE RIGHT OF EVERYONE TO THE ENJOYMENT OF THE HIGHEST ATTAINABLE STANDARD OF PHYSICAL AND MENTAL HEALTH, ¶¶ 10-36, E/CN.4/2003/58 (Feb. 13, 2003) As interpreted by the Committee on Economic, Social and Cultural Rights (CESCR), access to essential medicines constitutes a core element of the right to the highest attainable standard of health under the International Covenant on Economic, Social and Cultural Rights. *See* CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) ¶ 43 [Twenty-Second Session of the CESCR, (Contained in UN Doc. E/C.12/2000/4, Aug. 11, 2000).

[284] Katrina Perehudof, Brigit Toebes, and Hans Hogerzeil, Essential Medicines in National Constitutions: Progress Since 2008, 18 HHJ 1, 146 (2016), *see*, Table 1. For a detailed analysis of essential medicines as part of the right to health *see* Thomas Pogge, *Montreal Statement on the Human Right to Essential Medicines* 16 Camb. Q. Health Ethics1, 97-108 (2007).

[285] Jennifer Anna Sellin, Does One Size Fit All? Patents, the Right to Health and Access to Medicines, 62 Neth. Int. Law Rev. 445 (2015).

[286] US-GASOLINE, *supra* note 83, para. 17.

[287] Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development, ¶ 1 (UNHC Res. A/HRC/RES/12/24, thirty-second meeting, twelfth session, agenda item 3, (Oct. 2, 2009), recognising that access to medicine is one of the fundamental elements in achieving progressively the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Economic and Social Council Committee

significance that in strict adherence to the principles of international law, the UN reminded governments of the primacy of human rights obligations over economic policies and agreements.[288] In addition, increasing access to affordable essential medicines is important for achieving the health-related Millennium Development Goals.[289] Relatedly, the UN Sustainable Development Goals[290] have affirmed the right of developing countries to utilise the TRIPS agreement flexibilities to ensure access to medicines for all.[291] Against this background, public health considerations were advanced in terms of its normative content and its legal recognition under the WTO system with a view to making access to medicines a permanent goal of states' policies and programmes.[292]

Therefore, if a compulsory licensing measure could be used to provide access to essential medicines for all to satisfy human rights obligations, such national action would be legitimate under WTO law, a notion already confirmed by WTO members.[293] This logical conclusion provides a framework for proper interpretative analysis of the doctrine of good faith as a tool for promoting access to medicines. The AB in *US – Anti-Dumping* case reasoned that a treaty is to be interpreted in good faith.[294] Therefore, it seems that the right to health has higher chances of being achieved if WTO members particularly, the developed country members act in good faith by allowing developing country members to interpret TRIPS in a manner that supports public health considerations.

Put differently, good faith interpretation of TRIPS will support the use of compulsory licensing to promote access to essential medicines.[295] Therefore, it

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on Economic Social and Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of which he is the Author, ¶ 35 (Article 15, para. 1(c), of the ICESCR). U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006).

[288] Intellectual Property Rights and Human Rights, Sub-Commission on Human Rights Resolution 2000/7, ¶ 3 (U.N. Doc. E/CN.4/Sub.2/Res/2000/7 (Aug. 17, 2000).

[289] Millennium Development Goals 2000. GA Res. A/RES/55/2 (New York, fifty-fifth session, Agenda item 60(b), 8th plenary meeting, Sept. 8, 2000). *See* Goal 4 - Target 5: reduce child mortality. Goal 5 - Target 6: improve maternal health. Goal 6 Target 7 & 8: combat HIV/AIDS, malaria and other diseases.

[290] Transforming our World: The 2030 Agenda for Sustainable Development. GA Res. A/RES/70/1 (New York, seventieth session Agenda items 15 and 116, Sept. 25, 2015).

[291] *Ibid.* Goal 3(3)(b).

[292] DOHA DECLARATION, *supra* note 181.

[293] *Ibid.* para. 4.

[294] Appellate Body Report, US - Anti-Dumping and Countervailing Duties on Certain Product from China, ¶ 326, WT/DS379/AB/R (Mar. 11, 2011).

[295] Muhammad Zaheer Abbas & Shamreeza Riaz, Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After TRIPS,

remains one of the legal mechanisms that these developing countries have in order to achieve their legitimate expectations. Consequently, as a matter of fundamental fairness in the application of TRIPS, key developed countries need to abide by the principle of good faith, and permit developing countries to resort to greater flexibility as part of their public policy exceptions to protect public health – an issue that was collectively settled by the Doha Declaration on TRIPS and Public Health.[296]

Notably, the foregoing Doha Declaration emphasised this by stating that TRIPS does not and should not prevent members from taking measures to protect public health.[297] Accordingly, the members reiterated their commitment to the TRIPS agreement by affirming that the agreement can and should be interpreted and implemented in a manner supportive of the right of WTO members to protect public health and, in particular, to promote access to medicines for all.[298] Furthermore, it reaffirmed that: 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.[299]

X. CONCLUSION

This paper has discussed the doctrine that protects legitimate expectations and the necessity for it to operate as a control mechanism in meeting the diverse interests under the WTO system. Although, WTO panels and the AB have both used the doctrine of legitimate expectations, it remains unclear how their interpretations could shed light on understanding legitimate expectations in relation to the granting of compulsory licences. Moreover, the analysis of this paper has importantly demonstrated that the reliance on this doctrine may lead to the achievement of fundamental fairness in the international trading system to ensure a balance of rights and obligations, and this will help counter any NVCs in the application of TRIPS flexibilities.

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4 ACAD. RES. INT'L. J. 2, 494 (2013), explaining that compulsory licensing is an effective cost-cutting and access-assuring tool at the hands of developing countries and LDCs to obtain affordable medicines. REICHMAN, *supra* note 136, 250, claiming that a threat of compulsory licensing can rein in the prices of selected essential medicines. *See* Michael Kremer, Pharmaceuticals and the Developing World, 16 J. ECON. PERS. 4 ,77 (2002), calling for the use of compulsory licensing of patents as a threat to lower prices in developing countries.

[296] DOHA DECLARATION, *supra* note 181.

[297] *Ibid.* para. 4.

[298] *Id.*

[299] *Ibid.* para. 5(b).

The essential element of this analysis has been to confront the issue of the legitimate expectations in relation to the use of compulsory licences to obtain affordable medicines for legitimate public health protection in developing countries. Consequently, this analysis has revealed how this doctrine could support the protection of public interests, and interact in the spirit of TRIPS to meet wider goals of public health policy, via technology transfer, as promised by the developed countries during the negotiation of TRIPS, and as stated in the Preamble to the agreement – a basis that has compelled developing countries to form legitimate expectations that the TRIPS flexibilities such as compulsory licensing will be used for the protection of legitimate public health.

So far, it has been successfully established that the WTO does permit use of customary international law and thus, legitimate expectations must be respected if they are a result of mutual intention and if they also satisfy other requirements as seen in *Japan-Film* and *EC-LAN*. However, in light of the conclusion reached in the analysis of *India-Patent* case, it seems that the DSB respected legitimate expectations but that of developed countries. What can thereupon tilt the balance in favour of developing countries would be the use of negotiating history to bring out promises unfulfilled by the developed countries and thus, make already present flexibilities such as compulsory licensing even broader.