THE TBT AND THE PPE CONUNDRUM: IS THE WTO EQUIPPED TO EFFECTIVELY ENFORCE STANDARDS?

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Abstract

In the battle against the COVID-19 virus, it is essential that the frontline workers are protected from the risk of infection. PPEs act as a barrier between the user and the virus. However, there have been several cases where the PPEs imported were faulty and not of the recommended international standard. The usage of these faulty PPE kits is hazardous to the health of the healthcare workers and in order to control the impact of the virus, the need of the hour is a healthy healthcare working force. As of now, there has not been an international dispute regarding such non-conformity of standards in the healthcare equipment market. Thus, we must look for a forum to address such issues if need arises. While the World Trade Organization sets the rules of international trade, it is not equipped to enforce these recommended international standards within its framework. This leaves an aggrieved State without any relief. In this article, the author has analysed the possibility of redressal mechanisms being made

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available to the States that have imported these substandard PPEs. The issue of non-conformity to standards can be addressed in the World Trade Organisation's Dispute Settlement Mechanism if it is brought under the aegis of a Covered Agreement. For this purpose, the article explores the possibility of negotiating and introducing a reference paper regarding the regulation of standards. The author contends that a reference will bind the members to adhere to the prescribed standards and provide a forum in the Dispute Settlement Mechanism, if a Member State violates the standards. The article finally argues that the Regulatory Chill effect and the Reputational Cost effect of the Dispute Settlement Mechanism ensure effective enforcement of these standards.

I. INTRODUCTION

Personal Protection Equipment (PPE) kits have been in the limelight throughout the COVID-19 pandemic. PPEs are equipment designed, constructed and worn to minimize the exposure of the user to hazards that can cause workplace injuries and illness.[1] In a medical setting, PPEs act as a barrier between infectious materials such as viral and bacterial contaminants and the skin, mouth nose or eyes.[2] PPEs are medical devices that include gloves, shoe covers, masks, respirators,

[1]'Personal Protective Equipment' (*United States Department of Labor*) <www.osha.gov/personal-protective-equipment> accessed 9 December 2021.

[2]'Personal Protective Equipment for Infection Control' (*Food and Drug Administration*, October 2020) <www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control> accessed 9 December 2021.

eye protection, face shield, head covers, goggles and gowns.[3] The COVID-19 virus spreads through droplet transmission and contact-routes via droplet particles that are greater than 5-10 μm in diameter,[4] which is considerably smaller in size than bacteria or dust. The COVID-19 virus is stable and capable of surviving up to 3 hours in aerosols, up to 4 hours on copper, 24 hours on cardboard and two to three days on plastic and stainless steel.[5] Health care workers are at a higher risk of getting infected as they are in direct contact with the infected patients and surrounding surfaces that are potential sources of infection. The World Health Organisation ("**WHO**") along with other organisations such as United States Centre for Diseases Control and Prevention and the European Centre for Disease Prevention and Control recommend a certain standard of PPEs to prevent the spread of infection.[6] For example, N95, FFP2 or FFP3 masks, in the absence of respirators, are the recommended standards for face masks to protect the user from infection.[7] It is imperative for healthcare workers to use the prescribed standard masks because masks made of materials such as cotton, synthetic fibres, t-shirts, scarves et cetera are

[3]'Components of Personal Protective Equipment (PPE)' (*United States Department of Health*) <www.health.state.mn.us/facilities/patientsafety/infectioncontrol/ppe/comp/index.html> accessed 7 January 2022.

[4]'Modes of transmission of Virus causing COVID-19: Implications for IPC precaution recommendations' (*World Health Organisation*, 29 March 2020) <https://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations> accessed 15 July 2021.

[5]Neeltje van Doremalen & others, 'Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1' (*New England Journal of Medicine*, 16 April 2020) <www.nejm.org/doi/10.1056/NEJMc2004973> accessed 15 July 2021.

[6]'Infection prevention and control and preparedness for COVID-19 in healthcare settings' (*European Centre for Disease Prevention and Control*, 9 February 2021) <www.ecdc.europa.eu/sites/default/files/documents/Infection-prevention-and-control-in-healthcare-settings-COVID-19_6th_update_9_Feb_2021.pdf> accessed 1 April 2021.

[7]ibid.

ineffective in filtering the virus or virus laden droplets.[8] The penetration of particles similar to droplet particles for the corona virus is up to 97 percent for cloth masks.[9] These reusable cloth masks can offer protection to the general population but do not provide requisite protection to the healthcare workers who work in highly infectious situations, and are in contact with patients for prolonged hours.

Amidst the rising demand for the PPE kits during the pandemic,[10] many countries have ramped up their domestic production and import of PPEs to fulfil their needs. However, there have been several cases where the PPEs did not meet the requisite standard and failed to provide the level of protection needed to prevent transmission.[11] In India, about 50,000 of 170,000 PPE kits from China failed the quality tests.[12] In Spain, thousands of health care workers tested positive and had to isolate after being exposed to the virus due to defective face masks.[13] Health care workers cannot be put at the risk of getting

[8]Samy Rengasamy & others, 'Simple Respiratory Protection – Evaluation of the Filtration Performance of Cloth Masks and Common Fabric Materials Against 20 – 100 nm Size Particles' (2010) 54(7) The Annals of Occupational Hygiene 789.

[9]Ming Hui Chua & others, 'Face Masks in the New Covid-19 Normal: Materials, Testing and Perspectives' (*US National Library of Medicine, National Institute of Health,* 7 August 2020) <www.ncbi.nlm.nih.gov/pmc/articles/PMC7429109/> accessed 1 April 2021.

[10]'Shortage of Personal Protective Equipment endangering health workers worldwide' (*World Health Organisation,* 3 March 2020) <www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide> accessed 1 April 2021.

[11]'Countries are returning masks imported from China: Here's Why' *The Indian Express* (New Delhi, 10 April 2020), <https://indianexpress.com/article/coronavirus/countries-finland-spain-netherlands-turkey-canada-are-returning-masks-imported-from-china-heres-why-6354291/> accessed 1 April 2021.

[12]Teena Thacker & Anandita Singh Mankotia, 'Tens of thousands of Chinese PPE Kits fail India safety test' *The Economic Times* (New Delhi, 16 April 2020) <https://economictimes.indiatimes.com/industry/healthcare/biotech/tens-of-thousands-of-chinese-ppe-kits-fail-india-safety-test/articleshow/75171817.cms?from=mdr> accessed 1 April 2021.

[13]Emilio de Benito & Cecilia Jan, 'Faulty batch of face masks prompts the isolation of more than a thousand Spanish healthcare staff*' El Pais* (Madrid, 21 April2020) <https://english.elpais.com/society/2020-04-21/faulty-batch-of-face-masks-

infected given their importance in controlling the spread of COVID-19. No country or hospital is safe for the patients if the healthcare workers are not safe.[14]

Through this article, the author seeks to explore the viability of regulating and enforcing standards within the WTO framework. The article is divided into six sections. Section I aims to determine whether WTO is the appropriate forum for addressing this issue. Section II attempts to define the term 'international standards'. In Section III, the author shall determine if the issue of manufacturing and exporting of substandard PPEs can be attributed to the State. In Section IV, the author shall examine the possibility of imposition of a ban on imports of PPEs under Article XX(b) of the General Agreement on Tariff and Trade, 1994 ("**GATT**"). For the purpose of this article, the author will limit the scope of discussion to Article XX(b)[15] since its objective is to *"protect human, animal or plant life or health"* and the Technical Barriers to Trade Agreement ("**TBT Agreement**") for it covers the aspect of technical regulation and standards imposed for the purpose of ensuring quality of its exports, protecting human, animal or plant life and health and protecting its national security interest.[16] Under Section V, the author shall determine whether bringing the regulation of standards under the WTO through the TBT Agreement via a reference paper can enable the aggrieved State to seek relief through the Dispute Settlement Mechanism ("**DSM**"). Finally in Section VI, the author will analyze how the involvement of the DSM shall induce a change in behaviour

prompts-the-isolation-of-more-than-a-thousand-spanish-healthcare-staff.html> accessed 1 April 2021.

[14]'Keep Health Workers Safe to Keep Patients Safe: WHO' (*World Health Organisation*, 17 September 2020) <www.who.int/news/item/17-09-2020-keep-health-workers-safe-to-keep-patients-safe-who> accessed 1 April 2021.

[15]Marrakesh Agreement Establishing the World Trade Organization, Annex 1A (adopted 15 April 1994) 1867UNTS 154, art XX.

[16]Agreement on the Technical Barriers to Trade (adopted 15 April 1994) 1868 UNTS 120, Chapeau.

of States and force the States to adhere to the recommended standards.

II. THE WORLD TRADE ORGANISATION AND INTERNATIONAL STANDARDS

Standards dictate the quality of product to be sold in a market and affect consumer behaviour as they inform and protect the consumer's interests. Standardization of products instils a certain level of confidence in a consumer that would be impossible to attain using their own judgment.[17] Similarly, a PPE kit with a quality certificate assures the user of its reliability and thus, their safety.

The World Trade Organisation ("**WTO**") is the only organisation that provides a multilateral forum for setting rules for trade and dispute settlement between its 164 Member States ("**Member**").[18] The **DSM** of the WTO has dealt with the issues of standards in several cases such *as EC-Asbestos,*[19] *EC-Hormones*[20] *and US-Shrimp.*[21] The term 'International Standards' has been used in the TBT Agreement; however, it has not been defined. The standards in the global trading system are not provided by the WTO itself. There are multiple standard setting organisations such as the International Organization

[17]'World Trade Report 2005: Exploring the links between trade, standards and the WTO' (*World Trade Organisation*, 2005) 24 <www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report05_e.pdf> accessed 1 April 2021.

[18]'Facilitating trade through regulatory cooperation: The case of WTO's TBT/SPS Agreements and Committees' (*World Trade Organisation*, 2014) 16 <www.wto.org/english/res_e/booksp_e/tbtsps19_e.pdf> accessed 1 April 2021.

[19]Appellate Body Report on *European Communities — Measures Affecting Asbestos and Asbestos—Containing Products*, WT/DS135/AB/R, adopted 5 April 2001.

[20]Appellate Body report on *European Communities — Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998.

[21]Appellate Body Report on *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998.

for Standardization (ISO), International Telecommunication Union (ITU) and the International Electro-technical Commission (IEC) that formulate international standards.

In any case, by virtue of the introductory clause of Annexure 1 to the TBT Agreement, the terms presented in the sixth edition of the ISO/IEC Guide 2:1991, when used in this Agreement have the same meaning as the definitions in the Guide.[22] Thus, the definition of international standards provided in the guide will hold true when read with the TBT Agreement. That said, the definition states that international standard is "*a standard that is adopted by an international standardizing/standards organisation and made available to the public*."[23]

While addressing what constitutes "international standards", the Panel in *US-Tuna II* provided three elements:*(i) a standard; (ii) adopted by an international standardizing/standards organisation; and (iii) made available to the public*.[24] The Appellate body in *US - Tuna II* pointed out that this definition suggests that a standard is of international character by virtue of the characteristics of the entity approving the standard.[25] For example, there is no doubt that ISO creates standards. An international body has been defined in Annexure 1 of the TBT Agreement as a body or system whose membership is open to relevant bodies of at least all Members.[26] It has a membership of 162

[22]TBT Agreement (n 16) Annex 1 chapeau.

[23]International Organisation for Standardization and International Electrotechnical Commission, 'ISO/IEC guide 2 2004 – Standardization and related activities General Vocabulary Provision 3.2.1.1' (*Eurostat*) <https://ec.europa.eu/eurostat/cros/system/files/ISO%20reference%20definitions%20-%20%20guide%202%20-%202004%20-%20rev.doc> accessed 1 April 2021.

[24]Panel report on *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products,* WT/DS381/R, adopted 13 June 2012, para 7.664.

[25]Appellate Body Report on *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products,* WT/DS381/AB/R, adopted 13 June 2012, para 353.

[26]TBT Agreement (n 16) Annex 1.4.

countries and has an observer status in the TBT Agreement. It has also been recognised by several WTO documents as an international standardising body.[27] It was even invited in the Second TBT Triennial Review for a better understanding of preparation of international standards.[28] Such virtues may deem the standards created by ISO to be of an international character. The compliance with these standards is mandatory when they are adopted as technical regulations by a State.[29] Since the ISO is a recognised international standardising body that formulates the standards for medical devices, it is only appropriate to focus on ISO for the purpose of this article.

Countries have their own domestic standard bodies that adopt and regulate standards created by international standardising bodies like the ISO.[30] Adherence to these standards is mandatory for selling a medical device in their territory. In India, for instance, there are many acceptable standards for different components of PPEs.[31] For N95 masks alone, there are three acceptable standards provided by the National Institute for Occupational Safety and Health (USA), European Standards (EN) and the ISO.[32] These standards aim to

[27]*Proposed GATT Code of Conduct for Preventing Technical Barriers to Trade, Contents of Revised Draft Prepared for Consideration by the Drafting Group on 11 Jan. 1972*, Spec (71)143 (30 December 1971) at s. II, art 3(a).
[28]*Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade*, G/TBT/9 (13 November 2000), Annex 1, para 2.
[29]'Technical Barrier to Trade' (*International Trade Centre*) <https://www.intracen.org/Part-3-Difference-between-standards-and-technical-regulations/> accessed 9 December 2021.
[30]'Standards in our World' (*International Organization for Standardization*) <www.iso.org/sites/ConsumersStandards/1_standards.html> accessed 7 January 2022.
[31]'Directorate General of Health Services Novel Coronavirus Disease 2019 (COVID – 19): Guidelines on rational use of Personal Protective Equipment' (*Ministry of Health and Family Welfare*) <www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf> accessed 1 April 2021.
[32]ibid.

protect the life and health of the user. The States have to ensure that the medical devices are of required quality, safety and efficacy.[33]

The cases of faulty PPE kits discussed in the previous sections show that, in the international scenario, the mere existence of these standards is not enough to protect public health. There is a requirement of *effective regulation* of these standards.

Therefore, the WTO has defined international standards under the TBT Agreement and the DSM has engaged with the question of what constitutes an international standard. However, before discussing the effective regulation and implementation of standards, it is pivotal to determine whether the issue of manufacturing of substandard PPEs is a behaviour attributable to the State.

III. IS THE STATE RESPONSIBLE FOR MANUFACTURING AND EXPORTING SUBSTANDARD PPE KITS?

The nature of the WTO Agreements and the obligations therein are such that it is binding only on national governments and separate customs territories under public international law.[34] The Agreements refer only to policies and actions of the governments, and not those of a private party.[35] While one can argue that the issue of procurement of PPE kits is a contractual matter between two private parties and not

[33]Lembit Rago & Budiono Santoso, *Drug Regulation: History, Present and Future in Drug Benefits and Risks in International Textbook of Clinical Pharmacology* (2nd edn, IOS Press 2008) 67.

[34]'Chapter 5.3: Only governmental measures of Members, Possible Object of a Complaint – Jurisdiction of Panels and the Appellate Body, Dispute Settlement System Training Module' (*World Trade Organisation*) <www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c5s3p1_e.htm#:~:text=As%20a%20general%20rule%2C%20only,object%20of%20(WTO)%20complaints.&text=The%20obligations%20contained%20in%20the,actors%20cannot%20infringe%20these%20obligations.> accessed 1 April 2021.

[35]Panel Report on *Japan – Measures Affecting Consumer Photographic Film and Paper*, WT/DS44/R, adopted 22 April 1998, para 10.52.

subject to the WTO Agreements, non-government private actors cannot infringe these obligations. Whether the actions of these parties are attributable to the State depends on the particularities of each case.[36]

To determine whether the State is liable for manufacturing and exporting faulty PPE kits, in accordance with Article 8 of the International Law Commission's responsibility of States for internationally Wrongful Act ("**ARSIWA**"**)** it must be determined if it is a result of government action or policy.[37] Under Article 5 of ARSIWA, the conduct of a person or an entity which is not an organ of the State to exercise elements of the governmental authority shall be considered an act of the State under international law provided that the person is acting in the capacity in particular instance.[38] The term 'person' or 'entity' includes public corporations and private companies and if a private company is contracted to provide a service attributed to the State, then the State is liable.[39] Article 8 states that the conduct of a person or a group of persons shall be considered an act of a State under international law if the person or group of persons is in fact acting on the instructions of, or under the direction or control of, that State in carrying out the conduct.[40] In such a case, the State can be held liable for the actions of the private party if the act is authorised by the State.[41]

[36]Japan – Trade in Semi-conductors (adopted May 4 1988) GATT B.I.S.D 35S/116, 117.
[37]'Yearbook of the International Law Commission 2001 Volume II Part Two' (2001) UN Doc. A/CN.4/SER.A/2001/Add.1 (Part 2), art 8.
[38]ibid art 5.
[39]James Crawford, *The International Law Commission's Articles on State Responsibility: Introduction, Text and Commentary* (Cambridge University Press 2002) 100.
[40]YILC (n 37).
[41]Danwood Mzikenge Chirwa, 'The Doctrine of State Responsibility as a Potential Means of Holding Private Actors Accountable for Human Rights' (2004) 5(1) MJIL 1.

The WTO Dispute Settlement Bodies have dealt with the issue of government versus private action in the past. The Panel in *Japan – Film*[42] stated that *sufficient government involvement* is the criterion to ascertain whether the actions of a private party may be deemed to be governmental. Further, in *Japan – Semi-Conductors*,[43] the GATT panel observed that administrative guidance must *create incentives or disincentives* for the industry to behave in a certain manner for that behaviour to be attributable to the government.

The case of China can be taken as a case study. China is dominating the global PPE market with supply chain command and control. It has exported 70.6 billion masks from March to May, 2020.[44] The Chinese government has played a major role in the rapid manufacturing and export of these kits. The Chinese government boosted the manufacturing by providing cheap lands to factory owners.[45] Additionally, millions of dollars were invested by the Chinese government through subsidies to these manufacturers.[46] The government extended its support to the medical industry and hastened the process for approvals required to expand the infrastructure required to manufacture PPEs at a larger scale.[47] In the early stages of the pandemic, the government even decided the countries that would receive crucial supplies and demanded profuse and public thanks in exchange.[48] This incentivizing of manufacturing shows involvement and interest of the government in manufacturing of the PPEs.

[42]Japan – Film (n 35) para 10.56.
[43]Japan – Semiconductors (n 36) para 109.
[44]Keith Bradsher, 'China Dominates Medical Supplies in This Outbreak and the Next' *The New York Times* (Beijing, 5 July 2020) <www.nytimes.com/2020/07/05/business/china-medical-supplies.html> accessed 1 April 2021.
[45]ibid.
[46]ibid.
[47]ibid.
[48]Edward Wong & Paul Mozur, 'China's 'Donation Diplomacy' Raises Tensions with U.S.', *The New York Times* (14 April 2020)

However, the State having a stake in the manufacturing of the PPEs is not enough to file a complaint in the WTO.

There are no Agreements or provisions that impose a duty on a State to adhere to the requisite international standards. The TBT Agreement makes it clear that a Member "*may*" take measures "*necessary to ensure the quality of its exports*".[49] The TBT Agreement only obligates the State to adopt the existing international standards in their technical regulations wherever possible.[50] States only have to assure that the measures are not in violation of the MFN and non-discrimination principle.[51] To ensure that the appropriate standards are complied with, the TBT Agreement has provisions for Conformity Assessment Procedures. Conformity Assessment Procedures are the procedures used to determine whether relevant requirements in technical regulations or standards are fulfilled and to accredit conformity assessment bodies.[52] The TBT Agreement creates an obligation to provide national treatment and most-favoured nation treatment with regard to access for suppliers from other Members to covered conformity assessment procedures of importing Members.[53] It also provides that the body responsible for the conformity assessment must conduct the procedure and inform the parties of conformity or non-conformity. However, the TBT Agreement fails to address the issues such as errors in conformity assessment or possibility of lack of conformity assessment infrastructure in the importing country. For example, the Dutch health ministry returned 6,00,000 face masks imported from China as the masks did not fit and

<www.nytimes.com/2020/04/14/us/politics/coronavirus-china-trump-donation.html> accessed 1 April 2021.

[49]TBT Agreement (n 16).

[50]TBT Agreement (n 16) art 2.4.

[51]TBT Agreement (n 16).

[52]'Standards and Conformity Assessment Systems' (*Ministry of Economy, trade and Industry, Japan*) <www.meti.go.jp/english/report/downloadfiles/gCT0330e.pdf> accessed 9 December 2021.

[53]Panel Report on *Russia – Measures Affecting the Importation of Railway Equipment and Parts Thereof*, WT/DS499/R, para 7.248.

their filters did not work even though they had quality certificates.[54] India is equipped with its conformity assessment procedures and infrastructures so it was able to identify that the PPEs imported are not up to the prescribed standards.[55] This poses a very significant question - what if a country without such infrastructure imports PPEs based on the quality certificate and it is later found that the PPEs do not work as expected? These loopholes and lacunas in the TBT Agreement show that it has no provisions to ensure that it is *regulated effectively*.

WTO is not a standard creating, standard enforcing or a standard regulating body. Though WTO only provides a *half measure* with regards to standards in goods, it shirks from the responsibility of enforcing it. A State has no redressal forum when another State exports faulty PPEs. The importing State can only have bilateral talks regarding the issue or hope that the exporting State adheres to the requisite standards in the future. This issue can be resolved if WTO set rules related to the necessity of adherence to these standards. A rule or Agreement creating an obligation will open the path of litigation for an aggrieved State that suffered from the substandard equipment.

Additionally, while only States are parties to International Covenant on Economic, Social and Cultural Rights ("**ICESCR**") and international treaties; private business sectors too have a responsibility in the realization of the right to health.[56] Article 12 of the ICESCR recognizes the "*right to highest attainable standard of physical and mental health*" as an international human right.[57] Scientifically and medically appropriate and good quality hospital

[54]'Coronavirus: Countries reject Chinese-made equipment' (*BBC News,* 30 March 2020) <www.bbc.com/news/world-europe-52092395> accessed 1 April 2021.
[55]Teena Thacker (n 12).
[56]UNHRC, CCPR General Comment No.14, 'The Right to the Highest Attainable Standard of Health (Art. 12)' (11 August 2000) U.N. Doc. E/C.12/2000/4 at 42.
[57]International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, art 12.

equipment is an essential element of the right.[58] The Inter-American Court of Human Rights in the *Velasaquez Rodriguez* case also held that *the acts of private parties if aided by the government, also makes the State responsible on the international place*.[59] This approach suggests that a State can be held liable for the manufacturing and exporting of faulty PPEs, even if the manufacturer and the exporter are private individuals. Therefore, despite being applicable only to the actions of the government, under specific conditions i.e., sufficient government involvement and creation of incentives and disincentives, the WTO obligations can be applied to the actions of the private parties within the territory of a member as well.

A violation of human rights is not a ground for filing a complaint in the WTO DSM. Relevant human rights law can be taken into account when interpreting WTO applicable law.[60] However, the absence of an obligation in the WTO to maintain standards makes it impossible for an aggrieved State to approach it for relief.

IV. IS THERE A SOLUTION WITHIN THE WTO FRAMEWORK?

A. Protection under Article XX: Is a ban on imports a feasible solution?

In the absence of explicit enforcement provisions in the WTO Agreements, the focus shifts to the possibility of protection in the existing framework. One can find the essence of protection provided

[58]General Comment 14 (n 56).
[59]I/A Court H.R., *Velasquez Rodriguez v. Honduras*, Judgment of July 29 1988, Series C, No. 4, para. 177.
[60]Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) Eur J Intl L 753.

to the Member States in the General Exceptions under Article XX of the General Agreement on Tariffs and Trade ("**GATT**").

Article XX(b) of GATT states that a Member State can adopt or enforce any measures that are "*necessary to protect human, animal or plant life or health*".[61] The WTO DSM in dealing with cases has laid down few criteria to decide whether a measure is in conformity with Article XX(b) of GATT. Firstly, the panel in *US-Gasoline* stated that a measure is justified under Article XX(b) of GATT if it fell within the range of policies designed for this purpose, is necessary and conforms to the introductory clause of Article XX.[62] Secondly, the Panel in *EC – Asbestos* touched upon the value of scientific data or evidence in justifying a measure as necessary. To decide the necessity, the existence of a public health risk on the scientific evidence must be examined.[63] The Appellate body in the same matter also stated that a State has the right to determine the *level of protection of health* they consider appropriate. The measure must be chosen to successfully provide the level of protection for human health and safety and to halt a health risk.[64] And lastly, the panel in *Indonesia – Chicken* held that the "*protection of human health is of utmost importance*"[65] and that *"trade restrictiveness cannot outweigh the contribution of the measure"*.[66]

For our analysis, we must apply these criteria under Article XX(b) of GATT and the decisions of the WTO DSM to the case of faulty PPEs and their impact. Faulty PPEs can wreak havoc in States with high population density and insufficient healthcare facilities. A ban on

[61]GATT 1994 (n 15).
[62]Panel Report on *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R adopted 20 May1996, para 6.20.
[63]Panel Report on *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/R, adopted 5 April 2001.
[64]*EC – Asbestos* (n 19).
[65]Panel Report on *Indonesia – Measures Concerning Importation of Chicken Meat and Chicken Products*, WT/DS484/R, adopted 22 November 2017, para 7.225.
[66]ibid para 7.227.

imports of these devices from a certain defaulting State shall prevent the State-owned and private entities in its territories from acquiring and circulating these kits. Given the importance of health care workers in the battle against COVID-19, this ban seems to be *necessary* to the objective of *"preserving human health"*. It aligns with the objective of halting the spread of COVID-19 which is currently a widespread health risk. Also, considering the weight of scientific evidence, any mask incapable of filtering the particle of size 5-10 µm is unfit for protecting a healthcare worker;[67] a ban on its import shall be legitimate.

However, the imposition of a ban seeking protection under Article XX(b) may not be the appropriate step as it has its own lacunae. Aside from the fact that pragmatically, no State will take the step of banning imports due to an already short supply of PPEs; Article XX does not impose a positive obligation on the exporter State to improve the standards of its production. The affected State is not empowered under Article XX to file a complaint in the DSM regarding the actions of the exporter State. Rather, the exporter State is empowered to file a complaint in the DSM challenging the ban by the aggrieved State.[68] This is because the burden of proof lies on the respondent States to prove that the introduced measure does not violate Article XX.[69] This is because the respondent State are the parties that benefit from the exception.[70] The ban may induce a change in the behaviour but during a pandemic when human life and protection is at stake, a State would prefer definite change over a possibility of change. Thus, Article XX is also inadequate in addressing the harm already caused.

[67]Ming Hui Chua (n 9).
[68]*US-Gasoline* (n 62) para 22-23.
[69]*US-Gasoline* (n 62).
[70]'Justifiable Reasons' (*Ministry of Economy, trade and Industry, Japan*) <www.meti.go.jp/english/report/data/2016WTO/pdf/02_06.pdf> 329 accessed 9 December 2021.

The possibility of a least developed country with no conformity assessment infrastructure suffering greatly from using these substandard PPE kits is high. States are suffering from economic slowdown due to lockdowns, and resources in developing and least developed States are limited and extinguishing. These States cannot be expected to invest their resources in acquiring PPEs from a State exporting faulty kits with the hope that the defaulting State will act on their best behaviour and subsequent batches of the kits will be functional.

This leaves us at a standstill as there is no redressal when a State has already suffered due to usage of substandard PPE kits. It leaves a void in the international arena for the enforcement of international standards through the creation of obligations.

B. Bringing Regulation of Standards under the Aegis of the TBT Agreement: The Way to Go?

As discussed above, Article XX of GATT does not explicitly deal with standards but is capable of protecting a measure adopted by a State to protect human life and health. Unlike the GATT, the TBT Agreement deals with international standards, technical regulations and conformity assessment procedures. It has the potential to provide a framework within the WTO for the strict enforcement of these standards. Similar to Article XX, the TBT Agreement also provides all members with the right to restrict trade for "*legitimate objectives*" that includes under its ambit, the *protection of human health or safety*.[71]

Though Article XX(b) of GATT and the TBT Agreement share similar objectives, they bring different paradigms to the table. As stated earlier, the interpretation and enforcement of Article XX has constricted its ambit to act as a defence. The provisions of the TBT

[71]TBT Agreement (n 16).

Agreement create a positive obligation on the Member States to adopt the existing international standards. The existence of this positive obligation ensures that a State can be held liable for violation of these obligations. The existence of this positive obligation however, does not create an obligation to effectively regulate these standards in exports. If the regulation of international standards is brought under the aegis of the TBT Agreement, it will pave a path for litigation against the export of substandard PPE kits as a State will be able to take another State like China head on for not adhering to the required international standards. Resultantly, the aggrieved State will be armed with an offense instead of a defensive measure. To determine if this incorporation of new obligation is feasible, the author will address two issues i.e., incorporation of standards in the TBT Agreement and their enforceability through the TBT Agreement.

Article 2.4 of the TBT Agreement states that the members shall use the international standards or the relevant parts of them as the basis of their own technical regulations when required, except when the international standards would be inappropriate or ineffective in achieving the desired objective.[72] It is a theme throughout the Agreement that international standards are the benchmark.[73] Considering that each Member State is already under the obligation to adopt international standards,[74] the first step should be an attempt to regulate the organisations creating these standards.

To regulate the standardisation process carried out by private organisations, Article 4 of the TBT Agreement obligates the Member States to accept the Code of Good Practice for the Preparation,

[72]TBT Agreement (n 16) art 2.4.
[73]Erik Wijkstrom & Devin McDaniels, 'International Standards and the WTO TBT Agreement: Improving Governance for Regulatory Alignment' (2013) World Trade Organization Staff Working Paper ERSD-2013-06, para 4.1 <www.wto.org/english/res_e/reser_e/ersd201306_e.pdf> accessed 8 January 2022.
[74]ibid para 2.3.

Adoption and Application of Standards ("**CGP**").[75] The CGP contained in the Annexure 3 of the TBT Agreement, negotiated by the Members,[76] provides guidelines for all central, local governmental bodies as well as non-governmental bodies. These guidelines include six principles for international standard development namely *Transparency, Openness, Impartiality and Consensus, Effectiveness and Relevance, Coherence and Development Dimension*.[77] The Member State is to take reasonable measures to ensure that the local government and non-governmental standardising bodies within their territories adhere to the CGP.[78] Many States that have accepted the CGP utilise the services of non-governmental organisation for the formulation of standards in their own territory.[79] What constitutes as a reasonable measure has not been cleared by the WTO as of now. The existence of the CGP and its acceptance by many non-governmental organisations shows that the TBT Agreement, through the CGP has the potential to regulate the standardisation process and practice. Although WTO Agreements are binding only on States, the TBT creates a scope of imposing a positive obligation on the State to regulate the behaviour of private, non-governmental bodies within its territory and ensure that they comply with the CGP. This poses an opportunity to enforce compliance with standards even when the defaulter is a private party.

Further, the WTO is not alien to the regulation of private party behaviour. The best example is the Agreement on Trade in Basic

[75]TBT Agreement (n 16) art 4.
[76]See *Negotiating History of the Coverage of the Agreement on Technical Barriers to Trade with Regard to Labelling Requirements, Voluntary Standards, and Processes and Production Methods Unrelated to Product Characteristics*, WT/CTE/W/10 & G/TBT/W/11 (adopted 29 August 1995).
[77]'Principles for the Development of International Standards, Guides and Recommendations' (*World Trade Organisation*) <www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm> accessed 1 April 2021.
[78]TBT Agreement (n 16) art 4.
[79]TBT Agreement (n 16) art 4.

Telecommunications Services "*Reference Paper*" in the Member's Schedule of the General Agreement on Trade in Services ("**GATS**").[80] Based on the Telecommunications services Reference Paper, a reference paper can be defined as a set of principles negotiated by the Member for covering matters in the field in which the members wish to employ it (for e.g., competition safeguards in the Telecommunications services Reference Paper), and would be used as a tool to lay down what regulatory disciplines are undertaken by the members as additional commitments.[81] The reference paper regulates the competition in the telecommunication sector even though anti-competition activity is private.[82] In case the incorporation of mandatory compliance to standards is undesirable by the Member States, a similar reference paper can be formulated and negotiated with provisions similar to the CGP creating positive obligations on the States to ensure that the entities within their territories comply with the requisite international standards. Failure to do so may attract litigation in the DSM.

While the above solution might seem desirable, amending the TBT Agreement or any Agreement under the WTO may become a tedious process.[83] Under Article X: 3 of the Marrakesh Agreement, an amendment to the TBT Agreement may take legal effect only after two – third of the Members deposit their formal instrument of acceptance to the Director-General.[84] Additionally, Article 15.4 of the

[80]General Agreement on Trade in Services, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B (adopted 15 April 1994) 1869 UNTS 183, Telecommunications Services Reference paper, Apr. 24 1996.

[81]'History of the telecommunication negotiations' (*World Trade Organisation*) <www.wto.org/english/tratop_e/serv_e/telecom_e/telecom_history_e.htm> accessed 4 August 2021.

[82]Petros C. Mavroidis & Robert Wolfe, 'Private Standards and the WTO: Reclusive No More' (2017) 16 WTR 1.

[83]Hunter Nottage & Thomas Sebastian, 'Giving Legal Effect to the Results of WTO Trade Negotiations: An Analysis of the Methods of Changing WTO Law' (2006) 9(4) JIEL 989.

[84]Marrakesh Agreement Establishing the World Trade Organization (adopted 15 April 1994) 1867 UNTS 154, art X(3).

TBT Agreement states that ideally, the TBT Committee shall review and propose amendments to the Council for Trade of Goods only at the end of each third year since its date of entry into force.[85] The delay in amendment process due to inaction of the Members is also not unseen. For instance, when the Trade Related Aspects of Intellectual Property Rights ("**TRIPS**") was amended to include Article 31*bis*, the United States deposited the instrument of acceptance only after six months of a unanimous agreement of the Members.[86]

A reference paper suffers no such handicap. A reference paper, such as the Telecommunications services Reference Paper, can be inscribed in the Schedules of members willing to participate in the negotiations of this reference paper.[87] This reference paper will be a non-tariff policy commitment for the Members. The WTO Schedules of Concessions is a legal instrument that describes the treatment a Member should provide to the goods of another Member State.[88] This schedule is a tool to ensure transparency and predictability to the trade regime.[89] The question of whether the Schedule of Concessions under GATT can be amended to incorporate an additional commitment like a reference paper has been addressed before by *Hoekman and Mavroidis*.[90] For this explanation, we must first understand what an MFN club is. An MFN club can be defined as "*a group of countries that commit to WTO compliant policy disciplines*

[85]TBT Agreement (n 16) art 15.4.
[86]Hunter Nottage (n 83) 992.
[87]Petros C. Mevroidis (n 82) 12.
[88]'What is a WTO Schedule' (*World Trade Organisation*) <https://goods-schedules.wto.org/what-is-a-wto-schedule> accessed 1 April 2021.
[89]ibid.
[90]Bernard Hoekman & Petros C. Mavroidis, 'MFN Clubs and Scheduling Additional Commitments in the GATT: Learning from the GATS' (2016) European University Institute, Robert Schuman Centre for Advanced Studies, Global Governance Programme Working Paper No. RSCAS 2016/06 <https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3371&context=faculty_scholarship> accessed 8 January 2022.

that go beyond the existing WTO rules, bind the signatories on to implementing them and the benefit of which extend non-discriminatorily to all the members."[91] Nothing is binding the WTO members from exploring the option of negotiating new instruments like a reference paper and adding it to their schedule as long as it does not violate the MFN and non-discrimination principle and does not violate the rights of WTO members and any WTO provisions.[92]

The 1995 Review Working Party on Other Barriers to Trade states that nothing prevents contracting parties non–tariff commitments as long as they do not conflict with provisions of other agreements.[93] Inclusion of subsidies and import licensing in the Schedule are examples of such additions.[94] Also, the Part III of the agreed format of Schedules[95] allows the WTO Members to include any non-tariff commitment in the Schedule as they deem fit.[96] As long as the commitment is applied in a non-discriminatory manner, non-participants cannot block other WTO members from moving forward and scheduling other commitments.[97] Once this negotiation is concluded and the reference paper is scheduled, the members of the club can push forward the new commitment to all the Members.[98]

Under GATS, the Members are allowed to schedule additional commitments for trade related services policies,[99] which led to the adoption of the telecommunications service paper.[100] The Signatories

[91]ibid 2.
[92]ibid 15.
[93]*Review Working Party on Other Barriers to Trade,* 3 March 1955, GATT B.I.S.D 3S/222, para 14ff.
[94]*1961 Working Party report on 'Operation of the Provisions of Article XVI'*, 1 March 1962, GATT B.I.S.D 10S/21, para 24ff.
[95]*Preparation of the Uruguay Round Schedules of Concessions on Market Access*, MTN.GNG/MA/W/25 (25 December 1993) para 15.
[96]Bernard Hoekman (n 90).
[97]Bernard Hoekman (n 90) 12.
[98]Bernard Hoekman (n 90) 13.
[99]GATS (n 80) art XVIII.
[100]History of Telecommunication Negotiations (n 81).

to the paper also amount to an MFN Club.[101] These commitments are legally binding and even non-signatories can initiate a dispute against a reference paper signatory if they violate the terms of the reference paper.[102] An automatic implication of scheduling a new commitment is that the non-participating members also will be able to file complaints in the DSM against the signatories as the schedules are binding and are applied on the MFN basis.[103] If a reference paper is negotiated, then the issue of substandard PPEs can be bought to the DSM. This reference paper can also aim to create a framework within which the standardisation bodies operate and the WTO can be the meta-regulator, an overseer to ensure that these bodies adhere to the terms of the reference paper. The reference may not directly hold the private parties responsible but hold the Member State liable for its own efforts in ensuring that these bodies apply the WTO principles.

Another pressing issue, that of multiplicity of standards shall also be resolved if regulation of standards and the standardizing bodies is brought under TBT Agreement. It is logical if different standards provide different levels of protection, but it becomes an issue if different standards under different nomenclature provide the same level of protection. Similar protection of multiple standards defeats the purpose of having multiple standards. The WTO was created with the aim of liberalising and harmonising international trade and the existence of multiple standards for similar objectives is a hurdle to this goal as it creates a burden on the international market. The TBT Agreement under Article 5 provides assessment of conformity by central government bodies.[104] Article 5.4 creates an obligation to use the guidelines issued by international standardizing bodies to ensure that the products conform with the technical regulations or

[101]Bernard Hoekman (n 90) 14.
[102]GATS (n 80) art XXIII.
[103]Bernard Hoekman (n 90) 13.
[104]TBT Agreement (n 16) art 5.

standards.[105] This conformity assessment comes with a fee for issuance of certificate assuring that the product is of a certain standard.[106] Now when there is multiplicity of standards for the similar objective such as standards of PPE, it is a bane for producer or an exporter as it has to get certification from different standardizing bodies raising the cost of an essential medical commodity. For example, for respirators, different standards and regulations apply for different countries. Australia requires the performance standard as per AS/NZS 1716:2012, Brazil requires ABNT/NBR 13698:2011, the EU requires EN 149:2001+A1:2009, India requires IS 9473:2002 and so on.[107] This multiplicity defeats the purpose of reduction of tariffs in the first place. This issue would not arise if the WTO, through a reference paper, recognises a central authority for standard formulation and conformation. There is a need for a harmonised central certification system for conformity assessment and standards creation to overcome this. A Memorandum of Understanding could have been negotiated for the term of the pandemic to recognise a single standard for the supplies. However, this was not done.

One of the possible solutions to this issue is recognizing a central authority or body for creation and regulation of standards. The ISO is the perfect candidate for this as it is the only standardization body that has an observer status in the TBT Agreement. The TBT Agreement already recognizes ISO as an authority regarding definitions concerning standards and related activities.[108] It is also an obligation to notify the ISO if any standardizing body accepts or withdraw from the CGP. The aforementioned reference paper can incorporate a clause recognizing ISO as the sole creator and regulator of standards. Domestic standardizing bodies can act as the enabling bodies to

[105]TBT Agreement (n 16) art 5.4.
[106]TBT Agreement (n 16) art 5.
[107]'Protective Face Masks Testing & Certification' (*SGS*) <www.sgs.com/en/campaigns/protective-face-masks> accessed 4 April 2021.
[108]TBT Agreement (n 16) Annex 1 chapeau.

regulate the application of these standards in their respective territories. This addition in the proposed reference paper will have additional effects on the standard creation and regulation in the international arena.

The centralization of standardization has not been done yet due to Global Competition and Control of the Global Standardization process. It was estimated in 2011 that approximately 80 percent of the global trade is affected by standards.[109] These standards control market access and whosoever has formulated a new product or the standard for a lucrative good, commands the initiative of the market.[110] Standards have also developed and come into being due to the dominant position of an industry in the market.[111]

It is not in the interest of the industries to have a central standardization system as that might snatch away their dominant position in the market as the standard controller. Given the WTO's goal of liberalisation and its application only to Member States, its hesitancy to entry the standards arena is seemingly justified. WTO is confronted with the dilemma of how to adopt a legalistic approach that would take international standards into account.[112] Since most countries adopt these international standards through their own central government standardisation bodies, attempting to regulate these

[109]S. Joe Bhatia, 'It's Hard to Win if You Don't Know the Game: The Critical Importance of Education on Standardization in Universities' (*Joint Meeting of the APEC SCSC Project Advisory Group on Education and the ANSI Committee on Education*, 28 February 2011) <https://share.ansi.org/shared%20documents/News%20and%20Publications/Speeches/2-28-11%20-%20Bhatia%20-%20APEC%20Standards%20Education.pdf> accessed 4 April 2021.

[110]Donald Purcell & others, 'Globalization and Standardization' (*IEEE Standards University*, 13 August 2016), <www.standardsuniversity.org/e-magazine/august-2016-volume-6/globalization-and-standardization/> accessed 4 April 2021.

[111]Signe Annette Bogh, *A World Built on Standards: A Textbook for Higher Education* (Danish Standard Foundation 2015) 58.

[112]Mbengue & Makane Moise, 'Private Standards and WTO Law' (2005) 5 Bio Res Trade and Environment Review 2.

bodies may be considered as an attempt to hijack the sovereignty of these States. Thus, a reference paper may open the path for WTO to meta-regulate standardising bodies.

Moreover, organisations like ISO have been stigmatized as a club dominated by private industries.[113] The example of American National Standards Institute ("**ANSI**") is best suited as it represents the interest of the American industries. A standard is created or changed by the request of an industry.[114] Thus, ISO invites industries and stakeholders affected by the standard and formulates the new standard.[115] This reduces the participation of the developing and least developing countries[116] since many countries do not have the industries in that sector, even though they will be affected by this standard.

These issues are in direct contravention of the six principles proposed by the TBT Committee in 2000 for the development of international standards.[117] These principles are transparency, openness, impartiality and consensus, effectiveness and relevance, coherence and to address the concerns of developing countries.[118] This is despite the privileged status ISO enjoys in the WTO. The absence of any obligation imposed on the ISO and lack of enforceability of these principles on an international standardizing body are the primary reasons behind these issues of legitimacy and accountability. ISO accords no

[113]Alessandra Arcuri, *The TBT Agreements and Private Standards in Research Handbook on the WTO and Technical Barriers to Trade* (Edward Elgar Publishing 2015) 495.
[114]'Key Principles in ISO Standard Development' (*International Organization for Standardization*) <www.iso.org/developing-standards.html> accessed 4 April 2021.
[115]'Good Standardization Practices' (*International Organization for Standardization*) 131 <www.iso.org/files/live/sites/isoorg/files/store/en/PUB100440.pdf> accessed 4 April 2021.
[116]Alessandra Arcuri (n 113).
[117]Technical Barriers to Trade (n 28).
[118]ibid.

importance to public interest in its consultation structure.[119] As per the Questionnaire for a Survey to Assist Developing Country Members to Identify and Prioritise their Specific Needs in the TBT Field, the members from developing countries do not serve as the secretaries or chairpersons of the technical committees that formulate standards.[120]

All these issues stated above can be addressed through the provisions of the reference paper. Bringing ISO under the obligations of the TBT Agreement will allow developing and least developing countries with no industry or expertise to seek technical assistance from ISO for understanding the procedure of development of the standard and enable them to address their concerns in standard creating and regulating regime. This will shift the process of standardization from the hands of private industries to other lesser developed stakeholders. A centralised international standard will spare these countries the trouble of establishing their own standardising body by enacting a legislation (like India had to enact BIS Act, 2016 to establish the Bureau of Standards[121]). ISO can establish their centres in these countries once they join the WTO. A single internationally acceptable standard will also provide the producers and exporters from these countries market access to all the WTO members. A single accepted standard would mean lower transaction costs as all the definitions and data models are similar between business partners, easily accessible information, more certainty in quality and process and a more

[119]Dave Bennett, 'A Report to the International Confederation of Free Trade Unions (ICFTU) Working Party on Health' (*Safety and Environment, Canadian Labour Congress*, July 2000) <www.ecologia.org/ems/iso14000/resources/opinions/bennet00.html#:~:text=The%20International%20Organization%20for%20Standardization,14000%20series%20on%20Environmental%20Management.> accessed 4 April 2021.

[120]*A Compilation and Summary of the Responses Received to the Questionnaire for a Survey to Assist Developing Country Members to Identify and Prioritise Their Specific Needs in the TBT Field*, G/TBT/W/186 (14 October 2002) 24.

[121]'About us' (*Bureau of Indian Standards*) <www.bis.gov.in/index.php/the-bureau/about-bis/> accessed 6 December 2021.

synchronised partnership with the rest of the world.[122] Considering the arguments presented, a reference paper regulating the behaviour of the standard creating body will pave a path for regulation of standards.

Therefore, a reference paper can be considered as a solution to the issue of regulation and enforcement of standards. The reference paper may create positive obligations towards the private parties or the governments to endure that the governments take appropriate measures to ensure that the action of the private parties are WTO compliant. The reference paper can also be moulded to recognise ISO as a central standardising body to eliminate multiple standards and make space for the developing and least developing countries in the standards formulation committees and forums.

Now, considering that a reference paper proposed in this section is adopted by the WTO members, it is crucial to address the question of how bringing the regulation of standards under the WTO rules will benefit the enforcement of these standards. The answer can be found in the nature of DSM of the WTO and its effects on the Member States.

V. ENFORCEMENT OF STANDARDS THROUGH THE DISPUTE SETTLEMENT MECHANISM

The TBT Agreement provides a framework for regulation of international standards under the WTO rules. But the issue of the enforceability of these standards once in the purview of the TBT Agreement remains unanswered. It does not provide for the effective *enforcement*. The WTO is set apart from the rest of the international

[122]'Five Reasons Why Organisations Can no Longer Avoid Standardization' (*Planon*, 19 September 2019) <https://planonsoftware.com/us/resources/blogs/five-reasons-why-organizations-can-no-longer-avoid-standardization/> accessed 8 January 2022.

organisations by its capability of enforcing its obligations and Agreements through its DSM, which is hailed as the crown jewel of WTO.[123] Any regulation will not be effective if it is not enforceable with a strong hand. The presence of a redressal forum to address a complaint of non-adherence to standards will result in *effective enforcement* of the standards. This will act as a combative measure for taking on the States that manufacture and export substandard PPE kits. The strict enforcement of standards through the DSM will work effectively due to two factors, *regulatory chill* and *reputational cost*.

Regulatory chill in terms of the health sector can be described as "*a term coined to describe the impact of the potential costs of trade disputes on governments willingness to introduce new health regulations.*"[124] For the lack of a strictly defined legal definition, regulatory chill can be understood as a reluctance of a government to take an action for fear of litigation. The threat and fear of litigation or arbitration can push a State to strictly enforce the international standard simply because it has a high potential cost as well as a reputational cost. This regulatory chill exists because States then may be reluctant in exporting faulty goods. For example, in *Phillip Morris v. Australia* case,[125] New Zealand did not enact a domestic legislation as per the WHO framework convention in Tobacco Control because Phillip Morris had filed a suit against the Australian government for doing the same. The fear of legal action stopped New Zealand and forced it to reflect on the legal consequences. Drawing a parallel to this, if a State X initiates a litigation against China for exporting substandard PPE, then State Z will be deterred from not adhering to

[123]'Press Release, WTO disputes reach 400-mark' (*World Trade Organisation*, 6 November 2009) <www.wto.org/english/news_e/pres09_e/pr578_e.htm> accessed 4 April 2021.
[124]Ronald Labonte & Matthew Sanger, 'Glossary on the World Trade Organisation and public health: part 2' (2006) 60(9) J Epidemiol Community Health 738.
[125]*Philip Morris Asia Limited v The Commonwealth of Australia*, UNCITRAL, PCA Case No. 2012-12.

international standards for PPE kits for the fear of litigation. The DSM will have a deterrent effect.

Another factor for consideration is reputational cost. Reputation is described as "*an opponent's current belief about the player's compliance strategy or set of strategies in connection with various commitments.*"[126] Given the transparency of information in the WTO DSM and the ease with which a State can access the instances of violation of trade and WTO Agreements, any State will look into the reputation of the other before entering into any Agreement. Repeated violation of trade Agreements will not only have an effect of the State's reputation in trade, but will also spill over to other adjacent issues such as economic Agreements.[127] As grim as the spread of COVID-19 and the death toll is, it has created a created a big market for the PPE business and the counties manufacturing PPEs would not want to miss out on this opportunity.[128] A record of non-compliance with the international standards governed by WTO Agreements will make a State undesirable for trading in the international arena. Eventually, the non-complying State faces the threat of being pushed out of the global market as no State would be willing to engage with it. This will cause a significant loss to the domestic industry of the non–compliant State and ultimately, the State itself. The loss of life on account of the faulty PPEs by the State is bound to have long lasting effect on the manufacturing industry of that State too. Non-compliance with the essential standards will now have an opportunity cost. Thus, it will force a State into strictly adhering to the standards.

[126]Drew Fudenberg & Jean Tirole, *Game Theory* (1st edn, MIT Press 1991) 368.
[127]Andrew T. Guzman, *How International Law Works: A Rational Choice Theory* (OUP 2008) 106.
[128]'Global Personal Protective Equipment (PPE) Market was Valued at USD 52.7 billion in 2019 and is Expected to Reach USD 92.5 billion by 2025, Observing a CAGR of 8.7% during 2020–2025' (*VynZ Research*, 14 April 2020) <www.globenewswire.com/news-release/2020/04/14/2015737/0/en/Global-Personal-Protective-Equipment-PPE-Market-was-Valued-at-USD-52-7-billion-in-2019-and-is-Expected-to-Reach-USD-92-5-billion-by-2025-Observing-a-CAGR-of-8-7-during-2020-2025-Vy.html> accessed 4 April 2021.

Consequently, if enforcement and regulation of standards is under the aegis of TBT Agreement, States like China will actively avoid being taken to the DSM to protect their interests.

VI. CONCLUSION

The issue of faulty PPE kits is of grave importance amidst the COVID-19 pandemic, since substandard PPE kits can be a matter of life and death for health care workers. The current WTO framework is not equipped to force a State into adhering to the international standards essential for preserving the life and health of the workers. As stated, Article XX(b) is a *shield* for defending a State's measures to protect it from substandard PPE kits. But a shield is not sufficient. It is inadequate for addressing the bigger picture of effective enforcement of standards. A reference paper, inscribed in the schedule of the members can add an additional commitment, ensuring that the members follow the laid down guidelines for regulation and enforcement of standards. Since schedules are applied on MFN basis, it will open a venue for litigation in DSM in case a signatory violates the provisions. A dispute settlement clause can be negotiated too for settling any issue arising out of its implementation. Moreover, it can aim to solve the issue of multiplicity of standards by recognising ISO as the central international standardising body. This would also enable the developing and least developing countries to overcome the hurdles faced by them and have a voice in the international standards formulation committees and forums.

Bringing regulation of international standards through the TBT Agreement will act as a *sword* against the States not adhering to the international standards. States are not obligated to restrict their complaints to the international trade regimes. Right to highest attainable standard of health provides a window for affected States to approach bodies concerned with human rights in case of loss of life

and health due to the substandard PPE kits. However, these bodies exercise considerably less power than the WTO. A win against a State exporting substandard PPE at the WTO will force a State into compliance and change in its practices, even provide some form of compensation for the damage caused. In this manner, the DSM will enable the sword to make an incisive cut.