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# A Review of WTO Disputes on TRIPS: Implications for Use of Flexibilities for Public Health

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 **SOUTH  
CENTRE**





**RESEARCH PAPER**

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PUBLIC HEALTH**

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**16 FEBRUARY 2022**

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## ABSTRACT

The use of TRIPS flexibilities by WTO members involves interpretation of the obligations under TRIPS which can be challenged under the WTO dispute settlement system. Mutually agreed solutions, panel or Appellate Body decisions adopted in such disputes can thus impact the scope of TRIPS flexibilities to address, among others, public health objectives. This paper explores how the WTO dispute settlement system applies to disputes under TRIPS, and reviews the outcomes of the disputes relating to the implementation of TRIPS obligations in the context of pharmaceutical products. The paper points to both systemic and substantive concerns arising from the application of the dispute settlement system to disputes under TRIPS. It finds that the dispute settlement system is not aligned to the unique nature of the TRIPS Agreement in the WTO as an agreement that creates positive obligations, and consequently how jurisprudence arising under disputes concerning other covered agreements having negative obligations, have led panels and Appellate Bodies to adopt narrow interpretations of the scope of TRIPS flexibilities in some of the few disputes arising under the TRIPS Agreement. Moreover, mutually agreed settlements adopted in the context of some of the disputes arising under TRIPS have also led to the adoption of TRIPS plus standards, limiting the scope of TRIPS flexibilities. However, in a recent decision, the WTO panel has also relied on the Doha Declaration on TRIPS and Public Health as a subsequent agreement to guide the interpretation of its provisions. In this context, the paper advances some suggestions to address the systemic and substantive issues arising from the application of the dispute settlement system to the TRIPS Agreement.

*El uso de las flexibilidades del Acuerdo sobre los ADPIC por parte de los miembros de la OMC implica una interpretación de las obligaciones del Acuerdo sobre los ADPIC que puede ser impugnada en el marco del sistema de solución de diferencias de la OMC. Las soluciones mutuamente acordadas, las decisiones de los grupos especiales o del Órgano de Apelación adoptadas en dichas disputas pueden, por tanto, influir en el alcance de las flexibilidades de los ADPIC para abordar, entre otros, los objetivos de salud pública. Este documento explora la manera en que el sistema de solución de diferencias de la OMC se aplica a las disputas en el marco del Acuerdo sobre los ADPIC, y examina los resultados de las disputas relacionadas con la aplicación de las obligaciones del Acuerdo sobre los ADPIC en el contexto de los productos farmacéuticos. El documento señala las preocupaciones tanto sistémicas como sustantivas que surgen de la aplicación del sistema de solución de diferencias a las controversias en el marco del Acuerdo sobre los ADPIC. Considera que el sistema de solución de controversias no está alineado con la naturaleza única del Acuerdo sobre los ADPIC en la OMC como un acuerdo que crea obligaciones positivas y, en consecuencia, cómo la jurisprudencia surgida en el marco de las controversias relativas a otros acuerdos cubiertos que tienen obligaciones negativas, ha llevado a los grupos especiales y a los órganos de apelación a adoptar interpretaciones estrechas sobre el alcance de las flexibilidades del Acuerdo ADPIC en algunas de las pocas controversias que han surgido. Además, los acuerdos mutuos adoptados en el contexto de algunas de las controversias que han surgido,*

también han llevado a la adopción de normas “ADPIC plus”, limitando el alcance de las flexibilidades del Acuerdo sobre los ADPIC. Sin embargo, en una decisión reciente, el panel de la OMC también se ha basado en la Declaración de Doha relativa al Acuerdo sobre los ADPIC y la Salud Pública como acuerdo posterior para orientar la interpretación de sus disposiciones. En este contexto, el documento avanza algunas sugerencias para abordar las cuestiones sistémicas y sustantivas que surgen de la aplicación del sistema de solución de diferencias al Acuerdo sobre los ADPIC.

*L'utilisation des flexibilités de l'Accord sur les ADPIC par les membres de l'OMC implique une interprétation des obligations découlant de l'Accord sur les ADPIC qui peut être contestée dans le cadre du système de règlement des différends de l'OMC. Les solutions mutuellement convenues, les décisions des groupes spéciaux ou de l'Organe d'appel adoptées dans le cadre de ces différends peuvent donc avoir une incidence sur la portée des flexibilités prévues par l'Accord sur les ADPIC pour répondre, entre autres, aux objectifs de santé publique. Ce document examine la manière dont le système de règlement des différends de l'OMC s'applique aux différends relevant de l'Accord sur les ADPIC, et passe en revue les résultats des différends relatifs à la mise en œuvre des obligations découlant de l'Accord sur les ADPIC dans le contexte des produits pharmaceutiques. Le document met en évidence des problèmes à la fois systémiques et de fond découlant de l'application du système de règlement des différends aux différends relevant de l'Accord sur les ADPIC. Il constate que le système de règlement des différends n'est pas adapté à la nature unique de l'Accord sur les ADPIC au sein de l'OMC en tant qu'accord créant des obligations positives, et par conséquent, comment la jurisprudence découlant des différends concernant d'autres accords couverts ayant des obligations négatives, a conduit les groupes spéciaux et les organes d'appel à adopter des interprétations étroites de la portée des flexibilités de l'Accord sur les ADPIC dans certains des rares différends découlant de l'Accord sur les ADPIC. De plus, les règlements mutuellement convenus adoptés dans le cadre de certains des différends découlant de l'Accord sur les ADPIC ont également conduit à l'adoption de normes ADPIC plus, limitant ainsi la portée des flexibilités de l'Accord sur les ADPIC. Toutefois, dans une décision récente, le groupe spécial de l'OMC s'est également appuyé sur la Déclaration de Doha sur les ADPIC et la santé publique en tant qu'accord ultérieur pour guider l'interprétation de ses dispositions. Dans ce contexte, le document avance quelques suggestions pour résoudre les problèmes systémiques et de fond découlant de l'application du système de règlement des différends à l'Accord sur les ADPIC.*

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## I. INTRODUCTION

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was one of the major outcomes of the establishment of the World Trade Organization (WTO). TRIPS established a globally harmonized standard of minimum levels of intellectual property (IP) protection and enforcement, requiring WTO members to take specific measures to implement the TRIPS obligations. One of the major areas where TRIPS raised the global standards of IP protection was the requirement for all WTO members, subject to transitional exemptions, to make pharmaceutical products eligible for patent protection for a minimum term of 20 years from the date of filing.<sup>1</sup> WTO members could no longer exclude pharmaceutical products such as medicines and vaccines from patent protection, unlike the practice that was very common among some States that had developed a viable local pharmaceutical industry.<sup>2</sup>

Contrary to the presumption of the proponents of TRIPS that it would spur pharmaceutical innovation, empirical evidence demonstrates that there has been a global decline in the approval of new innovative medicines more than 25 years after the adoption of TRIPS. Instead, the major impact of TRIPS has been an increase in price of medicines.<sup>3</sup>

To overcome or mitigate the adverse impact on access to medicines arising from the standards of protection required under TRIPS, the use of “flexibilities” available under TRIPS while designing national laws, administrative and policy instruments for TRIPS implementation have been strongly advocated by many.<sup>4</sup> The right of WTO members to use the flexibilities in the TRIPS Agreement was confirmed by the 2001 WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health (hereinafter the Doha Declaration).<sup>5</sup> In explicit recognition of the need for the use of TRIPS flexibilities for access to medicines, WTO members have extended the transitional exemption from implementation of TRIPS obligations for LDCs with regard to patents and protection of undisclosed information in respect of pharmaceutical products,<sup>6</sup> and have also adopted a waiver,<sup>7</sup> subsequently incorporated in the TRIPS Agreement itself, to allow the use of compulsory licensing for exports of pharmaceutical products for countries with non-existent or insufficient pharmaceutical manufacturing capacity.<sup>8</sup> In the context of the COVID-19 pandemic, more than 100 WTO members have supported a proposal for a waiver of certain obligations for health products and technologies.<sup>9</sup>

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<sup>1</sup> Article 27.1 of TRIPS requires patents to be granted in all fields of technology without discrimination. Article 33 of TRIPS establishes a minimum term of 20 years from the date of filing for all patents.

<sup>2</sup> See e.g., Government of India, Report on the Revision of the Patent Law, September 1959, pp. 36–38. Available from [https://www.ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-Justice\\_N\\_R\\_Ayyangar\\_committee\\_report.pdf](https://www.ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-Justice_N_R_Ayyangar_committee_report.pdf).

<sup>3</sup> Carlos M. Correa, “Flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights”, *Bulletin of the World Health Organization*, vol. 96, 2018, p. 148. Available from <https://www.who.int/bulletin/volumes/96/3/17-206896.pdf>.

<sup>4</sup> See Medicines Law & Policy, The TRIPS Flexibilities Database. Available from <http://tripsflexibilities.medicineslawandpolicy.org/>.

<sup>5</sup> WTO, document WT/MIN(01)/DEC/2, 20 November 2001. Available from [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>6</sup> See WTO, document IP/C/73, 6 November 2015. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/73.pdf&Open=True>. Also see South Centre, “South Centre calls on the WTO TRIPS Council to Support Access to Medicines and Technological Advancement for the Least Developed Countries.” Available from <https://www.southcentre.int/question/south-centre-welcomes-wto-decision-on-ldcs-and-trips/>.

<sup>7</sup> WTO, document WT/L/540 and Corr.1, 1 September 2003. Available from [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>8</sup> TRIPS Agreement, Article 31 bis.

<sup>9</sup> WTO, document IP/CW?669/Rev.1, 25 May 2021. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>. Also see

The use of TRIPS flexibilities by WTO members involves interpretation of the obligations under TRIPS and the policy space available in the light of those obligations. These interpretations can be, and have been challenged, both in national courts,<sup>10</sup> as well as in the dispute settlement system of WTO. A complaint under the WTO dispute settlement system can impact the use of TRIPS flexibilities in the following ways: 1) mutually agreed solutions (MAS) following consultations on the basis of complaints under the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) can lead to adoption of national laws or administrative measures limiting the scope of TRIPS flexibilities; 2) WTO panel or Appellate Body (AB) decisions could hold a national legal or administrative measure aimed at utilizing TRIPS flexibilities as inconsistent with TRIPS obligations; and 3) interpretations of TRIPS provisions by a panel or the AB can create persuasive precedents both for future panel or AB decisions, and also for national legislative bodies and courts. This may also impact the shaping of national laws to make use of the available flexibilities. One study has observed that the prospect of a possible WTO panel complaint challenging a measure for inconsistency with TRIPS obligations has generally led to a culture of overcompliance with TRIPS, consequently limiting the use of TRIPS flexibilities.<sup>11</sup>

Since the establishment of WTO, 42 disputes have so far arisen under the TRIPS Agreement. While many of these disputes have been resolved through MAS pursuant to consultations, in some cases the disputes have been adjudicated by a panel or the AB under the WTO's dispute settlement mechanism. This paper will explore how the dispute settlement system applies to disputes under TRIPS, and review the outcomes of the disputes relating to the implementation of TRIPS obligations in the context of pharmaceutical products, including MAS and relevant decisions of the WTO panels and the AB. The analysis in the paper is limited to panel and AB decisions that are related to obligations on patent protection under TRIPS, and does not address disputes on enforcement. The paper is comprised of five sections. Section II describes the salient features of the WTO dispute settlement system and its application in relation to disputes arising under TRIPS. Section III provides an overview of the disputes that have been initiated till date under TRIPS, the profile of countries that have predominantly initiated the majority of those complaints, the initiation of such complaints against certain specific developing countries, and the use of the consultation mechanism more than the adjudicatory panel process in disputes under TRIPS. This section also describes some of the

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generally, Henrique Zefereino de Menezes, *The TRIPS Waiver Proposal : An Urgent Measure to Expand Access to the COVID-19 Vaccines*, Research Paper 129 (Geneva, South Centre, 2021). Available from <https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf>; Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries : Lift the barriers to fight the pandemic in the Global South", Policy Brief No. 92, South Centre, April 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>; Faizel Ismail, "The WTO TRIPS Waiver Should Help Build Vaccine Manufacturing Capacity in Africa", Policy Brief No. 97 South Centre, July 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/07/PB-97.pdf>; Yousuf Vawda, "The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonising Intellectual Property", Policy Brief No. 99, South Centre, August 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/08/PB-99.pdf>; Olga Gurgula, "Compulsory licensing vs. the IP waiver : what is the best way to end the COVID-19 pandemic ? ", Policy Brief No.104, South Centre, October 2021. Available from [https://www.southcentre.int/wp-content/uploads/2021/10/PB104\\_Compulsory-licensing-vs.-the-IP-waiver\\_EN-2.pdf](https://www.southcentre.int/wp-content/uploads/2021/10/PB104_Compulsory-licensing-vs.-the-IP-waiver_EN-2.pdf).

<sup>10</sup> The most prominent example of a challenge to the use of TRIPS flexibilities occurred in 2001 when 39 multinational pharmaceutical companies challenged in the Pretoria High Court a law enacted by South Africa to allow measures such as parallel importation of generic medicines. See, e.g., Oxfam, "South Africa vs. the Drug Patents: A Challenge to Affordable Medicines", Oxfam Background Briefing, February 2001. Available from <https://oxfamlibrary.openrepository.com/bitstream/handle/10546/620381/bn-access-to-medicines-south-africa-010201-en.pdf?sequence=1&isAllowed=y>. Another major example is the unsuccessful challenge that was filed before the Supreme Court of India by Novartis on the rejection of patent claims on new forms of known pharmaceutical substances by applying under the Indian patent law (section 3(d) of the Patents Act) the flexibilities available under the TRIPS Agreement in respect of application of the patentability criteria. See e.g., Ravinder Gabbale and Jillian Clare Kohler, "To patent or not patent? the case of Novartis' cancer drug Glivec in India", *Globalization and Health*, vol. 10, pp. 3–6. Available from <https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-10-3.pdf>.

<sup>11</sup> See Molly Land, "Rebalancing TRIPS", *Michigan Journal of International Law*, vol. 33, p. 433 at p. 434.

understandings reached or measures adopted by developing countries through MAS pursuant to consultations, that have restricted the ability of those countries to use the flexibilities. Section IV analyses of some of the decisions adopted by panel and AB reports and the interpretations of relevant TRIPS provisions advanced therein, and their implications for use of TRIPS flexibilities in relation to patents on pharmaceutical products. Section V draws conclusions.

## II. THE WTO DISPUTE SETTLEMENT SYSTEM

The dispute settlement system of the WTO is one of the central features of the multilateral trading system established by the Agreement Establishing the World Trade Organization (hereinafter WTO Agreement). It marks a fundamental shift from a diplomacy based to a formal juridical approach to settlement of disputes.<sup>12</sup> Rules and procedures on the operation of the dispute settlement mechanism of the WTO are contained in the DSU, annexed to the WTO Agreement. These apply to all the specific multilateral agreements (hereinafter covered agreements) that are annexed to the WTO Agreement,<sup>13</sup> subject to any special or additional rules and procedures on dispute settlement in any of the covered agreements.

TRIPS is very different from other covered agreements in terms of the nature of rights and obligations arising from it.<sup>14</sup> Upon the conclusion of negotiations, there was limited time available for the TRIPS negotiators to review the applicability of the DSU to the TRIPS Agreement. The negotiations on the DSU were substantially informed by the experience of the dispute settlement mechanism under the General Agreement on Tariffs and Trade (GATT) that preceded the WTO. Thus, a dispute settlement mechanism that is oriented to an agreement of a very different nature became applicable to TRIPS.<sup>15</sup>

Dispute settlement between WTO members begins with a process of mutual consultation between the complaining and the respondent parties. If the mutual consultations are unsuccessful in resolving the dispute within a period of sixty days from the date of the request for consultations, the complaining party can request the establishment of an adjudicatory panel. The decision of a panel is required to be placed for formal adoption by the WTO Dispute Settlement Body (DSB) comprised of all the WTO members, unless the decision is appealed before the AB. The decision of the panel or AB is required to be formally adopted by the DSB. These reports are considered as adopted unless there is consensus among all WTO members in the DSB against the adoption of the report. This is referred to as the principle of reverse consensus.

### II.1 Consultation Phase

The consultation phase is essentially a process of diplomatic negotiations between the two parties with the aim of arriving at a mutually agreed solution (MAS). The United States (US) regarded the consultation phase as a mechanism through which the WTO agreements could be enforced even without resorting to a panel.<sup>16</sup> Successful resolution of the dispute through mutual consultations could involve the application, withdrawal or adjustment of a measure or even mere assurance of the same. Even after a panel is established, a dispute can still be resolved through mutual consultations. Empirical research shows that on average, the

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<sup>12</sup> See generally, John H. Jackson, Robert E. Hudec and Donald Davis, "The Role and Effectiveness of the WTO Dispute Settlement Mechanism", *Brookings Trade Forum*, 2000, pp. 179–81. Available from <http://www.jstor.org/stable/25063150>.

<sup>13</sup> These are the General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade in Services (GATS) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

<sup>14</sup> Unlike other WTO Agreements, TRIPS creates positive obligations for WTO members to take measures to enable protection and enforcement of IP rights in accordance with standards established under the Agreement. In contrast, other WTO Agreements restrain WTO members from taking measures that can undermine specific commitments made in respect of market access to goods and services.

<sup>15</sup> Matthew Kennedy, *WTO Dispute Settlement and the TRIPS Agreement: Applying Intellectual Property Standards in a Trade Law Framework* (Cambridge, UK, Cambridge University Press, 2016), pp. 31–3.

<sup>16</sup> Gary N. Horlick, "The Consultation Phase of WTO Dispute Resolution: A Private Practitioner's View", *The International Lawyer*, vol. 32, No. 3 (1998), p. 685. Available from <https://core.ac.uk/download/pdf/216909318.pdf>.

consultations are extended in practice beyond the “statutory” period of sixty days stated in the DSU.<sup>17</sup>

Article 3.7 of the DSU stresses that “A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred.” One study of MAS as a systemic aspect of the DSU observed that these bilateral understandings between the principal parties to a dispute have allowed the parties to add to or contract beyond the terms of the covered agreements.<sup>18</sup> In the context of TRIPS, the terms of MAS have in some cases added restrictive conditions to the application of flexibilities available under the Agreement (see section III.1 below).

## **II.2 The Panel and Appellate Body Stage**

If a dispute is not resolved after 60 days from the request for consultations, the complaining party can request the DSB to establish a panel. Such a request can be made earlier if both parties to the dispute agree that the matter cannot be resolved through consultations.

### **II.2.1 Establishment and Composition of a Panel**

Once a request for establishing a panel is made, the DSB must adopt a decision to establish a panel unless the same is denied by consensus. The panel is selected on an *ad hoc* basis for each dispute. After the DSB establishes a panel, the parties must agree on the composition of the panel of 3 or 5 members within a certain time frame.<sup>19</sup> In practice, many members frequently oppose the nominations of panel members proposed by the WTO Secretariat.<sup>20</sup> While either party may request the WTO Director-General, through the chair of the DSB, to nominate the panel if the parties cannot agree within 20 days of the decision to establish a panel, there is no time limit within which parties must agree on the composition of the panel. Thus, both parties can discuss and keep the composition of a panel suspended indefinitely by not requesting the intervention of the Director-General for composition of the panel.

The selection of an individual as a member of a panel is based on the acceptance of their nomination by the parties to the dispute. The WTO Secretariat maintains an indicative list of possible panelists from all members based on nominations received from the members, but panelists can be nominated from outside the indicative list also. In practice, former trade delegates of WTO members or capital-based trade officials, former WTO Secretariat officials, retired government officials and academics have regularly served on panels. However, panel members serve in their individual capacity and not as representatives of the governments nominating them. They also serve as panelists on a part-time basis, in addition to their regular professional activities. There is no limitation on panelists being re-nominated in future panels.

A panelist need not be a legal expert. The DSU only requires panel members to be “well-qualified” individuals from the governments or non-governmental entities with experience as panelists, trade lawyers, trade delegates, capital officials, scholars, etc. There is no special

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<sup>17</sup> Louise Johansson and Petros C. Mavroidis, *The WTO Dispute Settlement System 1995-2016 : A Dataset and its Descriptive Statistics*, Robert Schuman Centre for Advanced Studies Working Paper 72, European University Institute, 2016. Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2888358](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2888358).

<sup>18</sup> Wolfgang Alschner, “Amicable Settlement of Disputes: Bilateral Solutions in a Multilateral System”, *World Trade Review*, vol. 13, No. 1 (2014). Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2162466](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2162466).

<sup>19</sup> The parties can agree to a 5 member panel within a period of 10 days from the decision of the DSB to establish a panel. Otherwise, a panel is composed of 3 members. If the parties cannot agree to the composition of the panel within 20 days from the establishment of the panel, the WTO Director General is mandated to determine the composition of the panel at the request of either party.

<sup>20</sup> WTO, Dispute Settlement System Training Module: Chapter 6. Available from [https://www.wto.org/english/tratop\\_e/dispu\\_e/disp\\_settlement\\_cbt\\_e/c6s3p2\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s3p2_e.htm).

requirement of expertise on IP matters for panelists in disputes relating to TRIPS.<sup>21</sup> However, the indicative list of the Secretariat endeavours to include individuals with experience on TRIPS.

### II.2.2 Terms of Reference

The scope of issues that a panel can adjudicate depends on its terms of reference. Article 7.1 of the DSU states that the standard terms of reference of the panels will be to examine the matters referred to the DSB by a party, in the light of the relevant provisions under a covered agreement that are cited by a party to the dispute and make findings to assist the DSB in making recommendations or give rulings under those Agreements. The request for the establishment of a panel can also ask for establishing special terms of reference (article 6.2 of DSU).

### II.2.3 Legal basis for complaint

Article 6.2 of the DSU states that "... the request must identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly." Notably, while a request for complaint is required to identify the measures at issue in terms of article 4.4, a request for a panel must identify the **specific measures** at issue. This implies that unless the request lays down the particular measures at issue, a panel cannot give a ruling on that measure. However, in TRIPS disputes, the requests for establishing a panel have not always specifically identified the measures at issue.<sup>22</sup> In some cases, for example in *India–Patents*, new provisions were included within the scope of the determination of the panel (see section IV.1 below).<sup>23</sup>

### II.2.4 Function of the panel

The panels are required to make an objective assessment of the facts of the dispute and their applicability of and conformity with the relevant covered agreements.<sup>24</sup> The panel is thus not compelled to adopt a legal interpretation of all the claims in a dispute if it can assist the DSB in meeting its function of making recommendations or rulings aimed at achieving a satisfactory settlement of the matter. For example, in *India–Patents*, the panel also made some suggestions clarifying that those were not declaratory judgments (see section IV.1 below). In many cases, the panel has exercised "judicial economy" to not rule on the legal interpretation of certain provisions of covered agreements like TRIPS, as it considered that a solution to the dispute had been reached by its legal interpretation of other issues in the dispute.

A critical issue to consider is to what extent the panel phase is free from perceived bias. One study suggests that the *ad hoc* nature of panels makes them susceptible to bias when they rule against powerful countries, to strategically weaken judgments and limit the scope of

<sup>21</sup> It is noteworthy that under the Annex on Financial Services to the General Agreement on Trade in Services (GATS) establishes special rules for the composition of panels on disputes involving financial matters, to ensure expertise on such matters in the panel.

<sup>22</sup> Kennedy, *supra* note 15, pp. 108–9.

<sup>23</sup> *Ibid.*, p. 113. This could be because TRIPS creates positive obligations unlike other WTO agreements, and requires members to take measures towards implementation of those obligations. In most disputes under TRIPS, the lack of implementation of the legal obligations have been the basis for a complaint under the DSU, rather than challenging the adoption of a measure. As explained by Kennedy, the inconvenient requirement under the DSU to specify the measure at issue in the request for establishing a panel was overcome through the practice adopted by panels, the AB and the parties, thus ensuring that the disputes arising under TRIPS did not fail due to the inability to comply with the technical requirements about the content of the request. Another significant anomaly in the application of the requirements under DSU to disputes arising under TRIPS is that in many cases where the use of exceptions to IP rights have been challenged, no summary of the legal basis for the claims have been provided. Most of the claims challenging exceptions to IP rights have been made in this manner.

<sup>24</sup> Agreement Establishing the World Trade Organization, Annex 2, Article 11.

rulings when powerful countries are losing parties in a dispute.<sup>25</sup> A notable example of this in the context of use of TRIPS flexibilities for public health could be the ruling of the panel in *Canada-Pharmaceutical Patents* where the panel adopted a narrow interpretation of the scope of the exception to patent rights that WTO members could adopt under article 30 of TRIPS (see IV.2 below). Panel rulings are also susceptible to pre-empting anticipated legal rulings by the AB. For example, in *India-Patents* the panel had ruled on an alternative claim that was not included in the request for establishing the panel in the anticipation of a possible overruling of the panel decision on the original claim by the AB (see IV.1 below). Moreover, in cases where the panel does not rule on a question of law or legal interpretation of a TRIPS provision by exercising judicial economy, those questions cannot be examined by the AB.

In the panel phase, substantial reliance is placed on the legal interpretation of the provisions of the covered agreements by the respective WTO panels. Hence, the content of the rules under the covered agreements that are subjected to the process of legal interpretation by the panels and the AB can have a critical impact on the jurisprudence that emanates from the interpretations advanced by the panels and the AB. As one scholar has observed, "Since the substantive rules (under the covered agreements) essentially codify the interests of the dominant actors in 'international trade,' a rule-oriented system only contributes to the rigid enforcement of the embodied inequities."<sup>26</sup>

An important consideration in this respect is whether the panel or the AB can adopt interpretations of the provisions in the covered agreements that advance public interest objectives? While the panel or AB is prohibited in terms of article 3.2 of the DSU from adding to or diminishing the rights and obligations under the covered agreements, a good faith reading of the provisions of the covered agreements that is consistent with human rights obligations, such as the right to health, may be possible.<sup>27</sup> Hence, a harmonious reading of public interest objectives such as the right to health that is recognized under international human rights law can be possible to the extent that such reading is consistent with the substantive provisions of the covered agreements.

### **II.2.5 The Appellate Body**

In comparison to the panel, the Appellate Body is established for a specific term, with a specific number of experts who are appointed, and are required to have specific expert knowledge. Unlike the panel which is required to be composed of "well-qualified" individuals, the AB members must be persons of "recognized authority" with expertise in law, international trade, and the general subject matter of the covered agreements. AB members are appointed for a term of four years and may be reappointed for a second term. AB members are required to be always available, even on short notice. The expenses of AB members are met from the WTO budget. Administrative and legal support is also provided to the AB as required. This is facilitated through a dedicated Appellate Body secretariat.

An appeal is filed by submitting a notification to that effect to the DSB under article 16 of the DSU. In addition, the Working Procedures of the AB require a simultaneous filing of a notice of appeal with the AB secretariat, providing specific information.<sup>28</sup> Each appeal is assigned by

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<sup>25</sup> Ryan Brutger and Julia C. Morse, "Balancing Law and Politics: Judicial Incentives in WTO Dispute Settlement", *The Review of International Organizations*, vol. 10 (2015), pp. 179–205 at p. 181. Available from <https://link.springer.com/article/10.1007%2Fs11558-015-9216-x>.

<sup>26</sup> Bhupinder S. Chimni, "India and Ongoing Review of WTO Dispute Settlement System", *Economic and Political Weekly*, vol.34, No.5 (1999), p. 264. Available from [www.jstor.org/stable/4407601](http://www.jstor.org/stable/4407601).

<sup>27</sup> Gabrielle Marceau, "WTO Dispute Settlement and Human Rights", *European Journal of International Law*, vol. 13, No. 4 (2002), pp. 753–814.

<sup>28</sup> This should include a brief statement of the alleged errors on issues of law and legal interpretations in the panel report, list of legal provisions that panel is alleged to have erred in interpreting or applying, and an indicative list of the paragraphs of the panel report containing the alleged errors.

rotation to a division comprised of 3 members of the AB. However, AB Working Procedures require all members to meet regularly to discuss matters of policy, practice and procedure to draw on their individual and collective expertise, to ensure consistency and coherence in decision making.<sup>29</sup> More specifically, before finalizing the appellate report for circulation to the members, the AB division responsible for deciding the appeal is required to exchange views with other members.<sup>30</sup> Thus, through the working procedures, the AB has adopted practice that seeks to promote consistency with its past rulings, thereby promoting adherence to precedents in practice.

In examining the implementation of positive obligations created by TRIPS, WTO panels have sometimes addressed questions of interpretation of domestic law implementing TRIPS as examination of facts. Hence, the weight that a panel accords to a member's interpretation of its domestic law implementing TRIPS is particularly important. The AB review is only limited to issues of law covered in the panel report and legal interpretations developed by the panel. This implies that a panel may interpret the meaning of domestic law based on the evidence before it as a question of fact which could thus be outside the scope of review by the AB. However, in practice these questions have been reviewed *de novo* on appeal in several disputes under TRIPS. In some cases, the AB has erroneously arrived at new findings on interpretation of domestic law.<sup>31</sup>

Currently, the AB has been rendered non-functional as the US has blocked consensus in the DSB for filling up the vacancies in the AB, even though the DSU mandates that the vacancies should be filled up as they arise. This means that a panel report can be appealed into the void and can remain indefinitely “sub-judice” until the AB is functional again. Hence, panel reports would remain unadopted and this would render the eventual outcome of a dispute uncertain. Consequently, this could lead to a proliferation of unilateral coercive action by powerful members.<sup>32</sup> The fact that a WTO member can disable a critical element of the dispute settlement system like the AB could also influence the decisions of future panels by implicitly encouraging the tendency to be more biased or lenient in their decisions when powerful countries are impacted.

### **II.3 Dispute Settlement Related Provisions in the TRIPS Agreement**

Article 64 of TRIPS makes the dispute settlement provisions of GATT applicable. In terms of article 64.2 of TRIPS, the scope and modalities of non-violation and situation complaints under TRIPS is to be decided upon by consensus among the WTO members in the TRIPS Council. Currently, WTO members have agreed to a moratorium on initiating such complaints under TRIPS.<sup>33</sup> Article 6 of TRIPS states that subject to the obligations on most favoured nation (MFN) and national treatment, nothing in the Agreement shall be used to address the issue of exhaustion of IP rights. This excludes the applicability of the dispute settlement system in respect of disputes under article 6. This provision, therefore, makes any determination by a WTO member regarding when an IP right can be considered to have been exhausted, and on that basis undertake measures such as parallel importation, outside the scope of any complaint under the DSU. This is explicitly clarified in paragraph 5 (d) of the Doha Declaration:

<sup>29</sup> See WTO, document WT/AB/WP/6, 16 August 2010, para.4. Available from [https://www.wto.org/english/tratop\\_e/dispu\\_e/ab\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/ab_e.htm).

<sup>30</sup> *Ibid.*, para.4(3).

<sup>31</sup> Kennedy, *supra* note 15, pp. 137–41.

<sup>32</sup> See Danish and Aileen Kwa, “Crisis at the WTO’s Appellate Body (AB): Why the AB is Important for Developing Members”, South Centre, Policy Brief No.69, December 2019. Available from [https://www.southcentre.int/wp-content/uploads/2019/12/PB69\\_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members\\_EN-2.pdf](https://www.southcentre.int/wp-content/uploads/2019/12/PB69_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members_EN-2.pdf).

<sup>33</sup> See generally, Nirmalya Syam, *Non-violation and Situation Complaints under the TRIPS Agreement: Implications for Developing Countries*, Research Paper 109 (Geneva, South Centre, 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/05/Rp-109.pdf>.

“The effect of the provisions of the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion **without challenge**... (emphasis added).”<sup>34</sup> Nevertheless, the DSU procedures have been used by complainant parties to limit measures enabling parallel importation (see section III.1 below).

Some additional interpretative guidance on the scope of TRIPS flexibilities for public health can be drawn from the Doha Declaration.<sup>35</sup> Paragraph 4 of the Doha Declaration states that the TRIPS Agreement “... can and should be **interpreted** and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all (emphasis added).”<sup>36</sup> The Doha Declaration further elaborates on this interpretative principle by stating that “In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”<sup>37</sup> This rule of interpretation suggests that due deference to national law should be given in appropriate cases by the WTO panels and Appellate Body.<sup>38</sup>

However, unlike paragraph 6 of the Doha Declaration which has been given effect through the adoption of a protocol amending the TRIPS Agreement,<sup>39</sup> the interpretative guidance enshrined in paragraphs 4 and 5 of the Doha Declaration have not been subsequently incorporated in the Agreement. Nevertheless, in *Australia–Tobacco Plain Packaging* the panel interpreted paragraph 5 of the Doha Declaration as a subsequent agreement between the WTO members on the interpretation of each of the provisions of TRIPS.<sup>40</sup> This interpretation of the Doha Declaration was upheld by the AB.<sup>41</sup>

There is no national deference rule for interpretation of disputes in the TRIPS Agreement unlike, for example, such a provision in the WTO Agreement on Anti-dumping.<sup>42</sup> If such a provision were to apply to the TRIPS Agreement, conclusions reached by national authorities, for example, about the public health need for a measure would always be upheld, if the facts established and their evaluation by the national authorities to reach a decision is found to be objective and unbiased.<sup>43</sup> In the absence of such a national deference provision in the TRIPS Agreement, it is possible for a WTO panel to overrule the decision of a national authority based on its own interpretation of the provisions of the TRIPS Agreement. It is noteworthy here that at the time of adoption of the WTO Agreement, the ministerial conference had decided to undertake a review of the national deference provision under the Agreement on Anti-dumping

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<sup>34</sup> WTO, *supra* note 5, para. 5(d).

<sup>35</sup> Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, 2002, p. 11. Available from [https://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf?ua=1](https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf?ua=1).

<sup>36</sup> WTO, *supra* note 5, para. 4.

<sup>37</sup> *Ibid.*, paragraph 5.a.

<sup>38</sup> Correa, *supra* note 35, p. 14.

<sup>39</sup> Though paragraph 6 of the Doha Declaration has been given legal effect through an amendment of the TRIPS Agreement, the system as such has proved to be unusable in practice. See Carlos M. Correa, “Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?”, South Centre, Policy Brief No. 57, January 2019. Available from [https://www.southcentre.int/wp-content/uploads/2019/01/PB57\\_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf).

<sup>40</sup> WTO, documents WT/DS435/R, WT/DS/441/R, WT/DS458/R, WT/DS467/R, 28 June 2018, paragraph 7.2409. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/DS/435R.pdf&Open=True>.

<sup>41</sup> WTO, documents WT/DS435/AB/R, WT/DS441/AB/R, para. 6.656. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/DS/435ABR.pdf&Open=True>

<sup>42</sup> Article 17.6 of the Agreement on Anti-dumping states how a panel should examine the facts of a dispute arising under that Agreement, to the effect that even if the panel could reach a different conclusion, the decision of a national authority would not be reversed if the establishment of the facts and their evaluation by the relevant national authorities was unbiased and objective.

<sup>43</sup> An early draft of article 1.1 of TRIPS had allowed national laws and practice to make reasonable national interpretation of the TRIPS provisions, but the final provision was limited to members’ freedom to choose the method of implementation of the agreement. Kennedy, *supra* note 16, p. 159.

with a view to considering the possibility of general application of this rule to disputes under all WTO agreements.<sup>44</sup>

While a standard of review for disputes under TRIPS is not laid down in the TRIPS Agreement or the DSU, in practice, WTO panels have adopted a *de novo* standard of review in such disputes, thereby disregarding national decision making.<sup>45</sup> One study concludes in this regard that a *de novo* standard of review is inappropriate for interpreting many TRIPS provisions which contains indeterminate terms (such as “special”, “unreasonable”, “legitimate”, etc.) that warrant particular deference to national decision making; hence, it has proposed to develop a standard of review more suited to disputes under TRIPS that would take into consideration the purpose that a national measure seeks to achieve and give presumptive weight in favour of State policies that seek to promote and protect human rights, including the right to health.<sup>46</sup>

Some interpretative guidance is -exceptionally- provided in relation to the security exception under article 73 of the TRIPS Agreement. This provision states that nothing in the TRIPS Agreement shall be construed to a) require a member to furnish information which it considers contrary to its essential security interests; or b) to prevent a member from taking any action which it considers necessary for the protection of its essential security interests relating to i) fissionable material or material from which they are derived; ii) traffic in arms, ammunition and implements of war and other goods and material for the purpose of supplying a military establishment; iii) actions taken in times of war or other emergency in international relations. However, there is divergence of views about whether the use of the security exception is subject to any judicial scrutiny by a WTO panel.<sup>47</sup> Article 73 of TRIPS has been reproduced verbatim from article XX1 of GATT. The recent panel decisions on the question of justiciability of the security exception, however, have rejected the view that measures based on the security exception are excluded from any judicial review by a WTO panel (see section IV.4 below).<sup>48</sup>

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<sup>44</sup> Chimni, *supra* note 26, p. 266.

<sup>45</sup> For instance, in *Canada–Pharmaceutical Patents* the panel did not defer to Canada’s interpretation and provided its own concept of “legitimate interests”. See Land, *supra* note 11, pp. 464.

<sup>46</sup> Land, *supra* note 11, pp. 4639.

<sup>47</sup> See Tania Voon, “The Security Exception in WTO Law: Entering a New Era”, *AJIL Unbound*, vol. 113 (2019), pp. 45–50. Available from <https://www.cambridge.org/core/journals/american-journal-of-international-law/article/security-exception-in-wto-law-entering-a-new-era/CF8C3DCDF2CD924CAEEDD147840668F9>.

<sup>48</sup> Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper No.116 (South Centre, Geneva), 2020. Available from <https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf>, pp. 4–5.

### **III. DISPUTES UNDER TRIPS**

Since the establishment of the WTO, requests for consultations for settlement of disputes arising under the TRIPS Agreement have been made in 42 cases. Of these, panel or Appellate Body reports have been adopted in 15 cases, while one case is currently under appeal. In 15 cases the disputes were resolved through MAS. Consultations are ongoing between the parties in 8 cases, with some of the cases remaining in the consultative phase for a long period of time. The annex below presents an overview of the complaints that have been made under the DSU in relation to TRIPS.

Of the total number of disputes initiated under TRIPS, 29 complaints have been made by developed countries. Of these, 26 complaints have been from the US and EU. According to one study, many of these complaints were made soon after the entry into force of TRIPS with the possible motivation to push a favoured interpretation of certain provisions that remained ambiguous at the end of the treaty negotiations.<sup>49</sup> Fifteen complaints have been made specifically against developing country members, but no complaint has been made against least developed country members.<sup>50</sup> Out of the 15 complaints made against developing countries, 11 have been made by the US and EU, with 9 complaints made by the US alone. No other developed country has initiated a complaint under DSU for TRIPS infringement against a developing country. These complaints have specifically been against Argentina, Brazil, China, India and Indonesia. However, since the adoption of the Doha Declaration in 2001, such complaints have only been made against China. Since 2000 some developing countries have made a few complaints against developed countries.<sup>51</sup>

In 5 cases against developing country members, the dispute was resolved pursuant to a MAS. Panel or AB reports were adopted in only 4 cases where a complaint was made against a developing country. Out of the remaining 6 cases, panels were composed in 2 cases, 1 case is in the appellate stage, while 3 cases are currently in the consultation phase. There is no certainty on whether these cases will be subjected to an adjudicatory review by a panel.

As can be seen from the annex, some disputes initiated under TRIPS have been in the consultation phase for several years. Even though some of the disputes under consultation did not result in MAS within the period of 60 days before a request for composition of a panel could be made, the complaining parties neither submitted a request for establishing a panel, nor withdrew the complaints. It is possible to keep a dispute in the consultation phase indefinitely because the rules under the DSU do not specify a time limit to the period for concluding the consultation phase. There is no rule of limitation that bars a complaining party from requesting the establishment of a panel after the lapse of a reasonable period for consultations.

#### **III.1 Mutually Agreed Solutions**

In 13 cases, the complaints have been withdrawn after MAS between the parties. In some cases, these resulted in adoption of legislations that brought the legal standards of IP protection by the member complained against to the satisfaction of the complaining party. In

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<sup>49</sup> Mark Daku and Krzysztof J. Pelc, "Who Holds Influence over WTO Jurisprudence?", *Journal of International Economic Law*, vol. 20 (2017), pp. 233–55 at p. 243.

<sup>50</sup> Notably, Article 24 of the DSU requires members to exercise restraint in initiating complaints under the DSU against least developed country (LDC) members of the WTO.

<sup>51</sup> Silke von Lewinski, "The WTO/TRIPS Dispute Settlement Mechanism: Experiences and Perspectives", in *TRIPS Plus 20: From Trade Rules to Market Principles*, Hans Ullrich et.al. (eds.) (Springer, Heidelberg, 2016).

other cases, complaints were withdrawn merely upon satisfactory assurance given by the other party on how the legal provisions at issue would be applied in practice.

In relation to patents, these disputes pertained to the following matters:

- the introduction of a system for filing of pharmaceutical patent applications during a transitional period for developing countries that did not grant pharmaceutical patents at the time of entry into force of TRIPS (hereinafter mailbox system);
- grant of exclusive marketing rights (EMR) to mailbox applications on the basis of the grant of a corresponding patent in another territory;
- implementation the term for patent protection as required under TRIPS;
- making provisional enforcement measures for IP rights available;
- grant of compulsory licenses to remedy anti-competitive practices;
- the scope of application of the doctrine of exhaustion of IP rights to enable parallel importation;
- scope of process patents to include products obtained directly through a claimed process;
- the burden of proof in civil procedures concerning process patent infringement cases;
- application of preliminary injunctions in patent infringement cases;
- transitional protection of existing subject matter.

Some of the MAS in TRIPS related disputes have limited the scope of flexibilities that are available under the TRIPS Agreement.

For example, in *Pakistan–Patent Protection*, the MAS was the adoption of an ordinance to introduce a “mailbox system” for receiving patent applications for pharmaceutical substances and grant of exclusive marketing rights based on such applications being granted patent protection in other members and receiving marketing approval. However, in addition to these obligations, the ordinance also specified that exclusive marketing rights would not be subject to any exceptions, including grant of compulsory licenses.<sup>52</sup> These restrictions were introduced although there is no limitation under TRIPS on the exceptions and limitations that a member State could apply to exclusive marketing rights.<sup>53</sup>

In *Brazil–Patent*<sup>54</sup> the US withdrew its complaint against the use of a provision related to compulsory licensing under the Brazilian law on the ground of failure to work a patent, upon the assurance that if the provision were to be applied, prior consultations would be undertaken with the US. Notably, Brazil had consistently held the view that the provision is fully compliant with TRIPS.

However, in some instances these assurances have had the effect of the respondent party limiting the scope of TRIPS flexibilities. In *Argentina–Patents*<sup>55</sup> an assurance was given that compulsory licenses for anti-competitive practices would not be granted merely based on existence of any of the situations that are deemed to be anti-competitive under the IP law, but upon a prior finding of abuse of dominant position by the national competition authority. Such

<sup>52</sup> WTO, document WT/DS36/4, 7 March 1997. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/D/2A1.pdf&Open=True>.

<sup>53</sup> TRIPS Agreement, article 70.9.

<sup>54</sup> WTO, document WT/DS86/2, 11 December 1998. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/D/10a1.pdf&Open=True>.

<sup>55</sup> WTO, documents WT/DS171/3, WT/DS196/4, 20 June 2002. Available from [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S006.aspx?Query=\(@Symbol=%20wt/ds171/\\*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds171/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true).

a prior determination of abuse of dominant position by a competition authority, however, is not a requirement under TRIPS.<sup>56</sup>

The MAS in *Argentina–Patents* also restricted the scope of parallel importation to allow only the importation of a patented product put by an Argentinian patent holder in any market in the world, only upon the grant of a voluntary license for importation of such a product into Argentina. This was although the application of the DSU to disputes concerning the applied regime of exhaustion of patent rights is excluded under article 6 of the TRIPS Agreement (see above, section III.1).<sup>57</sup>

In addition to these conditions, Argentina also had to amend its law to place the burden of proving non-infringement of a patented process for obtaining a product even if the product is **not identical**. In terms of article 34 of TRIPS this requirement is limited to cases where an **identical** product has been obtained by the third party. Moreover, whereas article 34 requires the plaintiff (patentee) to prove the identity of the product and the novelty of the patented process in order to raise the presumption that the respondent had obtained an identical product through the patented process, this burden of proof was shifted away from the patent holder and placed on the defendant pursuant to the legal amendments undertaken to comply with the MAS.<sup>58</sup>

Significantly, the MAS did not address another challenge made by the US that Argentina had failed to appropriately protect test data and grant exclusive rights to such data submitted by the originator of a drug for marketing approval. The matter was left to be resolved through consultations under the DSU rules, with the option of constituting a panel being available. It was also mentioned in the same context that if the DSB were to adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data under article 39.3, Argentina would submit for approval to the National Congress an amendment to the law to bring it into consistency with the rights under article 39.3 as clarified by the DSB recommendations.<sup>59</sup> This route of exploring a solution through the establishment of a panel, however, was not pursued by the US.<sup>60</sup> Nevertheless, the US has continued to pursue the adoption of data exclusivity, going beyond the requirements of the TRIPS Agreement, through unilateral coercive measures such as the Special 301 watch lists, as well as bilateral trade agreements.<sup>61</sup>

As MAS between the disputing parties is an outcome of the consultation process to resolve the dispute, the framing of the issues on which consultation is requested is important. Article 4.4 of the DSU states that "... any request for consultations shall give the reasons for the request, including identification of the measures at issue and an indication of the legal basis for the complaint." However, in *Argentina–Patents*, in addressing the competition related compulsory licensing provisions in the Argentine patent law, the MAS exceeded the scope of the request for consultations made by the US, wherein this issue had not been raised.<sup>62</sup>

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<sup>56</sup> See United Nations Conference on Trade and Development, *Intellectual Property in the World Trade Organization: Turning it into Developing Countries' Real Property* (United Nations, New York and Geneva), 2010, p. 17. Available from [https://unctad.org/system/files/official-document/ditctncd20068\\_en.pdf](https://unctad.org/system/files/official-document/ditctncd20068_en.pdf).

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>59</sup> WTO, *supra* note 52, p. 6. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/D/22A1.pdf&Open=True>.

<sup>60</sup> Carlos M. Correa, "Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines", *Case Western Reserve Journal of International Law*, vol. 36 (2004), pp. 79–94. Available from <https://core.ac.uk/download/pdf/214078571.pdf>.

<sup>61</sup> Ibid.

<sup>62</sup> See Daya Shanker, "Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System", *Idea: Journal of Law and Technology*, vol. 44, No. 4 (2004). Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=423140](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=423140).

## IV. PANEL AND APPELLATE BODY DECISIONS ON TRIPS DISPUTES

The jurisprudence on the scope of TRIPS flexibilities emanating from WTO panel or AB decisions is limited. In only 2 cases (*India–Patents* and *Canada–Pharmaceutical Patents*) were panel or AB decisions specifically made on pharmaceutical patents. These cases focused on the use of the transitional period and obligations related to pharmaceutical products, and the scope of regulatory review (Bolar) exceptions, respectively. Another case—*Australia–Tobacco Plain Packaging*—concerns the scope of public health measures in the context of trademark obligations under TRIPS but has significant implications in terms of clarifying a public health perspective-based approach to interpretation of each provision of TRIPS (see below). Some other decisions have interpreted other provisions of TRIPS which can have a bearing on pharmaceutical patents as well.

### IV.1 *India-Patents*

In *India–Patent Protection for Pharmaceutical and Agricultural Products*,<sup>63</sup> the US, supported through third party submissions by the European Communities (EC), had complained that while making use of the transitional period available under article 65 of TRIPS to not implement patent protection for pharmaceutical and agricultural products until 1 January 2005, India had failed to implement its obligations under Article 70.8 (a) and 70.9 of TRIPS to establish a system for filing of patent applications (mailbox system) for pharmaceutical and agricultural products, and to grant exclusive marketing rights (EMR) to such applications. The panel and the AB found that India had acted inconsistently with the obligations under articles 70.8 (a) and 70.9 of TRIPS.<sup>64</sup> Subsequently, these findings were extended in a separate panel decision on the same issues against India on a complaint by the EC which, as noted, was also a third party in the original dispute between the US and India.<sup>65</sup>

The US alleged that India had failed to implement a mailbox system that allows patent applicants to file for pharmaceutical and agricultural patent applications **with a sound legal basis**. India contended that Article 70.8 (a) of TRIPS only required that a **means** for filing such applications be available and that such applications could be filed under the Indian patent law. In India's view, the existing law provided a means for filing of patent applications on pharmaceutical and agricultural products, and the examination of such applications was suspended till the end of the transition period by India through an administrative instruction issued by the Government.

A fundamental issue that came up in this dispute at the outset was the burden of proof. The panel relied on a previous AB decision in *US–Shirts and Blouses*<sup>66</sup> which had established "... a new standard advocating the shifting of the burden of proof"<sup>67</sup> once a *prima facie* case of nullification or impairment of benefits had been made. Applying this approach, the panel found that the US had been able to put forward "... evidence and legal arguments sufficient to

<sup>63</sup> WTO, document WT/DS50/R, 5 September 1997. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/50R.PDF&Open=True>.

<sup>64</sup> *Ibid.*, paras 8.1-8.2.

<sup>65</sup> WT/DS79/R, 24 August 1998, paras 9.1-9.2. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/79R.pdf&Open=True>.

<sup>66</sup> World Trade Organization, *WTO Dispute Settlement: One-Page Case Summaries 1995-2018* (Geneva, World Trade Organization), p. 20. Available from [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/1pagesum\\_e/ds33sum\\_e.pdf](https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds33sum_e.pdf).

<sup>67</sup> James H. Fitzer and Sheila Sabune, *Burden of Proof in WTO Dispute Settlement: Contemplating Preponderance of the Evidence*, Issue Paper No.9 (International Centre for Trade and Sustainable Development, Geneva, 2009), p. 12. Available from [https://www.peacepalacelibrary.nl/ebooks/files/ICTSD\\_Pfitzer\\_Burden-of-Proof.pdf](https://www.peacepalacelibrary.nl/ebooks/files/ICTSD_Pfitzer_Burden-of-Proof.pdf).

demonstrate that action by India is inconsistent with the obligations ...” under article 70.8 (a), and hence, the burden of rebutting such evidence and arguments, shifted to India.<sup>68</sup> The panel found that India had not been able to disprove the *prima facie* case made out by the US.

The panel held that the objective of the mailbox system required under article 70.8 (a) was to allow pharmaceutical and agricultural patent applicants to file patent applications with the legal certainty that the novelty and priority dates of those applications will be preserved when those are taken up for examination at the end of the transitional period.<sup>69</sup> It found that the administrative instructions issued by India **did not provide a legally sound basis** for preserving the novelty and priority dates of mailbox applications as, in the panel’s view, such instructions did not override the provisions in the patent law that required all applications to be placed for examination and disposed of, instead of withholding their examination until the end of the transition period. Hence, India was found to be in violation of its obligation under Article 70.8 (a). The panel observed that the means required under article 70.8 (a) should appropriately allow for the entitlement to file mailbox applications.<sup>70</sup> Elaborating on this, the panel laid down a standard of adequacy stating that:

... preservation of novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions so as to provide for effective future patent protection after examination of the applications as of, at the latest, 1 January 2005 is the central object and purpose of Article 70.8(a). This is a special obligation imposed on those Members benefitting from the transitional arrangements.<sup>71</sup>

With regard to the obligation under article 70.9 to grant EMRs to eligible applications, the panel had to decide whether India had an obligation to make EMRs legally available through enactment of specific legislative provisions from the date of entry into force of the TRIPS Agreement as claimed by the US. India had contended that the obligation to grant EMRs was subject to the occurrence of certain qualifying events,<sup>72</sup> and there could be no obligation to make EMRs generally available before such events occur. The panel framed the issue in terms of two questions: 1) Did India have an obligation to provide legal authority to its executive authorities to grant EMRs; and 2) the appropriate time by which such legal authority should be provided. The panel reasoned that since TRIPS creates positive obligations, including to grant EMRs, the executive authority should have specific legal authority to grant such rights. The panel observed that lack of legal authority mandated the executive not to comply with the member’s WTO obligations.<sup>73</sup>

Having ruled that a specific legislative authorisation to grant EMR was necessary to implement the obligation under article 70.9, the panel held that such legislative authorisation should be available from the date of entry into force of the WTO Agreement, i.e., 1 January 1995.<sup>74</sup> The panel’s rationale was that article 70.9 applied “notwithstanding the provisions of Part VI” of TRIPS,<sup>75</sup> i.e., the transitional arrangements provisions which delayed the application of TRIPS

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<sup>68</sup> WTO, *supra* note 63, para 7.40.

<sup>69</sup> *Ibid.*, para 7.31. The panel observed on the basis of the negotiating history of TRIPS that the deal that was struck was that if developing countries chose to not provide patent protection for pharmaceutical or agricultural chemical products during the transition period, they would have to put in place a means by which patent applications for such inventions could be filed “... so as to allow the preservation of their novelty and priority...” for the purpose of determining their eligibility for patent protection at the end of the end of the transition period.

<sup>70</sup> *Ibid.*, para. 7.29.

<sup>71</sup> *Ibid.*, para 7.28.

<sup>72</sup> These are – 1) the filing of a mailbox application; 2) the grant of a patent corresponding to the mailbox application, which is filed in another territory after the entry into force of TRIPS, and the grant of a marketing approval in such other territory.

<sup>73</sup> WTO, *supra* note 63, para 7.53.

<sup>74</sup> *Ibid.*, para 7.63.

<sup>75</sup> *Ibid.*, para 7.25.

till 1 January 2005 for developing countries. India had contended that article 70.9 was not intended to be so implemented from the date of entry into force of the TRIPS Agreement, because it does not state any such obligation to provide for a system to grant EMRs from a specific point of time unlike article 70.8 which requires a means for filing mailbox applications to be provided from the date of entry into force of the WTO Agreement. The panel rejected the distinction between the texts of articles 70.8 and 70.9 drawn by India and instead read the two provisions as a natural flow or part of a singular scheme.<sup>76</sup>

The panel also allowed the US to raise an alternative claim during the first oral submission before the panel, that India had failed to implement its obligations under Article 63 of the TRIPS Agreement to notify the TRIPS Council about the administrative instructions issued for implementing the mailbox system. India had objected to this claim on procedural as well as substantive grounds, as the claim was not specifically included in the request for establishing the panel. Moreover, India objected to the panel proceeding to give a ruling on the alternative claim, even after upholding the original claim by the US of violation of Article 70.8 (a) by India. The panel's reasoning for allowing the claim even though it was not specifically stated in the request by the US was that the claim was included in the request by implication as it was a direct response by the US to the arguments advanced by India in her rebuttal to the US claims on inconsistency of implementation of the mailbox system in India in terms of its TRIPS obligation.<sup>77</sup> However, the panel also noted that this was an exceptional case.<sup>78</sup> Moreover, the panel reasoned that it was understood by the parties that claims could be admitted until the end of the first meeting of the panel where oral submissions were made.<sup>79</sup> The panel also proceeded to rule on the alternative claim that India had failed to notify the TRIPS Council about the administrative instructions for mailbox applications, despite upholding the original claim of the US that India had failed to implement a mailbox system in order to avoid a legal vacuum in the event that, upon appeal, the Appellate Body were to reverse the panel's finding that India had failed to implement a mailbox system in terms of its obligations under article 70.8.<sup>80</sup>

The US had also requested that the panel should suggest to India to implement its obligations under Articles 70.8 and 70.9 of TRIPS in a manner similar to that indicated by Pakistan in its MAS with the US in *Pakistan–Patents*, i.e., by adopting a very strict regime of EMRs that does not allow for exceptions or limitations.<sup>81</sup> India objected to this request stating that such a ruling would be a declaratory judgment on a potential future action, and not a ruling on a measure taken. The DSU only applied to measures taken that nullify or impair the benefits accruing to a member under the provisions of a covered agreement.<sup>82</sup> The panel declined to specifically suggest a similar mode of implementation of EMRs as Pakistan had done under the MAS, as it would contravene India's right under Article 1.1 of TRIPS to choose how to implement its obligations under the Agreement.<sup>83</sup> The panel nevertheless suggested that India should protect "... the interests of those who would have filed such applications had the system been available" while noting that this observation was not a declaratory judgment but an attempt to secure a positive solution to the dispute.<sup>84</sup> In other words, the panel suggested to address the issue, without directing how this should be done.

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<sup>76</sup> *Ibid.*, para 7.55.

<sup>77</sup> WTO, *supra* note 63, para 7.15.

<sup>78</sup> *Ibid.*, para 7.13.

<sup>79</sup> *Ibid.*, para 7.9.

<sup>80</sup> *Ibid.*, para 7.44.

<sup>81</sup> *Ibid.*, para 4.36.

<sup>82</sup> *Ibid.*, para 4.32.

<sup>83</sup> *Ibid.*, para 7.65.

<sup>84</sup> *Ibid.*, para 7.66.

#### IV.1.1 Decision of the Appellate Body

The panel decision that India was in violation of its obligation under article 70.8 (a) to establish a mailbox system was upheld by the Appellate Body.<sup>85</sup> The AB rejected India's contention that the panel had erred in undertaking an interpretative exercise of the Indian patent law. Rather, the AB regarded that the panel had undertaken an "examination" of the Indian law to establish whether the same was in accordance with India's TRIPS obligations.<sup>86</sup> The AB also upheld the approach followed by the panel regarding determination of the burden of proof and its application by the panel.<sup>87</sup> The AB agreed with the panel's interpretative approach that ordinary meaning of the term "means" does not lead to a definitive interpretation as to what sort of "means" is required by article 70.8 (a).<sup>88</sup> Hence, the AB agreed with the panel, that the term should be interpreted in the light of the context of the provision, and the object and purpose of the TRIPS Agreement. The AB followed the panel's choice of articles 70.8 (b) and (c) as the context for article 70.8 (a) and held that the requirement of a sound legal basis for the mailbox applications flows inescapably from the scheme of the three sub clauses.<sup>89</sup> It went on to add that the panel finding is also supported by the preambular objective of "... the need to promote effective and adequate protection of intellectual property rights."<sup>90</sup>

However, the AB took a critical view of the approach followed by the panel towards interpretation of the TRIPS Agreement to apply a doctrine of "legitimate expectations" to find that the mailbox system should be legally so sound as "... to eliminate any reasonable doubt regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated."<sup>91</sup> The panel had reasoned that:

... when interpreting the text of the TRIPS Agreement, the legitimate expectations of WTO Members concerning the TRIPS Agreement must be taken into account, as well as standards of interpretation developed in past panel reports in the GATT framework, in particular those laying down the principle of protection of the conditions of competition flowing from the multilateral trade agreements.<sup>92</sup>

The AB rejected this interpretational approach of the panel and observed that in terms of previous GATT practice, the doctrine of legitimate expectations only applied to non-violation and situation complaints. However, such complaints are not applicable to TRIPS at present, and hence the doctrine could not be applicable to the interpretation of TRIPS. The AB also held that the panel had misunderstood the rule of treaty interpretation under Article 31 of the Vienna Convention on the Law of Treaties (VCLT) that a treaty should be interpreted in good faith as requiring the protection of legitimate expectations. The AB stated that "The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself" and that language must be interpreted in their ordinary sense that fits the context of the text. This context can be derived from the objects and purpose of the treaty. However, no word that is not in the text could be imputed, and no concept that was not intended, could be imported, while interpreting the text.<sup>93</sup> Accordingly, the AB struck down the ruling of the panel that the mailbox system should be such as to dispel any reasonable doubt about the outcome of the mailbox applications.<sup>94</sup>

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<sup>85</sup>WTO, document WT/DS50/AB/R, 19 December 1997. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/50ABR.pdf&Open=True>.

<sup>86</sup> Ibid., para 66.

<sup>87</sup> Ibid., paras 74–75.

<sup>88</sup> Ibid., para 57.

<sup>89</sup> Ibid.

<sup>90</sup> Ibid.

<sup>91</sup> WTO, *supra* note 63, para 7.31.

<sup>92</sup> Ibid., para 7.22.

<sup>93</sup> WTO, *supra* note 85, para 45.

<sup>94</sup> Ibid., para 48.

It is also noteworthy, that the AB construed the determination of the soundness of the Indian legal provisions and administrative instructions as a necessary question for examining their compliance with the relevant TRIPS obligations. Having upheld the analysis of the Indian legal and administrative provisions by the panel as a necessary examination to assess the extent of compliance with TRIPS obligations, the AB went further to undertake a *de novo* re-examination of the Indian law and reviewed additional provisions that were not referenced in the panel decision.

The AB upheld the panel's ruling that India had not implemented its obligation under Article 70.9 of TRIPS to establish a system for granting EMR through the adoption of necessary legislation from the date of entry into force of the TRIPS Agreement, i.e. 1 January 1995.<sup>95</sup> The AB reasoned that article 70.9 operated in tandem with article 70.8 (a) "... to provide a package of rights and obligations that apply **during** the transitional periods" and hence they apply from the date of entry into force of the WTO Agreement.<sup>96</sup>

The AB rejected the finding of the panel to allow the alternative claim by the US.<sup>97</sup> The AB clarified that while a panel had the discretion to determine which claims it must address to resolve the matter at issue in the dispute, its authority was still restricted to the claims made in the request for establishing a panel.<sup>98</sup> The AB also rejected the contention that the inclusive language in the US request allowed a claim on Article 63 to be included within its scope, as such language was not sufficient to meet the requirements of Article 6.2 of the DSU to describe the legal basis of the claim.<sup>99</sup> The AB further rejected the panel's reasoning that it had adopted a working procedure allowing claims to be admitted until the end of the first substantive hearing, to which both parties had agreed.<sup>100</sup> The AB ruled in this regard that while under Article 12 of the DSU the panels had the freedom to adopt their own working procedures after consulting the parties to the dispute, this did not allow the panels to disregard or modify express provisions in the DSU.<sup>101</sup>

#### IV.1.2 Complaint by the European Communities

The EC had made submissions as third party in the complaint brought by the US. However, following the decision in that dispute, the EC filed a complaint on the same issues against India to merely request the panel to formally extend the decision of the previous dispute to this dispute.<sup>102</sup>

The DSU rules allow WTO members to separately initiate dispute resolution proceedings on the same subject matter.<sup>103</sup> The DSU rules also provide the option to a WTO member to join in the consultations and panel proceedings as third parties.<sup>104</sup> At the same time, third parties can initiate a separate dispute resolution proceeding on a measure that is already the subject of a panel proceeding.<sup>105</sup>

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<sup>95</sup> *Ibid.*, para 84.

<sup>96</sup> *Ibid.*, para 82.

<sup>97</sup> *Ibid.*, para 96.

<sup>98</sup> *Ibid.*, para 89.

<sup>99</sup> *Ibid.*, para 90.

<sup>100</sup> *Ibid.*, para 92.

<sup>101</sup> *Ibid.*

<sup>102</sup> WTO, document WT/DS79/2, 15 September 1997. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/79-2.pdf&Open=True>; WTO, *supra* note 65, para 3.1.

<sup>103</sup> Dispute Settlement Understanding, article 9.

<sup>104</sup> *Ibid.*, article 10.

<sup>105</sup> *Ibid.*, article 10.4.

### Admissibility of the complaint

India submitted that the complaint should be inadmissible because the EC could have joined its complaint along with the US in the previous dispute. On a strict reading of article 9.1 with article 10.4 of the DSU, India suggested that these rules of the DSU required multiple complainants to submit their case to the same panel "whenever feasible" or "wherever possible".<sup>106</sup> The EC countered that these provisions did not obligate members to make a complaint at a given point in time.<sup>107</sup>

The panel ruled that the complaint by the EC was not in breach of articles 9.1 and 10.4 of the DSU, as article 9.1 did not impinge the freedom of members to decide whether or when to initiate a complaint under the DSU.<sup>108</sup>

India had also argued that if the panel considered the EC complaint to be admissible, then it should apply "normal dispute settlement procedures" to make an objective assessment of the facts and arguments presented in the dispute.<sup>109</sup> This implied re-examination by the panel of all the issues that were ruled upon by the previous panel in the previous dispute. The EC argued that points dealt with in that dispute should not be re-litigated, and that the panel should rather focus on any new or unknown facts or new arguments presented.<sup>110</sup> The panel ruled that it was not legally bound by previous panel or AB decisions even if the subject matter was the same. However, the panel considered that it would still "take into account" the conclusions and reasoning of the previous panel and AB reports, in the interest of security and predictability of the multilateral trading system and the need to avoid inconsistent rulings.<sup>111</sup> On this basis, the panel arrived at the same findings as in the previous panel decision, as modified by the AB.

### Burden of proof

The EC sought to shift the burden of proving nullification or impairment of benefits to the EC by claiming that the previous panel report raised a presumption in terms of article 3.8 of DSU that the breach of the relevant TRIPS rules by India adversely impacted the EC. Thus, it sought to place the burden of disproving that presumption on India. India contended that mere assertion by the EC that India had not amended its patent law to give effect to the ruling in the previous case did not absolve the EC from proving that India had failed to establish a mailbox system in terms of article 70.8 (a). The panel rejected this contention and held that EC had established a prima facie case of violation of the obligation under article 70.8 (a) by India, by reference to the finding in the previous case.<sup>112</sup> In doing so, the panel relied on the AB in the previous case ruling on the question of burden of proof.

## **IV.1.3 Implications of the decision**

Though the TRIPS provisions at issue in *India–Patents* have become redundant with the end of the transition period for developing countries, and the LDCs being exempted from those obligations under a waiver complementing the extended transition period for the LDCs in relation to pharmaceutical products, the jurisprudence emanating from the panel and AB reports in this dispute have significant implications for other disputes under TRIPS.

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<sup>106</sup>WTO, *supra* note 65, para 3.2.

<sup>107</sup> *Ibid.*, para 4.3.

<sup>108</sup> *Ibid.*, para 7.15.

<sup>109</sup> *Ibid.*, para 3.2.

<sup>110</sup> *Ibid.*, para 4.1.

<sup>111</sup> *Ibid.*, para 7.22.

<sup>112</sup> *Ibid.*, para 7.42.

Though the panel and AB found that India had acted inconsistently with the obligations under articles 70.8 (a) and 70.9 of TRIPS, a significant aspect of the AB decision was that the AB rejected the theory of “legitimate expectations” of the parties beyond what is reflected in the text of the agreement.

However, the panel and AB decisions brought out the following issues which could have implications for disputes relating to other provisions under TRIPS:

1. the authority of panels to examine the adequacy of implementation of TRIPS obligations by a WTO member through its implementing measures;
2. propriety of interpretation of indeterminate provisions of TRIPS by panels;
3. interpretation of absence of enabling legislation as evidence of non-compliance with TRIPS obligations;
4. implications of choice of context in interpreting a provision when alternative contextual choices are available;
5. admissibility of new complaints over the same issues;
6. the determination of burden of proof.

The panel undertook an exercise of interpretation of the textual language of articles 70.8 (a) and 70.9 to read into those provisions words which are not expressed in them. Thus, in respect of article 70.8 (a) the panel construed that the mailbox system must provide a **legally sound basis to preserve the novelty and priority dates** of patent applications filed in the mailbox. Though article 70.9 did not mention a date from which a system for granting EMR should be available, the panel read a date of implementation into the provision. In spite of the freedom available to WTO members under article 1.1 of TRIPS to determine the appropriate method of implementing TRIPS obligations, the AB confirmed that implementing legislations could be subjected to investigation under the DSU and the panels could disagree with a member about the propriety of the national measures to implement TRIPS obligations.<sup>113</sup> Moreover, the AB had also conducted a *de novo* review of the Indian law, including two provisions on delegated rulemaking under the patent law that were not examined by the panel. The restriction under the DSU for the AB to limit itself to questions of law emanating from the panel report was bypassed by construing the review of Indian law as evidence of compliance or non-compliance with TRIPS obligations. In this way, the examination of Indian law effectively changed from a question of fact to a question of law in the AB.

This means in other contexts where WTO members make use of what they consider to be within the scope of flexibilities in view of the text of a particular TRIPS obligation, measures adopted by them could be evaluated against what the panels interpret to be the requisite level of compliance in the light of the relevant TRIPS provision. For example, many WTO members adopt legislative provisions or administrative guidelines in respect of patentability of specific claims for pharmaceutical products, while complying with the requirements of article 27.1 of TRIPS. The adoption of such measures has been countered by countries like the US outside the WTO through unilateral coercive initiatives like the annual Special 301 reports<sup>114</sup> or through the negotiation of standards of patent protection in TRIPS plus free trade agreements that disallow such measures.<sup>115</sup> Though these measures have not been challenged through a formal WTO complaint under the DSU, it remains uncertain how a panel might interpret the TRIPS consistency of such measures based on its interpretation of article 27.1. However, under a proper interpretation of the TRIPS Agreement, in accordance with the VCLT, there

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<sup>113</sup> Carlos M. Correa, *Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd edition.), (Oxford University Press, Oxford, 2020), p. 27.

<sup>114</sup> See e.g., Office of the United States Trade Representative, Special 301. Available from <https://ustr.gov/issue-areas/intellectual-property/Special-301>.

<sup>115</sup> See, e.g., Carlos M. Correa, "Implications of bilateral free trade agreements on access to medicines", *Bulletin of the World Health Organization*, vol. 84, 2006, pp. 399–404. Available from <https://www.who.int/bulletin/volumes/84/5/399.pdf?ua=1>.

seems to be little or no doubt that measures establishing the level of patentability requirements have been fully left to the discretion of WTO members.

A related issue to consider in this regard is the scope of interpretative powers of a panel given the unique nature of TRIPS in the WTO as an agreement that creates positive obligations, and yet is replete with ambiguous textual language. Given this aspect, a question to consider is whether a panel should attempt to fill in the gaps in the text, e.g., by reading into the text of article 70.8(a) a standard of legal soundness, or whether panels should exercise judicial restraint and apply the doctrine of *non-liquet* to rule that the text is unclear?<sup>116</sup> A declaration of *non liquet* in *India-Patents*, for instance, would have meant that the panel would have stopped its enquiry upon finding that the meaning of the word “means” for filing mailbox applications under article 70.8 (a) was not clear, and hence, it could not reach a conclusion on whether the means used by India to implement the mailbox system was inconsistent with the obligations under TRIPS.

Some scholars have suggested that the panels and the AB should declare a *non-liquet* where the provision in a covered agreement is indeterminate.<sup>117</sup> It should be noted that article 3.9 of the DSU states that the provisions of the DSU are without prejudice to the rights of members to seek authoritative interpretation of the provisions of a covered agreement through the established decision-making processes under the WTO Agreement. Thus, the DSU defers to the powers of WTO members to interpret the provisions of a covered agreement under article IX.2 of the WTO Agreement.<sup>118</sup> While panels and the AB have justified interpretation of indeterminate provisions in terms of the recognition in article 3.2 of the DSU to apply the customary rules of interpretation in international law to clarify the provisions of the covered agreements, this interpretative responsibility is the mandate of the DSB—a body comprised of WTO members—and not the panels or the AB which are established by the DSB. The mandate of the panel is to make findings that will assist the DSB in the discharge of its functions. Thus, it would be preferable that panel and AB decisions make suggestions instead of definitive interpretations. If the WTO members in the DSB agree to the suggested interpretations, they could recommend the General Council or the Ministerial Conference to adopt such interpretation under article IX.2 of the WTO Agreement.

In both the *India–Patents* disputes, the respective panel and AB decisions were based on an examination of several provisions of the Indian patent law and the administrative practice through which India claimed to implement its mailbox obligations under TRIPS. However, these provisions of the Indian law were not mentioned in the request for establishment of the panel as the legal basis of the complaint.<sup>119</sup> This was although during the consultations, the complaining parties had been aware of the legal provisions under which India claimed to have implemented the TRIPS obligations at issue. However, it should be acknowledged here that the respondent also did not raise this procedural issue during the hearing.<sup>120</sup>

An important aspect of the *India–Patents* decision is that the panel and the AB, while justifying the need for examination of the implementing measures to assess their compliance with relevant TRIPS obligations, ventured into an exercise of simulating hypothetical situations to examine whether the mode of implementing the mailbox system by India provided legal

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<sup>116</sup> See R. Rajesh Babu, "Understanding the Role of International Law in WTO Law", in, *Indian Yearbook of International Law and Policy*, Deepaloke Chatterjee (ed.) (New Delhi, Satyam International), p. 287. Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1805113](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1805113).

<sup>117</sup> See Lorand Bartels, "The Separation of Powers in the WTO: How to Avoid Judicial Activism", *The International and Comparative Law Quarterly*, vol. 53, No. 4 (2004), p. 894.

<sup>118</sup> *Ibid.*, p. 872.

<sup>119</sup> Kennedy, *supra* note 15, p. 108.

<sup>120</sup> India contended that the panel could not undertake an interpretation of municipal law and should accept the interpretation advanced by India, but did not question the authority of the panel to examine those measures on the ground that those were not mentioned in the request for establishment of a panel.

certainty. In doing so, the panel went beyond an examination of facts to determine whether the TRIPS obligation concerning mailbox system was being implemented adequately. The panel ruled that the measures India had taken through administrative instructions did not override the express statutory mandate and could have dissuaded potential applicants from filing applications due to this legal uncertainty. The panel reached this conclusion based on past jurisprudence of the GATT panel in *Malt Beverages* where it was held that mere existence of mandatory legislation, even if it were non-enforceable, may influence the decision of economic operators.<sup>121</sup> This also demonstrates the influence of pre-existing GATT panel jurisprudence on the WTO panels examining disputes arising under an agreement of a very different nature. Reliance on trade jurisprudence emanating from disputes arising under other covered agreements to interpret the provisions of TRIPS has led panels to adopt overly restrictive interpretations that have disregarded the interpretative context provided by articles 7 and 8 of the Agreement and the public policy objectives that WTO members have sought to advance. This may have contributed, as noted above, to a culture of overcompliance, through the pursuit of a cautious approach by WTO members in implementing TRIPS flexibilities.<sup>122</sup>

How a panel construes the silence of domestic law in the light of TRIPS obligations therefore is of critical importance, as reflected in this decision. In this case, the adoption of an ordinance and subsequent introduction of a statutory amendment which lapsed, was construed by the panel and AB as demonstrating that the express provision in the existing law requiring transmittal of all applications for examination could only be overcome by a statutory amendment. However, the panel disregarded the affirmation by India that the same outcome could be achieved through other means such as administrative instructions.<sup>123</sup> For instance, it would have been possible for the Indian legislature to reject the proposed amendment in favour of an administrative instruction.

Another interesting aspect of the *India–Patents* decision was the choice of context for interpreting the provision at issue. The panel followed the well-established principle of treaty interpretation under article 31 of the VCLT, to deduce the ordinary meaning of the text in its context and the light of objects and reasons of a treaty. The panel had read the mailbox provision under article 70.8 as part of a package that included the obligation to grant EMR in terms of article 70.9 to extend the date of implementation of the mailbox application to the implementation of a system for granting EMRs. However, in doing so the panel ignored the option of reading article 27.1 to which article 70.9 was an alternative, as part of the context. Such a reading could have led the panel to a different conclusion.<sup>124</sup>

The *India–Patents* dispute also involved a separate complaint by the EC on the same legal issues already decided upon by the panel and the AB under the complaint made by the US. The complaining party in the second dispute was involved in the previous dispute as a third party and had the option to join as a complainant in the same dispute, as the issues and relief sought were the same. However, the panel rejected the preliminary objection raised by India on the admissibility of such complaint. The panel based its finding on the reasoning that article 9 of the DSU, relating to procedures for multiple complaints, did not put any limitation as to

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<sup>121</sup> WTO, *supra* note 63, para 7.35.

<sup>122</sup> Land, *supra* note 11.

<sup>123</sup> However, subsequently, this reasoning was not followed by the panel in *United States – Section 301–310 of the Trade Act 1974*, where the intention of the US administration expressed to the Congress and US assurances to the panel that it would not use the provisions of Sections 301–310 of the Trade Act in contravention of its obligations under WTO rules was relied upon by the panel to not suggest corrective action even though it had found that the said provisions were not in accordance with WTO law. See Chakravarthi Raghavan, "The World Trade Organization and its Dispute Settlement System: Tilting the balance against the South", Trade and Development Series No.9, Third World Network, 2000. Available from <https://www.twn.my/title/tilting.htm>. A similar approach was adopted by the panel and AB in *United States - Section 211 Appropriations Act* to observe "... where discretionary authority is vested in the executive branch of a WTO Member, it cannot be assumed that the WTO Member will fail to implement its obligations under the WTO Agreement in good faith."

<sup>124</sup> Kennedy, *supra* note 15, p. 170.

when a WTO member could request the establishment of a panel relating to the same matter, and that in terms of article 10.4 of the DSU, third parties to a dispute had the right to have recourse to normal dispute settlement procedures over the same measures that are the subject of a panel proceeding.<sup>125</sup>

This ruling on the admissibility of subsequent disputes over the same legal issues raises the question whether the same claims that have been already decided in a previous case could be barred in subsequent WTO proceedings involving the same parties by application of the principle of *res judicata*. This is a well-recognized general principle of law in municipal legal systems which regulates consecutive proceedings by precluding a party from re-litigating a matter that it has already litigated. In some legal systems, the principle also applies to third parties in a legal proceeding. However, the scope of the principle varies between different legal systems as well as its applicability to international disputes, which makes it challenging to apply the principle in WTO disputes.<sup>126</sup> Nevertheless, it may be possible to consider the application of the principle at least in a limited manner to prevent frivolous re-litigation of disputes between States on the same issues, particularly where the States were formally involved as parties to the dispute, the legal claims in the disputes are identical, and no different remedy is sought. In *India–Autos* the panel had observed that *res judicata* could be relevant to WTO dispute settlement if the specific measures at issue, the legal basis of the complaint, and the parties were the same.<sup>127</sup> However, it would be difficult to apply the principle to a subsequent complaint on the same measures with the same claims by a State that was not a complainant but a third party in a previous dispute.

In respect of the burden of proof, in both cases the panel followed the jurisprudence emanating from past disputes arising under other WTO agreements to first require the complaining party to provide evidence and legal arguments to make a *prima facie* case of the respondent party acting inconsistently with its obligations, and on that basis, shift the burden of disproving the case on the respondent. In the latter dispute initiated by the EC, the panel relied on the findings of the previous panel to hold that a *prima facie* case had been made by the EC. However, in the first dispute initiated by the US, the panel seemed to have followed the practice of other panels to bundle all the evidence presented by the complainant, the respondent as well as third parties together and then assess whether the complainant has presented a *prima facie* case for the subsequent shifting of the burden of proof. In considering the dispute over whether India was implementing its obligation under article 70.8 (a) the panel did not begin with an examination of whether the US had made a *prima facie* case of apparent non-implementation of the mailbox obligation. Rather, after identifying the issue before it, the panel went into an interpretative exercise to deduce the nature of the obligations arising under article 70.8 (a), followed by an examination of the mechanism used by India to implement that obligation. This was a substantive analysis on the merits of claims and counterclaims, and not a preliminary analysis of whether a *prima facie* case was made out by the US. In fact, while doing this assessment, the panel observed that in view of article 1.1 of TRIPS, "... it is up to India to decide how to implement its obligations...", and the mere fact that India relied on administrative instructions without legislative changes, or the lapse of the Ordinance that India had promulgated did not imply that India lacked a *means* of implementing the obligation under article 70.8 (a).<sup>128</sup> This would suggest that *prima facie* India's implementing measure seemed to be consistent with the obligations under TRIPS. Nevertheless, in the following paragraph after this preliminary observation the panel raised the need for enquiry as to whether the mechanism implemented by India provides sufficient legal security and predictability that

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<sup>125</sup> WTO, *supra* note 102, para 7.21.

<sup>126</sup> Son Tan Nguyen, "The applicability of Res Judicata and Lis Pendens in World Trade Organization dispute settlement", *Bond Law Review*, vol. 25, No. 2 (2013), p. 148. Available from <http://www.austlii.edu.au/au/journals/BondLawRw/2013/16.pdf>.

<sup>127</sup> *Ibid.*

<sup>128</sup> WTO, *supra* note 63, para 7.33.

patent applicants of other WTO members are entitled to legitimately expect.<sup>129</sup> The panel analyzed this question in considerable detail in the subsequent paragraphs and then observed that the US had raised those issues in a persuasive manner with sufficient legal arguments and evidence to establish a *prima facie* contention that India had acted inconsistently with its obligations.<sup>130</sup> Accordingly, the burden of proof shifted onto India to disprove the presumption thus raised against India's mode of implementation of mailbox obligation.

## **IV.2 Canada-Pharmaceutical Patents**

*Canada-Pharmaceutical Patents*<sup>131</sup> was a major decision from the WTO panel on the scope of exceptions to patent rights for pharmaceutical products. In this dispute the EC had complained that provisions in the Canadian patent law 1) allowing third parties to use a patented invention without the consent of the patent holder for conducting experiments and tests to obtain marketing approval of generic drugs before the expiry of the patent (hereinafter regulatory review exception), and 2) allowing manufacturing and stockpiling of generic medicines up to six months before the end of the patent term, were inconsistent with TRIPS. The EC claimed that these exceptions under the Canadian law violated obligations under articles 28.1 (rights conferred by a patent grant) and article 33 (term of protection) of TRIPS. It was also contended that these provisions in the Canadian law violated article 27.1 of TRIPS by discriminating between pharmaceutical patent holders and patent holders in other fields of technology (by treating pharmaceutical patent holders less favourably as these provisions were applied to pharmaceuticals only).

Canada requested the panel to reject the complaint on the ground that the disputed provisions of the Canadian law constituted limited exceptions<sup>132</sup> that are allowed under article 30 of TRIPS, that such limited exceptions were not inconsistent with article 27.1 of TRIPS,<sup>133</sup> and that these provisions did not reduce the minimum term of protection under TRIPS. Moreover, Canada submitted that the rights conferred by a patent in terms of article 28.1 and the term of patent protection under article 33 were also not excluded from the scope of exceptions possible under article 30.

The panel found that the regulatory review exception implemented by Canada was a limited exception within the meaning of article 30, but the provision allowing manufacturing and stockpiling of generic medicines six months before the expiry of the patent was inconsistent with the scope of the exception.<sup>134</sup>

One of the major issues of contention in this dispute was the scope of the "limited exceptions" to patent rights that WTO members could incorporate in their patent laws in accordance with article 30 of TRIPS. The EC contended that the limited exceptions allowed under article 30 did not apply to the requirement under article 27.1 of TRIPS, such that exceptions cannot be carved out for specific fields of technology such as pharmaceuticals but must be applied to all fields of technology. Canada rebutted this argument suggesting that such an approach would encourage broad general derogations from TRIPS, and a reading of article 30 and 27.1 in

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<sup>129</sup> Ibid., para 7.34.

<sup>130</sup> Ibid., paras 7.35-7.40.

<sup>131</sup> WTO, document WT/DS/114/R, 17 March 2000. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:WT/DS/114R.pdf&Open=True>.

<sup>132</sup> Ibid. In its submissions, Canada pointed out that both the regulatory review exception and stockpiling before the expiry of the patent were related and part of a single entity, for one could not manufacture and stockpile without obtaining marketing approval from the regulatory authority.

<sup>133</sup> Ibid. Canada argued that the provisions applied generally to all fields of patent protection and therefore did not discriminate between pharmaceutical patents and patents in other fields of technology.

<sup>134</sup> Ibid., para 8.1.

accordance with established rules of treaty interpretation under the VCLT suggested that exceptions for specific fields of technology were allowed under TRIPS.

The EC also contended that the Canadian legislations did not satisfy the terms of article 30. Canada suggested that on the contrary, article 30 was sufficiently broad in scope. Read in context, article 30 reflected, in Canada's view, the agreement of WTO members that the full application of all the rights included in a patent, always and in all circumstances, would be inconsistent with the balanced objectives of TRIPS. Hence, "Article 30 granted Members the discretion to limit the full application of patent rights in light of the particular circumstances that prevailed in their respective jurisdictions, when balance was required and when social and economic welfare had to be considered."<sup>135</sup> In this regard, Canada pointed out that the exception under article 30 was very different from other exceptions in TRIPS as well as in other WTO agreements.<sup>136</sup> Canada also pointed to the negotiating history of article 30 which suggested that attempts by the EC to carve out a narrow exception limited only to non-commercial purposes was rejected and the compromise reached in article 30 "... expressly allowed some degree of conflict with the normal exploitation of the patent and some degree of prejudice to the legitimate interests of the patent owner."

Objecting to a broad reading of the scope of exceptions under article 30 in the light of objectives of the TRIPS Agreement, the EC argued that public policy considerations could not be invoked to justify measures which are inconsistent with the provisions of TRIPS.<sup>137</sup> The EC argued further that article 30 did not state any specific public policy consideration necessitating an exception, unlike the exception provision under article XX of GATT.<sup>138</sup> Referring to article 8.1 of TRIPS, the EC argued that the requirement of consistency with the provisions of TRIPS "... demonstrated that the public health, nutrition and other public interests were to be considered **subordinate** to the protection of the intellectual property rights insofar as the minimum rights guaranteed by the TRIPS Agreement were concerned (emphasis added)."<sup>139</sup>

Australia, Brazil, Colombia, Cuba, India, Israel, Japan, Poland, Switzerland, Thailand, and the US made third party submissions in this dispute. Of these only Switzerland fully concurred with the views of the EC.<sup>140</sup> All other submissions were of the view that the Canadian law allowing use of the patented invention for the purpose of conducting tests, etc. for obtaining regulatory approval was within the scope of the exception under article 30. Nevertheless, Japan and the US were of the view that while the regulatory review exception was within the scope of article 30, the provision allowing manufacturing and stockpiling of the product near the expiry of the patent term would not be within the scope of article 30.<sup>141</sup> The US suggested that such a provision could violate the exclusive right of the patent holder to manufacture the product during the term of the patent.

The panel decided to interpret the provisions of TRIPS in an extended context, to consider not only the negotiating history of TRIPS itself, but also the negotiating history of the agreements incorporated by reference into TRIPS (Paris Convention and Berne Convention). Specifically, the panel opined that article 9(2) of the Berne Convention, which concerned the scope of exceptions to copyright protected works that could be permitted by a party to that convention,

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<sup>135</sup> Ibid., para 4.13.

<sup>136</sup> Ibid. Unlike exceptions provisions in other WTO agreements, article 30 of TRIPS did not include any necessity test (allowing the exception insofar as necessity is established), nor did restrict exceptions to special cases or circumstances.

<sup>137</sup> Ibid., para 4.30.

<sup>138</sup> Ibid.

<sup>139</sup> Ibid.

<sup>140</sup> Ibid., paras 5.28-5.29.

<sup>141</sup> Ibid., paras 5.24 and 5.36.

constituted an important contextual element of article 30 of TRIPS.<sup>142</sup> Thus, the panel compared the text of article 30 with the text of article 9(2) of the Berne Convention on which it was modeled, to examine the reason why negotiators adopted the expression “limited exception” rather than the Berne Convention language which allowed countries to legislate to allow reproduction on copyright protected works in “certain special cases.”

The panel concurred with the EC perspective that “limited exceptions” must be interpreted very narrowly, because accompanied with the word “exceptions”—implying a limited derogation—the word “limited” made the extent of the exception even narrower. Hence, the exception under article 30 must only make a small derogation from the rights in question.<sup>143</sup> The panel also adopted a literal reading of the exception to assess the extent to which the exception impacted legal rights rather than their economic impact. In this line, the panel examined the extent to which the legal rights conferred by a patent have been curtailed.<sup>144</sup> On this basis, the panel found that the stockpiling provision in the Canadian law did not constitute a limited exception in terms of article 30 of TRIPS as there was no limitation on the quantity of production that could take place under the exception as a derogation of the patentee’s right to manufacture.<sup>145</sup>

However, the panel found that the regulatory review exception under the Canadian law was a “limited exception” within the meaning of article 30 of TRIPS. The panel observed that “Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products.”<sup>146</sup> The panel also agreed that the exception could apply in this manner to the use of the patented invention for obtaining even foreign regulatory approval procedures.<sup>147</sup>

It is interesting to note that while the panel looked into the negotiating history of article 30 in an extended context to include the Berne Convention in its assessment in respect of the stockpiling exception, it did not accord weight to the negotiating history when considering the regulatory review exception, on the ground that there was no documented evidence of the negotiated understanding that article 30 was understood to permit regulatory review exceptions like Bolar exemptions. However, it reached the same conclusion by adopting a literal interpretation.

The panel held that an exception under article 30 must satisfy three conditions cumulatively, i.e., each of the three conditions must be satisfied by the exception: 1) the exception must be limited, 2) it should not conflict unreasonably with the normal exploitation of a patent; and 3) it should not unreasonably prejudice the legitimate interests of patent owners, taking into account the legitimate interests of third parties.

By following this approach, the panel refused to accept the Canadian proposition that effective exploitation of a patent right after the end of the patent term cannot be considered to be “normal exploitation” of a patent. It observed that “some of the basic rights granted to all patent owners, and routinely exercised by all patent owners, will typically produce a certain period of

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<sup>142</sup> *Ibid.*, para 7.14. An interesting fact to note here is that there was no expert on patent law in this panel that decided on the scope of exceptions to patent rights in the context of pharmaceutical patents. One of the panel members was a copyright expert and a former director of the copyright division in the World Intellectual Property Organization. See Kennedy, *supra* note 15, p. 59.

<sup>143</sup> *Ibid.*, para 7.30.

<sup>144</sup> *Ibid.*, para 7.34.

<sup>145</sup> *Ibid.*, para 7.36.

<sup>146</sup> *Ibid.*, para 7.45.

<sup>147</sup> *Ibid.*, para 7.46.

market exclusivity after the expiration of a patent”.<sup>148</sup> The panel also observed that the advantage gained by a patent owner in the months after expiry of the patent could also be considered a purpose of the patent owner’s right to exclude others from making or using the patented product during the term of the patent.<sup>149</sup> Thus, the panel construed a short period of extended market exclusivity after the end of the patent term as a natural outcome of patent protection.

However, having concluded that some degree of exclusivity after the expiration of the patent term would be legitimate, the panel found that in the case of regulatory review exception the period of such post-expiry exclusivity would be very long if the tests etc., required to be done for obtaining regulatory approval by generic manufacturers could only be allowed after the end of the patent term. Hence, the panel concluded that this would not be normal exploitation of the patent and upheld the regulatory review exception, as the scope of curtailment of patent rights through the exception was narrow.<sup>150</sup> In that light, the panel did not consider it necessary to further explore whether the exception unreasonably conflicted with normal exploitation of the patent, as such exploitation was not normal in its view.

The panel further concluded that the requirement under article 30 that an exception to a patent right “... must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties” should be construed as broader than legal interests.<sup>151</sup> The panel also declined to decide through adjudication on normative policy question of whether patentees have a legitimate interest in de facto extension of the patent term to compensate for loss of their effective patent term due to the time taken for obtaining regulatory approval after the grant of patent.<sup>152</sup>

#### **IV.2.1 Implications of the decision**

Though the panel decision upheld the permissibility of the regulatory review or “Bolar exemption”, in terms of jurisprudence it made certain questionable observations about the scope of the exceptions allowed under article 30.

First, the panel laid down that any national patent law implementing the exception must satisfy all the three conditions of article 30 cumulatively, requiring an exception to satisfy each of the three conditions under that article. However, this approach of cumulative consideration of the terms of article 30 is not justified under the rules of treaty interpretation under the VCLT.<sup>153</sup> Critiquing this approach of the panel, a number of distinguished intellectual property scholars agree that the three conditions under article 30 are not cumulative – “The three-step test may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed.”<sup>154</sup>

Second, the panel unduly narrowed down the scope of admissible exceptions by adopting a narrow concept of the word “limited” in article 30, focusing on the extent of curtailment of rights and not the economic implications arising from the exception. In effect, this implies that an exception with little economic effect may be disallowed under this approach even if in practice

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<sup>148</sup> WTO, *supra* note 131, para 7.56.

<sup>149</sup> *Ibid.*, para 7.35.

<sup>150</sup> *Ibid.*, para 7.45.

<sup>151</sup> *Ibid.*, para 7.71.

<sup>152</sup> *Ibid.*, para 7.73.

<sup>153</sup> Carlos M. Correa, *The Bolar Exception: Legislative Models and Drafting Options*, Research Paper No. 66 (Geneva, South Centre, March 2016), p. 6. Available from [https://www.southcentre.int/wp-content/uploads/2016/03/RP66\\_The-Bolar-Exception\\_EN1.pdf](https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf).

<sup>154</sup> Max Planck Institute for Innovation and Competition, Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, 5 June 2016. Available from <https://www.ip.mpg.de/en/nc/research/research-news/declaration-on-patent-protection.html>.

the patent owner is not negatively affected by the curtailment of the legal rights.<sup>155</sup> It has been suggested in this regard that an exception should be construed as limited if it is reasonably proportionate i.e., it is for a legitimate purpose, it is adequate to achieving that purpose and does not exceed what is necessary and sufficient to achieve it.<sup>156</sup>

Third, the panel also adopted a concept of “normal exploitation of a patent” to include the right to exclude third parties from using the patented invention. While the panel concluded that the regulatory review exception under the Canadian law did not conflict with the normal exploitation of a patent, the panel accepted in principle that some period of *de facto* exclusivity after the expiration of the patent is legitimate as normal exploitation. This reasoning is questionable because the right to exclude the use of a patented subject matter by third parties is a legal power that may be exercised or not by the patent owner, but not an exploitation of the patent. Exploitation of a patent consists of acts of making, using or commercializing inventions without competition from third parties.<sup>157</sup>

Having held that the length of the period of *de facto* market exclusivity after the expiry of the patent would be too long to constitute “normal exploitation” of the patent in the absence of a regulatory review exception, the panel did not find it necessary to interpret what kind of use of a patented invention without the consent of the patent holder would “unreasonably” conflict with the normal exploitation of a patent. Whether an exception is unreasonable would “... depend on the conceptual framework that underpins the granting of patents, which can vary between countries at different levels of development.”<sup>158</sup> However, the panel had failed to appreciate the considerable diversity in the objectives of patent protection in different national legal systems and only focused on incentivizing innovation as the only objective of patent protection. It ignored other possible objectives that can inform national patent systems such as diffusion of knowledge and technology, or advancement of public policy objectives.<sup>159</sup> In the light of such other societal objectives, the use of measures that constitute exceptions to patent rights in order to meet those objectives could very well be reasonable measures against the normal exploitation of a patent.

Fourth, the panel made some observations regarding the requirement of non-discrimination between patents in different fields of technology under article 27.1,<sup>160</sup> which so far has been the only observation by any WTO panel on this provision. The EC had claimed that the regulatory review exception in the Canadian law discriminated in practice against pharmaceutical patents. Though this contention was rejected by the panel on the ground that the regulatory review exception under the Canadian law did not constitute a discrimination *de jure* or *de facto*, it observed that both article 30 and article 31 of TRIPS were subject to the requirement of non-discrimination between patents in all fields of technology under article 27.1 of TRIPS.<sup>161</sup> This observation is questionable because it would be unreasonable to apply specific exceptional measures for certain fields of technology to other fields of technology. Article 27.1 of TRIPS allows differential treatment between patents in different fields of technology.<sup>162</sup>

Fifth, an important feature of the *Canada-Pharmaceutical Patents* decision was the clarification by the panel that the scope of the exception under article 30 and the limiting conditions therein must be examined bearing in mind the objectives and principles under articles 7 and 8 of TRIPS. However, despite this acknowledgement of the importance of the

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<sup>155</sup> Correa, *supra* note 113, p. 299.

<sup>156</sup> Max Planck Institute, *supra* note 154, p. 8.

<sup>157</sup> Correa, *supra* note 113, p. 300.

<sup>158</sup> *Ibid.*, p. 301.

<sup>159</sup> *Ibid.*

<sup>160</sup> WTO, *supra* note 131, Para 7.88-7.93.

<sup>161</sup> *Ibid.*, para 7.91.

<sup>162</sup> Correa, *supra* note 113, pp. 275-7.

objectives and principles of TRIPS, the panel did not analyze the content and implications of those provisions.<sup>163</sup> Instead, it introduced its own policy views on the objectives behind patent protection to construe the scope of normal exploitation of a patent, giving weight only to the interests of patent holders (see above).<sup>164</sup> It should be noted that subsequently the Doha Declaration has confirmed that "... the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives (article 7) and principles (article 8)."<sup>165</sup> In interpreting TRIPS provisions, WTO members and future panels should consider broader policy choices that are within the scope of the objectives and principles of TRIPS.

Significantly, in interpreting the third element of article 30 that the exception should not unreasonably prejudice the legitimate interests of patent holders, taking into account the legitimate interests of third parties, the panel rightly concluded that legitimate interests should be construed as broader than legal interests, "... as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."<sup>166</sup> This is supported by the text of article 30 which refers to a balance between legitimate interests of patentees and third parties, which could include interests of "... follow-on innovators, competitors and users, as well as the interests of society at large, for instance, in addressing a public health crisis or in ensuring the advancement of science and technology."<sup>167</sup>

The panel decision is also significant with regard to the question of how the provisions of TRIPS should be interpreted. In interpreting article 30, the panel not only looked at the text of article 30 in its context and in the light of its objects and purposes, and the negotiating history of TRIPS, but the panel also considered the negotiating history of pre-existing international IP agreements like the Berne Convention. This approach has also been followed in *US-Section 110(5) Copyright Act*<sup>168</sup> and in *US-Section 211 Appropriations Act*.<sup>169</sup> It should be noted that many developing countries were not parties to these pre-existing IP conventions at the time of the adoption of TRIPS (which made those conventions applicable to them) and were hence not party to the understanding reflected by the negotiating histories of those conventions.<sup>170</sup>

### ***IV.3 Decisions on Interpretation of Objectives and Principles of TRIPS***

The objectives and principles under articles 7 and 8 of TRIPS have received very limited attention in panel and AB rulings. In *Canada-Pharmaceutical Patents*, as discussed above, Canada had called upon the panel to interpret the scope of article 30 in the light of articles 7 and 8 of TRIPS. Canada stated that "Article 7 made it clear that intellectual property rights were not conferred in a vacuum, and that the TRIPS Agreement therefore did not aim to achieve a degree of protection for those rights which would unduly prejudice the vital public interest in social and economic welfare or the rights of others."<sup>171</sup> The use of the exception under article 30 should therefore be construed as a means of achieving the balance contemplated by article 7.<sup>172</sup> The panel, however, seemed to align with the view of the EC that

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<sup>163</sup> Ibid., p. 94.

<sup>164</sup> Ibid., pp. 85–6.

<sup>165</sup> WTO, *supra* note 5, para 5(a).

<sup>166</sup> WTO, *supra* note 131, para 7.69.

<sup>167</sup> Correa, *supra* note 113, pp. 301–2. However, though the panel analysed the interests of the patent owner, it did not assess the interests of third parties. See Kennedy, *supra* note 15, p. 146.

<sup>168</sup> WTO document, document WT/DS/160/R, 15 June 2000, para 6.65. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:WT/DS/160R-00.pdf&Open=True>.

<sup>169</sup> WTO, document WT/DS176/R, 6 August 2001, para 8.13. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:WT/DS/176R.pdf&Open=True>.

<sup>170</sup> Correa, *supra* note 113, pp. 44–5.

<sup>171</sup> WTO, *supra* note 131, para 4.13.

<sup>172</sup> Ibid., para 4.14.

“Articles 7 and 8 are statements that describe the balancing of goals *that had already taken place in negotiating the final texts of the TRIPS Agreement* (emphasis added)”<sup>173</sup> and proceeded to interpret article 30 in the light of the limiting conditions mentioned therein, without diving into an analysis of articles 7 and 8. However, in *US-Section 211 Appropriations Act*, the panel observed that the expression in article 7 of TRIPS that IP protection should contribute to a balance of rights and obligations was in the nature of a good faith principle, and obligations under the Agreement should be implemented in accordance with it.<sup>174</sup>

In *Australia-Tobacco Plain Packaging*, the panel held that paragraph 5 of the Doha Declaration on TRIPS and Public Health provides general guidance that each provision of TRIPS must be interpreted in the light of the object and purpose of the Agreement, as particularly expressed in its objectives (article 7) and principles (article 8), making these provisions of “central relevance.”<sup>175</sup> The panel held that the interpretative guidance in paragraph 5 of the Doha Declaration may be considered as a “subsequent agreement” between WTO members in terms of article 31.3(a) of the VCLT.<sup>176</sup>

The panel decision in *Australia-Tobacco Plain Packaging* is significant because it contains “An interesting and detailed elaboration on the weight of Articles 7 and 8 of the TRIPS Agreement...”<sup>177</sup> The panel clarified that article 7 of TRIPS reflects “... the intention of establishing and maintaining the balance between the societal objectives mentioned therein ...” while article 8.1 “... expresses the intention of the drafters of TRIPS to preserve the ability of WTO Members to pursue certain legitimate societal interests.”<sup>178</sup> The panel affirmed that public health is such a recognized societal interest.<sup>179</sup>

#### **IV.4 Other Decisions**

Some of the other panel decisions have interpreted general provisions such as national treatment and MFN, term of patent protection for patents existing on the date of application of TRIPS, and the security exception. In *Indonesia-Autos* the panel held that even though there was a preference for Indonesian trademarks for benefiting from a subsidy programme, that did not violate the national treatment obligation under article 3 of TRIPS as foreign companies could also register their trademarks.<sup>180</sup> In *EU-Trademarks and Geographical Indications* the panel held that any matter concerning the protection of IP that is covered under TRIPS would be within the scope of the national treatment and MFN obligations. It observed that even where a higher level of protection than required under TRIPS is accorded, such higher level of protection would have to be subject to national treatment and MFN.<sup>181</sup> The panel also followed a doctrine of “effective equality of opportunities”, following the panel and AB in *US-Section 211 Appropriations Act*, to interpret the “no less favourable treatment” standard in article 3.1, implying that even if there was no discrimination in law based on nationality, if the substantive effect of other requirements would effectively amount to discrimination *de facto* based on

<sup>173</sup> Ibid., para 7.25.

<sup>174</sup> WTO, *supra* note 169, para 8.57.

<sup>175</sup> Thamara Romero, “Articles 7 and 8 as the basis for interpretation of the TRIPS Agreement”, Policy Brief No. 79, South Centre, Geneva, June 2020, p. 5. Available from <https://www.southcentre.int/wp-content/uploads/2020/06/PB-79.pdf>.

<sup>176</sup> In *EU-Seizure of Generic Drugs in Transit India* also submitted in its request for consultations that as the measures at issue (seizure of generic drugs in transit) had serious adverse impact on the ability of developing countries and LDCs to protect public health and provide access to medicines for all, the relevant provisions relating to protection and enforcement under TRIPS must be interpreted and implemented in the light of the objectives and principles under articles 7 and 8 of TRIPS.

<sup>177</sup> Correa, *supra* note 113, p. 459.

<sup>178</sup> Ibid.

<sup>179</sup> Ibid.

<sup>180</sup> WTO, *supra* note 66, p. 27.

<sup>181</sup> WTO, document WT/DS/174/R, 15 March 2005, para, 7.130 and 7.702. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:WT/DS/174R.pdf&Open=True>.

nationality, the same would constitute a measure according less favourable treatment to other nationals.<sup>182</sup> In *Canada–Patent Term* the panel and AB ruled that in the light of the obligation of WTO members under article 70.2 which makes the TRIPS obligations applicable for all existing subject matter existing on the date of application of the Agreement, the term of patent protection as stipulated under article 33 is applicable to such patents.<sup>183</sup>

In *Saudi Arabia–Protection of Intellectual Property Rights*<sup>184</sup> the panel considered the scope of the security exception under article 73 of TRIPS. Specifically, the panel had to decide a) whether an emergency in international relations stated in article 73(b)(iii) existed, b) whether the essential security interests to be protected were articulated with sufficient clarity and precision, and c) whether the action taken as considered necessary for the protection of those essential security interests include any of the measures challenged in the dispute. The panel noted that both the parties as well as the majority of third parties had agreed to the interpretation of the term “emergency in international relations” adopted by the panel in relation to the similar security exception under GATT in *Russia–Traffic in Transit*, where the term was construed as implying a military or public law and order emergency.<sup>185</sup>

The panel’s interpretation of the security exception, while not a binding precedent, may have implications for possible future use of the security exception for public health purposes. It has been suggested that the exception could also apply to any action taken in pursuance of health security interests.<sup>186</sup> It is uncertain how the panel would interpret the security exception in such a context, particularly whether the existence of a public health emergency would constitute a situation of “emergency in international relations”. As mentioned by the panel in *Saudi Arabia–Protection of Intellectual Property*, WTO panels are not meant to make law through authoritative interpretation, and hence the panel did not rule on certain issues discussed by the parties or third parties about how a panel should proceed in a case where it is not persuaded that an “emergency in international relations” exists, or is presented with an insufficient basis upon which to make any determination of that issue. This suggests that the scope of emergency in international relations for which a security exception can be invoked are not exhausted by the panel rulings in *Russia–Traffic in Transit* and *Saudi Arabia–Protection of Intellectual Property*.

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<sup>182</sup> Ibid., para 7.133.

<sup>183</sup> WTO, *supra* note 66, p.71. Article 70.1 of TRIPS would still exclude a WTO member from any obligation to provide a remedy for acts in relation to existing subject matter that took place before the TRIPS Agreement became applicable. For instance, compulsory licenses granted over existing patents before the relevant date of TRIPS application would not be subjected to the conditions under article 31. See UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press, New York, 2005), pp. 758–9; Correa, *supra* note 113, p. 479.

<sup>184</sup> In this dispute, Qatar had requested the panel to rule that Saudi Arabia had acted inconsistently with its obligations under TRIPS by denying remedies against infringement of copyright of a Qatari sports broadcasting company. Saudi Arabia requested the panel to dismiss the claim on the ground that the measures taken by Saudi Arabia were pursuant to the invocation of the security exception under TRIPS.

<sup>185</sup> WTO, document WT/DS567/R, 16 June 2020, para 7.245. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/DS/567R.pdf&Open=True>.

<sup>186</sup> Abbott, *supra* note 48.

## V. CONCLUSIONS

The use of TRIPS flexibilities by a WTO member through implementation of national legal, administrative and policy instruments necessarily involves an interpretation of the obligations under TRIPS and the policy space available in the light of those obligations. A complaint under the WTO dispute settlement system can impact the use of TRIPS flexibilities through terms of mutually agreed solutions limiting the scope of TRIPS flexibilities, decisions of panels or the Appellate Body on the inconsistency of measures implementing TRIPS obligations (e.g., inconsistency of mailbox implementation in *India-Patents*) or using flexibilities (e.g., inconsistency of stockpiling provision in *Canada-Pharmaceutical Patents*). Moreover, interpretations of TRIPS provisions by a panel or the AB can create persuasive precedents both for future panel or AB decisions, and determination of scope of obligations and flexibilities under TRIPS by national legislative, policymaking or judicial authorities.

Adoption of legal interpretations of the provisions of any covered agreement, including TRIPS, is not the mandate of the DSB which administers the system. Authoritative interpretation of the text of an agreement is the exclusive domain of WTO members, who can adopt such interpretations under article IX.2 of the WTO Agreement. The WTO dispute settlement system involves, at the outset, a process of consultations between the WTO members that are parties to the dispute, including involvement of interested third parties, with the aim, and expressed preference, for a mutually agreed solution. Hence, this process substantially involves renegotiation of what the text of the TRIPS provisions says, and in the light of that, the implementation obligations. Even when a dispute is placed for formal decision by a panel, the option of consultations is still available. The panels are *ad hoc* and their composition usually includes former trade diplomats and WTO officials. There is no requirement for legal specialization or domain expertise in areas such as IP in the composition of a panel. The *ad hoc* panels are mandated to make such findings based on an objective assessment of the facts of the dispute and the applicability and conformity of the covered agreements, that would assist the DSB (a body of WTO members) to make recommendations or rulings. The findings of the panel on questions of law, i.e., on the applicability and conformity of the covered agreement in question, can be challenged before the AB. In practice, the rule of decision-making by reverse consensus in the DSB results in making the panel and AB reports adopted in all disputes, and legally gives the seal of approval of Member States to the rulings of the panel or AB. Panels and AB reports have drawn extensively from previous WTO and GATT panel reports, even on matters relating to agreements of a different nature, which have developed in practice, through the assured adoption of the reports by the DSB, a body of unofficial interpretation of different provisions of covered agreements. Indeed, the Working Procedures of the AB require an AB division reviewing an appeal to consult with other AB members to facilitate such consistency in practice.

In spite of the very unique nature of TRIPS as an agreement that creates minimum positive obligations for WTO members to take certain measures for protection and enforcement of IP rights covered under the Agreement, in contrast to other covered agreements that create negative obligations requiring members not to take certain measures, the WTO dispute settlement system does not have specific rules to orient it towards the nature of the Agreement and the different nature of the disputes arising thereunder. Indeed, jurisprudence of WTO panels and previous GATT panels in the context of agreements of a different nature have informed the practice of WTO panels in interpreting the provisions of TRIPS. Panels have also developed a practice of admitting claims under TRIPS even though the requirements under the DSU of describing the specific measures at issue and the legal basis of the complaint have not been followed in requests for establishing panels.

There are certain limitations to the application of the DSU to certain kinds of complaints under TRIPS. First, non-violation and situation complaints are currently inapplicable to disputes under TRIPS in accordance with a moratorium on initiation of such complaints. Second, disputes in relation to implementation of the doctrine of exhaustion under article 6 cannot be challenged under the DSU. However, in practice these limitations have been ignored in some cases. For example, in *India–Patents* the panel had ignored the non-applicability of non-violation and situation complaints to TRIPS to apply a doctrine of legitimate expectations to determine the degree of legal certainty that the mailbox system should provide to pharmaceutical patent applicants. This interpretation of the panel was subsequently overruled by the AB. In *Argentina–Patents* limitations were imposed on the scope of parallel importation pursuant to a MAS, even though the application of the doctrine of exhaustion is excluded from the ambit of dispute settlement challenge.

While the TRIPS Agreement gives WTO members the freedom to choose how to implement it, in doing so members will have to interpret the scope of obligations and flexibilities in the text of TRIPS. This interpretation of the text by a member can be reviewed by a panel or the AB, if a complaint is brought before it. There is no national deference rule in TRIPS. The application of a national deference rule in TRIPS could imply that conclusions reached by national authorities about the public health need for a measure would always be upheld, if the facts established and their evaluation by the national authorities to reach a decision is found to be objective and unbiased. At the time of adoption of the WTO Agreement, it was agreed that a review of the national deference provision under the Agreement on Anti-dumping with a view to considering the possibility of general application of this rule to disputes under all WTO agreements (including TRIPS) would be considered, but this has not happened. However, the 2011 Doha Declaration provides crucial interpretative guidance which is akin to a national deference principle and has been interpreted by the *Australia–Tobacco Plain Packaging* as an authoritative interpretation and a subsequent agreement between members. It remains to be seen whether future panels also follow this reading of the Doha Declaration, if the occasion arises. WTO members could also formally adopt an authoritative interpretation under article IX.2 of the WTO Agreement to elevate the interpretation advanced in this case to a rule that will be binding and not just persuasive on future panels.

Article 73(b) of TRIPS also provides an interpretative guidance that nothing in the Agreement shall be construed to prevent a member from taking any action which it considers necessary for the protection of its essential security interests, including those relating to actions taken in times of war or other emergency in international relations. WTO members could also adopt an authoritative interpretation under article IX.2 of the WTO Agreement in this regard to confirm that use of the security exception in a public health emergency is legitimate.

The number of disputes relating to TRIPS has been small in comparison with disputes under other covered agreements, and only a few disputes have been decided by a panel or the AB. Some of the disputes have been resolved through MAS. In some of the disputes that were resolved through this route, the respondents had to adopt TRIPS plus standards of protection or accept limitations on the use of flexibilities. These included retrospective acceptances of “mailbox” applications and grant of exclusive marketing rights, withdrawal of all exceptions to exclusive marketing rights, conditioning the grant of compulsory licenses on grounds of failure to work a patent to prior consultation between the members, restrictions on procedures to be followed for issuance of compulsory licenses on grounds of anti-competitive practices, restrictions on parallel importation, shifting of the burden of proof of non-infringement of a patented process even where a non-identical product had been obtained, shifting of the burden of proof in cases of patent infringement upon the defendant, and authorizing judicial authorities to order a search for infringing materials, documents or other relevant evidence in cases of IP infringement.

The application of TRIPS provisions to pharmaceutical patents has been considered by the panel in only 2 disputes so far— *India–Patents* which was further reviewed by the AB, and *Canada–Pharmaceutical Patents*. The only other dispute on a public health measure that has been decided by a panel is *Australia–Tobacco Plain Packaging*—a dispute relating to trademark rights. However, panel decisions in some of the other disputes concern interpretation of the general provisions of TRIPS such as MFN and national treatment, objectives and principles of TRIPS, term of patent protection, certain enforcement obligations under TRIPS, and the use of security exceptions. Panel or AB decisions on these provisions could also impact their application in the context of pharmaceutical products. These decisions raise both systemic issues concerning how the panels or AB arrive at their decisions, as well as substantive issues concerning the scope of some of the TRIPS provisions as interpreted by the panel.

### V.1 Systemic Issues

As ruled by the panel and AB in *India–Patents* despite the freedom of WTO members under article 1.1 of TRIPS to determine the appropriate method of implementing its provisions, implementing measures could be subjected to investigation under the DSU and the panels could disagree with a member about the propriety of the national measures to implement TRIPS obligations. This implies that measures adopted by members to implement any TRIPS flexibility could be evaluated against the panel’s interpretation of what is within the scope of the relevant TRIPS provision. While a restrictive interpretation of the provisions of TRIPS by WTO panels in the past may have contributed to a limited implementation and use of TRIPS flexibilities, recent jurisprudence emanating from the *Australia–Tobacco Plain Packaging* could provide valuable guidance for interpretation and application of the flexibilities derived from each provision of TRIPS in a fulsome manner, and encourage WTO members to explore the limits of flexibilities available under TRIPS.<sup>187</sup>

A related issue is the extent to which a panel or the AB can examine national implementing laws to assess their conformity with TRIPS obligations. For instance, could a panel construe the silence of domestic law on implementation of a TRIPS obligation as non-compliance with the obligation? In certain legal systems, international treaty obligations become part of domestic law without need for specific implementation through statutory enactment. In the absence of a rule on deference to the interpretation of its own domestic law suggested by a member, panels and AB have a lot of discretion on whether to accept the interpretation given by a member of its own implementing legislations in the context of its national legal system. In this regard, WTO members could consider the possibility of adopting a national deference principle as a standard of interpretation for disputes under the TRIPS Agreement.<sup>188</sup>

The TRIPS Agreement is replete with indeterminate provisions throughout the text, reflecting strategic ambiguities that were retained in the text to accommodate different national interests. Indeed, the TRIPS flexibilities are derived from these strategic ambiguities. Panels and the AB have resorted to rules of treaty interpretation to fill in the gaps, though treaty interpretation is not part of their mandate. As discussed above, even contextual interpretation of a TRIPS provision could vary depending on the contextual choice made by a panel. Hence, a pertinent issue to consider is whether panels should interpret indeterminate provisions, which are present throughout the TRIPS text, or apply the doctrine of *non-liquet* to declare that the provision is not clear for it to make a definitive finding. A panel giving such a finding could

<sup>187</sup> See Carlos M. Correa, “Interpreting the Flexibilities under the TRIPS Agreement”, in *Access to Medicines and Vaccines: Implementing Flexibilities under Intellectual Property Law*, Carlos M. Correa and Reto M. Hilty (eds.) (Springer, 2021), pp. 1–30 at pp. 26–7. Available from <https://link.springer.com/book/10.1007/978-3-030-83114-1?sap-outbound-id=D373B17C34B74056795B3A9DC07A57A39E8B7BBA>.

<sup>188</sup> Land, *supra* note 11.

recommend possible alternative interpretations of the text for the DSB to take into consideration.

The *India–Patents (EC)* dispute was in effect a frivolous re-litigation of the *India–Patents (US)* dispute. The panel admitted the complaint based on the DSU rules that allow third parties to request the establishment of a panel on a measure that is already the subject of a WTO panel proceeding. In this light, it would be pertinent for WTO members to clarify whether the principle of *res judicata* may be applied to prevent frivolous re-litigation of disputes between States on the same issues, particularly where the States were formally involved as parties to the dispute, and the legal claims in the disputes are identical, and no different remedy is sought.

A critical issue in disputes under TRIPS is the question of on which party the burden of proof should rest and when that burden of proof would shift. The DSU rules are silent on the question of burden of proof, and panels have addressed this issue drawing from precedents, particularly the AB decision in *US–Wool Shirts and Blouses*. Following this practice, panels apply a requirement for the complainant to establish a *prima facie* case of a measure being inconsistent with the obligation under the relevant covered agreement. If the *prima facie* case is proved, then it would raise an assumption that the measure is inconsistent with the WTO obligation, which would then have to be disproved by the respondent. In the context of TRIPS, an assumption that a national implementing measure is *prima facie* inconsistent with TRIPS obligations, would place the burden of proving the consistency of the measure on the respondent. A *prima facie* case should be clear from the basic evidence presented by the complaining party at the preliminary stage of a panel hearing, that if the factual assertion of the complainant is correct, then there is a likelihood that there has been a violation of the WTO obligation concerned. In practice, panels have worked backwards after determination of the substantive issues based on the submissions and rebuttals of the parties, to determine whether a *prima facie* case had been made by the complainant, and whether the same was disproved by the respondent. Hence, it would be pertinent for WTO members to generally incorporate specific rules on how the burden of proof should be determined by the panels.

## V.2 Substantive Issues

The panel decision in *Canada-Pharmaceutical Patents* is so far the only decision by a WTO panel on the scope of exceptions under article 30 of TRIPS. Given the critical importance of this exception to enable WTO members to adopt measures in the nature of exceptions to patent rights in furtherance of public health objectives, the determination of the scope of this article is of critical importance. While the panel decision has clarified the legitimacy of the regulatory review or Bolar exception under article 30, it has adopted a narrow reading of the scope of exceptions allowed under article 30, finding measures such as stockpiling of generic products shortly before the expiry of the patent term as beyond the scope of the exception. As several critiques of this decision have pointed out, the panel had erred in deciding that each of the three conditions under article 30 must be satisfied individually for an exception to be allowed, as well as its narrow interpretation that the exception must not derogate substantially from the legal rights of the patentee, and that exclusion of all forms of competition is part of normal exploitation of a patent.

Moreover, the panel decision did not interpret what would constitute an unreasonable exception to the normal exploitation of a patent. The scope of article 30 is much broader than viewed by the panel, and WTO members may design exceptions under article 30 based on a broader construction of its scope. In this regard, the interpretation suggested by the “Declaration on Patent Protection: Regulatory Sovereignty under TRIPS” of the Max Planck Institute for Innovation and Competition, that each of the conditions under article 30 need not be satisfied individually for a measure to be regarded as an exception allowed under article 30 should be considered as an authoritative basis for the interpretation of article 30, as it

reflects the unanimous views on this matter among distinguished publicists in the field of IP and public health.<sup>189</sup>

Significantly, the patentability standards under article 27 of TRIPS have not been challenged in any WTO dispute. *Canada–Pharmaceutical Patents* is the only dispute so far where the principle of non-discrimination between patents in terms of article 27.1 was addressed in a limited manner in the context of the applicability of the principle to exceptions under article 30. Though the panel found that the measure at issue in the dispute did not constitute a discrimination in terms of article 27.1, it nevertheless held that the non-discrimination principle under that article was applicable to both articles 30 and 31. This appears to be an impractical interpretation. For instance, it would be impractical to issue a compulsory license to patents in all fields of technology when compulsory licenses are by their very nature specific to particular patents even within the same field of technology.

The provisions on objectives and principles of TRIPS under articles 7 and 8 have not been addressed much in WTO panel decisions in disputes under TRIPS. The importance of bearing in mind the objectives and principles while interpreting the provisions of TRIPS was acknowledged by the panel in *Canada–Pharmaceutical Patents*, but was not applied in the process of the evaluation of the scope of exceptions allowed under article 30. However, in *Australia–Tobacco Plain Packaging* the panel found that paragraph 5 of the Doha Declaration was an agreement between members on the approach to be followed in interpreting each of the provisions of TRIPS. This ruling of the panel has set a standard of interpretation of the provisions of TRIPS from a public health perspective. It remains to be seen whether future WTO panels apply this rule of interpretation. However, as panels are not bound by any precedent set by previous panels, WTO members could also adopt this ruling as an authoritative interpretation of member States under article IX.2 of the WTO Agreement.

### V.3 *Recommendations*

In view of the systemic and substantive aspects relating to the use of TRIPS flexibilities in the context of the WTO dispute settlement system, the WTO members could consider the following suggestions:

1. Explore the possibility of extension of a national deference rule to disputes under TRIPS, similar to article 17.6 of the Agreement on Anti-Dumping.
2. WTO panels and AB could be required through amendments to the terms of their Working Procedures to apply the doctrine of *non-liquet* where alternative interpretations of a TRIPS provision is possible.
3. In cases where the same issue, the same claim and the same remedy is raised in a subsequent normal dispute settlement complaint, the doctrine of *res judicata* should be applied.
4. Panels should be required, through amendments to the Working Procedures, to give a ruling on the establishment of a *prima facie* case by the complainant at the outset of the panel hearings.
5. The interpretative approach to all TRIPS provisions in terms of paragraph 5 of the Doha Declaration as confirmed in *Australia–Tobacco Plain Packaging* could be incorporated as an authoritative interpretation under article IX.2 of the WTO Agreement, to ensure this becomes a binding rule on the approach to TRIPS interpretation for any future panel.

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<sup>189</sup> Max Planck Institute, *supra* note 154. In terms of article 38 of the Statute of the International Court of Justice, which enumerates the different sources of international law, the teachings of the most highly qualified publicists can be considered as a subsidiary means for determination of the rule of law. Statute of the International Court of Justice, article 38.1 (d). Available from <https://www.icj-cij.org/en/statute>.

6. An authoritative interpretation under Article IX.2 of the WTO Agreement could also be adopted to clarify the applicability of public health emergencies to the security exception under article 73 (b).

**Annex 1 – Status of WTO Disputes Initiated Under the TRIPS Agreement**

Case	Complaining Party	TRIPS Provisions Claimed to be Infringed	Status
DS590: Japan – Measures related to the exportation of products and technology to Korea	Republic of Korea	Art. 3.1, 4.1 and 28.2	Panel established, but not composed
DS583: Turkey - Certain measures concerning the production, importation and marketing of pharmaceutical products	European Union	Art. 3.1, 27.1, 28.2, 39.1 and 39.2	Panel composed
DS567: Saudi Arabia – Measures concerning the protection of intellectual property rights	Qatar	Art. 3.1, 4, 9, 14.3, 16.1, 41.1 and 42. 61	Panel report under appeal to AB
DS549: China – Certain measures on the transfer of technology	European Union	Art.3, 28.1(a), 28.1 (b), 28.2, 33, 39.1 and 39.2.	In consultations
DS542: China – Certain measures concerning the protection of intellectual property rights	United States	Art.3, 28.1 (a), 28.1 (b) and 28.2.	Panel composed
DS528: Saudi Arabia – Measures relating to trade in goods and services, and trade-related aspects of intellectual property rights	Qatar	Art.3 and 4	In consultations
DS527: Bahrain – Measures relating to trade in goods and services, and trade-related aspects of intellectual property rights	Qatar	Art.3 and 4	In consultations
DS526: United Arab Emirates – Measures relating to trade in goods and services, and trade-related aspects of intellectual property rights	Qatar	Art.3.1,4,41.1,42 and 61	Panel composed
DS467: Australia – Certain measures concerning trademarks, geographical indications and other plain packaging requirements applicable to tobacco products and packaging	Indonesia	Art.1.1, 2.1, 3.1, 15.4, 16.1, 16.3, 20, 22.2(b), and 24.3	Panel report adopted
DS458: Australia – Certain measures concerning trademarks, geographical indications and other plain packaging	Cuba	Art.2.1, 3.1, 15.1, 15.4, 16.1, 16.3, 17, 20, 22.2(b), and 24.3	Panel report adopted

requirements applicable to tobacco products and packaging			
DS441: Australia - Certain measures concerning trademarks, geographical indications and other plain packaging requirements applicable to tobacco products and packaging	Dominican Republic	Art. 16.1	Appellate Body report adopted
DS435: Australia - Certain measures concerning trademarks, geographical indications and other plain packaging requirements applicable to tobacco products and packaging	Honduras	Art.8 and 17	Appellate Body report adopted
DS434: Australia - Certain measures concerning trademarks, geographical indications and other plain packaging requirements applicable to tobacco products and packaging	Ukraine	Art. 1.1, 3.1, 15.1, 15.4, 16.1, 16.3, 20 and 21	Authority for panel lapsed
DS404: European Union and a member State – Seizure of generic drugs in transit	Brazil	Art. 1.1, 2. 28, 31, 41.1, 41.2, 42, 49, 50.3, 50.7, 50.8, 51, 52, 53.1, 53.2, 54, 55, 58 and 59	In consultation
DS408: European Union and a member State – Seizure of generic drugs in transit	India	Art.2, 7, 8, 28, 41 and 42	In consultation
DS372: China – Measures affecting financial information services and foreign financial information suppliers	European Communities	Art.39.2	Mutually agreed solution
DS362: China – Measures affecting the protection and enforcement of intellectual property rights	United States	Art. 3.1, 9.1, 14, 41.1, 46, 59 and 61	Panel report adopted
DS290: European Communities – Protection of trademarks and geographical indications for agricultural products and foodstuffs	Australia	Art.1,2,3,4,10,16,20,22.2, 24.5,41,42,63.1,63.3 and 65.1	Panel report adopted
DS224: United States – US Patents Code	Brazil	Art.27 and 28	In consultation
DS199: Brazil – Measures affecting patent protection	United States	Art.27.1 and 28.1	Mutually agreed solution
DS196: Argentina – Certain measures on the protection of patents and test data	United States	Art.27,28,31, 34,39,50,62,65 and 70	Mutually agreed solution

DS186: United States – Section 337 of the Tariff Act of 1930 and amendments thereto	European Communities	Art.2,3,9,27,41,42,49, 50 and 51	In consultation
DS176: United States – Section 211 Omnibus Appropriations Act 1997	European Communities	Art. 2.1, 3.1, 4, 16.1 and 42	Appellate Body report adopted
DS174: European Communities – Protection of trademarks and geographical indications for agricultural products and foodstuffs	United States	Art.1.1, 2.1, 3.1, 4, 16.1, 20. 22.1, 22.2, 24.5, 41.1, 41.2, 41.4, 42,44.1, 63.1, 63.3 and 65.1	Panel report adopted
DS171: Argentina – Patent protection for pharmaceuticals and test data protection for agricultural chemicals	United States	Art.27,39.1, 65 and 70	Mutually agreed solution
DS170: Canada – Term of patent protection	United States	Art.33 and 70	Appellate Body report adopted
DS160: United States – Section 110(5) of US Copyright Act	European Communities	Art.9.1	Panel report adopted
DS153: European Communities – Patent protection for pharmaceutical and agricultural chemical products	Canada	Art.27.1	In consultations
DS125: Greece – Enforcement of intellectual property rights for motion pictures and television programmes	United States	Art.41 and 61	Mutually agreed solution
DS124: European Communities – Enforcement of intellectual property rights for motion pictures and television programmes	United States	Art.41 and 61	Mutually agreed solution
DS115: European Communities – Measures affecting the grant of copyrights and neighbouring rights	United States	Art.9,13,14,41,42,43, 44,45,46,47,48,61,63 ,65 and 70	Mutually agreed solution
DS114: Canada – Patent protection for pharmaceutical products	European Communities	Art.27,28 and 33	Panel report adopted
DS86: Sweden – Measures affecting the enforcement of intellectual property rights	United States	Art.50, 63 and 65	Mutually agreed solution
DS83: Denmark – Measures affecting the enforcement of intellectual property rights	United States	Art.50, 63 and 65	Mutually agreed solution

DS82: Ireland - Measures affecting the grant of copyrights and neighbouring rights	United States	Art.9,13,14,41,42,43,44,45,46,47,48,61,63,65 and 70	Mutually agreed solution
DS79: India – Patent protection for pharmaceutical and agricultural chemical products	European Communities	Art.27,65 and 70	Panel report adopted
DS59: Indonesia – Certain measures affecting the automobile industry	United States	Art.3, 20 and 65	Panel report adopted
DS50: India – Patent protection for pharmaceutical and agricultural chemical products	United States	Art.27, 65 and 70	Appellate Body report adopted
DS42: Japan – Measures concerning sound recording	European Communities	Art. 14.6 and 70.2	Mutually agreed solution
DS37: Portugal – Patent protection under the Industrial Property Act	United States	Art.33, 65 and 70	Mutually agreed solution
DS36: Pakistan – Patent protection for pharmaceutical and agricultural chemical products	United States	Art.25, 65 and 70	Mutually agreed solution
DS28: Japan – Measures concerning sound recordings	United States	Art.3,4,14,61, 65 and 70	Mutually agreed solution

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