Interpretation TRIPS Flexibilities under International Law

Asian Regional Course for Judges on Intellectual Property and Public Health 2021

While TRIPS has led to some degree of harmonization of national intellectual property (IP) laws, it is not a uniform law on IP rights. On the one hand, it is a minimum standards agreement that allows WTO members to adopt higher levels of IP protection and enforcement, unilaterally or pursuant to TRIPS plus bilateral or regional free trade agreements (FTA) that address IP protection and enforcement. On the other hand, the TRIPS Agreement leaves some room for WTO members, whether developed or developing countries, to implement the Agreement's provisions in different manners, to legislate in areas not subject to the minimum standards under the Agreement, and to develop legal interpretations of such provisions to determine the scope and content of the applicable obligations.

The possibility, and admissibility, of differences in the implementation of the provisions of the TRIPS Agreement are expressly recognized in Article 1.1 of the Agreement: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

The room for different interpretations may result from the absence of definitions. One example is the lack of a definition of the concept of 'invention,' which differs among countries and allows WTO members not to grant patents, for instance, on developments without a technical effect (such as under European law), or to grant or not grant patents on genetic materials. In many cases, the space for different interpretations derives from general expressions or ambiguities in the text resulting from compromises reached in the negotiation of the Agreement. An outstanding example is the WTO members' right to grant compulsory licenses due to lack of working of a patent, an issue indirectly referred to in Article 27.1 of said Agreement. The task of the interpreter is particularly daunting when the text includes general terms such as "reasonably," "unreasonably," "unjustifiable," or "unjustifiably."

The policy space available under the TRIPS Agreement—beyond those areas not covered under the Agreement—depends on the interpretation of the Agreement's provisions.

Definition of TRIPS Flexibilities

"TRIPS flexibilities" is a general expression that is used to refer to the policy space available under the TRIPS Agreement and the diversity of legislative options available to WTO members to implement their obligations under the Agreement. The term encompasses possible variations in the manner in which the TRIPS Agreement's provisions are interpreted and implemented as they are applied to countries actually subject to them. Such terminology was used for the first time with this latter meaning in the context of the WTO in paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health which was adopted by the WTO Ministerial Conference

(the highest decision making body of the WTO) in response to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines, without limitation to certain diseases, in the interest of public health.

Doha Declaration on TRIPS and Public Health

> 4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide *flexibility* for this purpose.

Since the adoption of the Doha Declaration, the concept of 'TRIPS flexibilities' has been referenced in a vast body of literature, especially (but not only) in relation to access to medicines, and in numerous resolutions of UN agencies and bodies. For example, in 2003 the World Health Assembly of the WHO adopted a resolution urging its member States "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities" in the TRIPS Agreement. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property explicitly referred to the flexibilities reaffirmed by the Doha Declaration, including the research exception, transitional period for least developed countries, and the regulatory review (Bolar) exception. The UN Sustainable Development Goals, in the context of the health goals (Goal 3) also explicitly sets the target to provide access to medicines for all through the use of TRIPS flexibilities to protect public health.

Goal 3: Target 3b – Sustainable Development Goals

> Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

Types of TRIPS Flexibilities

The TRIPS flexibilities can be categorized into the following types

- Flexibilities relating to the process of acquisition of the right
- Flexibilities defining the scope of the right
- Flexibilities relating to enforcement of the right

Given the possible variations in national regimes in interpreting and implementing the TRIPS Agreement, it would be an impossible task to identify all flexibilities. They can be found in all the areas covered by the Agreement, and they can be identified as new circumstances arise.

Broadly, the following flexibilities can be identified in relation to public health.

Choice of patentability criteria, including for chemical entities and biologics
WTO members have considerable policy space to define what an 'invention' is and to apply rigorous standards of patentability to avoid the grant of patents that, without making a genuine technical contribution, may distort market competition.

Compulsory license
Widely recognized in the legislation of developed and developing countries—and granted since the adoption of the TRIPS Agreement by administrations or courts in countries such as Thailand, Ecuador, Indonesia, India, USA, Italy, and Germany—compulsory licenses may be necessary to correct market distortions (abuses of market power, unfair pricing, refusal to license, etc.).

Government use
In many cases governments may decide, consistently with the TRIPS Agreement, to use patented inventions for non-commercial purposes, such as for ensuring the supply of essential medicines.

Compulsory licenses for the supply of medicines to countries with a lack of or insufficient manufacturing capacity
Compulsory licenses exclusively for the export of medicines can be granted under the amendment introduced to the TRIPS Agreement in 2017 and the waiver adopted by WTO in 2003.

Test data protection
The TRIPS Agreement (Article 39.3) requires WTO members to protect test data against unfair competition, which does not create exclusive rights. The Agreement is complied with if legislation on unfair competition is implemented to protect such data.

Exemptions for least developed countries (LDCs)
Countries designated by the United Nations as LDCs need not grant patents for pharmaceuticals and test data protection at least until 2033 under the extended transition period provided for under Article 66.1 of the TRIPS Agreement.

Parallel importation
Importing protected medicines from any country where they can be purchased cheaper than locally is consistent with the TRIPS Agreement.

Pre and post patent grant opposition
Procedures before patent offices provide for the possibility for third parties to contribute to the examination process through 'observations' or 'oppositions,' whether before or after the grant of a patent, or both.

Use of competition law to address the misuse of IPRs
Competition law may be applied to correct market distortions created through the abuse of IPRs.

Regulatory Review (Bolar) exception
'Bolar exceptions' are important to accelerate the entry of generic products soon after the expiry of the patent and promote a dynamic market for medicines.

Research or experimentation exception
This exception allows research to be conducted by third parties on patented inventions, for instance, to improve on them or derive new inventions.

Disclosure requirement, particularly for biologics
The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.

Flexibilities in IP enforcement
Measures to enforce IPRs—such as reversal of the burden of proof, determination of infringement by equivalence and damages, and border measures—if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. Provisional injunctions need to be cautiously granted so as not to distort the market dynamics, generally after giving the alleged infringer an opportunity to articulate his defense. Permanent injunctions may be denied for public health reasons under certain circumstances.

Security exception

Compliance with obligations under the TRIPS Agreement can be suspended, inter alia, in cases of emergency in international relations, such as in the case of a pandemic (Article 73 (b) of the Agreement).

Examples of Use of TRIPS Flexibilities

- While TRIPS requires patents for inventions in all fields of technology, it does not define the concept of invention. Countries have adopted different interpretations of this concept, for instance, to not grant patents on developments without a technical effect (such as under European law), or to grant or not grant patents on genetic materials.
- Adoption different standards of novelty.
- Refusal of injunction as a remedy in cases of infringement.
- Adoption of measures to facilitate grant of compulsory licenses.

TRIPS Flexibilities in WTO "Jurisprudence"

The WTO dispute settlement system is also applicable to disputes arising under TRIPS. The dispute settlement system is comprised of a phase of mutual consultation for settlement of the dispute between member States, and an adjudicatory phase where the complaining party can request the establishment of a panel to decide on the consistency of the measure of a party with terms of the agreement concerned. In the case of TRIPS, panels have decided on whether members have implemented their obligations under the TRIPS Agreement.

In practice, while a number of dispute settlement proceedings have been initiated under TRIPS, very few disputes have been heard by a panel or Appellate Body. Most disputes leading to the establishment of a panel have been against developed countries, with only a few developing countries being respondents in a complaint that went to the panel phase.

The panel and Appellate Body reports produced in relation to the disputes under TRIPS have, in practice, addressed the policy space available under the TRIPS Agreement, but they have only occasionally referred to the concept of 'flexibilities.'

Precedential Value of WTO Panel/Appellate Body Decisions

WTO panel or Appellate Body decisions do not create binding legal precedents to be followed by panels in future disputes. Likewise, they do not create binding legal precedents to be followed by respective national courts and tribunals when deciding on questions concerning use of flexibilities in the national laws or administrative measures. Nevertheless, panel decisions may create persuasive precedents that future WTO panels or national courts may choose to rely on.

Therefore, WTO jurisprudence in the context of disputes arising under other WTO Agreements unrelated to IP, may be relied on and applied in the context of disputes arising under the TRIPS Agreement. The panel *in India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, for instance, held that although the TRIPS Agreement has a "relatively self-contained, *sui generis* status within the WTO," it also was "an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947." In *United States—Section 110(5) of the U.S. Copyright Act*, while the panel noted that caution was required when interpreting the TRIPS Agreement provisions in the light of precedents developed in GATT dispute settlement practice, it stated that as TRIPS was part of a single undertaking alongwith other WTO multilateral trade agreements (GATT and GATS) it would be appropriate to develop interpretations of the legal protection conferred on IP right holders under TRIPS which are not incompatible with the treatment conferred to products and services under the GATT or GATS, in the light of pertinent dispute settlement practice.

The application of general GATT and WTO jurisprudence to cases involving the TRIPS Agreement would ignore the specificity of intellectual property issues and one major difference between the TRIPS Agreement and other WTO covered agreements: the former provides for disciplines on IP rights, which are private rights, the exercise of which may restrain rather than facilitate international trade (as in the case of other WTO agreements).Therefore, in contrast to the general GATT/WTO jurisprudence, the exceptions in the TRIPS Agreement need not be read narrowly, but instead with the aim of achieving the objectives as defined in Article 7 (objectives of the Agreement).

Approach to Interpretation of TRIPS

Though WTO panel or Appellate Body decisions do not create a formal official interpretation of any WTO Agreement (an official interpretation can only be adopted by the Ministerial Conference or the WTO General Council), in practice panels and Appellate Bodies have interpreted the provisions of WTO agreements, including TRIPS, in order to determine whether a party has acted inconsistently with the obligation under the agreement. In doing so, panel and Appellate Body decisions have relied on the rules of treaty interpretation in the Vienna Convention on the Law of Treaties (VCLT).

Ordinary Meaning of the Terms

One of the basic steps for interpretation under Article 31 of the VCLT is the determination of the 'ordinary meaning' of the terms employed in the treaty, provided that "a special meaning shall be given to a term if it is established that the parties so intended" (Article 31.4). Many WTO panel and Appellate Body reports clearly indicate that such ordinary meaning is searched in the dictionary in order to clarify the scope and content of the relevant texts. For example, in *China—Intellectual Property Rights*, the panel observed that "Where the terms are a single term, or ordinarily used together, then the treaty interpreter should refer to the ordinary meaning of that single term, or of each term in the particular context of each other." While the rule regarding the ordinary meaning seems clear, an important question relates to the temporal aspect of the interpretation, that is, a term should be interpreted in its ordinary meaning at time of negotiation or adoption of an agreement, or whether the meaning as evolved at the time of interpretation should be relied upon. WTO panels have adopted both approaches in different cases.

Use of Context

In accordance with Article 31 of the VCLT, the terms in a treaty need to be considered taking their context into account. The preambles of WTO agreements have often been considered as the relevant context for the interpretation of particular provisions. In *India–Patents (US)*, the Appellate Body referred to the Preamble of the TRIPS Agreement for the interpretation of Article 70.8(a): "The Panel's interpretation here is consistent with the object and purpose of the TRIPS Agreement." According to the Appellate Body, the object and purpose of the Agreement is, inter alia, "the need to promote effective and adequate protection of intellectual property rights." References to the preamble were also made in *China—Intellectual Property Rights*. The Preamble of the Agreement on Technical Barriers to Trade was largely invoked as well by the panel in *Australia—Tobacco Plain Packaging*.

The appropriate choice of treaty provisions that provide the context for interpreting other provisions is crucial. The choice of context can be based on the Preamble, the objects (Article 7) and purpose (Article 8) of the TRIPS Agreement, as elaborated by the panel in *Australia—Tobacco Plain Packaging* –

Articles 7 and 8, together with the preamble of the TRIPS Agreement, set out general goals and principles underlying the TRIPS Agreement, which are to be borne in mind when specific provisions of the Agreement are being interpreted in their context and in light of the object and purpose of the Agreement.

The panel further elaborated on the 'balance' suggested by Articles 7 and 8.1 of the TRIPS Agreement and, in particular, on the fact that the Agreement did not intend to prevent WTO members from adopting measures to protect public interests, such as public health.

Panel observations in Australia- Tobacco Plain Packaging

Article 7 reflects the intention of establishing and maintaining a balance between the societal objectives mentioned therein. Article 8.1, for its part, makes clear that the provisions of the TRIPS Agreement are not intended to prevent the adoption, by Members, of laws and regulations pursuing certain legitimate objectives, specifically, measures "necessary to protect public health and nutrition" and "promote the public interest in sectors of vital importance to their socio-economic and technological development," provided that such measures are consistent with the provisions of the Agreement (para. 7.2403).

Article 8 offers, in our view, useful contextual guidance for the interpretation of the term "unjustifiably" in Article 20. Specifically, the principles reflected in Article 8.1 express the intention of drafters of the TRIPS Agreement to preserve the ability for WTO Members to pursue certain legitimate societal interests, at the same time as it confirms their recognition that certain measures adopted by WTO Members for such purposes may have an impact on IP rights, and requires that such measures be "consistent with the provisions of the [TRIPS] Agreement" (para. 7.2404).

The specific objectives expressly identified in Article 8.1 do not, in our view, necessarily exhaust the scope of what may constitute a valid basis for the "justifiability" of encumbrances on the

use of trademarks under Article 20. However, their identification in Article 8.1 may shed light on the types of recognized "societal interests" that may provide a basis for the justification of measures under the specific terms of Article 20, and unquestionably identify public health as such a recognized societal interest (para. 7.2406).

While the Preamble and Articles 7 and 8 of the TRIPS Agreement provide the context for the interpretation of all its provisions, the careful choice of other specific provisions to examine the scope and extent of particular obligations is key to preserving the flexibilities under that agreement. An example is given below:

Article 27.1 of TRIPS requires that "*patents* shall be available and *patent rights* enjoyable *without discrimination* as to the place of invention, the field of technology and *whether products are imported or locally produced*."

Article 28 defines patent rights as a set of negative rights that allow the patent holder to restrain others from specific acts involving the patented invention without the authorization of the right holder.

In the light of article 28, the rule of non-discrimination in article 27.1 between products that are imported or locally produced would seem to be only limited to infringing products. Such a reading will not prevent the establishment of differential obligations with regard to non-infringing imported and locally-made products (i.e., products made or imported by the patent owner or with his/her consent). As such differentiation can be made, compulsory license issued on the patented product on grounds of lack of local working (in the sense of being locally produced instead of being imported) would not be inconsistent with the non-discrimination rule under article 27.1.

Another example in which the correct identification of the context for a provision may have decisive effects relates to Article 39.3, which has been interpreted by the US and the European Commission as requiring the grant of exclusive rights ('data exclusivity') with respect to test data for pharmaceuticals and agrochemical products. This interpretation is clearly inviable in light of Article 39.1 which provides an essential contextual element and only requires protection against unfair commercial practices, which does not entail such exclusive rights.

Object and Purpose

In some cases the textual reading of a provision or a term thereof in its context may still leave ambiguity as to the legal meaning of a text. At this point, the identification of the 'object and purpose' of the treaty, conceived as part of the literal interpretation and not as a separate step, acquires particular importance. It should be noted here that identifying the object and purpose of the TRIPS Agreement is different from characterizing the purpose of intellectual property rights, as the objectives pursued by governments with these rights, as well as the way of implementing them, may differ significantly, even while they comply with the standards of the Agreement and other applicable international treaties).

Articles 7 ('Objectives') and 8 ('Principles') of the TRIPS Agreement are key for the determination of the object and purpose of the Agreement, in conjunction, as discussed below, with the Doha

Declaration as a subsequent agreement among the parties.

TRIPS Provisions on Objectives and Principles

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

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

Importantly, those provisions are not just hortatory provisions but have been incorporated—upon the demand of developing countries during the negotiations —among the prescriptive provisions of the Agreement. Paragraph 5(a) of the Doha Declaration confirmed the importance of Articles 7 and 8 for the interpretation of the TRIPS Agreement:

> Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
>
> a. 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.

In *Australia-Tobacco Plain Packaging* the panel observed that paragraph 5 of the Doha Declaration is formulated in general terms, inviting the interpreter of the TRIPS Agreement to

read "each provision of the TRIPS Agreement" in the light of the object and purpose of the Agreement, as expressed in particular in its objectives and principles. The panel also concluded that Articles 7 and 8 have central relevance in establishing the objectives and principles that, according to the Doha Declaration, express the object and purpose of the TRIPS Agreement relevant to its interpretation. This view was upheld by the Appellate Body.

The reference, in the VCLT, to the 'object and purpose' of the treaty as one of the elements for interpretation has been understood by some courts (e.g., the European Court of Human Rights) as leaving room to consider the 'intention' of the negotiating parties or to apply a teleological approach. The WTO panel in *Canada-Pharmaceutical Patents* also held that the provisions of article 7 and 8 as well as other provisions of TRIPS that indicate its object and purpose must be borne in mind when interpreting a provision under the Agreement. However, the panel did not explain which other provisions it considered as constituting the object and purpose. the consideration of the object and purpose should be limited to the ordinary meaning of the text of the treaty. In the case of the WTO agreements, adherence to the treaty text and avoiding 'activism' in the interpretation of their provisions is of utmost importance so as not to expand the Members' obligations or create new ones, and to provide certainty to their trade relations. Panels and Appellate Body need to be guided by the text of the Agreement and not by the individual views of the members of those bodies.

Doha Declaration on TRIPS and Public Health: Interpretative Guide

In *Australia-Tobacco Plain Packaging*, the panel made a key assertion that the Doha Declaration must be considered a 'subsequent agreement' as defined in the VCLT. In accordance with Article 31.3(a) of the VCLT, "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" shall be taken into account, together with the context. The panel decision confirmed the legal status of the Doha Declaration, rejecting the assertion by the USTR tha the Doha declaration was merely a political declaration.

The panel ruling suggests that a pro-public health interpretation is not only tenable but also mandated, and confirms the room that governments have to confidently adopt pro-public health measures without fearing the risk of costly and burdensome litigation under the DSU. This is an important development that could provide the basis for a further step in that jurisprudence: the integration of human rights law, as a component of international law, in the analysis of the obligations imposed by that Agreement and of the leeway that states should preserve for the realization of such rights.

Doha Declaration on TRIPS and Public Health

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

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.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in 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, subject to the MFN and national treatment provisions of Articles 3 and 4.

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

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Exercise

- Do you agree with the statement –
  - TRIPS does not establish a globally uniform standard on protection and enforcement of intellectual property rights
  - The flexibilities allowed under the TRIPS Agreement are limited to what is explicitly allowed under the provisions of the Agreement
  - WTO panel or Appellate Body decisions constitute authoritative interpretations of the provisions of the TRIPS Agreement
  - The Doha Declaration on TRIPS and Public Health mandates a pro-public health approach to the interpretation of TRIPS
- What are the approaches to interpretation of the provisions of TRIPS? Discuss with reference to the Doha Declaration on TRIPS and Public Health and relevant WTO panel and Appellate Body decisions.
- Choose the right option to complete the statement
  - In ---------- the WTO panel held that the Doha Declaration on TRIPS and Public Health constitutes an agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement.

  A) *Canada – Pharmaceutical Patents* B) *India – Patents* C) *Australia – Tobacco Plain Packaging*
- Match the following provisions of TRIPS to the relevant interpretative question (multiple provisions can be chosen)

Object and Purpose of TRIPS	
Context of a term in a substantive article	

Options – a) Preamble, b) Article 1, c) Article 7, d) Article 8, Related Substantive Provisions

- How would you decide the following case scenario
  - TRIPS allows members to determine the grounds for issuing compulsory licenses. The national patent law allows the grant of a compulsory license if 3 years after the grant of patent the invention is not worked in the country. The law does not define or explain what is meant by working of the invention. The patent holder is importing the patented product X into the country, but it is not being manufactured locally. TRIPS requires patent rights to be available without discrimination as to whether the products are being imported or locally produced. Will the grant of a compulsory

license on the ground of lack of local manufacturing of the patented product be consistent with the obligations under TRIPS?