

15. THE ISSUES OF INTERNATIONAL LAW ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS

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ABSTRACT

Public health is highly significant for the common interest of mankind. The rule of international law about public health relating to intellectual property (IP) rights was initially provided by Article 8.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a general principle which expressly provides the necessary protection of public health in addition to other provisions implied by this issue. This principle was addressed directly or indirectly with limited scope by the dispute settlement body (DSB) during the dispute settlement process of the World Trade Organization (WTO) in respect of public health and IP. The principle was further promoted by the Doha Declaration on the public health and the amendment of the TRIPS Agreement upon considering the needs of developing and least-developed countries (LDCs) regarding accessibility and affordability of medicines. However, the problems arising from the application of this principle in practice reveal the limits of international law such as exceptions to protect IP rights for public health. Facing the unprecedented challenge to combat COVID-19, China proposed to build a global community of health for all by strengthening the rules of international law. By reviewing the origin and evolution of the issues of international law about public health relating to IP rights, it might be better to understand the limits of the existing international laws. Accordingly, the research on the issues of IP rights in international cooperation to fight the COVID-19 pandemic would be helpful to improve the relevant rules of international law.

Keywords: international law, public health, intellectual property rights, COVID-19, medical patent, test data, waiver.

1. INTRODUCTION

The COVID-19 pandemic brought unprecedented challenges for global public health. It may need application of the existing international intellectual property (IP) laws relating to public health such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), for effective legal solutions against COVID-19. For instance, Article 8.1 of the TRIPS Agreement provides a general principle for Members of the World Trade Organization (WTO) to adopt measures necessary to protect public health if such measures are consistent with the provisions of this Agreement.¹ This principle was affirmed in the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) with some flexibilities for Members to enforce their rights in this regard.² However, it appears to be difficult to apply either this principle or its flexibilities for combating COVID-19. For example, the WTO Members could not reach a consensus on the proposal for a temporary waiver of the TRIPS obligations in response to COVID-19 until the WTO Ministerial Conference adopted a Decision on the TRIPS Agreement recently.³ The proposal does not mention Article 8.1 and simply requires waiving off the TRIPS obligations of the Members.⁴ The adopted Decision provides any eligible developing country with a temporary waiver of obligations under Articles 28.1 and 31(b), (f) and (h), but the adequate remuneration of compulsory licensing will not be waived. It shows the problems of limitation or lack of applicable international laws about public health relating to IP. However, it might be immature to consider and elaborate the Decision in

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¹ Legal text of the TRIPS Agreement, see *the WTO Agreements, updated edition of the legal texts* (Cambridge University Press 2017) 396.

² The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (20 November 2001).

³ Draft Ministerial Decision on the TRIPS Agreement, Revision, WT/MIN (22)/W/15/Res.2 (17 June 2022).

⁴ Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19, Communication from India and South Africa, IP/C/W/669 (2 October 2020).

detail at the moment and would be updated by another paper in the future.

These problems have already been implied by the disputes settlement body (DSB) panels as well as appellate body (AB) in the cases of *India-Patents*⁵ and *Australia-Tobacco Plain Packaging*⁶. The AB ruled that the panel in the *India-Patents* case misunderstood the concept of legitimate expectation to protect IP rights provided for in the TRIPS Agreement. However, it noted that the panel correctly reached the conclusion that India had not complied with its obligations under the TRIPS Agreement to make a unique way (so-called mailbox) available for other WTO Members' nationals to apply for medical patents during the transitional period.⁷ Article 8.1 was not referred to at all in the *India-Patents* case because any measure necessary to protect public health was to be adopted only if the measure was consistent with the provisions of the TRIPS Agreement, such as the requirement of a mailbox for application of medical patents. It might be the reason why India and South Africa proposed to waive the TRIPS obligations instead of resorting to the general principle under Article 8.1. The waiver proposal does not mention Article 8.1 at all, because it is not enough to adopt the domestic measures necessary to combat COVID-19 from the Indian and South African perspectives. They proposed to suspend IP rights for fighting against COVID-19.

The panel in the *Australia-Tobacco Plain Packaging* case believed that the Doha Declaration may be considered as a 'subsequent agreement' between the WTO Members for the purpose of treaty interpretation.⁸ But the AB does not clarify the legal status of the Doha Declaration in terms of whether it should be regarded as a 'subsequent agreement'.⁹ Therefore, even now, the legal status of the Doha Declaration remains uncertain while the

international community battles the COVID-19 pandemic. In case of uncertain legal status of the Doha Declaration, it seems no binding rules relating to domestic measures under Article 8.1. The issues arising from such uncertainty would include the accessibility and affordability of COVID-19 vaccines and protection of medical patents or undisclosed clinic trial data, the special measures of protection for traditional knowledge to treat patients affected by COVID-19. The key issue is how to control the COVID-19 pandemic on account of IP rights resulting from medical research and production.

Additionally, while focusing on exceptions to patent rights under Article 30 of TRIPS Agreement, the panel in the *Canada-Pharmaceutical Patents* case does mention Article 8.1 saying that 'the exact scope of Article 30's authority will be examined with particular care on this point. Both the goals and limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those in other provisions of the TRIPS Agreement which indicate its object and purposes.'¹⁰ However, the panel did not interpret Article 8.1 through its discussion on exception to patent rights. It ruled that the regulatory review exception (Bolar exception) could be justified for the reasons of no prejudice to the 'legitimate interests' of affected patent owners within the meaning of Article 30 because of limited test production for only regulatory review and no conflicts with a normal exploitation of patents. The legal issue of this case is actually related to the conflict of commercial interest between medical patent holders and generic producers. For this reason, it may not be necessarily included in the analysis of public health.

To analyse the issues of international IP law regarding public health from the academic perspective, firstly, the paper traces the origin of Article 8.1 of the TRIPS

⁵ India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/R (5 September 1997), WT/DS50/AB/R (19 December 1997).

⁶ Australia-Certain Measures Concerning Trademarks, Geographical Indications and other Plain Packaging Requirements Application to Tobacco Products and Packaging, WT/DS435, 441,458,467/R, 28 June 2018, WT/DS435,441/AB/R (9 June 2020).

⁷ Ibid 5, WT/DS50/AB/R, para. 97.

⁸ Ibid 6, WT/DS435.441,458,467/R, para. 7.2409.

⁹ Ibid 6, WT/DS435, 441/AB/R, para. 6.657.

¹⁰ Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000), para. 7.26.

Agreement to understand the intentions of the drafter and the legal status of the Doha Declaration. Secondly, it reviews the jurisprudence in the *India-Patents* and *Australia-Tobacco Plain Packaging* cases to understand the limits of the TRIPS Agreement with respect to public health. Thirdly, it focuses on the regulatory issues regarding accessibility and affordability of the COVID-19 vaccines and other aspects relating to IP rights. Lastly, the paper presents its conclusions.

2. THE ORIGINAL RULE OF INTERNATIONAL LAW ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS AND EVOLUTIONARY CHANGES

There were no rules about public health in international IP laws until Article 8.1 of the TRIPS Agreement was introduced which requires that WTO Members ‘may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health’, ‘provided that such measures are consistent with the provisions of this Agreement.’ What was the intention to make this rule? The following analysis is based on the official documents of the TRIPS negotiation. There might be different ideas in regarding the TRIPS balance for further tracing of more sources of the negotiation. However, these documents did disclose the original draft of Article 8.1 and its evolutionary changes.

Article 8.1 was drafted originally as an exception to the availability of medical patents. The United States (US) was the initiator to include the TRIPS as the new subject of the multilateral trade negotiation that begun in the later 1980s.¹¹ One of the purposes underlying this initiation was to extend patent protection to all fields of technology, in particular, the pharmaceutical industry, which was reflected in Article 27.1. This Article first appeared in the early draft of the TRIPS Agreement, i.e., the Chairman’s draft of 23 July 1990.¹² This draft had the original article on patentable subject matter with several

exceptions of patentability including public health, which provides as follows:

‘1.1 Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technologies,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.

1.4.1 Invention [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].

1.5B PARTIES may exclude from patentability certain kinds of products, or processes for manufacture of those products on ground of public interest, national security, public health or nutrition.’ (underline added).

The Chairman’s draft also had the original Article 8.1 including the protection for public health:

‘8B.2 In formulating or amending their national laws and regulations on IP rights, PARTIES have the rights to adopt appropriate measures to protect public morality, national security, public health and nutrition, ...’ (underline added).

Article 27.1 of TRIPS Agreement finally provides as follows:

‘Subject to the provision of paragraphs 2 and 3, patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve

¹¹ US Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, MTN.GNG/NG11/W/14 (3 November 1987).

¹² Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/76 (23 July 1990).

an inventive step and are capable of industrial application [...].’

But, the final text of Articles 27.2 and 27.3 provides exceptions of patentability without referring to ‘public health’. This means that public health should not be regarded as the legitimate exception of patentability. In comparison with the early draft of TRIPS Agreement on the exception of patentability including public health, the final text of this matter indicates the particular favour for the pharmaceutical industry because of no exception of medical patentability for public health. However, the final text of Article 8.1 preserves the public health as a general principle to adopt necessary regulatory measures in formulating or amending the Members’ IP laws and regulations. It must be noted that this preservation of public health and other reasons for such measures includes a substantial condition: ‘provided that such measures are consistent with the provisions of this Agreement’. It was added in the last stage to finalize Article 8.1.¹³ In contrast with eliminating the public health as an exception of patentability in Article 27, the added restriction would be mandatory for any such measure possibly taken. It is interesting that the Brussels Draft of December 1990¹⁴ had no such restriction as the previous Chairman’s draft, but the Dunkel Draft of December 1991¹⁵ added it as the final legal text of the TRIPS Agreement. It was disclosed that, during the last phase of negotiation, delegations from developing and least-developed countries (LDCs) strongly called for a balance between the interests of IP holders and public policies in the TRIPS Agreement,¹⁶ but the final results did not favour them because the final text of Articles 27.2 and 27.3 provide the exceptions of patentability excluding public health while allowing Members to adopt necessary measures to protect public health under the

restrictive condition in Article 8.1. No further official information was disclosed in respect of such evolutionary changes. It might be the reason that Article 8.1 as a principle for protection of public health to favour developing countries and LDCs. However, the wordings of restriction in fact are not favoured. It is unknown why and how such restriction was proposed and finally added.

The intention to finalize Article 8.1 would be understood by the above examination of its origin and evolution. It seems that the drafters did not want to make Article 8.1 a mandatory rule to protect public health relating to IP rights, because the text uses the word ‘may’, thereby providing an option to Members to adopt necessary measure to protect public health while imposing a mandatory obligation, i.e., such measure to be consistent with provisions of the TRIPS Agreement, especially those relating to patent protection. Professor Daniel Gervais, a member of the drafting team of TRIPS, believes that ‘Article 8 is thus essentially a policy statement that explains the rationale for measures taken under Articles 30, 31 and 40.’¹⁷ The principle under Article 8.1 as ‘a policy statement’ is definitely different from the exceptional provision as a substantial right. The draft of the Article about public health relating to IP rights was originally an exception to the availability of medical patents, which would provide the WTO Members with substantial rights to adopt necessary measures to protect public health without restricted conditions. However, the final text of the TRIPS Agreement has no such substantial right and instead places a restricted option to protect public health as a principle. It is obviously not balanced because the principle to protect public health as ‘a policy statement’ and the substantive exception of patentability for public health are not equivalent. The Doha

¹³ Gervais D, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell 1998) 68.

¹⁴ Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations, MTN.TNC/W/35/Rev.1 (3 December 1990). This draft was submitted to Ministers meeting in Brussels including the draft on TRIPS, therefore it is entitled as “Brussels Draft”.

¹⁵ See the Text of the December 1991 draft agreement (“Dunkel Draft”), MTN.TNC/W/FA (30 December 1991). Arthur Dunkel was the GATT’s Director-General (1980-1993).

¹⁶ See Meeting of Negotiating Group of 27 and 28 June 1991, Restricted MTN.GNG/TRIPS/1 (25 July 1991), para. 3; Meeting of Negotiating Group of 16 and 22 October 1991, Restricted MTN.GNG/TRIPS/3 (18 November 1991), para. 11.

¹⁷ Ibid 13. Articles 30, 31 and 40 provide respectively the exception to patent rights conferred, other use without authorization of patent right holder and control of anti-competitive practice in contractual licenses.

Declaration intended to balance public health and IP rights as follows:

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.'

The problem is the uncertainty of its legal status. Shortly after adopting it, some comments were made, such as '[T]he legal status of the Doha Declaration is ambiguous. One possibility is that they are merely political statements or moral commitments of trade ministers.'¹⁸ It was also asserted that '...except for that application deadline for LDCs on patents and trade secrets regarding pharmaceuticals, the Ministerial Declaration does not provide anything new nor offer further clarity than already existed.'¹⁹ These negative comments further indicated the intention to finalize Article 8.1 with the principle on public health that would be difficult to apply in practice because Article 8.1 remains unchanged as 'a policy statement' after the Doha Declaration in the view of these comments. Of course, Article 31 has been amended in accordance with the Doha Declaration for developing countries and LDCs to obtain affordable medicine,²⁰ which demonstrates the mandatory restriction on any measures of public health. Article 31

had to be amended, otherwise, such measures would be inconsistent with the provisions of the TRIPS Agreement.

In addition to Article 8.1 as a general principle expressly providing the necessary protection of public health, other provisions may imply public health. For example, Article 27.3(a) provides an optional exception of patentability for "diagnostic, therapeutic and surgical methods for the treatment of humans". It might be relevant to public health. However, the drafting history as discussed above has indicated that it would not be regarded exclusively for public health. "It also remains uncertain whether the exclusion also applied to invention that is only partly, or even just potentially, used to treat human".²¹ It is uncertain whether other implied provisions are in fact relevant to public health, which depends on a case-by-case analysis such as with the *India-Patents* and *Australia-Tobacco Plain Packaging* cases.

3. JURISPRUDENCE OF CASES ABOUT PUBLIC HEALTH RELATING TO IP RIGHTS

The jurisprudence of the *India-Patents* and *Australia-Tobacco Plain Packaging* cases tells us more about the limits of the TRIPS Agreement with respect to public health. The *India-Patents* case was the first TRIPS case with rulings passed by a WTO panel and the AB in 1997. The US and European Union (EU) accused India of violating the TRIPS Agreement because of its failure to provide medical patent holders with the required way to apply for a patent while granting them exclusive marketing rights during the transitional period. Traditionally, India produced generic drugs to meet the needs of public health without patent protection.²² Articles 65.2 and 65.4 of the TRIPS Agreement offer developing countries a maximum transitional period of

¹⁸ Charnovitz S, 'the Legal Status of the Doha Declarations', *Journal of International Economic Law*, Vol. 5, No. 1 2002, 211.

¹⁹ Garcia-Castrillón CO, 'an Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health', *Journal of International Economic Law*, Vol. 5, No. 1 2002, 218.

²⁰ The TRIPS Agreement was amended to have Article 31bis on special arrangement of compulsory license for medical patent through the

Protocol Amending the TRIPS Agreement, done at Geneva on 6 December 2005, which entered into force on 23 January 2017.

²¹ Malbon J, Charles Lawson and Mark Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, A Commentary* (Edward Elgar, 2014)440.

²² See Chaudhuri S, *the WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (Oxford University 2005).

10 years to establish their patent regime. However, Articles 70.8(a) and 70.9 respectively provide as follows:

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural products commensurate with its obligations under Article 27, the Member shall: (a) Notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval in such other Member.'

These provisions were drafted carefully to protect essentially the interests of medical patent holders in developing countries during the transitional period. Although within that period of time there would be no obligations for developing countries to protect patent, they had to provide, upon the entry into force of the WTO Agreement, the medical patent holders with the exclusive marketing rights. It requires that patentees have already obtained the patents and marketing approvals in their home countries before applying for the medical patents for future examination through the 'mailbox' in developing countries. In comparison with the

normal application of the TRIPS Agreement even for developed countries from 1 January 1996 under Article 65.1, it shall be begun on 1 January 1995 under Article 70.8(a) to protect the exclusive marketing rights for medical patents. One year earlier even in the transitional period for developing countries under Article 65.2. The *India-Patents* case clarified the meaning of the term 'a means' as 'mailbox' under Article 70.8(a) and the date begun on 1 January 1995 to grant the exclusive marketing rights under Article 70.9.

India-Patents is a case relating to medical patents. However, India did not claim the necessary protection of public health for its domestic measures because of possible inconsistency with Articles 70.8(a) and 79.9. India argued that 'a means' as the transitional way had existed for a patent application, but the exclusive marketing rights could not be granted upon entry into force of the WTO Agreement. The panel rejected India's arguments by interpreting the relevant Articles based on the principle of legitimate expectations derived from the jurisprudence of pre-WTO dispute settlement. 'In conclusion, we find that, when interpreting the text of the TRIPS Agreement, the legitimate expectations of WTO Members concerning the TRIPS Agreement must be taken into account'.²³ In applying this principle, the panel interpreted the words 'a means' as 'mailbox' to receive applications of medical patents to 'sufficiently protect the legitimate expectations of other WTO Members as to the competitive relationship between their nationals and those of other Members, by ensuring the preservation of novelty and priority in respect of products which were the subject of mailbox applications.'²⁴ The panel also traced the same approach to find that 'India failed to implement its obligation under Article 70.9 and honour the legitimate expectations of its trading partners to that effect.'²⁵

²³ Ibid 5, WT/DS50/R, para. 7.22. The panel refers the pre-WTO case 'United States – Taxes on Petroleum and Certain Imported Substances' (adopted on 17 June 1987, BISD34S/136, para. 5.2.2).

²⁴ Ibid 5, WT/DS50/R, para. 7.31.

²⁵ Ibid 5, WT/DS50/R, para. 7.63.

The AB, on the other hand, stated that:

'we do not agree with the Panel that the legitimate expectations of Members and private rights holders concerning conditions of competition must always be taken into account in interpreting the TRIPS Agreement.'²⁶

However, it upheld the panel's final rulings. It found that India had failed to fulfil its burden of proof by not providing sufficient evidence of the existing 'means' in the form of 'mailbox' and consequently violated its obligation to grant exclusive marketing rights for the medical patent holders of other Members upon entry into force of the Agreement.

The AB's ruling in the *India-Patents* case is quite interesting, especially its interpretation of the Agreement provisions. The panel misunderstood the principle of interpretation, but its conclusion could be correct based on India's failure of its burden of proof in accordance with the AB's rulings. In fact, this conclusion mainly came from the panel's misinterpretation of the Agreement to find India's failure to sufficiently protect the legitimate expectations of other WTO Members. It is very unusual in WTO dispute settlements to misinterpret the Agreement while getting a correct conclusion. In other words, it is a unique case with the AB's affirmation of the panel's decision and partial rejection of its legal reasoning on the legitimate expectations. Of course, there are a number of cases where the AB reversed the panels' interpretations of the covered agreements while upholding their decisions. However, in some cases, the panel actually correctively made its interpretation. It might be a different understanding of the AB's interpretation on case-by-case basis. For example, the AB reversed the panel's interpretation of the word 'seek' under Article 13 of Understanding on Rules and Procedures Governing the

Settlement of Disputes broadly without properly considering its text ('to seek') and context ('Each panel shall have right to seek information...' underline added) in compliance with Article 31 of Vienna Convention on the Law of Treaty.²⁷ In essence, the AB grants the rights of submission to the non-requested information provider.

Returning to the *India-Patents* case, the underlying idea of the jurisprudence might be described by a commentator's words: 'securing compliance with the TRIPS Agreement'.²⁸ That's all. It does not matter whether the domestic measures have been taken to protect public health or not, the priority is compliance with the mandatory provisions of the TRIPS Agreement. The unbalanced rules inevitably restrict the application of the principle to protect public health. As described above, the final text of TRIPS Agreement does not have the original proposed exception of patentability for public health instead of a principle to protect public health with mandatory restriction. Meanwhile, Articles 70.8(a) and 70.9 provide the medical patentees with exclusive marketing rights in developing countries upon entry into force of the Agreement in the case to meet 'mailbox' requirements. It is unbalanced overall. India could not resort to the principle of Article 8.1 as the exception of applications of these articles regarding 'mailbox' because of compliance requirements with the mandatory restriction which prevail over the principle as such. It must be noted that the *India-Patent* case did not address the principle of Article 8.1 to interpret the words 'necessary' and 'consistent'. The above comment on the rulings of the panel and AB of this case aims to reveal the limits of Article 8.1 in regard of public health relating to IP rights. Therefore, it is not necessary to discuss further on the test of necessity and consistency of this Article as some commentators made.²⁹

²⁶ Ibid 5, WT/DS50/AB/R, para.48.

²⁷ US-Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (12 October 1998), paras. 104-110. Actually, the AB did not refer to the Vienna Convention.

²⁸ Reichman JH, 'Securing Compliance with the TRIPS Agreement after *US v India*', *Journal of International Economic Law*, Vol. 1, No. 4 1998, 585.

²⁹ See Stoll PT, et al., ed., *WTO – Trade-Related Aspects of Intellectual Property Rights* (Leiden: Martinus Nijhoff Publishers, 2009) 197-198, III. Necessity, IV Consistency with the TRIPS Provisions.

Could the Doha Declaration be applied in practice to have a balanced effect? We may get either a ‘yes’ or ‘no’ from the jurisprudence in the *Australia-Tobacco Plain Packaging* case.³⁰ No doubt, this case touches upon the issue of public health. Australia promulgated the Tobacco Plain Packaging Act³¹ (TPP measures) in 2011 to regulate retail packaging and appearance of tobacco products in order to improve public health and give effect to certain obligations in the Convention on Tobacco Control which Australia joined in 2004. The TPP measures would be considered as legitimate measures for public health purposes under Article 8.1 if they are consistent with its provisions. Article 20, in particular, is relevant, and it reads as follows:

‘The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of undertaking from those of other undertakings.’

The critical issue is the interpretation of the terms “special requirements” and “unjustifiably encumbered”. Do the TPP measures constitute such “special requirements”? If the answer is in the affirmative, then do they “unjustifiably encumber” the use of a trademark in the course of trade? The complaints’ claim in the case stood affirmed. The panel, firstly, interpreted the elements and clarified that the term ‘special requirements’ referring to a condition that must be complied with, has a close connection with or specifically addresses the ‘use of trademark in the course of trade’, and is limited in application. This may include a requirement not to do something, in particular a prohibition on using a trademark.³² The TPP measures are

‘special requirements’ because of its prohibition on using any trademark or other mark appearing anywhere on tobacco products, therefore, ‘encumbrances arising from special requirements’ may include a prohibition on the use of a trademark in certain situation.

Secondly, the panel interpreted ‘unjustifiably encumber’ stating that ‘Article 20 does not expressly identify the types of reasons that may form the basis for the ‘justifiability’ of an encumbrance.’³³ Then, the panel opined that ‘Article 8 offers, in our view, useful context guidance for the interpretation of the term ‘unjustifiably’ in Article 20.’³⁴ Additionally, the Doha Declaration could be considered as a ‘subsequent agreement’ of WTO Members. The panel’s conclusion is that ‘Article 20 reflects the balance intended by the drafters of the TRIPS Agreement between the existence of legitimate interests of trademark owners in using their trademarks in the marketplace, and the right of WTO Members to adopt measures for the protection of certain social interests that may adversely affect such use.’³⁵ Overall, the AB agreed with the panel’s interpretation stating that ‘encumbrance on the use of trademarks by special requirements under Article 20 may also be imposed in pursuit of public health objectives.’³⁶ The AB did not clarify whether the Doha Declaration constitutes a ‘subsequent agreement’ or not. It is vague that the AB affirmed the panel’s decision based on interpretation of Article 20 in the context of Article 8.1 and kept silence on the legal status of the Doha Declaration. It might be understood that the AB used to be cautious to confirm a subsequent agreement. It was only once in the case of *US-Clove Cigarettes* the AB interpreted that ‘in our view, paragraph 5.2 of the Doha Ministerial Decision can be characterized as a ‘subsequent agreement’ with the meaning of Article 31(3)(a) of the Vienna Convention [on the Law of Treaties] provided that it clearly expresses a

³⁰ *Australia-Tobacco Plain Packaging* is the biggest case ever in the history of dispute settlement under the TRIPS Agreement. It was initiated by five WTO Members, Honduras, Dominican Republic, Cuba, Indonesia and Ukraine in 2012. The Reports of the Panel and the AB issued respectively in 2018 and 2020 have more than 1000 pages. Ukraine withdrew from the panel proceeding, then Honduras and Dominican Republic continued the appeal.

³¹ See Voon T, *et al.*, ed., *Public Health and Plain Packaging of Cigarettes* (Edward Elgar, 2012).

³² *Ibid* 6, WT/DS435.441,458,467/R, para. 7.2231.

³³ *Ibid* 6, WT/DS435.441,458,467/R, para. 7.2397.

³⁴ *Ibid* 6, WT/DS435.441,458,467/R, para. 7.2404.

³⁵ *Ibid* 6, WT/DS435.441,458,467/R, para. 7.2429.

³⁶ *Ibid* 6, WT/DS435, 441/AB/R, para. 6.649.

common understanding, and an acceptance of that understanding among Members with regard to the meaning of the term 'reasonable interval' in Article 2.12 of the TBT Agreement.³⁷ The AB may believe that Doha Declaration should not be regarded as a subsequent agreement as *US-Clove Cigarettes* case because of no decision to express 'common understanding' and 'an acceptance of that understanding among Members' regarding the public health under Article 8.1. The Declaration may not be equivalent to the decision as the legislative interpretation under Article 9.2 of Marrakesh Agreement Establishing the World Trade Organization.

The *Australia-Tobacco Plain Packaging* case favours public health as the Doha Declaration requires having the balanced effects over the trademark owners' rights. That is the answer of 'yes' referred above. It refers to Article 8.1 expressly and the Doha Declaration for the purpose of interpretation of Article 20. It appears to have clarified the term 'unjustifiability' to mean that the necessary measures may be justifiable to pursue the public health objectives. However, it should be noted that the text of Article 20 itself already provides the types of reasons that may form the basis to find the unjustifiability of an encumbrance, i.e., 'such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of undertaking from those of other undertaking'. Those listed types of special requirements should be interpreted as acts with potential effects to unjustifiably encumber the use of a trademark in the course of trade. Professor Daniel Gervais explained that the use of the term 'such as' shows that the Article lists *prima facie* forms of unjustifiable special requirements.³⁸ Article 20 is not silent on the types of reasons that may form the basis for the justifiability of an encumbrance. Therefore, it seems unreasonable for both the panel and the AB in *Australia-Tobacco Plain Packaging* to disregard the '*prima facie* forms' listed in Article 20 as the primary contextual guidance to interpret the relevant terms.

Article 8.1 and the Doha Declaration are simply purported to be taken as the 'context' or 'supplementary means' of interpretation (not applicable laws) for supporting the public health objectives. It might have good intentions; however, it is not appropriate for treaty interpretation. That is the answer 'no' in the terms of proper interpretation. The embarrassing situation as such in practice reflects again the limits of applicable law under the TRIPS Agreement regarding public health. The cases discussed above show that India could not resort to the principle of Article 8.1 to protect public health by non-application of 'mailbox' obligation, and Australia argued its TTP measures for public health under Article 20 by the WTO adjudicator's unsound interpretation. The limits of TRIPS Agreement on public health are inherited in the unbalanced regime of public health and medical patent protection.

More discussions might be needed on the *Australia-Tobacco Plain Packaging* case regarding Article 8.1. However, the critical review above seems enough to explain the uncertain legal status of the Doha Declaration and limits of existing international law about public health related to IP rights.

4. THE REGULATORY ISSUES UNDER THE TRIPS AGREEMENT TO COMBAT COVID-19

We know from the drafting history of Article 8.1 and its applications as well as the uncertain legal status of the Doha Declaration that there are limited rules of international law relating to IP rights in practice. The *India-Patents* case does not resort to Article 8.1 because of Indian domestic measures being inconsistent with its provisions, even though they may concern public health. The ruling in the *Australia-Tobacco Plain Packaging* case refers to Article 8.1 as the interpretive context to clarify Article 20, however, Article 20 itself already has the '*prima facie* forms' of unjustifiable special requirements, which may not be interpreted to support the domestic

³⁷ US-Measures Affecting the Production and Sale of Clove Cigarettes, WT/DS406/AB/R (4 April 2012), para. 267.

³⁸ Ibid 13, 117.

measures for public health. These are the limits of applicable law regarding public health related to IP rights under the TRIPS Agreement when the international community is cooperating to combat COVID-19. The COVID-19 pandemic is a public health emergency of international concern with huge impacts on world trade. However, it may not constitute 'other emergency in international relations' under Article 73(b)(iii) of TRIPS Agreement in the panel's view of the *Russia-Traffic in Transit* case.³⁹ The fight against COVID-19 had to be primarily relied on medical control instead of resorting to anything of security exception, and meanwhile the great efforts must be made to improve the existing international laws about public health relating to IP rights. It appears obvious by learning from the jurisprudence in WTO cases in distinguishing the security exception from public health emergency of international concern.

China proposed to build a global community of health for all by international cooperation under the rules of international law. From these viewpoints, several regulatory issues should be analyzed. The 'regulatory issues' refer to the issues regarding the measures necessary to control the COVID-19 pandemic at the national and international levels, in compliance with both the provisions of the TRIPS Agreement and the flexibilities under the Doha Declaration.

A. THE ACCESSIBILITY AND AFFORDABILITY OF THE COVID-19 VACCINES

The first issue is the accessibility and affordability of the COVID-19 vaccines as public goods. Some pharmaceutical companies have made the COVID-19 vaccines available

for emergency use. In addition to a few vaccines listed by the World Health Organization (WHO) for international use,⁴⁰ several other vaccines have been approved by the national authorities for domestic use.⁴¹ The COVID-19 vaccines are mostly purchased by national governments and international organizations at reasonable prices to cover the costs of researchers, developers, and manufacturers so as to be accessible and affordable for anyone, anywhere. It might be free for citizens seeking to be vaccinated, but it is not free to purchase the vaccines from producers. Otherwise, it would be impossible for pharmaceutical companies to continue their innovative research and production of the COVID-19 vaccines.

The utilization of the patent or its know-how may be a regulatory issue of the COVID-19 vaccines relating to IP rights. For example, Ms. Chen Wei, the Chinese vaccine scientist, invented the COVID-19 vaccine Adenovirus Type 5 Vector that was firstly put into domestic phase I clinical trial in March 2020 and then had successful phase II and III trials overseas.⁴² This vaccine was developed through cooperation between the Chinese pharmaceutical company Cansino Biological Inc. and the Beijing Institute of Biotechnology. They are the co-owners of the granted patent of this invented vaccine.⁴³ It has been approved by the Chinese medical regulator for domestic emergency use. Under Chinese patent law in compliance with the TRIPS Agreement, it is prohibited to make, use, sell, offer for sale, and import the patented products, or to use the patented process for production without the patent owner's consent.⁴⁴ It would be an appropriate approach to first invent the COVID-19 vaccine through an individual or institutional scientist's research or clinic trial supported by the developer, and then allow the developers to use the invented or

³⁹ The panel interpreted the terms of 'other emergency in international relations' as 'a situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state'. *Russia-Measures Concerning Traffic in Transit*, WT/DS512/R (5 April 2019), para. 7.76. It was confirmed by the case *Saudi Arabia-Measures Concerning the Protection of Intellectual Property Rights*, WT/DS567/R (16 June 2020), para.7.256.

⁴⁰ The WHO listed COVID-19 vaccines are Pfizer, Astraneca, Janssen, Moderna, Sinopharm/BIBP, Sinovac, Bharat Biotech, Novavax and

CanSinoBIO. See Status of COVID-19 vaccines within WHO EUL/PQ evaluation process, 26 May 2022.

⁴¹ For an example, the Chinese company produced the vaccine (CanSinoBIO) which has been approval for domestic emergent use while waiting approval of WHO until 26 May 2022. *Ibid* 40.

⁴² See Phase I Registration No. ChiCTR2000030906 (2020-03-17), Phase III ChiCTR200034780 (2020-07-19) and NCT04540419 (2020-09-07).

⁴³ See China Patent No. 20201093587.8 (2020-08-11).

⁴⁴ Patent Law of People's Republic of China was promulgated on 12 March 1984 and the new amendment was made on 17 October 2020.

patented technologies for the manufacture and marketing of vaccine. It is the same for other COVID-19 vaccines such as Vero cell developed by Sinopharm, the Chinese pharmaceutical manufacturer, and Wuhan Institute of Biological Products as well as, AZD1222 developed by AstraZeneca, the global leading biopharmaceutical company and the University of Oxford.⁴⁵ It has been accounted that ‘the legal status of the 74 patent families involved in the 10 COVID-19 vaccines is highly divergent across different jurisdictions’.⁴⁶ The transfer of IP rights has not been disclosed in detail for any licensing of foreign patents or know-how about COVID-19 vaccines at national level. No dispute has arisen from the activities of research, manufacture and marketing of the COVID-19 vaccines in domestic forums. In considering many patents relating to COVID-19 vaccine existed in different countries including developing countries such as India and South Africa,⁴⁷ it is understandable for developing countries to propose the waiver of IP rights to control the COVID-19 pandemic. It is necessary to protect the public health by utilizing the patents owned mostly by the leading companies of developed countries for manufacture of COVID-19 vaccines in these developing countries.

It is apparently not enough to develop and manufacture COVID-19 vaccine by a few leading companies themselves. “Safe and effective vaccines have been developed and approved at record speed, giving us a crucial new way, in addition to traditional public health measures, to protect people from the virus. Now we must ensure they are available to everyone, everywhere.”⁴⁸ It

is a top priority to make the COVID-19 vaccines available globally as public goods. Under the existing regime, there are parallel ways to supply COVID-19 vaccines to countries without sufficient capacity to manufacture. The WHO led program, COVAX,⁴⁹ is the primary way as a global pool with financial sources donated or provided by the national governments, international organizations and private companies to purchase the WHO listed vaccines supplied by its allied members and to allocate these countries in a fair and equitable basis. The license shall be given for the multi-national manufacture of the listed vaccines so as to maximize production. For example, the listed vaccine AZD1222 in the first round of allocation by the COVAX facility was manufactured by AstraZeneca and licensed to and manufactured by Serum Institute of India (SII/AZ).⁵⁰ The SII/AZ shall obtain the license from AstraZeneca to produce the AZD1222 in India as required under the TRIPS Agreement. The second way is a bilateral agreement between the supplying and receiving countries to provide the COVID-19 vaccines that may not be listed by WHO yet. So far, there are no disputes referred to any adjudicators in these transnational ways to afford the vaccines. In addition, it could be requested for compulsory patent licensing under Article 31*bis*.⁵¹

Overall, it is true that the current battle against COVID-19 has not brought out any disputes at national or international forums in terms of violation of any provisions of the TRIPS Agreement. National governments adopted the necessary measures to speed up research on COVID-19 vaccines with clinic trial so as to produce them for emergency use domestically or abroad

⁴⁵ See the landscape of candidate vaccines in clinical development, 12 March 2021, <<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>> accessed 15 March 2021.

⁴⁶ Chiang TW, Wu X, Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (VAXPAL), WTO Staff Working Paper ERSD-2022-01 (10 February 2022), p.5.

⁴⁷ Ibid 46, p. 5. It is reported that ‘the great majority of the 74 patent families have subsequent patent filings in other jurisdictions, mainly including Canada; Australia; Japan; China; India; Republic of Korea; Singapore; Israel; Mexico; New Zealand; Hong Kong, China; Brazil; Russian Federation; EAPO Member States; and South Africa.’

⁴⁸ See Ghebreyesus TA, Waive COVID-19 vaccine patents to put world on war footing, 7 March 2021. <<https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing>> accessed 15 March 2021.

⁴⁹ COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance (Gavi) and the WHO working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, and others. It is the only global initiative that is working with governments and manufacturers to ensure the COVID-19 vaccines are available worldwide to both higher-income and lower-income countries.

⁵⁰ The COVAX Facility: First round of allocation: Astra Zeneca/Oxford Vaccine (manufactured by AstraZeneca and licensed and manufactured by SII), February-May 2021-last updated 2 March 2021.

⁵¹ Bolivia formally notified the WTO of the country’s need to import the COVID-19 vaccine, taking another step towards using flexibilities of Article 31*bis* of TRIPS Agreement as part of its pandemic response. See Notificación en virtud del acuerdo sobre los adpic enmendado, IP/N/9/BOL/1 (11 May 2021).

while protecting possible patents and other IP rights with flexibilities under the TRIPS Agreement. No compulsory patent licensing has been enforced yet. Therefore, it seems that the limits of existing international law on public health relating to IP rights has not blocked the ways for the international community to combat COVID-19, at least in respect of medical patent protection. However, the exceptional circumstances of the COVID-19 pandemic still necessitate to have a special arrangement to waive eligible developing countries' obligations under the TRIPS Agreement to utilize patents as effective as possible.

B. PROTECTION OF CLINIC TRIAL DATA OF THE COVID-19 VACCINES

The second issue is that of clinical trial data. It is mandatory to submit sufficient data of clinical trials of safe and effective COVID-19 vaccines for emergency use for national approval or approval through the WHO emergency use listing. There are two kinds of information in the clinical trial data of COVID-19 vaccines. The first is the updated information posted on the WHO website for public awareness or the data with scientific analysis published by the medical journals for professional discussion. Public awareness is very important because vaccination is based on individual voluntary consent. WHO posts updated information twice a week of the global COVID-19 vaccines candidates in clinical development, including the vaccine platform, type of vaccine candidate, number of doses, schedule of vaccination, route of administration, developer, phase and current status of clinical evaluation (trial registries and public reports).⁵² This kind of information is not relevant to IP.

The second should be test data, in particular for regulatory purposes. The Chinese medical regulatory authority issued guidelines for submission of clinical trial

data for marketing⁵³ in 2020 that improved the previous policies. The guidelines apply to emergency use of the COVID-19 vaccines requiring the applicants to submit the original database, database of analysis, explanatory documents of data, explanation for reading data, report table of cases and codes of procedure. These clinical trial data shall be submitted for regulatory review only. The WHO emergency use listing of the COVID-19 vaccines might need more submission of clinical trial data in comparison with the national requirements. For example, the Chinese vaccine, Vero cell developed by Sinopharm had been approved for emergency use in China and other countries respectively by early 2021, but it was still in the process of the WHO's assessment for global emergency use and not listed until 26 May 2022. It is obvious that the test data submitted for national and international regulatory review is more than that for public awareness. This kind of information is relevant to IP rights.

Article 39.3 of the TRIPS Agreement provides that WTO Members shall protect the test data as undisclosed information submitted for regulatory review of marketing pharmaceutical chemical products against unfair commercial use. It does not specifically require a term of protection. The national medical regulatory authorities may take further measures to protect such test data for certain period of time. China provides six years of protection.⁵⁴ The COVID-19 vaccines are not pharmaceutical chemical products; however, they should be protected as the biological medicine, along with the clinical trial data. A few regional trade agreements having IP provisions impose obligations on contracting parties to protect undisclosed test data or other data of a new pharmaceutical product that is or contains a biologic for certain period of time from the date of the first marketing approval of that product by that party. However, they

⁵² Ibid 40.

⁵³ China National Medical Product Administration: The Principles of Guideline for Submission of the Medical Clinical Trial Data (provisional measure), July 2020.

⁵⁴ China National Medical Product Administration: The Implementation of Protection for Pharmaceutical Clinical Trial Data (provisional measure), April 2018.

were either suspended⁵⁵ or finally taken out.⁵⁶ It is still a public health issue for the necessary sharing of clinical trial data of COVID-19 vaccines globally if such data submitted for regulatory review shall be protected.⁵⁷ Currently, no case has been filed for national or international disclosure of such vaccine data for emergency use.

C. PROTECTION FOR TRADITIONAL KNOWLEDGE TREATING THE COVID-19 PATIENTS

The third issue is the protection of traditional knowledge. The new medicines treating COVID-19 patients have not been available everywhere. It was reported that an American pharmaceutical company used the existing drug “Remdesivir” to treat COVID-19 patients with effective results and had applied for patent of the second-use medicine in China.⁵⁸ It was also disclosed that a new drug LY-CoV016 Etesevimab developed by the Chinese company, Junshi Biosciences, in cooperation with an American company, Eli Lilly, had been approved by European Medical Regulations Authority respectively for emergency use to treat COVID-19 patients together with another drug Bamlanivimab after an effective clinical trial.⁵⁹

However, Chinese experiences to treat the COVID-19 patients mostly depend on combination of existing chemical and traditional Chinese medicines.⁶⁰ As traditional knowledge, Chinese medicine could not be protected by the existing IP regime because of its unknown individual right holder. Chinese Patent Law

requires the patent applicant to disclose the genetic resources of the invention made based on such resources⁶¹ that might be related to traditional knowledge. Experts have made great efforts to define the traditional knowledge associated with genetic resources as the knowledge ‘which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning genetic resources.’⁶² The TRIPS Agreement does not require disclosure of the possible genetic resources for patent application. Therefore, it lacks applicable laws under the TRIPS Agreement incorporated with other IP conventions, in particular, industrial property for the protection of traditional knowledge associated with genetic resources.

5. CONCLUSIONS

The COVID-19 pandemic is a crisis of global public health that affected over hundreds of millions of people. The proposal of India and South Africa to waive the TRIPS obligations exposed the limits of existing international IP laws with regard to public health. It is reflected in Article 8.1 as the original rule of international law in this regard. The Doha Declaration aims to balance IP protection and the public health interest, but its legal status remains uncertain. These limits were also reflected in the WTO jurisprudence under the TRIPS Agreement. However, no dispute on IP rights has resulted from the battle against COVID-19 in developing vaccines and medicines yet. The barrier of IP rights may not be the

⁵⁵ Article 18.51, Comprehensive and Progressive Agreement for Trans-Pacific Partnership. This Article has been suspended in accordance with Article 2 of Preamble of this Agreement. See Annex 7(f).

⁵⁶ Article 20.49, Agreement between the US, United Mexican States, and Canada. This Article were included by a version of this Agreement in October 2019 but removed by the final version in December 2019.

⁵⁷ It has been proposed by the G7 health ministers to make an agreement entitled as “therapeutics and vaccines clinical trials charter for globally sharing test data of the COVID-19 vaccines”. G7 Health Ministers’ Declaration, Oxford, 4 June 2021. <<https://www.gov.uk/government/publications/g7-health-ministers-meeting-june-2021-communique>> accessed 5 June 2021.

⁵⁸ Wang M, Cao R, Zhang L, *et al.*, “Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro”, *Cell Research* 30, 269-271 (2020).

⁵⁹ See The scientific opinion under Article 5.3 of regulation 726/2004 provided by European Medicines Agency’s (EMA) Committee for Medical Products for Human Use (CHMP), 5 March 2021. Lilly licensed LY-CoV016 etesevimab from Junshi Biosciences after it was jointly developed by Junshi Biosciences and the Institute of Microbiology, Chinese Academy of Science (IMCAS).

⁶⁰ See the report on Chinese traditional medicine treating COVID-19 (4 April) 2020 <<http://www.satcm.gov.cn/xinxifabu/meitibaodao/2020-04-04/14460.html>> accessed 19 March 2021.

⁶¹ *Ibid* 44, Article 26.5.

⁶² Article 1, ALT 1, Consolidated Document relating to Intellectual Property and Genetic Resources, WIPO/GRTKF/40/6 (9 April 2019).

block to supply COVID-19 vaccines to countries not having the capacity to produce vaccines. The real problem might be the capacity to develop and manufacture more effective and safe vaccines as global public goods. The COVAX facility must be operated in a fair and equitable way to favour developing countries and LDCs. Meanwhile, it should be encouraged to promote more international cooperation in multilateral or bilateral agreements to provide any countries with vaccines or to transfer technology for joint manufacture of vaccines. There are some regulatory issues relating to IP rights in fighting the COVID-19 pandemic such as protection of patent, clinical trial data and traditional knowledge. The recent WTO ministerial decision on the TRIPS Agreement is a remarkable balance of different claims between developing and developed countries. It would be a challenge for international community to make the possible permanent amendment of relevant provisions of the TRIPS Agreement in the future.

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