

7. COVID-19 PANDEMIC: CONGENITAL FLUIDITY OF PROPOSAL FOR WAIVER OF IP RIGHTS AND THE ROAD AHEAD

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ABSTRACT

This paper argues that the proposal for waiver from the obligation to implement or apply certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is neither a complete solution nor the only solution to deal with the crisis of COVID-19 pandemic mainly because the waiver proposal has congenital fluidity. It is further argued that the solution lies in the effective enforcement of existing provisions of the TRIPS Agreement. It is also argued that the world needs more and not less patents on pharmaceutical products during the pandemic to help scale up production, improve global supply chain and promote competition to ensure equitable access to such products by all. The paper seeks to highlight congenital fluidity of the waiver proposal and demonstrates how existing provisions of the TRIPS Agreement can be effectively used during pandemics. However, the TRIPS Agreement would have been more efficacious had it expressly provided for pandemics. In hindsight of the COVID-19 pandemic, future pandemics cannot be ruled out. Time has come which demands that provisions on pandemics should be incorporated in the TRIPS Agreement. However, explicit mentioning of pandemics in the TRIPS Agreement alone cannot be sufficient to deal with pandemics. Therefore, it is further suggested that instead

of piecemeal and *ad hoc* arrangements, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should collaborate to develop an effective international legal framework to deal with both present and future pandemics.

Keywords: COVID-19 pandemic, pharmaceutical products, intellectual property rights, TRIPS, waiver proposal, WHO, WIPO, WTO.

1. INTRODUCTION

The COVID-19 pandemic¹, amongst other things, brought divergent views of WTO Members at the center stage in regard to the implementation of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). On 2 October 2020, India and South Africa requested the TRIPS Council to recommend to the General Council waiver from obligation to implement or apply Sections 1 (Copyright and Related Rights), 4 (Industrial Designs), 5 (Patents), and 7 (Undisclosed Information) of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement in relation to the prevention, containment, or treatment of COVID-19² (original proposal). Since then, several communications supporting and opposing the waiver proposal have been made to the TRIPS Council.³

At a formal meeting of the TRIPS Council on 23 February 2021, Members discussed the temporary waiver of the TRIPS obligations but were unable to reach

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¹ On 11 March 2020, the WHO declared the coronavirus outbreaks to be a pandemic. 'WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020' <<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>> accessed 27 June 2021.

² WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (2 October 2020), IP/C/W/669 <https://www.wto.org/english/tratop_e/covid19_e/proposals_e.htm> accessed 24 March 2021.

³ WTO, 'COVID-19 Proposals' <https://www.wto.org/english/tratop_e/covid19_e/proposals_e.htm> accessed 27 June 2021.

any concrete decision.⁴ Members only agreed on an oral status report to the General Council reflecting the state of discussions and the lack of consensus on the waiver proposal.⁵

At a formal meeting of the TRIPS Council on 8-9 June 2021, Members moved closer to a 'text-based' process.⁶ Members reiterated their well-known differences on where the emphasis should be placed to ensure their shared objective on a rapid and effective response to the pandemic.⁷ They expressed their willingness to engage constructively in a discussion based on two proposals:

- (i) revised proposal co-sponsored by over 60 delegations for 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19',⁸ and
- (ii) communication from the European Union (EU) on 'Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property'.⁹

The questions are whether: (i) the waiver proposal is born with congenital fluidity, (ii) the existing provisions of TRIPS Agreement can be effectively used to mitigate so-

called rigors of intellectual property (IP) rights, (iii) the world needs patents on pharmaceutical patents during pandemics, and (iv) more can be done to deal with present and future pandemics.

The waiver proposal seems to present a picture as if IP rights are part of the pandemic crisis. The reality, however, is entirely different. Mismanagement of COVID-19 pandemic is because of a myriad of factors including lack of cooperation amongst world leaders,¹⁰ relatively dysfunctional international systems,¹¹ rise of nationalism¹² and deglobalization, dearth of availability of active pharmaceutical ingredients (API),¹³ and lack of capacity of certain countries to manufacture health products. Therefore, to call patent an accomplice of the crisis is not fair.

Besides its congenital fluidity, the waiver proposal creates fear of patent. This fear is baseless for several reasons. One, the waiver proposal ignores the legal nature of patent right which is only an 'exclusive and negative' right and not a positive right. The positive right to make, use, offer for sale, sell, import, or export health products can be exercised by a patentee or other persons only after getting approval of the national drug authority.

⁴ WTO, 'Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic' (23 February 2021) <https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm> accessed 12 March 2021.

⁵ WTO, 'Members discuss TRIPS waiver, LDC transition period and green tech role for small business' (11 March 2021) <https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm#:~:text=At%20a%20meeting%20of%20the,to%20cover%20small%20business%20and> accessed 12 March 2021.

⁶ WTO, 'Members approach text-based discussions for an urgent IP response to COVID-19' (9 June 2021) <https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 27 June 2021.

⁷ *ibid.*

⁸ WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 Revised Decision Text (25 May 2021), IP/C/W/669/Rev.1 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>> accessed 27 June 2021.

⁹ WTO, Communication from the EU to the TRIPS Council (4 June 2021), IP/C/W/680

<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True>> accessed 27 June 2021.

¹⁰ 'Lack of Global Cooperation Is Crippling the COVID-19 Response: Vaccines Will Not Be the Silver Bullet, Says AHF' (*Business Wire Los Angeles*, 11 January 2021) <<https://www.businesswire.com/news/home/20210111006093/en/Lack>

-of-Global-Cooperation-Is-Crippling-the-COVID-19-Response-Vaccines-Will-Not-Be-the-Silver-Bullet-Says-AHF> accessed 26 June 2021; Bhalla AS, 'Leadership Challenges and the COVID-19 Pandemic' (2021) Observer Research Foundation 299/2021 <<https://www.orfonline.org/research/leadership-challenges-and-the-covid-19-pandemic/>> accessed 2 April 2021; Nichols M, 'UN chief laments lack of global leadership in coronavirus fight' (*Reuters*, 1 May 2020) <<https://www.reuters.com/article/us-health-coronavirus-guterres-idUSKBN22C3IS>> accessed 26 June 2021.

¹¹ Bernes T, *et al.*, 'Challenges of Global Governance Amid the COVID-19 Pandemic' (2020) Council on Foreign Relations <https://cdn.cfr.org/sites/default/files/report_pdf/challenges-of-global-governance-amid-the-covid-19-pandemic.pdf> accessed 14 June 2021; Patrick S, 'When the System Fails COVID-19 and the Costs of Global Dysfunction' (*Foreign Affairs*, July–August 2020) <<https://www.foreignaffairs.com/articles/world/2020-06-09/when-system-fails>> accessed 25 June 2021.

¹² Badie B, 'When COVID-19 leads to dangerous variants of nationalism' (*ID4D*, 6 May 2021) <<https://ideas4development.org/en/covid-19-nationalism/>> accessed 26 June 2021.

¹³ Thrasher R, Wirtz V, 'Patents, Protections and Pandemic: A Trade and Access to Medicines Roundup' (*BU*, 2 June 2021) <<https://www.bu.edu/gdp/2021/06/02/patents-protections-and-pandemic-a-trade-and-access-to-medicines-roundup/>> accessed 22 July 2021; 'IFPMA Statement on WTO TRIPS IP Waiver' (*IFPMA*, 5 May 2021) <<https://www.ifpma.org/resource-centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/>> accessed 22 July 2021.

Two, it ignores the law that patent is a territorial and conditional right. Global, international and world patents simply do not exist. Three, in furtherance of Article 8,¹⁴ Members may take consistent measures relating to patented health products provided they grant patent on such health products. Four, a patent on health products does not worsen the health conditions of patients, rather such patents create hope for at least those who can afford patented items. The necessity and significance of invented health products cannot be overemphasized, especially during the pandemic situation. Fear of patent on health products is likely to have a negative impact on investment on research and development (R&D) of health products in the absence of incentive in the form of patent. Five, there is no cause-and-effect relationship between patent and high prices of health products as there are off-patented medicines having high price tag.¹⁵ The problems of equitable access and affordability to health products are mainly because of global poverty and governance deficit. It is a well-known fact that people cannot afford even one square meal a day,¹⁶ paying for health products would be even more difficult. Therefore, the waiver proposal has at least abovementioned five congenital fluidities and hence requires a closer and deeper look.

The paper begins by highlighting the congenital fluidity of the waiver proposal. Then, it moves on to demonstrate how existing TRIPS provisions can be effectively used during pandemics. In the next leg, an attempt has been

made to develop a model road to avoid or at least minimize the devastating impact of pandemics at least in the future.

2. CONGENITAL FLUIDITY OF WAIVER PROPOSAL

The original waiver proposal seems to have generated more heat than light. Every successive proposal and counterproposal added to the fluidity of the original proposal. As noted above, in the formal meeting of the TRIPS Council on 8-9 June 2021, Members moved closer to a 'text-based' process¹⁷ on two proposals¹⁸ and the paper seeks to highlight the congenital fluidity of these.

The revised proposal noted that 'exceptional circumstances exist for justifying waivers from TRIPS obligation'.¹⁹ The Draft Decision Text annexed to the revised proposal may be summarized as follows. One, the scope of the operative paragraph (1) as to waiver from obligation under Sections II and III of the TRIPS remained the same as the original proposal. The scope of the subject matter has however been narrowed down²⁰ to only 'health products and technologies'²¹ for the prevention, treatment and containment of COVID-19.²² Two, the waiver shall be available for at least three years from the date of decision and thereafter the General Council shall review the existence of exceptional circumstances and if such circumstances cease to exist, the General Council shall terminate the waiver.²³ Three,

¹⁴ TRIPS Agreement (15 April 1994) 1869 U.N.T.S. 299, 33 I.L.M. 1197 <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 14 March 2021.

¹⁵ Tessema FA, Kesselheim AS, Sinha MS, 'Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs' (2020) 71 (4) Hastings LJ <https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3898&context=hastings_law_journal> accessed 25 June 2021; Labonte R, Johri M, 'COVID-19 drug and vaccine patents are putting profit before people' (*The Conversation*, 6 December 2020) <<https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270>> accessed 25 June 2021; 'Abuse of the patent system is keeping drug prices high for patients' (*Association for Accessible Medicine*) <<https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients>> accessed 25 June 2021; Pollack A, 'Drug Goes From \$13.50 a Tablet to \$750, Overnight' (*The New York Times*, 20 September 2015) <<https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>> accessed 24 June 2021.

¹⁶ March 2021 global poverty update from the world bank provides an estimate of global poverty as follows: below USD 1.90 per day 696 million people, below USD 3.20 per day 1821 million people and below USD 5.50 per day 3269 million people. By this estimate, a total of 5786 million people, roughly around three fourth of the population, are living below USD 5.50 per day. Castaneda Aguilar RA, *et al.*, 'March 2021 Global Poverty Update From The World Bank' (World Bank Blogs, 16 March 2021) <<https://blogs.worldbank.org/opendata/march-2021-global-poverty-update-world-bank>> accessed 22 June 2021.

¹⁷ Text-based discussions (n 6).

¹⁸ Revised Decision Text (n 8) and EU Communication (n 9).

¹⁹ Revised Decision Text (n 8) last preambular text.

²⁰ It was noted that original decision text was too broad. *ibid.*, para. 4.

²¹ The term 'health products and technologies' has been used to include 'diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture'. *ibid.*, para. 1.

²² *ibid.*

²³ *ibid.*, para. 2.

the General Council shall review the waiver annually until the waiver terminates.²⁴

It is clear from the revised proposal text that the original proposal was too broad. The revised proposal text, though claimed to be narrowed down, still remains too wide and self-contradictory. It is unfathomable how copyright in artistic, musical, dramatic work and cinematograph films impede access to health products and technologies. How does the protection of industrial design that covers only the visual features of articles which appeal to the eyes become a roadblock for the right to vaccination? Is the container of vaccine coming in the way of the vaccination? Undisclosed information remains protected as long as it is a secret or has not been misappropriated. If trade secret is known by honest means through reverse engineering, law does not come in the way of such reverse engineering. Therefore, it would have been fairer and more feasible had the proposal been confined to the waiver from obligation to implement, apply and enforce patent rights under Sections II and III of the TRIPS Agreement. A strategy guided by greed rather than by need is likely to fail. Focus on 'possibility' of success of the proposal instead of 'desirability' considerations could have been a more workable strategy. In the alternative, developing countries could have approached the WTO Dispute Settlement Body (DSB) for the enforcement of Article 7 for the transfer and dissemination of patented technology. Working within the system and seeking to bring about change from within is a more practical method than questioning the system from outside. The waiver proposal seems to be guided by political desirability than legal possibility. Hence, the waiver proposal may be appropriately described as congenitally fluid.

The EU and other developed countries which have granted patents on pharmaceutical products and technologies, are arguing from within the TRIPS system. As noted above, the TRIPS Council has taken the EU communication along with the revised proposal to move towards a 'text-based' discussion.

The EU communication may be summarized as follows: One, the WTO must step up its efforts to ensure that the rule-based global trading system plays its role in response to the pandemic.²⁵ Two, the most urgent challenge is to ensure rapid and equitable rollout of vaccines and therapeutics globally.²⁶ Three, there is an urgent need for multilateral Trade and Health initiative. EU has been engaged in discussions on a temporary IP waiver and has supported the initiative to consider practical ways to enhance production capacity and cooperation with the private sector.²⁷ Four, there is an urgent need to agree on the global trade initiative for equitable access to COVID-19 vaccines including clarification and facilitation of the TRIPS Agreement flexibilities relating to compulsory licences.²⁸ Five, the role of IP is not only limited to incentivizing the development of vaccines as it also plays an important role in enabling equitable access to vaccines.²⁹ Six, public health crisis requires both acceleration of vaccine production and its equitable global distribution.³⁰ Seven, 2001 Doha Declaration on the TRIPS Agreement and Public Health clarifies the links between the TRIPS Agreement, its flexibilities and public health.³¹ Eight, limit the use of compulsory licensing. However, as the pandemic is a circumstance of national emergency, therefore the requirement to negotiate with right holders may be waived and the remuneration for patent holders should reflect such affordable prices.³² Nine, the EU is ready to consider which actions and what support the TRIPS Council and each Member individually can provide to other Members to facilitate the use of Articles 31 and 31*bis*.³³ Ten, a proposal for a

²⁴ *ibid*, para. 5.

²⁵ EU Communication (n 9) para. 1.

²⁶ *ibid*, para. 2.

²⁷ *ibid*, para. 3.

²⁸ *ibid*, para. 4.

²⁹ *ibid*, para. 6.

³⁰ *ibid*, para. 7.

³¹ *ibid*, para. 8.

³² *ibid*, paras. 9, 10, 11 and 12.

³³ *ibid*, para. 13.

comprehensive WTO initiative for equitable access to COVID-19 vaccines and therapeutics should facilitate finding a common solution among Members and bring about a concrete urgent response to the COVID-19 crisis.³⁴

The EU communication does not support the waiver proposal as it states that the pandemic crisis should be dealt from 'within' the existing framework of the TRIPS Agreement. A real problem arises when the EU communication seeks to **limit** the use of compulsory licences on pharmaceuticals. This TRIPS flexibility is already available to Members. It can only mean that the EU is desirous of taking away the existing TRIPS flexibility relating to grant of compulsory licence. Further, the EU appears to offer a flexibility wherein the EU communication states, '[t]he pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived.'³⁵ There is nothing new in this offer as this flexibility is already exists in Article 31(b).

The fundamental difference between the revised proposal and the EU communication adds to the congenital fluidity of the waiver proposal. The EU is using both legal and political methods in discussions relating to the pandemic and patent waiver. On the one hand, the EU is emphasizing the importance of global cooperation and a rule-based global trading system. On the other, the EU wants to restrict the existing TRIPS flexibilities. The EU proposal may be described as unfair for the reasons stated above but feasible because the EU stands to lose nothing even if its proposal is not accepted. The objective of the EU will be served if it succeeds in delaying or blocking the waiver proposal. Under the given scheme of things, the EU communication has succeeded in establishing that the waiver proposal is congenitally fluid.

It appears that the proponents of the waiver proposal are on the right platform but are trying to board the wrong train. This train will move only if there is a consensus between Members. On the face of it, the waiver proposal is both congenitally fluid and unfair. It is fluid because Members, particularly the EU and other developed countries, are unlikely to accept the proposal. Feasibility of acceptance of the proposal seems to be a remote possibility as evolving consensus on this contentious issue is, at best, a long-drawn process. It is unfair as it asks for more than what is necessary, ignores the interest of a patentee and raises serious doubts about the patent system itself. The waiver proposal could have been limited to patents. The waiver proposal misses a vital point as to the territoriality of patent rights. Assuming that the waiver is accepted, how will it serve the interest of Members who have not granted patents on pandemic related health products? Patent waiver can help only those countries who granted patents on these health products. Even without accepting the waiver proposal, Members granting a patent have enough flexibilities under the TRIPS Agreement to limit patent right on grounds of public health. Had patent right been global, such proposal would have been desirable. Hence, there cannot be an international waiver of patent right as there is no international patent right. Given the existing approach of the EU, proponents of the waiver proposal may lose already existing TRIPS flexibilities like the grant of compulsory license on health products.

Though some developed countries, including the United States (US), have extended their support for text-based negotiation,³⁶ and negotiation at the international fora is a long drawn process given the consensus-based approach. Garnering consensus in support of the waiver proposal is not only difficult but also impossible. A thing which is not doable because of its congenital defects should not be pursued at all. Endeavor should be made to do what is doable. Working within the existing framework

³⁴ *ibid*, para. 14.

³⁵ *ibid*, para. 9a.

³⁶ 'India asks WTO members to finish TRIPS waiver on COVID-19 vaccines talks by July-end' (*Business Today India*, 10 June 2021)

<<https://www.businesstoday.in/current/economy-politics/india-asks-wto-members-to-finish-trips-waiver-on-covid-19-vaccines-talks-by-july-end/story/441290.html>> accessed 12 June 2021.

of the TRIPS Agreement is doable. In the following section, an attempt is made to develop an argument that existing TRIPS provisions can be and should be effectively used by Members to deal with the pandemic crisis.

3. ADEQUACY OF THE TRIPS AGREEMENT TO MITIGATE THE RIGORS OF PATENT RIGHTS DURING PANDEMICS

It is argued that TRIPS provisions are adequate to mitigate the rigors of patent rights during pandemics. The TRIPS Agreement creates certain equitable and fair obligations but also provides certain flexibilities. This Section deals with only those obligations and flexibilities relating to the patent dimension of the pandemic.

First and foremost, the obligations³⁷ of Members is called 'Objectives' and enunciated in Article 7³⁸. Article 7³⁹ may be described not only as the heart and soul of the TRIPS Agreement but also as its conscience keeper. These objectives are in the nature of obligations. Neither protection nor enforcement of IP rights are the objectives of the TRIPS Agreement. They are only a means to achieve the objectives for the 'promotion of technological innovation and 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'. Therefore, if either protection or enforcement of IP is not contributing to (i) promotion of technological innovation, or (ii) transfer and dissemination of technology, then such a protection or enforcement of IP frustrates the very

objectives of the TRIPS Agreement. The word 'should' instead of the word 'shall' in the objectives⁴⁰ seems to have been used for reasons of deference to sovereigns and to envision aspirations of the people of the world. It appears that Members are not giving due attention to the Article 7 to promote the transfer and dissemination of COVID-19 related health products. Article 7 should be read with Article 29.1⁴¹ which requires that 'an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art'. If a patent is granted on health products by any Member, then the information relating to it falls in public domain. If another Member has not granted a patent on the said product, then the TRIPS Agreement does not make it obligatory for any Member to grant a patent on such products merely because such patent has been granted by another Member. In other words, Members may use the invention under TRIPS flexibilities to deal with the COVID-19 crisis. Though it may be fairer that other Members first grant a patent and then use the TRIPS flexibilities.

Article 1.1 states 'Nature and Obligations' and gives Members an option to 'implement in their law more extensive protection than required by this Agreement' which 'does not contravene the provisions of this Agreement'. There are only two⁴² WTO cases making reference to Article 1.1. In **European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs**,⁴³ the Panel interpreted Article 1.1 as follows:

³⁷ Article 7 is in the nature of obligation by virtue of Article 1.1 which *inter alia* provides, 'Members shall give effect to the provisions of this Agreement'. TRIPS Agreement (n 14).

³⁸ All references to 'Article' are references of the TRIPS Articles unless otherwise stated.

³⁹ The only WTO case making reference to Article 7 is *DS408: European Union and a Member State – Seizure of Generic Drugs in Transit* WT/DS408

<https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm> accessed 6 May 2022. The latest update on the case shows that the consultation has been requested on 11 May 2010.

⁴⁰ Apart from Article 7, the word 'should' have been used two more times in subparagraphs 2(b)(ii) and 5 of Annex to TRIPS Agreement. *ibid.*

⁴¹ No WTO case is available on Article 29.1.

⁴² Two WTO cases on Article 1.1 are: (i) *DS290: European Communities – Protection of Trademarks and Geographical Indications for Agricultural*

Products and Foodstuffs WT/DS290 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds290_e.htm> accessed 6 May 2022; and (ii) *DS434: Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* WT/DS434 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e.htm> accessed 6 May 2022. In the second case, Panel's jurisdiction lapsed on 30 May 2016. See *Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging – Lapse of Authority for the Establishment of the Panel* (30 June 2016) WT/DS434/17 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/434-17.pdf&Open=True>> accessed 6 May 2022.

⁴³ *DS290: European Communities* (n 44).

7.755. . . [T]he first sentence creates an obligation for Members to give effect to the provisions of the TRIPS Agreement and the second sentence recognizes Members' freedom to implement more extensive protection, subject to a condition. After the expiry of the transitional arrangements in Articles 65 and 66 (and 70.8 and 70.9), as applicable, a Member is obliged to give effect to the provisions of the Agreement with respect to each category of IP right, irrespective of whether it implements more extensive protection in the same or another category of IP right.⁴⁴

Exercising this flexibility may not be an appropriate measure to deal with the pandemic as a more extensive protection may impede scaling up production of health products, resulting in adverse effect on global supply chain of patented products. Article 1.1 also provides freedom to Members to 'determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. Use of this flexibility may help promote large-scale production of patented health products at least for domestic use.

Article 8.1⁴⁵ allows Members to 'adopt TRIPS consistent measures necessary to protect public health. . . , and to promote the public interest in sectors of vital importance to their socio-economic and technological development, [. . .]' Public health and public interest are both victims of COVID-19. Members may fruitfully use Article 8.1 to amend their laws to deal with the COVID-19 crisis, both at national and international levels. Article 8.2 may be used by Members to prevent:

- (i) abuse of patent right on health products by patentees, and

- (ii) practices which unreasonably restrain trade or adversely affect the international transfer of technology related to health products. International transfer of technology is not only an objective but is also an obligation.

A law, whether national or international, generates respect from people when it remains true and honest to its stated objectives. Members, while granting a patent on health products, may make it mandatory for a patentee to: (i) grant voluntary licence on fair, reasonable and non-discriminatory (FRAND) model to all the eligible pharmaceutical entities, and (ii) fully and completely disclose all the essential and non-essential features of health products and should not protect the same such invention both as patent and trade secret to help avoid undue experimentation for replication purposes.

Article 27.2⁴⁶ allows Members to 'exclude from patentability inventions, . . . which is necessary to protect *ordre public* or morality, including to protect human'. Article 27.3(a) further allows Members to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans.' Exclusion of health products from patentability may be a prescription worse than the disease during the pandemic. Health products should not be excluded from patentability in the absence of any alternative mechanism to incentivize research and invention. Mechanism should be evolved to further promote R&D in pandemic related health products. In hindsight, it can be safely said that invention begets invention, patents beget patents and technology begets technology. Invention can be hardly encouraged or promoted by excluding pandemic related health products from patentability.

Article 30⁴⁷ allows Members to provide reasonable and 'limited exceptions to the exclusive rights conferred by a

⁴⁴ European Countries – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs – *Report of the Panel* (15 March 2005) (WT/DS290/R 05-0936) 163 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/290R.pdf&Open=True>> accessed 6 May 2022. The Panel in this case exercised judicial economy. See *ibid* at para. 7.756.

⁴⁵ No specific WTO case is available on Article 8.1. The only case available on Article 8 is *DS408: European Union and a Member State* (n 41).

⁴⁶ WTO cases are not available on Articles 27.2 and 27.3.

⁴⁷ No WTO case is available on Article 30.

patent.’ This Article may be used by Members to limit the scope of patent right on health products to deal with the pandemic crisis.

Article 31⁴⁸ allows other use⁴⁹ of patent by government or third parties authorized by the government, without authorization of the right holder. One of the condition precedents stipulated by Article 31(b) is that the efforts to get the authorization from the right holder on reasonable terms have not been successful. However, the Article carves out an exception for waiver of the condition precedent in case of ‘national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. Therefore, Article 31 may be invoked by any Member to deal with the pandemic crisis ‘predominantly for supply of the domestic market of the Member’ under Article 31(f). Use of the word ‘predominantly’ does not prohibit Members from granting compulsory licence for export.

Article 31bis⁵⁰ carves out certain exceptions to Article 31 and makes provisions for grant of compulsory licence in patented pharmaceutical products. Paragraph 1 of Article 31bis creates an exception to Article 1(f) and allows the Members to grant compulsory licence ‘for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)’. The Annex to the TRIPS Agreement further explains the provisions of Article 31bis. The Appendix to the Annex to the TRIPS Agreement makes provisions regarding the ‘Assessment of Manufacturing Capacities in the Pharmaceutical Sector’. Article 31bis when read together with the Annex and its Appendix make it abundantly clear that pharmaceutical patents have been given special treatment. Article 31bis places health of the people first. It seeks to provide the least developed countries (LDCs),

developing countries, and developed countries equitable and fair treatment without sacrificing the interest of the patentee. Members granting patents on health products may invoke this Article to effectively deal with the pandemic crisis.

Instead of making a fluid waiver proposal, Members particularly from the developing countries, could have introduced ‘Fast Track Patent Prosecution Procedure’ for granting patents on COVID-19 health products by amending their laws within the TRIPS flexibilities. Instead of waiting for patent applications from inventors of health products, these countries could have requested these inventors to file patent applications. Patents on such products could have been granted in an expedited manner on the basis of patents granted in other countries for reasons of national emergency and extreme urgency. These countries could have declared the COVID-19 pandemic as a national emergency. Whether any developing country has granted a patent on any COVID-19 vaccine is an open question and information in this regard is not readily available. After granting patents on health products, developing countries could have used all the TRIPS flexibilities to deal with the crisis both domestically and globally. In the alternative, developing countries and their pharmaceutical entities could have approached patent holders seeking voluntary licences to make and sell health products in their domestic market. This could have been done and could still be done. Developing countries will be better off if they start investing more in R&D to build their technological capacity. Instead of asking for waiver of obligation under the TRIPS Agreement, it would be better to focus on the implementation of TRIPS provisions, in letter and spirit, particularly as to the obligation of transfer and dissemination of technology. It will still be better for

⁴⁸ Three WTO cases making a reference to Article 31 are available: (i) *DS196: Argentina — Certain Measures on the Protection of Patents and Test Data* WT/DS196 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm> accessed 6 May 2022; (ii) *DS408: European Union and a Member State — Seizure of Generic Drugs in Transit* (n 41); and (iii) *DS409: European Union and a Member State — Seizure of Generic Drugs in Transit* WT/DS409

<https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm> accessed 6 May 2022. In the first case, parties reached a mutually agreed solution and in the last two cases, consultation was requested. Hence no consideration by the Panel on Article 31.

⁴⁹ TRIPS Agreement (n 14). “Other use” refers to use other than that allowed under Article 30. *ibid.*

⁵⁰ No WTO case is available on Article 31bis.

developing countries to invest more on education and research to become producers of new knowledge and useful technology. Being only a permanent importer of new knowledge and technology produced by developed countries is the surest prescription for permanent dependency by developing countries. This road of dependency will only lead to colonization of health.

Pandemic situations require more inventions of health products. It follows that the world requires more patents than less. More patents on pharmaceutical products means more producers and suppliers which will promote competition. Competition will check the abuse of dominant position by one or few pharmaceuticals. Competition will also ensure that better quality products are available at reasonably affordable prices. However, both the patentee and Members granting patents on pharmaceuticals owe not only a moral duty but also a legal duty to humanity. Legal duty of the patentee is to serve and promote social good by making patented health products available to the public at reasonably affordable prices by entering into voluntary licences on fair, reasonable and non-discriminatory terms and conditions so that demand of humanity can be met. If a patentee lacks the capacity to scale up production of health products, he must resort to licensing on fair, reasonable and non-discriminatory terms and conditions. Such an arrangement is bound to produce only winners and no losers.

The above analysis reveals that the TRIPS provisions as such are adequate and sufficient to deal with the so-called rigors of IP during pandemics. However, the time has come for evolving an international legal framework especially designed to deal with pandemic situations.

4. WHAT MORE NEEDS TO BE DONE: THE ROAD AHEAD

COVID-19 is a clarion wake-up call to get ready and prepare for future pandemics and evolve mechanisms to deal with the present crisis and future pandemics. Perhaps because of undue focus on the waiver proposal, lack of resources and capacity, policy paralysis and governance deficit, developing countries could not take refuge under the existing TRIPS provisions to deal with the pandemic crisis. Had the TRIPS Agreement made explicit mention of the pandemic, handling of COVID-19 might have been more convenient. During the Uruguay Round Negotiations on IP,⁵¹ the problem of a pandemic of such a catastrophic magnitude was not foreseen.⁵² Perhaps a pandemic itself was not foreseeable. It may be noted that the expression 'public health' has been used six times in the TRIPS Agreement, but the word 'pandemic' has not been used anywhere. What was not foreseeable during the Uruguay Round Negotiations or in the Doha Declaration⁵³ is now facing us. COVID-19 makes out a very strong case for explicit inclusion of 'pandemic' in the TRIPS Agreement to provide for international measures for international emergency. It is suggested that the following provisions may be inserted in the TRIPS Agreement to deal with pandemic situations in a more efficient and equitable manner:

1. Members shall provide 'Fast Track Patent Prosecution Procedure' in their laws for pandemic related health products and technologies and should grant patents on such products or processes in an expeditious manner if such products or processes are approved by the WHO;
2. In furtherance of the objectives in Article 7, Members shall require the patent holders of pandemic related health products and

⁵¹ WTO, 'The Uruguay Round' <https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> accessed 18 April 2021.

⁵² Stewart TP (ed), *The GATT Uruguay Round: A Negotiating History (1986-1992)* (Kluwer Law International 1993).

⁵³ WTO, Declaration on the TRIPS Agreement and public health (14 November 2001) WT/MIN(01)/DEC/2 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 12 April 2021.

technologies to grant voluntary licences on fair, reasonable and non-discriminatory terms and conditions to all pharmaceutical entities having the capacity to manufacture such patented health products and technologies;

3. Members shall evolve a mechanism to give primacy to patent protection over trade secrets of health products and shall promote reverse engineering of unpatented health products; and
4. Subject to Article 29, during pandemic situations, Members shall require that an applicant for a patent on health products shall fully and completely disclose:
 - (a) All the know-how, trade secret, and technology relating to claimed invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Nondisclosure or insufficient disclosure of any information relating to the claimed invention shall be sufficient ground for denial of patent application and revocation of patent; and
 - (b) Full and complete audited books of accounts showing all the capital and revenue expenditures incurred in the R&D of the claimed invention so that reasonable amount of compensation may be determined to reward the inventor/patentee.

Full and complete disclosure of claimed invention, in the real sense, is necessary for the following reasons:

- 1) Despite the requirement of sufficiently clear and complete disclosure of invention as envisaged under Article 29 and the identical requirement under national laws, patent applicants generally do not disclose all the essentials of the invention in the patent specification. Patent specification and claims may be drafted in such a language that it conceals more and reveals less. Standard

approach of patent application in these cases is that 'I did not claim this essential of invention, therefore I did not disclose it'. The point is that the essence of the invention which has not been claimed may be essential to replicate the patented invention without undue experiments;

- 2) Protecting an invention or certain essential features of the invention as trade secret is standard industry practice; and
- 3) Patent protection is generally sought when decoding the essentials of invention by reverse engineering techniques does not require undue experimentation by competitors.

The argument is not that the invention should not be protected as trade secret. Trade secret is a recognized form of IP both in Article 39 and national laws. The argument is that when the inventor is choosing patent over trade secret for her invention, she should disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art indicating the best mode for carrying out the invention known to the inventor. The practice of using both trade secret and patent to protect the same invention should be abandoned. Invention must become patent (open) in all respects after the grant of patent. An inventor has at least three choices as to her invention. One, she may voluntarily disclose the invention by way of publication or otherwise. Two, she may protect her invention as trade secret. Three, she may protect her invention as patent. Inventor is the master of her invention. Law does not compel an inventor to protect or not to protect her invention. Once, the inventor decides to use patent protection for her invention, she must come with clean and open hands. She should not be allowed to keep her cake as trade secret and eat it too as patent.

The main point of argument is that TRIPS should explicitly provide for pandemic situations and create mechanisms to use patent as the predominant solution. At the minimum, the word 'should' used in Article 7 should be

read as 'shall' during pandemic situations. Full and complete disclosure of all the essentials of the claimed invention including technical know-how, trade secret and other technology will make the meaning of 'patent' really open.

There is also a need to evolve an international legal framework to deal with pandemic situations. Such a framework should envisage the following:

- 1) A World Pandemic Organization (WPO) through a multilateral agreement should be established at the international level. Detailed structure, objectives, powers and functions of WPO should be worked out under the umbrella of the United Nations (UN) and WTO; and
- 2) A Permanent World Pandemic Fund (PWPF) should be created and may be jointly managed by the WTO, WIPO and WHO. Every country should be required to make an annual contribution to PWPF as may be agreed. Countries should contribute a portion of money collected in the form of taxes, or otherwise, for the existence and healthy survival of people. Philanthropists and donors may be encouraged to contribute to this fund. A certificate of recognition may be issued to such philanthropists and donors to encourage them. Corporations may be encouraged to contribute generously to this fund as part of their corporate social responsibility. A mechanism of giving tax exemptions to such corporations may be evolved to encourage contribution to this fund. PWPF may be used to:
 - (i) Promote R&D in pharmaceuticals both at international and regional levels;
 - (ii) Provide reasonable and adequate compensation to patent holders who volunteer to transfer their patented products and technologies relating to the prevention, treatment and containment of a pandemic;

- (iii) Provide prizes and awards to persons and entities who voluntarily disclose their trade secrets and know-how relating to pandemic related health products and technology so that such health products may be manufactured at large scale and made available to the world population at reasonably affordable prices; and
- (iv) Provide during a pandemic, vaccines, medicines, and diagnostics to the world population as quickly as possible. Timely vaccination is the essence of the matter.

The aforementioned suggestions may be used to initiate discussion for evolving an international framework to tackle present and future pandemic crises.

5. CONCLUSIONS

The waiver proposal creates unwarranted fear of IP rights. The proposal is not only congenitally fluid but is also unfair. The proposal (i) is still too wide and self-contradictory; (ii) ignores the interest of IP holders; (iii) raises serious doubts about the necessity and utility of the patent system in particular and the IP system in general; (iv) is asking for more than what is necessary to deal with the pandemic situation; (v) should have been limited to patents; (vi) misses vital points as to exclusivity and territoriality of patent right; (vii) neglects that a patent applicant does not come with clean and open hands as patent specifications generally do not disclose all the essential and non-essential features of claimed invention and the patent applicant generally discloses only as much as she thinks is necessary and protects certain features of claimed invention as trade-secret; (viii) does not give due weight to the TRIPS Agreement in general and TRIPS flexibilities in particular; and (ix) considering the well-known differences between Members and also the consensual mechanism of the WTO in such matters, makes the proposal even more fluid. Instead of the waiver proposal, a workable solution could have been to file a complaint with the WTO DSB for

enforcement of obligations under Article 7 against Members who have granted patents on health products. Because of its fluidity, the waiver proposal may become part of the problem instead of solving it.

The EU communication argues within the TRIPS framework. It is workable because the EU stands to lose nothing even if the proposal is not accepted. The purpose of the EU proposal will be served if it succeeds in delaying or blocking the waiver proposal. Unfairness of the EU communication is clear as it seeks to place more restrictions on existing TRIPS flexibilities, particularly on the use of compulsory licence.

It will be in the interest of both the patentee and the people if Members implement Article 7. Protection and enforcement of patent right are against the objectives of the TRIPS Agreement if it does not promote the transfer and dissemination of patented technology globally. Therefore, TRIPS provisions as such can be effectively used by enforcing these in letter and in spirit to overcome the pandemic crisis. An analysis of the TRIPS provisions reveals that even without a waiver, Members granting a patent have enough flexibilities to limit patent right on several grounds. However, the granting of a patent is a condition precedent for use of such flexibilities. Under TRIPS flexibilities, Members could use 'Fast Track Patent Prosecution' for expeditious grant of patent on health products during pandemics. In the alternative, Members and their business entities can seek voluntary licenses from the patent holder and can manufacture and sell the patented health products.

Given the silence in the TRIPS Agreement on pandemics, it is suggested that the TRIPS Agreement may be amended to explicitly provide for pandemic situations. It is further suggested that (i) a WPO be established at the international level; and (ii) a PWPF be established to deal with present and future pandemics.

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