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Compulsory Licence vs. TRIPS Waiver: Analysing Legal - Political Dimensions

Aditi Mukherjee Chakravorty[1], Shweta Rathore[2] and Himanshu Shukla[3]
[1]School of Law, Christ (Deemed to be) University, India
[2,3]School of Law, G D Goenka University, India

ABSTRACT
The outbreak of COVID-19 pandemic has generated serious concern regarding accessibility, availability and affordability of life saving drugs. This paper shall analyse the mechanism of compulsory license and the waiver proposal put forward by India and South Africa, which aims to resolve the accessibility of COVID 19 technologies and drugs. This paper will also analyse the political and legal intersectionalities among them.

Keywords: Compulsory License, COVID 19, Pandemic, Patent, Public-Health, TRIPS.

INTRODUCTION
The COVID-19 pandemic situation has started a new Intellectual Property (IP) tale and repeatedly demonstrated how monopoly rights granted to pharmaceutical corporations have hampered affordable and adequate access to life-saving drugs, vaccines, diagnostics, and health technologies. When the world is combating the Coronavirus Pandemic, the search for the best medicine to treat and cure COVID-19 is in full swing. The World Health Organization (WHO) has announced a series of worldwide clinical trials to test COVID-19-treatment medicines. The medicines to be tested include in combination Remdesivir, Lopinavir and Ritonavir; Lopinavir / Ritonavir plus interferon-beta; and Chloroquine and Hydroxychloroquine. Many of these are known medicines which were originally produced for other indications. The patent system has frequently been accused of access to affordable drugs inter alia, of granting large-scale monopoly power in price control and encouraging profiteering rather than real innovation. This situation triggered thinkers to grasp the impact of IP on COVID-19 calamity and it has also pushed for finding answers on the working of compulsory licensing provision, which is an exception to the patent system, in this exceptional circumstance. However, in October 2020, South Africa submitted a proposal to the World Trade Organisation (WTO)for a temporary waiver during the COVID- 19 pandemic to allow WTO members to choose not to apply, enforce or implement certain IP rules concerning COVID 19 medicines, vaccines and other related technologies and materials. This proposal was later revised in May 2021 and has been widely supported. Several WTO Member Nation States, including the European Union, Norway, the United Kingdom and Switzerland, however, oppose the IP waiver, claiming, among other things, that the current TRIPS flexibilities, such as compulsory licensing, are sufficient and could be used to deal with intellectual property (IP)-related barriers concerning vaccines and other medical products. While each of these mechanisms may help to improve the production of COVID-19 vaccines to various degrees, they both have their strengths and weaknesses.

COMPULSORY LICENSING OF PATENTS: TRIPS & INDIA
One of the important mechanisms to improve access to pharmaceuticals is compulsory licensing. Under the TRIPS Agreement, the compulsory licensing system is subject to multiple conditions for its grant. This includes prior negotiation with the patentee to secure a voluntary license on reasonable commercial terms. But under all circumstances, this condition cannot be followed. One such condition is a **'public health crisis'**. In such circumstances, TRIPS specifies special provisions to overcome the crisis. Accordingly, it provides under **Article 31(b):**

"This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

as soon as reasonably practicable. In the case of public non- commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;".

Therefore, in case of a National Emergency, the TRIPS Agreement permits for the waiver of the condition and the Member States can determine when 'national emergency or extreme urgency' circumstances justify granting a compulsory license. There is no doubt that compulsory licensing can be an effective tool in facilitating access to affordable medicines, as can be evidenced by its use in relation to life-saving drugs by several countries in the past. While Article 31 does not limit the grounds for the grant of a compulsory license/government use, it does subject it to several conditions.

The Doha Declaration on TRIPS and Public Health acknowledged this privilege. In accordance with paragraph 5(c) of the Declaration:

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

However, this clarification is necessary for several reasons. First, it implies that 'public health crises' can represent 'a national emergency or other circumstances of extreme urgency', thereby allowing for the granting of compulsory licenses or government use when provided for under national law and, under TRIPS Article 31(b), without the obligation for prior negotiation with the patent owner. Second, the reference to 'HIV/AIDS, tuberculosis, malaria and other epidemics' indicates that an 'emergency' may not only be a short-term problem but a long-lasting situation, as is the case with the epidemics specifically mentioned, merely for illustrative purposes. This recognition implies that specific measures to deal with an emergency may be adopted and maintained as long as the underlying situation persists, without time constraints. Third, the wording in paragraph 5(c) seems to place the burden on a potentially complaining Member to prove that an emergency or urgency invoked by another Member does not exist. Finally, there are no formalities or prescribed criteria for the determination of what constitutes a national emergency or other circumstances of extreme urgency. A formal declaration by the Member is not required. The determination can be made upon granting the compulsory license or authorizing government use, or in any other manner.

In addition, Articles 7 and 8 with Article 31 of TRIPS Agreement seek to provide a balance of the public interest with the rights and incentives for innovations. The phrase 'in a manner conducive to social and economic welfare' in Article 7 means that the recognition and enforcement of intellectual property rights are subject to higher social values. While, Article 8 is an important provision for framing national laws that respond to particular public health and nutrition and to promote public interest. The fourth WTO Ministerial Conference stated, in Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001, that

"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."

This paragraph may be regarded as an indication that IPRs should not be an obstacle to the realization of public health. In brief, Article 7, read in accordance with article 8, recognizes the right of Members to implement the obligations under the TRIPS Agreement in a manner consistent with public policies amenable to social and economic welfare and public health protection.

INDIAN SCENARIO & TRIPS

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

India is one of the important member countries to sign the TRIPS Agreement in 1995, which ultimately got implemented in India in 2005. In India, the provisions of compulsory licensing were introduced into the Patent Act under the recommendation made by the Ayangar Committee, considering the fact that the abuse of patent rights, which had become a matter of concern. In India, Compulsory Licensing is dealt with under Chapter XVI of the Patent Act, 1970. The conditions of Compulsory Licensing are provided for under Sections 84 and 92 of the Patent Act. The provision under section 92 is kind of different from the general compulsory licensing process based on section 84, whereby a prospective applicant must wait at least three years before applying for a compulsory license and, in addition, must first seek to negotiate a voluntary license with the patentee. Section 92 provides a special provision of compulsory license. It states that the Controller of Patent can file application of compulsory license under circumstances of national emergency; other circumstances of extreme urgency and a case of public non-commercial use. The usual grounds of grant required to be proven by the applicant under section 84 are not applicable under section 92. The Act also says that such exceptional circumstances can include 'public health crisis' relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus (AIDS), tuberculosis (TB), malaria, or other epidemics. Emergency or urgency in the context of a patent refers to a situation where any of the grounds referred to in Section 84 must exist and requires immediate government intervention due to a crisis. The authorities in India should consider various factors when defining the terms, including the general principles described in Section 83 of the Act. In the absence of definition, it can be safely inferred that these terms refer to serious situations and reparations. Thus, one can strongly argue that emergency refers to unexpected serious circumstances, whereas extreme urgency is the outcome of circumstances that resulted in seriousness. This provision is time-efficient because, unlike in the case of a normal compulsory license, a license may be issued even after a patent is immediately issued. This effectiveness is also because a prospective compulsory licensee is not allowed to seek a voluntary license with the patentee(s) under section 92. Thus, a pandemic like Covid-19 directly creates a situation where the Indian Government can exercise its power under Section 92.

ANALYSING THE CHANGING LEGAL AND POLITICAL DYNAMICS

In the aftermath of the pandemic, several countries have amended or introduced new legislation in light of the COVID-19 pandemic to provide for compulsory licensing. In 2020, Countries Like Australia, Canada, Chile, Colombia, Germany, Ecuador, Hungary, Indonesia and Russia amended their domestic laws to facilitate easier and quicker process for issuance of compulsory licenses or government use licenses in the pandemic.

Apart from, these countries there are few other instances in the pandemic where governments issued a compulsory license to enable generic production and supply of medicine. On March 19 2020, **Israel** was the first country to issue compulsory patent licenses related to Lopinavir/Ritonavir (brand name Kaletra), a HIV drug, that is currently being tested for efficacy in COVID-19 treatment in combination with other drugs. The license allows a generic company to import lopinavir / ritonavir**.** In late 2020, the **Hungarian** government granted a compulsory license on remdesivir, citing their newly promulgated law. The compulsory license was issued to support domestic manufacture by the Hungarian company Richter, which was approached by the government to produce the drug during the first wave of the pandemic. In August 2020, civil society organizations asked the Russian government to issue a compulsory license on remdesivir. Earlier the patent holder company, Gilead Sciences, refused to grant a voluntary license to Pharmasyntez, a Russian manufacture that had developed a generic version of the treatment. Gilead also restricted **Russia** to receive a generic version of remdesivir from **Egypt, India and Pakistan** due to existing bilateral voluntary licensing agreement with nine generic manufacturing countries in these countries. Finally, in December 2020, a compulsory license was granted to Pharmasyntez to produce and provide the generic version of remdesivir to the people of Russian Federation.

Previously, Countries like Zimbabwe Mozambique, Zambia, Indonesia, Eritrea, Ghana used the compulsory license in national emergency which emerged out of HIV/AIDS epidemic.

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

INDIA'S STANCE ON COMPULSORY LICENSE: A CRITIQUE

India has been the strongest voice amongst the developing countries against the corporate interests of pharmaceutical MNCs and it played a leading role in the creation of a more public health- oriented pharmaceutical patent law of global significance. But as of now, only one compulsory license was granted in 2012 to Natco Pharma to manufacture an affordable generic version of the anti-cancer drug, sorafenib tosylate, marketed as Nexavar, against Bayer. There is a sequence of denials of compulsory license application after this. It weakens in a way the use of this versatility that TRIPS attempts to strike a balance between the patent holders' rights and obligations. The provision under India was the strongest voice amongst the developing countries against the corporate interests of pharmaceutical MNCs and it played a leading role in the creation of a more public health- oriented pharmaceutical patent law of global significance. But as of now, only one compulsory license was granted in 2012 to Natco Pharma to manufacture an affordable generic version of the anti-cancer drug, sorafenib tosylate, marketed as Nexavar, against Bayer. Although, when the compulsory license application was rejected in BDR-BMS Dispute on DASATINIB (for treating Leukemia) as the applicant did not follow the law scheme and found no prima facie case for making an order pursuant to Section 87 of the Act. The Ministry of Health then in 2014 planned to oblige Dasatinib to license. But it was denied by the Department of Industrial Policy and Promotion (DIPP) stating that it is inappropriate to use Section 92 as there is no national emergency or national emergency situation in the country. Another, attempt was made by the end of 2014 by CIPLA for Onbrez (used to treat Compulsory Pulmonary Obstructive Disease (COPD)). But Health Ministry (MoH) did not find strong basis of the application and suggested to file a fresh application. Later MoH sent its revised comments to DIPP and after consultation with the Drug Controller General of India (DCGI) and National Health Systems Resource Centre (NHSRC), it was of the opinion that there was no case for extreme urgency or national emergency and thus couldn't lend support to Cipla's plea under section 92. Thus, the provision under Section 92 is never thoughtfully explored by India. The usage of this provision by the government is only to address the extreme health crisis which will be ceased with the end of crisis. Thus, there is no conflict with the rights of the inventor. Hence, it paved the way to secure both private and public interest, which is the very cornerstone of IPRs. But the pressure at both international and domestic realms created multiple ways in which access to the public can be prevented, and if public access is obstructed, public interest suffers. In such a case, in the absence of adequate, affordable, and meaningful access to medicines or other products, there is a denial of the **Right to Health** and, therefore, of the **Right to Life** itself, which is guaranteed by Article 21 of the Constitution. If the government is genuinely interested in removing the constant threat to life-saving drugs and desires to offer adequate supplies at affordable rates then it is high time for India to come forward and use this never used extraordinary solution in the time of such crisis.

LIMITATIONS OF COMPULSORY LICENSE

During this pandemic, several countries have already issued COVID-19-related compulsory licenses/ government use, in particular, **Hungary and Russia** for Remdesivir, and Israel for Lopinavir/Ritonavir as well as revised their laws related to compulsory licensing, including **Australia, Brazil, Canada, Germany, Indonesia and Russia.** The current regime to compulsory license under the TRIPS Agreement were not design to be effective in the time of COVID 19 Pandemic. Using of compulsory license for access to medicine has also been inappropriately politicised, and countries are discoursed from the usage for fear of trade retaliation. Moreover, a compulsory license can usually be granted only in relation to existing patents and, thus, cannot be applied to patent applications. As some of the COVID-19 technologies are new, patent applications are currently being filed and will be granted in the coming years. Until the time when the patent is granted, the mechanism of compulsory licensing may not, therefore, be applicable. The TRIPS Agreement sets up some procedural and substantive conditions for using compulsory license by Government. The use of compulsory license to be based on a country-by-country basis and individual merits, suggesting a case-by-case and product-by-product approach. Apart from this Compulsory

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license must be primarily used to supply a domestic market, unless the license is issued to remedy competition violations.

IP WAIVER

The above stated limitations of compulsory licensing suggest a practical need for additional legal options. On October 2, 2020, India and South Africa proposed a temporary TRIPS waiver for certain IP obligations under the TRIPS Agreement and it's been **19 months and counting**, the WTO members have yet to reach a resolution on the proposal submitted by India and South Africa. Later in May 2021, the revised version of the proposal the concerns are on "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19." It is proposed that the waiver would be in force for at least three years from the date of the decision. This proposal has generated widespread support, including a partial support from the US.

The IP waiver has the potential to overcome some of the limitations of the compulsory licensing system. These include the product-by-product requirement of compulsory licensing that restrict the effective and speedy application of this mechanism, as well as the need to spend time on identifying the patents that cover the products in question prior to issuing a compulsory license. With the adoption of the IP waiver, these obstacles would be removed. In addition, the barrier posed by marketing authorizations would also be eliminated. Moreover, the issue of remuneration would not arise, unless there was an agreement to provide certain remuneration to the rightsholders. This is, however, undesirable, as this would complicate the process, the aim of which is to remove the complexities in the first place. Moreover, the waiver would also remove the need to comply with the cumbersome procedure of Article 31bis TRIPS in the case of exporting COVID-19 vaccines or medicines to other countries with no or limited manufacturing capacity.

But at the same time, several WTO Members oppose the IP waiver claiming, among other things, that there is a risk of low quality COVID-19 medicinal products if produced by other manufacturers, that there is no evidence that IP is a barrier, and that the implementation of the IP waiver would affect innovation. The quality of COVID-19 products cannot be continued as rigorous pharmaceutical regulations would apply to all new producers, as they currently apply to original manufacturers. With the implementation of waiver an additional problem that deserves attention: it is necessary to have access to knowledge and know-how to rapidly accelerate the production of COVID-19 vaccines. Such information is typically confidential and protected by trade secrets, and it is currently owned by several pharmaceutical companies. Unfortunately, pharmaceutical companies are not willing to share their technology voluntarily and entering into Bilateral Agreements with generic companies. Moreover, there are no mechanisms in IP laws that would force them to provide access to such information. Without that knowledge, other potential manufacturers need to develop their own manufacturing processes and knowhow necessary to manufacture vaccines, which may take a lot of additional time and effort, and, thus, may significantly reduce our chances to end the pandemic in the near future. European Union (EU) in its proposal before WTO TRIPS Council has suggested Compulsory licences are a perfectly legitimate tool that governments may wish to use in the context of a pandemic if voluntary solutions are not available.

After more than 20 months since the proposed TRIPS waiver for COVID-19 vaccines, medicines, and diagnostics has been decided by the World Trade Organization (WTO) at 12th Ministerial Conference. The Conference authorised a controversial partial TRIPS waiver, but it only applied to vaccines. Governments may use tools like executive orders, emergency decrees, government use authorizations, and judicial or administrative orders to authorise the use of a patent's subject matter by a domestic manufacturer without the holder's approval under the waiver.

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

CONCLUSION

To conclude, while the deadly coronavirus has been ravaging the world for more than a year and a half now, legal battles around IP that protect life-saving COVID-19 vaccines and medicines continue. This has stalled the rapid response to the global pandemic by governments worldwide, resulting in the loss of thousands of lives that could have been saved otherwise. The HIV / AIDS crisis has been the only basis that few nations have used to invoke compulsory licenses to address public health issues. Hence, it is not unfair to say that member countries do not make full utilization of this meticulous 'national emergency or extreme emergency' clause. Its usage is very limited as use of compulsory license invites unwarranted pressure. Thus, there is a trend among developing nation to discourage the using compulsory license for access to medicine due to pressure from developed nations and from pharmaceutical corporations. During this pandemic also there is continuous pressure from pharma company over the use of this mechanism. India plays one of the world's leading pharmaceutical products market, and supplies drugs and medicinal equipment to many developed and developing countries. India exported critical drugs like hydroxychloroquine, paracetamol as well as azithromycin to over 55 countries which includes United States in the west to Bangladesh in the east. For both commercial and humanitarian aid, this step has been taken. But India is yet again on the Priority Watch List of the United States Trade Representative (USTR) Special 301 Report. Additionally, another blow was given to the developing countries the ineffectual decision made after more than 20 months of discussion about the waiver of intellectual property rights for COVID-19 medical tools. Even after a pandemic that has claimed the lives of more than 15 million people, the total waiver suggested in October 2020 covering all COVID-19 medical devices and including all nations, even those who unable to be agreed upon.

Thus, it will be interesting to see how the developed and developing countries establishes a balance between private and public rights.

REFERENCES / FOOT NOTES

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2. World Trade Organization (WTO), document IP/C/W/669. available at: https://docs. wto.org/ dol2fe/ Pages/SS/directdoc.aspx?filenam e=q:/IP/C/W669.pdf&Open=True (accessed on 21 May 2022).
3. WTO, Document IP/C/W/669/Rev.1. available at: https:// docs.wto.org/ dol2fe/ Pages/ SS/ directdoc.aspx?filena me=q:/IP/C/W669R1.pdf&Open=True (accessed on 20 May 2022)
4. MSF Access Campaign, "Opposing countries must stop filibustering negotiations on 'TRIPS Waiver' at WTO", Press Release, 26 July 2021. Available from https://msfaccess.org/opposing-countries-must-stopfilibustering-negotiations-trips-waiver-wto; Nature, "A patent waiver on COVID vaccines is right and fair", 25 May 2021. Available from https://www.nature.com/articles/d41586- 021-01242-1 ((accessed on 20 May 2022)).
5. Article 31 TRIPS Agreement states, "Other Use Without Authorization of the Right Holder Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

6. (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
7. the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
8. the owner of the first patent shall be entitled to a cross licence on reasonable terms to use the invention claimed in the second patent; and
9. the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."
10. World Trade Organization Agreement on Trade-Related Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, in World Trade Organization Available at: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed on 20 May 2022)
11. Examples of compulsory licensing, including public noncommercial use, can be found in the TRIPS Flexibilities Database that provides worldwide information on the instances when authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular, to assure access to medicines. See Medicines Law &Policy, The TRIPS Flexibilities Database. Available at:http://tripsflexibilities.medicineslawandpolicy.org/ (accessed on 20 May 2022)
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13. C M Correa, Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 316 (Oxford University Press 2007)..
14. Article 7 TRIPS Agreement states, "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."
15. Article 8 (1) TRIPS Agreement states, "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."
16. See, Supra Note 8
17. See, Supra Note 9, Pg – 101.
18. Section 84(1) Patents Act, 1970 states, "At any time after the expiration of three years from the date of the grant of a patent, any per- son interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or (c)that

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

the patented invention is not worked in the territory of India."

19. Section 92 Patent Act 1970 states, "Special provision for compulsory licences on notifications by Central Government. –

(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say-

20. the Controller shall on application made at any time after the notification by any person interested grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;

21. in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(1) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(2) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in-

22. a circumstance of national emergency; or

23. a circumstance of extreme urgency; or

24. a case of public non-commercial use,

25. which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section: Provided that the Controller shall, as soon as may be practicable, inform, the patentee of the patent relating to the application for such non-application of section 87."

26. Reto M. Hilty and Kung-Chung Liu (eds.), Compulsory Licensing Practical Experiences and Ways Forwards 12 (Springer, New York, 2015).

27. Available at: https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies (accessed on 19 May 2022)

28. Ibid

29. Ibid

30. Bayer Corporation v. Natco Pharma Ltd., Order No. 19/2013 (Intellectual Property Appellate Board, Chennai), Available at: www.ipabindia.in/Pdfs/Order-19-2013.pdf

31. Ibid

32. In the matter of M/s. BDR Pharmaceuticals International Pvt. Ltd. Vs. M/s. Bristol Myers Squibb Company, Compulsory Licence Application No. 1 of 2013 at 1; Also see: Available at: https:// spicyip. com/ 2013/10/breaking-news-india-rejects-compulsory-licensing-application-at-threshold.html (accessed on 19 May 2022)

33. Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma" 20 JIPR 285(2015); Also see: CIPLA, Representation Under Sections66and 92of The Patents Act, 1970 On Behalf Of Cipla Limited, Available at: https://donttrade

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 10, 2022

ourlivesaway. files. word press. com/ 2014/11/indacaterol-copd-medicine-cipla-petition-to-dipp-to-revoke-patents.pdf (accessed on 19 May 2022)

34. Article 31(f). TRIPS Agreement

35. In the original version of the proposal, South Africa and India called for the waiver of patents, but also industrial designs, copyrights, and trade secrets that are guarded by the WTO agreement on TRIPS.

36. Available at: https:// docs.wto.org/dol2fe/ Pages/SS/ directdoc.aspx? filename=q:/ IP/C/ W669R1.pdf&Open=True, See Para 1

37. Ibid, See Para 3

38. Available at: https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159605.pdf; (accessed on: 20 May 2022)