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Impact of Compulsory Licence on Affordability and Availability of Medicines in India: The Present Scenario

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Abstract

Skyscraping price of essential life saving medicines poses potential threat to their affordability. Patenting of pharmaceutical products is one of the responsible factors for the same. India as a welfare nation under the Patent Act, 1970 only protected the process of manufacture of the medicines. Medicine itself was not protected by product patent. In this surrounding reverse engineering ensured the affordability of medicines. In compliance with the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement, 1994 India was forced to introduce medicinal products within product patent regime through the Patent (3rd Amendment) Act, 2005. This affects the affordability of medicines. The Compulsory Licensing provision works as safety valve to secure accessibility of medicines not only in ordinary situation but also at the time of national emergency or extreme urgency. The present study reviews the impact of existing system of compulsory licence to secure affordability and availability of medicines in India.

Keywords: Compulsory Licence, National Emergency, Extreme Urgency, Affordability and Availability.

I. Introduction:

Heath as one of the significant parameters is included in the Human Development index.[1] Nation is under mandatory obligation to secure affordability and availability of medicines. This should not be subjected to any constrained.

Paragraph 12 of the General Comment 14 on the International Covenant on Economic, Social and Cultural Rights, 1966 asserts that right to health subjects to four interrelated social determinants- availability, accessibility, acceptability and quality.[2] Availability in the context of health means all the health care facilities including essential medicines must be available to all. Affordability means economic accessibility. The concept of affordability is based on the principle of equality. Economic condition should not be a yard stick for accessibility of medicines. Medicine which is one of the

1. Human Development Reports, The United Nations Development Program, hdr.undp.org/en/content/human-development-index-hdi
2. Substantive Issues Arising in the implementation of the International Covenant on Economic, Social and Cultural Rights, General Comment No. 14 (2000), United Nations- Economic and Social Council, https://digitallibrary.un.org/record/425041?ln=en

essentials of curative and preventive health care must be within access to all whether economically sound or marginalised group. Even sometime exorbitant price of life saving medicines becomes economic burden to affluent section of society also.

Patenting of pharmaceutical products undoubtedly revolutionaise the medical sector, incentivise the research and developmental work through the grant of exclusive monopoly right for a limited period of time to the inventor for his novel, non obvious invention in the area of medicines. During the tenure of patent protection patentees here the branded pharmaceutical companies impose discretionary rate on their products which becomes detrimental to the large section of society in term of affordability of essential medicines.

To secure affordability of medicines to all its citizens in India the Patent Act, 1970 did not grant product patent for the substances themselves used for or being used as food and medicine or prepared or produced by chemical processes.[3]

Though the inventor's interest for his inventions relating to essentials like medicines was not secured through the product patent but process of manufacturing of these products was secured by the process patent. In this environment system of reverse engineering was stimulated. Reverse engineering helped any person to produce the same product of inventors with slight addition or/and alteration of already existing patented process which was not considered as infringement. Reverse engineering played a catalytic role to flourish the generic companies. This resulted affordability and availability of cost effective essentials medicines.

In the year 2005 India has introduced product patent for newly invented medicines through the Patent (3rd Amendment) Act, 2005 in compliance with the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement, 1994.

This is the most controversial area from the human health perspective in terms of affordability and availability of medicines.

At the time of implementation of the binding provisions of the TRIPs Agreement, 1994 in observance of human rights obligation India has tried to uphold the public heath interest. This has also been asserted in the Vienna Declaration and Programme of Action 1993[4] that it is the nation's susceptibility to ensure human rights of public at large in designing of and complying with the socio economic policies at national and international level.

Compulsory Licence is a notable effort to give effect to the above mentioned ethos.

To evaluate how far the present provisions of compulsory licence in the Patent Act, 1970 are effective to meet the public requirement of affordable medicines as well as the Government's initiatives towards the same the present paper has been designed in the following sections.

Firstly paper explains the Pre TRIPs system of compulsory licence on availability of affordable medicines. In the second part Post TRIPs impact of compulsory licence on accessibility of medicine has been analysed. The third section of the paper discusses the Government's role to grant compulsory licence for availability of low cost essential medicines to society at larger. Lastly the paper has been concluded.

3. Section 5 of the Patent Act, 1970.
4.Cullet Philippe, Patent and Medicine: Relation between TRIPs and Human Right to Health, Vol.79(I), International Affairs, 2003, PP 139-160, 2003, jstor.org/stable3095545

II. Compulsory Licence In The Pre TRIPs Era:

Compulsory licence is one of the most crucial instruments to check the unjustified exploitation of patented monopoly rights by the pharmaceutical companies to make easy accessibility of life saving medicines.

In India root of compulsory licence can be traced back in the Patent and Design Act, 1911.

The Patent and Design Act, 1911 mainly granted compulsory licence to prevent the misuse and abuse of patent. Any interested person after expiry of three years from the date of sealing of patent could apply for compulsory licence to the Controller of Patent. This Act of 1911also granted compulsory licence if the patented products were not worked in India to its fullest extent or failed to meet the public demand to an adequate basis on reasonable term or on refusal to grant of licence by patentee on reasonable condition, or on refusal of licence to export patented articles manufactured in India. Overall the Patent and Design Act, 1911 granted compulsory licence to prevent unjustified explotation of monopoly right under the patent system.

After independence it has been shown that the existing patent system was completely unsatisfactory to adhere the sovereign, socialist, democratic principles of nation. In this back ground the Government of India appointed two review committees namely Justice Bakshi Tek Chand Review Committee and Justice N. Rajagopal Ayyangar Review Committee in the year 1949 and 1957 respectively.

The Bakshi Tek Chand Committee Report, 1950 was highly influenced by the Patent and Design Bill, 1949 pending before the British Parliament in respect of upholding the public interest relating to affordability of food and medicines. This report recommended that the application for compulsory licence could be applied to the Comptroller General on the ground that the commercial or industrial activities were being hampered due to condition imposed by the patentee for using patented product or the Government itself on behalf of private person could apply for licence to enable private individual to work upon the patented invention to secure public interest. This provision extended the scope of compulsory licence through the inclusion of public interest as one of the grounds.[5]

Here it is important to mention that these suggestions already were introduced through 1950 Amendment to the Patent and Design Act, 1911 before the final Report, 1950 was released.

The study of Basheer and Kachupillai[6] shows that Justice N. Rajagopal Ayyangar Committee[7] Report, 1959 stated that 80-90% of Indian Patent were held by foreign multinational companies to extend their monopolistic control over domestic market specially in the areas of food and medicines, as a result of which these products are unaffordable. As well as more than 90% of these patents were not worked satisfactorily to meet the public requirements. Along with this the said committee also observed that the provision of compulsory licence in the existing statute is inadequate to address the misuse and abuse of exclusive right by foreign patent holders.

Million of Indians for their basic life saving medicines like penicillin, insulin etc had to depend upon the foreign multinational pharmaceutical companies.[8]

5. Addman M.J. & Baldia S, Prospects and Limits of the Patent Provision in the TRIPs Agreement: The Case in India, Vol: 29, I 3,Vanderbilt Journal of Transitional Law (VJTL), P 507, 2021.
6. Basheer Shyamnad and Kochupillai Mrinalini , The 'Compulsory Licence' Regime in India: Past, Present and Future, SSRN Electronic Journal, July 2005, PP 1-55, http://www.researchgate.net/publication/228173575
7. The Government of India in 1949 constituted a committee under the chairmanship of Justice (Dr.) Bakshi Tek Chand, Retd. Judge of Lahore High Court to review the patent system in India.
8. The Planning Commission, Govt. of India-1st 5 Year Plan Chapter 1 (Dec.7, 1952), http://planningcommission.nic.in/plan/plans1/fiveyr/default.html

This fact was reiterated through the decision of the Bombay High Court in Farbwerke Hoechst & Burning Corporation v Unichem Laboratories and Ors.[9] The fact of the case was that in the Bombay High Court the West German Chemical Hoechst won the injunction order against Unichem Laboratory to prevent it from manufacturing Hoechst's patented anti diabetic medicine Tolbutamide. Plea of the UInichem Laboratory was that it manufactured the same medicine under the licence which was rejected by the Bombay High Court.[10]

Final observations of Justice Ayyangarh Committee were as follows: that the existing compulsory licence provisions were inadequate to control misuse of patented rights specially by the foreign patent holders. The Report of 1959 reviewed that previously very few numbers of compulsory licence was granted. Reasons are listed as follows: because the existing provisions of compulsory licence might have boosted grant of voluntary licence. Here it is important to state that no proper stastical information was available in this regard;

Scope of granting compulsory licence was narrow so that application of compulsory licence might be agitated;

Licensees found difficulty to compete with licensors' well known internationally branded products;

Another important observation was that provisions of compulsory licence failed to make it mandatory to transfer 'know-how' from licensor to licensee;

In this backdrop the proper working or processing of patented work might be facing trouble as a result object of compulsory licence would be frustrated.

Considering the two committees' reports[11] it is clearly shown that the then existing system of compulsory licence was unsatisfactory and new transformation was required to introduce in the compulsory licensing regime. Recommendations of Justice Ayyangarh Committee Report, 1959 were the basic foundation of the Patent Act, 1970 which came into force on 20th April, 1972.

Form the public welfare perspectives to ensure affordability of essential medicines some important provisions of the Patent Act, 1970 before the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement, 1994 have been mentioned here.

The study[12] shows that there is polar opposite difference in between cost of patented medicines (cost of patented cancer medicine up to 1,00,000/-(approx) per patient per month) and generic ones (cost up to 10,000/- (approx) per patient per month).

In the year1981 on 6th May at the World Health Assembly the then Prime Minister Smt. Indira Gandhi stated that medical innovations must not be included within patent protection to secure interest and welfare of the nation because there should not be any profit from human health.[13]

The Patent Act, 1970 as a social welfare legislation secures the public interests toward accessibility of medicines through its various provisions. Some of the important provisions are here:

9. 1969 AIR 56 Bombay255.
10. An Old Pharma Decision: Bombay High Court (1968) I, thedemandingmistress.blogspot.com/2010/12/old-pharma-decision-bombay-high-court.html
11. Justice Bakshi Tek Chand Committee Report, 1950 and Justice N. Rajagopal Ayyangar Committee Report, 1959.
12. Daniel Goldstein et al, Global differences in cancer drug prices: A comparative analysis, Vol.34, Journal of Clinical Oncology, 2015, suppl. LBA6500-LBA6500, DOI:1110.1200/JCO,2016.34.18_suppl.LBA6500researchgate.net/publication/316865656_Global_difference_in_cancer_drug_prices_A_comparative_analysis
13. Iyer V.R. Krishna, Human Health and Patent Law, Oct.4, 2000,frontline.thehindu.com/other/article30255155.ece

No product patent shall be granted for the substances themselves used for or capable of being used as food and medicine or prepared or produced by chemical processes.[14]

Under the Patent Act, 1970 invention relating to the method or process of preparing stuff which is used as food or medicine was protected for five years from the date of sealing of the patent or from the date of patent application the duration was seven years whichever was shorter and the tenure of protection of any other inventions was for fourteen years from the date of application.[15]

The objective[16] of the Patent Act, 1970 is to draw a balance between advancement of research and developmental work through the recognition of intellectual labour of inventors which positively boosts up the nation's economic growth and to secure interest of public at large in the way of keeping out food and medicines from product patent provision to make them affordable.

In return of patent protection it is the duty of the patentee to use his invention to such an extent that to serve the interest of nation, meet the necessary public requirements along with gaining for himself in a justified manner. Often he intentionally fails to observe this principle and arbitrarily exploits the monopoly rights which become detrimental to affordability of medicines.

In this background grant of compulsory licence is a significant mechanism to control arbitrary exploitation and to uphold public health interest in the way of making available the cost effective medicines.

Chapter XVI comprises of sections 82-94 deals with detailed provisions of compulsory licence in the Patent Act, 1970.

The objective of granting compulsory licence is to guarantee that the patented invention should be worked on commercial scale[17] to such an extent that to ensure affordability of patented invention to public[18] along with reasonable profit for licensee also.[19]

There are four broad ground of granting compulsory licence.

1. Section 84[20] grants compulsory licence to prevent abuse of patent right;
2. Compulsory licence can be granted in case of licensing of related patent under section 91;[21]
3. Under section 92[22] compulsory licence is granted on national emergency, extreme urgency or on the ground of securing public interest;
4. One of the most vital grounds has been introduced through inclusion of section 92A[23] by the Patent (3rd Amendment) Act, 2005. Under the said section compulsory licence is granted exclusively for exporting of pharmaceutical products. This has been discussed in the third section of study under the head compulsory licence in the Post TRIPs Era.

Hereinafter the following grounds have been discussed in details.

1) Section 84 of The Patent Act, 1970: To Prevent Abuse of Patent Right:

Section 84 of the Patent Act, 1970 provides that any interested person may apply for compulsory licence to the Controller of Patent after expiry of three years from the grant of patent. There are several sub gro-

14. Supra note 3.
15. Section 53 of the Patent Act, 1970.
16. Section 83 of the Patent Act, 1970.
17. Section 89 (a) of the Patent Act, 1970.
18. Setion 90 (1) (iii) of the Patent Act, 1970.
19. Section 90 (1) (ii) of the Patent Act, 1970.
20. The Patent Act, 1970.
21. Ibid
22. Ibid
23. Ibid

unds for granting compulsory licence under the said section.[24] These are as follows:

1. if the reasonable requirement of public is not fulfilled by the patentee;[25] or
2. if the patented inventions are not accessible at affordable price;[26] or
3. if the patentee fails to work his invention to such an extent in India to secure nation's interest;[27]

According to section 84 (7)[28] reasonable requirements of public are considered to be not fulfilled:

- if on the refusal of patentee to grant voluntary licence on reasonable terms and conditions the establishment or improvement of new and existing trade or industry respectively are adversely affected;[29] or
- if the patented products are not available at adequate extent to reach the public requirement;[30] or
- if the patented invention fails to run on reasonably practicable commercial level.[31]

According to the provision of section 84(6)[32] the Controller has to take into consideration the following facts:

- nature and importance of the patented invention as well as patentee's effort to make full utilisation of his invention to serve the nation;[33]
- amount of expenditure for invention and improvement along with cost for obtaining patent.[34] These are taken into consideration for calculating the quantum of royalty payable to patentee or any beneficiaries;
- efficiency of the applicant to work with the invention to secure public interest;[35]
- risk taking capacity of the applicant in case of investment of capital for entire working out with the patented invention after getting licence to achieve the ultimate objective behind the provisions of compulsory licence;
- another matter which has to be taken into consideration at the time of grant of compulsory licence whether applicant initially approaches to patentee for licence and the same has not been duly addressed within reasonable time under the reasonable terms and condition.

In this regard reasonable time means time not exceeding 6 months[36] with a view to prevent patentee to extent voluntary negotiation which becomes deleterious to public interest.[37]

At the time of national emergency, extreme urgency or for non commercial use of patented invention above mentioned conditions have not been observed by the controller.

2) Section 91 of The Patent Act, 1970: Licensing of Related Patent:

Under section 91[38] the compulsory licence can be granted for a patented invention without utilisation of

24. Section 84 of the Patent Act, 1970.
25. Section 84 (1) (a) of the Patent Act, 1970.
26. Section 84 (1) (b) of the Patent Act, 1970.
27 . Section 84 (1) (c) of the Patent Act, 1970.
28. Supra note 20.
29. Section 84 (7) (a) (i) of the Patent Act, 1970.
30. Section 84 (7) (a) (ii) of the Patent Act, 1970.
31. Section 84 (7) (a) (iii) of the Patent Act, 1970.
32. Supra note 20.
33. Section 84 (6) (i) of the Patent Act, 1970.
34. Section 90 (1) (i) of the Patent Act, 1970.
35. Section 84 (6) (ii) of the Patent Act, 1970.
36. Explanation to section 84 (6) (iv) of the of the Patent act, 1970, has been inserted through the Patent (3rd Amendment) Act, 2005.
37. Basheer Shaamnad, India's Tryst with TRIPs: The Patent (Amendment) Act, 2005, Vol .I. Indian Journal of Law and Technology 2005, PP 1-46, http://papers.ssrn.com/so113/papers.cfm?abstract-id=764066

which other patented work cannot be worked.

3) Section 92 of The Patent Act, 1970: Grant of Compulsory Licence in Case of National Emergency or Extreme Urgency:

In case of national emergency or extreme urgency under section 92[39] compulsory licence can be granted on patented inventions. Heath emergency is considered as an instance of national emergency. In the case of emergency the Central Government declares by notification in the Official Gazette that compulsory licence should be granted for any patented medicines during tenure of patent whichever is required to tackle the particular health issue without prior intimation to patentee as well as without waiting for three years as mentioned under section 84.[40] In other words it can be said that on the event of emergency compulsory licence must be issued without any delay.

According to paragraph 5 of the Doha Declaration on TRIPs Agreement and Public Health, 2001 the WTO member states have power and freedom to decide when and on what ground compulsory licence can be granted.

Paragraph 5 (c) of the Declaration, 2001 enumerates that public health crisis including HIV/AIDS, tuberculosis, malaria and other epidemic can be considered as the cases of national emergency or extreme urgency.[41]

Here it is important to mention about the 'Licence of Right'. To secure public right if the Controller was of opinion that the reasonable requirements of public have not been fulfilled by the patentee or the patented inventions were not available at affordable price he could endorse patent with 'Licence of Right' at any time after expiry of three years from the date of sealing. [42] It was also within the provision of the Patent Act, 1970 that any interested person can work on patented inventions like food and medicines endorsed with the 'Licence of Right' without informing the patentee and establishment of any ground.[43] The object of 'Licence of Right' was to avoid procedural difficulties for preparing the low cost essential medicines in order to serve the nation. This has been repealed by the Patent (2nd Amendment) Act, 2002.

Before the TRIPs era grant of compulsory licence is very insignificant. Firstly because of flourishing of generic industries under reverse engineering system[44] and secondly for shorter tenure of patent protection for medicinal products had made them available to public earlier at affordable price.

Post TRIPs effect on the provision of the compulsory licence and availability of medicines have discussed here.

III. Compulsory Licence In The Post TRIPs Era:

In the realm of the intellectual property rights the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), 1994 is one of the most crucial multilateral treaties. This Agreement of 1994 provides a uniform legal framework to the intellectual properties across the world. It becomes

38. Supra note 20.
39. Supra note 20.
40. Supra note 20.
41. The Case of Compulsory Licensing during Covid -19-PMC-NIH, National Institute of Health, https://pmc.ncbi.nim.nih.gov
42. Section 86 (1) of the Patent Act, 1970.
43. Section 87 of the Patent act, 1970.
44. Chowdhuri Sudip, The WTO And India's Pharmaceutical Industry: Patent Protection, TRIPS And Developing Countries, Oxford University Press, 2005, Chapter 6, PP 200-220.

mandatory for all the World Trade Organisation (WTO) member states to comply with the provisions of the TRIPs Agreement, 1994.

Before the TRIPs Agreement, 1994 forty countries[45] including India had not granted patent for pharmaceutical products.

In compliance with the TRIPs Agreement, 1994 the Patent Act, 1970 faced three phases of amendments: The Patent (1st Amendment) Act, 1999; The Patent (2nd Amendment) Act, 2002; and The Patent (3rd Amendment) Act, 2005.

In observance of the Article 27(1)[46] of the TRIPs Agreement, 1994, the Patent Act, 1970 mandatorily includes essentials like food and medicines under the product patent regulation through the Patent (3rd Amendment) Act, 2005.[47] This is the most debatable provision form the point of view of accessibility of life saving medicines.

Under the TRIPs administration both the medicines and the process of manufacturing the same are patentable subject matters. One is protected through the product patent and the other is under process patent protection respectively.

The Patent (2nd Amendment) Act, 2002 has extended the tenure of patent protection for period of 20 years for any kind of invention whether product or process, even for medicines also.[48]

Under the TRIPs environment the sky high price of the patented pharmaceutical products because of product patent protection of medicines and delayed availability at affordable price of the same due to extended tenure of patent protection for 20 years for any kind of invention including medicines become a looming menace to affordability of life saving medicines.

Initially compulsory licence was granted only for domestic purpose. Export was not permitted under the provision of compulsory licence. This provision was same in both the Patent Act, 1970 and the TRIPs Agreement, 1994.[49]

This became a critical hurdle to supply cost effective medicines to developing and least developed countries with insufficient financial capacity and manufacturing structure. Grant of compulsory licence to them would be meaningless, because in the absence of adequate infrastructure they were unable to produce low cost generic equivalent of branded medicines. In this situation it was quite obvious that residents of those countries had faced crisis to avail affordable life saving medicines.

This became violation of right to health and also contravened the objectives of the Patent Act, 1970[50] as well as the TRIPs Agreement, 1994.[51] Objective is to advancement of science and technological innovation, nation's economic growth, transfer of information and dissemination of new, useful invention and to make affordable life saving medicines to secure public health interest. In short the aim is to balance between private interest of patentee and public right to health.

45. Boulet P, Perrien S J., Renaud-Thery F & Velasquez, G., 2000, Pharmaceuticals & the WTO TRIPs Agreement: question & Answer-UNAIDS/WHO, http://apps.who.int/medicinedocs/pdf/whozip18e/whoZip18epdf
46. Article 27 Clause 1 of the TRIPs Agreement, 1994 provides that any new technological or scientific invention with inventive step and industrial application is subject matter of patent protection.
47.Section 5 of the Patent Act, 1970 has been repealed through the Patent (3rd amendment) Act, 2005.
48. Section 53 of the Patent Act, 1970.
49. Article 31(f) of the TRIPs Agreement, 1994.
50.Section 83 of the Patent Act, 1970.
51. Article 7 of the TRIPs Agreement, 1994.

Relating to grant of compulsory licence for exporting generic medicines the provision of the Doha Declaration on TRIPs Agreement and Public Health 2001 is very crucial.[52] The Doha Declaration, 2001 emphasises that the provisions of the TRIPs Agreement, 1994 must be implemented and interpreted in a conducive manner so as to ensure the affordability and accessibility of life saving medicines to all throughout the world.[53]

Paragraph 6 of the Doha Declaration, 2001 states that difficulties in effective utilisation of compulsory licence could be faced by the World Trade Organisation (WTO) member states in the absence of or with the insufficient manufacturing capacity in pharmaceutical sector. To give effect to paragraph 6 of the Doha Declaration, 2001 the WTO General Council in the year 2003 decided to grant compulsory licence to generic medicine manufacturers to export the cost effective essential medicines to developing and least developed countries with inadequate infrastructure. This has been introduced in the Article 31 (f)[54] in 2005 through the first ever amendment of the TRIPs Agreement, 1994 which has come into force in 2017.[55]

To comply with the TRIPs provision of Article 31 (f) section 92A has been inserted in the Patent Act, 1970 by the Patent (3rdAmendment) Act, 2005. Now in India compulsory licence is also granted for exporting affordable medicines to other developing and least developed nations.

IV. The Government's Initiatives to grant compulsory licence for ensuring affordability of life saving medicines:

It is the time to review the Government's role to secure affordability of medicines under the existing system of compulsory licence.

The land mark decision of the Intellectual Property Appellate Board in Natco Pharma v Bayer Corporation[56] sets a precedent in the area of compulsory licence in India. It was the first time in India in the year 2012 when compulsory licence was granted to generic pharmaceutical manufacturer. The Controller of Patent, Design and Trademarks of India granted compulsory licence to Natco Phatma to produce generic equivalent of Nexaver. Bayer obtained the United States patent in 1999 for invention of Sofranib Tosylate to treat advanced stage of liver and kidney cancer. In 2005 the said medicine has been internationally launched under the brand name Nexaver.

Indian generic pharmaceutical company Natco pharma initially approached to Bayer Corporation for voluntary licence to produce and sell the generic version of Nexaver, which has been refused. Bayer's appeal to the Intellectual Property Appellate Board against the decision of the Controller of Patent, Design and Trademarks of India to grant compulsory licence in favour of Natco Pharma has been rejected.

There are other instances for eg. Roach Products (India) Pvt. Ltd v. Drugs Controller General of India,[57] Bristol Myers Squibb v. Hetero Drug Ltd[58] and Lee Pharma Ltd.v. Astrazeneca,[59] where applications for

52. WTO Fourth Ministerial conference held in Doha Qutar from 9- 13 November, 2001 and the Doha Declaration on TRIPs Agreement and Public Health was adopted on 14th November 2001.
53. Paragraph 4 of the Doha Declaration on TRIPs Agreement and Public Health, 2001.
54. The TRIPs Agreement, 1994.
55. Public health protection in patent laws: selected provisions, World Health Organisation, UHC technical Brief, 2017, apps.who.int>iris>rest>bitstreams>retrieve
56. Order no 45/2013, Intellectual Property Appellate Board, Chennai.
57. CS (OS) NO. 355/2014.
58. Del. H.C Ex Parte Order 9th December, 2008.
59. AB, C.L.A.1, 2015.

compulsory licence have been made by the Indian companies but these applications were rejected for not qualifying with the criteria of compulsory licence under the Patent Act, 1970.

In mid 2000 on sudden outbreak of bird flu- H5N1 strain showed the struggle behind the grant of compulsory licence to produce generic version of patented medicine to treat the disease.

Tamiflue from Roach , Gilead and Releza from Glaxo Smith Kline are effective medicines for treatment of bird flu. Report[60] shows that the Cipla approached to Roach for granting of voluntary licence to produce the generic version of Tamiflue. Roach did not response.

The Secretary General D.G. Shah of Indian Pharmaceutical Alliance was of opinion that pre- planning to face pandemic situation is crucial. The pivotal plan of which is to ensure adequate availability of essential medicines to treat the particular health issue. According to Shah in India it poses a peculiar problem.

There were two options to the Government either to import these medicines or to issue compulsory licence to generic companies to make generic version of said medicines under section 84 of the Patent Act, 1970. The main setback of section 84[61] is that it is dilatory procedure which may lead injunction.

In this tough situation without any palliative to treat the disease and of repeated significant pressure the Government did not issue compulsory licence for the Tamiflue.[62] Shah emphasised on grant of compulsory licence under section 92 to avoid the legal hurdle.

In respect of the present study it is important to highlight the decision of the Kerala High Court in X v. Union of India.[63]

In this case the petitioner breast cancer patient a retried bank employee approached to the Union Health Ministry, Department of Pharmaceuticals and Department of Promotion of Industry and Internal Trade to reduce the cost of branded medicine Ribociclib essential to treat breast cancer. It was also mentioned that 78% of monthly income has been spent for said medicine. The Government did not properly address the plea and take any effective initiative in this regard. The Hon'ble Kerala High Court has noticed the frightening situation that owing to exorbitant price of cancer drug it becomes inaccessible to large number of population which ultimately results death. It must be the mandatory obligation of the Government to secure affordability and accessibility of medicine to uphold the health right of its subjects otherwise it will be treated as massive violation of right to life under article 21 of the Constitution of India[64].

According to above mentioned provision of Paragraph 5 (c) of the Doha Declaration 2001the Covid 19 pandemic was obviously a critical public health crisis results national emergency and situation of extreme urgency.

At the time of Covid 19 severe shortage of essential life savings medicines, struggle to get vaccine, even if available their price were so high, black marketing of medicines over all these resulted acute public health catastrophe. In this tremendous critical situation even in the presence of strong legal frame work of compulsory licence the Government of India instead of granting compulsory licence preferred to voluntary negation with multinational foreign pharmaceutical companies like the Gilead Sciences for

60. The Telegraph Online, 15.11.2005, Drug firms on bird flu alert-Telegraph India http://share.google/eczXxEf0KmvEmqlz
61. Supra note 20.
62. Muller Janice M. The Tiger Awakens: The Tumultuous Transformation Of India's Patent System And The Rise Of Indian Pharmaceutical Innovation, Vol. 68 No.3, University Of Pittsburgh Law Review, 2007, PP 491-641, file:///C;/Users/User/Downloads/79-Article%20Text-157-1-10-20110930%20(4).pdf
63. 2022 SCC.
64. Mudur G.S. Income-devouring Cancer drug nudge, The Telegraph, Calcutta Monday, 4th July, 2022.

patented medicine Remdesivir, Eli Lilly for patented Baricitinib and to approach to the World Trade Organisation to waive the TRIPs mandates from medicine required to treat the Corona.[65]

Irrespective of repeated request, constant pressure from the civil society groups, opposition party and of some states like Kerala, Punjab compulsory licence has not been granted for essential medicines to face Covid 19 situation. Even the Supreme Court of India suo moto asked on India's reluctancy for invoking provision of section 92 of the Patent Act, 1970.

Assumption is that India wanted to avoid open conflict with multinational branded pharma companies because of force licensing might be pernicious for future voluntary transfer of technical knowhow for complicated biological medicines.[66]

In this situation neither public health issue has been duly addressed as an emergency basis of its own nation according to the Paragraph 5(c) of the Doha Declaration, 2001 nor the health rights of the citizens of other developing or least developed countries have been secured with the supply of low cost generic version of essential medicines to treat corona.

While India is known as 'World Pharmacy', response towards invoking compulsory licence during Covid 19 public health crisis raises the question what should be the best possible way to tackle the future emergency situation.

V. Conclusion:

At the end of the entire study it can be concluded that the exorbitant charges of medicines treatment of various critical diseases becomes unaffordable and the ultimate result is death. Even the charges of daily medicines for cholesterol, pressure, gastritis, renal problem etc become overburden for public at large. The compulsory licence has an immense important role to secure the availability of affordable essential medicines. Provisions relating to effective grant of compulsory licence have been nicely arranged in the Patent Act, 1970. Since 2012 till date only one compulsory license has been granted. Now it is the time to show how the easy, fast availability of affordable life becomes saving medicines is possible in usual situation and in emergency time.

The Government has significant role to ensure easy speedy accessibility and affordability of life saving medicines. The Government should take effective steps to increase the number of grant of compulsory licence. The proper plan should be designed to face the future health crisis strategically. The planning must be relating to: What types of crisis may be raised in future, what may be the probable extent of the same, what should be the treatment guidelines, probable infrastructure, finance must be within contemplation for preparation of necessary vaccine and medicines, it should also be in consideration that whether patent will be granted or not for invention of new pharmaceutical products to meet the urgent requirement, if granted then how effectively the compulsory licence can be issued to ensure accessibility of medicines not only within India but also for other developing and least developed nations worldwide. Effective future planning is possible with the constant research work in the area of public health. Collaboration in between medical sector, planning committee, financial committee, administrative and legislative wings are very important to achieve this objective. National and international cooperation is required. Judiciary has also pivotal role in this respect. Over and above

65. India demands patent waiver for Covid-19 vaccine at WTO, 26th November, 2021, economicstimes.indiatimes.com/news/economy/foreign-trade/india-demandspatent-waiver-for-covid-19-vaccine-at-wto/articleshow/87929930.com?

66. Purohit Ananya, The Evolution of Compulsory Licensing in India : Post Covid Trends, https://www.iiprd.com

whatever the strategies or steps will be adopted to ensure availability of essential medicines strict monitoring system along with effective implementation is a crucial task.

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