



## DOHA DECLARATION AND COMPULSORY LICENSING FOR PHARMACEUTICAL PATENTS: IMPLICATIONS ON PUBLIC HEALTH

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### ABSTRACT

As far as compulsory licensing is concerned; it is basically an act wherein the State can permit an individual or an organization of pharma sector companies to make full use of patented medicine stuff without taking the permission of the holder of such patent. The agreement on TRIPS and Doha declaration have made such viability of compulsory licensing possible. For the first time, we did find the advent of such formulation in the law book of Great Britain under its Statute of monopoly having sixteen hundred and twenty-three patents. Such concept of compulsory licensing on one hand gives more power to domestic manufacturers for creating such medical products including medicines whereas on the other hand it also makes it possible for the original holder of such patent to be incentivized for such utilization of his innovative invention. As of now, there are plenty of countries of developing nations as well as developed nations which have got such provision inducted into their domestic laws. Moreover, such obligations were earlier forbidden as authority authorizing third person to either create, utilize, or sell such an innovation without being permitted by the actual owner of such patent. Therefore, such stumbling blocks keeping in view the public health obligations undertaken by States have always been poles apart. The critical analysis has been done in this article by the researcher to find out the best practices which could make compulsory licensing a blessing in disguise for the developing nations.

**KEYWORDS:** Patents, Law, Regime, Comp Licensing, Medicine, Regulations.

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## INTRODUCTION

With regard to the utilization of access to essential drugs and health care, it has not been put to use fully by third world nations including India. It is being felt by such mostly affected nations that pathetic repercussions may come out of from such unequitable treatment in regard of having access to essential medicines and healthcare products while considering the public health scenario prevailing in the developing nations and least transition economies. There could be possible hazards with regard to the supply chain of such medical stuff while getting it reached to the poor nations in the times to come. It could lead to asymmetries and juxtaposed approaches. Truth be told, near about forty thousand human beings breathe their last every day because of such asymmetrical approaches in the pharmaceutical sector. There have also been millions of kids who have been dying every year for want of such essential medication in terms of better health care facilities and essential medicines. Which could otherwise have saved their lives from life threatening ailments like: Cancer, Tuberculosis, HIV-AIDS, Pneumonia, Heart disease. In keeping with the assessment done by the world health organization, it has been able to find out 3 important parameters which are very important to be factored in for having equitable access to health products including essential medicines such as: Financing to be done on sustainable basics, Pricing of such medicines to be set considering the affordability of the people at large, Supply chain whether national/international to be made more robust and trustworthy.

Having taken such concretized steps, it may be said that such medicines are to be of best quality. The cancer burden in the year 2017 and 2018 in India has been shown and we have noticed substantial growth of such patients which is still on the upgrade. The state wise presentations show cancer patients and available treatment for them

which need to be audited once again and the newly developed patented formulations to treat such life threatening disease must be brought under the purview of price regulatory regime in India so that the access to such medicines could be made more patient friendly representing the grassroot level of Indian society. Consumer in India spend out of their pocket near about

51.67% rupees to get treatments for such diseases. Pharmacy in the rural area has been questionable as it does not have ample access to the availability segment of such lifesaving drugs which could be made available to the poor and needy people in such areas. In another table, the rising presence of pharma base in India is shown along with their market share. Moreover, they are also to be reasonably chosen and are got to be wisely used<sup>1</sup>.

In accordance of the report submitted by the special rapporteur<sup>8</sup>, it was also said that a great emphasis has to be laid on to the accessibility and affordability of such medicines as a right to health and health care. It may furthermore go into the hands of nations concerned and then stakeholders. So much so, it has also been observed that the outdated and less effective medication is also being introduced into the developing nations. Therefore, such maneuvers of the developed nations had raised so many concerns to be handled with sheer caution and precision.

## THE EFFECTIVE ROLE OF THE STATE

It has become therefore very important for the international community to take necessary steps to put full stop to such resale of outdated and duplicate medicines in the markets of developing nations. Another important issue which has drastically percolated the developing nations is the lack of health infrastructure including requisite health insurance as lot of the purchase of life saving medicines is done by paying the price out of the wallet.

### **Millennium developmental goals and the right to health**

If we see the goal number eight of the millennium developmental goals launched by the United Nations, it talks about the mutual interaction with the pharma industries thereby giving desirable access to the affordability<sup>2</sup> of essential medicines as a matter of right to health and health care to the needy and poor populace. It was also found by such goals that developing nations are in no position to have access to requisite piece of information with respect to the accessibility of available health infrastructure, health products and essential medicines to the needy and poor people. There has been huge indifference of opinion found between the private and public sector enterprises. Truth be told, the available stock of the essential medicines with in the states control department is found to be nearly 1/3<sup>rd</sup> in comparison to that of 2/3<sup>rd</sup> in the private sector scenario. The situation has been found to be more pathetic as the cost of essential medicines and their generic versions have been as big as six point five times greater than the fixed international pricing. Such grave situations have umpteen times given sue moto warnings to the developing nations that they have to buy such medicines at alarming prices from the private markets or they may not be able to get themselves treated for the same ailments for want of financial incapacities.

Therefore, efforts were made by the world trade organization nations to motivate pharma sector through TRIPS regime and compulsory licensing regime to keep working on making the availability and accessibility of such pharma products including essential medicines within the reach of a common person of developing nations.

A reference can also be made to a case which made possible the access to essential medicines and <sup>3</sup>right to health and healthcare through the Constitutional

provisions. The President of South Africa had proclaimed that the health statute in place had to undergo sea change there by enabling the poor and needy to have access to essential and lifesaving drugs. Such a verdict was gone against by the US pharma sector and pressurized the south African regime to avert this decision with the help of trade restrictions. Later, USA left all this pressure apart in the year of two thousand after being embarrassed by the people at large. Moreover, in the year two thousand and one, more than forty pharma multinational firms filed a case against the said African regime. Saying that, such a statute could tear apart the south African commitments so taken under TRIPS regime. Having charged by the people at large and the media coverage, the wholesome support was rendered to the South African regime thereby enabling the government to put right to health and healthcare on top of their public health agenda. Such an unprecedented development forced pharma companies to take back their case law and later the bonhomie was shown by them to the South African public so that they could get along with their national requirements of maintaining public health and infrastructure at the affordable cost. There has also been another important development of such predicament through another case which was filed against the State of Brazil which had made the law with respect to the accessibility and availability of HIV medicines with the help of compulsory licensing regime but United States of America did not like such attempt and declared unilaterally such law to be in violation of the Articles twenty-seven and twenty-eight of the TRIPS agreement. Accordingly, on fifth of July two thousand and one, the state parties concerned made it known to the dispute settlement body of the world trade organization. After some point of time, the said matter was sorted out amicably. It happened because of the reason that the said factual circumstances of the case and the verdict thereafter gave rise

to the potential danger of damaging the rapport of pharma sector companies. Accordingly, the international community did consider the problem of lack in access to essential medicines especially in the developing nations as a matter of right to health and better healthcare.

### **Compulsory licensing and problems of health infrastructure**

As far as developing nations are concerned, the population explosion has been always on the upgrade and has been still continuing. There are more than two billion of people who have not been able to have access to affordable medicines for essential medical treatments worldwide. According to world health organization, every year near about ten crores of populace have been found to have been dead after having been declared infected with deadly diseases<sup>4</sup>. More than ninety percent of such causalities have taken place in the developing nations. The skyrocketing cost of essential medicines being put forward by the so-called hardcore protections provided by the pharmaceutical patenting regime have given rise to the predicaments and distrust amongst developing nations like India. Such unwanted pharma issues have been found to have been created in the form of so-called legal disputes with respect to the national health laws protections which have been made to create safest net for meeting health needs.

### **Trips plus regime**

Even free trade agreement safety protection has been made to have been induced through TRIPS plus regime which has made such intellectual property's safety net stronger. In keeping with the report made by the world health organization, near about ten percent of the global research and development is dedicated to the ailments being founded in developing nations like India. Therefore, a large gap between the right to health and intellectual

property regime has been foreseen. Moreover, it has now become a proven fact that the health infrastructure in the developing nations has been vulnerable undermining the availability and accessibility of the essential medicines as a matter of right to the poor and needy people. In keeping with TRIPS accord, the situation in regard of medical infrastructure has become worsen over the years. Before such measures, there was no such criterion to favor the Poor Nations.

We have already seen the area wise compulsion for the compulsory licensing which has given rise to a lot of impossibilities for developing nations thereby not giving room for manufacturing capabilities in terms of importing less costly versions of essential medicines. Various opinions have been made against such move as provided in TRIPS agreement as it is believed by the affected nations that such a scenario may create disparity and unwanted tiresome burden on such developing nations.

### **Public health scenario in developing nations: trips compliance**

In keeping with Doha declaration, important developmental process with regard to the health scenario started but till date the objectives to make essential medicines available to poor nations have been fulfilled at least on paper. The reference can also be made to a very important Geneva convention wherein, in the year of two thousand and four, emphasis was laid on the fact that the poor nations ought to have access to important weapons to enforce world trade organization's Doha declaration thereby putting in practice the flexibility regime as per TRIPS accord to keep up the agenda of making available essential medicines to the vulnerable sections of the universal population. As far as India is concerned, in the year two thousand and five, it introduced the patenting regime to pharma products including essential medicines as a

matter of right which in fact gave rise to the unavailability of cost-effective new types of innovative drugs important to treat life threatening ailments which have been mostly impacting the developing nations for years.

## CONCLUSION

As far as India is concerned, it has raised all these issues once again in the summit of G20 where in the request has been made to create a pact which might make the nations to take full advantage of the flexibility provisions of TRIPS agreement thereby making the accessibility of essential/lifesaving drugs approachable at the pricing which could be afforded by the millions of people of developing nations. During the summit, proposal has also been tabled to have a consensus on the other related medical facilities including treatment mechanisms, healthcare products to be provided to the poor nations at affordable costs. Having taken up the flexibility regime, it would be a welcoming step towards the production of cheap and quality medicines in terms of their generic versions and the poor nations shall be benefited a lot out of such productions world-wide. Even the COVID-19 pandemic has brought forward the challenges to provide better and accessible medical treatments including the essential medicines in the developing nations. We have already seen the scarcity of the vaccinations in the Asian and African regions. World health organization has also requested the developed. As of now no further progress has been found in concrete sense. Even today, availability and accessibility of essential medicines is still in fancy mode and is yet to become a reality. The lifesaving medicines are still out of reach of the marginalized people. The health infrastructure of the Nations like India needs to be made more robust and result oriented. The list of essential medicines must include the newly patented medicines or substances which

may be of great help to the people of the developing nations.

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