Analysis of Compulsory Licensing in India and its Perceived Impact During the Covid Era

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Abstract:
Compulsory licensing can be defined as a mechanism which would enable the State to use the invention without the prior consent from the inventor or the patent right holder. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement provides provisions for patenting of drugs, it also provides certain provisions for compulsory licensing mechanism, to keep a check on the possible abuse of patent rights. There has been an imbalance between profits and drug accessibility to people throughout the world, including India. The Indian patent regime has changed drastically since the landmark Judgment of Bayer v. Natco[2], it was evident that the judicial approach upheld the public interest and ensured that the pharmaceutical companies do not abuse their position. Granting patent security to pharmaceuticals particularly fundamental medications has dependably been a challenged one. Further, the subsequent judgements on the said subject matter has created confusion as far as the stance of compulsory licensing standards in India are concerned. The inborn tussle between profit driven medication organizations and welfare arranged governments trying to guarantee less expensive access to fundamental prescriptions has as often as possible involved the worldwide attention. The Covid 19 pandemic has disrupted many lives all over the world, but since the invention of numerous vaccines, there has been a ray of hope to cure the virus at a large scale. However, the governments and the pharma companies need to have an agreement in order to provide vaccine and healthcare to vast majority of population. Thus, the compulsory licensing route is being explored by various governments in order to provide healthcare, this paper aims to explore the fundamentals of compulsory licensing in India and its possible application in the Covid 19 scenario.

Keywords: *Intellectual Property, Compulsory license, Covid 19, Patent Security, Bayer – Natco*

Introduction:

Conceptually, compulsory licensing is a government mechanism which grants the license to the third party for the use of an invention without the consent of the patent owner. The patent rights in India are granted to the patentee to encourage inventions and acknowledge the technical and entrepreneurial capability of the applicant. The objective of the compulsory licensing is to prohibit the monopoly of the patent holder and to ensure that the invention is put to use for the general public. It acts as a balancing power between awarding the inventor for his invention and making the invention available to the large section of the people at a reasonable price. The TRIPS was introduced in the year in 1995 after various countries have agreed to establishing an additional multilateral intellectual property agreement. The genesis of compulsory licensing can be found in the TRIPS Agreement.

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[2] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on November 7th, 2021)

TRIPS Agreement

In order to facilitate the trade and commerce between the members of the World Trade Organization (WTO) and for the better use of the intellectual property rights, the TRIPS came into force. The inventors were engaged to peruse the inventions and put their inventions to profitable use. In Article 27, of agreement aims to provide a suitable platform to foster invention and innovation on various products and processes.

However, in order to counterbalance the profitability of a patent and to providing welfare, the TRIPS also provide an exception to the general rule of patentability. Article 30 of TRIPS is mentioned below,

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[3]*"*

Furtherance, Article 31 of the TRIPS enables the Member States to 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[4]. It allows the authorization under exclusive circumstances broadly, prior efforts to obtain authorization from the patentee, non-exclusive use, and non-assignable use, payment of adequate remuneration etc.

The impact of Doha Declaration:

On November 14th, 2001 the Declaration on TRIPS Agreement and public health was adopted in Doha[5]. The declaration reaffirmed that the TRIPS agreement shall be interpreted and implemented which is supportive to the WTO members, right to protect public health and in particular to promote access to medicines was emphasised. It resolved the issue of compulsory licensing of exporting drugs to developing countries. The deceleration further enabled the states to determine definitive grounds for compulsory licensing. A conscious attempt was made in order to acknowledge the interests of 'least economically' developed nations, as the regime enabled the member states to manufacture and export the generic medicines to the aforementioned nations.

By virtue of the latest development, all WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing that they will not use the system to import[6].

Compulsory Licensing in India

In order to comply with the International obligations, the Indian Patent Act has been amended in regard to the grant of compulsory licensing to be in consonance with the TRIPS Agreement. Under the Indian Patents Act,1970 the Sections 84 to 94 deals with compulsory licensing.

An application for the compulsory license can be may made any time after the expiration of 3 years from the date of grant of the patent[7]. It shall contain a statement describing the nature of the applicant's interest along with the necessary particulars as may be prescribed and the facts upon which the application is being made.

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[3] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

[4] *Supra* note 1

[5] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002)

[6] *Supra* note 1

[7] Indian Patents Act, 1970 § 84, No 39, Acts of Parliament, 1970 (India).

Broadly, there are three important grounds for the grant of compulsory licensing in India[8],

a. The reasonable requirements of the public with regards to the patented invention have not been satisfied.
b. The patented invention is not available to the public at a reasonable price.
c. The patented invention has not worked within the territory of India.

In the year 2012, in a landmark case between Bayer Corporation V. NATCO Pharma Ltd, India granted its first ever Compulsory License. This move has created a huge impact in the pharmaceutical industry.

I. Bayer Corporation V. NATCO Pharma Ltd

Bayer Corp. is a pharmaceutical company headquartered in Leverkusen, Germany. It has invented "*Sorafenib Tosylate*", a cancer drug which is primarily used in the treatment of Kidney cancer. The said drug was marketed in the name of *"Nexavar"* by Bayer Corp., the Indian Patent Office has granted a patent to Nexavar in the year 2008. On the other hand, NATCO Pharma Ltd (Natco) is an Indian pharmaceutical company which deals in the manufacture of drugs and medicines. In December 2010, when Natco has approached Bayer Corp. for the issuance of voluntary license to manufacture '*Nexavar'*. Unfortunately, Bayer Corp. has rejected the request. Subsequently in the year 2011, Natco approached to the Controller for the grant of compulsory license[9] under S. 84 of the Indian Patents Act, 1970.

The question which the controller was to answer, if the said issue falls within the purview of S.84 in which the conditions for granting for compulsory licensing are enlisted.

Natco filed an application for compulsory licensing before the controller in the year 2011. The controller granted the compulsory license to Natco on March 9, 2012. Aggrieved by the decision of the controller, Bayer Corp. approached the then Intellectual Property Appellate Board (IPAB). The Controller, as well as IPAB's decision, was fundamentally similar in nature by granting the compulsory license to Natco, the reasons are substantiated below.

NATCO attempts to obtain voluntary license

Bayer Corp contended that Natco had not made reasonable efforts to negotiate after the initial proposal and felt that before exploring the option of voluntary license, grant of compulsory license cannot be granted. IPAB has made an observation stating, *"…respondent is not required to make another request when its efforts had failed. The law does not require that…"*.[10]" Therefore, IPAB concluded that the requirement of the law was only to make attempts to negotiate which has been met and the contention of Bayer Corp fails.

Reasonable requirements of the Public

S.84 1(a) of the Patents Act,1970 clearly lays down conditions for the grant of Compulsory license. Natco had submitted facts to support its claim that Nexavar has not met the reasonable requirements of the public. It contended that, a total of 23,120 bottles of Nexavar were needed to the patients suffering from kidney cancer for which no bottles of Nexavar were imported in the year 2008 followed by 200 bottles in 2009 and no

[8] *Id.*

[9] Dewan M, Compulsory license revisited-India, RK Dewan & Co, 10 September 2014, http://www.lexology.com/library/ detail.aspx?g=fc41db30-6793-4f92-90ae-a0bb82e6fdaa, (accessed on 27 October 2020).

[10] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, Para.16, available at http://www.ipabindia.in/pdfs/order-45-2013.pdf, last visited on June 5th, 2019.

bottles imported in the year 2010[11]. IPAB declared that since the benefits of the rights are conferred directly to the Patentee (Bayer) it is essential for the patentee to ensure that the drug is reachable to the public at large.

Reasonably affordable Price

Natco substantiated its claim by relevant statistics , it contended that the price of Nexavar was priced at an extortionate price and more than majority of the population was not in a position to buy the drug. The then price of Nexavar is approximately at INR 2,80,248 /- as compared to a generic version of the drug manufactured by Natco's at INR 8,800/-. In deciding this claim, IPAB had taken a public welfare stance and said one of the primary requisites of a Patent holder is to ensure that his drug is reasonably affordable[12].The other interesting contention from Natco was that, Bayer Corp was eligible for Drug Tax Credit which would have lowered the net cost of research and development. Bayer chooses not to avail Drug Tax Credit, if the benefit was availed by Bayer, that would have reduced the manufacturing burden consequently the price of the drug would have been priced low. As a result of which the IPAB stated that, the said invented drug was not available to the public at a reasonable cost and declared it against Bayer.

Not worked within the territory of India

The literal interpretation of the clause is to be deduced from the other two conditions laid down in S.84, the said drug is not available to the public at large and not available at reasonable price, consequently the said drug has not worked within the territory of India. Natco argued the word 'worked' meant to be 'manufactured within India'. Bayer had also failed to establish the reason 'why it failed within the territory of India', as a result by which it was ruled against Bayer Corp.

The decision by IPAB may be lauded as one of the landmark judgments which emphasized the public health motive over patentee rights but the IPAB had left many questions unanswered. It rightfully applied facts of the case to the existing mechanism of law in the country and decided the case based on merits but it adopted a policy and set a precedent which might be harmful to India's patent regime in coming years. During the entire proceedings, Bayer Corp had made an important argument; it argued that CIPLA, another pharmaceutical company in India had been manufacturing the same drug which is similar to the invention of '*Soranfenib Tosylate'*, Bayer Corp had already filed a patent infringement suit against CIPLA for alleged infringement. IPAB had not taken cognizance of the claim stated by Bayer Corp. CIPLA had been selling the drug at much lower price as compared to Bayer, consequently reducing the market share of Bayer[13]. There is an irreparable damage caused to the Patentee as when an infringer infringes the Patent and sells at a much lesser price, the patentee is coerced to either reduce the price of the drug considerably or the patentee's drug loses substantial market share and ultimately fails the test of compulsory licensing and results in granting of compulsory license to the applicant. IPAB has set a wrong precedent in the case as it will adversely affect the pharmaceutical investors in India.

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[11] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, Para 35, available at http://www.ipabindia.in/pdfs/order-45-2013.pdf, last visited on June 5th, 2017.

[12] Bayer Corporation v. Natco Pharma Ltd, Order No. 45/2013, Para 40, available at http://www.ipab.tn.nic.in/045-2013.htm Last visited on June 5th, 2017.

[13] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, Para 25-26 available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on May 12, 2013)

The patent holder is discouraged to start his pharmaceutical regime as his right to exclusive use is under threat. The research and development costs are not met by the manufacturer for his drug in practice in India , which will deter his investment in India. This decision is set to increase competition in Indian markets as the manufacturers are in a constant tussle to provide the requisite drug at an accessible price. It is also a boon for patients suffering from life-threatening diseases. As in India, the poverty rate is prevalent in many states and the majority of the population do not have adequate access to quality healthcare. IPAB's decision with public health perspective in mind is a welcome move to poor as the life-saving drugs is available at many affordable prices.

II. Lee Pharma v. Astrazeneca[14]

In this case, Lee Pharmaceuticals which is a Indian manufacturer sought Compulsory License for the drug '*sexagliptin'* a drug which is primarily used in the treatment of Diabetics, marketed as *'Onglyza'*. It is one of the very few drugs available in India which treats Type-II Diabetics disease, which works in controlling glycemic control without weight gain[15]. The said drug was granted to Bristol-Myers Squibb[16], it was later assigned to AstraZenica which is an Anglo-Swedish Company.

Analysis

For an application to succeed for compulsory license, as discussed earlier the essentials of S.84[17] of the Patent Act, 1970 needs to be satisfied. One of the primary requisites to grant license, the attempts made by the petitioner to obtain a voluntary license from the manufacturer. Like in the case of NATCO v. Bayer Corp , Lee Pharmaceuticals too had made attempts to obtain a voluntary license from the patent holder. Bristol-Myers Squibb has received a request from Lee Pharmaceuticals, however it refused to negotiate on the terms offered. It contended that the patented invention has not met the reasonable requirements of the public at large. Even after 8 years of securing the right to manufacture, it has not manufactured the drug in India[18]. As per Form-27 for the calendar year 2013 which was published in the year 2014, Saxagliptin has not been manufactured in India, it has been imported from USA or Ireland. The total number of tablets from the drug (Onglyza and Kmbiglyze, forms of Saxagliptin), for the year 2013, 8,23,855 units were manufactured which amounts to Rs. 6,54,629, by breaking down costs, the cost of importing is only 0.80 Rupee but it is sold at INR 49/-, which clearly shows the abuse of monopoly by Bristol-Myers. However, unlike Bayer's case, there are large substitutes available for Saxagliptin, the four other available inhibitors on the market, with Sitagliptin, Vildagliptin, and Linagliptin[19]. The existence of further alternatives makes Lee Pharmaceuticals' argument flawed, the mere presence of like for like substitutes for the drug is likely to meet the demands of public health at large. It has to be noted that, the IPAB has discarded this notion in the previously discussed the Bayer's case and stated

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[14] C.L.A. No. 1 of 2015

[15] Onglyza – A Saxagliptin drug, available at http://www.diabetes.co.uk/diabetes-medication/diabetes-and-onglyza.html, last visited on June 8th, 2017.

[16] US Patent No - US 7,943,656 B2, dated May 17th, 2011, available at https://patents.google.com/patent/US7943656B2/en, (last visited on June 23, 2021).

[17] S 84(1)- (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 the patented invention is not worked in the territory of India.

[18] Compulsory License Application by Lee Pharmaceuticals, Pg 10, available at https://spicyip.com/wp-content/uploads/2015/07/Saxagliptin-CL.pdf, (last visited on June 8, 2021)

[19] Compulsory Licensing application filed over AstraZeneca's Saxagliptin- available at https://spicyip.com/2015/07/compulsory-licence-application-filed-over-astrazenecas-saxagliptin.html, last visited on June 8, 2021

that, the patentee shall meet the criteria individually, which is contradictory to present case however the nature of the drug is such that there are close substitutes it may or may not be possible to meet the criteria individually. Hence, in an economic sense, the existence of substitutes in the market is likely to impact the product.

With respect to the patentable invention not available to the public at a reasonable price, Lee Pharmaceuticals stated that it could produce each tablet at a mere cost of 30/- INR which is 15/- cheaper than Bristol-Myers. It also stated that is it capable enough to produce 10,00,00 units each day[20]. As said above, Lee Pharmaaceuticals has demonstrated that in spite of 8 years since the patent was granted and from the data from Form 27, clearly indicate that patent holder has not produced the medication in India and merely importing the units from different nations.

Lee Pharmaceuticals had contended before Intellectual Property Office(IPO) there are more than 60 million diabetic patients in India with a premise that majority of the patients might be potential consumers of the drug , but it was rejected the plea on grounds that, not all patients are potential customers and more so, there is a possibility that they might prescribe to a lifestyle change which shall mitigate the effect of diabetics[21]. The IPAB has also rejected the claim of Lee Pharmaceuticals on the grounds that 'Sexaglipton', just 10% of Indian diabetics were prescribed Saxagliptin,

In quashing the under supply argument made by the applicant, the Controller stated that *" such assumptions cannot be used to argue that the reasonable requirement of the public has not been met – 'authentic data/statistics' are required to make such a claim"*. While all the empirical data supplied by the applicant has been around diabetics in general, the Controller holds that this would not suffice, as mere under supply of the drug is not a valid stance in establishing that the said drug has not worked in the territory of India. More so, the existence of substitutes in the market is adequate in meeting the public health demands. Further, the high cost/unit argument made by the applicant fell flat on stomach, as all the other alternatives of Saxaglipton are priced at a similar range , between INR 42- INR 52. In hindsight, for this argument to succeed, the applicant ought to have established that the other alternatives of Sexaglipton too, are priced at a higher range and by the issuance of compulsory license, it is likely to produce at a lesser price and subsequently offering a reasonable healthcare to the patients. The failure to do so, Lee Pharmaceuticals has failed in its onus to prove the necessary requisites of S. 84 of the Patent's Act.

In addition to the above legality, a compulsory license may be issued by a notification from the Government. Section 92 of the Patent's Act, 1970 enables the government to grant compulsory licensing by a notification. The objective behind this section is to provide healthcare facilities to the general public in solely case of a health calamity. This license can be granted without any prior notification to the manufacturer or patent owners. i The said provision is in consonance with the TRIPS agreement under Article 31.

COVID 19- COMPULSORY LICENSING THE WAY OUT ?

The novel Corona Virus has caused widescale destruction to millions of lives all across the globe. Late in the year 2020, there arose a hope to provide vaccination to large scale population. But the real challenge was to have technical expertise on production and acute strategies for its distribution. The policy makers look upon the compulsory

[20] Compulsory License Application by Lee Pharmaceuticals, available at https://spicyip.com/wp-content/uploads/2015/07/Saxagliptin-CL.pdf, last visited on June 8, 2021

[21] Order by Controller in rejecting compulsory licensing, available at https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/Lee-prima-facie-notice_en20160119.pdf, last visited on June 11 2021.

licensing process as a solution to overcome the crisis. As the policy makers are hopeful that the involvement of larger players in the production market will ensure enough doses to be produced to the mass population in India.

The problem of vaccine production and their distribution is a far more complicated set of events and compulsory licensing of a particular vaccine formula cannot be treated as a wholesome solution. It is pertinent to understand the nature of the challenge the policy makers are facing in order to respond to the ever evolving virus. Fredreich Hayek, the great Austrian Economist has made a study on simple and complex phenomenon[22]. Hayek in 1967 stated that , in order to respond to a policy there are two ways , the simple phenomena and the other is the complex phenomena. The key distinction Hayek tries to make is that, in a simple system, it is possible to devise a policy by control and planning by directive intelligence the policy makers or the governments derive from. The later, however such control and directive intelligence cannot be made as there is an overwhelming knowledge problem. India like many other countries currently face with the problem of centralised approach to vaccine distribution and production. As stated, in a simple system it is possible to define a policy by massive control and a set of planned events. However, the pandemic is a complex amalgamation of issues for which having knowledge of the same is the most important aspect. The word 'Knowledge' in this specific context means, information about market conditions, demand and supply and customer behaviour in the market. As, ultimately the production and distribution of vaccine is an economic exercise. The Government with its centralised approach, may not posses all these attributes. The players in the market, are in a far better position in order to understand the knowledge problem. An ideal market economy, coordinates all of the decentralized knowledge held by individuals or players throughout the economy.

Each district, state and territory offers a unique set of challenges in vaccine distribution in India. With a centralised approach, it may not suffice the motto- *vaccine for all*. The United Kingdom's (UK) , approach vis-à-vis European Union's (EU) approach offers a blue print as far as vaccine procurement and distribution is concerned. As on data published by UK's National Health Service (NHS) on 16th May, 2021 a total of 3,04,35,887 have completed their first dose of vaccination[23], it is around 84.49/100 population which is one of the best among the countries in the world. According to data[24] published by the European Centre for Disease Prevention and Control merely 39.6% have availed single dose of vaccination. The primary reason which accelerated UK's vaccination drive was ,early approval of vaccines by regulatory authorities and a decentralised approach catering to the requirements of its own population. The European Union has however, have taken a more complex approach in vaccinating it's member countries. The European Medicines Agency, the EMA the recommendatory body to EU, has delayed the approval of vaccine distribution among member states. The rigid bureaucratic route of the EU has hampered the vaccine distribution, countries like Hungary has superseded the rigorous EU route for vaccine distribution and approved the Russian Make- Sputnik-iv for its distribution in Hungary. The UK, on the other hand, had a more meticulous and measured approach in vaccine distribution but also vaccine research. UK was one of the first countries to place 40 million doses of Pfizer/BionTech

[22] Hayek, F.A. (1967) The theory of complex phenomena, in Hayek, F.A. (1967) Studies in philosophy, politics and economics, London: Routledge

[23] england.nhs.uk, available at https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/, last visited on 21 May,2021.

[24] European Centre for Disease Prevention and Control- qap.ecdc.europa.eu, available at https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab, last visited on 21 May, 2021.

vaccine, UK has also established large scale vaccine facilities for the vaccine to be filled and sealed in multiple vials for distribution, which is vital in distribution process[25]. The distinguishable approaches by both EU and UK, largely dictated vaccine numbers. Vital policies such as vaccine approvals and vaccine distribution measures were better planned and approached by UK. The vital decisions were as a result of decentralised approach taken by UK. It was better placed to assess its resources, budgets and technology for vaccine distribution. However, factors such as diplomacy, economic strength of a nation, diplomacy etc play an important role in vaccine production and distribution. Nevertheless, the purpose of this comparative analysis was to indicate that the decentralised approach is more plausible as opposed to a centralised approach. In India's context, the governments of states are better equipped in gauging strategies for overall benefit of people. Even with compulsory licensing , the success may not be guaranteed with a central set up. The policy makers are hopeful that with the help of compulsory licensing, it can meet the demands of production and distribution by polling in resources, but the more pertinent and critical decision lies in the approach to do so as accumulation of power to make decisions may not result in desirable results. As stated previously about the process of acquiring compulsory license and application, it's success is however is not assured.

To study the beneficial advantages of compulsory licensing historically, the research conducted by Joerg Baten, Nicola Bianchi, and Petra Moser[26] has suggested interesting insights. As a sample size, the study studies the impact of Trading with the Enemy Act of 1917, which was introduced by USA in order to gain access and grant compulsory license to all such patents from Germany after the commencement of the World War-I. Around 1246 patents were licensed to USA's players from a period between 1918- 1922. The study rightly reaffirms the relationship between competition and innovation, it indicates that German inventors have in fact applied for more patentable inventions post 1918 repercussions after World War-I. However, a closer analysis indicate that patentability has increased in the fields wherein the pre-existing economic conditions of competition were strong in specific fields. This is supported by periodic increase of 2.97 patents per year from 1918 in the fields of chemical invention, more specific to dye-stuff and explosives. Even though, compulsory licences were issued for all categories of invention but the increase in innovation and patentability was only confined to more competitive markets. Though the market conditions , economic/political scenarios are vastly different from the periods of post-World War-I to current world, the evidentiary value cannot be ignored. The increase in innovations was more specific to economically viable fields and specific markets. Increase in innovations plays a major role on the usefulness of a patent, especially in the pharmaceutical industry. More so, one of the primary expectations of proponents of compulsory licensing is to share the technical know-how and increase in the serviceability of patented drugs. The study relied upon by the authors, suggests such serviceability of drugs is only foreseeable in the markets of higher economic significance. It has to be noted that, there is already prevalence of large scale research and innovation in the development of vaccines in battle against covid-19, the sharing of patented formula to the other manufacturers may not result in upscale in supply and more importantly, the development of the vaccine.

[25] United Kingdom's Department of Health and Social Care- UK Covid -19 vaccines delivery plan, published on January 11, 2021, www.gov.uk, available at https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan, last visited on 21st May, 2021.

[26] "Does Compulsory Licensing Discourage Invention? Evidence from German Patents After WWI," National Bureau of Economic Research Working Paper no. 21442, July 2015.

In another study[27], the impact or pricing from compulsory licensing was studied. The prices of Antiretroviral Drugs purchased through compulsory licensing and other international procurement mechanisms were compared. It was determined that, compulsory licenses for antiretroviral drugs proceeded in prices that were higher than the prices achieved by peer countries that has sourced the drugs from international procurement markets which are either monitored by the World Health Organization or the Global Fund between the years 2002-2011/12. The percentage reduction of costs as a result of compulsory licensing was 71% in comparison to reduction of 79% of costs through other means[28]. Interestingly, the pricing disadvantage was more so evident in developing countries[29]. This study however has its own limitations, as it does not explore the possibility of special circumstances (in this case, a pandemic) which may have resulted in reduction of prices. The authors conceive this study only as a source of information that adoption of compulsory licensing may not result in direct reduction of prices , which is an perceived outcome of this process.

The importance and impact of voluntary licenses was briefly discussed in the case of Bayer, however a discussion on Thailand's case of compulsory licensing of vital drugs such as kaltera manufactured by Abbot Inc. is an important viewpoint in this scenario. The importance of voluntary co-operation and licensing can never be ignored. After the Thai government's announcement of potential compulsory licensing of its manufactured drug, Abbot Inc promptly negotiated its terms by reducing the per person cost in Thailand. Reminiscent of the bidding process, when the generic manufacturers suggested the cost reduction to 1300 USD $, Abbot Inc has dropped its per person cost to 1000$, Finally the pooled procurement of the drug from various NGOs and other agencies has drastically reduced the per person cost to 676$. It is a classic case of a free market functionaries working to the benefit of the consumer.

Voluntary licensing has been a successful tool to efficiently manufacture distribute drugs globally as per a study[30]. The case in point was, when Gilead Scienes Inc has licensed its drugs for the treatment of hepatitis-c to large scale Indian pharma manufacturers. The licensees are also allowed to determine the prices for export to other countries. Such voluntary arrangements will significantly benefit the IP owners in development of vaccines. Depending upon the licensing arrangement, these licensees may also sub-license these life saving drugs to increase supply. It may be contended that, these are the exact same functions which will be performed as a result of compulsory licensing but, a forceful intervention of state is largely different from individual mutual cooperation among players in the market. As stated before in this article, in a decentralised approach the players possess important 'knowledge' for sustainable and profitable distribution of vaccines.

The mutual cooperation among the pharma companies play a major role in the pandemic. Such as the collaboration of Moderna, Pfizer and BioNtech has gained momentum in production and distribution of vaccines. The Compulsory Licensing is an extreme phenomenon to try and ensure the production and distribution of vaccines not only in India but also across the world.

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[27] Beall, Reed & Kuhn, Randall & Attaran, Amir. (2015). Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement. Health Affairs. 34. 493-501. 10.1377/hlthaff.2014.0658.

[28] Supra 6

[29] Public Citizen. Compulsory licenses and right to health litigation: Kaletra campaign [Internet]. Washington (DC): Public Citizen; c2014 [cited 2015 Jan 13]. Available from: http:// citizen.org/Kaletra-campaign

[30] Friedman MA, den Besten H, Attaran A. Out-licensing: a practical approach for improvement of access to medicines in poor countries. Lancet. 2003;361(9354):341–4.

The complex infrastructure necessary to adequately increase the drug production is extremely arduous and complex. As mentioned, the coordination/collaboration and technical expertise which is required for efficient supply and distribution of vaccines is necessary. The move by a welfare government may be able to produce a feasible solution for a temporary time frame but in the longer run, the technical expertise, innovation and government policies play a far more crucial role. Incentivisation of a patent plays a vital role in the development of an invention , especially in pharmaceutical sector because as the vital intellectual information in this field is constantly under supplied.

The companies are incentivised to produce large amounts of vaccine, even at a lower price when they retain the power of knowhow as, they are much better placed to understand the cost vs benefit analysis. The best price of the product may also be achieved through tiered pricing, pooled procurement, compulsory licensing etc. As the best price is often the equilibrium price or the Austrian economists call it, the market clearing price when the forces of demands and supply accurately arrive at a specific point. Therefore, in order to arrive at an ideal price which is feasible for large scale distribution of vaccines may be attained by other processes.

Conclusion

It is trusted that this period will get more difficulties terms of conceding/dismissal of Compulsory Licensing for more protected medications. More ion is yet to be seen between Indian pharma goliaths and bigger MNCs. The working of Indian Patent office in managing CL case will likewise realize greater lucidity the eventual fate of CL in India and the standards won such laws in India. Albeit patent empowers syndication and overpricing, it is an essential wickedness in light of the fact that without patent security firms have no motivation to grow new items. Accordingly, patent security is important to guarantee development; the patent is in this way a flawed yet successful instrument to advance the advancement of new items.

As discussed in this article, compulsory licensing is a prominent tool for policymakers to look up to increase the production and distribution of drugs and medicines amidst the crisis. It has been discussed , the specific circumstances in which the compulsory licensing is invoked. Though, it is an efficient mechanism previously adopted by various governments and even the Indian government, it has to be borne in mind about the limited advantage is offers. The invention of vaccine has surely created a new hope in combating the menace of virus but, its usage and distribution to large masses still remains a challenge. The adoption of radical government policy such as compulsory licensing may not be an ideal move given the limitations. Hence, the policy makers are required to devise a balancing policy which incentives the inventors and provide necessary health care to masses at large, by creating a suitable environment for intellectual property to thrive.