International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

Pharmaceutical Patenting In India: A Detailed Analysis

A. Guru Charan
BBA LLB

Date of Submission: 25-12-2020 Date of Acceptance: 10-01-2021

ABSTRACT: Health is the basic Human Right that has to be provided to all the people by their respective nations. But the system of patenting is putting a barrier for the same as the grant of pharmaceutical patent will give monopoly to the company whose main motive is profit making. The aspect of motivation being one of the purposes of patenting, the companies cannot be held liable for pricing their inventions high. This paper deals with the problems that are being faced by the third world countries and developing countries due to the introduction of patenting system. It hinders access to the lifesaving drugs for poor people. There are concepts of compulsory licensing, insurance schemes for the poor people, etc., which prefers public interest to patent owner's interest. Keeping the health of the public as an important factor, there are several judgements pronounced by the Supreme Court of India which will be analyzed in this paper. The paper also criticizes the way pharmaceutical patenting is regulated as it is neglecting the interests of the patent owner which will affect the society because it demotivates them from proceeding with further inventions. Eventually, the paper will be concluded by suggesting few guidelines that have to be followed for proper regulation where the interests of both owner of patent and public are balanced so that the third world countries and developing countries can also provide access to life saving drugs for the poor people.

Keywords: Health, Compulsory licensing, insurance, Pharmaceuticals, Human Rights, Patents.

I. INTRODUCTION:

India has been endeavoring to modify patent law with regard to pharmaceuticals in consideration with the domestic health needs, underlining more on the common man needs, making sure it is in line with the country's development. A large part of population in India is surviving below poverty line with utmost difficulty as their pockets are empty to spend on medical expenses which clearly projects the problem of health crisis due to the defectiveness with respect to healthcare and the accessibility, affordability and availability of the medicines in India.[1]Meanwhile, during 1980s, India was providing medicines at a price which can be afforded by anyone as there was no recognition of product patents for pharmaceuticals erstwhile India taking membership in the World Trade Organization (WTO).[2]Many national and International organizations have put a pondered effort to standardize the laws governing Intellectual Property laws. The process of standardization, however, has not been free from disagreement, especiallyin concern with thepharmaceutical patents law.The main reason behind this is the ongoing conflicts among the large, multinational pharmaceutical companies, and developing nations that has the deficiency of both the infrastructure and capital to establish their own self-surviving pharmaceutical industries.[3]Theacclamation for the advent of the generic industry has tobe given entirely tothe Patents Act enacted in 1970 that replaced the colonial Patents and Designs Actof 1911. Two important provisions of Patents Act, 1970, were largely influential in the growth of local entrepreneurship in the pharmaceutical industry. The first step taken was to terminate the product patent regime which covers all the chemicals and introducing a process patent regime. The second step taken was to reduce the duration of the patent

[1]Shubra Khanna, "TRIPS, PHARMACEUTICAL PATENTS AND HEALTH CARE FOR THE POOR IN INDIA" *ILJ Law Review* 71-72 (2016).
[2] Biswajit Dhar and Reji K. Joseph, "The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS" *Springer Link* 300 (2019).
[3] William J. Bennett, "Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India" *Washington University Global Studies Law Review* 535 (2014).

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

rights with respect to the pharmaceutical processes to 5 years from grant or 7 years from the date of application, whichever was shorter, in contrast to14 years for all other fields of technology. The process patent regime permitted theIndian companies to exploredifferent processes to produce generic versions ofproprietary drugs.[4]With all these aspects taken into consideration, this paper deals with the difficulties related to technical aspects of pharmaceutical patenting system in India and attempts to give a solution for the same.

TRIPS influence on Patenting system:

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of IntellectualProperty Rights (TRIPS) [5]obliges all nations to grant pharmaceutical patents. Except the Least Developed Nations,remaining WTO members whohave not permitted pharmaceuticalpatents when TRIPS came into effect, have to start granting patents until 2005.TRIPS necessitated the members to receive and hold applications in the mailbox throughout the transition period. Thus, ifin a respective country pharmaceutical patents were to be granted as of 1999, from 1995 to1999 the country use to receive applications in the mailbox which would be examined as of1999, besides the other applications received from that date onwards.During the Uruguay Round Trade negotiations of the late 1980s and the early 1990s, India[6]hadchallenged TRIPS along with the other nations. India opposed the insertion of rules inintellectual property policies of the nation and practices in the international trade regime.Oncethe trade-IP linkage was formed and TRIPS negotiations began, India obstinatelychallengedthe following obligation that all nations shouldgrant patents topharmaceuticals. The product patents have been terminated in India since 1970 though process patents were still being granted. The deficiency in patent protection in India overlapped with substantial development of thelocal pharmaceutical sector, and TRIPS was thus distinguished as a serious threat. India waited until 2005 to grant patents for pharmaceutical products which would be the maximumperiod allowed. In fact, India is the only countrythat has used the transition period in full andpostponed pharmaceutical patenting until 2005. And, also in resenting compliance with the country'snew international obligations, which were there in 1999 India also started to receive applications in a mailbox which willbe examined as of 2005during the operation of product patent regime.In 2005, while proposing the final amendments to the Patents Act which shall allow patents forpharmaceuticals, the Indian government introducedsection 3(d), which will put a blockage for secondary patents.[7]The WorldTrade Organization (WTO) Trade Related Aspects of Intellectual Property Rights Agreement(TRIPS), however, lays down the minimum standards which will be useful for the protection of intellectual propertyincluding pharmaceutical patenting. TRIPS propose safeguards to eradicate negative effects ofpatent protection or misuse of patent. Trade-Related Aspects of Intellectual PropertyRights(TRIPS) endeavors to hit an equilibrium between the long-term social objective which is to provide incentives for forthcoming inventions and creations and the short-term objective which is toallow people to make use of prevailing inventions and creations so that both the parties may be benefitted. TRIPS try the difficult task ofmaintaining balance between private and public interests. On the one hand, the interest of pharmaceutical companies who put in a lot of investments in research and development of drugs is being protected andon the other, the member nations are given with proper infrastructure to protect public health. TRIPS agreement states that the protection and enforcement of the Intellectual Property Rights should result in the progression, transfer and dissemination of the technological innovation so that both producers and users of the same are benefitted thereby resulting the balance of rights and obligations.[8]The member nations are given liberty to encompass required nations provisions in theprevailing laws and regulations to protect public health and nutrition by the TRIPS agreement. It states that member nations may take measures during the amendment of the laws in such

[4]*Supra* note 2.
[5]Bhaveen N Sampat& Kenneth C, "Indian Pharmaceutical Patent prosecution: The changing role of section 3(d)" *PLOS ONE* 3 (2018).
[6]*Id.*
[7]*Id.*
[8]"Section 3 of the Indian Patents Act." *LawTeacher.net.11 2013. All Answers Ltd., available at:* <https://www.lawteacher.net/free-law-essays/commercial-law/section-3-of-the-indian-patents-act-commercial-law-essay.php?vref=1> (last visited on March 03, 2020).

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

a manner that public interest is given more importance than their socio-economic and technological developments so far as the measures taken are in conformity with the provisions of the agreement and also they should not lead to abuse of Intellectual Property rights by the right holders and thereby restraining trade and technological development.[9]Article 27 of the TRIPS also allows the member nations to exclude from patentabilityinventions which are necessary to protect public health etc. It statesthat member nations may avoid from granting patents if it is vital for the public, animal or plant life or if it is prejudice to the environment inasmuch as the reason is genuine and legitimate and not just because it is prohibited by their laws.[10]So, TRIPS has given member nations enough flexibility to incorporate the necessary provisions under the national legislation so that the interests of the common people of thecountry can be protected. India, on the basis of these flexibilities, has encompassedvarious provisions in theIndian Patent Act, 1970 so that the public health can be protected.[11]

Section 3(d): Prevents patenting on minor changes:

There is an important provision under the Indian patent law which shall prevent the grant of patents on the basis of minor modifications of known substances. Section 3(d) [12]does not permit grant of patents on "mere discovery of a new form of a known substance or the mere discoveryof different property or differentuse for a recognized substance or of the sheer use of a recognized process, machine or apparatus unless such known process results in a different product or following: employing at least one new reactant". There is an explanation provided to thissection which states that the substances will be regarded as different only when they differ in properties with respect to efficacy.[13]. Themain intention behind the exclusionis to ensure that a product can be taken into consideration for the grant of patent onlywhen the applicant is able toprove that the claimed invention has "enhanced efficacy"over aprevailing product.[14]

Discussions in the Uruguay Round negotiations has led to the adoption of theTRIPS Agreement which provides the basis for Section 3(d). Participants resided on the setbackssurfacing from too short a period of patent protection torecover the returns of investments that were made in research and development (R&D). They,therefore, argued that new rules and standards of intellectual property (IP) protectionwere required which includes longer period of patent protection. This, they lectured as a reason thatwould necessarily incentivize R&D activities so that new molecules can be produced.These arguments were consistent with the persuasive position taken byDouglass North, who had argued that "development of a patent system and other laws protecting intellectual property … encouraged the growth of innovation". This suggests that longer term of patent protection can be rationalized only when innovatorsprovide innovative products and processes rather than minor modifications ofknown substances. In other words, it can be contended that granting 20-year patentprotection for minor modifications of prevailing substances would be identical to terriblerent seeking and would therefore lead to anti-competition and anti-innovation.[15]Section 3(d) essentially provides for a harder standard for getting patents granted. The companies have to make sure their pharmaceutical products must establish that the new versions has morebenefits than that of their earlier versions whose patents got expired.[16]According to section 3(d) of the Patents Act, 1970, India is in a position to put a stop to"evergreening," which critics describe as a "common abusive patenting practice" where pharmaceutical companies try to cover patent protection by makingminor changes to prevailing drugs. Predictably, India's strict patent

[9] B&B Associates LLP: Advocates & Legal Consultants, *Novartis Ag Vs. Union of India & Others,* 2013, *available at* <https://bnblegal.com/landmark/novartis-ag-vs/> (last visited on March 03, 2020)
[10] *Id.*
[11] Dr. Pradip Kumar Das, "Patent Law, TRIPS & Protection of Public health in India: A Review" 4 *Journal of Law and Legal Jurisprudence Studies* 293-294 (2017).
[12] The Patents Act, 1970, s. 3(d).
[13] William J. Bennett, "Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India", 13 *Washington University Global Studies Law Review* 535 (2014) *available at:* <http://openscholarship.wustl.edu/law_globalstudies/vol13/iss3/12>(last visited on March 4, 2020).
[14] *Supra* note 6 at 295-296.
[15] *Id.*
[16] *Supra* note 13 at 544.

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

regime has generated dissatisfaction among large multinational pharmaceutical corporations interested in utilizing India's growing market.[17]

Analysis of Novartis Judgement:

Lately, few large multinational pharmaceutical corporations have taken their disappointments with the Indian patent system to court.The struggle of Novartis with the Indian patent regime started way back in 1993, when it filed for patents throughout the world for its manufacture of the molecule imatinib.According to Novartis, the only way the molecule can be administered to cancer patients is as imatinib mesylate.The resultant drug is patented in forty nations as Glivec (Gleevec in the United States) presently.After the establishment of WTO, TRIPS has been passed in 1995 in which Novartis applied for patent for Glivec in India in harmony with the "mailbox" obligation.In January 2006, the Madras Patent Office has rejected the application on the ground that there is no significant difference in the efficacy with the prevailing substance.Following the incorporation of section 3(d) of the 2005 Act, the Patent Office pronounced that Glivechas not provednovelty, inventiveness and the increased efficacy which is mandated by the law.[18]. In response, Novartis petitioned theMadras High Court in May 2006, arguing that the Controller General of Patents has failed in reviewing properly as section 3(d) is not in conformity with the provisions of the TRIPS agreement and also violates Article 14 of the Constitution of the India.[19]The Madras High Court adjudicated Novartis's case which challenged the constitutionalityofsection 3(d) and its adherence to TRIPS and thereby the Intellectual Property Appellate Board (IPAB) has reviewed the reason behind the rejection by the Patent Controller[20]. The High Court as well as the IPAB restored decisions against Novartis.The Madras High Court while answering the question of compliance with the TRIPS concluded thatthe Court has no jurisdiction on International matters and that the proper venue for such an issue would be the WTO.The matter has been appealed to the Supreme Court of India where the Supreme Court pronounced its decision byupholding the previous court rulings in which Novartis failed to demonstrate Glivec's enhanced or superior efficacy in harmony with section 3(d).The Court, however, did not findany requirement to enunciate a single, exhaustive definition for"enhanced (therapeutic) efficacy"so as to come to a conclusion. The Court also specified that Novartis case should not be interpreted as a general prohibition of all patents for progressive inventions of chemical and pharmaceutical substances[21].[22]

Validity of section 3(d):

The major allegation of the Novartis is that section 3(d) is non-complying with TRIPS.The commentators claim that the WTO would rule it against the Novartis if it the matter goes before it.Article 27 of the TRIPS Agreement is their basis for the same as a fair amount of flexibility is being provided to member nations during the enactment of patent laws so that the national interest can be protected and that the law is in conformity with the same. However, the nations are not allowed to make laws that are arbitrary.[23]Article 27 of the TRIPS Agreement states that patents shall be granted to any invention if they are new, involve an inventive step and are capable of industrial application. Providentially for WTO member nationslike India, many of the termsmentioned in TRIPS have been left undefined.Article 27 has permitted India to formulate its own standards for patentability, as illustrated by the section 3(d) which mandates the presence of development from the existing efficacy.The Supreme Court in Novartis AG v. Union of India[24]statedsimilar points in its pronouncement which concerns about the conformity of Indian patent laws with TRIPS, though it lacks jurisdiction to rule conclusively in such matters. Professor Shamnad Basheer argues whether section 3(d) is in conformity withTRIPS as it is based on the construction of the term "efficacy."[25][26]

[17] *Supra* note 3 at 545-548.
[18] *Supra* note 13 at 546.
[19] William J. Bennett, "Indian pharmaceutical patent law and the effects of Novartis AG. v. Union of India", *The Free Library,* September 22, 2014, *available at* <https://www.thefreelibrary.com/Indian+pharmaceutical+patent+law+and+the+effects+of+Novartis+AG+v....-a0410506403> (last visited on March 03, 2020)
[20] *Supra* note 13 at 547.
[21] *Supra* note 13 at 548.
[22] *Supra* note 3at 549-550.
[23] *Supra* note 13 at 549.
[24] AIR 2013 SC 1311,
[25] *Supra* note 13 at 550.
[26] *Supra* note 3 at 550-552.

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

Public interest under the Novartis decision:

Many proponents of affordable healthcare were worried that decision might come in favor of Novartis which would be a "death sentence" for patients who cannot pay for medicines and treatment. The challenge of providing affordable pharmaceuticals is especially proclaimed in nations like India, where the insurance system has not been developed.

The main reason behind the IPAB's decision to uphold the patent office rejection in granting the patents to Glivec is to make sure that the drugs are affordable to all sectors of the people in India.According to section 3(b) of the Patents (Amendment) Act, 2005,patents shall not be granted if the objective of the same is commercial which is prejudice to human, animal and plant life and also hazardous to the environment.[27] Following this provision, the IPAB concluded that the Glivec patent was rejected on two grounds. The first ground being the absence of enhanced efficacy as mandated by section 3(d) and the second ground being the grant of patent will lead to exorbitant pricing of the drug which cannot be afforded by the common man.[28]

ISSUE: WHETHER THE CONCEPT OF COMPULSORY LICENSING BENEFITTING BOTH PUBLIC AND PATENT OWNERS?

Concept of Compulsory Licensing in India:

The Indian patent act states"an application for the grant of compulsory license can be made only after three years from the date of the grant of patent unless exceptional circumstance like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date". Three wide-ranging grounds for the grant of compulsory licenses havebeen suggested thus;

i) reasonable requirements of the public with respect to the patented invention have not been satisfied[29];
ii) the patented invention is not available to the public at a reasonably affordable price;[30]
iii) the patented invention is not worked in the territory of India. [3132]

The patents act sets out the circumstances under which "reasonable requirements of the public" would not have been met. Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which, in turn, affects:

i) Development of new trade or industry in the country;
ii) Establishment or development of commercial activity within India; and
iii) The major impact of this provision can be felt in the pharmaceutical sector where India could well emerge as a major supplier of the generic pharmaceutical to those developing nations which do not have sufficient domestic manufacturing facilities (development of the export market for the patented article) The purpose of granting compulsory licenses in India is to see that the patented inventions are worked on a commercial scale in the territory of India and that the interest of any person working or developing an invention is not prejudiced.[33]

Advantages & Disadvantages of Compulsory Licensing:

As regards concern for protection of IPRs, thenations can be divided into twogroups whose behavior is totally different depending oninterests of each group. It is a general observation thatdeveloping and under developed nations are not so muchworried about protection of IPRs and are not ready tospend on development of a costly administrative mechanismto implement the protection of intellectual property rights. Thereare various reasons behind this intentional casual approachtowards protection of IPRs.

Firstly, permissibility of piracy helps both developing and underdeveloped nations to provide

[27] *Supra* note 19.
[28] *Supra* note 13 at 551.
[29] *Supra* note 2.
[30] Bharadwaj A., Devaiah V., *et.al.* (eds.) *Multi-dimensional Approaches Towards New Technology*, Local Working of Patents: The Perspective of Developing Countries, 315-337, (Springer, Singapore, 24 July 2018) *available at*https://link.springer.com/chapter/10.1007%2F978-981-13-1232-8_15#citeas (last visited on March 03, 2020).
[31] Prarthana Patnaik, "Government's Dilution of Patent Working Disclosure Requirements and the Implications on Compulsory Licensing", *Spicy IP,* July 8, 2019, *available at* <https://spicyip.com/2019/07/governments-dilution-of-patent-working-disclosure-requirements-and-compulsory-licensing.html> (last visited on March 03, 2020).
[32] The Indian Patents Act, 1970, s. 84.
[33] *Supra* note 1 at 87-88.

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

required goods and services to their citizens at cheaper prices.

Secondly, it provides employment to a lot of people as there will be many local industries that will be opening up for imitating the licensed goods.

Thirdly, the third world countries can progress in science and technology due to the maximum accessibility that is being provided in the field of intellectual property.

Fourthly, as more than 80% of patents are held by the people of technologically developed nations and it being difficult for the third world nations to develop mechanisms for the regulation of IPRs of advanced states it would be easy for them to get licenses and use the products for the benefit of their people.

Disadvantages:

Developed nations, on the differing side, are very muchworried about protection of intellectual property rightsbecause their development and economic growth, to a great level,depends on investment in research and development. Theirpatent system incentivizes to accelerate theirtechnological progress, boost their productivity, andenrich their world trade position by strengthening theireconomy. In Italy, for instance, pharmaceutical researchand development increased by more than 600 percent in adecade after Italy approved drug patent law in 1978[34]. The exclusive right which is limited has to be given to the patent owner to recover his costs that he had invested on research and development which would incentivize him and motivates him to invest in the research and development for the forthcoming inventions.If there is something which obstructs with the exclusive right of the patentee would probably disincentivize him to invest in research and development.The main reason behind the growth of the developed nations being extensive inventive research they are more worried about the protection of IPRs and they resist any obstacle or restrictions in the enjoyment of their exclusive rights of the patentee of the invention.“Compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right toother upon the terms decided by the government”[35].Though the Government pays the royalty amount to the owner of the patent still there is no consent given by him. Compulsory license is thereforeinfringing the exclusive rights of the patentee of theinvention. There will be a weakening of incentive to innovate and create new works due tocompulsory licensing. Theremust be an incentive to invent because commercialization ofnew ideas involves money and effort and the raising economy is also one of the factors for invention. “The amount ofroyalties set by the state granting a compulsory license cannot be considered as an incentive for further research; it is no way near the potential financial benefit which the patent owner would have enjoyed on an exclusive basis”. Compulsorylicensing is therefore opposed by many developed nations.The nations which implement compulsory licensingprovisions are criticized by the United States and the foreignmultinational firms because the licensee reaps the benefits ofothers research without contributing their fair share to thecosts incurred on research and development.

Critics of compulsory licensing further contend that over 90percent of the drugs included in the Essential Drugs Listpublished by the World Health Organization (hereinafterWHO) are not protected by United States patents. The problem of compulsory licensing is two faced ascompulsory licenses may raise safety concerns where theconsumers of forged products are at risk because theinferior quality unapproved generics may contain manydangerous impurities. But this may be not that a great concern as medicines can be sold only after the approval of respected authorities. If the medicines are sold illegally for cheaper prices which the public tend to buy as the other medicines are unaffordable, then arises the problem. Furthermore, there are many diseaseswhich aredistinctive to the third world nations. If patentprotection is safeguarded in these nations, it would provide anincentive to multinational pharmaceutical companies to invest in the research toexamine these diseases which wouldotherwise chronic because multinational pharmaceutical companies carry outinvestment on research and development only after consideringthe potential financial gain. Improbability about patentprotection may stop search for new drugs which are much required bythird world nations. Absence of business-friendly legalclimate may disincentivize patent owning firms to start any newventures in a country that enforces compulsory licensingprovisions.In addition to this, use of compulsory license may causetrade friction with

[34]Muhammad Zaheer Abbas, “Pros and Cons of Compulsory licensing: An analysis of Arguments” 3 *International Journal of Social Science and Humanity* 254-256 (2013).
[35]*Id*. at 254.

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

the nations which produce patenteddrugs. Not only the enforcement of compulsory licensing discourages but also the fear that it would be enforced will have a terrible effect on trade relations between nations. As the local industries are heavily dependent on the income that comes from the foreign companies, thedecision of a government to grant compulsory licenses maycause a huge loss of foreign direct investment. In an idea toprotect their products from compulsory licensing, thepharmaceutical companies may find an alternatelocation fortheir clinical trials. Therefore, a country may lose a potentialsource of economic growth by issuance of compulsorylicenses. Furthermore, as a result of weak intellectualproperty regime, a country becomes less competitive, andbrain drain is an observable result. It would be dreadfulfor such nations to hold their human capital as thebrilliantscientists and researchers leave the country in search of betteropportunities somewhere else in the world.Another important contention against compulsory licensingof pharmaceuticals is that the pharmaceutical companiesnormally reduce their prices, even to the extent of mere cost ofproduction, of their much-needed products in the leastdeveloped nations on humanitarian considerations which makes no sense for the concept of compulsory licensing.Thus, in the opinion of developed nations, compulsorylicensing is neither an effective nor necessary cost controllingmeasure.

Advantages:

The contentions which are in favor of Compulsory Licensing are:

Firstly, threat of non-voluntary licensing may be helpful innegotiating anaffordableprice of the required drug tolerableto both the patent owner and the government.

Secondly, thoughts of 'neocolonialism' might raise due to the antagonism towards compulsory licensing by progressed nationsbecause patent protection disparately favors advancednationsbecause developing nations have fewer patents toprotect.

Thirdly, compulsory licensing of pharmaceutical patentsis inevitable sometimes as it is necessary to save the lives of population as it gives access to drugs at cheaper prices and also the monopoly existing in the market over such drugs will be eradicated which is a disadvantage of patenting.

Fourthly, compulsory licensing helps in resolving the disputes between developer and original patentee which leads to deadlocks by compelling the original patentee to come to theterms of an agreement with the developer which can thereforehelp in generating rapid technical progress.

Fifthly, compulsory licensing also helps in dealing with the situations like 'patent suppression' by pressurizing thepatent holders to work on the patent to maximum benefit of the nation.

Sixthly, if anyone refuses compulsory licensing then it may lead to an obstacle in utilizing the inventions in future for technological progress or economic growth.

Seventhly, the concept of compulsory licensing is in no way a discouraging factor as they can cover their losses by selling the products in developed countries at higher prices as people over there can afford those prices and also that the developed nations have very rigid patent rules where they can get absolute protection.

Eighthly, it is contended that compulsory licensing plays akey role in developing and promoting a local genericpharmaceutical industry.

Lastly, apart from all these economic contentions, compulsory licensing is used for protection of the public interest which can bedefended on the basis of social justice as strictobservance of patentprotection can hardly be suggestedat the cost of humanlives.[36]

This implies that there are both advantages and disadvantages to the concept of Compulsory Licensing. The disadvantages are mainly due to the deficiency of the authorities to regulate the concept of compulsory licensing properly and also the lack of proper inspection check on the local companies that are involved in counterfeiting the licensed products. Also, the royalty amount has to be properly negotiated so that the owner of the patent will not suffer any losses. If the disadvantages are tackled properly and a solution is suggested to all those disadvantages then the concept of compulsory licensing will not be a problem to both public and owner of the patents.

II. CONCLUSION:

There are both advantages and disadvantages because of the concept of Compulsory Licensing. The emphasize should be laid on advantages and also there must be proper regulations so that there would not be any disadvantages. The main reason for disadvantages

[36] *Supra* note 34 at 255.

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 1 Jan-Feb 2021, pp: 96-103 www.ijprajournal.com ISSN: 2249-7781

is improper regulation. There are also many alternatives to Compulsory licensing like providing insurance covers to all the people who are below poverty line, to sell the medicines at the cost of production for them basing on the locations the medicines are being sold and the people buying them. The companies themselves are reducing the price of the medicines to make it more affordable for the people in the third world nations and the developing countries. When companies themselves are taking such initiative then the concept of compulsory licensing makes no sense. Only when the companies are reluctant to sell their products at affordable prices the concept of compulsory licensing can be applied. Even then care has to be taken that the people who have acquired license should not diminish the quality of the actual product which would affect the consumers. If that happens then the main objective of compulsory licensing i.e. for public health will be backfired. The main reason behind patenting being protection of their products from being replicated or forged, the concept of compulsory licensing breaks that very basic principle of patenting. Also, the other reason being gaining profits by recovering money they invested in Research and Development the royalty amounts the Government pays them is in no way an encouraging factor to go for forthcoming inventions. So, the alternatives of compulsory licensing must also be considered as the concept of compulsory licensing is biased only towards the public health where there is no incentivizing factor for the inventors or scientist who put in lot of money and time in research and development.In this way, pharmaceutical patenting can be regulated where care is taken to make sure there is no miscarriage of the concept of compulsory licensing and also that the patentee of the invention is getting his profits which incentivizes him to involve himself in future researches. Also, if the problems related to compulsory licensing are solved then the patenting system of pharmaceuticals will be the best among the other developing countries as it would be beneficial to both public and patent holders.