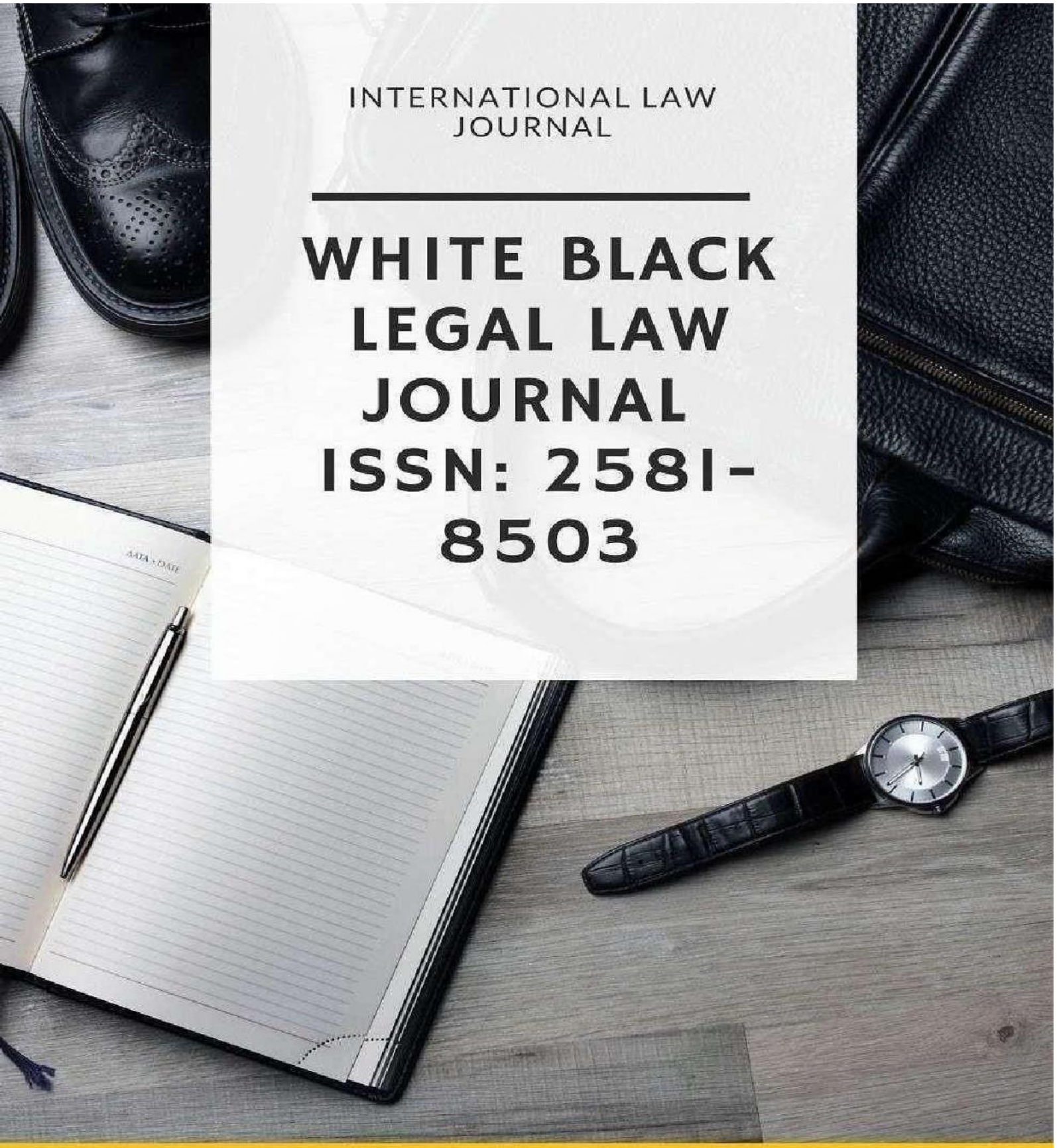

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THE EFFECT OF COMPULSORY LICENSING ON INNOVATION IN THE PHARMCEUTICAL SECTOR

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ABSTRACT

Access to health-care facilities is a primary right of every individual. Although, right to health is considered as an integral part of right to life. Compulsory licensing involves manufacturing and distribution of patented things by other companies. This is done to prevent abuse of monopoly through exclusive patentee's rights over patent. Due to technological differences and lack of infrastructure people opt for compulsory licensing in order to provide the life-saving drugs at affordable rates. This paper assesses the positive and negative effects of compulsory licensing and impact on innovation. After providing a background of patent law and generic drugs, the analysis of compulsory licensing and operations in pharmaceutical sector is done. This paper is based on doctrinal research.

Keywords: Compulsory Licensing, TRIPS, Innovation, Doha Declaration, Royalties, access to drugs.

LITERATURE REVIEW

Most of the inventions have been developed based on previous inventions. Although, patents can hinder future innovations. Inventions in pharmaceuticals can be classified into basic inventions and second-generation inventions. An invention is considered a breakthrough, which opens doors for future innovations, referred to as a basic invention. Usually, second-generation inventions are improvements and applications of the basic inventions. The distinction between innovation and invention has been analyzed in Schumpeter's Theory of Economic Development.[1] In January 1995, when WTO came into existence, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement came up with the concept of

[1] Hyewon Ahn, 'Pharmaceutical Inventions, Innovations & Products', *Second Generation Patents in Pharmaceutical Innovation* (1st edn, Nomos Verlagsgesellschaft mbH 2014) <https://www.jstor.org/stable/j.ctv941t5f.5> accessed 18 August 2024.

minimum standards. This aids in protecting and enforcing intellectual property rights.[2]As, patent protection provides exclusive rights to inventors. Sometimes, this may lead to charging of higher prices as compared to those that would prevail under the relevant market. Subsequently, some consumers can't afford such patented products.[3]

It is the agenda of the developed countries to provide high-priced pharmaceutical products to developing or under-developed countries through compulsory licensing. Some patent holders voluntarily license their products to generic manufacturers, in the form of Medicine Patent Pool. If there is no policy for voluntary licensing for a particular drug, then compulsory licensing tends to be a viable and feasible option.

Generally, consumers have no choice in purchasing the products, particularly in pharmaceutical sector. The pharmaceutical products fall under necessary goods, with low price elasticity of demand. So, prices need to be regulated based upon the essentiality of the drug. In India, there is a list for such essential drugs i.e., National List of Essential Medicines of India (NLEM) which need to be revised after every 5 years. In public health crisis some of the medicines or drugs taken through compulsory licensing for effective use which are listed under this list.[4]

Compulsory Licensing refers to the rights granted to exploit a patent without patentee's authorization. Compulsory Licensing used as a remedy in antitrust issues. It also helps in avoiding anti-competitive practices in a relevant market and protection of consumer choices.[5] Once, compulsory license issued the recipient engages in strategic imitation on expanding public access to specific drugs and medicines.[6] The effect of strategic imitation and incentives to innovation wholly depends upon the rate and manner of determining royalties which need to be paid to the patentee.[7] Usually, the compulsory licensing schemes include a standard for setting royalties to be paid to the patentee. Under U.K. patent law, the royalty rate must be reasonable enough.

In 1984, the Hatch-Waxman Act formally known as Drug Price Competition and Patent Term

[2] Anthony Johnson, 'An Impediment to Personalized Medicine Commercialization Is the Lack of Understanding of the Value of the Testing' (2016) 22 Journal of Commercial Biotechnology <http://commercialbiotechnology.com/index.php/jcb/article/view/732> accessed 8 September 2024.

[3] Eduardo Urias and Shyama V Ramani, 'Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence' (2020) 3 Journal of International Business Policy 367.

[4] Tripathy Ishita G., Yadav Surendra S. and Seema Sharma, 'Impact of Product Patents on the Indian Pharmaceutical Industry: A Summary of Recent Literature' (2012) 59 The Indian Economic Journal 34.

[5] 'Journal of Medical Society' <https://journals.lww.com/jmso/fulltext/2020/34020/compulsory_licensing_of_patents_and_its_effect_on.1.aspx> accessed 9 October 2024.

[6] https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

[7] Adi Gillat, 'Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry' (2003) 58 Food and Drug Law Journal 711.

Restoration Act which established a legal and regulatory framework for biopharmaceutical industry.[8] The U.S. biopharmaceutical industry thrives with a balance of innovation and price competition because of this Act. The level of generic medicines increased at a rapid rate, after the enactment of Hatch- Waxman Act. During the early 1980s, the level of generic dispensing of drugs was round 10%, and in the mid-1990s it reached a level of forty percent.[9] This sudden increase caused by the market and economic factors. Generic competition has continued to accelerate in terms of innovation and growth. There was decline in sales of the patented drugs.[10] Regulated licensing can mitigate the sensitivities of pharmaceutical innovation to some extent.[11]

Sections 84 to 94 of the Indian Patents Act, 1970 contain regulations regarding compulsory licensing. The applicant needs to prove that there is prime facie case. According to Section 84, any interested party may apply for a compulsory licensing three years after the grant of the patent.[12] Also, the widespread use of the compulsory licensing adversely impacts innovation. The pharmaceutical companies incur huge losses due to compulsory licensing, results in reduction of funds for reinvestment purpose in R&D.[13]

INTRODUCTION

Intellectual Property Rights grants exclusive rights to the inventor or author. Patents play an important role in public health and access to medicines and drugs. The patented drugs are sold in their original or alternative forms, i.e., generic drugs that are available in the market. Affordability and availability the major concerns for the government in the case of life-saving drugs and medicines. India has experienced a significant surge in the development of medicines and drugs during the late 19th and early 20th centuries.[14] The Constitution of India guarantees right to health under Article 21 to its citizens. Moreover, Article 47 expressly states that it is the obligation of the State to improve public health.[15] So, constitutional goals need to be

[8] https://www.bloomberglaw.com/external/document/X9P0AP7G000000/health-care-operations-compliance-professional-perspective-hatch
[9] Gillat (n 9).
[10] ibid.
[11] ibid.
[12] Jamal Ibrahim, Dr Abdullah and Dr Mohammed Jamshed, 'Impact Of Compulsory Licensing On Research & Innovation With Reference To Indian Pharma Companies' (2021) 18.
[13] ibid.
[14] Subhadeep Chowdhury, 'MEDICINE AND COLONIAL PATENT LAW IN INDIA: A Study of Patent Medicines and the Indian Patents and Designs Act, 1911 in Early- Twentieth-Century India' (2020) 75 Journal of the History of Medicine and Allied Sciences 408.
[15] Ranjan Babu Joseph, 'An Exploratory Study on Compulsory Licensing of Pharmaceuticals and Issues Related to It' (2022) 4 Issue 3 Indian Journal of Law and Legal Research 1.

achieved while balancing the private rights of the patentee. In November 2001, the Declaration on the TRIPS Agreement and Public Health (also known as Doha Declaration) stated that member countries could use compulsory licensing in case they face difficulties in manufacturing such pharmaceutical products. When India signed the TRIPS Agreement, 'mailbox' provision was incorporated in intellectual property laws.[16]

Apart, from price reduction, compulsory licensing can be part of industrial policy in order to foster local manufacturing capacity. There is a need to build standards for local firms, in order to be at par with International pharmaceutical giants in terms of technological and manufacturing capabilities.[17]

Patents and drug products are closely related. The exclusive rights granted by patents are essential to pharmaceutical products. The drug price tends to be higher because of such exclusivity. Although, governments reduce such costs through schemes like compulsory licensing. By compulsory licensing, any interested party can use and exploit the patented invention without the permission of a third party. Obviously, royalties need to be paid by the applicant at the rates decided by the government.[18] Article 31 of the TRIPS Agreement states that adequate remuneration need to be paid the patentee in case of the compulsory licensing.[19] Generally, the royalty rates are set by an agency or the court, and not by the patent holder. This prevents the inventor from recouping the R&D investment and hinders innovation.[20]

RESEARCH OBJECTIVES:

- To examine the issues associated with compulsory licensing of pharmaceuticals
- To analyze how compulsory licensing affect innovation

RESEARCH PROBLEM:

- Insufficient royalties
- Inadequate regulatory mechanism
- Hinders innovation and reinvestment in R&D

[16] ibid.
[17] ibid.
[18] Chowdhury (n 16).
[19] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[20] Gillat (n 9).

WHAT IS COMPULSORY LICENSING?

The U.S. Constitution promotes the progress of science and useful arts, by securing protection of exclusive rights for a limited time period to their respective writings and discoveries. Once a patent has been granted, then making, selling, or using it without the owner's permission amounts to infringement. Similarly, in the pharma sector, the producers are able to sell generic drugs without the patentee's permission after the expiration of the protection period. Compulsory licensing can be an exception to such exclusivity.[21] Any third party has the right to utilize the patented invention without the owner's permission by means of compulsory licensing, in exchange for payment such as a royalty, which the patent owner is required to receive. In a compulsory licensing patent, the owner simply receives royalties from third parties without taking any further action. Also, the threat of compulsory licensing encourages the patentees to grant licenses voluntarily.[22] Voluntary licensing is more suitable in nature as it reduces the cost of production and generates more revenue. Compulsory licensing increases the availability of expensive pharmaceutical products to the general public.[23]

According to Section 84 of the Patents Act, 1970, one can file an application for compulsory licensing to the Controller after the expiration of three years from the grant of a patent based on the following grounds:

- The patented invention does not meet the reasonable requirements of the public.
- The public cannot access the patented invention at a reasonable cost, or
- The patented invention has not been worked on in the territory of India.

The Controller can revoke patents for non-working after two years have passed since the date of the order granting compulsory licensing. The Controller will decide on each such application within a year of its presentation under Section 85. The terms and conditions of compulsory licensing are discussed under Section 90. Section 92A implies compulsory licensing for the export of patented pharmaceutical products in certain exceptional circumstances in order to address public health problems.

ISSUES AND CONCERNS OF CL

The Indian Government granted the compulsory license on a cancer drug that Bayer had priced so high in India that it was available to only two percent of the patients who needed it.

[21] Alan M Fisch, 'Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem' (1994) 34 Jurimetrics 295.
[22] ibid.
[23] ibid.

Compulsory Licensing for the export has been granted after 2005. India's first compulsory license was granted to Nacto Pharma in 2012 for the production of generic drugs of Bayer's Nexaver, a life-saving drug used for treatment of liver and kidney cancer. Bayer was selling this drug at a very high rate within one month's worth of treatment, costing around Rs. 2.8 lakhs. Nacto Pharma offered to sell the drug for Rs. 9,000, making it affordable for the general public. The royalties paid quarterly by Nacto Pharma to Bayer at the rate of 6% of all sales, which was in accordance with the guidelines set by the United Nations Development Programme (UNDP).[24]

Increase in the grant of compulsory licenses will disincentivize research and development. Economic factors drive innovation. Drug companies focusing on developing the most saleable drugs instead of the most needed ones. A longer protection period will increase the profits of pharmaceutical companies.[25] On the other hand, such lifesaving drugs must have greater access through compulsory licensing. Due to income inequalities, it is difficult for the State to provide essential medicines at affordable prices.[26]

Patent thickets can pose a significant threat to compulsory licensing. It refers to the overlapping of claims, which makes the innovators to commercialize new technologies in the market. One needs to license all the related technologies for production.[27] Similarly, for pharmaceutical companies, multiple licenses need to be granted for the production of generic versions of the patented drug. Companies would be discouraged from filing for compulsory licenses because of the saturation of the market with the generic versions of the same drug. The generic drugs manufactured will be unaffordable for the public in general and tends to be anti-competitive in nature.[28]

In Nacto Pharma Ltd vs Pfizer/ Roche, an application for compulsory licensing was filed by Nacto Pharma Ltd before the Controller General of Patents. Nacto Pharma manufactures generic drugs and contends that the generic version can be made at one-fifth the cost of the patented drug.[29]

Under Section 92 of the Indian Patent Act, express provisions for compulsory license upon notification by the Central Government provided. Such provisions are:

- When a situation of national emergency arises.

[24] Mansi Sood, 'NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA'.
[25] https://nujslawreview.org/wp-content/uploads/2016/12/mansi.pdf
[26] ibid.
[27] Fisch (n 21).
[28] ibid.
[29] Harshita Mathur, 'Compulsory Licensing under Section 92A: Issues and Concerns'.

- When a state of extreme urgency.
- In case of public non-commercial use.

During an outbreak of an epidemic or health crisis, such as AIDS, COVID-19, the government must initiate actions to acquire, distribute and store the necessary drugs for public.[30] Negotiations undergone with the branded drug producers to allow the generic manufacturers to manufacture the drugs for non-commercial purposes.[31]

Regulated licensing can be justified for many reasons. But it must restore competition and maintain public access at affordable rates.[32] In time of national emergency, important patented drugs available at affordable rates, so that the public in general can access it.[33] Therefore, the rates must not be high and it doesn't compensate the royalty as per the agreement.[34] Royalty is calculated based upon certain factors, i.e., the volume of product to be sold, the number of buyers, the license duration, product's market value, etc.[35] The Government fixes the royalty rates without taking into account the interests of the patentee's, resulting in a decrease in profit margins or potential losses.[36]

IMPACT ON INNOVATION AND ACCESS TO DRUGS

The transnational use of compulsory licensing adversely impacts the patent system's ability to encourage innovation. The pharmaceutical companies incur losses due to compulsory licensing. There has been a significant decline in revenues, which reduces their funds for re-investment in research and development purposes.[37]

Remdesiver is an antiviral therapeutic manufactured by the pharma giants i.e., Gilead Sciences. During the outbreak of COVID-19, regulatory authorities in the US and Japan for emergency use authorization to treat hospitalized COVID-19 patients. Remdesiver was priced at $2340 per patient (for a 5-day treatment) in developed countries, while it costs have been estimated to be $5-$10 per patient.[38]

Although, wider use of compulsory licensing to fight the COVID-19 pandemic may create undesired effects on R&D. It lowers the incentives that IPRs create for the purpose of

[30] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[31] https://www.prometheusip.com/patents/compulsory-licensing-of-patents/
[32] 'Journal of Medical Society' (n 7).
[33] https://gun.av.tr/insights/articles/determination-of-royalty-in-case-of-compulsory-license#top
[34] Joseph (n 17).
[35] ibid.
[36] ibid.
[37] Ibrahim, Abdullah and Jamshed (n 14).
[38] Urias and Ramani (n 3).

innovation. On the other hand, governments must initiate necessary agreements in order to safeguard public health.[39] A National emergency or public health crisis is a major concern for the state than incentivizing the inventors for their creations or encouraging innovation.

One of the reasons for lack of appropriate medicines is due to the lower incentives to produce them for neglected and poverty-related diseases. Due to lower value, there has been a reduction in research and development of drugs for such diseases. In any case, companies involved in research and development of drugs for such poverty-related diseases, must avoid the negative impacts of compulsory licensing in order to generate enough revenue for further investment.[40] Usually, the patentee can recoup its costs in rich markets and would not impact innovation. Moreover, the rich markets do not enforce compulsory licenses. The major concern is parallel imports. Many rich countries don't apply the principle of national exhaustion. The profits of pharmaceutical companies are reduced because drugs produced under compulsory licenses in developing countries may not be accessible through parallel imports, due to inadequate safeguards.[41] Counterfeiting drugs manufactured by other market players without obtaining a license once the right has been granted. This may lead to financial losses for both the nation and the patentee.[42]

CONCLUSION

Innovation plays an important role in pharmaceutical companies. Encouraging innovation and promotion of research and development proves to be beneficial for the development of nations. Compulsory licensing aids in the accessibility of drugs but serves as a barrier against the exclusive rights granted under patent. There must be a regulatory mechanism to set the prices of the drugs based upon the economic circumstances of the country.[43] In exceptional circumstances, violation of the patentee's rights takes place in order to prevent abuse of monopoly and promote the right to health.[44] The Indian government needs to take action and utilize the legal provisions related to compulsory licensing to regulate the market and access to medicines for life-saving drugs at affordable rates.[45] Effective implementation of the TRIPS agreement and enforcement of compulsory licensing can achieve this, ensuring that it does not discourage innovation and simultaneously upholds the interest of public health. Following the

[39] ibid.
[40] Ibrahim, Abdullah and Jamshed (n 14).
[41] ibid.
[42] Joseph (n 17).
[43] Ibrahim, Abdullah and Jamshed (n 14).
[44] ibid.
[45] ibid.

approval of the first compulsory licensing application in India, generic companies filed a greater number of applications. Moreover, the Doha Declaration states that the member countries can determine the grounds for granting licenses.[46] Accessibility and affordability are major concerns in India, considering poor coverage of public insurance, poverty-related diseases and low per capita income.[47] However, the multinational companies need to adopt different business strategies in India while working with pharmaceutical products, and the Indian companies need to find out alternative solutions for manufacturing and facilitating access to such life-saving drugs.[48]

[46] Johnson (n 2).
[47] ibid.
[48] ibid.