RESEARCH
www.commprac.com
ISSN 1462 2815

A SURVEY OF PUBLIC PERCEPTIONS ON COMPULSORY LICENSING AND ACCESS TO MEDICINES

Haranarayan Mahapatra [1] and Srinibas Nayak [2]

[1,2] Assistant Professor (Law), SNIL, Sikhya 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha, India.

DOI: 10.5281/zenodo.11613275

Abstract

Although there was anticipation that Trade-Related Aspects of Intellectual Property Rights (TRIPS) would increase the cost of patented medications, the agreement included tools to deal with this problem, therefore no one could agree on how it would ultimately affect access. As an example, one key countermeasure was compulsory licensing, which allowed for price reductions. The effectiveness of forced licensing in lowering the pricing of essential patented pharmaceuticals is, however, largely unknown. To address this knowledge vacuum, this study reviews the literature systematically on how compulsory licensing affects medication costs. A patented drug's price is expected to drop after a forced licensing event, according to 51 observations of pricing before and after the event, with a few exceptions. Furthermore, contracts with local businesses are not as likely to reduce medicine costs as required licensing purchases from the worldwide market. In the haste to increase admitted COVID-19 patients' access to Remdesivir, these results are confirmed. The significance of biologics among life-saving medications, the growth of manufacturing capacities in underdeveloped nations, and potential future procedural improvements to facilitate its implementation will all determine the prevalence and effect of compulsory licensing.

Keywords: Compulsory Licensing, IP Protection, Pharmaceutical Industry, Accessibility of Medicines.

INTRODUCTION

Due to the lack of basic medicine legislation since the 1990s and the high cost of anti-retroviral drugs (ARVs) in countries with poor or no income, there is an imbalance in the pharmaceutical patent system. Even in public health, the numbers were shocking: 40 million people in poor nations are dealing with life-threatening diseases.

As a result, India is a country that produces generic medications and is also seen as a means to provide these medications to emerging and least-developed nations.

At the national and international levels, the most significant and controversial aspects of the Indian patent law 1970, which pertains to generic medications and forced licensing, are those that serve the public interest. Several nations, including Ghana, Malaysia, and Thailand, have expressed their regrettable worry about the accessibility, price, and availability of necessary medications. Article 21 of the Indian Constitution, which protects the right to life, also includes the right to health. But Article 47 stresses once again that it is the government's responsibility to enhance public health. After satisfying the rigorous invention, inventive step, and industrial application requirements, the patentee's exclusive right will be substantially altered by the terms of forced licensing, in addition to patent issuance. Consistent with the Ayyangar Committee's recommendations, the purpose of forced licensing is to restrict the use of patents. As Per Section 84 of the Patents Act, the compulsory licensing requirements have been in place since the introduction of the law. A time restriction on a third party seeking forced licensing was introduced in 2005 as an amendment to the relevant rules.

At issue here is whether or not compulsory licensing is the best strategy to ensure that patients have unfettered access to adequate supplies of patented medications at fair prices. To achieve this goal, the industry must simultaneously seek out the most effective pricing strategy and implement it in emerging nations. Also, the Essential Commodities Act of 1955 establishes a framework for the government of India to regulate the pricing of drugs by setting prices for certain active pharmaceutical ingredients and formulations. Also, the Drug and Cosmetic Act of 1940 raises the question of what the government is doing to counteract activities that are deemed invalid and irregular. This was considered a crucial area for the operation and quality of generic medications.

Challenges with Compulsory licensing as compared across cases

A review study was carried out to get a better understanding of the challenges, concerns, and problems surrounding the acquisition of generic medications. This research included a case-by-case investigation of persuasive or compulsory licensing in several nations, including Japan, Australia, Mexico, South Africa, the USA, and India. All of the case studies served as inspiration for the various settings and circumstances. After a thorough search for all required licenses that have been awarded or contested since 1994, a database and focal cases were created to analyze the fight for access to standardized pharmaceutical medications.

India and Compulsory Licence Issues

We have been focusing on the issue of forced licensing and its impact on India's ability to get generic medications. The concept of mandatory licencing is not a novel idea, but it has recently become critically important under patent laws, especially for consumer groups and generic drug manufacturers, to guarantee the supply of the necessary medications for life-threatening illnesses to the public and their trade interests. The price of these pharmaceuticals drops dramatically when the government makes them accessible, as contrasted to when patent holders sell them to countries that need them. Compelled patent licencing for pharmaceutical items are highly expensive for residents of underdeveloped nations, yet they are forced to grant them by law for certain reasons. The production and distribution of such pharmaceuticals are authorized by the government. To address the problem of consumer deficit caused by abuse of dominant position and unjust refusal of trade or licensing, the government is considering implementing mandatory licensing as a means to join the market. Additionally, a statute for the issuance of such licenses has been enacted in India with the goals of reducing anti-competitive practices, striking a balance between compensating patent holders and encouraging the development and production of novel pharmaceutical products at declining prices so that they may be accessible to a larger demographic, and so on. As discussed in detail earlier, Chapter XVI Sections 82 to 94, of Indian Patent Act, have been added in compliance with 2002 amendment and Section 84 explicitly provides for grant of CL after three years have passed from the date of award of a patent on an application by an interested person before the controller of patents for any of the following items (along with a declaration of the existence of the interest). Further clarification is provided in Clause 7 of the same section regarding situations where existing trade, businesses, or their creation and establishment are hindered. In such cases, the public's reasonable demands are deemed unmet, the innovation need is not satisfied, either in a substantial or reasonable way, or the export market is unavailable.

Paragraphs (b) and (f) of Section 83 state categorically that patents cannot be granted to grant patent owners a privilege in the production of the patented medicine, which is a crucial component of the system of mandatory licensing for the use of exclusive patent technology. Imports of the patented medications are therefore free from their area270 as they were not included in the terms 84(1)(c) in the Indian Territory.

The aforementioned license must be extended to include the production of medicines as well, lest the patentees abuse and monopolize their export rights, resulting in massive uneven profits. It should be mentioned that according to Article 27(1) of TRIPS, the imported products are considered to be in use of patents, but the "lack of local use" might be used as a basis for TRIPS flexibility under Article 5B or f of the Paris Convention. However, India is still being treated unfairly due to the fact that the term patent research framework still includes the importation requirement. Because not all companies will set up shop in India, many argue that imports should be included when calculating medicine prices. However, there are those who argue that this will only lead to higher manufacturing costs and medication prices because local producers will be more likely to partner with their licence-based manufacturers in India, and that India is already a major supplier of generic medicines.

The controller needs to consider the innovation's core features and the capacity to implement them before granting the license, taking into account the reasons why the patentee cannot do so or the applicant's failed attempts to obtain voluntary licenses from the patentee 271.

The Patent Amendment Act of 2005 included Section 92A, which allows CL for the export of the patented invention in certain rare cases. It is said that this license and the authorized pharmaceuticals will be made accessible to produce and sell the licensed medications to those nations to tackle public health difficulties, as long as the importing country has granted its consent. Something like this was said after the Doha Declaration on Public Health. However, the Section does not recognize public health concerns; so, the exporting country has a lot of room to provide the importing country obligatory licensing272, even when there is no urgency. Furthermore, this will allow the pharmaceutical companies of the exporting nations to reap unwarranted economic gains, which will hurt the interests of the patentee.

In addition, the clause does not specify the amount of royalty or compensation to be given in place of that subsidy, and it provides the controller, to whom the application has been made, significant power to decide on the terms and circumstances of that award.

Competition Law and Compulsory Licensing

Collaboration between CL and competition law is intricate and purpose-specific. While the pharmaceutical industry's mandatory licencing program helps prevent monopolies from being used unfairly, the implementation of

By limiting some types of innovation, the rule of competition facilitates the attainment of public health objectives. The fundamental goal of protecting intellectual property rights is to stop anyone from making the same product or using similar ideas in order to boost honest competition in the market. Contrarily, competition legislation has a tendency to restrict exclusiveness when it is used to try to exclude others from commerce via the introduction of anticompetitive practices. Section 83(1)(f) of the Indian patent law specifies some limitations in order to establish broad guidelines for

the efficient operation of licensed patents. This prevents the assignee or patentee from engaging in commercial practices that unfairly impede trade or have negative effects on technology transfer, hence limiting their ability to exploit intellectual property. Additionally, this provision restricts antimonopoly actions in accordance with patent law. Both intellectual property rights regulation and competition law aim to raise capital, which in turn encourages innovation and, by prohibiting unfair monopolistic practices, provides a chance to ensure that all suppliers and enterprises get a fair share of the profits.

The major goal of competition law, as stated in the Indian Competition Act, 2002, is to prevent anti-competitive actions and to guarantee that all market players enjoy fair and equitable trading opportunities. What this means is that the pharmaceutical industry in India is subject to the same competition laws as the rest of the country's trade system, which means that in the event of an unfair increase in the price of patented drugs or an unreasonable obstacle to the sale of generic or branded medicines, the patentee will be able to engage in less conflicting activities. In order to ensure that individuals can purchase life-saving medications, the state grants obligatory licencing to generic pharmaceutical businesses operating inside the patent sector.

When it comes to pharmaceuticals, IPR has helped create less competitive and open marketplaces. However, public protection is impossible to provide in an ideal market where all sellers are willing to accept the same price for identical commodities. To effectively manage patentee monopoly rights while also protecting the public interest, India's competition regulations need a complete overhaul. So, a method to ensure that enterprises that seem to hurt consumers' and competitive interests often refrain from anticompetitive actions is to give licenses under section 84 of the Indian patent Act, 1970. However, in order to resolve issues where the exclusivity provided by the IP has been utilized to obtain uneven authority, section 27 of the Indian Competition Act asks for the granting of compulsory licensing to grant equal rights. Section 28 also allows the Commission to transfer intellectual rights, including IPRs. Compulsory licensing can help with competition, but it may be uncompetitive in the long term and hurt innovation incentives, especially if one manufacturer uses it to his advantage. Therefore, concentrating on forced licencing should be the final strategy for preserving a robust market.

The Indian patent law, in accordance with Section 84 and TRIPS, only issues compulsory licenses in certain conditions. Foreign direct investment (FDI) in the nation may also suffer as a result. Commercial enforcement anti-competitive actions must be overseen, according to Article 40 of TRIPS. Article 31's cited rules, which authorize many further uses of patents without the owner's consent, further confirm this. Based on a unified reading of these provisions, it seems that the Member States will not grant compulsory licensing in drug patents if doing so would restrict competition, damage commerce, or impede the transfer and dissemination of technology. As a result, compulsory licensing isn't always the solution to prevent monopoly rights from being abused; in fact, it may cause anti-competitive actions, which harm both the public interest and the consumer.

Compulsory Licensing and Public Health Services

According to the functional (Utilitarian) philosophy of intellectual property rights, the goal of designing security and implementing the IPR should be to make as many people as possible happy. The idea behind the intellectual property rights system is

that it will lead to a public good or social gain. accomplish, to benefit inventors and developers in the immediate term while also benefiting all others in the long run. After the creators choose to share their product with the public instead of keeping it under patent protection, the design becomes available to everyone after the patent expires. Conversely, such protection for the IPR is denied in cases when the exercise of monopoly rights reduces the public benefit. Thus, the research's overarching goal is to bolster public interest in innovations; when seen through the lens of the pharmaceutical industry's promotion and growth, this goal narrows down to the development of novel, life-saving medications for the treatment of contagious diseases and epidemics that threaten product availability. The primary goal of pharmaceutical patents is, therefore, to safeguard public health. The lack of inexpensive access to essential medications is one of the world's most pressing challenges. Therefore, there is a growing consensus that the obligatory authorization technique may lower the cost of medicinal interventions, making them more accessible. Hence, without the permission of the patentee, generic drug items may be manufactured at much cheaper prices via forced licencing, which generally improves the medicine's availability. By providing access to crucial pharmaceutical items for a big portion of the population, this grant once again provides some highly indisputable social advantages, since the prices of medicinal goods are determined by considering market variables.

State governments also have a responsibility to ensure their citizens' right to health care. The protection of public health and nutrition and the advancement of public interest in sectors vital to socio-economic development, as outlined in Article 8 of the TRIPS Agreement, serve as the guiding principles for the implementation of the Agreement's provisions, which includes the right to health and the right to be free from drugs. Thus, even this intriguing argument implies that public health is vital when the essential life-saving pharmaceuticals are easily accessible to the public. Once again, this proves that the pharmaceutical obligatory licencing system helps keep the people healthy. A sovereign nation has the authority to issue compulsory licenses in times of national emergencies, as stated in the 2002 Doha TRIPS and Public Health Declaration. Worldwide, over 14 million people have respiratory illnesses each year, and the HIV/AIDS pandemic is a reflection of poverty, according to a research that compared the most and least developed countries. While developing-world workers get compensation of just four or six months per year, the expense of therapy for a whole year is comparable to their earnings over thirty years. They have to give up their life for the pitiful salary they barely get, and it's clear that these costly meds are out of reach for a large portion of the population. The uniformity of the prescriptions delivered may have the same influence as the reduction of pricing, undermining public health once again, even though compulsory licensing helps with that. Policymakers should consider this when evaluating national drug policies and establishing regulatory standards to guarantee the quality of generic pharmaceuticals; this is not an attempt to criticize generic providers or the Compulsory Licence.

The Effects of Natco-Bayer Judgement

The facts, concerns, and decision-making process surrounding this case study have previously been thoroughly covered in chapter four of the aforementioned research. People all throughout the globe, including pharmaceutical corporations, were taken aback by the ruling in this case. In fact

Their negative arguments against TRIPS flexibility and India's forced licensing were not left behind by many Western nations. Article 21 of the Indian Constitution guarantees the right to life, thus the IPAB took a public health perspective on the matter and used the trial test outlined in Article 84(1) of the Indian Patent Act to identify the most important concerns. The controller considered the fact that Natco intended to sell their generic model for 8,800 for one month, whereas Naxavar had been granted the obligatory license by Bayer for 2.80 lakhs for one month. Not only has this ruling muddled the rules around these medications' distribution, but it also asserts that the companies behind them should be free to use their monopoly power to profit from research and development—something that developing and least developed nations simply cannot afford. The other

A reasonable and acceptable pricing was not provided by the controller, which was a 217 raised issue.

Even if the owner approves of Natco's pricing, some people just cannot afford it. A question emerged over whether the patentee or its agent would automatically fulfil the claim for the patented invention or whether a third party would be involved. The diplomatic ties between India and other countries have suffered as a result of this move. Like other poor nations that rely on this process to provide their citizens with pharmaceuticals, India found itself on the United States' watch list, which only served to exacerbate the issue. As a result of international trade pressure from industrialized nations, several individuals and pharmaceutical corporations later sought compulsory licenses under sections 84 and 92A, but these requests were denied.

CONCLUSION AND SUGGESTIONS

Finally, this poll sheds light on the intricate relationship between public opinion, legislation, and medication accessibility. In order to provide cheap access to necessary pharmaceuticals, it is crucial to understand public sentiment against compulsory licensing, as the data highlights.

As a first point, the poll shows that people have different views on compulsory licensing. Some think it's a great way to make sure everyone can afford the medications they need, while others are worried about how it may affect innovation and IP rights. The need of thoughtful policy talks that take into account different stakeholders' viewpoints is underscored by this.

The importance of public awareness and education programs in molding public opinion is also highlighted by the poll. Since many people who took the survey didn't know what obligatory licensing was, it's clear that more education on the topic and its effects on people's ability to get medical treatment is needed.

In order to make decisions based on facts, lawmakers should think about what this poll has shown. To keep access to life-saving pharmaceuticals cheap and fair for everyone, we need strategies that strike a balance between pharmaceutical firms' interests, public health, and patients' needs.

Furthermore, further studies should be conducted to investigate if and how public views of mandatory licensing change over time and across various demographics. The variables impacting perspectives on this policy tool and its use in various settings should be better understood with the help of longitudinal research and comparative analysis.

Finally, this survey may be used as a springboard for further in-depth investigations into the intricate dynamics of mandatory licensure and medication accessibility. The worldwide problem of making sure everyone has access to life-saving pharmaceuticals may be better met if lawmakers, healthcare providers, and the general public work together to discuss the issue and find answers.

References

1) Abbott, F. M., & Reichman, J. H. (2010). The Doha round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. The Journal of Law, Medicine & Ethics, 38(2), 236-253.

2) Attaran, A., & Gillespie-White, L. (2001). Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? JAMA, 286(15), 1886-1892.

3) Beall, R., & Kuhn, R. (2012). Trends in compulsory licensing of pharmaceuticals since the Doha declaration: A database analysis. PLoS Medicine, 9(1), e1001154.

4) Berger, J., & Iskarpatyoti, B. (2016). The World Trade Organization and access to medicines in the South: Assessing the impact of the implementation of the WTO's Doha Declaration on TRIPS and public health ten years on. Global Health Governance, 10(3), 42-61.

5) Correa, C. M. (2008). Implications of bilateral free trade agreements on access to medicines. Bulletin of the World Health Organization, 86(6), 399-404.

6) Darrow, J. J., & Sarpatwari, A. (2017). The market-exclusivity drug patent game. New England Journal of Medicine, 376(14), 1393-1395.

7) Dugger, C. W., & Fergusson, J. (2002). AIDS drugs for Africa--How do we achieve a grand bargain? New England Journal of Medicine, 346(10), 781-785.

8) Emanuel, E. J., & Wertheimer, A. (2011). Public health. Who should get influenza vaccine when not all can? Science, 333(6048), 914-915.

9) Gathii, J. T. (2005). Globalization, patents, and access to pharmaceuticals in Africa: The role of the World Trade Organization. The Review of International Organizations, 1(1), 77-107.

10) Gostin, L. O., & Buckley, G. J. (2016). PEPFAR's pivotal role in the global response to HIV/AIDS. JAMA, 316(2), 135-136.

11) Grabowski, H., & Kyle, M. (2007). Generic competition and market exclusivity periods in pharmaceuticals. Managerial and Decision Economics, 28(4-5), 491-502.

12) Holmer, A. F. (2010). Strengthening intellectual property rights globally: Strengthening intellectual property rights globally: A US perspective on compulsory licensing. Journal of Generic Medicines, 7(3), 270-276.

13) Kapczynski, A. (2007). The Access to Knowledge Mobilization and the New Politics of Intellectual Property. Yale LJ, 117, 804.

14) Kapczynski, A., & Chaifetz, S. (2009). Do patents prevent access to drugs for HIV in developing countries? Medicine and Law, 28(1), 33-69.

15) Kaul, I., & Mendoza, R. U. (2003). Advancing access to affordable medicines for developing countries: A framework for action. In Global Public Goods (pp. 261-283). United Nations Development Programme.

16) Love, J. (2002). No easy answers: The compulsory licensing of patents for antiretroviral drugs. Globalization and Health, 1(1), 3.

17) Mazzucato, M., & Tancioni, M. (2008). Pharmaceutical drugs and intellectual property rights: A failed strategy for innovation. Globalization and Health, 4(1), 1-8.

18) Moon, S., Jambert, E., Childs, M., & von Schoen-Angerer, T. (2011). A win-win solution? A critical analysis of tiered pricing to improve access to medicines in developing countries. Globalization and Health, 7(1), 39.

19) Osewe, P. L., Ntawukulilyayo, J. D., & Nkengasong, J. (2011). Ensuring Africa's access to new medicines: The role of global health actors. Journal of Pharmaceutical Policy and Practice, 4(1), 1-9.

20) Outterson, K. (2005). Access to essential medicines in poor countries: Making generic competition work. Health Affairs, 24(5), 1323-1333.

21) Palmedo, M., & Sinha, R. (2014). Assessing compulsory licensing as a policy tool for pharmaceuticals: What is the evidence for impact? Journal of Health Economics and Outcomes Research, 2(2), 172-189.

22) Pogge, T. (2005). Human rights and global health: A research program. Metaphilosophy, 36(1-2), 182-209.

23) Reich, M. R. (2002). Public-private partnerships for public health. Harvard University Press.

24) Sell, S. K., & Prakash, A. (2004). Using ideas strategically: The contest between business and NGO networks in intellectual property rights. International Studies Quarterly, 48(1), 143-175.

25) Shadlen, K. C. (2007). The political economy of AIDS treatment: Intellectual property and the transformation of generic supply. International Studies Quarterly, 51(3), 559-581.

26) Shaffer, E. R. (2010). Defining an access to medicines framework for trade agreements. Journal of Law, Medicine & Ethics, 38(2), 208-221.

27) Smith, R. D., Correa, C., & Oh, C. (2009). Trade, TRIPS, and pharmaceuticals. The Lancet, 373(9664), 684-691.

28) Tashakkori, A., & Teddlie, C. (Eds.). (2003). Handbook of mixed methods in social & behavioral research. Sage.

29) UNAIDS. (2017). Ending AIDS: Progress towards the 90-90-90 targets. UNAIDS.

30) Waning, B., Kaplan, W., & King, A. C. (2010). Pharmaceutical patents and prices: A preliminary empirical assessment of the TRIPS Agreement in the pharmaceutical sector. World Development, 38(10), 1471-1481.