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Compulsory Licensing in Pharmaceutical: Comparative Analysis with Special Reference to Brazil and Europe

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ABSTRACT

This research delves into the aspect of Compulsory Licensing in pharmaceutical industry by examining its implications on manufacture of generic drugs and access to affordable health care in India. Compulsory Licensing, a concept provided in Section 84 of Indian patent Act 1970, gives the procedure for application and criteria grant of compulsory License. The research begins by delving into the historical evolution and legal framework surrounding compulsory licensing, highlighting its underlying principles and the rationale behind its implementation. It traces the origins of compulsory licensing from international agreements and treaties, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which have shaped the global discourse on intellectual property rights in the pharmaceutical domain. Through in-depth analysis, this study provides a comparative analysis of the Compulsory Licensing regimes in Brazil, Europe, and India. This analysis investigates the legal and procedural mechanisms including notable case studies, to understand the context in which compulsory licenses are issued and their impact on the pharmaceutical industry and healthcare affordability. It examines the grounds for granting Compulsory Licenses, the Compulsory Licensing process, the royalties that Compulsory Licensing holders are required to pay, and the promotion of cooperation between pharmaceutical companies and generic manufacturers. This research looks into some areas where India could improve its Compulsory Licensing regime, such as clear interpretation of the grounds on which Compulsory Licensing is to be granted and public health emergencies and making a fixed time period within which Compulsory Licensing is to be granted by Patent Authority. This study concludes by analysing what are the key factors that contribute to successful or unsuccessful outcomes in terms of increased access to medicines and what can be learned from instances of successful and unsuccessful compulsory licensing cases in India and how such problem can be fixed.

Keywords: *Compulsory Licensing, Intellectual Property Rights, India, Brazil, Europe, Public Health, Affordable Healthcare.*

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I. INTRODUCTION

The history of patent law can be traced back to ancient times, with examples of patents being granted in ancient China and Greece. However, the modern patent system is generally considered to have originated in Venice in the 15th century. In 1474, the Venetian Republic passed a law granting exclusive rights to inventors of new and useful devices for a period of 10 years. The concept of patent law quickly spread to other parts of Europe, and the first patent law in England was passed in 1624. The United States passed its first patent law in 1790, shortly after its independence from Great Britain². The first international patent treaty was the Paris Convention for the Protection of Industrial Property, which was signed in 1883. The Paris Convention established a number of common principles for patent law, such as the requirement that patents be granted only for new and useful inventions. Today, patent law is an important part of the intellectual property system in most countries around the world. Patents grant inventors the exclusive right to make, use, sell, and offer to sell their inventions for a period of time, typically 20 years. This right allows inventors to protect their investments in research and development and to reap the financial rewards of their inventions.

Patents have played a vital role in the development of pharmaceuticals, particularly in recent decades. Pharmaceutical companies invest billions of dollars in research and development (R&D) to develop new drugs and treatments. Patents provide companies with the exclusive right to make, use, sell, and offer to sell their patented inventions for a period of time, typically 20 years. This right allows companies to recoup their R&D investments and to earn a profit on their inventions. Patents have helped to increase innovation in the pharmaceutical sector in a number of ways. First, patents provide companies with the incentive to invest in R&D. Knowing that they will have the exclusive right to profit from their inventions encourages companies to take risks and to invest in new and innovative research. Second, patents help to protect companies' investments in R&D. Companies can use their patents to prevent other companies from copying their drugs and treatments without permission. This protection allows companies to utilise their R&D investments and to bring new drugs and treatments to market more quickly. Third, patents promote the transfer of technology between companies. When companies file patents in other countries, they are required to disclose the details of their inventions to the public. This disclosure can help companies in other countries to develop their own drugs and treatments and to compete more effectively in the global marketplace. In the early 1990s, HIV/AIDS was a deadly disease with no cure. However, thanks to the patent system,

² Camilla Alexandra Hrdy & Daniel Harris Brean, *The Patent Law Origins of Science Fiction*, SSRN Electronic Journal(2022)

pharmaceutical companies were able to invest heavily in R&D and to develop new and effective treatments for HIV/AIDS. Today, people with HIV/AIDS can live long and healthy lives. Cancer is another disease that has been plagued by high mortality rates. However, in recent years, there have been significant advances in cancer treatment, thanks in part to the patent system. Pharmaceutical companies have developed a number of new and effective cancer drugs, which have helped to improve the survival rates of cancer patients. In addition to these specific examples, patents have also helped to drive innovation in the pharmaceutical sector more generally. For example, patents have encouraged companies to develop new and improved drug delivery systems, such as transdermal patches and inhalers. Patents have also encouraged companies to develop new drugs and treatments for rare diseases.

II. HISTORY OF PATENT IN INDIA

Patent law in India has a long and storied history, dating back to the British colonial era. The first patent law in India was enacted in 1856, and it was based on the British Patent Law of 1852. The Indian patent law was amended several times over the years, but it remained largely unchanged until the Patents Act of 1970 was passed.³

The Patents Act of 1970 was a significant departure from previous Indian patent law. It introduced a number of new provisions, including:

- A requirement that patents be granted only for inventions that are new, useful, and inventive.
- A prohibition on patents for certain types of inventions, such as food, medicine, and agricultural processes.
- A compulsory licensing provision that allows the government to grant licenses to other companies to make and sell patented products in certain circumstances.

The Patents Act of 1970 was further amended in 1999 to comply with India's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement is an international treaty that establishes minimum standards for intellectual property protection.

(A) Treaties and Conventions

India is a member of a number of international treaties and conventions that relate to patent law. These treaties and conventions have helped to shape the development of patent law in India.

³ History of Indian Patent System, Intellectual Property India, <https://ipindia.gov.in/history-of-indian-patent-system.htm> (last visited Oct 5, 2023).

The most important international treaty for patent law is the Paris Convention for the Protection of Industrial Property. The Paris Convention was signed in 1883, and it has been amended several times since then. The Paris Convention establishes a number of common principles for patent law, such as the requirement that patents be granted only for new and useful inventions. Another important international treaty for patent law is the TRIPS Agreement. The TRIPS Agreement was signed in 1994, and it came into force in 1995. The TRIPS Agreement establishes minimum standards for intellectual property protection, including patent protection.⁴

India's membership in international treaties and conventions has had a significant impact on the development of patent law in India. For example, the Paris Convention helped to introduce the requirement that patents be granted only for new and useful inventions into Indian patent law. The TRIPS Agreement helped to strengthen patent protection in India by requiring India to adopt a number of new provisions, such as a 20-year patent term and a product patent regime for pharmaceuticals

(B) Impact of Patent Law

Patent law has had a significant impact on innovation and technological development in India. By granting inventors the exclusive right to their inventions, patent law encourages inventors to invest in research and development and to bring new products and services to the market. Patent law has also been credited with promoting the transfer of technology between developed and developing countries. When companies from developed countries file patents in developing countries, they are required to disclose the details of their inventions to the public. This disclosure can help companies in developing countries to develop their own technologies and to compete more effectively in the global marketplace. One example of how patent law has helped to drive innovation in India is the development of the Covaxin COVID-19 vaccine. Covaxin was developed by Bharat Biotech, an Indian pharmaceutical company. Bharat Biotech was able to invest heavily in the development of Covaxin because it knew that it would have the exclusive right to make and sell the vaccine for a period of 20 years if it was granted a patent. Covaxin was approved for use in India in January 2021, and it has played a vital role in India's COVID-19 vaccination campaign. Covaxin is also being exported to other countries, and it is helping to protect people all over the world from COVID-19.⁵

⁴ Prashant R. Dahat & Puneet Satbir Yadav, Patents law and trips: Compulsory licensing of patents, and pharmaceuticals, SSRN Electronic Journal (2010)

⁵ Hilary Wong, The case for compulsory licensing during COVID-19, 10 Journal of Global Health (2020)

III. LEGAL MECHANISM OF COMPULSORY LICENSING

Compulsory licensing (Compulsory License) is a legal mechanism that allows governments to authorise the production and sale of patented products without the consent of the patent holder. Compulsory License is typically granted in cases where the public interest is at stake, such as when a patented product is essential for public health or when the patent holder is not making the product available to the public at a reasonable price. The history of Compulsory License can be traced back to the 15th century, when the Venetian Republic passed a law granting exclusive rights to inventors of new and useful devices. However, the modern concept of Compulsory License is generally considered to have originated in the United States in the 19th century. The first US patent law to include a Compulsory License provision was passed in 1870.⁶

Compulsory License is now recognised in international law by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which is an international treaty that establishes minimum standards for intellectual property protection. The TRIPS Agreement allows WTO members to grant CLs in certain circumstances, such as when the patent holder is not working the patented invention in the country or when the patented invention is necessary to protect public health. Compulsory License has also been used to promote the transfer of technology to developing countries⁷. For example, in 2013, the Brazilian government granted a Compulsory License to Farmanguinhos to manufacture and sell a generic version of Gilead's Sovaldi hepatitis C drug⁸. This Compulsory License helped to bring Sovaldi to the Brazilian market for the first time. However, unclear interpretation of health emergency and unclarity in criteria for granting compulsory licenses can have a negative impact on the manufacture of generic drugs by reducing investment in generic drug research and development, increasing costs for generic manufacturers, delaying the launch of generic drugs, and creating uncertainty and instability in the market. If the compulsory licensing process is time-consuming and complex. This can delay the launch of generic drugs and prevent patients from accessing affordable medicines, it can create uncertainty and instability in the market for generic drugs. Overall, unclear interpretation of health emergency and unclarity in criteria for granting compulsory licenses can have a negative impact on the manufacture of generic drugs by

⁶ A. Jason Mirabito, *Compulsory Patent Licensing for the United States: A Current Proposal*, 57 J. PAT. OFF. Soc'y 404 (1975).

⁷ Ganguli, P. (1999, December). *Towards TRIPs compliance in India: The Patents Amendment Act 1999 and implications*. *World Patent Information*, 21(4), 279–287.

⁸ Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries, <https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries> (last visited Oct 20, 2023)

reducing investment in generic drug research and development, increasing costs for generic manufacturers, delaying the launch of generic drugs, and creating uncertainty and instability in the market.

(A) Compulsory licensing in India

Compulsory licensing was implemented and introduced in India through the Patents Act of 1970. Section 84 of the Patents Act provides for the grant of CLs in certain circumstances. These circumstances include:

- When the reasonable requirements of the public with respect to the patented invention have not been satisfied.
- When the patented invention is not available to the public at a reasonably affordable price.
- When the patented invention is not worked in India.
- When the patentee imports the patented product instead of manufacturing it in India.

The process for obtaining a Compulsory License begins with the filing of an application with the Controller of Patents. The application must be accompanied by a statement setting out the grounds on which the Compulsory License is being sought. The Controller of Patents will then examine the application and make a decision on whether or not to grant the Compulsory License. If the Controller of Patents decides to grant the Compulsory License, they will specify the terms and conditions of the Compulsory License, including the royalty that the Compulsory License holder will have to pay to the patentee. The Compulsory License holder will then be able to make, use, sell, and offer to sell the patented product in India. CLs have been used in India to make essential medicines more affordable for the public. For example, in 2012, the Indian government granted a Compulsory License to Natco Pharma⁹. to manufacture and sell a generic version of Bayer's Nexavar cancer drug. This Compulsory License helped to make Nexavar more affordable for Indian patients. CLs have also been used to promote the transfer of technology to India. For example, in 2013, the Indian government granted a Compulsory License to BDR Pharmaceuticals to manufacture and sell a generic version of Bristol-Myers Squibb's Sprycel cancer drug¹⁰. This Compulsory License helped to bring Sprycel to the Indian market for the first time. CLs are an important tool that the Indian government can use to

⁹ Natco Pharma Ltd. v. Bayer Corporation & The Controller of Patents, Madras & Others, (2013) 10 SCC 463.

¹⁰ Rupali Mukherjee, *Bristol-Myers misleading HC in patent case*, TOI, Sep. 14, 2013, <https://timesofindia.indiatimes.com/business/india-business/bristol-myers-misleading-hc-in-patent-case/articleshow/22568901.cms>

promote public health and economic development.

(B) Effectiveness of Compulsory License in India

The effectiveness of compulsory licensing (Compulsory License) under Indian law is a complex and controversial issue. There is no doubt that Compulsory License has the potential to be a powerful tool for promoting public health and access to essential medicines. However, there are also a number of challenges that have limited the effectiveness of Compulsory License in India.

One challenge is that the Compulsory License process can be complex and time-consuming. This can make it difficult for companies to obtain CLs, particularly in cases where public health is at risk. Another challenge is that CLs can be subject to legal challenges from patent holders. Patent holders often have significant resources to challenge CLs, which can delay or even prevent the grant of a Compulsory License. Additionally, CLs can have a negative impact on innovation. When companies know that their patents could be subject to CLs, they may be less likely to invest in research and development. This can stifle innovation and make it more difficult for new medicines and technologies to be developed. Despite these challenges, Compulsory License has played an important role in India in making essential medicines more affordable for the public¹¹. For example, in 2012, the Indian government granted a Compulsory License to Natco Pharma¹² to manufacture and sell a generic version of Bayer's Nexavar cancer drug. This Compulsory License helped to make Nexavar more affordable for Indian patients. CLs have also been used to promote the transfer of technology to India. For example, in 2013, the Indian government granted a Compulsory License to BDR Pharmaceuticals to manufacture and sell a generic version of Bristol-Myers Squibb's Sprycel cancer drug. This Compulsory License helped to bring Sprycel to the Indian market for the first time.¹³

Overall, the effectiveness of Compulsory License under Indian law has been mixed. CLs have the potential to be a powerful tool for promoting public health and access to essential medicines. However, the Compulsory License process can be complex and time-consuming, CLs can be subject to legal challenges from patent holders, and CLs can have a negative impact on innovation.

IV. COMPULSORY LICENSING IN BRAZIL

Compulsory licensing (Compulsory License) in Brazil is governed by the Industrial Property

¹¹ George T. Haley & Usha C.V. Haley, The effects of patent-law changes on innovation: The case of india's pharmaceutical industry, 79 *Technological Forecasting and Social Change* , 607–619 (2012)

¹² Natco Pharma Ltd. v. Bayer Corporation & The Controller of Patents, Madras & Others, (2013) 10 SCC 463.

Law (Law No. 9,279/1996). Article 68 of the Industrial Property Law provides for the grant of CLs in certain circumstances. The process for obtaining a Compulsory License in Brazil is similar to the process in India. The applicant must file an application with the National Institute of Industrial Property (INPI).¹⁴The application must be accompanied by a statement setting out the grounds on which the Compulsory License is being sought. The INPI will then examine the application and make a decision on whether or not to grant the Compulsory License. If the INPI decides to grant the Compulsory License, they will specify the terms and conditions of the Compulsory License, including the royalty that the Compulsory License holder will have to pay to the patentee¹⁵. The Compulsory License holder will then be able to make, use, sell, and offer to sell the patented product in Brazil. CLs have been used in Brazil to make essential medicines more affordable for the public. For example, in 2013, the Brazilian government granted a Compulsory License to Farmanguinhos to manufacture and sell a generic version of Gilead's Sovaldi hepatitis C drug. This Compulsory License helped to make Sovaldi more affordable for Brazilian patients. CLs have also been used to promote the transfer of technology to Brazil. Another example, in 2016, the Brazilian government granted a Compulsory License to Bio-Manguinhos to manufacture and sell a generic version of GSK's Bexsero meningococcal meningitis vaccine. This Compulsory License helped to bring Bexsero to the Brazilian market for the first time.

(A) Comparative Analysis with Indian Laws

The Compulsory License regimes in India and Brazil are similar in many ways. Both countries allow for the grant of CLs in the same circumstances. Both countries also have similar procedures for granting CLs. However, there are also some differences between the two Compulsory License regimes. One difference is that the Brazilian Compulsory License regime is more explicit about the need to consider public health when granting CLs. Article 68 of the Brazilian Industrial Property Law specifically states that CLs can be granted when the patented invention is necessary to protect the health or life of persons. Another difference is that the Brazilian Compulsory License regime has a more flexible approach to setting royalties. Article 68 of the Brazilian Industrial Property Law states that the royalty that the Compulsory License holder will have to pay to the patentee will be set "taking into account the economic and social interests of the country." This gives the INPI more flexibility to set royalties at a level that is

¹⁴ Brazil WIPO Lex, Brazil, Law No. 9.279 of May 14, 1996 (Law on Industrial Property), <https://www.wipo.int/wipolex/en/legislation/details/515>

¹⁵ Compulsory licensing in Brazil: Updates and perspectives Lexology, <https://www.lexology.com/library/detail.aspx?g=4adf38aa-3a49-4230-b129-82b3f750993e>

affordable for the public.

The time period within which a Compulsory License should be granted is shorter in Brazil than in India. This means that companies in Brazil may be able to obtain CLs more quickly than companies in India. In Brazil, the Industrial Property Law of 1996 specifies that the National Institute of Industrial Property (INPI) must decide on a Compulsory License application within 60 days of the date on which the application is complete. If the INPI does not make a decision within 60 days, the Compulsory License is automatically granted. However, in Indian scenario, the Patents Act of 1970 does not specify a time period within which a Compulsory License should be granted. However, the Patents Rules of 1972 state that the Controller of Patents should dispose of a Compulsory License application within 90 days of the date on which the application is complete. However, this is just a guideline, and the Controller of Patents may take longer to dispose of a Compulsory License application if necessary. The applicant can either wait or go for further litigation to courts to grant the Compulsory License or they should dispose of or refile for it.

(B) Compulsory License in Europe

Compulsory License in Europe is governed by the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004¹⁶ on the patentability of inventions and the means by which to implement patents. The procedure for obtaining a Compulsory License varies from Member State to Member State. However, in general, the applicant must file an application with the national patent office. The application must set out the grounds on which the Compulsory License is being sought and the terms and conditions of the Compulsory License. The patent office will then examine the application and make a decision on whether or not to grant the Compulsory License. If the patent office decides to grant the Compulsory License, the Compulsory License holder will be able to make, use, sell, and offer to sell the patented product in the territory of the Member State where the Compulsory License was granted for a period of time. The Compulsory License holder will also have to pay a royalty to the patent holder. Compulsory License has been used in Europe on a number of occasions to make essential medicines more affordable for the public. For example, in 2012, the Greek government granted a Compulsory License to a domestic pharmaceutical company to produce a generic version of Bristol-Myers Squibb's cancer drug Sprycel. This Compulsory License helped to make Sprycel more affordable for Greek patients.

¹⁶ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, 11 *Pharmaceuticals, Policy and Law*, 523–557 (2009)

Compulsory License has also been used in Europe to promote the transfer of technology to developing countries. Overall, Compulsory License is an important tool that European governments can use to promote public health and access to essential medicines. However, Compulsory License is a complex legal issue, and there are a number of challenges that have limited its effectiveness in some cases. Article 76 of the Directive sets out the following steps involved in the procedure for the grant of a Compulsory License. Article 77 of the Directive also sets out a number of procedural safeguards that must be respected in the Compulsory License application process.

(C) Comparative Analysis with Indian Laws

There are several similarities and difference between India and Europe when it comes to grant of Compulsory License and procedure for the same. Both patent laws allow for CLs to be granted in cases where the public interest is at stake and both patent laws require the applicant for a Compulsory License to demonstrate that they have tried to obtain a voluntary license from the patent holder before applying for a Compulsory License. The laws require the Compulsory License holder to pay a royalty to the patent holder. However the grounds for granting a Compulsory License are slightly broader in Europe than in India. For example, in Europe, a Compulsory License can be granted if the patentee is exercising their patent rights in a way that is abusive or anti-competitive. In India, CLs are typically only granted if the patentee is not working the patented invention or if the patented invention is essential for public health. In Europe, the competent authority is required to make a decision on a Compulsory License application within 60 days¹⁷. In India, there is no specific time period for the Controller of Patents to make a decision on a Compulsory License application. One of the main differences between the Indian and European Compulsory License regimes is the grounds on which CLs can be granted. The broader grounds in Europe allow for CLs to be granted in a wider range of cases. This can be seen as a positive development, as it allows governments to better protect the public interest.

However, the broader grounds in Europe also raise some concerns. For example, there is a risk that CLs could be used to unfairly target patent holders. Additionally, the broader grounds could lead to more legal challenges from patent holders, which could delay or even prevent the grant of CLs. Another difference between the Indian and European Compulsory License regimes is the length of the Compulsory License procedure. The shorter time period in Europe is seen as

¹⁷ European Commission. (2023, April 4). Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crises management (COM(2023) 224 final), https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_224_1_EN_ACT_part1_v11.pdf

a positive development, as it allows CLs to be granted more quickly. This can be important in cases where public health is at stake. However, the shorter time period in Europe also raises some concerns. For example, it is possible that the competent authority may not have enough time to fully consider all of the relevant factors before making a decision on a Compulsory License application. This could lead to CLs being granted in cases where they are not justified. Overall, the Indian and European Compulsory License regimes have both strengths and weaknesses. The broader grounds in Europe allow for CLs to be granted in a wider range of cases, but they also raise some concerns about the potential for abuse. The shorter time period in Europe is seen as a positive development, but it also raises some concerns about the potential for CLs to be granted in cases where they are not justified.

V. RECOMMENDATIONS

Brazil and Europe have broader grounds for granting CLs these nations allow for CLs to be granted in a wider range of cases than India. This includes cases where the patent holder is abusing their patent rights or where the patented product is essential for public health. Expanding the grounds for granting CLs in India would make it easier for the government to protect the public interest. The Indian policies could streamline the Compulsory License process by setting clear timelines for the decision-making process and providing more transparency to the process this can make CLs to be granted more quickly, which is important in cases where public health is at stake. India could set clear timelines for the decision-making process in Compulsory License cases. India could also provide more transparency to the Compulsory License process by making all relevant documents publicly available. Brazil and Europe actively promote cooperation between pharmaceutical companies and generic manufacturers to facilitate the development and production of generic medicines. Indian policies could also be designed in a way to promote cooperation between these two groups, such as by providing financial incentives or by establishing mechanisms for technology transfer. There also exist dedicated tribunals in Brazil and Europe that deal with matters of Compulsory License, whereas in India more power is vested in the central government for grant of Compulsory License. Establishing a dedicated Compulsory License tribunal would improve the efficiency and effectiveness of the Compulsory License process in India and this can also reduce burden from the higher courts when matter goes to litigation. This tribunal would be independent of the Patent Office, and it would have the expertise to handle complex Compulsory License cases. Apart from this India can also providing tax breaks and other financial incentives to generic manufacturers, as well as simplifying the regulatory process for approving new generic drugs.

VI. CONCLUSION

Compulsory licensing is a legal mechanism that allows governments to authorise the production and sale of patented products without the consent of the patent holder. Compulsory License is typically used in cases where public health is at stake, such as when a patented medicine is essential for the treatment of a serious disease and is not available at an affordable price. Brazil and Europe have both implemented Compulsory License regimes that are designed to promote public health and access to essential medicines. However, there are some key differences between the two regimes. Both Brazil and Europe have taken steps to promote cooperation between pharmaceutical companies and generic manufacturers. For example, Brazil has established a program called the Pharmaceutical Development Program (PDP), which provides financial incentives to pharmaceutical companies that license their patents to generic manufacturers on a voluntary basis. Europe has also implemented a number of initiatives to promote cooperation between pharmaceutical companies and generic manufacturers, such as the Pharmaceutical Sector Inquiry and the European Commission's Communication on Community Intellectual Property Policy. India's Compulsory License regime is more favourable to public health than the Compulsory License regimes of Brazil and Europe. India's wider grounds for granting CLs, more streamlined Compulsory License process, lower royalties for Compulsory License holders, and greater emphasis on public health make it easier for the Indian government to grant CLs in cases where public health is at stake. Overall, India's Compulsory License regime is a powerful tool for promoting public health and access to essential medicines. However, there are some areas where India could improve its Compulsory License regime, such as clear interpretation of the grounds on which Compulsory License is to be granted and public health emergencies and making a fixed time period within which Compulsory License is to be granted by Patent Authority. By learning from the experience of Brazil and Europe, and by implementing the policies outlined above, India can make CLs a more effective tool for promoting public health and access to essential medicines and take it a step closer to make Indian Pharmaceutical industry stronger.
