European Economic Letters
ISSN 2323-5233
Vol 14, Issue 3 (2024)
http://eelet.org.uk

Compulsory Licensing & It's Implication on Innovation: A Study of Indian Pharma-Industry

Jamaal Ibrahim[1*], Vivek Aggarwal[2]

[1*]School of Business Galgotias University, Greater Noida, India.
Email: jamalibrahim84@gmail.com
[2]School of Business Galgotias University, Greater Noida, India. Email: vivek.aggarwal@ galgotiasuniversity.edu.in
https://orcid.org/0000-0003-3618-3008

***Corresponding Author:** Jamaal Ibrahim
*School of Business Galgotias University, Greater Noida, India.
Email: jamalibrahim84@gmail.com

Abstract
One of the most contentious issues surrounding the constantly changing patent rules ismandatory licensing under Section 98 of the Indian Patents Act, which permits the export of protected medications. This study examines patents as a true obstacle to drug accessibility as well as the extent to which compulsory licensing changes the landscape. It does so by referencing the most recent legal development, Natco v. Pfizer, which has brought the key provisions under close scrutiny from the legal community. The goal of this research is to evaluate the problem of patents within the context of the probable verdict in this historic case.

Keywords: Compulsory licensing, Indian Patents Act, Section 98.

1. Introduction

Pharmaceutical compulsory licensing has been a topic of discussion for a considerable amount of time **(Ford, 1999)**. Therefore, it was a historic day in Indian pharmaceutical patenthistory on March 4, 2013, when the Intellectual Property Appellate Board (IPAB) ignored theappeal filed by Bayer Corporation (Bayer) and upheld the compulsory license granted to Natco Pharma Ltd. (Natco) for the production of Bayer's patented kidney cancer drug Nexavar (referred to as "the drug") **(Bayer Corporation v. Natco Pharma Ltd)**. Part II of the study looks at how developing countries like India have been fighting a protracted war with large pharmaceutical companies to improve access to necessary medications, even as attention has been drawn to mandatory licensing regimes following the adoption of the Doha Declaration **(The Doha Declaration on the TRIPS Agreement and Public Health, 2001)[1]**. In light of this, the ruling in Bayer Corporation v. Natco Pharma Ltd. (Natco v. Bayer) **(Bayer Corporation v. Natco Pharma Ltd.,)**, which is examined in Part III, throws additional light on questions raised by this discussion and provides a quick overview of what compulsory licensing in India could entail in the future.

1. TRIPS came into force on January 1, 1996. It was followed by the Doha Declaration on November 14, 2001 which specifically sought to address concerns regarding this issue.

Although this in no way suggests that innovation be sacrificed entirely, the urgent need for public health may require a compromise that lowers the value of innovation. Pharmaceutical industries fight specifically against such a compromise, with the backing of industrialized governments **(Adelman and Baldia, 1996)**. They contend that better innovation results from more patent protection, and that their motivation to develop is negatively impacted by such a compromise. But as was previously shown, this assumption is no longer valid. Research indicates that innovation is not influenced by the extent of pharmaceutical patent protection, particularly in developing countries **(Germano, 2007)**. This means that these worries have nobearing on the appropriateness of obligatory licenses. However, since the TRIPS agreement was passed, several developing countries have chosen various approaches to address this power struggle **(Sykes, 1990)**. Though some countries, like Brazil **(Tina Rosenberg)**, have successfully used the threat of compulsory licensing to force pharmaceutical corporations to submit, other countries, including the US **(Opderbeck, 2009)**, have taken umbrage to Egypt and Thailand **(TRIPS, January 1, 1996 and Doha Declaration, November 14, 2001)**. In actuality, despite several attempts by academics to create viable models of collaboration, signatories to TRIPS have not yet been able to reach a mutually agreeable middle ground **(Outterson, 2005)**.

The purpose of the patent system is to incentivize creativity, promote technological advancement, and facilitate the sharing of new ideas. Many arguments, including thosepertaining to incentive to invention, natural rights, moral reward, and encouragement to innovation, have been used to justify the limitation on the free flow of ideas that comes with issuing a patent. The prevailing view in contemporary discussions and the law of many nations is that patents are required in order for an investor to recover its investment in R&D **(Gutterman, 1997)**.

Despite the fact that the ability to secure exclusive rights to utilize ideas has played asignificant role in the creation and exploitation of many technological innovations, the patenting system is still far from achieving its goals **(Archibugi and Malaman, 1991)**. The patent system has been severely distorted as a result of the extension of the patentable subject

matter from inanimate to biological forms, the acceptance of wide claims covering enormous technological domains, the relaxation of the patentability standards, and flaws in the examination procedure **(Jaffe and Lerner, 2011)**. A multitude of defensive as well asoffensive patenting methods are largely responsible for the explosion of patent applications and approvals **(Granstrand, 1999)**.
Our innovation metrics center on the degree of advancement of the products of R&D investment activity by Indian pharmaceutical companies and international companies, as wellas their disease-focused approach.

2. Methodology

2.1. Research Design

The research that was conducted was descriptive in nature as well as included an analytical framework. In the major data portion, a survey was used to supplement the study's conclusions with a quantitative method. Data on many consumer engagement characteristics were gathered via the use of a structured questionnaire and a variety of structured questions in survey research methods.
In order to investigate the impact of licensing on innovation, availability, and cost of life- saving drugs, we used secondary data from case studies of many countries both before and after obligatory licensing was enacted in each country. Furthermore, we have obtained secondary data from the database on the different R&D costs that the companies spent before to and throughout the implementation of required licensing for that particular business in India.

2.2. Sample Size

From 2018-19, 19 of the biggest Indian pharmaceutical firms made up our sample. Using information from industry websites, management interviews, industry studies, and media publications, we selected the firms in our sample. XB Labs as well as the Columbia Mailman School of Public Health collaborated to create the India Big Patents database, which we utilized to search for patents under the product-patent regime from 2018 to2019. As of January 1, 2005, the database solely recorded Indian patents. As a result, from2018 to 2019, we monitored the firms in our sample's accessible patents under the process-patent regime by analyzing media stories' content and company-reported filings at the Indian Patent Office. We compared patent numbers in both time periods to filter out duplicate patent entries and categories the invention as either a method or a product. Our classifications' relative objectivity was shown by their very high inter-coder reliability. Since complete patent descriptions were not yet available at the time of data collection for 2018, we did not categories patents as either method or product.

2.3. Measurement Development

Based on the objectives of the research project, a total of two variables have been identified (Table 1).

Table 1 Measurement Items

S. No.	Variables	Operational Definition of Variables
1	Innovation	R&D Expenditure of the firms (Rs. millions)
2	Affordability	Price of the drug

2.4. Data Collection

The gathering of information includes primary and secondary data.

2.4.1. Primary Data

Primary data refers to information that a researcher has collected from first-hand sources using methods like surveys, interviews, or experiments. It is collected with thestudy subject in mind, straight from the original sources.

2.4.2. Secondary Data

Information gathered from experiments, surveys, studies, and other research efforts that has already been assembled or reviewed by others is referred to as secondary data. For our research endeavor, we collect both primary and secondary data. Numerous sources, including BIO-SPECTRUM, WIPO, IQVIA, and PROWESSIQ Patents Statistics Database, are the sources of secondary data.

2.5. Statistical Technique Usage

Following data collection as well as preparation for analysis, the necessary statistical tools—including *Excel* and *SPSS* are used to analyses, apply, and interpret the data.

3. Result

A description of the link between mandatory licensing and innovation in the Indian pharmaceutical industry within the

context of evolving pharmaceutical discoveries was given by this study. The chapter's opening part recognizes the significant concerns raised by obligatory licensing and the relentless pursuit of scientific development, emphasizing the delicate balancing act that has to be done between innovation and public health regulations.
Table 2 delineates the respondents' gender-based knowledge of required licensing in the pharmaceutical business.

Table 2 Crosstab of gender & concept of licensing

How well do you understand the concept ofmandatory licensing in the pharmaceutical industry?					
Count		Not familiar at all	Somewhat familiar	Very familiar	Total
Gender	Female	12	11	0	23
	Male	42	29	1	72
	Others	3	2	0	5
Total		57	42	1	100

Out of all the responders, 57 in total, the majority said they have no idea what required licensing is. Men make up a significant portion of this group. 42 out of 100, or a significant majority, show a relatively acquainted comprehension; men dominate in this area. Only one male responder claimed to have a very familiar comprehension, indicating how rare very familiar replies are. This table provides a gender-specific perspective on the distribution of survey participants' knowledge levels with required licensing.
As Table 3 illustrates, analyzing the relationship between categorical variables, the chi-squarestatistic (with a value of .755; see the 'Value' column directly next to 'Pearson Chi-Square') evaluates the relationship. The related p-value (.944) is higher above the typical significance threshold of 0.05 and can be found in the 'Asymptotic Significance (2-sided)' column. This suggests that there is no meaningful relationship between the gender based on the Concept licensing, indicating that there is not enough data to reject the null hypothesis.

Table 3 Chi-Square gender & concept of licensing

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	.755[a]	4	.944
Likelihood Ratio	1.018	4	.907
N of Valid Cases	100		
a. 5 cells (55.6%) have expected count less than 5. The minimum expected count is .05.			

The table 4 you provided summarizes responses to the question about the implementation of compulsory licensing in India, categorized by gender. 11 females' respondents answered "No," indicating they are not aware of instances of compulsory licensing in India. 12 females'respondents answered "Yes," indicating awareness of such instances. 31 males' respondents answered "No," while 41 males' respondents answered "Yes." And in others 1 respondent answered "No," and 4 respondents answered "Yes. The majority of respondents across all gender categories are aware of instances of compulsory licensing in India ("Yes" responses).

Table 4 Cross tabulation

Are you aware of any instances in India where compulsory licensing has been implemented?				
Count		No	Yes	Total
Gender	Female	11	12	23
	Male	31	41	72
	Others	1	4	5
Total		43	57	100

The above table 5 shows that The Pearson Chi-Square value is 1.298 with 2 degrees of freedom. The p-value is 0.023, which is less than the conventional significance level of 0.05. This suggests that there is a statistically significant association between the variables. The Likelihood Ratio Chi-Square value is 1.398 with 2 degrees of freedom. The p-value is 0.047, indicating statistically significant evidence to reject the null hypothesis at the 0.05 significance level.

European Economic Letters
ISSN 2323-5233
Vol 14, Issue 3 (2024)
http://eelet.org.uk

Table 5 Chi-Square Tests

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi- Square	1.298[a]	2	.023
Likelihood Ratio	1.398	2	.047
N of Valid Cases	100		
a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 2.15.			

The above table, denoted as table 6, and Figure 1 illustrate that 13 respondents (13.0%) agreed that mandatory licensing is a good way to improve access to essential medicines, whereas 25 respondents (25.0%) disagreed, expressing doubts about its effectiveness. One respondent (1.0%) was undecided, neither agreeing nor disagreeing. Sixteen (16.0%) respondents strongly agreed that mandatory licensing is an effective strategy for improving access. The majority, consisting of 45 respondents (45.0%), strongly disagreed with the effectiveness of mandatory licensing in improving access to essential medicines.

Table 6 Impact of Required Licensing for Essential Medicines in Low- income countries

Do you think mandatory licensing is a good way to improve access to essential medicines in low-income countries?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	13	13.0	13.0	13.0
	Disagree	25	25.0	25.0	38.0
	Neutral	1	1.0	1.0	39.0
	Strongly agree	16	16.0	16.0	55.0
	Strongly disagree	45	45.0	45.0	100.0
	Total	100	100.0	100.0	

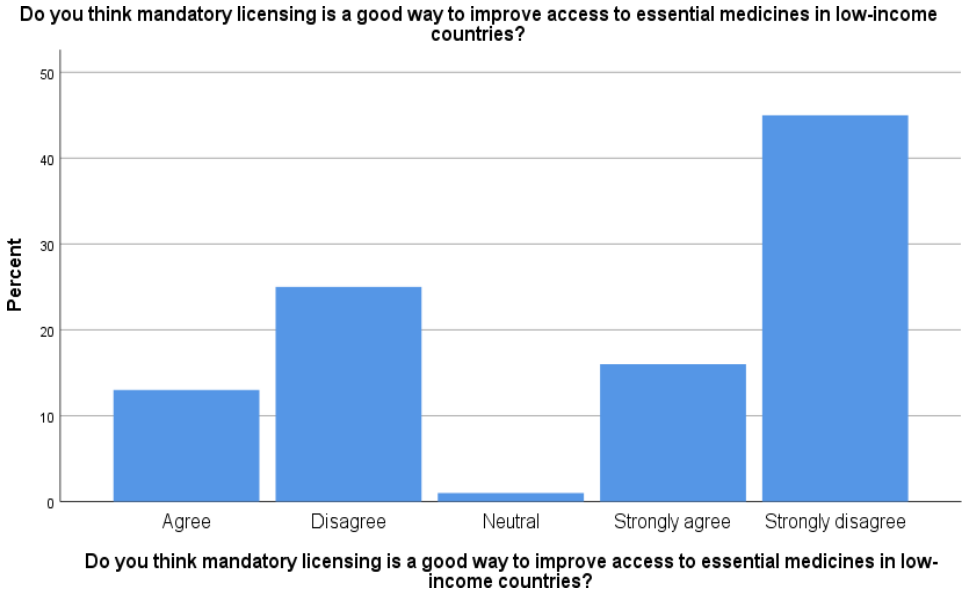

Figure 1 Impact of Required Licensing for Essential Medicines in Low-Income Countries

The table 7 below shows that ANOVA results indicate a non-significant F-statistic (F = 0.441, p = 0.724), suggesting that there are no significant differences in knowledge scores among the groups (Positively, Negatively, No Impact, Not Sure). The high p-value (0.724) indicates that we do not reject the null hypothesis, indicating that there is no significant variation in knowledge scores across the various categories of compulsory licensing perceptions.

European Economic Letters
ISSN 2323-5233
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http://eelet.org.uk

Table 7 ANOVA Results Knowledge of Compulsory Licensing

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	22.598	3	7.533	.441	.724
Within Groups	1638.442	96	17.067		
Total	1661.040	99			

Respondent perceptions on factors influenced by compulsory licensing in the Indian pharmaceutical industry are presented in table (8) and Figure (2). Twenty-five percent (25.0%) of respondents believe compulsory licensing has an impact on market competition inthe Indian pharmaceutical industry. The majority of respondents (39.0%) believe that mandatory licensing has an impact on the quality of pharmaceutical products. Only one respondent (1.0%) believes that compulsory licensing has an impact on R&D investments. A sizable proportion, 35 respondents (35.0%), believe that mandatory licensing influences the time to market for new drugs. Overall, respondents attribute various influences to mandatory licensing, with a particular emphasis on its impact on pharmaceutical product quality and time-to-market for new drugs.

Table 8 Compulsory Licensing's Influence on the Indian Pharma Industry

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Market competition	25	25.0	25.0	25.0
	Quality of pharmaceuticalproducts	39	39.0	39.0	64.0
	Research and Development (R&D) investments	1	1.0	1.0	65.0
	Time-to-market for new drugs	35	35.0	35.0	100.0
	Total	100	100.0	100.0	

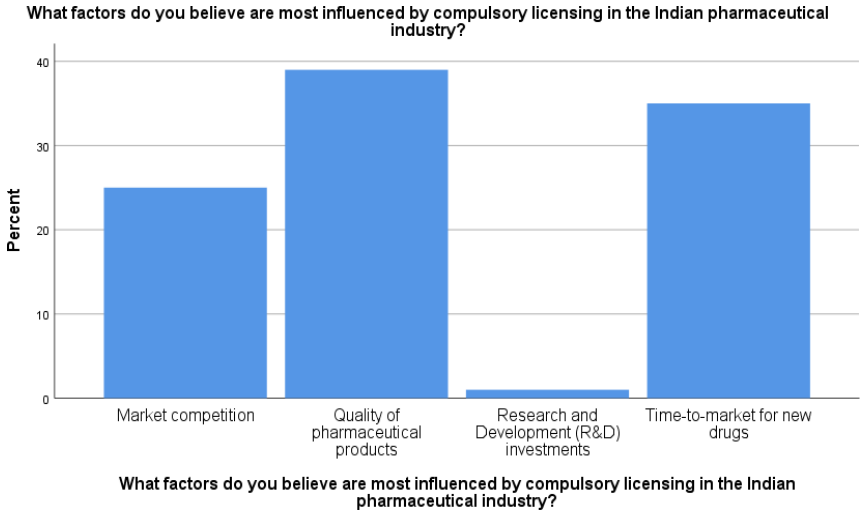

Figure 2 Compulsory Licensing's Influence on the Indian Pharma Industry

The table (9) and figure (3) present respondents' opinions on how India's pharmaceutical industry has reacted to mandatory licensing in terms of innovation.

Table 9Impact of Mandatory Licensing on Innovation in Indian Pharma

		Frequency	Percent	Valid Percent	CumulativePercent
Valid	Decreased innovation efforts	40	40.0	40.0	40.0
	Increased innovation efforts	24	24.0	24.0	64.0

	No significant change	19	19.0	19.0	83.0
	Not Sure	17	17.0	17.0	100.0
	Total	100	100.0	100.0	

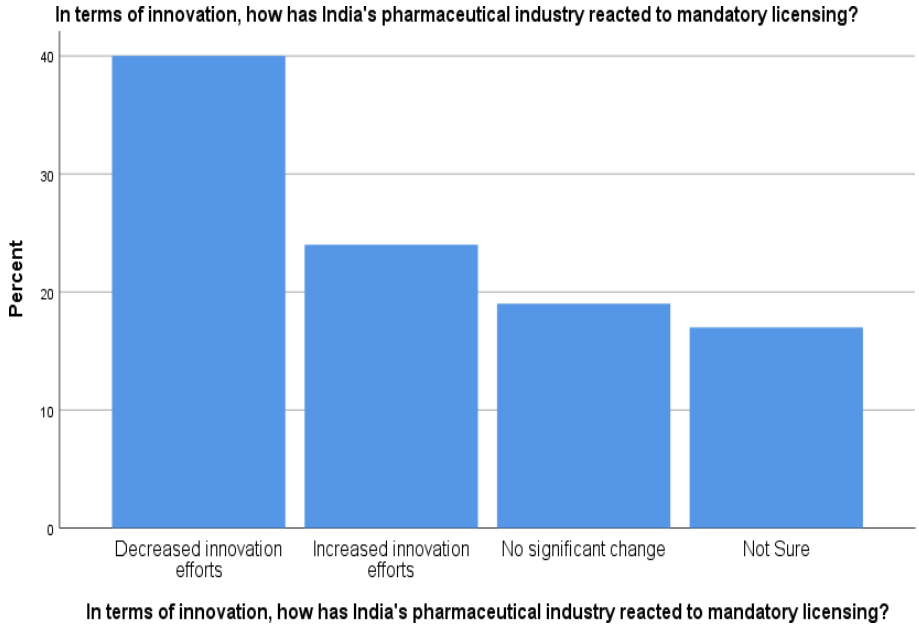

Figure 3 Impact of Mandatory Licensing on Innovation in Indian Pharma

4. Discussion

The results indicate mixed perceptions regarding mandatory licensing in the Indian pharmaceutical industry. While most respondents doubt its effectiveness in improving access to essential medicines, they recognize its impact on market competition and product quality. Additionally, there's a perceived decrease in innovation efforts, highlighting concerns over the long-term effects on R&D.

Although it is believed that compulsory licenses compromise exclusive ownership, theyactually act as a deterrent to monopoly rights. Even although licenses may be required, it's crucial to keep in mind that they shouldn't stand in the way of development and growth **(Ibrahim and Abdullah, 2021)**. India needs this protection since the majority of its citizens are underprivileged economically.Yet, the challenge is that it has to follow international standards for patent protection while also safeguarding public health **(Shukla, 2019)**.

In the absence of patent protection, patents offer corporations little incentive to develop new products, therefore even if they encourage monopolies and exorbitant pricing, they are an inevitable evil. Patents are a flawed but effective instrument for promoting the developmentof new products since innovation cannot be secured without patent protection. Pharmaceutical patent protection, yet, is only really successful in high-income countries because the general public can afford to buy expensive patented drugs. For a number of reasons, the most important being the absence of affordable access to drugs, it is ineffective in the poorest and least developed countries **(Abbas, 2013)**.

5. Conclusion

India is a major player in the global pharmaceutical market, yet it does not provide its own people with access to necessary medications. Evidence that Indian generic businesses have made medications more accessible to US customers supports the contradiction. These businesses have been successful in opposing the MNCs' patents and accelerating the arrivalof generic medications in the US, which has resulted in lower costs **(Chaudhuri, 2007)**. In India, the state has been crucial to the growth of the sector. The state established the conditions and possibilities necessary for the potential of the domestic private sector to beachieved via investments in manufacturing and research and development, especially aftereliminating product patent protection in the pharmaceutical industry in the early 1970s.

The state must become much more involved and widespread if the goal of health policy ensuring that pharmaceuticals are accessible to everyone is to be met. The subject is too important to be left to the private sector and the market. The government must control the producers, use its negotiating leverage to drive down costs, and provide direct or indirect funding for the medical needs of individuals who are sick but cannot afford treatment **(Gupta et. al., 2022)**. The state may then use the creative potential of the private sector for the benefit of the under privileged, according to sporadic experiences like the Delhi Model.

References

1. Abbas, M. Z. (2013). Pros and cons of compulsory licensing: An analysis of arguments. International Journal of Social Science and Humanity, 3(3,) 254-258.
2. Adelman, M. J., & Baldia, S. (1996). Prospects and limits of the patent provision in the TRIPs Agreement: the case of India. Vand. J. Transnat'l L., 29, 507.
A. K. Gupta, S. Dash, V. Aggarwal and P. D. Yadav (2022), Critical Success Factors influencing success of SMEs, 2022 3rd International Conference on Computation, Automation and Knowledge Management (ICCAKM), Dubai, United Arab Emirates, 2022, pp. 1-4, doi: 10.1109/ICCAKM54721.2022.9990271.
3. Agarwal, D. & Agarwal, R. (2016). The Dismal History of Compulsory Licences in India, Indian Institute of Technology, Madras, India retrieved May 13, 2020 from http://patentblog.kluweriplaw.com/2016/04/21/the-dismal-history-of-compulsory-licences-in-india/
4. Archibugi, D., & Malaman, R. (1991). Il brevetto come strumento di appropriazione dell'attività inventiva e innovativa: 1'insegnamento delle indagini empiriche. in Malaman, Roberto,(1991), Brevetto e politica dell'innovazione. Organizzazione a funzioni dell'Ufficio Brevetti, 11.
5. Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on May 12, 2013).
6. Chaudhuri, S. (2007). The gap between successful innovation and access to itsbenefits: Indian pharmaceuticals. The European Journal of Development Research, 19, 49-65.
7. Ford, S. M. (1999). Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents. Am. U. Int'l L. Rev., 15, 941.
8. Germano, S. (2007). Compulsory licensing of pharmaceuticals in Southeast Asia: Paving the way for greater use of the TRIPS flexibility in low-and middle-income countries. UMKC L. Rev., 76, 273.
9. Granstrand, O. (1999). The economics and management of intellectual property: Towards intellectual capitalism. In The Economics and Management of Intellectual Property. Edward Elgar Publishing.
10. Gutterman, A. S. (1997). Innovation and competition policy. (No Title).
11. Ibrahim, J., & Abdullah, D. M. J. (2021). Impact Of Compulsory Licensing On Research & Innovation With Reference To Indian Pharma Companies. Webology (ISSN: 1735-188X), 18(2).
12. Jaffe, A. B., & Lerner, J. (2011). Innovation and its discontents: How our broken patent system is endangering innovation and progress, and what to do about it. Princeton University Press.
13. Opderbeck, D. W. (2009). Patent damages reform and the shape of patent law. BUL Rev., 89, 127.
14. Outterson, K. (2005). Pharmaceutical arbitrage: balancing access and innovation in international prescription drug markets. Yale J. Health Pol'y L. & Ethics, 5, 193.
15. PIB. (2016). Clarification on Media Reports regarding Compulsory licence, retrieved May13,2020fromhttps://pib.gov.in/newsite/PrintRelease.aspx?relid=138271&utm_source=twitterfeed&utm_medium= twitter
16. Shukla, N. (2019). Compulsory Licensing In India, retrieved May 13, 2020 from https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india
17. Sykes, A. O. (1990). The doctrine of commercial impracticability in a second-best world. The Journal of Legal Studies, 19(1), 43-94.
18. The Doha Declaration on the TRIPS Agreement and Public Health, 2001 (Adopted on November 14, 2001).
19. Tina Rosenberg, Look at Brazil, The New York Times January 28, 2001, available at http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html?pagewanted=all&src=pm (Last visited on May 12, 2013).