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A Study on Compulsory Licensing through Bibliometric Analysis

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This article is a study on Compulsory Licensing through the use of bibliometric analysis of 503 publications available in the Scopus database. It presents how Compulsory Licensing has gained importance over the years. It highlights the prominent authors in the field and the collaborations among them. It also shows the top institutions engaged in research in the field of compulsory licensing. This article lists the top publications and journals on the topic. The authors have also examined the trends in the topic and the major themes on which research is happening across the globe. A comparison has been drawn between the opinions of Indian Authors vis-à-vis the Authors from developed countries on the topic of Compulsory Licensing. It is observed from the publication database that the academic discourse on the topic took off from the year 2000 onwards, and there has been a sustained interest in the area. The top three countries that contribute to this discourse are the USA, India, and the UK. It is observed that, while India and other developing countries are in favour of a need-based compulsory licensing, developed countries, like the USA, UK, and Canada, are not in favour of compulsory licensing. Kingston W. is the most prominent author with the highest number of publications and citations. The Journal of Intellectual Property Rights has the highest number of publications. Publications on the topic are spread across institutions, and there is no single institution that stands out in terms of volume of contributions to publications.

Keywords: Compulsory Licensing, IPR, Patents, TRIPS, Doha Declaration, Voluntary Licensing

The genesis of compulsory licensing (CL) is rooted in the Paris Convention, 1883. Article 5 (2) says, "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuse which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work". As per WTO (TRIPS Agreement 1995, Article-31), compulsory licensing (the TRIPS language is that other use without the authorization of the right holder) is a special grant given by a State to its domestic companies to produce a patented product or use a patented process, without the consent of the patent owner. Other TRIPS provisions that are important are Articles 1, 6, 7, 8, 31 bis, 40, and 44, as well as the provisions of the 2001 Doha Declaration on TRIPS and Public Health.[1] A patent owner has a monopoly right over the commercial use of the patent for a pre-determined period, and compulsory licensing is a conscious violation of this right. The State issues a license when it is in the public interest. While this prerogative of compulsory licensing is available to the members of the WTO, it is rarely used, as it alienates the patent holders.[2] Matter of compulsory licensing is contained in Part-XVI(Sec. 84 to 92) of the Indian Patents Act, 1970. The first ever and only compulsory licensing given by the Indian Patent Office was for a generic version of Bayer's Nexavar (a medication for liver and kidney cancer) to Natco Pharma in 2012.[3] Accessibility and Affordability are two main concerns in the Indian healthcare system, yet the option of CL has been used rarely.[4] Even when compulsory licensing is granted, the patent holder is entitled to a royalty in accordance with the standards established by the United Nations Development Programme (UNDP). Compulsory licensing was generally meant for the domestic market. But in the Doha Ministerial Conference in 2001, it was decided that countries that have no production facility can also use the compulsory licensing method to get the drugs produced elsewhere for their domestic use (Article 31bis of TRIPS). One of the important preconditions before a compulsory license is issued is that the firm must have engaged with the patent holder for a voluntary license, and that it did not work out. There are countries that are liberally interpreting the compulsory licensing

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options and are making decisions that are alienating the patent holders, many of whom are based in developed countries. Indonesia has issued such licenses to nine patented drugs with the logic that those companies do not have a manufacturing facility in Indonesia. One of the ways patent holders are dealing with this situation is by issuing voluntary licenses or entering into strategic alliances with domestic companies.[5] Hoffman La Roche's tie-up with Emacure Pharmaceuticals to manufacture cancer drugs and Gilead Sciences' tie-up with Strides Arcolab to manufacture HIV drugs in India are examples of such ways adopted by the multinational patent holders. Article 12 of the United Nations International Covenant on Economic, Social and Cultural Rights (UN-ICESCR) says, "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Therefore, a member state has to keep this perspective in mind while deciding on the matters of compulsory licensing. When there is a dilemma between human rights and IPR, the former must take precedence. Countries use multiple grounds for granting compulsory licenses, like Refusal to deal, non-working and inadequate supply, Public interest, Anti-competitive practices, Governmental use, facilitate the use of dependent patents, Compulsory licenses for medicines, and Licenses of right.[6]

During COVID-19, there was a sharp rise in the discourse around compulsory licensing. Access to generic medicines, vaccines, diagnostics, and medical apparatus, and also resources to produce them, was essential to battle COVID-19.[7] Besides the patents, there was an urgent need for compulsory licensing of the trade secrets related to the vaccine manufacturing process for easy production and distribution of COVID-19 vaccines across the globe.[8] In 2020, India and South Africa, supported by more than 100 countries, approached the WTO for a temporary suspension of IP rules, including TRIPs (IP waiver), so that member countries can produce and use drugs, vaccines, and other pharmaceutical products to fight the pandemic and save precious lives.[9] An IP waiver was necessary for bridging the supply-demand gap of medical products to fight the pandemic.[10] Between compulsory licensing and IP waiver, the latter is a better option.[11] On the other hand, authors like[12] argued that the flexibility available in Article-31 and Article-31bis are good enough to bypass IP rights and go ahead with manufacturing and distributing essential drugs and vaccines to the public to fight the pandemic which is a public emergency and a right step in protecting human rights. Many multinationals acted selfishly during Covid-19 and protected their IP rights to ensure their nation's citizens get the vaccine first[13] Such a myopic use of IP rights is a violation of human rights. In an increasingly interconnected world where hostile pathogens can traverse sovereign borders, the initiatives to fight them must be global, and nationalism should not take precedence over humanism. In a global crisis, patent holders must produce enough and cater to the global need or else license out their technology and know-how to third-party manufacturers.[14] During Post COVID pandemic, countries reviewed their IP Laws and suitably amended those to meet future crises. The EU[15] is actively working on such a proposal to secure the rapid deployment of patent-protected inventions in times of crisis or emergency, without eroding patent protection as an incentive to innovate.

There are contrarian views against the use of compulsory licenses as well. Some think that unreasonable and unrestricted use of compulsory licenses will adversely affect drug innovation, healthcare, and the health economy.[16] A few authors think it is good to use compulsory licensing in moderation so that there is a balance between the rights of IP owners and the public right.[17] The author goes on to say that though developing countries are often blamed for misuse of compulsory licensing, developed countries have issued more CLs than others. It is pertinent to mention here that the USA is known to have issued thousands of compulsory licenses across product segments, including drugs. But when such CLs are issued by developing countries, there is a backlash from developed countries. In addition to CL, a state has the instrument of price control to help its citizens get the drug at a lower price.[18] There is a general belief that CL adversely affects innovations. But when the USA allowed CL of all German patents post WW-I by the Trading with the Enemy Act (TWEA), innovation in Germany increased by 30%.[19] One of the side effects of CL

is that the CL in the underdeveloped countries adversely affects the prices of the patented products in the developed countries.[20]

Obtaining Dataset

Data was extracted from the Scopus Database using the phrase "Compulsory Licensing". (https://www.scopus.com/results/results.uri?sort=plf-f&src=s&st1=%22 Compulsory + Licensing%22&sid=06475b67a47dec1467baef84597bdfbb&sot=b&sdt=b&sl=37&s=TITLE-ABS-KEY% 28%22 Compulsory+Licensing%22%29&origin=searchbasic&editSaveSearch=&yearFrom=Before+1960&yearTo=Present&sessionSearchId=06475b67a47dec1467baef84597bdfbb&limit=10).

From the search, 503 documents were found, and that data was downloaded in a .csv file format. Later, for the purpose of data analysis, this file was converted to an .xlsx file. In this data, there are 324 articles, 74 reviews, 63 book chapters, 15 conference papers, and 8 editorials. H-Indices of the journals were collected from Scimago-Journal Matrix.

Data Analysis Tools

VOSViewer software was used to find out the most influential authors, top sources, leading institutions involved in research in the area, most cited documents, etc. This software was also used to find out co-authorship and trends in the area of Compulsory Licensing.

Findings

Figure 1 shows the year-wise documents published on Compulsory Licensing. It is observed that till the year 2000, there were very low or no publications in this area on a year-to-year basis. Between 2000-2010, there was a strong positive growth of publications. There has been a positive growth trend post-2010, but in some years, there has been a drop in publications. On an overall basis, there is a positive trend in publications. There are two schools of thought on Compulsory Licensing. One group of authors underscores that a huge investment is needed for the invention of medicines, and hence, a patent for 20 years is necessary. By this, the institution or corporation that invested money will be able to recover the cost

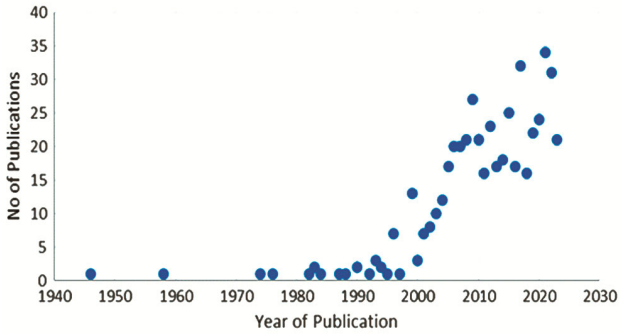

Fig. 1 — Growth of Publications on Compulsory Licensing

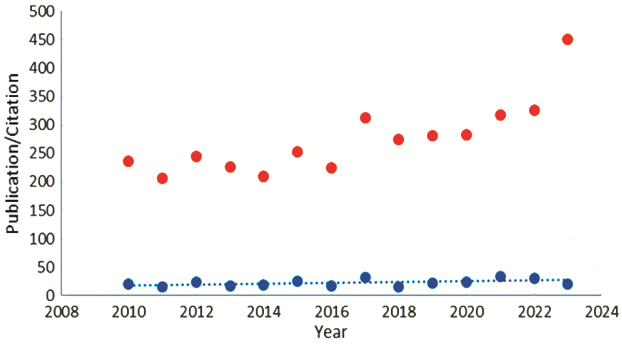

Fig. 2 — Relationship between Publication and Citation (2010-2023)

and get some return from the investment. The other school of thought highlights the affordability issue. They think that the prices of the newly invented products are sometimes very high, and a large segment of the global population, particularly in developing countries, can't afford such medicine. Therefore, the country should have the right to give compulsory licensing so that generic medicines can be produced and supplied at affordable prices. Both arguments are logical, and the need of the hour is to bring some kind of balance between the two.

Figure 2 shows the relationship between publications and citations. The Citation overview of the Scopus database gives the total citation for pre-2010 and then the year-wise citation for the period 2011 to 2023. It can be noticed that the publication has remained the same in the range of 30-45 during 2010-2023. On the other hand, the citations remained within the range of 200-250 during 2010-2016, and then there was a growth of citations, and in the year 2023, it touched 450. Therefore, it can be said that the earlier works on the subject are getting traction and authors are citing them in their publications.

Table 1 shows the list of authors with high citations. Kingston, W, is the most cited author with just two documents authored by him, and also has the highest Citation/Document ratio. He is followed by two authors, Matthews D. and Reichman J.H. with 80 and 63 citations, respectively. Bond E.W.; Saggi K. are the two authors with the number of publications, which is the highest. There is just one author with more than 100 citations, and 12 authors/co-authors who have more than 10 citations.

Table 1 — Most Cited Authors (Search criteria - minimum 2 documents and minimum 5 citations)

Author	Documents	Citations	Citation/Document
KINGSTON W.	2	103	52
MATTHEWS D.	2	80	40
REICHMAN J.H.	3	63	21
LEXCHIN J.	3	59	20
SCHÜKLENK U.; ASHCROFT R.E.	2	59	30
SON K.-B.; LEE T.-J.	2	37	19
BOND E.W.; SAGGI K.	8	36	5
OWOEYE O.A.	2	29	15
RAMANI S.V.; URIAS E.	2	26	13
ELLIOTT R.	3	23	8
SUNDARAM J.	2	15	8
WEISSMAN R.	2	12	6
BAGLEY M.A.	3	9	3
GUENNIF S.	2	8	4
MANU T.	5	8	2
SANDERS A.K.	2	8	4
URIAS E.	2	8	4
TREMBLAY J.-F.	2	7	4
ASOK A.	2	6	3
BASHEER S.	2	5	3
SON K.-B.	2	5	3

Figure 3 shows the Co-authorship diagram. As can be seen, the number of documents produced through co-authorship is low, and hence, there are 102 clusters. But there are 4 clusters that are relatively prominent. Bond ew and Saggi k are the top co-authorship with 8 documents to their credit. The other three are individual authors who have 3 documents each to their credit. They are Elliott R, Lexchin J and Reichman J H.

Table 2 shows the list of highly cited documents in the area of compulsory licensing. “Compulsory licensing: Evidence from the Trading with the Enemy Act,” published in 2012, has the highest number of citations, followed by “Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations,” published in 1996.

Fig. 3 — Co-Authorship diagram(Search criteria - min 1 document and min 10 citations)

Table 2 — Top 10 cited articles in the area of Compulsory Licensing

Publication Year	Document Title	Citation
2012	Compulsory licensing: Evidence from the Trading with the Enemy Act	248
1996	Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations	238
2003	Differential pricing for pharmaceuticals: reconciling access, R&D and patents.	196
2007	Sustaining access to antiretroviral therapy in the less-developed world: Lessons from Brazil and Thailand	136
2002	Post-trips options for access to patented medicines in developing nations	109
2012	Trends in compulsory licensing of pharmaceuticals since the Doha declaration: A database analysis	103
2007	The Doha round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions	103
2007	Brazilian policy of universal access to AIDS treatment: Sustainability challenges and perspectives	101
2001	Innovation needs patents reform	93
2007	Managing the hydrological impacts of South African plantation forests: An overview	83

Table 3 — Top 20 Journals in the area of Compulsory Licensing

Journal Title	No of Documents	Sum of Citation	Citation/ Document	H-Index
Journal of International Economic Law	6	338	56	54
American Economic Review	1	248	248	12
California Law Review	1	238	238	38
AIDS	2	237	119	226
International journal of health care finance and economics	1	196	196	34
Journal of Law, Medicine and Ethics	4	187	47	63
Nature Reviews Genetics	2	156	78	406
Bulletin of the World Health Organization	4	127	32	184
Research Policy	4	118	30	271
Journal of Intellectual Property Rights	19	110	6	14
International Journal of Health Services	4	106	27	65
PLoS Medicine	1	103	103	258
Forest Ecology and Management	1	83	83	196
Journal of Economics/ Zeitschrift fur Nationalokonomie	2	83	42	36
Globalization and Health	5	74	15	70
Journal of Political Economy	1	68	68	207
Journal of Medicine and Philosophy	2	62	31	56
Global Public Health	5	60	12	54
Nature Reviews Clinical Oncology	1	60	60	198
International Journal of Intellectual Property Management	11	52	5	12

Table 3 shows the list of highly cited journals that published articles on Compulsory Licensing. It can be seen that "Journal of International Economic Law" has the highest number of citations. However, in terms of Citations/documents, "American Economic Review leads the publication, followed by "California Law Review".

Table 4 and Fig. 4 show the country-wise publications on Compulsory licensing. The USA leads in terms of the number of documents, followed by India and the United Kingdom. In terms of citations, the three leading countries are the USA, UK, and Canada. It is interesting to note that some of the leading economies of the world, like China, Germany, and Japan, have a very limited number of documents on the subject. Of course, this analysis is based only on the documents indexed in the Scopus database. In terms of the link strength, the top three countries are the USA, the United Kingdom, and the Netherlands.

Table 5 shows the leading organizations that have published documents related to Compulsory licensing. Unu-Merit, Maastricht, Netherlands, has the highest number of publications. In terms of citations, the Department of Law, Duke University, School of Law, Durham, Nc, United States, leads, followed by Global Health Affairs Program, Josef Korbel School of International Studies, University of Denver, Denver, Co, United States

Table 4 — Country-wise Publications and Citations (Min 5 documents and Min 10 citations)

Country	Documents	Citations	Total Link Strength
United States	122	1739	43
India	74	194	6
United Kingdom	53	420	31
Canada	33	315	9
Australia	25	208	11
South Africa	21	300	9
Brazil	20	476	11
Switzerland	15	293	13
Netherlands	15	190	17
China	15	22	5
France	14	115	14
Germany	13	92	11
Thailand	9	187	5
Japan	9	162	8
Italy	8	65	10
South Korea	7	48	1
Hong Kong	7	17	1
Belgium	6	93	2
Spain	5	77	1

Figure 5 shows the keywords that have been mentioned in the documents related to compulsory

licensing. While compulsory licensing is the core topic on which a lot of research is happening, authors are also working in many connected and allied areas. The keywords in the network diagram show the trends of research. Doha Declaration and TRIPS flexibilities prominently feature as key words. It is also noticed that healthcare-related words are extensively present in the Keyword distribution.

Global Perspective on Compulsory Licensing

Developing countries do not perceive CL in the same way that developed countries do.[21] Close to 80% of the patents in the developing countries belong to multinational companies, and many of these developing countries do not show commitment towards IPR and related contract enforcement. They control the patented items through price control, favorable voluntary licensing, or compulsory licensing. On the other hand, developed countries believe that developing countries piggyback on their R&D investment of developed countries. Such action adversely affects the return on investment in R&D of developed countries and also diminishes the entrepreneurial initiative for innovation. While developed countries look at IPR from the economic point of view, developing countries think all innovations should be used for the greater interest of humanity. The Global South and Global North have different goals and strategies. Global North pursue economic benefits through market entry in the Global

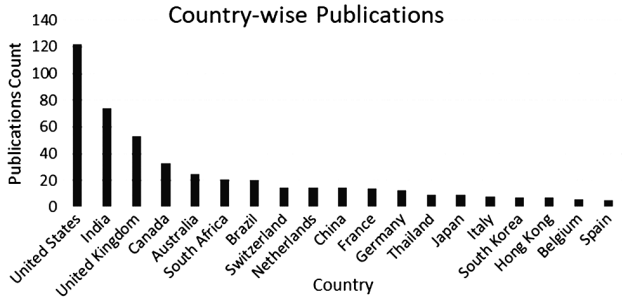

Fig. 4 — Country-wise publications of articles on compulsory licensing

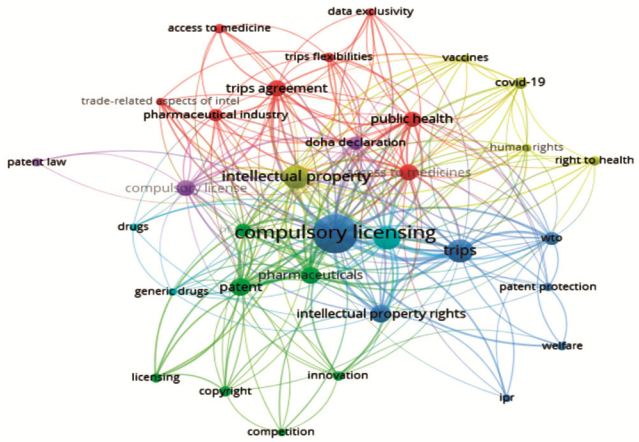

Fig. 5 — Network Diagram of Keyword Distribution (5 times occurrence of the Author's keyword)

Table 5 — Organization-wise Publications and Citations (Min 2 documents and Min 5 citations)

Organization	Documents	Citations	Citation/ Document
Department of Law, Duke University, School of Law, Durham, Nc, United States	2	162	81
Global Health Affairs Program, Josef Korbel School of International Studies, University of Denver, Denver, Co, United States	2	109	55
Unu-Merit, Maastricht, Netherlands	4	51	13
Department of Public Health Science, Graduate School of Public Health, Seoul National University, Seoul, South Korea	3	43	14
Institute of Health And Environment, Seoul National University, Seoul, South Korea	3	43	14
Athena Institute, Vu Amsterdam, Amsterdam, Netherlands	3	33	11
Elabora Consultoria, São Paulo, Brazil	3	27	9
Department of Economics, Vanderbilt University, United States	4	24	6
Law School, University of Buckingham, Buckingham, United Kingdom	2	15	8
School of Law, City University of Hong Kong, Hong Kong	2	11	6
Harvard Law School, United States	2	10	5
College of Pharmacy, Ewha Womans University, Seoul, South Korea	2	6	3
National Law School of India University, Nagarbhavi, Bangalore, 560 072, Karnataka, India	2	6	3
Duke University, United States	3	5	2

South either directly or through voluntary licensing. On the other hand, the global south considers affordability and accessibility, particularly in healthcare, and adopts price control and compulsory licensing as their ways to achieve their goals.[22]During Doha declaration (2001), many developed countries thought that CLs would be overused to their disadvantage. But it was seen that most CL episodes that occurred between 2003 and 2005 involved drugs for HIV/AIDS, and occurred in upper-middle-income countries (UMICs). Aside from HIV/AIDS, few CL episodes involved communicable disease, and none occurred in the least-developed or low-income countries.[23] More over it was found that the use of CL diminished after 2006. Though the IP Law of the USA does not specifically contain any provision of CL, it is used in various circumstances, including antitrust under various laws like The Atomic Energy Act, Clean Air Act, The Plant Variety Protection Act, etc.[24] Many developing countries like Malaysia, Brazil, Zimbabwe, Ecuador, India, Philippines, Indonesia, Argentina, etc have used CL and other flexibilities in TRIPS, to particularly address the healthcare needs of the citizens.[25] There are also multiple instances where CL has been used to counter antitrust activities in the market. In a survey conducted by the World Intellectual Property Organization (WIPO), it was found that as many as 32 countries used CL for countering anti-competitive practices.[26]

Even during the peak of COVID-19 pandemic, developed countries, where most of the pharmaceutical and vaccine patent holders are located, thought compulsory licensing and IP waivers would harm everyone, including the developing countries. Inferior quality and an inadequate distribution system were cited as the primary reasons for such a view. On the other hand, India, South Africa, and many other developing countries felt that IPR created a hurdle in producing a large quantity of vaccine and catering to the huge population waiting for the same. One can understand the economic angle stressed by the developed countries and their insistence on IP protection in normal times. But their rigidity for such rights during a global crisis like COVID-19 is not acceptable, as the cost of such rights was human lives. Developed countries should have gone ahead with a moratorium on IP rights at least till the end of the COVID-19 crisis. Of course, later, many global pharmaceutical companies collaborated with domestic manufacturers for the production of vaccines, ventilators, test kits, accessories, etc. Some developing countries also came up with new vaccines to meet their local needs. India is one of the pioneers in this direction. It not only took care of the vaccination of its citizens in record time but also supplied vaccines to the neighboring countries free of cost.

Conclusion

Compulsory licensing is a contentious issue. On the one hand, innovators invest a huge amount of money in R&D to bring out new products to the market. Logically, they need protection of their IP rights so that they can get a commensurate return from their investment. If this right is not protected, there will be no incentive for innovation, and there will be no novel product in the market. On the other hand, there are allegations that IP Rights are being used for profiteering and anti-competitive practices. In many situations, IP rights are in loggerheads with human rights, and this became apparent during the COVID-19 pandemic. Every State has a moral and legal responsibility to take care of its citizens. Therefore, in exceptional situations, some States have used the TRIPS flexibility of compulsory licensing. But such use has been far and few. Even during the COVID-19 pandemic, there was minimal use of compulsory licensing. Every innovation has an egalitarian public purpose, and therefore, it should be available to everyone. Compulsory licensing is the last resort available to a State to provide such access to the public. This is a win-lose situation, where the State wins and the Innovator loses. Many win-win alternatives can be worked out by proper dialogue between the Innovators and the State, like voluntary licensing, collaborative manufacturing, technology transfers, etc. WTO should also look into this contentious issue and find out how a balance can be maintained between private IP rights and public human rights.

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