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Compulsory Licensing of Pharmaceutical Patents in Pakistan Patent Ordinance

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Abstract: In Pakistan, access to affordable medicines is a critical challenge due to high disease burdens and exorbitantly priced patented drugs that leave millions without essential healthcare. Compulsory licensing (CL) under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement provides a legal mechanism for the production or importation of generic versions of patented medicines to ensure their affordability and availability. This article considers how CL can be used as one avenue to begin bridging the gap between intellectual property rights (IPRs) and public health imperatives in Pakistan. The study focuses on the prevailing health-related condition of both high prices for patented medicines and healthcare expenditure by out-of-pocket expenses. Under this context, it evaluated the compulsory licensing regime in Pakistan in conformity with the provisions under Patents Ordinance 2000.Several issues have been encountered in that course including institutional inefficiency, weak technical capacity, and international pressures being in the front lines. Drawing from worldwide experience in countries as varied as India, Brazil, and Thailand, this article explains precisely how CL allows equity in medical access, with an assurance of the need for the local manufacture of pharmaceutical products and cuts off healthcare costs. The recommendations are policy priorities on the strengthening of legal frameworks, enhancement of regulatory capacity, promotion of local production, and tapping into international support. The article concludes that CL is not only a legal tool but an ethical commitment to the right to health. With bold action and coordinated efforts, it is possible for Pakistan to employ CL as a tool in transforming its healthcare system and ensuring that life-saving medicines are truly affordable and accessible to all.

Keywords: Compulsory licensing; Pakistan patent ordinance; pharmaceutical patent; Trade-Related Aspects of Intellectual Property Rights

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1. Introduction

Access to reasonably priced healthcare is a basic human right and a cornerstone of social justice (Rumbold et al. 2017). However, millions of people in Pakistan, are deprived of access to life-saving medicines being high-priced. Affordability is a critical public health issue as in Pakistan around 25% of the population is below the poverty line and the health system is largely based upon out-of-pocket spending for lifesaving drugs worsening it further. The Universal Declaration of Human Rights 1948 establishes the adequate standards of health as one of human rights for an individual and his family through article 25. Similarly, 1966 International Covenant on Economic, Social and Cultural Rights, reaffirms this right to the highest achievable degree of physical and mental health vide Article 12. The right of well-being of citizen is also recognized in article 38 of Constitution of Pakistan, 1973. This Article mentions the provision of medical facilities as one of the basic necessities of life. Under the said Act the patent holder has the duration of 2 years to enjoy the protection of its intellectual effort to the exclusion of others in matter of production, marketing or stocking etc.

In this context, compulsory licensing (CL) is a reasonable solution to increase access to medicines. This is a legal mechanism of government bypassing patent exclusivity and authorizing the production or importation of generic versions of patented medicines at often a fraction of the price (Meyer 2023). The World Trade Organization's TRIPS Agreement emphasizes compulsory licensing. In TRIPS Agreement, provisions exist for the member states to grant CL in cases involving public health for emergencies or where the medicines are too expensive. This flexibility can be a game-changer for countries like Pakistan, which faces high burdens of both communicable and non-communicable diseases, including hepatitis, diabetes, tuberculosis, and cancer. For example, treatments for hepatitis C,

which afflicts over 8 million people in Pakistan, can cost upwards of several thousands of dollars under patent-protected brands, beyond the purchasing power of the average citizen (Son and Lee 2018; Urias and Ramani 2020).

However, CL in Pakistan is has never been issued due to the resistance of multinational pharmaceutical firms. Besides these, serious challenges or shortcomings in attaining essential CL technical and regulatory capacity both within and outside the countries' healthcare systems and IP institution are further impairing the effective deployment and issuing of CL regarding public health's outcomes for Pakistan. Besides these challenges, the economic dependencies further make the government avoid taking bold measures against the patent holders, even when this affects public health (Reichman 2009).

Around the world, countries like India and Thailand have successfully used CL provisions to tackle public health challenges and ensure access to affordable medicines. In India, for example, a CL issued in 2012 allowed the production of a generic version of Bayer's cancer drug Nexavar, thus causing making medicine affordable by reducing the cost up to 97%. This is good example that CL is not only providing support in the establishing of basic rights to health and regulating the intellectual property (Bognar et al. 2016). Prior to the TRIPS, patent protection term was different in different countries. TRIPS, however set the minimum patent duration of 20 years for an invention. Article 31 of TRIPS agreement since 1995 allows various felicities followed by Doha Declaration assuring to use these flexibilities by the member countries at their discretion of through.

This article explains the role of CL in the context of Pakistan. Compulsory licensing provisions of TRIPS, their interpretation in the Doha Declaration and Patent Ordinance of Pakistan 2000 were studies by comparative legal research method. Primary research resources including the Pakistan Patent Ordinance 2000, the TRIPS Agreement and the Doha declaration and secondary resources consisting of research papers, and books related to the topic were studied.

2. Understanding Compulsory Licensing

Compulsory licensing is a legal tool for any country to utilize or allow the use of patented formulation, products or procedure without taking permission of the patentee in unusual circumstances of national emergency or public health. It is very useful in maintain the balance in granting access to necessities and at the same time protecting IPRs (Ibrahim and Abdullah 2021). The concept of CL is based on the TRIPS agreement established by the World Trade Organization (WTO) to regulate the IPRs in WTO member countries. Article 31 of the TRIPS Agreement explicitly permits member states to issue compulsory licenses under specific conditions. These include ensuring that the use primarily benefits domestic needs and that patent holders receive "adequate remuneration" for their invention (Vincent 2020).

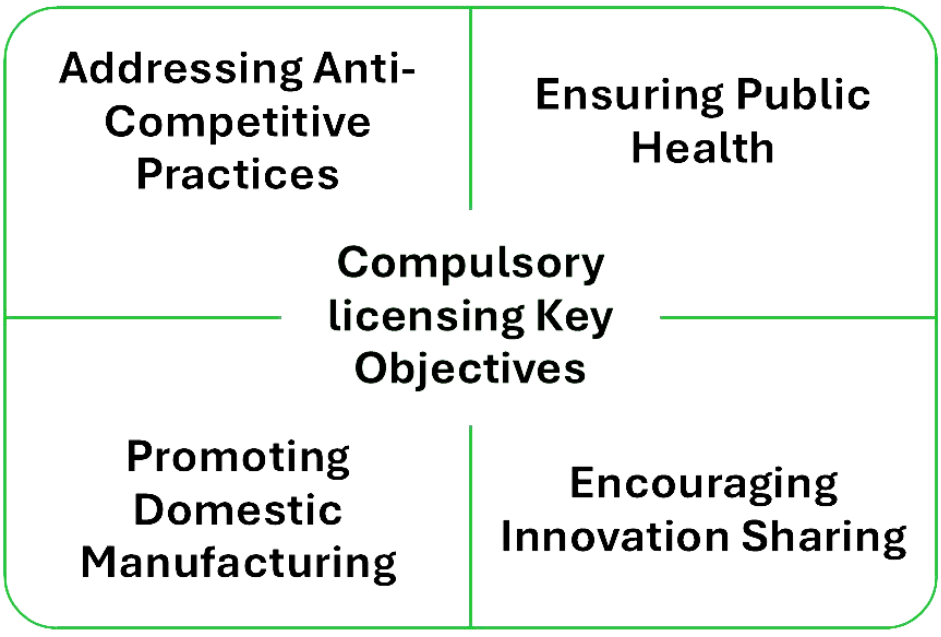

Figure 1. CL Key objectives

The first objective as depicted in Figure 1, ensuring public health will facilitate the access to essential medicines during health emergencies or for treating diseases where the cost of treatment is prohibitively high. Secondly, CL addresses the anti-competitive practices, that control and safeguard against monopolistic behavior of patent holders that restricts market access or inflates prices. Thirdly CL promote the manufacturing and production of patented products domestically. It includes the production of generic medicine thus self-support of the country will be strengthened. Fourthly, CL encourage innovation sharing by balance the sharing and protection of innovation through patenting to serve the society for affordable and accessible solutions.

The mechanism of CL is given in Figure 2 and 3. The process begins with the government or an authorized agency issuing a CL, allowing the use or production of a patented product or process without the patent holder's consent. These licenses are usually restricted to non-commercial or domestic purposes to ensure that the patent holder's rights are not unduly impacted. The patent holder is compensated through royalties, which are typically determined by the government based on factors like the economic value of the patented product. CLs are often issued for specific purposes, such as addressing public health emergencies, and are limited to a defined timeframe or target population.

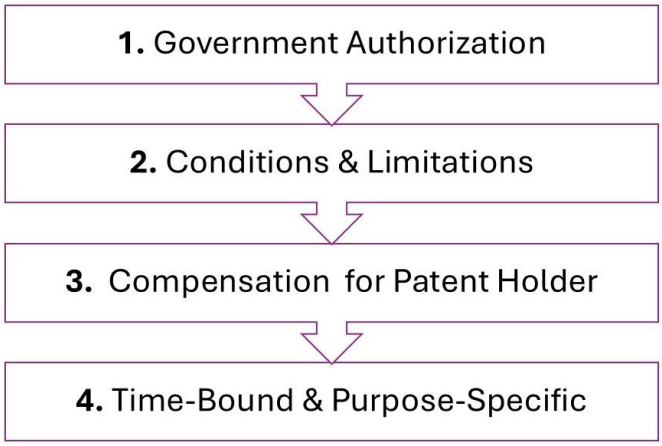

Figure 2. Mechanism of Compulsory Licensing

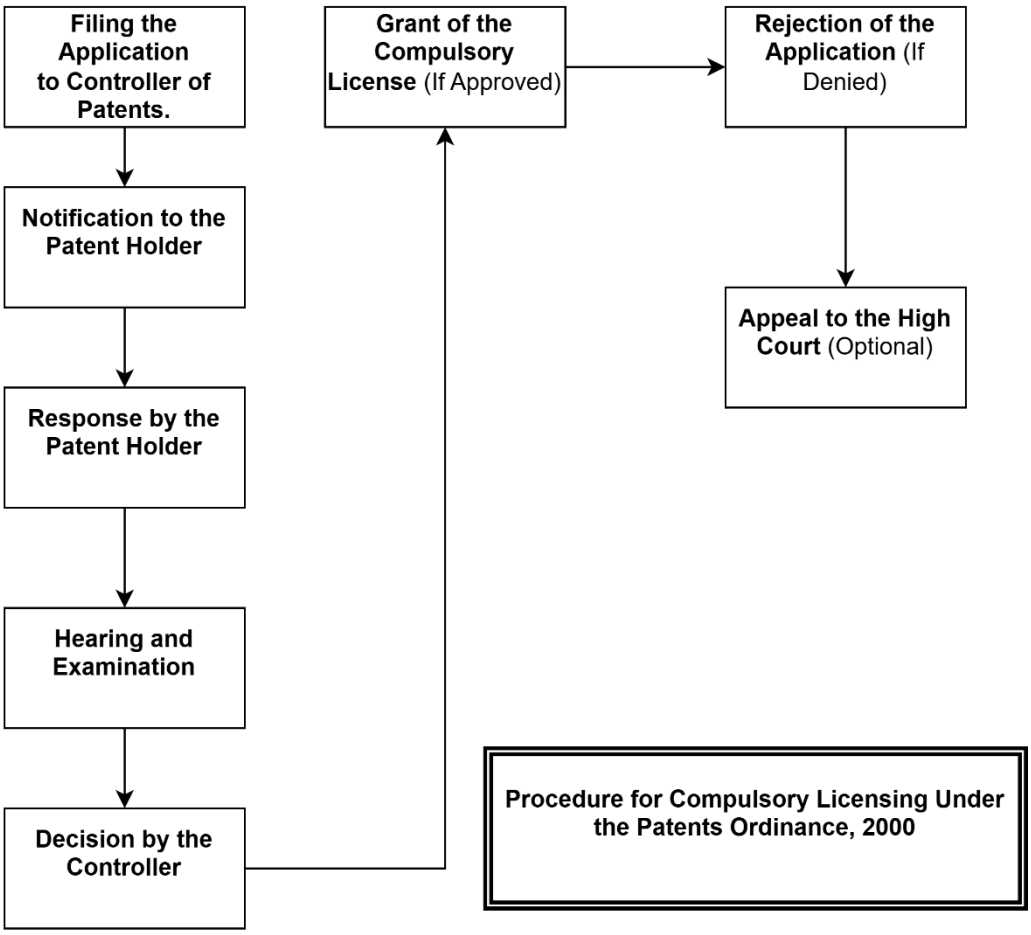

Figure 3. Procedure for compulsory licensing under the patent ordinance 2000, Pakistan

The Doha Declaration on the TRIPS Agreement and Public Health (2001) reinforced the right of the WTO member states to use CL as a tool to protect public health (WTO 2001). Hence, member countries can define the grounds for issuing a CL, which can go beyond emergencies to include issues like unaffordable medicine prices or supply shortages.

Several countries (Table 1) have successfully implemented CL, to make medicines more affordable and accessible. India issued in 2012 a CL under section 84 of Indian Patent act for Bayer's cancer drug Nexavar, reducing its cost dramatically—from around $5,600 to just $175 per month The Thai government utilized CL for several HIV/AIDS medications, significantly lowering costs and improving access to treatment (Ford et al. 2007). Brazil in 2007 issued a CL for Merck's HIV/AIDS drug Efavirenz to ensure broader access to treatment for its population (Rodrigues and Soler 2009).

While CL promote public health, these have their own drawbacks. It is argued that CL undermines innovation by reducing the financial incentives for research and development (R&D) (DiMasi et al. 2003). High-income countries with strong pharmaceutical

industries frequently exert diplomatic pressure to discourage the CL (Sell 2003). Many countries, especially those with limited technical and regulatory expertise, face difficulties in effectively implementing CL provisions (Correa 2000).

CL holds significant potential for Pakistan to tackle pressing healthcare challenges, particularly the high costs of medicines for conditions like cancer, hepatitis, and diabetes (Correa 2011). By utilizing the flexibilities provided under the TRIPS Agreement, Pakistan can ensure that life-saving medicines are affordable and accessible to all, while remaining compliant with international legal standards. This approach can play a transformative role in improving healthcare equity across the country (Zaidi et al. 2013).

Table 1. Global Legislative Actions for Access to Medicines During Health Emergencies.

Country	Law/Action	Year	Health Emergency	Key Features
Israel	Importation Authorization	2020	COVID-19	import of a generic version of AbbVie's Kaletra from India for treating COVID-19 patients (Wong 2020)
Canada	COVID-19 Emergency Response Act	2020	COVID-19	the Patent Act amended to allow a simpler and quicker process for issuing CLs (Ewing 2020)
Germany	Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance	2020	COVID-19	Empowered the Federal Ministry of Health to issue CLs for patented inventions (Färber 2021)
France	Emergency Health Law	2020	COVID-19	Allowed the Prime Minister to seize goods and control prices to ensure accessibility of medicines; authorized generic manufacturing (Chamboredon et al. 2020)
Chile	Resolution by the Chamber of Deputies	2020	COVID-19	Declared that COVID-19 justifies issuing CLs (Jiménez et al. 2022)
Ecuador	Resolution by the National Assembly	2020	COVID-19	Authorized the Minister of Health to use CLs (Binder 2024)
Colombia	Decree by the Ministry of Health and Social Protection	2020	COVID-19	Granted power to the Ministry, facilitating CL (Prada et al. 2022)
Hungary	Government Decree 212/2020	2020	COVID-19	Allowed the government to issue CLs (Bonadio and Contardi 2023)
Indonesia	Presidential Regulation No. 77 of 2020	2020	COVID-19	Expanded government power to use patents for urgent public needs (Mietmer 2020)
Russia	Ordinance under Article 1360 of the Civil Code	2020	COVID-19	Issued CLs in the interests of defense and security, subject to payment of commensurate remuneration (""Remdesivir" Decision of the Supreme Court of the Russian Federation 27 May 2021-Case No. АКПИ21-303," 2021)
South Africa	Medicines and Related Substances Control Act	1997	HIV/AIDS	Allowed import and CL of antiretroviral drugs to improve access for HIV/AIDS treatment (Bombach 2001)
Thailand	CLs for Antiretrovirals	2007	HIV/AIDS	Issued CLs for patented antiretrovirals such as Efavirenz to reduce costs and expand access (Mohara 2017)
Brazil	Presidential Decree	2007	HIV/AIDS	Declared Efavirenz of public interest and issued a CL to produce the drug domestically (Galvao et al. 2009)
India	CL for Nexavar	2012	Cancer	Issued a CL for Bayer's cancer drug Nexavar, citing high prices and public interest (Srinivasan 2012)
United States	Executive Order on Ensuring Essential Medicines	2020	COVID-19	Directed the FDA to develop a list of essential medicines and encouraged domestic production to reduce dependence on foreign manufacturers (Guharoy and Noviasky 2021)

Malaysia	CL for Sofosbuvir	2017	Hepatitis C	Issued a government-use license to import generic of the Hepatitis C medication Sofosbuvir (Chan et al. 2020)
Zimbabwe	General Notice 240 of 2002	2002	HIV/AIDS	Issued a declaration allowing the government to authorize the manufacturing or import of generic antiretroviral drugs (Noguera et al. 2003)
Mozambique	CL for Antiretrovirals	2004	HIV/AIDS	Granted a CL to produce generic versions of antiretroviral drugs (Asok 2017)
Zambia	Statutory Instrument No. 39	2004	HIV/AIDS	Allowed the production and import of generic antiretroviral drugs through CL (Chirawu 2006)
Ethiopia	Proclamation No. 123/1995	1995	General Health Access	Included provisions for CL to ensure the availability of essential medicines (Demeke 2021)
Malaysia	CL for HIV Medicines	2003	HIV/AIDS	Issued a two-year CL to import generic versions of Didanosine, Zidovudine, and a combination of Lamivudine and Zidovudine from India (Khor 2009)
United States	Authorization for Ciprofloxacin	Post-2001	Anthrax Scare	After anthrax attacks, the government threatened to issue a CL for Ciprofloxacin to lower prices (Adalja 2012)
Brazil	Health Ministry Compulsory Licensing	2007	HIV/AIDS	Issued a CL for Merck, Efavirenz, citing high prices and the need for affordable access to antiretrovirals (Possas 2008)
India	Compulsory License for Nexavar	2012	Cancer	Ensured access to affordable cancer treatment by issuing a CL for Bayer's Nexavar to produce cheaper generics (Srinivasan 2012)

3. Compulsory Licensing in the Context of Pakistan

Pakistan's healthcare system faces significant hurdles in ensuring equitable access to quality essential medicines. With a population of over 241.49 million, Pakistan mainly relies on loan from IMF for financial support, the health care facilities are not as per the population, due to significant burden of diseases (Khan et al. 2023). Most of the people are underprivileged and marginalized while the price of medications is higher and the situations are getting worsen day by day as the country has to depend mainly on the import of raw materials, and technology while the energy crisis in the country further aggravates the situations (Moon et al. 2011). Major public health concerns include infectious diseases like TB (Pakistan is at 7th globally), and 8 million hepatitis patients (Waheed et al. 2009; WHO 2024). Chronic non communicable diseases account for more than 58% of Pakistan's yearly fatalities, these diseases include diabetes, cardiovascular diseases, and cancer that are due to urbanization, changes in lifestyle, and aging (Basit et al. 2018; Kazmi et al. 2022). Many of these disease conditions require long term care and expensive and patent protected medications that are usually not affordable for common man. In most of the situations, the cost of these medications is covered by the person's own pocket money, which is estimated to be almost 60% of the total health expenditures (Khalid et al. 2021). Thus, CI may be an alternate solution to reduce the cost for patented medicines. For example, Imatinib for chronic myeloid leukemia and Sorafenib for liver cancer treatment may cost up to thousands of dollars for complete course of therapy in Pakistan for patented drugs which are costly than generic versions of same drugs in India (Hill et al. 2014; Siddiqui and Rajkumar 2012). In these cases, CI may be an urgent solution of affordable medications for Pakistani community.

Pakistan allocates 1.2% of the GDP for providing health services which is very low and government cannot subsidize medications or other services to the maximum extent. Hence, private sector health institution usually predominates making health services less affordable (Nishtar et al. 2013). Higher prices are from both local and international pharmaceutical firms but local firms usually manufacture generic medications, while the patented necessary medications are not available at reasonable price. Preference of metropolitan areas over rural from marketing point of view deprives the rurales, and lack of support for domestic production might be another problem faced by generic manufacturers (Ahmed and Chandani 2020; Correa 2011). Due to these higher priced medications and disproportionate access particularly in rural areas where women and children are among the highly affected as their monthly salary is not sufficient to pay the cost of a single dose of patented medicine (Atif et al. 2017; Shaikh and Hatcher 2005). Thus, taking advantage of CL provision in patent ordinance 2000 may play role in the affordability of necessary medicine.

4. Legal Framework and Challenges to CL in Pakistan

Pakistan Patents Ordinance, 2000 provide legal base for both patenting and CL. This ordinance was promulgated in 2000 with aim for legal protection of innovation and invention and to comply with WTO TRIPS agreement. This ordinance was amended several times till date, lastly in 2016. Section 58 of the ordinance provides legal base for the CL in Pakistan. This section allows non-exclusive

CLs, if a patented invention is not meeting public demand, is unavailable at a reasonable price, or its refusal unfairly affects trade or industry in Pakistan, ensuring public access while providing fair compensation to the patent holder (WTO 2001). If the patent holder fails to meet demand within the country, for public interest, particularly during public health crises, CL can be issued. Section 29 of the ordinance allows the use of patented inventions for non-commercial purposes, such as research and education (Gujjar et al. 2024). However, till now, despite of emergency situations as given in table 2, no advantage has been taken of this provision to address public health concerns, due to various reasons such as gaps in enforcement, limited awareness, and regulatory challenges (Gujjar et al. 2024).

Pakistan is a member of the WTO and has adopted the flexibilities outlined in the TRIPS Agreement. Article 31 of TRIPS permits CL for public health needs. The Doha Declaration on TRIPS and Public Health (2001), reaffirmed Pakistan's right to use TRIPS flexibilities to address public health challenges, including issuing CLs for essential medicines. While Pakistan is not classified as an LDC, the provisions under TRIPS allow developing countries to prioritize health over patents in exceptional circumstances (WTO 2001).

The Drug Regulatory Authority of Pakistan (DRAP) is the primary body overseeing the pharmaceutical sector, including the regulation of drug prices, quality assurance, and market availability. While DRAP plays a crucial role in ensuring that medicines are accessible, several regulatory challenges hinder its effectiveness. Although DRAP regulates drug prices, patented medicines often remain prohibitively expensive due to market exclusivity granted by patents. Regulatory hurdles discourage local production of generic versions of patented drugs, even when a CL is issued. The mechanisms for enforcing CL provisions remain underdeveloped, leading to limited use of this legal tool.

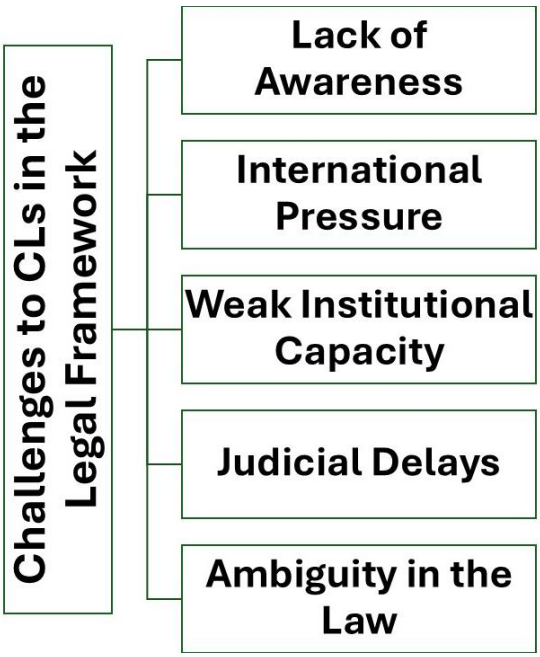

Figure 3. Challenges to CLs in the legal framework

As explained in the figure 3, limited understanding of TRIPS flexibilities among policymakers and healthcare stakeholders has prevented the strategic use of CL. Pakistan often faces diplomatic and economic pressure from high-income countries and multinational pharmaceutical companies to avoid issuing CLs. The lack of technical experts in DRAP and other regulatory intuitions might be a reason for not effectively implementing the CL provisions. Despite the legal back up for CL in ordinance 2000, still some terms such as "public interest" or "reasonable price" need reasonable clarification for an encouraging environment by avoiding litigation for the government and local manufacturers to pursue CLs as the extended legal battles in courts often discourage them from pursuing CLs. The patent holders are usually not in favor of CI because of reduced incentives and loss of revenue. One example of this the issuing of CL by Indian Government in 2012 keeping in view the higher price to Natco Pharma for Nezvar (a cancer drug Sorafenib tosylate) patented by Bayer. But the multinational pharma challenged it in several courts which led to prolonged legal battle using judicial delays to maintain their monopolies and ultimately the non-availability of generics. Similarly, South Africa faced legal proceeding of pharmaceutical association (PMA) of 39 pharmaceutical companies for implementing CL for life saving drugs to treat HIV/AIDS which significantly delayed the affordability of medicines.

Another challenge is the lack of technical expertise and infrastructure in Pakistani industries to produce high-quality generic versions of complex drugs inability to meet the demands of CL. Weak enforcement mechanisms and bureaucratic inefficiencies to devise fast track process for issuing CL in Pakistan's regulatory system hinders the effective implementation of CL provisions. The legal, institutional, political, and economic factors collectively deter the effective utilization of CL. High-income countries often control trade agreements and exert diplomatic influence to protect the interests of their companies. Pakistan due to the fear of economic sanctions or withdrawal of trade privileges, cannot utilize the CL provision. United States trade representative in its special 301 report stated that countries issuing CL may be placed on a "priority watch list," indicating trade and investment risks. In its 2024 Special 301 Report, the United States Trade Representative (USTR) included Pakistan on its Watch List of trading partners that need to address intellectual property (IP) issues. Pakistan's dependence on foreign aid and international funding for its healthcare programs restricts its ability to uphold autonomy in challenging pharmaceutical monopolies. The lack of awareness about the CL to be used legally for health care

emergencies leads to the underutilization of CL. There should be innovative incentives sufficient to encourage innovation, create and legal debates for CL implementation.

Table 2. Significant Events in the History of Pakistan Demanding the Implementation of CL.

Event	Year	Description	Need for CL	Missed Opportunity
Polio Epidemic	2000s	Persistent polio cases in conflict-affected areas	Local production of polio vaccines to ensure adequate supply	Continued reliance on international donations for Vaccines (Habib et al. 2017)
Kashmir Earthquake	2005	Earthquakes caused 86,000+ deaths and massive health crises	Antibiotics, vaccines, and pain management drugs	Focused on international aid rather than utilizing CL for local drug production (Matthias 2005)
Super Floods	2010	Historic flooding displaced millions, leading to health emergencies	Vaccines (cholera, typhoid) and essential medicines for displaced populations	Relied on foreign aid; no initiative to leverage CL ("2010 Pakistan floods," 2010)1
Hepatitis C Epidemic	2012-Now	High prevalence of Hepatitis C, with expensive treatments like sofosbuvir	Generic production of sofosbuvir to provide affordable treatment	Failed to challenge patents for essential drugs despite local manufacturing capacity (Morikawa et al. 2018)
Tuberculosis Crisis	Ongoing	Pakistan ranks among the top high-burden TB countries globally	Affordable second-line TB treatments like bedaquiline	Dependency on global funds instead of leveraging CL (Yu et al. 2023)
COVID-19 Pandemic	2020-2022	Global pandemic with medicine and vaccine shortages	Production of remdesivir, vaccines, and other antiviral drugs under CL provisions	Missed opportunity to use TRIPS flexibilities for local production of treatments and vaccines (Ranjan and Praharsh 2023)
2022 Floods	2022	Catastrophic floods affecting 33 million people and creating severe health crises	Vaccines for waterborne diseases, essential medicines, and nutritional supplements	Focused on donor-driven responses; no domestic production through CL (Iqbal et al. 2022)
Rising Cancer Treatment Costs	Ongoing	Increasing rates of cancer, with inaccessible patented drugs like trastuzumab (Herceptin)	Local production of biosimilars for life-saving cancer therapies	No policy initiative to make cancer treatments affordable through CL (Shukar et al. 2024)

5. Opportunities and Benefits

Implementing CL in Pakistan, may help to tackle the challenge of inaccessible and costly medicines. Thus, healthcare access can be improved, the equitable availability of essential treatments can be ensured, and economic growth can be promoted. The figure 4 can easily depict the main opportunities and benefits while implementing CL effectively in Pakistan.

The generic versions of patented medicines can be produced that will not only be readily available but will also be cost effective. India implemented CL in Bayer's cancer drug Nexavar and the price was reduced by 97%. Implementing CL in a similar way in Pakistan will not only lower the drug price but also enable more low-income populations to access essential medicine for serious illnesses such as cancer or hepatitis. Hence, treatment rates will be increased, reducing the burden of diseases. Health emergencies can also be handled in a better way with CL implementation. It will also reduce the accessibility gap between urban and rural populations due to wider availability. The local industries and labor may get benefits from the increased manufacturing and production leading to increased industrial growth and improved quality of life.

[1] Available from https://en.wikipedia.org/wiki/2010_Pakistan_floods

Figure 4. Opportunities and Benefits of Compulsory licensing (CL)

6. Policy Recommendations

To improve access to affordable medicines in Pakistan through compulsory licensing (CL), a robust and well-defined policy framework is essential. The key recommendations include:

- Introduce clear CL guidelines, explicitly define concepts like "fair price" and "public interest," and establish fixed timelines for processing CL applications.
- CL examples from countries like India, Brazil, and Thailand may be studied to benefit from CL.
- There is need to update the CL related regulations according to the Doha Declaration on the TRIPS Agreement and Public Health as a guiding framework to align domestic policies with the best global practices.
- Establish mechanisms for fast track and automatic CL of essential medicines during public health emergencies to minimize delays and accelerated medicines access.
- Dedicated departments for CL may be created to enhance the capacity of the DRAP. For the capacity building of these dedicated sections specialized training on CL and IP shall be provided. Collaboration with international organizations like WIPO and WHO to strengthen expertise and working competence should be increased.
- To encourage local production of generic drugs, economic incentives such as tax exemptions and subsidies shall be provided. Domestic industries may be strengthened by streamlining the regulatory procedures for manufacturing and attracting investors in funding R&D programs.
- Efforts shall be made at diplomatic level to counter external pressures and establish Pakistan's right to implement CL under the TRIPS Agreement and the Doha Declaration.
- Awareness campaigns shall be initiated about the role of CL and the importance of affordable medicines. Stakeholders, including civil society, healthcare professionals, and the pharmaceutical industry should be engaged by should be highlighting Successful case studies, to advocate for CL.

Key performance indicators should be established for effective implementation of CL in improving drug accessibility and the progress reports should be published regularly.

7. Conclusions

Compulsory Licensing (CL) can be a useful tool for Pakistan to tackle the availability of affordable medicines while protecting citizens' right to health. Pakistan is facing high burden of diseases, insufficient healthcare infrastructure, and the high cost of patented drugs. The low-income communities are badly affected and have limited access to essential medicine due to the healthcare model. Despite several emergencies in Pakistan till date the CL provision have not been utilized. Keeping in view, the CL implementation by the county of the regions it is presumed that CL can be a powerful mechanism for change, providing a means to bridge these gaps promoting equitable healthcare for all. Pakistani patent ordinance aligns with the TRIPS Agreement and the Doha Declaration on Public Health for CL, the country has yet to recognize the capability of CL. In CL implementation, the authorities are facing challenges such as regulatory inadequacies, international pressures, inadequate local manufacturing capacity, and lack of awareness. These hurdles can be managed by targeted policy reforms, capacity-building initiatives and well-organized campaigns that ultimately help in unlocking

the CL's transformative potential. Following India for implementing CL, Pakistan can get long term benefits, for increased production of affordable generics, reduced healthcare costs, enhanced industrial growth, and higher treatment outcomes, and decreased burden of diseases. Pakistan can move toward a healthcare system that treats access to obligatory medicines as a primary right, not a privilege.

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