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Compulsory Licensing in Pharma: How it Affects Drug Prices and Accessibility

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KEYWORDS

compulsory licensing, drug prices, accessibility, TRIPS, patents, generic drugs, public health.

ABSTRACT: This review critically examines the role of compulsory licensing (CL) in the pharmaceutical industry as a tool to balance public health needs with intellectual property rights. Grounded in the TRIPS Agreement under the World Trade Organization, CL enables governments to authorize the production or import of generic versions of patented medicines without the consent of patent holders, especially during public health emergencies. Drawing from over 25 global research articles and policy analyses, the paper evaluates how CL has improved drug affordability and access in low- and middle-income countries, with case studies from Brazil, Thailand, India, and Canada. While effective in curbing monopolistic pricing and enhancing accessibility, CL's implementation is often hampered by legal, political, and economic barriers such as retaliatory trade pressures and weak manufacturing infrastructure. The study highlights the need for international support, clearer legislation, and capacity-building to fully leverage CL as a pro-public health mechanism. It concludes that with strategic reform and equitable governance, CL can serve as a sustainable model for achieving global drug equity without undermining pharmaceutical innovation.

1. INTRODUCTION

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement under the World Trade Organization (WTO) standardized pharmaceutical patent protection globally. While fostering innovation, it raised concerns about medicine affordability and accessibility in developing countries. Compulsory licensing (CL) emerged as a TRIPS-sanctioned flexibility to counterbalance the monopolistic effect of patents. This review explores the evolution, impact, and controversies surrounding CL in enhancing drug accessibility while maintaining innovation incentives.

2. LITERATURE REVIEW

Several studies affirm the role of CL in reducing drug prices and expanding access to medicines, particularly during public health crises. The Doha Declaration (2001) reaffirmed members' rights to use TRIPS flexibilities for public health protection. Cases from Brazil, Thailand, India, and Latin American countries show how CL was applied to bypass patent restrictions for HIV/AIDS and other critical diseases.

However, multiple articles highlight the procedural and political challenges nations face, especially pressure from developed countries and pharmaceutical corporations. Limited manufacturing capabilities and stringent legal criteria further restrict the practical utility of CL mechanisms.

Key literature includes:

- WHO's bulletin on TRIPS flexibilities (Nicol & Owoeye, 2013),
- Case analyses of Thailand's HIV licensing (Outterson, 2009),
- TRIPS-compliance challenges in Latin America (Oliveira, 2004),
- Doha Implementation Decision review (Watal, 2000),
- Bioethics perspectives on IP rights (Cohen & Illingworth, 2003).

3. DISCUSSION

Compulsory licensing has helped many countries access affordable generic drugs, especially in pandemics or emergencies. For instance, Brazil's cost savings from issuing CL for antiretrovirals highlight economic and public health benefits.

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Despite legality under TRIPS, CL often invites diplomatic friction, trade retaliation, and reduced foreign investment. Moreover, TRIPS-plus agreements in bilateral treaties restrict CL scope. The limited use of CL by high-income nations—despite moral obligations—is largely due to political economy factors rather than legal feasibility.

Studies show that CL is most effective when coupled with strong local manufacturing and regulatory systems. In light of global inequality in drug access, streamlining CL procedures and ensuring global support are crucial.

Case-specific highlights:

- **Thailand** issued CLs for HIV and heart disease drugs, facing backlash but reducing costs.
- **India**, pre-2005, supplied global generics, now constrained by full TRIPS compliance.
- **Canada** exported ARVs to Rwanda under CL but the process was lengthy and complex.
- **Latin America and the Caribbean** partially adopted TRIPS flexibilities, but many haven't fully leveraged them.

4. CONCLUSION

Compulsory licensing remains a vital policy tool for improving access to essential medicines, particularly in developing countries. While it effectively lowers drug prices, its broader implementation is hindered by legal, political, and economic barriers. There is a need for clearer international consensus, legislative simplification, and capacity-building in manufacturing to maximize the potential of compulsory licensing in achieving equitable healthcare access.

5. REFERENCES

1. Bond E.W., Saggi K., Compulsory licensing, price controls, and access to patented foreign products, Journal of Development Economics, April 2014, 217–228.
2. Lanjouw J.O., Patents, price controls and access to new drugs: How policy affects global market entry, National bureau of economic research, May 2005.
3. Correa C.M., Pharmaceutical innovation, incremental patenting and compulsory licensing, South centre, Sep 2011.
4. Akaleephan C., Wibulpolprasert S., Sakulbumrungsil R., Luangruangrong P., Jitraknathee A., Aeksaengsri A., Udomaksorn S., Tangcharoensathien V., Tantivess S., Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal, Health Policy, 2009, 174–182.
5. Henry D., Lexchin J., The pharmaceutical industry as a medicines provider, Medicines, society, and industry III, 2002, 1590–95.
6. Smith R.D., Correa C., Oh C., Trade, TRIPS, and pharmaceuticals, Trade and Health 5, 2009, 684–91.
7. Love J.P., Recent examples of the use of compulsory licenses on patents1, Knowledge Ecology International, May 2007.
8. Maskus K.E., Parallel imports in pharmaceuticals: implications for competition and prices in developing countries, World Intellectual Property Organization, April 2001.
9. Babar Z., Ibrahim M., Singh H., Bukahri N., Creese A., Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia, PLOS, March 2007, 4(3), 466-475.
10. Weerdt E.D., Simoens S., Hombroeckx L., Casteels M., Huys I., Causes of drug shortages in the legal pharmaceutical framework, Regulatory Toxicology and Pharmacology, Jan 2015, 251–258.
11. Kyley M., Qianz Y., Intellectual Property Rights and Access to Innovation: Evidence from TRIPS, Dec 2014.
12. Kanavos P., The pharmaceutical distribution chain in the European Union: structure and impact on pharmaceutical prices, LSE Research, Mar 2011.
13. Danzon P.M., Wwanf Y.R., Wwang L., The impact of price regulation on the launch delay of new drugs evidence from twenty-five major markets in the1990s, Economics of the pharmaceutical industry, 2005, 269–292.
14. Correaa C.M., Implications of bilateral free trade agreements on access to medicines, Public Health Reviews, May 2006, 84(5), 399-404.
15. Danawala S., Zhang Z., Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower and Middle Income Countries, GSTF International Journal of Nursing and Health Care, October 2013, 1-11.
16. Nunn A.S., Fonseca E.M., Bastos F., Gruskin S., Salomon J.A., Evolution of Antiretroviral Drug Costs

in Brazil in the Context of Free and Universal Access to AIDS Treatment, PLOS, Nov 2007, 1804-1817.
17. Kohler J.C., The Morally Uncomfortable Global Drug Gap, Ethics, Nov 2007, 82(5), 610-614.
18. Lage A., Global Pharmaceutical Development and Access: Critical Issues of Ethics and Equity, MEDICC Review, July 2011,13(3), 16-22.
19. Watal J., Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?, 1-6.
20. Wilson D., Cawthorne P., Ford N., Aongsonwang S., Global trade and access to medicines: AIDS treatments in Thailand, THE LANCET, 1999, 1893–95.
21. Cohen J.C., Illingworth P., The dilemma of intellectual property rights for pharmaceuticals: the tension between ensuring access of the poor to medicines and committing to international agreements, Developing World Bioethics, 2003, 1471-8847.
22. Hoen E., Berger J., Calmy A., Moon S., Driving a decade of change: HIV/AIDS, patents and access to medicines for all, Journal of the International AIDS Society, 2011, 1-12.
23. Outterson K., Disease-based limitations on compulsory licenses under articles 31 and 31BIS, Research handbook on intellectual property law and the WTO, 2009.
24. Nicol D., Owoeye O., Using TRIPS flexibilities to facilitate access to medicines, Bull World Health Organ, 2013, 533–539.
25. Oliveira M.A., Bermudez J., Chaves G.C., Velasquez G., Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?, Bulletin of the World Health Organization, 2004, 815-821.