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Compulsory Licensing and Women's Access to Medicines

A Critical Assessment of the Gender-Neutral
TRIPS Framework

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Abstract

Women's access to essential medicines is restricted by intersecting barriers such as economic dependence, reproductive health stigma, information gaps, and pharmaceutical R&D priorities that overlook their needs. Access to medicines is simultaneously shaped by international intellectual property law, particularly patent protection under the TRIPS Agreement, which has been criticised for restricting the availability and affordability of medicines in developing countries.

Against this background, this thesis asks: How effective is TRIPS' compulsory licensing in enabling states to safeguard women's right to essential medicines in developing countries? To answer this, it employs doctrinal legal analysis, a human rights-based approach, and a critical lens grounded in feminist legal theory. It first maps the relevant legal framework under TRIPS and international human rights law. The availability, accessibility, acceptability, and quality framework, and the tripartite state obligations under ICESCR and CEDAW, are then used to derive a gender-sensitive benchmark. Mousmouti's four-stage effectiveness test is applied to assess compulsory licensing against this benchmark across purpose, compatibility, results, and integration.

The thesis finds that although compulsory licensing under TRIPS is necessary to improve public health, it is not sufficient to ensure that women in developing countries can access essential medicines. The key findings reveal that the framework lacks a gender-sensitive purpose and does not refer to women's specific health needs. Although legal space for compulsory licensing exists, structural barriers, political pressure and judicial formalism consistently prevent it from reaching women in practice. Documented compulsory licences specifically for medicines addressing women's health conditions appear to be scarce, and the mechanism remains insufficiently aligned with international human rights obligations. These findings support the feminist critique that international law's assumption of universality conceals gendered inequalities. Gender-sensitive implementation criteria, sex-disaggregated monitoring and stronger alignment with human rights standards are required if compulsory licensing is to genuinely serve women's health needs.

Keywords: compulsory licensing, TRIPS, women's right to health, essential medicines, AAAQ framework, tripartite state obligations, gender sensitive benchmark, developing countries, international law universality

Abbreviations

AAAQ	Availability, Accessibility, Acceptability and Quality
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CESCR	Committee on Economic, Social and Cultural Rights
CL	Compulsory Licensing
CLA	Critical Legal Analysis
Doha	
Declaration	Doha Declaration on the TRIPS Agreement and Public Health
ESC	Economic, Social and Cultural
GC	General Comment
GR	General Recommendation
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HRBA	Human Rights-Based Approach
HRL	Human Rights Law
ICESCR	International Covenant on Economic Social and Cultural Rights
IHRL	International Human Rights Law
IP	Intellectual Property
LDCs	Least Developed Countries
R&D	Research and Development
SDG	Sustainable Development Goal
TAC	Treatment Action Campaign
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
WHO	World Health Organization
WHOMLEM	World Health Organization Model List of Essential Medicines
WTO	World Trade Organisation

1 Introduction

1.1 Background

For much of modern medical history, women have been treated as smaller versions of men.¹ As a result, women are underrepresented in biomedical research, which leads to diagnostic delays, higher rates of adverse drug reactions, and inadequate attention to reproductive health conditions.² In the context of access to essential medicines, these problems are not only medical, but also legal and structural.

Access to essential medicines is a necessary condition for the practical enjoyment of the right to health.³ A legal guarantee of healthcare has limited impact if the medicines required for prevention, treatment and care are unavailable, unaffordable, unsafe or unsuitable. These difficulties are intensified for women in developing countries, where economic, social, and cultural (ESC) barriers further restrict their access to healthcare and essential medicines.⁴

At the same time, access to medicines is shaped by international intellectual property (IP) law. Patent protection under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁵ is generally justified as a means of encouraging pharmaceutical innovation by granting inventors exclusive rights for a limited period.⁶ However, this exclusivity is criticised for restricting access to medicines and their affordability, particularly in developing countries.⁷

The problem is therefore not that TRIPS expressly disadvantages women, but that it operates on unequal terrain.⁸ Where women already face economic dependence, limited decision-making power and social barriers to healthcare, formally equal patent rules may produce unequal consequences. This tension between incentivising innovation and ensuring access to healthcare raises questions about whether the mechanisms available under TRIPS are equipped to address the structural inequalities that shape women's access to essential medicines in developing countries.⁹

¹ Grégory Fléchet, 'Santé Des Femmes, Le Grand Oubli' (CNRS *Le Journal* 2022) <<https://lejournel.cnrs.fr/articles/sante-des-femmes-le-grand-oubli>> accessed 25 May 2026.

² Gayathri Delanerolle, 'Mind the Women's Health Data Gap: A Critical Factor for Global Health Equity' (2025) 63 *Biomedical Journal of Scientific & Technical Research* 55636; Caroline Criado Perez, *Invisible Women: Exposing Data Bias in a World Designed for Men*. (Vintage 2020) 204.

³ Jennifer H Mike, 'Access to Essential Medicines to Guarantee Women's Rights to Health: The Pharmaceutical Patents Connection' (2020) 23 *The Journal of World Intellectual Property* 473, 474.

⁴ Anh-Nga Tran-Nguyen and Americo Beviglia Zampetti (eds), *Trade and Gender: Opportunities and Challenges for Developing Countries* (United Nations Publications 2004) 1, 256.

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS).

⁶ Tran-Nguyen and Zampetti (n 4) 251.

⁷ *ibid.*

⁸ *ibid* 256.

⁹ Mike (n 3) 492, 502.

1.2 Literature Review and Contribution

A substantial body of research has explored the relationship between access to medicines and IP law, especially pharmaceutical patents under TRIPS. Much of this literature emerged in response to the HIV/AIDS epidemic, which exposed the tension between patent protection, high medicine prices and access to essential medicines.¹⁰ Compulsory licensing (CL) and other flexibilities, as clarified by the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), have since become central to debates about how law can respond to public health crises.¹¹

Yet, research shows that the formal availability of TRIPS flexibilities does not necessarily translate into meaningful access. Developing and least-developed countries (LDCs) continue to face administrative, legal, and political challenges with these mechanisms.¹² Even when CLs have been issued and prices have fallen, whether access has genuinely improved in a broader human rights sense remains largely unexamined.¹³ Further, previous research has mainly approached access to medicines as a general or population-wide issue, with limited attention to gender specific dimensions.¹⁴ While some studies have addressed women's health and human rights more broadly, the relationship between CL and women's access to medicines remains underdeveloped. Existing normative assessments,¹⁵ while valuable, remain anchored in national contexts and do not fully explore how effectively CL operates for women in developing countries.¹⁶

This thesis addresses this gap by examining TRIPS' CL through a gender-sensitive human rights lens, using women's right to health as the benchmark for assessing whether the mechanism can respond to women's specific access barriers in developing countries.

1.3 Purpose and Research Questions

This thesis investigates whether CL under TRIPS¹⁷ constitutes an effective mechanism for states to safeguard women's right to essential medicines in developing countries. It examines whether the mechanism can respond to women's specific access barriers, including affordability, availability, stigma, information

¹⁰ Brigitte Tenni and others, 'What Is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review' (2022) 18 *Globalization and Health* 1, 11; Ellen t Hoen and others, 'Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All' (2011) 14 *Journal of the International AIDS Society* 1, 1.

¹¹ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) (Doha Declaration), para 4.

¹² Standing Committee on the Law of Patents, 'Constraints Faced by Developing Countries and Least Developed Countries (LDCs) in Making Full Use of Patent Flexibilities and Their Impacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in Those Countries (Update of Document SCP/26/5)' (WIPO, 16 September 2024) SCP/36/5 (WIPO Report), para 3.

¹³ WIPO Report (n 12) para 76.

¹⁴ Rosemary Morgan and others, 'Gendered Health Systems: Evidence from Low- and Middle-Income Countries' (2018) 16 *Health Research Policy and Systems* 1, 1.

¹⁵ Mike (n 3) 473.

¹⁶ Jennifer H Mike, 'A Re-Evaluation of the Framework for the Protection of Patents, Women's Health in Nigeria and the Issue of Accessing Pharmaceutical Innovation in Africa: Designing Strategies for Medicines' (2019) 22 *The Journal of World Intellectual Property* 162, 162.

¹⁷ TRIPS, art 31.

gaps, reproductive and maternal health needs, and the quality and suitability of medicines.

Therefore, this thesis answers the following main research question: *‘How effective is TRIPS’ CL in enabling states to safeguard women’s right to access essential medicines in developing countries?’*

Naturally, this can be divided into several sub-questions, each addressed in a separate chapter. The second chapter of this thesis asks: *‘What legal framework governs CL under TRIPS, and what obligations do states have under international human rights law to ensure women’s access to essential medicines?’*

The third chapter then turns to: *‘What gender-sensitive legal benchmark can be derived from the right to health, respectively the availability, accessibility, acceptability, quality framework and states’ obligations to respect, protect and fulfil?’*

Lastly, the fourth chapter draws on the preceding analysis to answer: *‘How effective is CL when assessed against this benchmark through the criteria of purpose, compatibility, results and integration?’*

1.4 Delimitations

This thesis focuses on women in developing countries as its core demographic. This reflects both the research gap and the disproportionate burden that patent-related access barriers place on this group.¹⁸ The analysis does not extend to an intersectional assessment of how race, disability or other identity factors compound these barriers, although their relevance is acknowledged.

This thesis further limits itself to international state-level obligations under TRIPS, the Doha Declaration, the International Covenant on Economic, Social and Cultural Rights (ICESCR)¹⁹ and the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW).²⁰ Domestic implementation is beyond scope, and national examples are used illustratively rather than comparatively. Among TRIPS flexibilities, CL is the most extensively debated mechanism, enabling an in-depth assessment of its effectiveness.

While effectiveness may be assessed through economic, political, or social indicators, this thesis evaluates it through a human rights lens. It does so by using women’s right to health as the benchmark to address the gap in the literature.

Finally, while patent law is a crucial factor shaping access to medicines, it is not the only one. Pharmaceutical system capacity, regulatory frameworks and underfunded

¹⁸ WIPO Report (n 12) para 20.

¹⁹ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR).

²⁰ Convention on the Elimination of All Forms of Discrimination against Women (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW).

healthcare systems also influence outcomes.²¹ These factors fall outside the scope of this analysis, though their broader influence on the status quo is acknowledged.

1.5 Methods and Materials

This thesis utilises the doctrinal method of legal analysis to describe, identify and interpret key legal sources.²² It maps the relevant legal frameworks in Chapter Two, derives a human rights benchmark in Chapter Three, and tests it against TRIPS' CL provisions in Chapter Four.

That said, the methodology of this thesis is not strictly doctrinal; it is also rooted in human rights law (HRL) and critical feminist theory to provide a normative perspective. This thesis employs a human rights-based approach (HRBA), a methodology grounded in international human rights standards that uses human rights norms as an analytical framework to identify inequalities and power imbalances and their impact on development issues.²³ It is well-suited for assessing compatibility between HRL and other areas of law, such as IP,²⁴ and for research on public health inequalities.²⁵ In this thesis, the HRBA functions as both an interpretative and evaluative tool, by providing the normative content of the right to health through the AAAQ (i.e., availability, accessibility, acceptability, quality) framework²⁶ and tripartite state obligations (i.e., respect, protect, fulfil).²⁷ Together, these form the gender-sensitive benchmark against which CL's effectiveness is assessed. For clarity, this benchmark is presented in Chapter Three in a table that consolidates the AAAQ criteria and tripartite state obligations.

However, HRBA does not typically incorporate a gender-sensitive perspective.²⁸ This thesis, therefore, makes a distinct contribution by employing a gendered lens through a qualitative methodology. While numerical indicators offer objectivity, they simplify data into measurable units, thus obscuring relevant differences among women and leading to heteronormative assumptions.²⁹ This concern is reflected, for example, in global development frameworks. Sustainable Development Goals (SDG) indicator 3.b.3, designed specifically to track medicine access,³⁰ has been

²¹ Mike (n 3) 477, 478, 500.

²² Jan M Smits, 'What Is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' [2015] SSRN Electronic Journal 1, 6.

²³ United Nations Sustainable Development Group, 'Human Rights-Based Approach' (unsdg.un.org 2022) <<https://unsdg.un.org/2030-agenda/universal-values/human-rights-based-approach>> accessed 19 May 2026.

²⁴ Mike (n 3) 490, 502.

²⁵ Leslie London, 'What Is a Human-Rights Based Approach to Health and Does It Matter?' (2008) 10 Health and Human Rights 65, 65-66.

²⁶ UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health' (2000) UN Doc E/C.12/2000/4 (GC 14), para 14.

²⁷ Ida Elisabeth Koch, 'Dichotomies, Trichotomies or Waves of Duties?' (2005) 5 Human Rights Law Review 81, 84; Henry Shue, *Basic Rights: Subsistence, Affluence, and U.S. Foreign Policy* (40th Anniversary Edition, Princeton University Press 2020) 160.

²⁸ Food and Agriculture Organization of the United Nations, 'Gender Mainstreaming and Human Rights-Based Approach: Guidelines for Technical Officers' (FAO Regional Office for Europe and Central Asia 2017) 7 <<https://openknowledge.fao.org/handle/20.500.14283/i6808e>> accessed 25 May 2026.

²⁹ Debra J Liebowitz and Susanne Zwingel, 'Gender Equality Oversimplified: Using CEDAW to Counter the Measurement Obsession' (2014) 16 International Studies Review 362, 364-365.

³⁰ Iris R Joosse and others, 'SDG Indicator 3.b.3 – an Analysis of Its Robustness and Challenges for Measuring Access to Medicines for Children' (2023) 23 BMC Health Services Research 1, 2.

criticised for lacking gender-disaggregated data³¹ and for relying on affordability metrics that exclude women without independent income.³² For that reason, a qualitative approach allows this thesis to engage with legal frameworks without reducing gender equality to a measurable variable.

This gendered lens is grounded in feminist theory and critical legal analysis (CLA). Feminist theory provides a basis to challenge the law and unmask social and economic inequalities.³³ Within feminist thought, CLA is the method that enables the deconstruction of the perspective that law is universal and neutral.³⁴ It does so by considering women's lived experiences.³⁵

While alternative frameworks for assessing legal effectiveness exist, such as Snyder's conception of effectiveness as a dynamic social process, these largely remain context-specific.³⁶ Instead, this thesis relies on Mousmouti's effectiveness test,³⁷ which offers a robust, qualitative framework broadly applicable across legal contexts. In this thesis, Mousmouti's four-stage test determines whether TRIPS' CL is designed to achieve its objectives. The first stage considers whether the law has a clear purpose, evaluating if CL provisions set objectives that meet the benchmark.³⁸ The second explores whether the framework is designed to achieve this in practice, particularly for women's access to essential medicines.³⁹ The third examines if tools exist to measure the law's results, such as monitoring and reporting mechanisms.⁴⁰ The fourth reviews how the framework interacts with the broader legal order,⁴¹ including other TRIPS flexibilities and international human rights law (IHRL).

The primary sources relied upon are the TRIPS Agreement and the Doha Declaration, as well as ICESCR and CEDAW, together with their General Comments and Recommendations. The analysis also draws on relevant case law and institutional documents from both the trade and human rights regimes, supplemented by academic literature on IP law, HRL, and feminist legal theory.

1.6 Outline

Chapter Two provides the relevant legal framework by examining patent protection under TRIPS, CL as a public health flexibility, and the human rights framework under ICESCR and CEDAW. Chapter Three builds on this by developing a gender-sensitive benchmark for women's access to essential medicines, which is derived

³¹ Open Data Watch, 'Ready to Measure: Twenty Indicators for Monitoring SDG Gender Targets' (Data X and Open Data Watch, September 2015) 2 <<https://opendatawatch.com/wp-content/uploads/2016/03/ready-to-measure.pdf>> accessed 25 May 2026.

³² Joosse and others (n 29) 4.

³³ Hilary Charlesworth, Christine Chinkin and Shelley Wright, 'Feminist Approaches to International Law' (1991) 85 *The American Journal of International Law* 613, 613.

³⁴ Charlesworth, Chinkin and Wright (n 32) 634-644.

³⁵ *ibid* 634.

³⁶ Francis Snyder, 'The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques' (1993) 56 *The Modern Law Review* 19, 26.

³⁷ Maria Mousmouti, 'The "Effectiveness Test" as a Tool for Law Reform' (2014) 2 *IALS Student Law Review* 4.

³⁸ *ibid* 6.

³⁹ *ibid* 6.

⁴⁰ *ibid* 7.

⁴¹ *ibid* 7-8.

from the AAAQ framework and the tripartite state obligations. Chapter Four applies Mousmouti's effectiveness test to CL. It assesses its purpose, compatibility, results and integration with HRL. Chapter Five concludes that CL is a necessary but insufficient mechanism for safeguarding women's access to essential medicines, unless supported by stronger gender-sensitive implementation, monitoring, and integration with human rights obligations.

2 Patent Protection, Compulsory Licensing, and the Human Rights Framework

2.1 Introduction

This chapter outlines the relevant legal frameworks for CL and women's right to access essential medicines. It first examines patent protection under TRIPS and the role of CL as a public health flexibility, and then it provides the human rights framework under ICESCR and CEDAW.

2.2 Patent Protection and TRIPS

Patent protection is a central mechanism of IP law that grants inventors exclusive rights for a limited period. A patent can be granted for any technology that is new, inventive, and industrially applicable.⁴² Although the duration of protection is limited to 20 years, the monopoly conferred is quite strong; it protects against reproduction and prevents third parties from using the invention without authorisation.⁴³ Two main objectives generally justify patent protection. First, patents provide incentives for innovation by conferring exclusive rights that enable inventors to recoup their R&D costs.⁴⁴ Second, patents aim to ensure the dissemination of knowledge.⁴⁵ However, in the pharmaceutical sector, patent exclusivity can also restrict competition, thus limiting access to essential medicines, particularly by affecting their availability and affordability.⁴⁶ At the international level, patent protection is governed by TRIPS, a core WTO agreement.⁴⁷ TRIPS sets minimum standards for the protection of IP rights across all WTO member states.⁴⁸

Regarding patents, TRIPS sets out key obligations for member states. Article 27 requires patent protection to be available for inventions in all fields of technology, subject to limited exceptions. Article 28 grants patentees exclusive rights to prevent third parties, without consent, from making, using, offering for sale, selling, or importing the patented product.⁴⁹ Article 33 further provides for a minimum term of protection of 20 years.⁵⁰ Taken together, these provisions establish a strong patent

⁴² Dan L Burk, 'Patents and Related Rights: A Global Kaleidoscope' in Rochelle Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press 2017) 463.

⁴³ *ibid* 473.

⁴⁴ *ibid* 464.

⁴⁵ James Boyle, *The Public Domain: Enclosing the Commons of the Mind* (Yale University Press 2008) 6.

⁴⁶ Tenni and others (n 10) 36.

⁴⁷ Klaus Liebig, 'Protection of Intellectual Property Rights in the World Trading System: The TRIPS Agreement and Developing Countries' (Briefing Paper No. 1/2001, German Development Institute 2001) <<https://www.econstor.eu/bitstream/10419/199575/1/die-bp-2001-01.pdf>> accessed 20 May 2026, 1.

⁴⁸ Tenni and others (n 10) 1.

⁴⁹ Peter-Tobias Stoll and Jan Busche (eds), *WTO--Trade-Related Aspects of Intellectual Property Rights* (Martinus Nijhoff Publishers 2009) 514.

⁵⁰ TRIPS, art 33.

regime and reflect the Agreement's broader objective of preventing distortions in international trade.

Although TRIPS establishes a strong system of patent protection, it also preserves space for public-interest considerations.⁵¹ This is reflected in Articles 7 and 8, which set out the Agreement's objectives and principles. Article 7 frames IP protection as a means of promoting innovation and the dissemination of knowledge in a manner conducive to social and economic welfare,⁵² and it can also be relied upon to argue for increased access to medicines for women.⁵³ Article 8 permits members to adopt measures necessary to protect public health and public interest.⁵⁴ Read together, these provisions support a public-health-oriented reading of TRIPS for developing countries. However, they function as guides rather than autonomous exceptions, and their practical effect depends on how states implement them.⁵⁵ The following subchapter examines how this space is operationalised through CL.

2.3 Compulsory Licensing as a TRIPS Flexibility

TRIPS flexibilities refer to the latitude WTO members have in implementing their obligations under the Agreement. While the term is not defined in TRIPS, various provisions recognise the need for flexibility in implementing IP obligations in ways that support development, particularly for LDCs.⁵⁶ The Doha Declaration, adopted by the WTO Ministerial Conference, strengthened the recognition of these flexibilities.⁵⁷ It affirmed that TRIPS 'does not and should not prevent' members from taking measures to protect public health,⁵⁸ and that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all'.⁵⁹ However, the concept remains legally uncertain.⁶⁰ No binding instrument defines 'flexibilities' with precision, leaving their scope open to interpretation and uneven application in practice.⁶¹

CL is one of the most significant flexibilities for addressing public health concerns.⁶² It is defined as a government authorisation to use a patented invention without the right holder's consent. The patent remains valid, but the holder's exclusive control over production is temporarily limited.⁶³ In the pharmaceutical context, a

⁵¹ Tamara Romero, 'Articles 7 and 8 as the Basis for Interpretation of the TRIPS Agreement' (Policy Brief No 79, The South Centre June 2020) <<https://www.southcentre.int/wp-content/uploads/2020/06/PB-79.pdf>> accessed 19 May 2026, 1.

⁵² Jennifer Anna Sellin, *Access to Medicines: The Interface between Patents and Human Rights. Does One Size Fit All?* (Intersentia 2014) 167.

⁵³ Mike (n 3) 495.

⁵⁴ Sellin (n 51) 168.

⁵⁵ *ibid* 169.

⁵⁶ WIPO Report (n 12) para 4.

⁵⁷ *ibid* para 7.

⁵⁸ *ibid*.

⁵⁹ Doha Declaration, para 4.

⁶⁰ Joint United Nations Programme on HIV/AIDS, 'Doha+10 Trips Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future' (UNAIDS November 2011) 3 <https://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA+10TRIPS_en_0.pdf> accessed 25 May 2026.

⁶¹ WIPO Report (n 12) para 9.

⁶² Ellen t Hoen and others, 'Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 Bulletin of the World Health Organization 188.

⁶³ *ibid* 185.

government may produce the medicine itself, authorise a generic manufacturer, or source it from an authorised supplier, usually at a lower price than the patented version. The legal basis is found in Article 31 TRIPS. Although Article 31 does not expressly mention CL, its acceptance is implied when read alongside Article 2(1) TRIPS and Article 5(A)(2) of the Paris Convention.⁶⁴ This covers both government use and use by authorised third parties, with the patent holder retaining the right to adequate remuneration.⁶⁵

The granting of CL is subject to procedural and substantive conditions. In practice, a state must first attempt to obtain a voluntary licence on reasonable commercial terms.⁶⁶ However, this requirement may be waived in cases of national emergency, extreme urgency, or public non-commercial use. In such cases, the patent holder only needs to be notified ‘as soon as reasonably applicable’.⁶⁷ The Doha Declaration confirms that each member has the right to define what constitutes a national emergency.⁶⁸ For example, Brazil issued a CL for the HIV/AIDS drug Efavirenz by classifying the situation as a national emergency, making the drug more affordable for its population.⁶⁹ In cases of public non-commercial use, the patent holder needs only to be notified promptly, and members may determine the details of that notification and the scope of the non-commercial use.⁷⁰ Similarly, while anti-competitive practices may justify the issuance of a CL, TRIPS does not define what constitutes such practices, leaving members to develop their own definitions within the bounds of the Agreement.⁷¹

Article 31 was designed to allow countries to grant CLs to balance the interests of patent holders and public health.⁷² In practice, however, this is limited to developing countries that cannot manufacture medicines themselves. Article 31(f) requires CLs to be ‘predominantly for the supply of the domestic market’, which means they cannot be used mainly for export.⁷³ This created a significant gap for states without pharmaceutical manufacturing capacity, since they could authorise a licence in theory, but still could not easily obtain affordable generics from producers abroad.⁷⁴ In practice, only about a dozen developing countries, such as China, India, Brazil, Argentina and South Africa, have sufficient manufacturing capacity to produce

⁶⁴ Anthony P Valach Jr., ‘TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries’ (2005) 4 Chicago-Kent Journal of Intellectual Property 156, 161; Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, last amended 28 September 1979) 828 UNTS 305.

⁶⁵ t Hoen and others (n 61) 185.

⁶⁶ TRIPS, art 31(b); Kanchana Kariyawasam and Lasantha Ariyaratne, ‘Pharmaceutical Patents and Access to Generic Medicines in Developing Countries’ (2020) 42 European Intellectual Property Review 109, 112.

⁶⁷ TRIPS, art 31 (b).

⁶⁸ Doha Declaration, para 5(b).

⁶⁹ Eva Belmonte, ‘Medicamentalia’ (*Medicamentalia* 20 March 2018) <<https://medicamentalia.org/access/compulsory-license/>> accessed 19 May 2026.

⁷⁰ Justin Malbon, Charles Lawson and Mark Davison, ‘Article 31: Other Use Without Authorisation of the Right Holder’, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (Edward Elgar Publishing Limited 2014) 500.

⁷¹ Brook K. Baker, ‘Producing HIV/AIDS Medicines for Export/Import under TRIPS, Articles 31(F), (K), and 30’ (Trans-Atlantic Consumer Dialogue 6 November 2001) <<https://tacd.org/wp-content/uploads/2013/09/TACD-IP-2001-Briefing-Paper-on-HIV-Aids-Medicines-under-TRIPS.pdf>> accessed 19 May 2026, 9.

⁷² Carlos Maria Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd Edition, Oxford University Press 2020) 304-305.

⁷³ TRIPS, art 31(f).

⁷⁴ ‘Public Health or Patent-the Role of Compulsory License under Article 31 of Trips’ (*Lexology*) <<https://www.lexology.com/library/detail.aspx?g=bb42fd79-3c9c-476c-adfd-f16b3e835b7c>> accessed 21 May 2026, 4.

significant quantities of generic drugs.⁷⁵ This gap led to the adoption of paragraph 6 of the Doha Declaration and, subsequently, Article 31bis, the first amendment to TRIPS,⁷⁶ and thus created a mechanism for export to eligible importing members. Yet, this mechanism has been severely criticised, and it has had very limited use. It has been used only once, when Canada exported an antiretroviral medicine to Rwanda in 2008.⁷⁷ The experience has shown that the system is complex, costly, and burdensome for both importing states and manufacturers.⁷⁸

What initially appeared to be a promising development after the Doha Declaration has been undermined by implementation challenges. Pharmaceutical companies engaged in substantial R&D have lobbied against broad use of TRIPS flexibilities.⁷⁹ At the same time, states that initially supported the Doha framework have adopted a more restrictive stance. The Office of the United States Trade Representative, for example, publishes an annual ‘watch list’ criticising countries that make use of TRIPS flexibilities, including CL.⁸⁰ Countries such as India have been repeatedly scrutinised for issuing CL for a high-cost cancer medicine, while Colombia and Malaysia have faced similar criticism for leukaemia treatments.⁸¹ Such unilateral pressure has caused a ‘chilling effect’, that discourages states from fully exercising their rights under TRIPS.⁸²

2.4 Human Rights Framework

2.4.1 The International Covenant on Economic, Social and Cultural Rights (ICESCR)

Human rights are universal and inalienable entitlements, inherent to all people because of their humanity.⁸³ Among the most central of these is the right to health, as the enjoyment of other rights is dependent on its realisation.⁸⁴ The right to health entails the highest attainable standard of physical and mental health.⁸⁵

The ICESCR contains one of the most comprehensive legally binding international frameworks for the right to health. Article 12 recognises the ‘highest attainable standard of physical and mental health’ for all people, and provides the steps for

⁷⁵ Duncan Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (2004) 7 *Journal of International Economic Law* 73, 78.

⁷⁶ World Trade Organization General Council, ‘Amendment of the TRIPS Agreement’ (Decision of 6 December 2005, 8 December 2005) WT/L/641.

⁷⁷ Eduardo Urias and Shyama V Ramani, ‘Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence’ (2020) 3 *Journal of International Business Policy* 367, 377.

⁷⁸ *ibid* 377.

⁷⁹ Frederick M Abbott, ‘The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health’ (2005) 99 *The American Journal of International Law* 317, 317.

⁸⁰ Rachel Thrasher, ‘Reigniting the Spirit of the Doha Declaration: Why a TRIPS Waiver Extension is Key to the Legitimacy of the World Trade Organization’ (Policy Brief No 27, Global Development Policy Center February 2024) 4 <<https://www.bu.edu/gdp/files/2024/02/GEPI-PB-027-DOHA-FIN.pdf>> accessed 19 May 2026.

⁸¹ *ibid*.

⁸² *ibid*.

⁸³ Martin Birley, *Health Impact Assessment: Principles and Practice* (Routledge 2011) 10; Mike (n 3) 481.

⁸⁴ Carmel Shalev, ‘Rights to Sexual and Reproductive Health: The ICPD and the Convention on the Elimination of All Forms of Discrimination against Women’ (2000) 4 *Health and Human Rights* 38, 42; Mike (n 3) 482, 488.

⁸⁵ Mike (n 3) 482.

states to achieve the full realisation of this right.⁸⁶ These include ensuring access to medical services, facilities and resources, promoting children's health, and preventing and treating disease.⁸⁷ Article 2 further requires states to take concrete legislative, economic and judicial steps towards a progressive realisation of the right to health.⁸⁸

The UN Committee on Economic, Social and Cultural Rights (CESCR) oversees the implementation of these provisions through authoritative guidance in its General Comments (GC).⁸⁹ Notably, GC 14 and 22 provide the normative content of the right to health through the AAAQ framework⁹⁰ and clarify the three state obligations: respect, protect and fulfil.⁹¹

2.4.2 The Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)

CEDAW is a key legally binding international instrument for women's rights to health and equality. It situates women's rights and lived experiences within the broader human rights framework and affirms the equal enjoyment of fundamental rights by all women and girls.⁹²

The Convention is designed to protect women's rights in two ways: the first part addresses gender discrimination generally, while the second part provides substantial provisions to safeguard specific individual rights in various areas of women's lives.⁹³ The Convention opens with Article 1, which defines discrimination against women as any unequal treatment that harms women's enjoyment of human rights.⁹⁴ This broad definition, by inference, also covers healthcare discrimination.⁹⁵ Article 12, by referring to the principle of equality, explicitly requires the elimination of discrimination within healthcare⁹⁶ and the guarantee of unrestricted access to health services.⁹⁷ Thus, Article 12 focuses on healthcare, while other parts of the Convention reinforce this duty.⁹⁸ For instance, Article 2 requires states to ensure equal treatment and eliminate legal, administrative, or policy barriers that discriminate.⁹⁹ Article 3 complements this by mandating that states take all necessary measures across all sectors to guarantee women's full enjoyment of human rights.¹⁰⁰

Importantly, the implementation of CEDAW is mandated by the Committee on the Elimination of Discrimination Against Women through its General

⁸⁶ ICESCR, arts 12(1), 12(2) ICESCR.

⁸⁷ ICESCR, art 12(2) ICESCR.

⁸⁸ ICESCR, art 2(1).

⁸⁹ United Nations, 'OHCHR | Committee on Economic, Social and Cultural Rights' (OHCHR 2025) <<https://www.ohchr.org/en/treaty-bodies/cescr>> accessed 19 May 2026.

⁹⁰ GC 14, para 12.

⁹¹ GC 14, para 33.

⁹² United Nations, 'Convention on the Elimination of All Forms of Discrimination against Women' (Un.org 2009) <<https://www.un.org/womenwatch/daw/cedaw/>> accessed 25 May 2026; Mike (n 3) 484.

⁹³ Rebecca J Cook and World Health Organization, *Women's Health and Human Rights: The Promotion and Protection of Women's Health through International Human Rights Law* (Who 1994); Mike (n 3) 484.

⁹⁴ CEDAW, Art 1.

⁹⁵ Mike (n 3) 484.

⁹⁶ CEDAW, art 12(1).

⁹⁷ CEDAW, art 12(2).

⁹⁸ Mike (n 3) 484-485.

⁹⁹ CEDAW, art 2.

¹⁰⁰ CEDAW, art 3.

Recommendations (GR). Notably, GR 24 clarifies that Article 12 requires states to ensure access to healthcare services that address women's specific needs, including reproductive and maternal health.¹⁰¹ States must also remove barriers that hinder women's access to health-related goods and services.¹⁰² Further, the Committee indicates that the realisation of women's right to health should be guided by the same principles developed under the ICESCR framework, including the AAAQ dimensions¹⁰³ and the tripartite obligations to respect, protect and fulfil.¹⁰⁴

2.5 Main Takeaways

In sum, this chapter sets out the legal framework for assessing TRIPS' CL and women's access to essential medicines. It explains the main patent protections under TRIPS, the role of CL and other flexibilities, and the relevant human rights standards under ICESCR and CEDAW. These frameworks provide the normative basis for the analysis in the following chapter, where TRIPS' CL is assessed against a gender-sensitive human rights benchmark.

¹⁰¹ UN Committee on the Elimination of Discrimination Against Women, 'General Recommendation No 24: Article 12 of the Convention - Women and Health' (4 May 1999) UN Doc A/54/38/Rev.1 chap. I, (GR 24) para 11.

¹⁰² GR 24, paras 21, 31(b).

¹⁰³ GR 24, paras 20-22.

¹⁰⁴ GR 24, para 7.

3 Constructing a Gender-Sensitive Benchmark for Women's Access to Medicines

3.1 Introduction

This chapter develops the gender-sensitive human rights benchmark for assessing TRIPS' CL. It interprets women's access to medicines through the AAAQ (availability, accessibility, acceptability, quality) framework and the tripartite obligations under ICESCR and CEDAW, and then, using a table, it synthesises these elements into the legal benchmark applied in Chapter 4.

3.2 Gendered Perspective on the Normative Content of the Right to Health: ICESCR, CEDAW and the AAAQ Framework

The implementation of the right to health under the ICESCR is assessed using the AAAQ framework, which was formally articulated in GC 14 and notably advanced by the UN Special Rapporteur Paul Hunt.¹⁰⁵ The framework was later further elaborated in GC 22 in the context of sexual and reproductive health.¹⁰⁶

Availability requires sufficient healthcare goods and services to meet a state's demand.¹⁰⁷ Accessibility entails the availability of medicines without discrimination, regardless of geographical location or socioeconomic status.¹⁰⁸ Acceptability ensures that healthcare is provided ethically and free from stigma.¹⁰⁹ Quality mandates that healthcare goods and services meet a high standard of safety.¹¹⁰ However, despite their importance, these four elements are often missing in practice. This is evident through sexual and reproductive health information gaps, geographical barriers in rural areas, and cultural and quality-related issues.¹¹¹ Recognising these shortcomings, GC 22 was later adopted to clarify the implementation of the right to health in the context of sexual and reproductive health, implicitly acknowledging the disproportionate impact of these gaps on women.¹¹²

Contrastingly, CEDAW goes further by explicitly acknowledging the structural and systemic barriers women face in accessing healthcare.¹¹³ The CEDAW Committee

¹⁰⁵ Paul Hunt, 'The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (Commission on Human Rights, 16 February 2004) UN Doc E/CN.4/2004/49; CESCR GC 14.

¹⁰⁶ Mike (n 3) 485, 486.

¹⁰⁷ UN Committee on Economic, Social and Cultural Rights, 'General Comment No 22: The Right to Sexual and Reproductive Health' (2 May 2016) UN Doc E/C.12/GC/22 (GC 22), paras 12-14; Mike (n 3) 486.

¹⁰⁸ GC 22, para 12(b) and 15-19; Mike (n 3) 486-487.

¹⁰⁹ GC 22, para 12(c); Mike (n 3) 487.

¹¹⁰ GC 22, para 21; Mike (n 3) 487.

¹¹¹ Hunt (n 104) para 42.

¹¹² GC 22, para 4; Hunt (n 104) para 42.

¹¹³ Mike (n 3) 485.

builds on this by referring to the AAAQ framework to define the right to health. GR 24 further explores each AAAQ dimension through a gender-sensitive lens, recognising that issues affect women differently from men. More specifically, availability focuses on reliable prevention and detection of women-specific diseases.¹¹⁴ Accessibility addresses cultural, socioeconomic, and financial barriers unique to women.¹¹⁵ Acceptability requires intersectional measures responsive to the needs of vulnerable and marginalised women.¹¹⁶ Quality means providing high-level, safe healthcare tailored to women's needs.¹¹⁷ Given their convergence, ICESCR and CEDAW are best applied concurrently, each framework reinforcing the other.¹¹⁸ Thus, this thesis uses both instruments to construct the gender-sensitive benchmark discussed in section 3.3.

Furthermore, central to this analysis is access to essential medicines, which is widely recognised as a core component of the right to health and thus essential for the full realisation of other fundamental rights. Without it, the right to health remains formally guaranteed but practically hollow.¹¹⁹ This is especially relevant for women in developing countries, who face compounding structural barriers to access. Within this context, the following section examines the state obligations established by ICESCR and CEDAW that confer legal force on the health rights and, implicitly, access to medicines.

3.3 State Obligations in Ensuring Access to Medicines

The right to health creates enforceable obligations for states. To clarify these obligations, GC 14 relies on principles such as non-discrimination. It also specifies that steps towards realisation must be deliberate, concrete and targeted.¹²⁰ For analytical purposes, these steps are organised using the tripartite typology of respect, protect and fulfil.¹²¹ Although this typology is not contained in the text of the ICESCR, and GCs are not formally binding,¹²² it was articulated by the CESCR in GC 12 on the right to food and has since been consistently applied by international bodies and domestic courts as an authoritative framework for identifying state obligations.¹²³

¹¹⁴ GR 24, paras 10-12; Mike (n 3) 487.

¹¹⁵ GR 24, para 21; Mike (n 3) 487.

¹¹⁶ GR 24, para 22; Mike (n 3) 487.

¹¹⁷ GR 24, para 22; Mike (n 3) 488.

¹¹⁸ Mike (n 3) 487.

¹¹⁹ Mike (n 3) 488; Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge 2015) 3 <<https://www.taylorfrancis.com/books/mono/10.4324/9781315564845/human-rights-framework-intellectual-property-innovation-access-medicines-joo-young-lee>> accessed 25 May 2026.

¹²⁰ GC 14, para 30.

¹²¹ GC 14, para 33.

¹²² Stig Langvad and Marite Decker, 'The Purpose and Use of UN Treaty Body General Comments' (*ENIL* 8 November 2018) <<https://enil.eu/the-purpose-and-use-of-un-treaty-body-general-comments/>> accessed 25 May 2026.

¹²³ Eibe Riedel, Gilles Giacca and Christophe Golay, 'The Development of Economic, Social, and Cultural Rights in International Law' in Eibe Riedel, Gilles Giacca and Christophe Golay (eds), *Economic, Social, and Cultural Rights in International Law: Contemporary Issues and Challenges* (Oxford University Press 2014) 18.

3.3.1 Obligation to Respect

The obligation to respect requires states to refrain from interfering, directly or indirectly, with ESC rights, including the right to health. Thus, states have a duty to avoid laws or actions that restrict healthcare access or undermine women's basic health needs.¹²⁴ GC 14 clarifies that this includes not restricting access to contraceptives, reproductive health services, or health-related information.¹²⁵ By extension, states must also remove structural and systemic barriers, such as traditions, social norms, and economic factors, which disproportionately hinder women's access to healthcare.¹²⁶ Therefore, based on the obligation to respect, states must ensure that formally neutral laws and policies, including those on IP, do not reinforce existing inequalities in women's access to healthcare.

In the context of access to medicines, states have an obligation to ensure their regulatory frameworks uphold the right to health.¹²⁷ Specifically, states must ensure domestic laws, including IP regulations, do not hinder the availability or affordability of essential medicines. Patent protection must be balanced so that IP regimes, such as those under TRIPS, do not raise prices or limit supply despite their objective of promoting innovation. States that fail to assess the impact of such agreements on access to medicines risk creating legal frameworks that are 'manifestly incompatible' with their obligations under the right to health in the ICESCR.¹²⁸

3.3.2 Obligation to Protect

The obligation to protect requires states to prevent third parties from interfering with the enjoyment of the right to health, including access to medicines.¹²⁹ This entails legislative and institutional measures that ensure that healthcare goods and services meet the standards of availability, accessibility, acceptability and quality, and that private actors do not compromise these standards.¹³⁰ The obligation also has a gender dimension, requiring states to protect women and other vulnerable groups from private conduct, social practices and institutional conditions that adversely affect their health.¹³¹ CEDAW reinforces this duty by mandating that states should prevent discrimination against women, including by private organisations and enterprises operating within state-regulated frameworks.¹³²

In the context of access to medicines, the obligation to protect specifically requires states to regulate private pharmaceutical actors, ensuring that their influence on the price, supply, and marketing of medicines does not restrict availability or affordability.¹³³ States also have a duty to align national legislation granting patent rights with this obligation, to ensure that these rights do not hinder access to essential

¹²⁴ International Network for Economic, Social and Cultural Rights and International Women's Rights Action Watch-Asia Pacific, 'Claiming Women's Economic, Social and Cultural Rights' (2013) 18 <<https://www.iwraw-ap.org/resources/claiming-womens-economic-social-and-cultural-rights/>> accessed 25 May 2026.

¹²⁵ GC 14, para 3.

¹²⁶ CEDAW, preamble.

¹²⁷ CEDAW, art 2.

¹²⁸ GC 14, para 48.

¹²⁹ GC 14, para 35.

¹³⁰ GC 14, para 35.

¹³¹ GC 14, para 35.

¹³² CEDAW, art 2(e).

¹³³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 109.

medicines. This duty also extends to their international commitments, which must not compromise the fulfilment of their human rights obligations.¹³⁴ Where necessary, this may require states to rely on TRIPS flexibilities to safeguard access to medicines.¹³⁵

3.3.3 Obligation to Fulfil

The obligation to fulfil requires states to take positive measures to ensure individuals' realisation of the right to health.¹³⁶ This includes deliberate, concrete and targeted steps towards the progressive realisation of ESC rights, while also ensuring that measures are non-discriminatory.¹³⁷ In practice, states must adopt appropriate legislative, regulatory and administrative measures to create conditions necessary for all to enjoy the right to health.¹³⁸

For women's access, this obligation entails concrete duties relating to sexual and reproductive health services, maternal healthcare, health education, medical research, essential medicines and appropriate mental health treatment and care.¹³⁹ It therefore goes beyond non-interference and requires active state involvement in ensuring compliance with the basic objective of women's right to health.¹⁴⁰

The obligation to fulfil also includes a duty of promotion, requiring positive state action to create, maintain and restore the health of the population.¹⁴¹ In relation to women's health, legislation and policies must rely on scientific and ethical research reflecting women's health needs.¹⁴² Healthcare services and medical personnel must also be responsive to the needs of vulnerable groups.¹⁴³ CEDAW reinforces this by mandating gender-sensitive training for healthcare professionals.¹⁴⁴ Women must also be supported in making informed decisions about their health, including through access to information on treatment options, benefits, risks, and available alternatives.¹⁴⁵

Although this understanding of the obligation to fulfil is comprehensive and responsive to women's needs, its implementation appears to be uneven, particularly in resource-constrained settings. This thesis confirms that women's access to medicine cannot be assessed solely by formal legal availability. It also entails examining whether states actively create the gender-sensitive conditions necessary for access in practice.

¹³⁴ GC 14, para 48.

¹³⁵ Jenifer Anna Sellin, 'Access to Medicines and the TRIPS Agreement: Recognising Extraterritorial Human Rights Obligations' in Mark Gibney and others (eds), *The Routledge Handbook on Extraterritorial Human Rights Obligations* (Routledge 2021) 345.

¹³⁶ Koch (n 26) 85.

¹³⁷ ICESCR, art 2.

¹³⁸ GC 14, para 36.

¹³⁹ GC 14, para 17.

¹⁴⁰ GR 24, paras 13-17.

¹⁴¹ GC 14, para 37.

¹⁴² GR 24, para 9.

¹⁴³ GC 14, para 37.

¹⁴⁴ GR 24, para 31(f).

¹⁴⁵ GR 24, para 20.

3.4 Defining Women's Access to Medicines: A Legal Benchmark

This section utilises a table to synthesise the normative content from sections 3.2 and 3.3 into a gender-sensitive legal benchmark. This table serves as the reference point for assessing the effectiveness of TRIPS' CL (Table 1). The AAAQ framework defines the substantive requirements for women's access to medicines, while the tripartite typology identifies how and by whom each requirement may be violated: through inadequate state interference (respect), insufficient regulation of third parties (protect), or a lack of positive action (fulfil).

Table 1: Gender-Sensitive Legal Benchmark for Women's Access to Essential Medicines

AAAQ Framework & Generic Standard	Gender Sensitive Standard	Failure under Tripartite Obligations	Impact on CL
Availability Essential medicines must be available in sufficient quantity to meet population needs. ¹⁴⁶	States must ensure that availability reflects sex-differentiated health needs. This includes biological, socio-economic, and psychosocial factors affecting women.¹⁴⁷ States must also adopt measures to prevent, detect, and treat conditions that specifically affect women.¹⁴⁸ Availability must reflect women's specific health needs. These include biological, socio-economic, and psychosocial factors.¹⁴⁹ Women-specific conditions should be prevented, detected, and treated.¹⁵⁰	Respect: states must not maintain IP or regulatory regimes that restrict the supply or development of medicines addressing conditions that specifically and disproportionately affect women (women-specific medicines).¹⁵¹ Protect: States must prevent private third parties from blocking the production, import or generic supply of women-specific medicines.¹⁵² Fulfil: States must take positive steps to ensure medicines for women-specific conditions are produced and distributed in sufficient quantities.¹⁵³	Where medicines addressing women-specific conditions do not exist, CL may be ineffective.
Accessibility Access to medicines must be ensured across four interrelated dimensions:	<i>Non-discriminatory:</i> States must ensure women can access medicines without interference from discriminatory barriers. A	Respect: States must not deny or limit access to healthcare services, contraceptives or other means of sexual and reproductive health.¹⁶⁰	Where legal, economic, or structural barriers prevent the use of CL, medicines may remain unaffordable or inaccessible to women despite

¹⁴⁶ Paul Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, para 48.

¹⁴⁷ GR 24, para 12 (a), (b), (c).

¹⁴⁸ GR 24, paras 10, 11.

¹⁴⁹ GR 24, para 12 (a), (b), (c).

¹⁵⁰ GR 24, paras 10, 11.

¹⁵¹ GC 14, para 34.

¹⁵² GC 14, para 35.

¹⁵³ Hunt (n 145) para 59.

¹⁶⁰ Hunt (n 145) para 47.

<i>non-discriminatory</i> access; <i>physical accessibility</i> for all, including those in remote or hard-to-reach areas; <i>economic accessibility</i> to ensure affordability based on equity; and <i>information accessibility</i>, with specific attention to overcoming barriers such as limited access to contraceptives or lack of culturally appropriate information.¹⁵⁴	healthcare system that lacks medicines designed to prevent, detect, and treat women-specific conditions is in and of itself discriminatory.¹⁵⁵ States must also remove procedural barriers such as spousal or parental authorisation requirements that disproportionately obstruct women's access to medicines.¹⁵⁶ <i>Physical accessibility:</i> States must remove physical barriers that disproportionately affect women, including distance from health facilities and lack of affordable public transport to reach them.¹⁵⁷ <i>Economic accessibility:</i> States must eliminate financial barriers that disproportionately burden women, such as high fees for health-care services and requirements for preliminary spousal or parental authorisation as a condition of access.¹⁵⁸ <i>Information accessibility:</i> States must ensure women are fully informed by trained personnel of their treatment options, benefits, and alternatives, and must protect patient confidentiality.¹⁵⁹	Protect: States must prevent pharmaceutical companies from pricing medicines beyond the reach of women, particularly those in socio-economically disadvantaged positions.¹⁶¹ Fulfil: States must take decisive steps to deploy all available mechanisms to reduce prices and guarantee informational and physical accessibility for women.¹⁶²	the formal availability of the mechanism.
Acceptability Medicines must be provided in an ethical and	Upholding women's dignity requires the removal of medically unnecessary or coercive practices, including	Respect: states must not maintain policies that stigmatise women's health needs or exclude	Where medicines relevant to women's health are excluded from essential medicines frameworks or public health

¹⁵⁴ GC 14, para 12.

¹⁵⁵ GR 24, para 11.

¹⁵⁶ GR 24, para 14.

¹⁵⁷ GR 24, para 21.

¹⁵⁸ GR 24, para 21.

¹⁵⁹ GR 24, paras 12(d), 20.

¹⁶¹ UN Office of the High Commissioner for Human Rights, 'Fact Sheet No 31: The Right to Health' (June 2008) UN Doc 1014-5567 (Fact Sheet 31), 25.

¹⁶² GR 24, paras 14, 21.

culturally acceptable manner. This means they must be safe, effective, scientifically appropriate, and provided in a way that upholds individuals' dignity and confidentiality.¹⁶³	mandatory pregnancy testing as a condition for employment. It also requires the recognition of reproductive health medicines as essential parts of healthcare.¹⁶⁴	reproductive and sexual health medicines from essential medicines designations.¹⁶⁵ Protect: States must prevent discriminatory practices by healthcare providers, third-party consent requirements, and denial of access to medicines for women.¹⁶⁶ Fulfil: States must also ensure reproductive and sexual health medicines are formally recognised as essential medicines.¹⁶⁷	priorities, CL may not be practically applicable.
Quality Medicines of good quality should be available in every state's jurisdiction.¹⁶⁸	States' positive duty to ensure women's access to high-quality medicine requires them to account for biological factors that affect women differently to ensure that medicine is effective. Factors include menstrual cycles, menopause, or a higher possibility of contracting sexually transmitted diseases.¹⁶⁹	Respect: States must not permit the distribution of medicines that fail safety standards for their population, especially women.¹⁷⁰ Protect: States are obligated to prevent manufacturers, including generic producers, from producing and distributing medicines that do not meet safety standards.¹⁷¹ Fulfil: States are obligated to establish effective medicine regulation to ensure only safe, effective, and quality medicines reach both the public and private sectors.¹⁷²	Inadequate regulatory oversight in CL legal frameworks can result in imported or produced medicines that fail to meet appropriate safety and efficacy standards, including those relevant to women's health needs.

¹⁶³ Hunt (n 145) para 50.

¹⁶⁴ GR 24, paras 11, 22.

¹⁶⁵ GR 24, para 14.

¹⁶⁶ GR 24, para 14.

¹⁶⁷ GC 14, paras 11, 43(d).

¹⁶⁸ Hunt (n 145) para 17(d).

¹⁶⁹ GR 24, para 12(a).

¹⁷⁰ Fact Sheet 31 (n 160) 25.

¹⁷¹ Fact Sheet 31 (n 160) 26.

¹⁷² Hunt (n 145) para 71.

3.5 Main Takeaways

The purpose of this chapter was to establish the gender-sensitive legal benchmark that structures the remainder of this thesis. Based on Table 1, the benchmark provides that women's right of access to essential medicines is fulfilled when several cumulative conditions are met. Medicines are *available* on demand and responsive to women's specific needs, such as those related to maternal and reproductive health. *Access* is ensured with awareness of the biological, socio-economic and psychosocial barriers women face. Medicines are *acceptable*, safe, effective and available without stigma, and they meet sex-specific *quality* standards. Additionally, states must *respect* these requirements by not restricting access, *protect* them by preventing excessive or discriminatory pricing, and *fulfil* them by using legal mechanisms to ensure access.

4 Effectiveness Assessment of TRIPS' Compulsory Licensing

4.1 Introduction

This chapter answers the main research question by applying Mousmouti's effectiveness test to TRIPS' CL in four steps: purpose, compatibility, results and integration. This is conducted within the context of IHRL.

4.2 Purpose

The first step is to determine whether the law's purpose is clearly stated.¹⁷³ Since this thesis focuses specifically on TRIPS' CL, the relevant question is whether the purpose of CL is sufficiently clear within the Agreement. The purpose can be inferred from the interpretation of both the TRIPS Agreement and the Doha Declaration, and it is two-fold.¹⁷⁴ CL primarily aims to protect public health by improving access to affordable medicines.¹⁷⁵ It also seeks to balance patent rights with public health.¹⁷⁶ However, neither objective is explicitly stated in Article 31 itself. Article 31, which mandates CL, is purely procedural. Further, Articles 7 and 8 offer interpretive principles for TRIPS as a whole. They do not provide specific guidance for CL. The Doha Declaration offers clarification, but as a ministerial declaration rather than a binding legal instrument, its normative weight is debated.¹⁷⁷ Additionally, it also addresses TRIPS flexibilities broadly. This can result in a purposive gap that could undermine clarity of implementation and effectiveness.¹⁷⁸

Beyond this gap, this thesis also examines whether the CL objectives align with the benchmark established in Chapter 3. At the purpose stage, the analysis focuses on the AAAQ dimensions, as the tripartite obligations concern state conduct rather than legislative design. Assessed against this dimension, the framework appears incomplete. The reference to 'access to medicines for all'¹⁷⁹ in the Doha Declaration might be interpreted as encompassing women's health needs and thus meeting the availability requirement. However, this interpretation is generous, as no provision explicitly addresses women-specific medicines, research gaps, or reproductive health needs. Accessibility is framed solely in economic and structural terms, thus omitting gendered barriers or information gaps.¹⁸⁰ Stigma and acceptability are not

¹⁷³ Mousmouti (n 36) 6.

¹⁷⁴ Mousmouti (n 36) 6.

¹⁷⁵ Doha Declaration, paras 3, 4; TRIPS, art 8; Raadhika Gupta, 'Compulsory Licensing under TRIPS: How Far It Addresses Public Health Concerns in Developing Nations' (2010) 15 *Journal of Intellectual Property Rights* 357, 359.

¹⁷⁶ TRIPS, arts 7, 8(2).

¹⁷⁷ David Vivas Eugui, 'Brief on the Treatment of Intellectual Property in the Doha WTO Ministerial Declaration: Mandated Negotiations and Reviews' (Center for International Environmental Law February 2002) 3, 5 <https://www.ciel.org/Publications/Doha_IP.pdf> accessed 25 May 2026.

¹⁷⁸ Mousmouti (n 36) 6.

¹⁷⁹ Doha Declaration, para 4.

¹⁸⁰ Doha Declaration, paras 3,4,6,7; TRIPS, art 66.

considered, and reproductive health medicines are not listed as essential medicines. Quality is neither mentioned nor approached from a sex-specific perspective.

The TRIPS framework is constructed neutrally, without a gendered dimension. This is unsurprising, as international trade agreements are not typically designed to contain gender-sensitive provisions.¹⁸¹ The absence of such provisions does not legally prevent states from implementing gender-sensitive measures at the national level either.¹⁸² However, this discretion is constrained in practice by structural inequalities. As developing countries have argued, IP laws ‘do not exist in a vacuum’. They operate on unequal terrain, and their effects are not gender-neutral, even when their texts are.¹⁸³ This reflects the broader feminist critique that the universality of international law can conceal the substantive inequality affecting women.¹⁸⁴ Therefore, while CL’s objectives are broadly inferable, they neither clearly meet Mousmouti’s purposive threshold nor align sufficiently with the human rights benchmark.

4.3 Compatibility

Mousmouti’s effectiveness test is a dynamic tool used to identify faults across different dimensions of a legal framework.¹⁸⁵ Each step can be conducted somewhat independently to fulfil the test’s purpose.¹⁸⁶ Stopping after one failed stage would undermine the method’s goal of recognising ineffectiveness across different areas of the law, such as content or enforcement.¹⁸⁷ Consequently, proceeding with the analysis is a contribution. Thus, the following section assesses whether CL’s substantive rules constitute appropriate means of achieving access to medicines.¹⁸⁸ For this, CL is analysed through each dimension of the human rights benchmark.

4.3.1 Availability

Availability requires medicines to meet a state’s demand. A textual interpretation of Article 31(f) could suggest that CL should address internal state needs.¹⁸⁹ In practice, this provision restricts export-oriented licences and creates significant barriers for developing countries and LDCs with limited manufacturing capacity.¹⁹⁰ Article 31bis and the Doha Declaration attempt to address this through an export mechanism, but its complexity, costs and patent-blocking risks make it unreliable.¹⁹¹ This also raises issues for the obligation to fulfil. While, in theory, TRIPS supports

¹⁸¹ Manjiao Chi and Zhiyuan Yin, ‘Article: Trade-Gender Alignment of International Trade Agreements: Insufficiencies and Improvements’ (2024) 58 *Journal of World Trade* 807, 828.

¹⁸² Mike (n 3) 500.

¹⁸³ Mike (n 3) 495; Africa Group and others, ‘TRIPS and Public Health’ (Submission to the TRIPS Council, 20 June 2001) IP/C/W/296 para 18.

¹⁸⁴ Charlesworth, Chinkin and Wright (n 32) 625.

¹⁸⁵ Mousmouti (n 36) 6.

¹⁸⁶ Mousmouti (n 36) 8.

¹⁸⁷ Mousmouti (n 36) 9.

¹⁸⁸ Mousmouti (n 36) 6.

¹⁸⁹ TRIPS, art 31(f).

¹⁹⁰ Correa (n 71) 311.

¹⁹¹ Correa (n 71) 326, 327, 328.

this obligation through technology transfer and financial and technical cooperation,¹⁹² these mechanisms remain limited due to their complexity.

Availability should also reflect sex-differentiated health needs. While TRIPS makes no explicit reference to this, states retain discretion for issuing CL,¹⁹³ which could theoretically permit gender-sensitive implementation in practice.¹⁹⁴ Nevertheless, this optimistic assumption is questioned in three ways. First, sex-specific medication might be unavailable because it simply does not exist. R&D priorities are mainly driven by market incentives.¹⁹⁵ Since women in developing countries have limited purchasing power,¹⁹⁶ conditions affecting them may remain under-researched. Thus, even where CL mechanisms exist, they cannot ensure availability if medicines are not produced or prioritised. The case of *Association for Molecular Pathology v Myriad Genetics Inc* illustrates this failure.¹⁹⁷ The patent holder's exclusive rights over breast cancer genes restricted other researchers from exploring alternative treatments and medicines for women, ultimately hindering further innovation.¹⁹⁸ This demonstrates that when patents are permitted to obstruct the development of essential medicines, the legal framework fails to meet its obligation to fulfil access to care, making even seemingly robust CL mechanisms ineffective.¹⁹⁹ Second, even when medicines exist, states with strong IP industries exert political pressure that discourages low-income countries from invoking CL.²⁰⁰ This reflects a failure of the obligation to respect, as states' own inaction under political pressure undermines CL discretion and restricts access. Third, domestic courts often interpret IP rules narrowly and formally, avoiding human rights approaches, as seen in South Africa.²⁰¹ The Celgene²⁰² case illustrates this: a cancer drug for multiple myeloma was protected by 32 secondary patents. These were granted for minor modifications rather than genuine innovation, therefore blocking 95% cheaper generics until 2026.²⁰³ By failing to test for genuine innovation, the state allowed monopoly rights to override the right to health and impose a major obstacle on disadvantaged women.²⁰⁴ This barrier reflects a failure of the obligation to protect, as the state's failure to scrutinise patent validity allowed a private actor to obstruct access to an essential medicine.

Further, availability requires states to ensure treatment and preventive care for women. TRIPS grants states the flexibility to define public health emergencies.²⁰⁵ While this could cover women-specific crises, relying on this discretion appears challenging. The Trastuzumab case in Brazil illustrates these difficulties.

¹⁹² Doha Declaration, para 7; TRIPS arts 66(2), 67.

¹⁹³ Doha Declaration, para 5(b).

¹⁹⁴ Mike (n 3) 495.

¹⁹⁵ Correa (n 71) 327.

¹⁹⁶ Tran-Nguyen and Zampetti (n 4) 72.

¹⁹⁷ *Association for Molecular Pathology v Myriad Genetics Inc* 569 US 576 (2013) (US Supreme Court).

¹⁹⁸ Mike (n 3) 480.

¹⁹⁹ Mike (n 3) 497.

²⁰⁰ Yousuf A Vawda, 'Compulsory Licenses and Government Use: Challenges and Opportunities' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer 2022) 75.

²⁰¹ *ibid* 93.

²⁰² Celgene is the patent holder of the drug in question.

²⁰³ Mike (n 3) 480.

²⁰⁴ Mike (n 3) 481.

²⁰⁵ Doha Declaration, paras 1, 5(c); TRIPS, art 8(1).

Trastuzumab, an essential drug for breast cancer, was sold at discriminatory prices by its patent holder, Roche. Although the Public Ministry contested this, the judiciary upheld Roche's patent rights without public health intervention.²⁰⁶ This demonstrates that, despite formal authority, monopoly tactics and judicial formalism can obstruct both the availability of women's medicines and the fulfilment of states' positive duty to ensure access to treatment and preventive care.²⁰⁷ This also reflects a failure of the obligation to protect. TRIPS acknowledges that patent rights may be abused to restrict medicine availability and encourages states to take measures against such practices.²⁰⁸ Roche's discriminatory pricing constituted precisely such an abuse, but the state failed to counter it. The protective obligation, therefore, proved ineffective where it was most needed: when a private right holder restricted access to an essential medicine for women.

To sum up, while CL theoretically accommodates women's health needs through state discretion, its gender-neutral structure and practical barriers appear to systematically limit its effectiveness in ensuring availability for women. Similarly, while TRIPS appears to allow states to fulfil their obligations from a woman-centred perspective, this impact is limited in practice by barriers that specifically affect LDCs.

4.3.2 Accessibility

For accessibility, the benchmark requires medicines to be accessible across four dimensions: non-discrimination, physical access, economic access, and information access. These dimensions must be ensured through state obligations and addressed through a gendered lens. This section, therefore, assesses whether CL's substantive rules can achieve this, both in terms of its stated purpose and in alignment with the benchmark.

For non-discrimination, paragraph 4 of the Doha Declaration mandates 'access to medicines for all'.²⁰⁹ This could be interpreted to require non-discriminatory CL access for any disease,²¹⁰ including perhaps women-specific conditions. However, this requirement is not always met in practice. Due to the high cost of patented medicines, these remain inaccessible for most populations.²¹¹ The *Minister of Health v Treatment Action Campaign (TAC)* landmark case from South Africa exemplifies this.²¹² In this case, the court ruled that restricting the distribution of nevirapine, a drug which limits the risk of HIV transmission from mother to child, constituted discrimination against mothers who do not have the means to access private healthcare.²¹³ Furthermore, in Ghana and across Africa, patients with greater means

²⁰⁶ Calixto Salomão Filho and Vitor Henrique Pinto Ido, 'Courts and Pharmaceutical Patents: From Formalist Positivism to the Emergence of a Global Law' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer 2022) 215-220.

²⁰⁷ *ibid.*

²⁰⁸ TRIPS, arts 8(2), 40(1).

²⁰⁹ Doha Declaration, para 4.

²¹⁰ Carlos M Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84 *Bulletin of the World Health Organization* 399, 399.

²¹¹ Laurence R Helfer and Graeme W Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011) 140.

²¹² *Minister of Health and Others v Treatment Action Campaign and Others* CCT 8/02 (2002) (Constitutional Court of South Africa).

²¹³ Mike (n 3) 499.

have access to higher-quality Western medicines, whereas those in poverty are left with cheaper, substandard, or illegally manufactured alternatives.²¹⁴ In addition, as already expressed regarding availability, pharmaceutical R&D favours diseases affecting wealthier populations, leaving conditions prevalent in developing countries and LDCs under-researched.²¹⁵ This gap disproportionately affects women.²¹⁶ Regarding state obligations, this reflects failures of both the obligation to respect, as states cannot ensure equal access across populations, and the obligation to protect, as market dynamics and pricing structures continue to disadvantage vulnerable groups, including women.

Article 31bis and paragraph 6 of the Doha Declaration address physical access for countries without manufacturing capacity by permitting imports.²¹⁷ However, as already established, this system is exceedingly complex and unreliable for suppliers.²¹⁸ Beyond this, women's access is further constrained by international funding priorities that override local health needs.²¹⁹ In Djibouti, for example, significant foreign funding was directed toward AIDS medicines while maternal mortality, the more pressing local concern, went unaddressed.²²⁰ This reflects failures of both the obligation to protect, as states are unable to prevent external actors from overriding women's health priorities, and the obligation to fulfil, as they cannot ensure that medicines correspond to actual local needs when international funding conditions dictate otherwise.

On financial accessibility, Article 31(h) limits remuneration to the patent holder.²²¹ Without a strict ceiling, states have the flexibility to lower costs significantly, in some cases to under 1% in developing countries.²²² This also restores market competition and drives prices toward production costs,²²³ which empirical data suggests is the most reliable mechanism for ensuring affordability.²²⁴ However, the Ghana case illustrates the gap between theory and practice. It also shows how even where a price mechanism exists, various barriers can render it ineffective. In 2006, Ghana obtained a CL for antiretroviral drugs, but production proved redundant in practice.²²⁵ To distribute the medicines, the government had to rely on the Global Fund, which imposed complex requirements that local manufacturers lacked the means and expertise to meet. This excluded them from their own market and forced them to sell elsewhere.²²⁶ This reflects another instance of external decision-making overriding local needs. It also illustrates a failure of the obligation to protect, where states are unable to deter external actors that price medicines beyond the reach of women.

²¹⁴ Emilie Cloatre, *Pills for the Poorest: An Exploration of TRIPS and Access to Medication in Sub-Saharan Africa* (Palgrave Macmillan 2013) 134, 137, 138, 144, 150.

²¹⁵ Helfer and Austin (n 209) 140.

²¹⁶ *ibid* 100.

²¹⁷ Doha Declaration para 6; TRIPS, art 31bis.

²¹⁸ Correa (n 71) 328.

²¹⁹ Cloatre (n 212) 158.

²²⁰ *ibid* 168.

²²¹ TRIPS, art 31(h).

²²² Correa (n 71) 312-313.

²²³ Samira Guennif, 'Is Compulsory Licensing Bad for Public Health? Some Critical Comments on Drug Accessibility in Developing Countries' (2017) 15 *Applied Health Economics and Health Policy* 557, 560.

²²⁴ Urias and Ramani (n 76) 372-373.

²²⁵ Cloatre (n 212) 53, 174.

²²⁶ *ibid* 174-175.

Furthermore, neither TRIPS nor the Doha Declaration addresses information accessibility for women, yet as established in the benchmark, it remains a state obligation. In practice, this requirement does not appear to be sufficiently met. For example, in Ghana, reproductive health products were widely available but sold without adequate usage information, making them ineffective. This gap was rooted in the absence of appropriate education.²²⁷ Additionally, this example also reflects a failure of the obligation to respect, as states' inability to ensure information access directly limits women's access to reproductive medicines. A related failure concerns improperly labelled substandard drugs, where information gaps have been documented to cause severe harm and even death.²²⁸ By failing to regulate substandard medicines, states also breach the obligation to fulfil, leaving women's physical safety compromised.

In sum, CL theoretically addresses accessibility within the TRIPS framework. However, legal, economic and structural barriers consistently undermine its effectiveness in practice, leaving medicines inaccessible to women regardless of their formal availability. The substantive rules are therefore insufficient to fulfil CL's stated purpose of access to medicines.

4.3.3 Acceptability

The benchmark requires medicines to be provided in an ethical and culturally appropriate manner that respects women's dignity, autonomy and confidentiality.²²⁹ Through the tripartite obligations, states must refrain from excluding women's health needs, protect women from discriminatory access conditions imposed by third parties and formally recognise reproductive and sexual health medicines as essential.

Article 31 does not appear to be compatible with these requirements. No subparagraph directly addresses acceptability, as the provision is procedural and operates through a state decision to authorise the use of a patent without consent. As already established regarding availability, CL's emergency framing²³⁰ structurally disadvantages women's specific conditions. Yet, even where formal recognition exists, it has not translated into practice. The World Health Organisation's Model List of Essential Medicines (WHOMLEM) recognises reproductive health medicines, including prenatal care, maternal health, and women-specific diseases such as breast cancer, confirming their status as essential at the international level.²³¹ However, this formal recognition has not translated into CL practice. Reproductive health medicines are frequently perceived as benefiting only a portion of the population rather than constituting a public health crisis, and states are merely encouraged, not required, to adapt the list to their national priorities.²³²

Furthermore, states must prevent discriminatory practices that condition women's access to medicines, including imposed consent requirements which directly

²²⁷ *ibid* 173.

²²⁸ *ibid* 138.

²²⁹ GR 24, paras 11, 22.

²³⁰ Doha Declaration, para 5(c).

²³¹ World Health Organization, 'The Selection and Use of Essential Medicines, 2025: WHO Model List of Essential Medicines, 24th List' (2025) B09474.

²³² Mike (n 16) 164.

undermine dignity, confidentiality and autonomy. The importance of protecting such clinical autonomy is illustrated in *Mrs Sidonia Vargas v Hospital San Juan de Dios*,²³³ where a woman with leukaemia and diabetes was refused the right to self-administer medication at home. The Costa Rican court ruled that this administrative restriction violated her fundamental rights to health and life.²³⁴ This case illustrates that acceptability requires respecting a woman's agency and dignity in how she receives care. However, Article 31 operates exclusively at the level of the relationship between states and patent holders. Pharmaceutical corporations and other private actors hold significant influence over health policies and, by extension, women's access to medicines.²³⁵ CL may limit the patent-based pricing power of pharmaceutical companies, but it does not regulate the broader social conditions under which women access medicines. Whether women face spousal consent requirements, discriminatory conditions imposed by healthcare providers, or stigma attached to reproductive health medicines, these barriers fall outside the scope of Article 31. The protective obligation, as defined in the benchmark, is therefore entirely outside the mechanism's subject matter.

The issue is therefore not that CL is formally unavailable for women's health medicines. It is that Article 31 leaves its recognition to state discretion within a structurally biased framework and contains nothing that reaches the social and clinical barriers women face in accessing medicines. The acceptability dimension of the benchmark, therefore, remains beyond its reach.

4.3.4 Quality

The quality dimension requires medicines to meet safety and efficacy standards responsive to women's biological needs. Through the tripartite obligations, states must refrain from permitting unsafe medicines, prevent manufacturers from distributing substandard products, and establish regulatory frameworks ensuring that medicines are safe and appropriate for women.

Article 31 does not engage with this dimension because its procedural conditions concern the authorisation of patent use, not the quality of the medicines produced or imported under that licence. It does not impose standards concerning safety, efficacy, dosage, pharmacovigilance or sex-responsive quality, leaving quality control to domestic pharmaceutical regulation rather than the CL mechanism itself.²³⁶ Article 31bis similarly contains procedural requirements relating to quantities, labelling, marking, notification and anti-diversion, but they are designed to ensure the controlled operation of the exporting system and do not guarantee that the medicines produced or imported under the CL meet sex-sensitive safety and efficacy standards. This gap is particularly significant for countries with weak regulatory capacity, where imported generics may circulate without reliable quality verification.²³⁷ For

²³³ *Mrs Sidonia Vargas v Hospital San Juan de Dios* 2390-C-94 (1994) (Constitutional Court of Costa Rica).

²³⁴ Mike (n 3) 497.

²³⁵ Danwood Mzikenge Chirwa, 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicine' (2003) 19 South African Journal on Human Rights 541, 562.

²³⁶ Muhammad Zaheer Abbas and Shamreeza Riaz, 'TRIPS Flexibilities: Implementation Gaps between Theory and Practice' (2013) Nordic Journal of Commercial Law 1, 22.

²³⁷ *ibid.*

example, the WHO (World Health Organisation) found that about 30% of malaria-curing medicines from Ethiopia, Kenya, Ghana, Cameroon, Nigeria, and Tanzania did not meet international quality standards.²³⁸

Compliance with Article 31, therefore, does not demonstrate compliance with the quality dimension of the right to health. From the benchmark perspective, CL may enable the production or importation of lower-cost medicines, but without gender-sensitive regulatory oversight, it cannot ensure those medicines meet standards responsive to women's biological specificities.

4.4 Results

At this stage, the question is whether sufficient information exists to determine whether CL improves women's access to medicines. The human rights benchmark determines what must be measured. It is not enough to ask whether CL was used or whether prices fell. The issue is whether CL produces measurable improvements across the AAAQ dimensions for women and whether those outcomes demonstrate compliance with the tripartite obligations. Against this standard, CL performs poorly at two levels: structurally, because TRIPS contains no mechanism for collecting gender-sensitive outcome data; and substantively, because existing empirical studies do not assess CL's impact on women's access to medicines.

At the structural level, TRIPS contains no obligations related to health outcomes and no gender-sensitive monitoring mechanism. Article 31 does not require states to report whether CL improved access to medicines, let alone women's access.²³⁹ Article 31bis introduces procedural notification requirements, but these concern eligibility rather than whether medicines reached women in importing states.²⁴⁰ Similarly, the WTO dispute settlement system assesses compliance with TRIPS obligations rather than human rights outcomes.²⁴¹ The Doha Declaration recognises the use of flexibilities to protect public health, but it does not establish any mechanism for collecting gender sensitive data.²⁴² Although CEDAW GR 24 requires states to report on health legislation and policies supported by reliable sex-disaggregated data, this obligation is not linked to the operation of CL.²⁴³ As a result, a state may comply with TRIPS procedures without generating the data required by the gender-sensitive benchmark.

At the substantive level, the available empirical record confirms what the structural analysis predicts. Documented CL cases are often cited as proof of the mechanism's effectiveness, and to some extent, rightly so, as CL can reduce prices and increase generic supply. However, none of the documented cases assesses whether women's health needs were taken into account, or generic medicines were evaluated against sex-differentiated quality standards. More significantly, while two instances in the

²³⁸ *ibid.*

²³⁹ TRIPS, art 31.

²⁴⁰ TRIPS, art 31bis.

²⁴¹ Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 *Netherlands International Law Review* 445, 456.

²⁴² *ibid.*

²⁴³ GR 24, para 9.

entire documented record concern breast cancer medicines, neither was issued on gender-specific grounds or framed around women's health needs.²⁴⁴ The mechanism has therefore never been used in a way that would generate results against the AAAQ benchmark for women, and the absence of such evidence is itself a finding.

The Nigerian context illustrates this pattern. Innovator brands cost between two and seven times more than generic equivalents, with patients paying up to 64 times the international reference price.²⁴⁵ Women constitute 65% of the population below the poverty line, and the 2008 Nigerian Demographic and Health Survey found that 56% of women cited financial constraints and 41% identified unavailability of medicines as primary barriers to access.²⁴⁶ Yet, this data does not measure the relationship between patent rights, CL and women's access to medicines. Documented access barriers are therefore insufficient on their own to assess whether CL satisfies the gender-sensitive benchmark.²⁴⁷

In sum, CL performs inadequately at the results stage. The mechanism does not produce bad results, but its gender-sensitive effects remain largely unmeasured. This reflects a broader critique of gender-equality measurements: limited quantitative indicators may suggest that complex, context-specific inequalities have been adequately captured, when they in fact overlook the lived conditions and agency that shape women's access in practice.²⁴⁸ Under the benchmark, price reduction alone is insufficient to demonstrate that CL improves women's access to essential medicines or supports compliance with the tripartite obligations.

4.5 Integration

4.5.1 Internal Integration within TRIPS

At the most basic level, Article 31 fits coherently within the TRIPS patent framework. Article 28 confers exclusive rights on patent holders, while Article 31 creates a structured limitation on those rights.²⁴⁹ In this sense, CL completes the patent framework by recognising that patent exclusivity is not absolute and may be overridden where public interests justify such use. However, the integration is limited by the permissive nature of Article 31. It creates a legal possibility for states to override patent exclusivity, but it does not require them to do so when access to medicines is obstructed.²⁵⁰ The internal coherence, therefore, does not translate into an internal obligation to ensure access.

Article 31bis illustrates both the potential and the limits of TRIPS' internal integration. As established in Chapter 2, it was adopted to address the gap created by Article 31(f). From an integration perspective, it improves the internal coherence of

²⁴⁴ 'TRIPS Database - Medicines, Law & Policy' (*Medicineslawandpolicy.org* 2025) <<https://tripsflexibilities.medicineslawandpolicy.org/>> accessed 21 May 2026.

²⁴⁵ Mike (n 16) 168.

²⁴⁶ Mike (n 16) 172.

²⁴⁷ Mike (n 16) 173.

²⁴⁸ Liebowitz and Zwingel, (n 28) 386.

²⁴⁹ TRIPS, arts 28, 31.

²⁵⁰ Abbas and Riaz (n 234) 1.

the CL system by creating an export route for countries lacking manufacturing capacity. However, it does so through an additional procedural mechanism rather than by integrating CL into a unified access-to-medicines framework.²⁵¹ The same partial integration appears when Article 31 is read alongside other TRIPS flexibilities. Some provisions create additional regulatory space, such as Article 6 on exhaustion and parallel importation and Article 30 on limited exceptions to patent rights.²⁵² Others support intervention against restrictive private conduct, particularly Article 40 on anti-competitive licensing practices.²⁵³ Articles 7 and 8 provide broader interpretative support for balancing IP protection with public health and social welfare.²⁵⁴ Together, these provisions could complement CL and contribute to a coherent access-to-medicines framework. However, TRIPS does not coordinate them into a single mechanism or explain how they should interact when public health concerns arise.

Effective use of TRIPS flexibilities requires states to identify and combine several provisions, each with its own conditions and uncertainties. This burden falls most heavily on states with limited institutional capacity, where women often face the greatest barriers to medicines.²⁵⁵ Internal integration is therefore only partial: Article 31 and Article 31bis provide legal routes for CL, but they are not coordinated with other flexibilities into a clear public health mechanism.

4.5.2 External Integration with International Human Rights Law

The weak external integration of CL with HRL reflects the broader problem of fragmentation in international law, in which norms of self-contained legal regimes may conflict with those of other regimes.²⁵⁶ TRIPS was not designed as a human rights instrument; its purpose is to strengthen the international system of trade-related IP protection rather than protect rights premised on human dignity.²⁵⁷ In line with this, TRIPS could not be considered to incorporate a human rights approach in its design or content.²⁵⁸ However, as long as international law continues to treat these frameworks as self-contained regimes operating in parallel, the tension between innovation incentives and the safeguarding of fundamental rights will remain unresolved.

From this perspective, CL and the human rights framework that defines women's access to medicines remain fundamentally disconnected. ICESCR and CEDAW require states to ensure access to healthcare and medicines without discrimination, but neither Article 31 nor Article 31bis incorporates these obligations. TRIPS does not require the application of the AAAQ framework or the assessment of gender-

²⁵¹ *ibid* 4.

²⁵² TRIPS, arts 6, 30.

²⁵³ TRIPS, art 40.

²⁵⁴ TRIPS, arts 7, 8.

²⁵⁵ Augustus Osborne, Peter Bai James and Camilla Bangura, 'Determinants of Poor Access to Health Care among Women of Reproductive Age in Sierra Leone: A Cross-Sectional Study' (2025) 25 *BMC Health Services Research* 1, 2.

²⁵⁶ Klaus D Beiter, 'Establishing Conformity between TRIPS and Human Rights: Hierarchy in International Law, Human Rights Obligations of the WTO and Extraterritorial State Obligations under the International Covenant on Economic, Social and Cultural Rights' in Hanns Ullrich and others (eds), *TRIPS plus 20: From Trade Rules to Market Principles* (Springer 2016) 447.

²⁵⁷ *ibid* 451.

²⁵⁸ *ibid* 451.

specific barriers when issuing a CL. This creates a definitional gap: TRIPS addresses access primarily through limitations on patent exclusivity and affordability, whereas ICESCR and CEDAW require access to fulfil the AAAQ framework, with a focus on women's specific needs and non-discrimination. As a result, the two frameworks operate in parallel. HRL provides the normative standard, while TRIPS supplies the patent law mechanism. The absence of a coordinating rule means that CL may assist states in fulfilling human rights obligations, but it does not ensure that they actually do so.

The institutional structure reinforces this separation: the WTO dispute settlement can assess compliance with Article 31, but it is not competent to enforce human rights treaties such as ICESCR or CEDAW.²⁵⁹ Consequently, a state's compliance with the procedural requirements of CL may be deemed sufficient without any corresponding assessment of whether women's right to access essential medicines has been realised. However, it does not relieve WTO members of their human rights obligations;²⁶⁰ rather, it shows that those obligations are not integrated into the TRIPS enforcement structure.

The problem is therefore not usually one of direct conflict, in which compliance with TRIPS would necessarily require a breach of human rights obligations.²⁶¹ It is a broader tension: TRIPS and IHRL may be formally compatible, yet still limit the realisation of women's right to health because the two frameworks are built around different values, concepts, and enforcement mechanisms.

4.6 Main Takeaways

This chapter assessed the effectiveness of TRIPS' CL through Mousmouti's framework, using a gender-based human rights benchmark. Four main findings emerge. First, the purpose of TRIPS' CL is not clearly articulated within TRIPS and instead emerges from the interpretation of TRIPS and the Doha Declaration. Further, the purpose is not gender-sensitive when tested against the AAAQ framework. Second, while CL can theoretically support greater access to medicines, its practical effectiveness is weak. When measured against the AAAQ framework and the tripartite state obligations, the mechanisms do not adequately address the gendered barriers that women in developing countries face. Third, CL's results cannot be adequately measured against the benchmark. TRIPS contains no gender-sensitive monitoring mechanism, and existing evidence focuses mainly on price reductions and generic supply rather than women's access in practice. Lastly, CL does not appear to be well integrated within legal frameworks. Internally, TRIPS flexibilities remain fragmented; externally, CL is disconnected from ICESCR and CEDAW. Overall, CL appears to be a theoretically apt but structurally limited mechanism whose gender-neutral design undermines its effectiveness in ensuring women's access to essential medicines in developing countries.

²⁵⁹ Sellin (n 239) 456.

²⁶⁰ Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights (adopted 28 September 2011), para 15.

²⁶¹ Beiter (n 254) 454.

5 Conclusion and Recommendations

This thesis set out to answer the following question, which captures the core tension between patent law and access to medicines in international law: *How effective is TRIPS' CL in enabling states to safeguard women's right to access essential medicines in developing countries?* The analysis shows that while CL can reduce patent barriers and improve affordability, its impact remains limited. The gender-neutral nature of CL overlooks women's needs. Persistent structural challenges, such as inadequate implementation, market-driven R&D, and IP regimes favouring right-holders, further constrain its effectiveness. Patent removal alone does not guarantee access, as broader socioeconomic barriers persist. The findings thus indicate that CL is necessary but insufficient in ensuring women's access to essential medicines in developing countries.

This conclusion rests on three findings. First, the legal framework for CL under TRIPS is technically structured but politically contested. While Article 31 provides the legal basis and the Doha Declaration reaffirms it, the framework is undermined in practice by the complexity of Article 31bis and persistent political and economic pressure. Within IHRL, states bear concurrent obligations under ICESCR and CEDAW to ensure women's access to essential medicines without discrimination. Read together, these instruments establish a comprehensive normative framework, one that TRIPS' CL is not structured to reflect.

Second, the gender-sensitive benchmark derived from the right to health, the AAAQ framework and the tripartite state obligations establishes that access to medicines is not satisfied by formal legal availability alone. It requires that medicines are available in sufficient quantity and responsive to women's specific health needs; accessible without discrimination, high cost or informational barriers; acceptable in a manner that respects women's dignity; and of good quality, including sex-sensitive safety standards. States must correspondingly respect, protect and fulfil these requirements in practice.

Third, when assessed against Mousmouti's effectiveness test, it becomes apparent that while CL is not flawed, it was never designed to ask the right questions for women. At the purpose stage, its objectives are inferable rather than clearly articulated and make no mention of women. For compatibility, while TRIPS creates legal space, its gender-neutral structure, procedural complexity and vulnerability to political pressure consistently prevent that space from reaching women. The Myriad Genetics case illustrates how exclusive patent rights can obstruct the development of women-specific medicines altogether, while the Celgene case demonstrates how secondary patenting blocks affordable generics for conditions affecting women. Together with the judicial formalism seen in the Brazilian Trastuzumab case and the external pressures that overrode women's actual health needs in Ghana and Djibouti, these examples reveal a consistent pattern of structural failure that the mechanism itself does not address. For results, the absence of gender-sensitive monitoring and empirical data makes it structurally impossible to assess whether CL improves

women's access to medicines. At the integration stage, CL remains only partially integrated within TRIPS and loosely connected to IHRL, leaving a significant gap between patent regulation and women's right to health.

This thesis also constitutes, to the authors' knowledge, the first systematic assessment of TRIPS' CL effectiveness through a gender-sensitive human rights lens. This thesis has thus offered a contribution by bridging the gap between patent law, HRL and women's health in developing countries. In doing so, it supports the feminist critique that international law's assumption of universality leaves gendered inequalities unaddressed.

These findings point to reform and further research. At the international level, TRIPS could be revised to better reflect human rights concerns, and states may have an obligation under IHRL to pursue such revision where existing IP rules obstruct the right to health.²⁶² However, a more realistic route could involve a gender-sensitive implementation of flexibilities at the national level, relying on public-interest measures.²⁶³ Nevertheless, because this approach depends on state discretion, its effects will remain uneven and vulnerable to structural constraints. This therefore strengthens the case for gender-sensitive criteria within the CL framework, mandatory sex-disaggregated monitoring, and clearer recognition of reproductive and maternal health needs as grounds for public-health measures under TRIPS.

Future research should move in two directions. First, national-level studies examining how TRIPS flexibilities are implemented in developing-country contexts are necessary to determine whether the gaps identified here translate into concrete failures on the ground. Second, the empirical dimension remains largely unexplored. Research measuring CL's actual impact on women's health outcomes, along with studies on how R&D incentives could be reformed to prioritise women-specific medicines, would provide the evidentiary base that this thesis has shown is absent.

The right to health and patent law do not exist in isolation. Both are influenced by existing economic dependence, social stigma, reproductive health marginalisation, and political inequality. Unless CL is accompanied by gender-sensitive implementation, effective monitoring, and genuine integration with states' existing human rights obligations, it is likely to remain an unfulfilled promise for those most in need.

²⁶² Beiter (n 254) 499.

²⁶³ Mike (n 3) 500-503.

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