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Bridging innovation and equity: Compulsory and voluntary licensing in global access to medicines

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Access to essential medicines remains a cornerstone of global public health, yet significant disparities persist due to patent protections, high drug prices, and inequitable distribution systems. Licensing mechanisms-particularly compulsory licensing (CL) and voluntary licensing (VL)-have emerged as critical tools to balance intellectual property (IP) rights with public health priorities. This review critically examines the legal, economic, and ethical dimensions of CL and VL within the framework of the TRIPS Agreement and global health governance. Drawing on recent developments, including the COVID-19 pandemic, it evaluates their effectiveness in improving affordability and availability of medicines. While voluntary licensing fosters collaboration and facilitates technology transfer, compulsory licensing remains an indispensable safeguard during public health emergencies. Persistent challenges-including geopolitical pressures, restrictive licensing terms, and limited manufacturing capacity-continue to constrain equitable access. Adopting a human-centred perspective, this review highlights the lived realities of patients in low- and middle-income countries (LMICs) and underscores the urgent need for more inclusive and transparent policy frameworks. The paper concludes with recommendations aimed at strengthening global health equity while preserving incentives for pharmaceutical innovation.

Keywords: Pharmaceutical innovation, Global health governance, Patent flexibilities, Compulsory licensing, Voluntary licensing, Medicine affordability, Public health policy

INTRODUCTION

Access to essential medicines remains one of the most pressing challenges in global health. Although remarkable advances in pharmaceutical research have led to innovative therapies for diseases such as cancer, HIV/AIDS, hepatitis, and COVID-19, millions of people-particularly in low- and middle-income countries (LMICs)-continue to face significant barriers to obtaining these treatments[1,60]. High medicine prices, limited healthcare resources, inadequate regulatory systems, and weak supply chains often prevent life-saving therapies from reaching those who need them most[45,86]. Consequently, improving access to medicines has become not only a public health priority but also a matter of equity and social justice[17,90].

At the heart of this challenge lies the need to balance pharmaceutical innovation with equitable access[1,16]. Patent protection is essential for encouraging research and development by allowing innovators to recover substantial investments; however, prolonged market exclusivity may also restrict generic competition and delay the availability of affordable medicines[54,57]. To address this tension, compulsory licensing (CL) and voluntary licensing (VL) have emerged as important policy tools[2,3,11,84]. Although compulsory licensing can improve affordability during public health emergencies, its implementation is frequently hindered by legal complexity and political resistance[4,8,44,99]. Conversely, voluntary licensing often facilitates technology transfer and collaborative manufacturing but depends largely on the willingness of patent holders and may include geographical restrictions[2,3,92,100]. Therefore,

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neither approach is universally effective. Rather, their success depends on disease context, manufacturing capacity, regulatory preparedness, and national health priorities[29,83]. This review critically evaluates the strengths, limitations, and future role of both licensing mechanisms in promoting equitable access to medicines while sustaining pharmaceutical innovation [97].

Literature search methodology

This review was conducted using a structured narrative approach to critically evaluate the role of compulsory and voluntary licensing in improving global access to medicines. A comprehensive literature search was performed across PubMed, Scopus, Web of Science, and Google Scholar, supplemented by reports and policy documents from the World Health Organization (WHO), World Trade Organization (WTO), World Intellectual Property Organization (WIPO), Medicines Patent Pool (MPP), and United Nations Development Programme (UNDP)[30,43]. The search included publications from January 2000 to March 2025 to capture developments following the Doha Declaration and recent experiences during the COVID-19 pandemic[34,35,47].

Search terms included "compulsory licensing," "voluntary licensing," "TRIPS Agreement," "Doha Declaration," "access to medicines," "pharmaceutical patents," "pharmaceutical innovation," "technology transfer," and "COVID-19." Eligible studies comprised English-language peer-reviewed research articles, systematic and narrative reviews, legal and policy analyses, and authoritative international reports relevant to pharmaceutical licensing and public health. Conference abstracts, editorials, duplicate records, non-English publications, and studies lacking direct relevance were excluded. The retrieved literature was screened based on titles, abstracts, and full-text assessment to ensure relevance and quality. As this article is a narrative review, a formal PRISMA flow diagram was not applied; however, a transparent and systematic literature selection process was followed to ensure a balanced and comprehensive synthesis of the available evidence.

Conceptual framework of licensing in pharmaceuticals

The pharmaceutical patent system is designed to balance two equally important objectives: encouraging pharmaceutical innovation[1,16] and ensuring equitable access to essential medicines. Patent protection provides innovators with temporary market exclusivity[54,57], enabling recovery of the substantial investments required for drug discovery, clinical development, and regulatory approval. This framework has driven the development of numerous life-saving therapies. However, prolonged exclusivity may also delay generic competition[65], maintain high medicine prices, and restrict access, particularly in low- and middle-income countries (LMICs)[66]. Consequently, the challenge is not whether patents should exist, but how intellectual property protection can be balanced with public health priorities[88].

To address this challenge, the international intellectual property framework incorporates licensing mechanisms that enable broader access to patented medicines without eliminating incentives for innovation[2,48]. The two principal approaches, compulsory licensing (CL) and voluntary licensing (VL), represent different strategies for achieving this balance. While both mechanisms have improved access to essential medicines, they differ considerably in their legal basis, implementation, and overall effectiveness[8,51]. Rather than viewing them as competing approaches, they should be considered complementary policy tools whose success depends on the specific public health context, manufacturing capacity, and regulatory environment[11,91].

Compulsory licensing

Compulsory licensing (CL) is a legal flexibility provided under Article 31 of the TRIPS Agreement[48], allowing governments to authorise the manufacture, importation, or use of patented medicines without the consent of the patent holder under specific circumstances[91], particularly during public health emergencies or when medicines are unaffordable or inadequately supplied[51]. By facilitating generic competition, compulsory licensing has substantially reduced medicine prices and expanded treatment access, as demonstrated by India's landmark compulsory licence for sorafenib[44]. Several studies have shown that compulsory licensing can reduce medicine prices substantially by enabling generic competition, although the magnitude of these reductions varies according to manufacturing capacity, market size, and procurement policies[70,80].

Despite these public health benefits, compulsory licensing is not without limitations. Its implementation is often constrained by lengthy legal procedures[49,74], political and trade pressures, limited domestic manufacturing capacity, and concerns that frequent use could weaken incentives for future pharmaceutical research and development[73,74]. Consequently, although compulsory licensing remains an essential safeguard for protecting public health, its practical effectiveness depends on supportive legislation, manufacturing capability, and international cooperation rather than legal authority alone[88]. Although compulsory licensing has demonstrated its value in improving affordability during public health emergencies, its broader application remains limited by legal complexity, political resistance, and concerns regarding foreign investment[99]. Consequently, while CL is an effective emergency measure, it is less suitable as a routine mechanism for improving long-term access to medicines[15,81].

Voluntary licensing

Voluntary licensing (VL) is a collaborative mechanism

through which patent holders authorize generic manufacturers to produce and distribute patented medicines under mutually agreed contractual terms[2,3,9]. These agreements, frequently facilitated by organizations such as the Medicines Patent Pool (MPP), have played an important role in expanding access to treatments for HIV/AIDS, hepatitis C, tuberculosis, and COVID-19[3,10]. In addition to increasing manufacturing capacity, voluntary licensing often includes technology transfer, quality assurance, and regulatory support, enabling faster and more sustainable expansion of medicine availability[58,62].

Nevertheless, voluntary licensing also has important limitations. Because participation is entirely at the discretion of patent holders, licensing agreements may contain territorial restrictions [2,92], exclude certain middle-income countries, or limit the range of licensed products[100]. As a result, populations with significant healthcare needs may remain outside the scope of these agreements. Therefore, while voluntary licensing generally receives greater industry acceptance and promotes long-term collaboration, it cannot fully replace compulsory licensing in situations where rapid government intervention is required. An effective pharmaceutical access strategy should integrate both mechanisms according to disease burden, market conditions, and national healthcare priorities, thereby balancing incentives for innovation with the imperative of equitable access to medicines[97].

Voluntary licensing generally provides a more collaborative and sustainable approach than compulsory licensing because it facilitates technology transfer and maintains stronger relationships between innovators and generic manufacturers[83]. Nevertheless, its dependence on patent-holder participation and territorial restrictions means that important patient populations may remain excluded[84]. To facilitate a clearer comparison of the legal basis, implementation pathways, strengths, and limitations of these two licensing mechanisms, Fig. 1 provides a conceptual overview of compulsory and voluntary licensing.

Although compulsory licensing has substantially improved access to affordable medicines during public health emergencies by enabling generic competition and reducing prices[1,2], its implementation remains constrained by political pressure, procedural complexity, international trade considerations, and concerns regarding potential effects on pharmaceutical investment. In contrast, voluntary licensing generally promotes stronger collaboration, technology transfer, and regulatory support, making implementation faster and more acceptable to industry[44]. However, because voluntary licensing depends on patent holders' willingness to participate and often includes territorial restrictions, it may fail to ensure equitable access for many low- and middle-income countries[58]. Consequently, neither approach should be regarded as universally superior. Instead, their effectiveness depends on disease burden, manufacturing capacity, regulatory preparedness, and broader public health priorities[84].

A detailed comparison of compulsory and voluntary licensing, including their legal foundations, implementation characteristics, advantages, limitations, and representative case studies, is presented in Table 1.

Pharmaceutical patent protection and TRIPS

TRIPS agreement and the global intellectual property framework

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[20], adopted by the World Trade Organization (WTO) in 1995, established the first globally harmonized framework for intellectual property protection[18,19,48,63]. By requiring member states to provide a minimum standard of patent protection [1], TRIPS created a predictable environment for pharmaceutical innovation, encouraging companies to invest in costly[16] and high-risk research and development[54,57]. Strong patent protection has undoubtedly contributed to the discovery of breakthrough therapies for cancer[54,55], HIV/AIDS, hepatitis, and other life-threatening diseases by enabling innovators to recover substantial development costs[56,59].

However, the benefits of robust patent protection have not been distributed equally. In many low- and middle-income countries (LMICs)[1,45], prolonged market exclusivity delays generic competition, resulting in medicine prices that remain beyond the reach of patients and public healthcare systems[65,69]. Consequently, the same legal framework that promotes innovation can also limit affordability and widen disparities in access to essential medicines[1,66,71,88]. This tension illustrates that protecting intellectual property and ensuring equitable healthcare are complementary objectives that require careful policy balancing rather than competing priorities [1,83,90].

Doha declaration and public health flexibilities

Recognizing these challenges, WTO member states adopted the Doha Declaration on TRIPS and Public Health in 2001[48,51], reaffirming that the TRIPS Agreement should be interpreted and implemented in a manner supportive of public health and universal access to medicines[64,91]. The Declaration clarified that countries retain the sovereign right to utilize TRIPS flexibilities[5], including compulsory licensing and parallel importation[53], particularly during public health emergencies[48,51,91,95].

The Doha Declaration represented a major shift in global health policy by acknowledging that intellectual property protection should not prevent governments from responding to urgent health needs[47,64]. It strengthened the legal confidence of many countries to improve access to affordable medicines during crises such as the HIV/AIDS epidemic and, more recently, the COVID-19 pandemic[80,81].

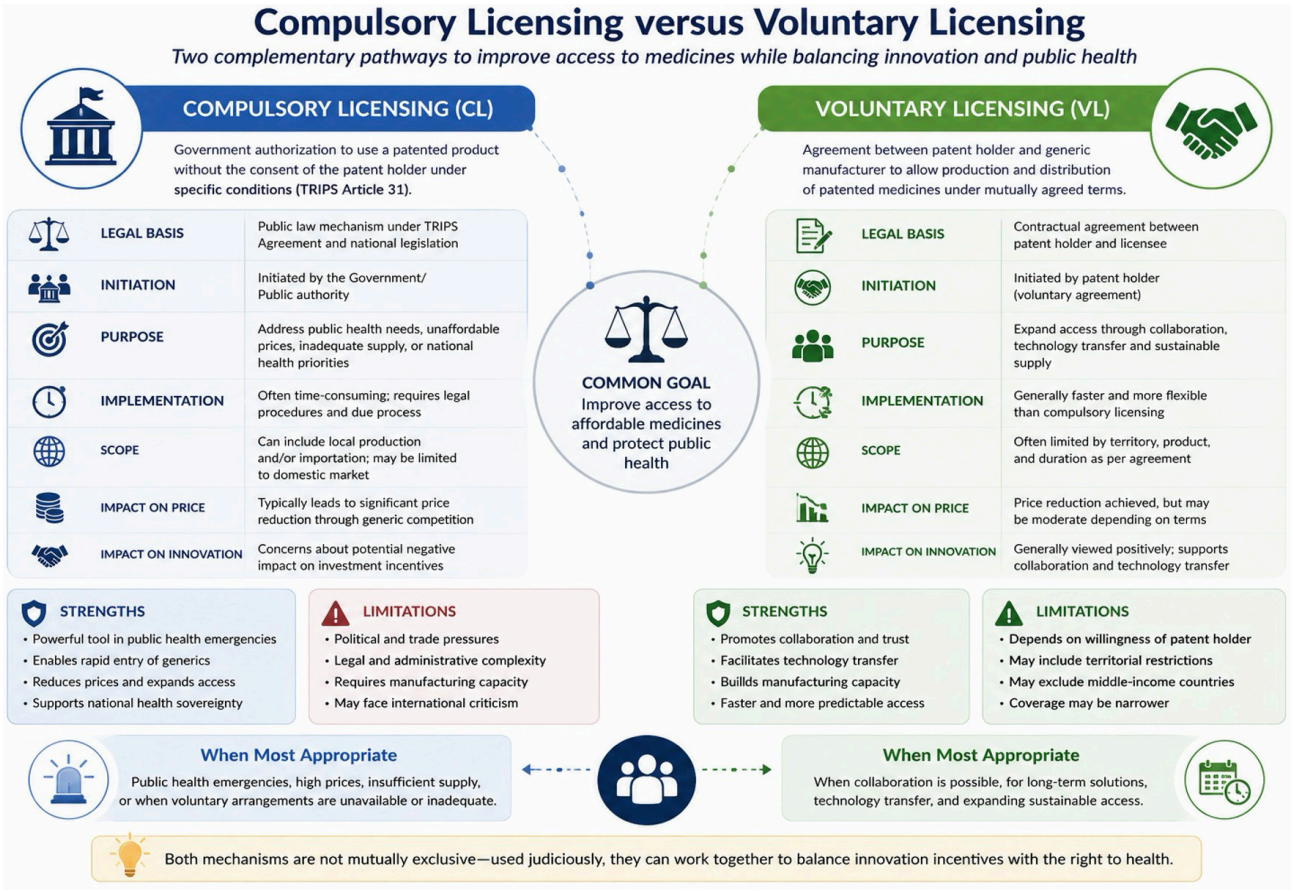

Figure 1. Compulsory licensing versus voluntary licensing

Nevertheless, translating these legal flexibilities into practice remains challenging[49]. Many countries continue to face political and trade pressures, complex administrative procedures, limited legal expertise[52], and inadequate manufacturing capacity[70], restricting their ability to effectively implement compulsory licensing[99]. While voluntary licensing has increasingly complemented TRIPS flexibilities by promoting collaboration and technology transfer[2,3,9], its dependence on patent-holder participation and territorial restrictions means that equitable access is not always guaranteed[58,100]. Therefore[29,30], achieving an effective balance between innovation and public health requires not only strong legal provisions but also supportive national policies, manufacturing capacity, regulatory preparedness, and sustained international cooperation[38,83].

Although the Doha Declaration strengthened countries' legal authority to prioritize public health[47], implementation has remained uneven because legal rights alone cannot overcome political[51], manufacturing, and institutional constraints[81]. These experiences highlight that legal flexibility must be complemented by practical capacity to improve medicine access[91].

While the TRIPS Agreement and the Doha Declaration establish the international legal framework governing pharmaceutical patents, their practical implementation depends on national patent legislation. India provides one of the most influential examples of incorporating TRIPS flexibilities into domestic law through the Patents Act, 1970.

The principal provisions of the TRIPS Agreement that influence pharmaceutical patent protection and access to medicines are summarized in Table 2, highlighting how individual articles balance innovation incentives with public health safeguards.

Table 2 illustrates that the TRIPS Agreement is neither exclusively innovation-oriented nor solely access-oriented[48]. Instead, it establishes a legal framework that attempts to balance intellectual property protection with public health objectives[63,64]. While provisions such as Articles 27 and 28 strengthen incentives for pharmaceutical innovation through market exclusivity[18], Articles 30, 31, and 31bis introduce important safeguards that enable governments to improve access to essential medicines under specific circumstances[48,51]. Nevertheless[47], the effectiveness of these safeguards depends on national legal capacity, manufacturing infrastructure, and political commitment[52,91]. Consequently, although the TRIPS framework provides significant flexibility[29], achieving

Table 1. Comparison of compulsory licensing vs. voluntary licensing

Feature	Compulsory licensing (CL)	Voluntary licensing (VL)	Advantages	Limitations	Representative case study
Definition	Government-authorized use of a patented invention without the patent holder's consent under specified legal conditions.	Patent holder voluntarily grants manufacturing and/or marketing rights to another party through contractual agreements.	CL safeguards public health when patent negotiations fail, while VL promotes collaborative technology transfer.	CL may generate legal disputes; VL depends on the patent owner's willingness.	Natco-Bayer (CL); Dolutegravir-Medicines Patent Pool (VL)
Legal basis	Authorized under Article 31 and Article 31bis of the WTO TRIPS Agreement and national patent laws.	Based on private licensing contracts governed by intellectual property and commercial law.	Provides internationally recognized legal mechanisms for expanding access.	National implementation of CL varies; VL agreements differ substantially between licensors.	TRIPS-compliant compulsory licences; Medicines Patent Pool licences
Trigger conditions	Public health emergencies, unaffordable prices, inadequate supply, or failure to meet reasonable public requirements.	Strategic partnerships, market expansion, corporate social responsibility, or global health initiatives.	Enables rapid expansion of manufacturing capacity when appropriate conditions exist.	CL requires statutory justification; VL depends on commercial incentives.	Sorafenib (India); Paxlovid voluntary licences
Control over licensing terms	Licensing conditions are determined primarily by government authorities or courts.	Licensing terms are negotiated and controlled by the patent holder.	CL allows governments to prioritize public health objectives; VL provides contractual flexibility.	CL offers limited flexibility for patentees; VL may include restrictive clauses and territorial limitations.	India Compulsory Licence (2012); MPP licensing framework
Speed of implementation	Generally moderate to slow because of administrative and legal procedures.	Usually faster once negotiations are concluded and manufacturing partners are selected.	VL can accelerate technology transfer; CL provides an alternative when negotiations fail.	CL may face litigation; VL negotiations can also be prolonged.	COVID-19 antiviral licensing initiatives
Drug affordability	Often substantially reduces prices through generic competition.	Improves affordability depending on royalty rates, competition, and market coverage.	Both mechanisms can significantly increase affordability compared with monopoly pricing.	Price reductions under VL may be smaller than under unrestricted generic competition.	Sorafenib price reduction (India); Dolutegravir access programmes
Industry acceptance	Frequently opposed by innovator pharmaceutical companies due to concerns over patent protection.	Broadly supported because it preserves patent ownership and commercial incentives.	VL maintains stronger industry collaboration and encourages technology sharing.	CL may discourage future investment if perceived as unpredictable.	Bayer-Natco dispute; Pfizer voluntary licensing

Table 1 ***cont.***

Feature	Compulsory licensing (CL)	Voluntary licensing (VL)	Advantages	Limitations	Representative case study
Scope of access	Potentially broad, depending on national legislation and international export provisions.	Often limited to specified countries, manufacturers, or disease programmes.	CL can maximize domestic access; VL facilitates coordinated global distribution networks.	VL commonly excludes upper-middle-income countries and high-income markets.	MPP territorial licences; Article 31bis export mechanism
Technology transfer	Generally limited because transfer of manufacturing know-how is not mandatory.	Frequently includes technical support, manufacturing know-how, quality standards, and regulatory assistance.	VL enhances manufacturing quality and production efficiency.	CL recipients may face technical barriers to production without access to proprietary know-how.	Paxlovid manufacturing partnerships
Innovation incentives	May reduce perceived exclusivity and commercial returns if used extensively.	Better preserves incentives for research, development, and future innovation.	VL balances innovation incentives with broader patient access.	Overreliance on CL may create uncertainty for innovators.	Global licensing strategies for antivirals
Representative therapeutic areas	Oncology, HIV/AIDS, hepatitis, and emergency infectious diseases.	HIV/AIDS, hepatitis C, tuberculosis, COVID-19 antivirals, and selected non-communicable diseases.	Demonstrates flexibility across multiple therapeutic areas.	Effectiveness depends on manufacturing capacity and regulatory readiness.	Sorafenib, Efavirenz (CL); Dolutegravir, Molnupiravir, Paxlovid (VL)

equitable access requires complementary policies[30], including efficient regulatory systems[83], technology transfer, sustainable financing, and international collaboration[90].

Indian patent framework and public health: Key provisions of the patents act, 1970

India's patent regime has evolved to balance the protection of pharmaceutical innovation with the constitutional objective of safeguarding public health. Following its compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005, India introduced product patent protection for pharmaceuticals while retaining several statutory safeguards that enable access to affordable medicines under appropriate circumstances. Among these, Sections 84, 92, 100, and 3(d) of the Indian Patents Act, 1970 (as amended) constitute the cornerstone of India's public health-oriented patent framework.

Section 84 provides the legal basis for granting compulsory licences after three years from the date of patent grant if any of three conditions are met: (i) the reasonable requirements of the public have not been satisfied, (ii) the patented invention is not available to the public at a reasonably affordable price, or (iii) the patented invention is not worked in the territory of India. This provision seeks to prevent the misuse of exclusive patent rights while ensuring that essential medicines remain accessible. The landmark Natco Pharma Ltd. v. Bayer Corporation (2012) case, involving the anticancer drug sorafenib tosylate (Nexavar®), remains the only instance in which India has granted a compulsory licence for a pharmaceutical product. The Controller of Patents concluded that Bayer had failed to meet the statutory requirements relating to affordability and availability, allowing Natco to manufacture and market a generic version at a substantially reduced price while paying royalties to the patent holder. The decision demonstrated the practical application of Section 84 in balancing patent protection with public health needs.

Section 92 authorizes the Central Government to notify compulsory licensing in situations of national emergency, extreme urgency, or public non-commercial use. Once such a notification is issued, the Controller General of Patents may grant compulsory licences without waiting for the three-year period prescribed under Section 84. This provision is particularly relevant during public health crises such as pandemics, epidemics, or other emergencies where rapid access to medicines, vaccines, or medical technologies is essential. Although Section 92 has not

Table 2. Key TRIPS provisions relevant to pharmaceutical patent protection and access to medicines[18]

TRIPS provision	Key provision	Contribution to innovation	Implications for access to medicines	Critical perspective
Article 27	Establishes minimum standards for patentable subject matter, including pharmaceutical products.	Encourages investment in pharmaceutical R&D by ensuring patent protection and market exclusivity.	Delays entry of generic medicines, often resulting in higher medicine prices, particularly in LMICs.	Essential for stimulating innovation, but prolonged exclusivity may widen inequalities in access if affordability measures are lacking.
Article 28	Grants patent holders exclusive rights to manufacture, use, sell, and import patented products.	Protects commercial returns and incentivizes continued innovation.	Restricts competition until patent expiry, limiting affordability of newer therapies.	Strong protection benefits innovation but requires complementary public health safeguards to avoid monopolistic pricing.
Article 30	Permits limited exceptions to patent rights under specific conditions.	Preserves the patent system while allowing limited research and regulatory activities.	Facilitates early generic preparation before patent expiry, supporting faster market entry.	Useful for balancing innovation and competition, although its scope remains relatively narrow.
Article 31	Permits compulsory licensing under defined legal conditions without patent-holder consent.	Maintains innovation incentives through royalty payments while allowing public health intervention.	Enables affordable generic production during public health emergencies or when medicines are unaffordable.	A powerful public health safeguard, but implementation is frequently constrained by legal complexity, political pressure, and manufacturing limitations.
Article 31bis	Allows export of medicines produced under compulsory licensing to countries lacking manufacturing capacity.	Extends the benefits of compulsory licensing beyond domestic markets.	Improves access for countries unable to manufacture essential medicines locally.	Valuable in principle, but administrative complexity has limited its practical use.
Doha Declaration (2001)	Reaffirms that TRIPS should be interpreted to support public health and access to medicines.	Clarifies that public health protection and innovation are compatible objectives.	Strengthens countries' legal confidence to use TRIPS flexibilities, including compulsory licensing.	A landmark policy achievement, yet many countries continue to face political, economic, and technical barriers to implementing its provisions effectively.

yet been invoked for pharmaceutical products, its existence provides an important legal mechanism that strengthens India's preparedness for future health emergencies.

Section 100 empowers the Central Government, or any person authorized by it, to use a patented invention for governmental purposes without obtaining prior authorization from the patent owner, subject to payment of appropriate remuneration. Unlike compulsory licensing under Section 84, government use under Section 100 primarily facilitates the procurement or production of patented technologies to meet public needs, including healthcare requirements. This provision offers additional flexibility by enabling timely government intervention during emergencies while preserving the patent holder's entitlement to reasonable compensation.

Another distinctive feature of the Indian patent system is Section 3(d), which excludes from patentability new forms, derivatives, or modifications of known substances unless they demonstrate a significant enhancement in therapeutic efficacy. Introduced to prevent "evergreening" of pharmaceutical patents, Section 3(d) seeks to ensure that secondary patents are granted only for genuine therapeutic innovations rather than incremental modifications intended primarily to extend market exclusivity. The provision gained international prominence through the Novartis AG v. Union of India (2013) decision, in which the Supreme Court of India rejected patent protection for the beta-crystalline form of imatinib mesylate, concluding that the

claimed invention did not satisfy the enhanced efficacy requirement under Section 3(d). The judgment reaffirmed India's commitment to balancing incentives for innovation with the broader objective of maintaining access to affordable medicines.

`Collectively, Sections 84, 92, 100, and 3(d) establish a comprehensive legal framework that aligns patent protection with public health priorities while remaining consistent with the flexibilities recognized under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. Together, these provisions provide multiple legal pathways to improve medicine accessibility during routine healthcare delivery and public health emergencies, while preserving incentives for meaningful pharmaceutical innovation. India's experience illustrates that a carefully designed patent system can reconcile intellectual property rights with broader societal objectives by promoting both innovation and equitable access to essential medicines.

While the TRIPS Agreement and the Doha Declaration establish the international legal framework governing pharmaceutical patent protection, their practical implementation depends on national patent legislation[46]. India provides one of the most influential examples of incorporating TRIPS-compliant public health safeguards through the Patents Act, 1970. Key statutory provisions, including those governing compulsory licensing, government use, and patentability standards, together with landmark judicial decisions that have shaped pharmaceutical patent jurisprudence, are summarized in Table 3.

As illustrated in Table 3, India's patent framework is among the most comprehensive examples of translating TRIPS flexibilities into domestic legislation. Provisions such as Sections 84, 92, and 100 provide important legal mechanisms to improve access to essential medicines under specific public health circumstances, while Section 3(d) prevents patent ever-greening by requiring enhanced therapeutic efficacy for incremental pharmaceutical innovations. Furthermore, landmark judicial decisions such as Natco Pharma Ltd. v. Bayer Corporation and Novartis AG v. Union of India have established internationally recognised precedents demonstrating that strong intellectual property protection can coexist with measures designed to promote medicine affordability, generic competition, and public health. These examples illustrate how national legal frameworks can operationalise international intellectual property obligations while maintaining an appropriate balance between pharmaceutical innovation and equitable access to medicines.

Collectively, Tables 2 and 3 demonstrate that achieving equitable access to medicines requires both an enabling international legal framework and effective national implementation. While the TRIPS Agreement establishes the legal basis for balancing intellectual property protection with public health objectives, the Indian Patents Act, 1970 illustrates how these flexibilities can be operationalized through domestic legislation. Together, these frameworks show that equitable access depends not only on international legal provisions but also on strong national institutions, regulatory capacity, and political commitment.

Licensing and access to medicines: A critical analysis

The relationship between licensing mechanisms and access to medicines is multifaceted[1], shaped by economic realities[2], public health priorities[83], and ethical considerations[90]. While compulsory and voluntary licensing are often discussed as technical or legal tools[2], their real-world impact extends far beyond policy frameworks-directly influencing who receives treatment[58], when[84], and at what cost[97]. A critical analysis of these dimensions reveals both the transformative potential and the inherent limitations of licensing as a strategy to bridge the gap between innovation and equity[1,44,88].

The multidimensional relationship between licensing mechanisms, medicine affordability, innovation, and public health outcomes is illustrated in Fig. 2.

Role of licensing in improving access

From an economic perspective, the pharmaceutical patent system plays a central role in shaping medicine pricing and market dynamics[7,45]. Patent-protected monopolies enable originator companies to set prices that reflect not only production costs but also investments in research and development, marketing, and risk recovery[16,54,59]. While this model sustains innovation, it often results in prices that are unaffordable for patients and healthcare systems in resource-limited settings.

In this context, compulsory licensing (CL) introduces market competition by enabling the entry of generic manufacturers[44,70,80]. This competition has consistently

Table 3. Key provisions of the Indian patents act, 1970 relevant to pharmaceutical patent protection and access to medicines

Provision	Purpose	Relevance to public health	Representative case
Section 3(d)	Prevents evergreening	Improves generic competition	Novartis v. Union of India
Section 84	Compulsory licensing	Affordable medicines	Natco-Bayer
Section 92	National emergency CL	Pandemic preparedness	COVID-19 policy discussions
Section 100	Government use	Public health procurement	Government authorization

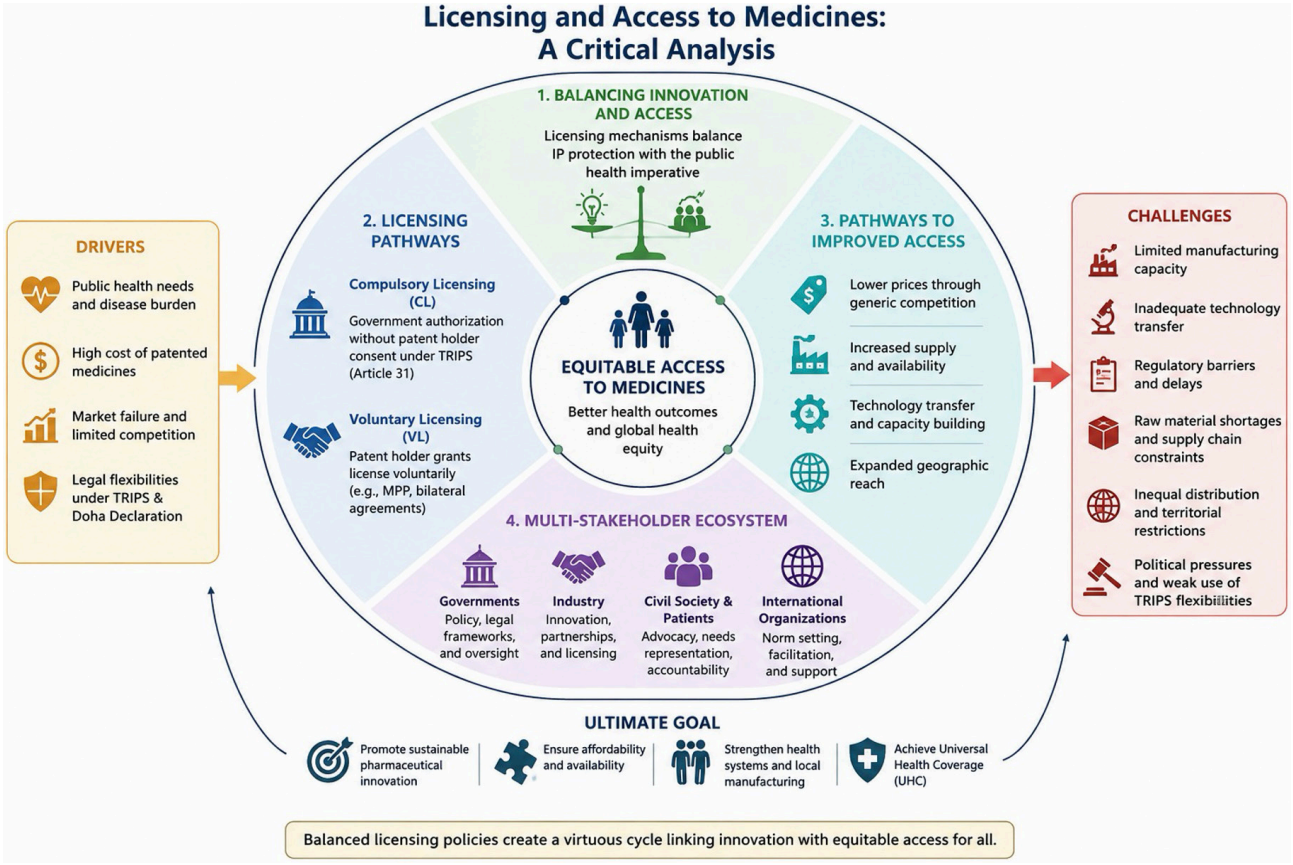

Figure 2. Licensing and access to medicines: A critical analysis

demonstrated the ability to drive substantial price reductions, sometimes by over 90%[44,51,80], thereby transforming previously inaccessible treatments into affordable options. Such reductions not only benefit individual patients but also allow governments to expand coverage within constrained healthcare budgets.

Voluntary licensing (VL), while also contributing to price reductions, operates within a more controlled framework[2,3,58]. Prices under VL agreements are often negotiated and may vary across regions, leading to uneven affordability. While VL can enhance supply and stabilize markets, its impact on pricing is typically less dramatic than that of CL, particularly in countries excluded from licensing territories[92,100].

Beyond pricing, broader economic factors-such as procurement systems, supply chain efficiency and healthcare financing models-also influence the effectiveness of licensing mechanisms [22]. In many low- and middle-income countries (LMICs), high out-of-pocket expenditures mean that even reduced prices can remain burdensome, highlighting the need for complementary policy interventions[86,97].

Critical comparison of compulsory and voluntary licensing

Compulsory licensing (CL) and voluntary licensing (VL) are complementary mechanisms for improving access to essential medicines, yet they differ substantially in their implementation, effectiveness, and implications for pharmaceutical innovation. Compulsory licensing, authorized under the TRIPS Agreement[48,51,91], empowers governments to permit the manufacture or importation of patented medicines without the patent holder's consent during public health emergencies or under specific legal conditions. Countries such as India, Thailand, and Brazil have successfully used CL to reduce the cost of medicines for cancer, HIV/AIDS, and cardiovascular diseases. India's compulsory licence for sorafenib (Nexavar) in 2012 reduced treatment costs by approximately 97%[44], significantly improving patient access[70,80]. Nevertheless, compulsory licensing may generate legal disputes, discourage foreign investment, and create concerns regarding long-term research and development (R&D) incentives if applied unpredictably[90,98].

In contrast, voluntary licensing is established through negotiated agreements between patent holders and generic manufacturers, enabling broader market access while preserving intellectual property rights and fostering collaboration[10]. The Medicines Patent Pool (MPP) has demonstrated the effectiveness of this approach by facilitating affordable access to HIV, hepatitis C,

tuberculosis, and, more recently, COVID-19 therapeutics. Voluntary licensing agreements for Paxlovid (nirmatrelvir/ritonavir) and Molnupiravir enabled production by multiple generic manufacturers for distribution across numerous low- and middle-income countries[11,62]. However, these agreements often contain territorial restrictions[92], exclude several middle-income countries, and remain dependent on the willingness of patent holders to participate[100].

Overall, compulsory licensing is most effective when voluntary negotiations fail or during public health emergencies requiring rapid intervention, whereas voluntary licensing provides a more collaborative and sustainable framework for expanding access while encouraging technology transfer and maintaining innovation incentives. A balanced strategy integrating both mechanisms, supported by transparent governance and international cooperation, offers the greatest potential to reconcile equitable access with continued pharmaceutical innovation.

Public health impact

The public health implications of licensing mechanisms are both significant and well-documented[2,44]. Compulsory licensing has played a critical role in expanding access to essential medicines across multiple disease areas, including HIV/AIDS, cancer, and, more recently, COVID-19[3,45]. By enabling the production or importation of affordable generics, CL has allowed countries to respond more effectively to health crises and improve treatment coverage[10,80].

Similarly, voluntary licensing has facilitated the rapid scale-up of essential therapies, particularly during global emergencies[30]. Through coordinated agreements-often supported by organizations such as the Medicines Patent Pool-VL has enabled multiple manufacturers to produce and distribute medicines simultaneously, increasing availability and reducing supply bottlenecks[38,47].

However, the public health impact of these mechanisms is not uniform. Variations in national policies, manufacturing capacity, regulatory infrastructure, and international cooperation can influence outcomes. In some cases, delays in issuing licenses or limitations in geographic scope have restricted the full potential of these tools. Nevertheless, when effectively implemented, licensing mechanisms have demonstrated their capacity to save lives, reduce disease burden, and strengthen health system resilience[21].

Importantly, the benefits of improved access extend beyond immediate health outcomes. Increased treatment availability contributes to reduced transmission of infectious diseases, improved workforce productivity, and broader socio-economic development. In this sense, licensing mechanisms function not only as health interventions but also as instruments of development policy[86,97].

Ethical considerations

Pharmaceutical licensing raises a fundamental ethical dilemma: how to balance the protection of intellectual property with the moral obligation to ensure access to life-saving medicines[71,75,78,94]. Patents are designed to reward innovation and encourage investment in research and development[54,56], but exclusive rights can also limit availability when medicines remain unaffordable or insufficiently supplied[90]. The central policy question is therefore not whether innovation or access should prevail, but how both can be advanced simultaneously[44,81].

Ethical decision-making in this area requires governments, industry, and international organizations to consider public welfare alongside commercial interests[2,3,84]. Compulsory licensing may be justified when urgent health needs cannot be met through ordinary market mechanisms, while voluntary licensing can promote cooperation and technology sharing without removing patent protection[71]. The challenge lies in designing licensing frameworks that are transparent, proportionate, and predictable[83]. Ultimately[71], ethical pharmaceutical policy should seek to preserve incentives for future drug development while ensuring that intellectual property rights are exercised in a manner consistent with public health responsibilities[72,73,79,94].

Lessons from the COVID-19 pandemic: Opportunities and limitations of licensing mechanisms during global health crises

The COVID-19 pandemic underscored the critical role of licensing mechanisms in expanding access to medicines while exposing important limitations in the global intellectual property [12,13,93] and pharmaceutical manufacturing ecosystem[2,3,10,29]. Voluntary licensing emerged as the primary strategy for increasing the availability of COVID-19 therapeutics[11,21,34,35,58]. Agreements facilitated by the Medicines Patent Pool (MPP) enabled generic manufacturers to produce antiviral agents such as Molnupiravir and Paxlovid for distribution across numerous low- and middle-income countries (LMICs)[10,11,62]. These partnerships accelerated manufacturing, promoted limited technology transfer, and improved the affordability and availability of essential medicines [3,10,30]. Simultaneously[13,31,32,33,47,76], discussions surrounding compulsory licensing and the TRIPS waiver highlighted the importance of legal flexibilities during public health emergencies[14,36,37,80,81].

Despite these achievements, several structural barriers restricted the overall effectiveness of licensing mechanisms[22,30,39,40]. Limited manufacturing capacity in many LMICs prevented rapid local production even when licensing agreements were available[3,62,84]. Technology transfer was frequently incomplete [68], particularly for complex biologics and mRNA vaccines, as patents alone could not provide the specialized expertise[23,38,39],

production know-how[37,77], and quality-control processes required for large-scale manufacturing[40,41,42]. Regulatory barriers[21,43], including lengthy approval procedures and limited harmonization among national regulatory authorities [(30)], further delayed product availability[93]. In addition[77], shortages of critical raw materials, active pharmaceutical ingredients, and manufacturing equipment disrupted global supply chains and constrained production capacity[93,94]. Perhaps most importantly[13], unequal global distribution persisted throughout the pandemic[47], with high-income countries securing early vaccine supplies while many resource-limited nations experienced prolonged shortages[73]. Furthermore[29], although the WTO TRIPS waiver stimulated global debate on intellectual property reform, its practical implementation remained limited due to prolonged negotiations[38], restricted scope, and the absence of mandatory technology transfer provisions. These experiences demonstrate that licensing alone cannot guarantee equitable access[43]. Future pandemic preparedness requires integrated strategies combining flexible intellectual property policies, effective technology transfer, regional manufacturing capacity, resilient supply chains, regulatory harmonization, and sustained international collaboration to ensure rapid and equitable access to essential medical products[83].

Representative examples of compulsory licensing implemented across different countries and disease areas are summarized in Table 4, illustrating the practical impact of licensing on medicine affordability and treatment access.

COVID-19 lessons and future preparedness

The COVID-19 pandemic demonstrated that effective responses to global health emergencies require more than rapid scientific innovation[29,30]; they depend on resilient manufacturing systems, coordinated regulatory frameworks, and efficient licensing strategies[38,43]. One of the most significant lessons was that intellectual property flexibilities alone are insufficient to ensure timely access to medicines unless accompanied by technology transfer, manufacturing expertise[3], and robust supply chains[62]. Future preparedness should therefore integrate licensing policies with investments in regional production capacity and workforce development[84].

The pandemic also underscored the need for greater transparency and international cooperation in licensing agreements[2,3,21]. While voluntary licensing expanded access to several COVID-19 therapeutics, geographical restrictions and limited technology sharing reduced their overall impact[10]. Similarly, compulsory licensing remained underutilized due to procedural complexities, political considerations, and concerns over international trade[47,70]. These experiences highlight the importance of developing streamlined legal mechanisms that can be activated rapidly during future public health emergencies[81,92].

India's experience provides valuable insights into balancing intellectual property protection with public health objectives[44]. Supported by a well-established generic pharmaceutical industry and a legal framework incorporating TRIPS flexibilities, India demonstrated its capacity to manufacture and supply affordable medicines and vaccines on a global scale[50]. The country's role during the pandemic reinforced the importance of strengthening domestic manufacturing capabilities while fostering international collaboration[80].

Looking ahead, future pandemic preparedness should prioritize harmonized regulatory systems[29], transparent licensing practices[30], effective technology transfer[38], and stronger public-private partnerships. Expanding regional manufacturing networks and promoting collaborative research can improve global responsiveness to emerging health threats[43]. Collectively, these lessons highlight that sustainable preparedness depends on integrating legal, scientific, and industrial strategies to ensure that essential medicines can be developed, manufactured, and distributed rapidly during future crises[83].

Challenges in licensing mechanisms

Despite the theoretical promise of both compulsory and voluntary licensing frameworks in improving access to essential medicines[24,27], their real-world implementation remains fraught with systemic, political, and ethical challenges[1,64]. These barriers are not merely technical-they reflect deeper inequities embedded within global health governance, intellectual property regimes, and economic asymmetries between nations[25,72]. While licensing mechanisms are often presented as flexible tools to balance innovation with access[65], their effectiveness is frequently constrained by structural limitations and competing stakeholder interests[88].

Table 4. Global case studies of compulsory licensing

Country	Drug	Year	Disease	Outcome
India	Sorafenib	2012	Cancer	Price reduced by ~97%; improved access
Thailand	Efavirenz	2007	HIV/AIDS	Expanded treatment coverage
Brazil	Efavirenz	2007	HIV/AIDS	Significant cost savings for government
South Africa	ARVs (proposed)	Various	HIV/AIDS	Policy reform and increased negotiation power

Structural barriers

One of the most persistent challenges lies in the limited manufacturing capacity in many low- and middle-income countries (LMICs)[22]. Even when legal provisions such as compulsory licensing are invoked, the absence of robust pharmaceutical infrastructure can delay or entirely prevent local production of affordable generics[40]. In addition, fragmented supply chains, inadequate technology transfer, and lack of skilled workforce further exacerbate these constraints[62].

Regulatory bottlenecks also play a critical role. Lengthy approval timelines, lack of harmonization across regulatory agencies[3,84], and insufficient technical expertise can significantly delay the availability of licensed products[23]. In emergency contexts-such as pandemics-these delays can translate into preventable morbidity and mortality, undermining the very purpose of licensing mechanisms[37,42].

Political and trade pressures

Licensing decisions are rarely made in a vacuum; they are deeply influenced by geopolitical dynamics and economic pressures[66,88,89]. Governments attempting to issue compulsory licenses often face resistance from multinational pharmaceutical companies, sometimes accompanied by threats of legal action or withdrawal of investments.

Moreover, bilateral and regional trade agreements increasingly include "TRIPS-plus" provisions that go beyond the minimum standards set by international intellectual property frameworks[49,72,91]. These provisions can restrict the use of public health safeguards, effectively limiting countries' ability to utilize compulsory licensing without facing diplomatic or economic repercussions. As a result, many nations remain hesitant to fully exercise these flexibilities, even in the face of pressing public health needs[68,72,91].

Limitations of voluntary licensing

While voluntary licensing is often portrayed as a collaborative and less contentious alternative[2,92], it is not without significant shortcomings[100]. One major concern is the selective geographic scope of such agreements[10]. Pharmaceutical companies frequently exclude middle-income countries-despite their substantial disease burden-creating a "missing middle" in global access efforts[58,100].
Transparency is another critical issue[2,3]. The terms and conditions of voluntary licenses, including pricing structures, royalty payments [(10)], and territorial restrictions, are often not publicly disclosed. This lack of openness limits accountability and makes it difficult to assess whether such agreements genuinely serve public health interests or primarily protect commercial priorities[58,62].

Additionally, voluntary licenses may impose restrictive conditions on sublicensees, including limitations on export markets or requirements that hinder competition. In some cases, they may also delay the entry of generics by controlling when and how technology transfer occurs.

Equity and ethical concerns

Beyond operational challenges, licensing mechanisms raise fundamental ethical questions about fairness and justice in global health[66,71]. The unequal distribution of decision-making power-largely concentrated in high-income countries and multinational corporations-can marginalize the voices and needs of vulnerable populations[67,78]. This imbalance often results in solutions that are technically viable but socially insufficient[94].

Dependence on external actors

Many LMICs remain dependent on external actors-whether multinational companies, international organizations[29], or donor agencies-for access to medicines and manufacturing know-how[83]. This dependency can weaken national autonomy and reduce the sustainability of access initiatives, particularly when global priorities shift[86].

Inconsistent implementation across countries

There is significant variation in how countries interpret and implement licensing provisions[47]. Differences in legal frameworks, administrative capacity, and political will lead to uneven outcomes, limiting the global effectiveness of these mechanisms[51,91].

Limited technology transfer

Access to patents alone is often insufficient without meaningful transfer of tacit knowledge, technical expertise, and production know-how[3]. In many licensing arrangements, especially voluntary ones, technology transfer remains partial or delayed, constraining large-scale production[62,84].

Market fragmentation

Licensing agreements that divide markets geographically can lead to inefficiencies[2], duplication of efforts, and inequitable pricing structures across regions[92]. This fragmentation undermines the potential for coordinated global responses[100].

Financial constraints

Even when licensing pathways are available[22], the financial burden associated with scaling up manufacturing[28], ensuring quality compliance, and navigating regulatory systems can be prohibitive for many countries[86].

Lack of global coordination

The absence of a unified global framework to streamline

licensing efforts leads to fragmented and reactive approaches, particularly during health emergencies[29,38]. Greater international coordination is needed to ensure timely and equitable access[43].

Delayed response in emergencies

Licensing mechanisms[47], particularly compulsory licensing, can be slow to activate due to procedural requirements and political hesitancy[70]. This delay can be critical during rapidly evolving health crises[81].

Trust deficit among stakeholders

A lack of trust between governments, pharmaceutical companies, and international institutions often hinders collaboration[2]. Concerns over intellectual property protection, profit margins, and public health priorities create tensions that limit the effectiveness of licensing initiatives[66,87].

Impact of licensing mechanisms on pharmaceutical innovation

Licensing mechanisms play a pivotal role in shaping pharmaceutical innovation by balancing intellectual property protection with the imperative of equitable access to medicines[1,54,83,90]. Patent protection remains a fundamental driver of research and development (R&D)[55,82,85], providing innovators with temporary market exclusivity to recover substantial investments associated with drug discovery[16,56], clinical development, and regulatory approval[59,86,94]. However[2,58], appropriately implemented compulsory and voluntary licensing mechanisms can complement rather than undermine innovation by ensuring that life-saving medicines reach underserved populations while preserving incentives for future research[61,84,98]. Voluntary licensing, in particular, promotes technology transfer[2], manufacturing capacity[3], and knowledge sharing through collaborations between originator companies and generic manufacturers[62,96], thereby strengthening pharmaceutical ecosystems in low- and middle-income countries[92,97]. Public-private partnerships, including initiatives led by the Medicines Patent Pool[9], have further demonstrated that collaborative licensing can simultaneously expand access and stimulate innovation[11,58,99]. Emerging alternative innovation models, such as delinkage mechanisms[28], prize funds, open science, and public financing of biomedical research[82], seek to reduce dependence on monopoly-based incentives while sustaining scientific advancement[83]. Looking ahead[29], integrating flexible licensing frameworks with transparent technology transfer [38], regional manufacturing capabilities[56], and collaborative R&D networks will be essential for accelerating future drug development[83]. Such balanced approaches can foster sustainable pharmaceutical innovation while ensuring that the benefits of scientific progress are equitably shared across diverse populations[56,83,90].

Future perspectives

The future of pharmaceutical licensing will depend on achieving an appropriate balance between protecting innovation and ensuring equitable access to medicines[1,83,90]. Recent global health emergencies have demonstrated that neither compulsory licensing nor voluntary licensing alone can adequately address the complex challenges of medicine accessibility[10,47,81]. Instead, both mechanisms should function as complementary policy tools within a broader framework that integrates scientific innovation, international collaboration, sustainable manufacturing, and effective intellectual property governance[29,38]. Emerging digital technologies and collaborative research models offer unprecedented opportunities to strengthen licensing systems[26], while persistent political, economic, and regulatory barriers continue to limit their global effectiveness[56,87].

Future opportunities

Several emerging developments have the potential to transform pharmaceutical licensing in the coming years[26,56]. Artificial intelligence (AI) and advanced data analytics can support evidence-based licensing decisions by rapidly evaluating patent landscapes[22], identifying potential licensing opportunities [39], and improving transparency during negotiations[40]. Establishing regional pharmaceutical manufacturing hubs, particularly in low- and middle-income countries, could strengthen local production capacity, reduce dependence on imports, and improve preparedness for future public health emergencies[83,92]. The creation of digital patent transparency platforms providing real-time information on patent status[2,6], licensing agreements[3], and technology availability would facilitate more efficient collaboration among governments[5], manufacturers, and healthcare organizations[84]. Furthermore[9], expanding public-private partnerships involving pharmaceutical companies, academic institutions, international organizations, and initiatives such as the Medicines Patent Pool can promote technology transfer, accelerate innovation, and enhance equitable distribution of essential medicines[11]. Strengthening these collaborative frameworks before future pandemics will enable faster and more coordinated global responses[29,38,43].

Future challenges

Despite these promising opportunities[87], several challenges continue to hinder the effective implementation of pharmaceutical licensing mechanisms[88,89]. Political and commercial interests often delay international consensus on licensing policies during public health crises[3,62,84].

Technology transfer remains difficult because successful medicine production requires not only patent access but also manufacturing expertise, technical know-how, quality assurance systems, and skilled personnel[22]. Persistent inequalities in manufacturing infrastructure and regulatory capacity further limit the ability of many developing countries to utilize licensing agreements effectively[44,86]. In addition[23], differences in intellectual property regulations and drug approval procedures complicate international regulatory harmonization and delay access to affordable medicines[37,42]. Sustainable financing also remains essential for strengthening research, manufacturing capacity, and health systems[28,82,83]. In our view, the future of global pharmaceutical licensing lies in integrating compulsory and voluntary licensing within a transparent, collaborative, and innovation-driven framework that encourages research while ensuring timely and equitable access to life-saving medicines[29,38]. Such an approach will be critical for improving global health security and preparing for future public health emergencies[83,90].

Policy implications

The effective use of compulsory and voluntary licensing requires coordinated action from multiple stakeholders to achieve an appropriate balance between pharmaceutical innovation and equitable access to medicines[48,51,91]. Governments should strengthen national intellectual property legislation by fully incorporating the public health flexibilities available under the TRIPS Agreement while investing in domestic pharmaceutical manufacturing, regulatory capacity, and technology transfer[3,62,84]. During public health emergencies, transparent and timely implementation of licensing mechanisms can substantially improve access to essential medicines[47,80,81].

At the international level[30], the World Health Organization (WHO) should continue providing technical guidance[32], promoting regulatory harmonization[43], and supporting capacity-building initiatives that facilitate equitable medicine distribution[37,42]. Similarly[48,49], the World Trade Organization (WTO) should encourage greater clarity in the application of TRIPS flexibilities and foster international cooperation to reduce legal and administrative barriers that delay access to affordable medicines[29,43,91].

The Medicines Patent Pool (MPP) should expand voluntary licensing beyond HIV[2], tuberculosis[3], and hepatitis C to include emerging therapeutic areas such as oncology, antimicrobial resistance, and rare diseases[9]. Broader participation from patent holders would enhance technology transfer and increase medicine availability in low- and middle-income countries[58].

The pharmaceutical industry has an important role in adopting responsible licensing practices that encourage innovation while supporting equitable global access through transparent licensing agreements[2], collaborative research, and strategic partnerships[22,23]. Generic manufacturers should continue investing in high-quality production capabilities[62], regulatory compliance[58], and technology acquisition to ensure rapid and reliable supply of affordable medicines following licensing agreements[84].

For low- and middle-income countries (LMICs)[22,29,39], strengthening manufacturing infrastructure[40], regulatory systems, and regional collaboration should remain a priority to reduce dependence on external suppliers and improve preparedness for future health emergencies[43]. Ultimately, sustainable pharmaceutical governance will require coordinated global policies that integrate legal flexibility[83], technology transfer, innovation incentives[90], and long-term investment in resilient healthcare and manufacturing systems capable of ensuring both equitable access and continued pharmaceutical innovation[97].

Conclusions

Neither compulsory licensing nor voluntary licensing, when implemented in isolation, can fully address the dual challenge of promoting pharmaceutical innovation while ensuring equitable access to essential medicines. Rather than viewing these mechanisms as competing approaches, they should be recognized as complementary policy tools whose effectiveness depends on the specific public health context, the strength of national legal and regulatory systems, manufacturing capacity, and the willingness of governments, industry, and international organizations to collaborate.

This review demonstrates that compulsory licensing remains an important legal safeguard during public health emergencies and in situations where patented medicines are unaffordable or inaccessible. Voluntary licensing, meanwhile, has shown considerable potential to expand access through collaborative agreements, technology transfer, and broader geographic distribution of medicines. However, the success of either mechanism depends on transparent implementation, timely regulatory action, robust manufacturing infrastructure, and equitable licensing terms that address the needs of low- and middle-income countries.

Experiences from the HIV/AIDS epidemic, hepatitis C treatment, and the COVID-19 pandemic illustrate both the value and the limitations of existing licensing frameworks. While these mechanisms have contributed to improving access to life-saving medicines in many settings, persistent challenges—including unequal manufacturing capacity, delays in technology transfer, restrictive licensing practices, and disparities in healthcare infrastructure—continue to limit their global impact. These experiences underscore the need for stronger international cooperation and more coordinated approaches to pharmaceutical governance.

Looking ahead, policies should move beyond debates focused solely on intellectual property protection and instead

embrace integrated strategies that balance innovation incentives with public health priorities. Strengthening technology transfer, investing in regional manufacturing capacity, enhancing regulatory preparedness, encouraging public-private partnerships, and promoting transparent licensing practices will be essential for improving timely and affordable access to medicines. At the same time, continued international collaboration is needed to ensure that intellectual property frameworks remain sufficiently flexible to respond effectively to future health emergencies without undermining long-term pharmaceutical research and development.

Ultimately, achieving equitable global access to medicines requires a balanced and pragmatic approach in which compulsory and voluntary licensing operate as complementary components of a broader innovation and public health ecosystem. By aligning legal flexibility with scientific innovation, sustainable financing, and international solidarity, policymakers can foster a pharmaceutical landscape that supports both the development of new therapies and the timely delivery of essential medicines to the populations that need them most.

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