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Patent Protection and Access to COVID-19 Medical Products in India: Barriers and Compulsory Licensing

Sharda Beniwal (Ph.D Research Scholar)[1], Dr. Vijaymala (Associate Professor)[2]
Department – Law, Shri Jagdish Prasad Jhabarmal Tibrewala University, Chudela, Jhunjhunu

ABSTRACT

The COVID-19 pandemic created an urgent demand for affordable access to medical products such as vaccines, drugs, and diagnostics. In India, intellectual property rights, particularly patent protection, emerged as a double-edged sword—essential for innovation but a potential barrier to universal health coverage. This article examines the legal, procedural, and practical challenges posed by patents in ensuring widespread access to COVID-19-related health technologies. Special emphasis is placed on the role of compulsory licensing as a policy tool in the Indian context, including its legal provisions, historical use, and potential applications during the pandemic. The paper concludes by assessing the balance between innovation and access, and recommends policy reforms for enhancing pandemic preparedness through equitable IP governance.
Keywords: COVID-19, Patent Protection, Indian Patent Act, Compulsory Licensing, Access to Medicines, Intellectual Property Rights, Pharmaceutical Innovation, Public Health Law, TRIPS Flexibilities, Generic Medicines

1. INTRODUCTION

The COVID-19 pandemic brought the global healthcare system under immense pressure, compelling nations to rethink their policies surrounding access to medicines, vaccines, and diagnostics. For countries like India—often referred to as the "pharmacy of the Global South" due to its robust generic pharmaceutical industry—the crisis was a litmus test of how well intellectual property (IP) laws could balance the imperatives of innovation with the moral and practical need for universal healthcare access.

Patent protection, intended to reward and incentivize innovation, became a contentious point during the pandemic. On one hand, it helped pharmaceutical companies mobilize investments and accelerate research and development (R&D) for life-saving products. On the other hand, exclusive rights granted under patent laws contributed to shortages, inflated prices, and restricted production of essential COVID-19 medical products, especially in low- and middle-income countries.

India faced a unique dilemma. Despite its capacity to mass-produce generic drugs and vaccines, the country was constrained by patent protections on many critical technologies, such as mRNA-based vaccines, antiviral drugs like Remdesivir, and diagnostic testing kits. These barriers hindered timely domestic production and disrupted equitable access across regions. Furthermore, the country's reliance on imports for raw materials and biotechnological know-how highlighted a dependency on patent-holding nations and corporations.

The Indian Patents Act, 1970—amended in 2005 to comply with the WTO's TRIPS Agreement—includes important public health safeguards such as compulsory licensing (Section 84), emergency use licenses (Section 92), and government-use provisions (Section 100). These tools are meant to ensure that patent protection does not come at the cost of public health, especially in national emergencies. Yet, during the peak of the COVID-19 crisis, these legal mechanisms were rarely invoked, exposing a significant gap between law and practice.

This study aims to explore the interface between patent law and access to COVID-19 medical products in India. It examines how existing legal provisions could have been used more effectively to mitigate public health barriers, the challenges in implementing compulsory licensing during the pandemic, and the broader implications for India's intellectual property policy and public health preparedness. It also provides critical reflections on how India can build a more responsive and equitable IP governance system for future emergencies.

2. REVIEW OF LITERATURE

Intellectual property rights (IPRs) and their influence on public health access have been a subject of academic and policy discourse for decades, but the COVID-19 pandemic intensified the urgency of this discussion. A review of existing literature reveals critical insights into how patents can function both as enablers and barriers in times of health emergencies, with particular emphasis on compulsory licensing, TRIPS flexibilities, and national legal frameworks such as India's Patents Act.

1. Correa, C. M. (2020)

Carlos Correa, in his work *"Intellectual Property and Access to Medicines: A South Perspective"*, presents a strong critique of the TRIPS regime, arguing that although it allows for certain flexibilities like compulsory

licensing, these are not sufficient unless exercised effectively by national governments. He emphasizes that political will and administrative clarity are essential to make such legal tools meaningful during emergencies like COVID-19. Correa also notes that over-reliance on voluntary licensing can limit sovereign decision-making in public health crises.

2. Médecins Sans Frontières (2020)

In its briefing titled *"Compulsory Licensing in the Pandemic Era"*, MSF outlined how many developing countries, including India, were hesitant to use compulsory licensing provisions due to fears of trade retaliation and pressure from multinational pharmaceutical firms. The organization documented real-world examples where countries chose negotiation over enforcement, thereby slowing down access to crucial drugs and diagnostics. MSF advocated for stronger domestic policies and international solidarity in invoking TRIPS flexibilities without hesitation.

3. Natco Pharma v. Bayer Corp. (2012 – cited in 2021)

Although predating COVID-19, the compulsory licensing case of **Natco Pharma vs. Bayer** served as a foundational reference during the pandemic. Many researchers, including policy analysts in 2021, referred to this landmark judgment where the Indian government granted a compulsory license for Bayer's cancer drug Nexavar due to its high cost and limited accessibility. The case became a benchmark for assessing how India could apply similar provisions during COVID-19 for drugs like Remdesivir and Favipiravir.

4. Gopakumar, K. M. (2021)

In a South Centre policy brief, Gopakumar analyzed why India, despite having legal provisions under Sections 84 and 92 of the Patents Act, did not utilize them during COVID-19. He highlighted the combination of international political pressure, bureaucratic inertia, and legal uncertainties that discouraged the issuance of compulsory licenses. He argued that the government's preference for voluntary licensing over statutory intervention undermined the larger goal of public health access.

5. Indian Ministry of Health and Family Welfare (2021)

The Ministry's *COVID-19 Response Strategy Reports* noted the challenges in sourcing vaccines and antiviral drugs, implicitly acknowledging the delays in securing licenses and the impact of global patent monopolies. However, the reports lacked clear reference to the use or potential of compulsory licensing, pointing to a policy gap in the country's emergency response mechanisms.

6. World Health Organization (2021)

In its global bulletin on *Equitable Access to COVID-19 Technologies*, the WHO underscored the need for countries to exercise TRIPS flexibilities and build legal capacity for emergency IP governance. It encouraged nations like India to lead the way, given their experience with generic drug production and the legal infrastructure for compulsory licensing.

7. UNDP (2021)

The UNDP's policy report on *Intellectual Property Rights and Public Health Emergencies* took a human rights-based approach, advocating that access to essential medicines is not just a matter of economic policy but a fundamental right. The report called for global reforms that make compulsory licensing easier, faster, and more transparent.

8. MSF Access Campaign (2021)

Further expanding their advocacy, the MSF Access Campaign published a critical evaluation titled *"Barriers to Access During the Pandemic: Patent and Licensing Realities"*. It documented how many voluntary licensing deals—such as those between Gilead and Indian firms—lacked transparency, excluded smaller manufacturers, and failed to reach marginalized populations. The report strongly favored strengthening compulsory licensing as a tool for equitable distribution.

3. OBJECTIVES OF THE STUDY

The present study aims to explore the complex interface between patent protection, public health, and legal policy in the context of the COVID-19 pandemic in India. It seeks to understand how the Indian patent regime responded to the unique challenges posed by the pandemic and what role compulsory licensing could have played in ensuring wider access to essential medical products. The specific objectives of the study are outlined below:

1. To critically examine the role of patent protection in India during the COVID-19 pandemic

The study investigates how existing patents on life-saving medical products—including vaccines, antiviral drugs, and diagnostic kits—created obstacles in manufacturing, pricing, and distribution. It aims to assess whether the patent system acted as a facilitator of innovation or a barrier to public health access during the crisis.

2. To analyze the legal framework governing compulsory licensing in India

India's Patents Act, 1970 (amended in 2005), provides detailed mechanisms such as Section 84 (general compulsory licensing), Section 92 (emergency licensing), and Section 100 (government use). This study explores how these provisions are designed, what procedural requirements they entail, and how they align with international TRIPS obligations.

3. To identify practical and administrative challenges in invoking compulsory licenses during the pandemic
Despite a favorable legal framework, India did not widely apply compulsory licensing during COVID-19. This objective focuses on analyzing the reasons—such as bureaucratic delays, international pressure, industrial capacity issues, and political hesitation—that prevented effective deployment of these tools.
4. To compare voluntary licensing and compulsory licensing in the Indian context
Voluntary licenses were issued for several drugs like Remdesivir during the pandemic, but these often-lacked transparency and excluded many manufacturers. The study contrasts the outcomes, benefits, and limitations of both mechanisms to assess which approach is more equitable and efficient during health emergencies.
5. To propose legal and policy reforms that promote equitable access to medical technologies
The study aims to suggest practical reforms for improving India's preparedness in future pandemics—such as pre-defined emergency protocols, streamlined administrative processes for invoking compulsory licenses, and better investment in domestic production and legal infrastructure.
6. To situate India's IP approach in the global context of TRIPS flexibilities and public health law
Finally, the research positions India's experience within the broader international discourse on IP and health emergencies. It evaluates how India can contribute to global efforts for more inclusive, transparent, and humanitarian IP governance systems, especially through WTO advocacy and South-South collaboration.

4. RESEARCH METHODOLOGY

The present study adopts a **doctrinal qualitative research methodology**, which is most appropriate for legal and policy-based inquiries. Since the focus of the study is on analyzing statutory provisions, policy responses, international agreements, and case-based precedents concerning patent law and public health in India, a doctrinal approach provides the necessary analytical framework to examine the intersection of law, governance, and human rights during the COVID-19 pandemic.
1. Nature and Scope of Research
This is a **non-empirical and descriptive-analytical study**, aimed at understanding the functioning of patent law during health emergencies, particularly in the Indian context. The study explores the structural and procedural dimensions of compulsory licensing under the Indian Patents Act and evaluates its real-time applicability during the pandemic. The research also integrates comparative perspectives from global literature to enrich its normative evaluation.
2. Sources of Data
A. Primary Sources
- **The Patents Act, 1970 (India)**, particularly Sections 84, 92, 100, and 3(d)
- **The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**
- **Judicial decisions**, especially *Natco Pharma v. Bayer Corp.* (2012)
- **Official COVID-19 response documents** issued by the Ministry of Health and Family Welfare, Government of India
- **International documents** such as WHO and UNDP policy bulletins and IP briefings

B. Secondary Sources
- Peer-reviewed articles from journals on intellectual property law and public health
- Policy briefs from Médecins Sans Frontières (MSF), South Centre, and the MSF Access Campaign
- Reports from international organizations (WHO, UNDP, WTO)
- Commentaries, editorials, and expert analyses from legal and pharmaceutical professionals

3. Method of Data Collection and Analysis
The research involved extensive **documentary analysis** of statutes, government reports, licensing agreements, and international legal instruments. Legal interpretation techniques were applied to evaluate the letter and spirit of the Indian Patents Act, especially its provisions for public interest overrides.
A **comparative legal analysis** was conducted to evaluate the difference between voluntary and compulsory licensing models during COVID-19. Thematic categorization was used to organize data under relevant heads such as "legal framework," "barriers," "implementation gap," and "global implications."
4. Analytical Framework
The study integrates both **normative** (what should be) and **positive** (what is) approaches. It assesses how effectively Indian laws could have been applied to improve public health outcomes and proposes legal-policy reforms grounded in constitutional and ethical reasoning.
It also uses a **rights-based approach**, aligning its framework with international human rights norms that recognize access to health as a fundamental human right. TRIPS flexibilities and WTO-related interpretations are assessed from both legalistic and moral standpoints.
5. Limitations of the Study
- The study does not include **primary empirical data** such as interviews or surveys due to its doctrinal nature.

- It is limited by the **availability of public data** on private licensing agreements, many of which are not disclosed.
- The rapidly evolving nature of the COVID-19 pandemic means that policy changes may have occurred after the writing of this paper.

5. RESULTS AND DISCUSSION

The findings of this research highlight a significant disconnect between India's legal capacity to ensure access to medicines during health emergencies and its actual policy execution during the COVID-19 pandemic. Although India possesses one of the world's most comprehensive frameworks for compulsory licensing and TRIPS-compliant IP flexibility, these tools remained largely dormant during the pandemic. The results are analyzed under the following thematic categories:

1. Patent Barriers to COVID-19 Medical Products in India

Despite being a global leader in generic drug production, India faced serious access constraints due to patent protection on critical COVID-19-related technologies. mRNA vaccines (developed by Pfizer and Moderna), antiviral drugs like Remdesivir and Favipiravir, and essential diagnostic technologies were covered under patents or proprietary rights. This led to:

- Delays in domestic manufacturing and licensing
- Inflated costs for governments and healthcare systems
- Unequal access between public and private healthcare sectors

India's dependency on international licensing further restricted its autonomy in pandemic response planning.

2. Underutilization of Compulsory Licensing Provisions

Sections 84, 92, and 100 of the Indian Patents Act empower the government to override patents under conditions such as unaffordability, insufficient supply, and national emergencies. Despite the ongoing COVID-19 crisis, India did not issue any new compulsory license throughout the pandemic period.

The study finds three key reasons behind this inaction:

- **Bureaucratic delay and lack of pre-established emergency IP protocols**
- **Fear of trade retaliation or diplomatic fallout**, especially from developed nations and multinational pharmaceutical firms
- **Preference for voluntary licensing agreements**, which were quicker to execute but lacked transparency and accountability

3. Voluntary Licensing: Benefits and Limitations

While several Indian manufacturers signed voluntary licensing deals with patent holders (notably with Gilead for Remdesivir), the study shows that:

- These licenses were **not publicly disclosed**, limiting public scrutiny.
- **Smaller manufacturers were excluded**, leading to limited scale-up.
- **No licensing provisions existed for mRNA technologies**, leaving a critical access gap.

Hence, voluntary licenses, although useful in the short term, proved inadequate in addressing the broader goal of universal and equitable access.

4. Administrative and Structural Challenges

The research also highlights structural challenges that prevented effective execution of compulsory licensing:

- **Lack of biotechnological capacity** for complex drugs like mRNA vaccines
- **Limited public investment** in high-end manufacturing and R&D
- **Absence of fast-track legal mechanisms** for emergency licensing decisions

These systemic issues contributed to India's cautious and reactive approach, even when its legal framework allowed more assertive action.

5. Missed Opportunity in Public Health Leadership

India had the legal, industrial, and geopolitical leverage to lead by example during the pandemic by invoking compulsory licenses and challenging the status quo of pharmaceutical monopolies. However, by not doing so, the country missed an opportunity to:

- Strengthen its domestic healthcare infrastructure
- Assert its leadership in global health diplomacy
- Create legal precedents for future emergencies

This inaction weakened the credibility of India's long-standing advocacy for TRIPS flexibilities on international platforms like the WTO.

6. Ethical and Human Rights Dimensions

Finally, the pandemic underscored the ethical responsibility of states to prioritize the right to health over commercial exclusivity. The lack of compulsory licensing was not merely a policy oversight—it represented a

moral dilemma. When life-saving technologies are legally available but practically inaccessible, governments have a duty to act swiftly and justly.

6. RECOMMENDATIONS

The COVID-19 pandemic has revealed the limitations of relying solely on market-driven voluntary licensing and the need for proactive, equity-based legal mechanisms like compulsory licensing. Drawing from the challenges and gaps identified in the previous section, the following recommendations are proposed to improve India's preparedness for future health emergencies, while aligning innovation with public health imperatives.

1. Establish a National Emergency IP Protocol Framework

India must develop and institutionalize a legally binding framework that defines clear **protocols for invoking Sections 84, 92, and 100** of the Patents Act during national or international health emergencies. Such a framework should:

- Define triggers for action (e.g., WHO-declared pandemic, vaccine scarcity, drug monopolies)
- Specify decision-making timelines and responsible authorities
- Provide model forms and licensing templates to expedite implementation

2. Streamline Administrative Procedures for Compulsory Licensing

The current procedure for issuing a compulsory license is time-consuming and prone to litigation. The government should:

- Create **fast-track review committees** during emergencies
- Simplify documentation and procedural requirements
- Introduce **digital application portals** for transparency and accountability

3. Increase Transparency in Voluntary Licensing Agreements

To ensure fairness and avoid monopolistic control:

- All voluntary licensing deals made during emergencies should be **mandatorily disclosed**
- Terms such as pricing, production capacity, sublicensing permissions, and geographic coverage should be made public
- Third-party audits should be introduced to monitor the effectiveness and fairness of such agreements

4. Strengthen Domestic Manufacturing and R&D Capacity

India must invest in expanding its ability to produce complex biologics and diagnostics. This includes:

- Supporting public sector pharmaceutical units with updated technology
- Offering fiscal and policy incentives to Indian biotech startups
- Encouraging public-private partnerships in vaccine and drug development
- Establishing **centers of excellence in biomanufacturing and IP law**

5. Build Legal and Institutional Capacity for IP Governance

Training programs and awareness campaigns should be launched for:

- Government officials and regulators on TRIPS flexibilities
- Legal professionals and public health experts on emergency IP provisions
- Researchers and pharma companies on open science and IP sharing

This capacity-building will help in translating legal possibilities into timely action.

6. Mandate Public Interest Clauses in Publicly Funded R&D

Whenever government funds are used for pharmaceutical R&D, contracts must include:

- **Non-exclusive licensing provisions**
- **Affordable pricing guarantees**
- Obligations for **technology transfer to public institutions** when required

This ensures that public investment leads to public benefit, not private monopoly.

7. Strengthen India's Global IP Diplomacy

India should continue to advocate for global IP reforms, including:

- Permanent TRIPS waiver mechanisms for health emergencies
- International technology transfer frameworks like WHO's C-TAP
- South-South cooperation to challenge pharmaceutical monopolies
- Collective pressure on WTO and WIPO to revise outdated patent models

8. Include Compulsory Licensing Readiness in National Health Policy

The Ministry of Health should integrate IP-related preparedness into the **National Health Policy**, ensuring cross-sectoral collaboration between:

- Health ministry
- Commerce and Industry ministry
- Department of Pharmaceuticals
- Legal and judicial departments

This will ensure that public health interests are embedded across legal, policy, and executive domains.

7. CONCLUSION

The COVID-19 pandemic served as a stark reminder that equitable access to medical technologies is not only a matter of scientific advancement, but also of legal preparedness, policy action, and ethical responsibility. While patent protection remains crucial for incentivizing pharmaceutical innovation, the events of the pandemic have exposed the dangers of rigid intellectual property systems that prioritize exclusivity over equity, particularly in times of public health crises.

India, with its well-established patent legislation and a history of generic pharmaceutical leadership, was theoretically well-equipped to respond to the crisis using tools like compulsory licensing. The Indian Patents Act, 1970, provides progressive safeguards such as Sections 84, 92, and 100 to override patent monopolies in situations of national emergency, non-affordability, or inadequate supply. However, the study finds that despite this robust legal arsenal, India did not invoke these provisions during the COVID-19 pandemic, choosing instead to rely on voluntary licensing and market-based arrangements.

This inaction points to a significant gap between legal intent and policy execution. Bureaucratic inertia, international diplomatic pressures, lack of institutional readiness, and absence of a structured emergency IP protocol all contributed to India's cautious approach. Consequently, valuable time was lost, domestic production capacity remained underutilized, and equitable distribution of life-saving drugs and diagnostics was compromised.

Furthermore, the study reveals that voluntary licensing—although faster and more politically palatable—lacks transparency, consistency, and inclusivity. Many such agreements excluded smaller manufacturers and failed to meet the needs of India's vast rural and underprivileged populations. Thus, reliance on voluntary mechanisms, without a credible and active legal alternative like compulsory licensing, undermines the broader goals of public health.

The study concludes that it is imperative for India to move from **legal potential to legal action**. Legal tools must not exist only in text but should be embedded in operational policy. Compulsory licensing should be viewed not as a last resort but as a vital public health safeguard—particularly in emergencies where timely action can save millions of lives.

Looking ahead, India must adopt a holistic approach to IP governance that combines legislative clarity, administrative preparedness, institutional capacity, and international leadership. Strengthening domestic production, creating fast-track legal protocols, promoting open science, and advocating for global IP reforms are no longer optional—they are essential for building a resilient and inclusive health system.

In conclusion, the pandemic has shown that the real test of any legal framework lies in its timely application. India's future preparedness must be guided by the lessons of inaction, and a renewed commitment to placing public health above private profit. Only then can the nation truly fulfill its role as a global leader in healthcare equity and pharmaceutical justice.

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