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Patent Law and Bio-Crisis Containment: A Framework for Temporary Patent Freezes in India

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Bio-crises create a scenario where pharmaceutical drugs are in great demand. Pharmaceutical patents have a significant impact on public health as they directly affect the price, accessibility and availability of the drugs. The COVID-19 pandemic brought the issue of public health and protecting patents as commercial rights into the limelight, as access to pharmaceutical drugs and equipment was the need of the hour in light of the devastating impact of COVID-19, especially the second wave. The paper seeks to argue and base its premise on the fact that patents create a problem of availability and affordability, especially in a developing, populous country like India. The Indian Patent Act, 1970, enacted in line with the TRIPS Agreement, provides for a mechanism of Compulsory Licensing (CL) where the government can license the patented products to the licensee on an application under Section 84, or Suo motu, under Section 92. While Section 92 of the Act specifically provides for CL during national emergencies, the Covid-19 pandemic served as a strong example in highlighting the practical complexities involved in the issuance of such licenses. To ensure equitable access to COVID-19 vaccines, medicines, and other technologies, India and South Africa proposed a TRIPS waiver at the WTO by temporarily suspending patent rights. However, there was very little consensus on the same, especially among developed countries and the EU, which strongly opposed such a waiver. Many scholars admitted to the fact that CL, though plausible as a mechanism, is practically inadequate and underutilised, while a TRIPS waiver would increase accessibility and ensure equity. However, due to a lack of consensus between nations, an alternative mechanism was considered the need of the hour. This paper proposes an alternative mechanism by providing for a policy of temporary suspension of patent enforcement rights while the crisis subsists, thus allowing for generic manufacturing. The paper also evaluates the legal aspects of such a policy, such as TRIPS Compliance (specifically relying on the Doha

Declaration on the TRIPS Agreement and Public Health), and practical workability, including its impact on competition. The paper seeks to address the issue of inequity, inaccessibility, unavailability and unaffordability of pharmaceutical drugs in light of a crisis.

Keywords: *TRIPS, pharmaceutical patents, patents, bio crisis.*

INTRODUCTION

The Right to health is an intrinsic component of the Universal Declaration of Human Rights 1948,[1] as well as the International Covenant on Economic, Social and Cultural Rights 1966.[2] The Declaration of Alma-Ata 1978 recognizes the Right to health as a fundamental human right.[3] The World Health Organisation (WHO) recognises availability, accessibility, acceptability and quality as the core components of the right to health.[4]

A bio crisis, for this paper, encompasses a mass outbreak of diseases/deformities, threatening public health, whether contagious or not and creating a public health emergency requiring National/International intervention not just for the containment of the disease but also for ensuring access to the production and distribution of life-saving technologies. Such a situation may also be the result of biological warfare or the use of bio-hazard technologies. Where there is a public health emergency, availability of and access to medicines is a crucial factor.

Pharmaceutical drugs, on the other hand, are innovations which are covered by patent protection. Patents are exclusive rights granted over inventions, thereby disallowing any individual or entity other than the Patent holder from making, using, selling or importing the patented product/process without authorisation from the patent holder, resulting in monopoly rights for the patent holder for the patented product/process.[5] However, the term of a valid patent is limited to a period of 20 years from the date of grant. The patent protection is, on the one hand, beneficial in multifarious aspects such as protecting the intellectual

[1] Universal Declaration of Human 1948, art 25
[2] International Covenant on Economic, Social and Cultural Rights 1976, art 12
[3] Declaration of Alma Ata : International Conference on Primary Health Care, Alma Ata, USSR, 6-12 September 1978
[4] Committee on Economic, Social & Cultural Rights, 'General Comment No. 14: The Right to the Highest Attainable Standard of Health' (11 August 2000) UN Doc E/C.12/2000/4
[5] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 28

property of the inventor, incentivising further research and investment in R&D, availability of information about the innovation in the public domain and recovering the costs incurred in the process of innovation. While protection of intellectual property is very much essential for pharmaceutical companies and research organisations, such monopoly rights granted to the patent holder for pharmaceutical drugs/technologies raise concerns about the availability, accessibility and affordability, especially in the face of a crisis.

THE PATENT REGIME: TRIPS AND THE INDIAN PATENT ACT, 1970

The institution of patents is based upon granting a term-limited monopoly in exchange for disclosure of technical knowledge. This legal compromise is based on the premise that, without temporary exclusivity, firms would under-invest in Research & Development. However, in practice, patents also consolidate proprietary rights over knowledge. They enable private firms to charge supra-competitive prices under the garb of patent protection to recoup the massive investment made in R&D. This proprietary model of innovation is most prominent in the pharmaceutical sector, where the consequences of it are profound, such as duplication of research, fragmentation of knowledge and strategic practices like evergreening.[6] This, on one hand, is an incentive for innovation, but on the other hand, it generates acute problems of affordability and access, thereby functioning as instruments of monopoly.[7]

Many countries, therefore, to resolve this complexity, excluded product patents from patentability. The Indian Patent Act, 1970 reflected this approach as well. It deliberately excluded product patents, shortened patent terms and provided for compulsory licensing. This framework enabled domestic firms to reverse engineer the patented drug and market the bioequivalent generics at low prices. This ensured widespread access, and India became a major supplier of affordable generic medicines globally.[8] This model was adopted in countries like Brazil, Argentina, Egypt and other developing countries, illustrating that

[6] Olga Gurgula and Wen H Lee, 'COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations?' (2021) 17(2) Journal of Generic Medicines <https://journals.sagepub.com/doi/10.1177/17411343219931 82> accessed 10 June 2026

[7] Ximena Benavides, 'Inequitable by Design: The Patent Culture, Law, and Politics Behind COVID-19 Vaccine Global Access' (2023) 56(2) University of Michigan Journal of Law Reform 455 <https://repository.law.umich.edu/mjlr/vol56/iss2/5/> accessed 10 June 2026

[8] Uday S Racherla, 'Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry' in Kung-Chung Liu and Uday S Racherla (eds), *Innovation, Economic Development, and Intellectual Property in India and China* (Springer 2019) 271

recognising product patents, especially in pharmaceuticals, could severely undermine access to essential medicines.[9]

The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 marked a turning point in global patent law. TRIPS, negotiated under the framework of the World Trade Organisation (WTO), established minimum standards for intellectual property protection across all member states. Upon compliance with TRIPS, the WTO members were required to grant both process and product patents in all fields of technology, including pharmaceuticals, with a uniform twenty-year term.[10] This harmonisation entrenched strong patent protection globally. Stronger patent protection for pharmaceutical products enabled companies to set higher prices globally, benchmarked against high-income markets. For the poorer population, essential medicines are now beyond reach.[11] Although TRIPS includes procedural safeguards like compulsory licensing, the complexity of the same has limited its utility.

India signed the WTO in 1995 and automatically became a signatory to TRIPS in 1995. To bring its law into compliance with TRIPS, the Patents Act was amended in 1999, 2002 and 2005. The 2005 amendment extended patentability to product patents, including pharmaceuticals that were hitherto covered by process patents and extended the patent term to twenty years. This required a staged transition; therefore, Section 3(d) was inserted as a safeguard which excludes new forms of known substances from patentability unless they demonstrate enhanced therapeutic efficacy.[12]

Before the 2005 amendment in India, the regime of process patents had fostered competitive domestic manufacturing and low-cost supply, which was curtailed by TRIPS, thereby focusing on innovation incentives over access. This has led scholars to argue that TRIPS was

[9] Dr. Aqa Raza and Abhinav Gupta, 'Patent Law and Compulsory Licensing: Indian Perspective' (2024) 29(1) Journal of Intellectual Property Rights 5 <https://ssrn.com/abstract=4675117> accessed 10 June 2026

[10] Sanath Wijesinghe et al., 'The Proposal for Waiver of WTO's TRIPS Agreement to Prevent, Contain and Treat COVID-19: Investigating the Benefits and Challenges for Low- and Middle-Income Countries' (2022) 17(2) Journal of Intellectual Property Law & Practice <https://academic.oup.com/jiplp/article-abstract/17/2/179/6511677> accessed 10 June 2026

[11] Mahima Rath and Arnav Mohapatra, 'THE FUTILITY OF DEPENDING ON COMPULSORY LICENSES TO ACCELERATE MANUFACTURING CAPACITY OF COVID-19 VACCINES' (2022) 3(1) Bennett Journal of Legal Studies <https://www.bennett.edu.in/wp-content/uploads/2022/03/Article-8-130-to-146.pdf> accessed 10 June 2026

[12] *Novartis AG v Union of India and Ors* (2013) 6 SCC 1

'inequitable by design' in its effects on developing countries.[13] The transformation to a TRIPS-compliant regime post 2005 amendment captures the complexities between law, economics and patents in the global arena. Legally, TRIPS imposed a uniform model of product patents, whereas economically, it enhanced incentives for innovation while exacerbating access inequalities. Despite sufficient safeguards operating under the TRIPS constraints, the broader dilemma remains that patents are not just private property rights but also instruments that shape access to medicines, public health, and global equity.

THE COVID-19 PANDEMIC: A CASE STUDY

The COVID-19 pandemic had a devastating impact on public health all over the globe. While nations desperately tried to contain the spread of the pandemic by imposing lockdowns, mandating masks and social distancing, etc., the pandemic reignited the old debate on IP and access to medicines. The pandemic underscored various nuances in the IP regime across the globe and highlighted the disproportionate impact on the developing and underdeveloped countries that could not afford to pay heavy prices. While wealthier nations vehemently placed huge orders for the COVID-19 vaccine, the poorer countries had to wait.[14] Much of the problem of inaccessibility of medicines and their unaffordable prices has been attributed to the patents held by these pharmaceutical companies and the patent regime governing the grant and enforcement of pharmaceutical patents.[15] While the problem is not new, similar problems of inaccessibility and unaffordability was evident during the past crises - for instance, during the 2009 influenza outbreak, several developed countries advanced bulk orders of vaccines, to the deprivation of developing and underdeveloped nations[16] (the antiviral Tamiflu was patented which led to several debates on accessibility)[17] and during the HIV-AIDS outbreak in the 1990s and early 2000s, it was noted that the developing countries could not afford the antiretrovirals.[18]

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[13] Benavides (n 7)
[14] 'Race for Virus Vaccine Could Leave Poor Countries Behind' (*Al Jazeera*, 18 June 2020) <https://www.aljazeera.com/news/2020/6/18/race-for-virus-vaccine-could-leave-poor-countries-behind> accessed 10 June 2026
[15] Gurgula (n 6)
[16] Gavin Yamey et al., 'Ensuring Global Access to COVID-19 Vaccines' (2020) 395(10234) The Lancet 1405 <https://www.sciencedirect.com/science/article/pii/S0140673620307637> accessed 10 June 2026
[17] Jeanne Whalen, 'Rich Nations Lock in Flu Vaccine as Poor Ones Fret' (*Wall Street Journal*, 16 September 2009) <https://www.wsj.com/articles/SB124243015022925551?eafs_enabled=false> accessed 10 June 2026
[18] Joint United Nations Programme on HIV/AIDS, *Report on the Global HIV/AIDS Epidemic* (UNAIDS 2000) 8

Yet, there wasn't any significant change in the patent mechanism during the Covid-19 pandemic, and the shortcomings resurfaced. The policy of vaccines as IP was very ineffective for a Covid-19 pandemic response.[19] For instance, it was noted that people in South Africa were being denied access to lifesaving Covid-19 drugs such as Baricitinib because of its patent system and further concerns were raised about the patents granted for mRNA vaccines.[20] Acute shortages of critical drugs such as Remdesivir and Tocilizumab were reported during the second wave of Covid-19 in 2021, prompting the Delhi High Court to issue an Order directing the government to ensure timely availability of those drugs.[21] In Distribution of Essential Supplies & Services During Pandemic, In re,[22] the Supreme Court of India noted that several drugs that are at the core of the Covid-19 treatment protocol are patented in India, including Remdesivir, Tocilizumab and Favipiravir. Similar problems were observed in countries across the globe, which led to reforms in the patent systems of various countries.

Many countries like Brazil[23] and Canada,[24] in a bid to increase access to technologies to fight COVID-19, accelerated patent examination. On the other hand, the Plurinational State of Bolivia, for instance, notified the WTO about its intention to use the system of compulsory licensing set out in Article 31bis of the TRIPS Agreement. Antigua and Barbuda also notified the same. Canada,[25] Germany[26] and Italy[27] amended their national laws to provide for

[19] Brink Lindsey, 'Why Patents and Pandemics Don't—or Shouldn't—Mix' (*Brookings*, 03 June 2021) <https://www.brookings.edu/articles/why-intellectual-property-and-pandemics-dont-mix/> accessed 10 June 2026

[20] 'South Africa Must Urgently Revoke Patents on Key COVID-19 Treatments and Vaccines' (*Médecins Sans Frontières*, 09 February 2022) <https://msfaccess.org/south-africa-must-urgently-revoke-patents-key-covid-19-treatments-and-vaccines> accessed 10 June 2026

[21] *Dharmendra Kumar Aggarwal v Govt (NCT of Delhi)* (2021) SCC OnLine Del 1995

[22] *In Re: Distribution of Essential Supplies & Services During Pandemic* (2021) 18 SCC 201

[23] 'Informativo' (*Instituto Nacional da Propriedade Industrial*) <https://www.gov.br/inpi/pt-br/servicos/patentes/tecnologias-para-covid-19/Informativo> accessed 10 June 2026

[24] 'Notice announcing accelerated examination of patent applications related to COVID-19 relief for small entities' (*Canada Intellectual Property Rights Office*, 07 July 2020) <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04811.html> accessed 10 June 2026

[25] COVID-19 Emergency Response Act 2020 (Canada)

[26] Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite 2020; 'COVID-19: Measures regarding trade-related intellectual property rights' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm> accessed 10 June 2026

[27] 'LEGGE 29 luglio 2021, n. 108' (*Gazzetta Ufficiale*) <https://www.gazzettaufficiale.it/eli/id/2021/07/30/21G00118/sg> accessed 10 June 2026

compulsory licensing, while Hungary[28] passed a Special Legal Order for the same. The mechanism of compulsory licensing was also used in countries like Hungary and Indonesia,[29] whereas Israel issued a permit for the import of generic versions of lopinavir/ritonavir from India.

COMPULSORY LICENSING

The Mechanism of Compulsory Licensing: Compulsory Licensing is the mechanism where the government grants patent licenses without the consent of the patent holder, in limited circumstances. While Article 31 of the TRIPS Agreement provides for compulsory licensing under certain conditions, The Doha Declaration on TRIPS Agreement and Public Health, 2001, recognized the gravity of the public health problems afflicting many developing and least-developed countries, particularly those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,[30] and further emphasized that the TRIPS Agreement should not prevent members from taking measures to secure public health and that the same should be interpreted and implemented in furtherance of the right to protect public health and to promote the access to medicines to all, thereby conferring the right to use flexibilities provided in the TRIPS Agreement to all its members. It further stated that these flexibilities included the right to grant compulsory licenses and to determine the grounds on which such licenses are granted.[31] For instance, Sections 84 and 92[32] of the Indian Patents Act, 1970 provide for the grant of compulsory licenses in India. Section 84 reproduces the mechanism laid out under Article 31 of the TRIPS Agreement, allowing compulsory licenses under normal circumstances when public needs are unmet, prices are unreasonable, or the invention is not worked in India, while Section 92 deals with the grant of compulsory licenses in cases of national emergencies or extreme urgencies, including public health emergencies.

Usage of Compulsory Licensing: Despite a strong legal framework enabling the issuance of compulsory licenses under Sections 84 and 92 of the Patent Act, the mechanism has been

[28] 'Hungary: Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation Within Hungary' (*World Intellectual Property Office*, 17 May 2020) <https://www.wipo.int/en/web/wipolex/w/news/2020/article_0009> accessed 10 June 2026
[29] 'COVID-19: Measures regarding trade-related intellectual property rights' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm> accessed 10 June 2026
[30] Agreement on Trade-Related Aspects of Intellectual Property Rights (1995, art 31
[31] WTO Declaration on the TRIPS Agreement and Public Health 2001
[32] The Patents Act 1970, ss 84, 92

used very rarely. The first ever case of compulsory licensing was that of the drug Nexavar, patented by Bayer Corporation in 2008, and was marketed in India at Rs. 280000/- and the controller, on an application made by Natco Pharma based because i) Reasonable requirements of the public were not being met (Section 84(1)(a)), ii) The drug was not available at an affordable price (Section 84(1)(b)), and iii) The patented invention was not being worked in India (Section 84(1)(c)), granted a compulsory license to Natco Pharma directing it to sell the drug at Rs. 8,800 and pay a royalty of 6% to Bayer. This was upheld by the IPAB, which, however, increased the royalty to be paid to 7%.[33] However, the grant of compulsory license was subjected to extensive litigation in the Delhi and Bombay High Courts. It is also pertinent to note that this marks the only occasion where a compulsory license was granted in India. Even when the Supreme Court[34] and the Delhi High Court[35] highlighted the potentiality of Compulsory Licensing, in the light of the COVID-19 pandemic and the shortage of critical medicines like Remdesivir and Tocilizumab, the Indian Government refrained from exercising the compulsory licensing mechanism. Many applications for Compulsory Licenses were rejected on procedural grounds. For instance, in March 2013, BDR Pharmaceuticals applied for the compulsory license for 'Dasatinib', an anti-cancer drug, which was patented in India by Bristol-Myers Squibb. The application was rejected because the applicant had not made reasonable efforts to obtain a voluntary license from the patent holder on reasonable terms and conditions as required by Section 84(6)(iv) of the Patents Act, 1970.[36] Similarly, in 2015, Lee Pharma applied for a compulsory license for the drug 'Saxagliptin', which was patented by Bristol Myers Squibb and marketed by AstraZeneca AB in India and is used to treat type-II diabetes mellitus. The controller rejected the application for a compulsory license as the applicant failed to satisfy any of the three grounds for the grant of a compulsory license as prescribed by Section 84 of the Act.[37] The political sensitivity surrounding patents, coupled with procedural complexities, prevents the flexibilities from being an effective response.

[33] *Bayer Corporation v Natco Pharma Ltd* (2013) 56 PTC 545 (IPAB)
[34] *In Re: Distribution of Essential Supplies & Services During Pandemic* (2021) 18 SCC 201
[35] *Dharmendra Kumar Aggarwal v Govt (NCT of Delhi)* (2021) SCC OnLine Del 1995
[36] *BDR Pharmaceuticals v Bristol Myers Squibb* (2013) CLA No 1/2013
[37] *Lee Pharma v AstraZeneca AB* (2015) CLA No 1 of 2015

Insufficiency of Compulsory Licensing Mechanism –

Compulsory licensing was clearly proven to be ineffective in the wake of the COVID-19 pandemic primarily because of the following reasons:

Procedural Complexities: Compulsory licensing, as per Article 31 of TRIPS, is based on a country-to-country, case-by-case basis, making it an extremely cumbersome and procedurally complex process. Mandatory procedures under Article 31 of the TRIPS Agreement, which is incorporated in Section 87 of the Patent Act, 1970, shall be applicable, which makes the issue of a compulsory license a tedious process. Furthermore, in the case of a global pandemic, a newly developed vaccine or drug can involve multiple individual components, covered by a complex web of patents in multiple jurisdictions. For instance, a foundational setup or an innovation may be patented and licensed to a larger entity for further innovation.[38] The BioNTech/Pfizer vaccine carries 280 components, which are sourced from 19 countries.[39] Issuing licenses in such circumstances is impossible, as it would require conducting licensing proceedings in each country, for each specific patent, involving an extremely complex process, unworkable in an emergency. It can also expose the licensee to the risk of infringement suits because of the multiplicity of components and patented technologies involved. Moreover, the patent holder has to be adequately compensated, and a royalty has to be paid. It is pertinent to note that the determination of royalty leads to further procedural delay and opens the door to litigation challenging the amount fixed by the Controller. Thus, the procedural complications involved in the issuance of a compulsory license function as a main hurdle for its legitimate usage, as the problems of distribution and timely administration of medicines are not eliminated.[40]

Lack of Political Will: The usage of compulsory licensing may also invite backlash and retaliation from other countries and pharmaceutical companies. When Thailand issued a compulsory license under Article 31 in 2007, the United States placed Thailand on its 'Priority

[38] Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' (2021) 39 Nature Biotechnology 546, 548 <https://www.nature.com/articles/s41587-021-00912-9> accessed 10 June 2026
[39] Prof Brook K Baker, 'The Impracticality of Relying on Compulsory Licenses to Expand Production Capacity for COVID-19 Vaccines' (*Infojustice*, 06 June 2021) <https://infojustice.org/archives/43195> accessed 10 June 2026
[40] Daniel J Gervais, 'The Changing Landscape of International Intellectual Property' (2006) 1(4) Journal of Intellectual Property Law & Practice 251 <https://academic.oup.com/jiplp/article-abstract/1/4/249/2193686> accessed 10 June 2026

Watch List.'[41] Further, developed countries have also been involved in the seizure of pharmaceutical products as a measure of retaliation. For example, significant quantities of various drugs, almost all of which originated in India, bound for developing countries such as Brazil or Ecuador, were seized while in transit in the European Community, and the generic manufacturers were told that the drugs infringed both patents and Supplementary Protection Certificates granted in EU Member States. Thus, low- and middle-income countries refrain from issuing compulsory licenses, fearing political and diplomatic pressure.[42] This has been cited as a reason why the Indian Government refrained from issuing compulsory licenses during the pandemic.[43]

Export-Import Barriers: Under Article 31(f)[44] of the TRIPS Agreement, the use of Compulsory licensing shall be predominantly for the domestic market of the authorising country, unless the conditions mentioned in Article 31bis are satisfied.[45] These include mandatory notifications to the WTO, limited quantities, special packaging requirements, and separate compulsory licenses in both exporting and importing jurisdictions. For instance, Bolivia issued a compulsory license to import COVID-19 vaccines from Biolyse; however, Canada, which was the exporting country, did not issue the same, raising questions about the workability of export - oriented compulsory licenses, particularly for the Global South.[46]

A TRIPS WAIVER - THE WAY FORWARD?

The pandemic increased the global demand not just for vaccines but test kits, life-saving drugs and other equipment. The Marrakesh Agreement, which established the WTO, allows the Ministerial Conference to adopt waivers in exceptional circumstances.[47] In October 2020, a proposal was submitted to the World Trade Organisation (WTO) by India and South Africa,

[41] 'U.S. Trade Representative Places Thailand on Priority Watch List in Annual Report' (*KFF Health News*, 11 June 2009) <https://kffhealthnews.org/morning-breakout/dr00044614/> accessed 10 June 2026
[42] Sangeeta Shashikant, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines' (2014) South Centre Research Paper No 56 <https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENl.pdf> accessed 10 June 2026
[43] Krrishan Singhania and Vanshaj Mehta, 'Compulsory Licensing of Essential Drugs During the Covid-19 Pandemic' (*International Bar Association*, 12 August 2021) <https://www.ibanet.org/ip-july-2021-compulsory-licensing-essential-drugs-covid-19> accessed 10 June 2026
[44] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 31(f)
[45] *Ibid* art 31bis
[46] Muhammad Zaheer Abbas, 'Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case' (2021) SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4083054> accessed 10 June 2026
[47] Marrakesh Agreement Establishing the World Trade Organization 1995, arts IX(3) and IX(4)

requesting a temporary waiver on certain IP rules set out in the TRIPS Agreement so as to allow more access to all COVID-related medicines, technologies and treatments.[48] The objective of the proposed waiver was to remove legal barriers not just with respect to patents but also with the other intellectual property rights which may pose barriers, and offer operational freedom to manufacturers to scale up manufacturing and distribution of Covid-19 vaccines.

The proposal gained significant support from over 62 countries,[49] whereas developed countries like the USA, Japan, Switzerland, the United Kingdom, and the European Union opposed it.[50] While it was seen as a commendable measure to upgrade and quicken production and supply of the vaccine across the globe for COVID-19 treatment, including therapeutics, diagnostics, and other technologies,[51] it never came to fruition in the way it was envisaged. The TRIPS Waiver which was adopted was much narrower in scope, covering only COVID-19 vaccine patents,[52] as compared to the original proposal, which broadly covered patents, industrial designs, copyright, and undisclosed information 'in relation to prevention, containment or treatment of COVID-19,' including 'diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines.'[53] Thus, this clearly points to the fact that the lack of global consensus acts as a major impediment in formulating a multilateral framework to address pressing issues like public health.

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[48] WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19: COMMUNICATION FROM INDIA AND SOUTH AFRICA (02 October 2020) WTO Doc IP/C/W/669

[49] 'India, South Africa's patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary' *The Hindu* (10 June 2021) <https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece> accessed 10 June 2026

[50] Emma Farge, 'Even after U.S. shift, opponents resist COVID-19 vaccine patent waiver' *Reuters* (31 May 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/even-after-us-shift-opponents-resist-covid-19-vaccine-patent-waiver-2021-05-31/> accessed 10 June 2026

[51] Kshitij Kumar Rai and Sakshi Agarwal, 'Vaccine Crisis and Patent Rights—Issues and Challenges: A Global Perspective' (2021) 7(1) Journal of Law and Public Policy <https://repository.nls.ac.in/cgi/viewcontent.cgi?article=1106&context=jlpp> accessed 10 June 2026

[52] WTO Ministerial Decision on the TRIPS Agreement (adopted 17 June 2022) WT/MIN(22)/30

[53] Council for Trade-Related Aspects of Intellectual Property Rights, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (25 May 2021) WTO Doc IP/C/W/669/Rev.1

AN ALTERNATIVE FRAMEWORK: TEMPORARY SUSPENSION OF PATENTS

Despite the flexibilities provided in the TRIPS Agreement, equitable access to public health remains a big challenge. The poorer nations, and among them, the poorer sections of people, are excluded from life-saving medicines and healthcare innovations due to structural inequities in global trade and patent monopolies. Scholars have pointed out that a reconsideration of the bioethical aspects of patent law is much needed and has long been overdue.[54] Dr. Christos Christou, International President of Médecins Sans Frontières (Doctors without Borders), an independent, international medical humanitarian organization, urged Governments to consider using all available legal and policy options, including suspending intellectual property on COVID-19 medical tools, issuing compulsory licenses on key medical technologies to overcome patent barriers, and adopting new laws and policies to ensure the disclosure of essential technical information needed to support generic production and supply.[55]

This paper advances the idea of temporary suspension of patent rights as a policy response during bio-crises in India. It is built on the rationale of the TRIPS waiver, but is confined to the enforcement of patent rights at a national level. This framework would imply that the enforceability of patent rights on pharmaceutical drugs and technologies which are critical for the prevention, diagnosis and treatment of a disease during a bio-crisis stands suspended for a limited duration, until the crisis is contained. It is pertinent to note here that such a suspension would promote generic manufacturing in the country, thereby increasing the production, supply and accessibility of essential medicines, phenomenally. Developing countries such as Bangladesh, Brazil, Argentina, India, Indonesia, and South Africa contend that they are capable enough and ready to mass-produce vaccines.[56] India ranks third worldwide for pharmaceutical production by volume and 14th by value. The country has an

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[54] Aisling McMahon, 'Covid-19, Patents & Healthcare: The Need for A (Bio)ethics Space within Patent Law' (*Journal of Medical Ethics*, 16 April 2020) <https://blogs.bmj.com/medical-ethics/2020/04/16/covid-19-patents-healthcare-the-need-for-a-bioethics-space-within-patent-law/> accessed 10 June 2026; Susan K Sell, 'What COVID-19 Reveals About Twenty-First Century Capitalism: Adversity and Opportunity' (2020) 63 Development 150 <https://link.springer.com/article/10.1057/s41301-020-00263-z> accessed 10 June 2026

[55] 'Inability to agree a real pandemic intellectual property Waiver at WTO is a devastating global failure for people the world over' (*MSF Access*, 17 June 2022) <https://msfaccess.org/inability-agree-real-pandemic-intellectual-property-waiver-wto-devastating-global-failure-people> accessed 10 June 2026

[56] Stephanie Nolen, 'Here's Why Developing Countries Can Make mRNA Covid Vaccines' *The New York Times* (22 October 2021) <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html> accessed 10 June 2026

established domestic pharmaceutical industry, with a strong network of 3,000 drug companies and about 10,500 manufacturing units. Therefore, India possesses a vast manufacturing capability to meet the increased demand during emergencies, which can be leveraged by suspension of patents for the duration of the crisis.

LEGAL FEASIBILITY AND TRIPS COMPLIANCE

The Indian Patent Act, 1970 provides for flexibilities during national emergencies as stipulated in Section 92 of the Act,[57] while Section 100 of the Act provides for the use of patents by the government for government purposes, although the scope of such a mechanism is limited to the government and government-authorised contractors only.[58] However, these provisions highlight the fact that patent rights are not absolute and may be curtailed in exceptional circumstances. The Supreme Court in In Distribution of Essential Supplies & Services During Pandemic, in re,[59] held that it is up to the Central Government to choose the best possible measures it can undertake during the current crisis, keeping in mind that public interest is of paramount importance. In Paschim Banga Khet Mazdoor Samity v State of W.B.,[60] the Supreme Court held that, 'Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21.' Even though patent rights are granted to incentivise and reward innovation, and it contributes to the development of humankind, during health emergencies, patent enforcement directly obstructs access to technology. It is pertinent to note that the State has a positive obligation under Article 21 of the Constitution to secure the right to life.[61] Further, Article 47 imposes a duty on the State to regard the improvement of public health as one of its primary duties.[62] Thus, a temporary suspension framework is well within the ideals of constitutionalism and the welfare state.

Article 8(1) of the TRIPS Agreement[63] allows Members to formulate or amend their laws to adopt measures necessary to protect public health and nutrition in accordance with the Agreement. Article 30 authorises limited exceptions to patent rights for the legitimate

[57] The Patents Act 1970, s 92
[58] *Ibid* s 100
[59] *In Re: Distribution of Essential Supplies & Services During Pandemic* (2021) 18 SCC 201
[60] *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37
[61] Constitution of India 1950, art 21
[62] *Ibid* art 47
[63] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 8(1)

interests of third parties, provided that such exceptions do not unreasonably conflict with the patent holder's rights to exploit the patented innovation. The Doha Declaration further goes on to state that, 'the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health…the Agreement 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.' Therefore, a time-bound suspension of the enforcement of patent rights during crisis periods can be characterised as a 'limited exception' necessary to protect public health, and hence well within the TRIPS Framework.

MECHANISM OF TEMPORARY SUSPENSION

The proposed framework mirrors the existing legislative framework of notifications by the central government based on expert committee recommendations, thereby ensuring administrative legitimacy. Section 92 of the Indian Patents Act, 1970,[64] provides that Compulsory Licensing in cases of emergencies will be by way of a gazette notification, as against the general procedure for compulsory licensing under Sections 84 and 87 of the Act. The same procedure is envisaged as it will ensure expeditious action. The framework of temporary suspension of the enforcement of patents requires an amendment to the Patents Act, 1970, including the following:

Constitution of a high-level Committee: The Constitution of a high-level committee is essential to harmonise diverse interests during a crisis. The Notification is based on the recommendations of the Committee, as the issue of suspension involves complex legal, economic and scientific considerations. It may consist of all necessary stakeholders, including the Controller General of Patents, Representatives from the pharma industry and the Indian Medical Association, Officials from the Ministry of Health and Family Welfare, Public health and science experts with relevant technical expertise, and Legal Experts in Intellectual property law. It should be mandatorily formed as soon as a national health emergency is declared.

Role of the Committee –

This committee would assess:

[64] The Patents Act 1970, s 92

- The scale and magnitude of the crisis;
- The inventions and other technologies involved in the prevention, diagnosis and treatment of the disease;
- The extent of affordability and accessibility for the general public; and
- Whether the existing mechanisms such as compulsory licensing or government use shall suffice.

Based on this assessment, the committee shall forward a report to the Central Government on whether there needs to be a temporary suspension of patents.

Notification by the Central Government: Based on this report, the Central Government shall issue a notification within a time stipulated in the statute and shall record its reasons in writing in case the recommendation of the Committee is negated. The notification shall be subject to judicial review on the grounds of arbitrariness, mala fides, etc. The Suspension shall be strictly time-limited, and further, the patent enforcement rights must be immediately revived after the termination of the emergency notwithstanding the time stipulated in the notification.

Remuneration to the Patent Holder: The Compensation which has to be paid to the patent holder shall be determined by an independent expert panel constituted by the Controller of Patents, and a mechanism can be laid down in the amendment for determining the amount. The Central Government may also create a fund for this purpose. Compensation can also be in the form of non-monetary incentives to the patent holder, such as resource pooling via public-private partnerships, tax rebates, etc.

ADVANTAGES OF THE TEMPORARY PATENT SUSPENSION MECHANISM

Ensuring Equity and Access: The main issue addressed by the temporary suspension mechanism is that it ensures equitable access to the general public for vital pharmaceuticals in line with the constitutional principles of India.

Speed and Administrative Efficiency: The process, unlike compulsory licensing, is simple and speedy as there are fewer procedures involved. Therefore, this mechanism acts as a proactive measure during an emergency. Moreover, the problem of patent thickets is eliminated when the mechanism of temporary suspension is used, making the generic

manufacture and usage of crucial technologies much easier and accessible without procedural hurdles.

Generic Manufacturing and Competition: India, being a country with a strong pharmaceutical industry, is well placed to implement this mechanism, paving the way for generic manufacturing, which would enable increased production and supply of crucial pharmaceuticals. Moreover, this mechanism eliminates any form of monopoly during the emergency period, thereby inducing competition in the market. This results in affordable, competitive prices, thereby increasing accessibility to the general public.

CHALLENGES AND OPPORTUNITIES

Technology Transfer/know-how: A crucial aspect of the right to exclusivity lies not just in patenting the innovation but in the non-disclosure of the technology/data used. Patent suspension might be insufficient without the disclosure of the relevant know-how for complex biologics and vaccines. Patent suspension is not an end in itself but a gateway for generics to enter the market. However, without technology transfer arrangements, generic manufacturers may face significant difficulties in ensuring quality and efficacy and a risk of increased cost of production. Therefore, the government must negotiate structured technology-transfer partnerships and mandate disclosure of essential data and know-how, by affording adequate protection against its misuse.

Backlash and Retaliation Measures from Other Countries: The suspension mechanism might invite sanctions and rifts in diplomatic relations with other countries, especially the developed countries like the USA, UK and the European Union. It may also be alleged that the mechanism violates India's obligations under the TRIPS Agreement. Apart from formal disputes, India might be seen as having a hostile jurisdiction towards intellectual property, thereby severely impacting foreign investments. However, India's national interests and the welfare of the people should be a priority, and retaliation from other countries should be dealt with diplomatically. India can also engage in coordinated action with other countries, especially the countries in the Global South, akin to the Vaccine Maitri Initiative by the Government in 2021.[65]

[65] 'Vaccine Supply' (*Ministry of External Affairs*) <https://www.mea.gov.in/vaccine-supply> accessed 11 June 2026

Limitations Posed by Regional Suspension: Complex pharmaceuticals rely on globalised supply chains, and therefore, a region-specific suspension might not solve the problem of restrictions on the import of patented inputs. Similarly, export of Indian generics may also be blocked unless they are specifically authorised by the relevant governments. However, India has a strong pharmaceutical industry, which will negate these concerns to a large extent. Israel, for instance, authorised the import of generic versions of lopinavir/ritonavir from India for the purpose of treating COVID-19 patients during the COVID-19 pandemic.[66] Thus, India cannot only address its domestic concerns of accessibility and public health, but also help poorer nations that lack domestic manufacturing capabilities and cannot afford patented inventions.

Investment and R&D Concerns: Even though patents often lead to unaffordable high drug prices,[67] pharmaceutical companies claim that they require a robust regime for patent protection to secure their investments in R&D.[68] This is primarily because the pharmaceutical industry is inherently a high-risk, capital-intensive venture requiring substantial investment in research, innovation, clinical trials, and regulatory approval, and patent protection seeks to grant exclusivity to the inventors, which acts as an incentive to invest in R&D. During the COVID-19 pandemic, some countries prioritised patenting health technologies which can be used to fight the virus. A suspension of patents may discourage companies from venturing into research aimed at developing cures in India. However, this challenge can be overcome by providing adequate compensation to the patent holders and through non-monetary incentives like public-private partnerships and collaborative frameworks by the government.

CONCLUSION

The COVID-19 pandemic exposed the flaws in the patent regime across the globe, bringing to light the global inequalities between developed and developing nations when it comes to accessibility of vital health technologies. It further exposed the inadequacies of the TRIPS flexibilities in addressing public health needs. A framework for temporary suspension aligns

[66] 'Intellectual Property Measures – COVID-19: Trade and Trade-Related Measures' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm> accessed 11 June 2026

[67] *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices* (I-MAK 2018)

[68] 'Pharmaceuticals & Health services' (*European Commission*) <https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services_en> accessed 11 June 2026

proprietary rights of inventors with the constitutional principles of India by allowing equitable access to vital health technologies.

While temporary suspension of patents paves the way for increased and affordable access to crucial health technologies during an emergency, it is not an exhaustive mechanism in itself. The problems of global supply chains, diplomatic backlash, technology transfer and research initiatives persist. These challenges have to be addressed by innovative and responsive governance strategies, such as public-private partnerships, technology collaborations, promoting a system of open innovation and state-coordinated research for medicines.