# COVID-19 and IPR Waiver
## An Indian Perspective

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The Government of India is seeking an intellectual property rights waiver under Sections 1 (copyright and related rights), 4 (industrial designs), 5 (patents), and 7 (protection of undisclosed information) of the Agreement on Trade-Related Aspects of Intellectual Property Rights. Seeking an IPR waiver is based on the presumption that it will allow more firms to manufacture vaccines and medicines, thereby enhancing their availability at a cheaper price. However, IPR waivers for COVID-19 vaccines and medicines are unlikely to make any difference. A more effective approach is to use compulsory licences, and reduce tariffs and non-tariff measures.

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The 6th of May 2021 will go down in history as a day that India would love to forget about. On that day, India reported 4,14,433 new COVID-19 cases, accounting for one in every two infections and one in every four deaths recorded worldwide (Our World in Data 2021). The scale and extent of the second wave of the pandemic took Indian policymakers by surprise. Not long before, on 28 January 2021, in his address to the Davos Dialogue, World Economic Forum, Prime Minister Narendra Modi had announced that India had successfully controlled COVID-19. The vaccine shortage, inevitable in a country of India's size in the short run, was worsened by the second wave. In April 2021, the Serum Institute of India (SII) and Bharat Biotech, India's only two vaccine manufacturers, were producing around 3 million vaccine doses per day. To cover half the eligible population (850 million Indians above 18 years of age) by 31 October 2021, there is, however, a requirement to manufacture 4.6 million doses per day (Khan and Razvi 2021).

As a panacea for this supply shortage, India alongside South Africa is seeking for a waiver of the intellectual property rights (IPR) at the World Trade Organization (WTO). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provisions require all WTO members to grant patents with a minimum term of 20 years for inventions in all fields of technology.[1] In this article, we look at the merit of such an appeal to enhance the supply of COVID-19 vaccines and medicines, and reduce their imminent shortage.

### Why an IPR Waiver?

The Government of India (GOI) is seeking an IPR waiver under Sections 1 (copyright and related rights), 4 (industrial designs), 5 (patents), and 7 (protection of undisclosed information) of TRIPS. Seeking an IPR waiver is based on the presumption that it will allow more firms to manufacture vaccines and medicines, thereby enhancing their availability at a cheaper price. The importance of getting a wider section of the population vaccinated has been underlined regularly. A recent study from Mumbai indicates that people who are aged over 60 years and have received at least one dose of the vaccine are more likely to survive in comparison to those who are unvaccinated (Banaji 2021). Given the shortage in supply relative to the demand, there is a concern that the private players supplying vaccines will charge higher prices, adversely affecting the poor and deprived (Srinivasan and Rao 2021). Supply-side disruptions such as border closures, lockdown in the supply market, interruption in vehicle movements and international trade, labour shortage, and the maintaining of physical distance in manufacturing facilities and so on have led to some other challenges (Paul and Chowdhury 2020). Imports can ease the shortage in the domestic market, liquid oxygen being a case in point. During April 2021, India witnessed an acute shortage of oxygen supply, with a daily demand of oxygen jumping to over 9,200 metric tonnes (MT) in comparison to pre-COVID-19 daily requirement of 700 MT (Raghunandan 2021). India was able to tide over this shortage by importing over 5,000 MT of liquid oxygen. The country did not have to pay any royalty fee, as liquid oxygen is not patented.

### Would it Make a Difference?

The IPR waivers for COVID-19 vaccines and medicines are unlikely to make any difference in terms of augmenting the supply and/or reducing the price, owing to the following reasons.

First, out of the eight COVID-19 vaccines approved in various countries, five are already licensed or being manufactured in India (Reddy and Pai 2021). For instance, SII was contracted by AstraZeneca. Likewise, other Indian manufacturers, namely Dr Reddy's Laboratories, Hetero Healthcare, and Biological E, obtained licences from Gamaleya Institute, Novavax, and Johnson & Johnson to produce vaccines in India. The GOI is in discussion with Pfizer, leaving only Moderna and Sinovac Biotech, which presently do not have licences to produce in India. Moderna already stated that it will not enforce its patent if any companies were to manufacture vaccines (Sagonowsky 2020). Two other Indian firms, namely Gennova Biopharmaceuticals and Cadila Healthcare are in phase-3 of clinical trials (Sharma 2021). For remdesivir, an important medicine for treating COVID-19 patients, seven Indian firms, namely Cipla, Hetero Healthcare, Dr Reddy's Laboratories, Cadila Healthcare, Jubilant Pharma, Mylan, and Syngene International obtained licence from the United States (US)-based Gilead Sciences. As Table 1 shows, with increased availability in the domestic market, prices have gradually fallen for this COVID-19 medicine.

With the number of manufacturer-competitors rising, it is unlikely that any pharmaceutical company can afford to earn supernormal profits using the patent provision. On the contrary, India is a large market, and the GOI, as one of the largest buyers, dominates this market.[2] As per the new "liberalised and accelerated policy" announced by the GOI and implemented, starting 1 May 2021, the central government will purchase 50% of the vaccine produced in the country directly from the manufacturers. And 50% vaccine doses shall continue to be administered by the states and union territories for vaccinating the population in the "45 and above" age group, alongside the COVID-19 front-line workers, free of cost. For the remaining 50% of doses, vaccine manufacturers would be free to supply to the state governments (state quota of 25%), and corporate houses and private hospitals (the remaining 25%), at a pre-negotiated price. Further, in his address to the nation on 7 June 2021, Modi announced that the GOI will provide free vaccines to all citizens above 18 years of age. The GOI will now purchase 75% of the vaccine manufactured (increased from the earlier 50%) and provide to all the states and union territories, free of cost. With the states and union territories' quota of 25% now being procured by the central government, it implies that state governments and union territories will have to spend on vaccine procurement (Sharma 2021).

Table 2 shows that the prices of vaccines in the South Asian subcontinent and in Africa varied between $3 and $6.75. Hence, the argument that patented vaccine products will be far too costly is not backed by strong evidence. Also, even if India gets an IPR waiver, manufacturing vaccines for a new disease would be a complicated process. It requires importing critical material inputs and sharing of "undisclosed information" by the foreign manufacturers, which may not come seamlessly.

Second, to tide over supply of vaccines and medicines, the GOI may exercise Section 92 of the Indian Patent Act, 1970 and grant compulsory licences. WTO members can

> grant compulsory licences (paragraph 5(b)), wherein the government gives a third-party authorization to override a patent. (Cohen et al 2005)

TRIPS also allows for importation from overseas for those countries without domestic manufacturing capacity (the so-called "paragraph 6 system," which has only been used once to date, by Rwanda). Since 2001, several lower- and middle-income countries have issued compulsory licences (the majority for HIV medicines), generally citing high prices as a justification (Mohara et al 2012). India used the compulsory licences provision only once in 2012 for granting the right to domestic pharmaceutical company, Natco Pharma, to manufacture kidney and liver cancer drug, sorafenib tosylate, the patent for which is with the German multinational firm Bayer. Interestingly, in recent times, Natco pharmaceutical had applied for compulsory licences to manufacture Baricitinib, a COVID-19 drug, patent for which is with Incyte Holdings Corporation with a licence to Eli Lilly, an American multinational.

However, the GOI is not willing to grant compulsory licences. From an affidavit filed before the Supreme Court, the GOI has adopted a stance that issuance of compulsory licences will not help to increase the supply of COVID-19 drugs, as the main constraints to increase supply of remdesivir is unavailability of raw materials and essential inputs (Ranjan 2021). India's domestic position of not

**Table 1: Remdesivir Price in Indian Rupees (Maximum Retail Price [MRP] is for 100 mg vial)**

| Indian Firm | Brand Name | MRP (Old Price) | MRP (New Price) |
|---|---|---|---|
| Cadila Healthcare | Remdac | 2,800 | 899 |
| Syngene International | RemWin | 3,950 | 2,450 |
| Jubilant Pharma | Jubi-R | 4,700 | 3,400 |
| Dr Reddy's Laboratories | Redyx | 5,400 | 2,700 |
| Hetero Healthcare | Covifor | 5,400 | 3,490 |
| Mylan | Desrem | 4,800 | 3,400 |
| Cipla | Cipremi | 4,000 | 3,000 |

Source: Ministry of Chemicals and Fertilizers, Government of India. Prices were revised on 17 April 2021.

**Table 2: Government Rate for Procuring COVID-19 Vaccines**

| Supplier | Vaccine Name | Country/Region | Reported Price per Dose ($) |
|---|---|---|---|
| AstraZeneca | | | |
| AstraZeneca/Serum Institute | Covishield | African Union | 3 |
| AstraZeneca/Serum Institute | Covishield | Bangladesh | 4 |
| AstraZeneca/Serum Institute | Covishield | India | 3 |
| AstraZeneca/Serum Institute | AZD1222 | European Commission | 2.19–3.50 |
| AstraZeneca/Serum Institute | AZD1222 | US | 4 |
| Bharat Biotech | Covaxin | India | 4 |
| Pfizer/BioNTech | BNT-162 | African Union | 6.75 |
| | | European Commission | 14.70 |
| | | US | 19.50 |
| Gamaleya Research Institute | Sputnik V | Global (excluding Russia) | 10 |

Source: Vaccines Pricing Data, UNICEF (2021), https://www.unicef.org/supply/vaccines-pricing-data.

using the compulsory licences route to override IPR for COVID-19 vaccines and medicines is contradictory to its own stance, that of seeking an IPR waiver in the WTO forums.

## Trade Policy Framework

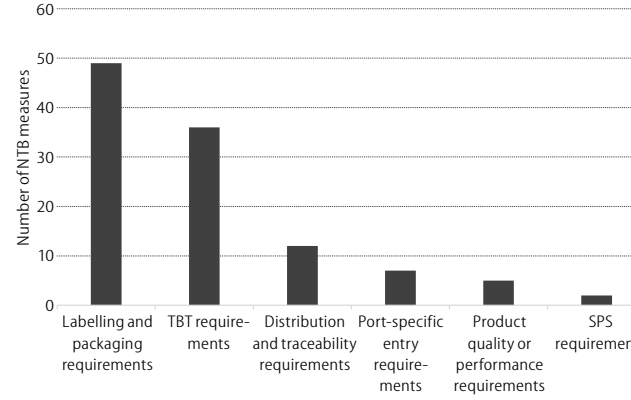
A shortage in the domestic market can be tied over through trade. Trade in COVID-19 vaccines and medicines are critically influenced by tariffs and non-tariff measures (NTMs). Import tariffs are the chief trade barriers responsible for inflating end prices as such border surcharges are amplified and compounded as a product moves down the distribution chain (Bauer 2017). Likewise, NTMs which are defined as policy measures, other than custom tariffs, can potentially have an economic effect on international trade in goods (UNCTAD 2016). Some prominent NTMs are sanitary and phytosanitary (SPS) measures, technical barriers to trade (TBT), port-specific entry requirement, distribution and traceability requirement, and packaging and labelling requirements. Many of the COVID-19-related vaccines and medicines are imported, and NTMs by restricting market access may impact their availability and, thereby, price. With the pandemic continuing, reduction and elimination of tariffs and NTMs are desirable to facilitate the smoother availability of medicinal goods in the domestic market.

Over the last two decades, average global tariffs on medicines have fallen from 4.9% in 2001 to 3.2% in 2018. This is lower in comparison to the global average tariffs for non-agricultural products, which stood at around 7.6%. Although India has overseen the biggest decrease in its average tariff in percentage terms since 2001, Nigeria, Ghana, Chile, Mongolia, Israel, and Bahrain have removed them altogether (Stevens and Banik 2020).

Table 3 summarises the import tariff scenario in India for select major pharma products, which over the last one year faced export restrictions occasionally (Ahmad et al 2020). Trade-weighted average tariff is reported instead of simple average, as the former underlines the extent of reforms in a better manner.

For observing the temporal perspective, the weighted average tariff rates in both the active pharmaceutical ingredients (API) and formulation segments are compared over four periods, namely 2001–05, 2006–10, 2011–15 and 2016–19, respectively. While in the first period, India adopted a cautious attitude by gradually embracing the product patent regime (from 1 January 2005), in the second period, the country emerged as a major exporter of generic medicines. The last two phases witnessed consolidation of the manufacturing sector in the country, initially with the "Make in India" scheme, followed by "Atmanirbhar Bharat Abhiyan," both of which helped in propelling the pharma export growth. During the last phase, India has undertaken a series of reforms covering both procedural and trade policy issues.

**Figure 1: Distribution of NTMs Imposed by India, 2020**




Source: Constructed by authors from Market Access Map data, International Trade Centre (https://www.intracen.org/).

It is evident from the data that to encourage domestic manufacture of medicines, average tariffs on APIs were reduced drastically. While during the 2001–05 period, the average tariffs for both APIs and formulations remained at around 25%–27%, a marked difference emerged from 2006 onwards. It is observed that the average tariff on APIs (classified under HS Code 29) declined at a relatively sharper rate, enabling Indian formulation (classified under HS Code 30) exporters to obtain cheaper access to intermediate inputs. The higher effective rate of protection, resulting from this tariff escalation, enabled India to consolidate trade balance in the formulation segment significantly. For instance, India's

**Table 3: Tariff (%) and Trade Balance ($ million) Scenario in Pharmaceutical Sector**

| Sl No | HS Code | Product | Weighted Average Tariff | | | | Trade Balance Scenario | |
|---|---|---|---|---|---|---|---|---|
| | | | 2001–05 | 2006–10 | 2011–15 | 2016–19 | 2016–20 | Feb 21 |
| 1 | 292229 | Paracetamol | 27 | 9.6 | 7.5 | 7.4 | -31.6 | -1.6 |
| 2 | 293329 | Tinidazole and metronidazole | 27 | 9.6 | 7.5 | 7.4 | 92.2 | 15.5 |
| 3 | 293339 | Hydroxychloroquine | 27 | 9.6 | 7.5 | 7.3 | 317.6 | 43.1 |
| 4 | 293349 | Hydroxychloroquine | 25 | 9.6 | 7.5 | 7.4 | 91 | 3 |
| 5 | 293359 | Acyclovir | 27 | 9.6 | 7.5 | 7.4 | 63.6 | 13.3 |
| 6 | 293399 | Hydroxychloroquine | 25 | 9.1 | 7.5 | 6. 6 | 174 | 8.8 |
| 7 | 293499 | Remdesivir API | 25 | 9.3 | 7.5 | 6.4 | 73.7 | -3.5 |
| 8 | 293622 | Vitamin B1 | 27 | 9.6 | 7.5 | 6.8 | -9.8 | -1 |
| 9 | 293625 | Vitamin B6 | 27 | 9.6 | 7.5 | 6.8 | -9.7 | -0.6 |
| 10 | 293626 | Vitamin B12 | 27 | 9.6 | 7.5 | 7.4 | -39.8 | -4.4 |
| 11 | 293723 | Progesterone | 25 | 9.6 | 7.5 | 7.4 | -42.8 | -2.4 |
| 12 | 294140 | Chloramphenicol | 27 | 9.6 | 7.5 | 7.3 | -0.35 | 0 |
| 13 | 294150 | Erythromycin salts | 27 | 9.6 | 7.5 | 7.4 | -6.4 | -1.9 |
| 14 | 294190 | Neomycin and clindamycin salts | 26.6 | 9.5 | 7.5 | 7.4 | -62.1 | -20.8 |
| 15 | 294200 | Ornidazole | 27 | 9.5 | 7.5 | 7.3 | 677.6 | 65.5 |
| 16 | 300420 | Formulations made of chloramphenicol, erythromycin and clindamycin salts | 27 | 11 | 10 | 10 | 999.7 | 77.1 |
| 17 | 300439 | Formulations made of progesterone | 27 | 11 | 10 | 9.6 | 13.5 | 5.9 |
| 18 | 300450 | Formulations made of vitamin B1, B6, B12 | 27 | 11 | 10 | 8.8 | 240.2 | 22.8 |
| 19 | 300490 | Formulations made of neomycin, ornidazole, paracetamol, metronidazole, tinidazole, acyclovir, remdesivir, amphotericin B, hydroxychloroquine, etc | 27 | 11 | 10 | 9.64 | 10593.1 | 1,142.10 |

Source: Computed by authors from WITS (https://wits.worldbank.org/) and Ministry of Commerce, Government of India (https://commerce.gov.in/trade-statistics/export-import-data-bank-monthly/) data.

export in the medicament segment (HS Code 3004) increased from $2.45 billion to $16.64 billion over 2006 to 2020. As seen from Table 3, while in several API sub-sectors, India suffered from trade deficit, the trade surplus in formulations increased. In 2020, the aggregate trade surplus for India in the APIs and formulations mentioned in Table 3 stood at $1.40 and $14.80 million, respectively. It is worth mentioning that India's long-standing trade surplus for remdesivir APIs turned to deficit in February 2021, when increased imports in the crisis period resulted in a deficit of $3.5 million.

Although tariffs on final medicines came down, it remained one of the highest in the world. For example, India has a high vaccine tariff of 10%, vis-à-vis the tariffs of 5% or lower elsewhere. In addition, although average tariffs have fallen, the number of dutiable tariff lines (tariffs coverage ratio) has fluctuated. For the pharmaceutical items (HS Code 3004), the number of tariff lines increased from 18 in 2001 to 252 in 2018 (Stevens and Banik 2020).[3]

Apart from the tariff barriers, the Indian market is characterised by several NTMs. Using MACMAP database, Figure 1 (p 21) has been constructed which summarises various forms of such barriers imposed on the products reported in Table 3. Understandably, while the SPS barriers on pharma imports are not significant, the TBT-related and packaging and labelling requirements are quite common across these products, which are crucial for both directly and indirectly fighting COVID-19. As the compliance requirements lead to cost escalation for the imported products, a look into the possible rationalisation of these provisions might play a crucial role in improving public health outcomes.

## Conclusions

India is seeking patent waivers on COVID-19-related medical products at the WTO, for the duration of the pandemic, which is expected to ease the supply. However, five out of eight approved vaccine makers have already entered into licensing agreements with Indian firms to manufacture vaccines in India. As an alternative to asking for patent waivers, India could have used the compulsory licences, a legitimate WTO provision. Interestingly, India is not keen on using compulsory licences provision on the premise that it may have an adverse consequence on its efforts in negotiating with other COVID-19 vaccine manufacturers, namely, Pfizer and Moderna. This standpoint of not using the accessible compulsory licences provision to override IPR for COVID-19 vaccines and medicines casts a shadow on future optimality of utilising the IPR waiver. There is another way to increase the supply of COVID-19-related medical products, and that can happen through trade. While India has already reduced tariffs in the pandemic times, it should also consider bringing down the NTMs. A lower tariff and NTM regime would lower final prices of both imported medicines and domestically produced medicines relying on API imports. The policymakers need to consider the practical utility of the waiver and evaluate the available options of granting compulsory licences and reforming tariff NTMs more closely.

### NOTES

1 In 1994, the push towards globally harmonised standards of intellectual property protection culminated in the TRIPS, administered by the WTO. India prior to 2005 did not grant product patents, for example, allowing generic manufacturers to work around existing inventions to produce copies.

2 In addition to the central government, earlier, many other state governments, such as Andhra Pradesh, Delhi, Goa, Maharashtra, Madhya Pradesh, Telangana, Kerala, Karnataka, Uttarakhand, Rajasthan, Odisha, and Uttar Pradesh, have decided to float global tender to procure vaccines.

3 HS 3004 has the following constituent components, namely HS 300410 (Medicaments Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives), 300420 (Medicaments Containing Other Antibiotics), 300431 (Medicaments Containing Insulin), 300432 (Medicaments Containing corticosteroid hormones, their derivatives or structural analogues), 300439 (Medicaments Containing Other Hormones), 300440 (Medicaments Containing Alkaloids or Derivatives Thereof), 300450 (Medicaments Containing Vitamins or Other Products of Heading 29.36), (Put up in Packings), 300490 (Other Medicaments).

### REFERENCES


Ahmed, A, Chakraborty, D and R Bhattacharyya (2020): "The Recent Coronavirus (Covid-19) Pandemic: A Review of Issues for Indian Pharmaceutical Exports," *Foreign Trade Review*, Vol 3, No 55, pp 418–35.

Banaji, Murad (2021): "Are COVID-19 Vaccines Saving Lives in Mumbai? Here's the Math," *Quint*, https://www.thequint.com/voices/opinion/covid-19-pandemic-mumbai-trends-deaths-cases-numbers-senior-citizens-young-population-vaccination-efficacy.

Bauer, M (2017): "The Compounding Effect of Tariffs on Medicines," European Centre for International Political Economy, Policy Brief, https://euagenda.eu/upload/publications/untitled-107591-ea.pdf.

Cohen, J C, M Gyansa-Lutterodt, K Torpey, L C Esmail and G Kurokawa (2005): "TRIPS, the Doha Declaration and Increasing Access to Medicines: Policy Options for Ghana," *Globalization and Health*, Vol 1, No 1, pp 1–10.

Khan, Amir Ullah and Saleema Razvi (2021): "Why States Will Now Jostle for Vaccines," *Mint*, https://www.livemint.com/news/india/why-states-will-now-jostle-for-vaccines-11619018494575.html.

Mohara, A, I Yamabhai, K Chaisiri, S Tantivess and Y Teerawattananon (2012): "Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand," *Value in Health*, Vol 15, No 1, pp S95–S99.

Our World in Data (2021): "Covid-19 Statistics," https://ourworldindata.org/.

Paul, Sanjoy Kumar and Priyabrata Chowdhury (2020): "A Production Recovery Plan in Manufacturing Supply Chains for a High-demand Item during COVID-19," *International Journal of Physical Distribution & Logistics Management,* https://www.emerald.com/insight/content/doi/10.1108/IJPDLM-04-2020-0127/full/html.

Raghunandan, D (2021): "COVID-19 and Oxygen Shortage in India," *Economic& Political Weekly*, Vol LVI, No 21, pp 8.

Ranjan, P (2021): "Compulsory Licences and ISDS in Covid-19 Times: Relevance of the New Indian Investment Treaty Practice," Journal of Intellectual Property Law & Practice, Vol 16, No 7, pp 748–59.

Reddy, Prashant T and Yogesh Rai (2021): "Why Intellectual Property Waiver for Vaccines Is Not so IP Hooray Today," *Economic Times*, https://economictimes.indiatimes.com/opinion/et-commentary/why-intellectual-property-waiver-for-vaccines-is-not-so-ip-ip-hooray-at-all/articleshow/82438489.cms.

Sagonowksy, Eric (2020): "Moderna Won't Enforce COVID-19 Vaccine Patents during Pandemic," *Fierce Pharma*, https://www.fiercepharma.com/pharma/leading-vaccine-player-moderna-won-t-enforce-patents-against-other-companies-during-pandemic.

Sharma, Manoj (2020): "Apart from Serum, Bharat Biotech, These 5 Vaccine Makers Are India's Hope against COVID-19," *Business Today*, https://www.businesstoday.in/coronavirus/apart-serum-bharat-biotech-5-vaccine-makers-india-hope-against-covid-19/story/439231.html.

Sharma, Harikishan (2021): "After Adverse Reaction, a Change in Dose: Free Covid Vaccines for All, Only Centre to Procure," *Indian Express,* https://indianexpress.com/article/india/pm-narendra-modi-address-free-jabs-centre-to-procure-covid-vaccines-7348171/lite/.

Srinivasan, Sandhya and Mohan Rao (2021): "Why India's Vaccine Companies Are Profiteering in the Pandemic," *Economic & Political Weekly*, Vol LVI, No 22, pp 12–14.

Stevens, Philip and Nilanjan Banik (2020): "Abolishing Pharmaceutical and Vaccine Tariffs to Promote Access," Geneva Network Working Paper, http://www.test.oddly.co/gnetwork/wp-content/uploads/2020/07/2020-tariffs-on-pharmaceuticals.pdf.

UNCTAD (2016): "Guidelines to Collect Data on Official Non-tariff Measures." United Nations, New York: US.