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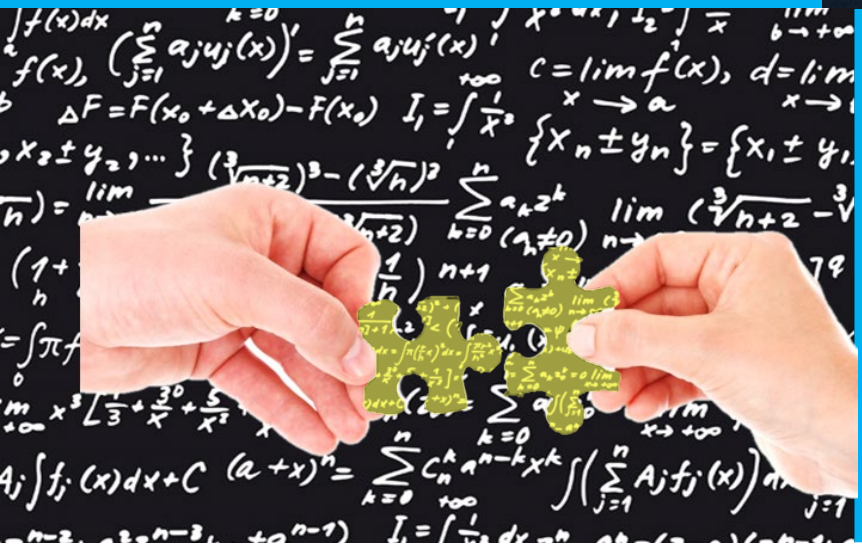
IPR waiver in vaccines and opportunities for India: what does the data show?



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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

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WORKING PAPER

IPR waiver in vaccines and opportunities for India: what does the data show?

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Abstract

In light of the spread of Covid-19 cases in India during the second wave, the Government of India (GOI) decided to negotiate for an IPR waiver under section 1 (copyright and related rights), 4 (industrial designs), 5 (patents), and 7 (protection of undisclosed information) of TRIPS Agreement under the World Trade Organization (WTO). The expectation of the GOI is that the proposed IPR waiver would allow more firms to come forward to manufacture vaccines, medicines, and other COVID-19 related medical items, which would in turn augment their availability at an affordable price. The current paper concludes that IPR waivers as such are unlikely improve the cheaper access to medicine. Instead, the focus should be on granting of compulsory licenses, reduction of import tariffs and non-tariff measures (NTMs) to reduce prices of COVID-19 medicines, vaccines, and other pharmaceutical items. The analysis with trade data points out India currently lacks a comparative advantage in several categories of active pharmaceutical ingredients, manufacturing medical equipment and devices, disinfectants and sterilisation products, and personal protective equipment. In contrast, it holds a comparative advantage in manufacturing vaccines and formulations. Interestingly, India imposes higher tariffs and NTMs on both sets of products, irrespective of the comparative advantages. The analysis concludes that the focus of the policymakers should be on reduction and elimination of tariffs and NTMs. This will ensure smoother availability of medicinal goods in the domestic market at an affordable price on one hand and augment competitiveness in the world market on the other.

Keywords: COVID-19, Medical Products, Competitiveness, Tariffs and Non-tariff measures

JEL Codes: F13, F15, I18

Contents

1. Introduction

During the last two decades, exports of generic medicines from India increased considerably (Export Import Bank of India, 2016). The Indian pharmaceutical industry is the second largest in the world accounting for 70% of the bulk intermediate and formulation drugs (Panda, 2017). Taking note of the growth path of the domestic pharmaceutical sector, for example, active pharmaceutical ingredients (APIs), [4] vaccines and formulations,[5] the Government of India (GOI) has regularly introduced policies to support them. Some of the key initiatives include establishment of the National Manufacturing Competitiveness Council (NMCC) in 2004, launch of the 'National Manufacturing Policy' in 2011, introduction of the 'Make-in-India' scheme (2014) and 'Atmanirbhar Bharat Abhiyan,' (2020).[6] In addition, the supports extended through the foreign trade policies also deserve mention. Several instruments introduced under these policies successfully supported the manufacturing and export capabilities of this sector. First, the schemes like 'Market Access Initiative' (MAI), Focus Product Scheme (FPS), etc., launched through various foreign trade policies, enabled the pharma companies in their internationalization attempts. It has recently been decided to continue the MAI scheme in revised form, to the advantage of the exporters (GOI, 2021). Second, in the foreign trade policy (2015-20), pharma and biotechnology sectors were included under the 'Focus Market Scheme, (FMS)' with the GOI providing incentives on exports that can be used later to settle against the future import duties on raw material to be used for pharmaceutical exports.[7] Third, for enhancing Research and Development (R&D) activities in the country, approval of 11 National Institutes of Pharmaceutical Education & Research (NIPERs) has been granted (GOI, 2018). Fourth, to facilitate technology transfer from developed countries, foreign direct investment (FDI) in the pharma sector has been allowed up to 100% through the automatic route for manufacturing of medical devices. Fifth, the 'Pharma Vision 2020' has been introduced to streamline end-to-end drug manufacture in India (Make in India, undated). Sixth, under the Draft Science, Technology and Innovation Policy (STIP) 2020, the government proposes to build up a dedicated pool of scientists on pharma and biotech sector, with appropriate R&D consequences (GOI, 2020).

This set of reforms have led to a mixed result so far. In some sectors, in particular, in the case of high-value-added pharmaceutical exports such as formulation and vaccines, India is doing well. The share of domestic value-added content in foreign final demand went up by 6.2%, from 32.6% in 2005 to 38.8% in 2016 (Export Import Bank of India, 2016). However, as we showcase through our results India continues to sustain higher trade deficits in certain segments of API, personal protective equipment, disinfectant, and medical equipment segments, indicating a differential impact of reforms.

[4] API are chemicals used to make medicines of any form, such as tablets, liquids, ointments, injectables, or infusion drugs. A change in API will change the medicines.

[5] Formulations are made up of API (bulk drug) and inactive pharmaceutical ingredients (other intermediate inputs).

[6] During September 2014, GOI launched the program, 'Make in India'. The idea is to transform India as the preferred global destination hub for manufacturing. Subsequently, on May 2020, the GOI launched, 'Atmanirbhar Bharat Abhiyan,' to make India self-reliant and to revive the Indian economy at the time of COVID-19.

[7] As per Foreign Trade Policy 2015-20, GOI, exporters are entitled to get back, "2%/3%/5%/7% of FOB value of notified goods exported to notified markets in free foreign exchange or FOB value of exports as given in the Shipping Bills in free foreign exchange, whichever is less".

India also continues to depends heavily on foreign imports, in particular, when there was a high requirement during the unexpected arrival of second wave of COVID-19 during April-May 2021.[8] The country recorded 4,14,433 new COVID-19 cases on 6 May 2021, marking the deep spread of the pandemic, accounting for one every two infections and one every four deaths recorded worldwide (Our World in Data, 2021). While an ailing healthcare system resulting from lack of hospital beds, compounded by an understaffed and under-skilled health workforce is partly to be blamed, India also severely faced shortage of COVID vaccines, drugs, and oxygen cylinders. The rising domestic demand also led to a ban on the export of vaccines (India Today, 2021).

As a panacea for this supply shortage, India alongside South Africa is seeking for a waiver or suspension of the Intellectual Property Rights (IPR) at the World Trade Organization (WTO).[9] The WTO provisions permit any country to seek the waiver following Articles IX.3 and IX.4 of the Marrakesh Agreement establishing the WTO. As per the legal text of Article IX.3 of the Agreement, "A request for a waiver concerning this Agreement shall be submitted to the Ministerial Conference for consideration pursuant to the practice of decision-making by consensus. The Ministerial Conference shall establish a time-period, which shall not exceed 90 days, to consider the request. If consensus is not reached during the time-period, any decision to grant a waiver shall be taken by three fourths of the members."[10] The legal text rightly anticipates a possible absence of consensus given potential conflict of interests, and accordingly paved a road for decisions based on majority voting. Pursuant to Article IX.3, Article IX.4 states, "A decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate. Any waiver granted for a period of more than one year shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates."[11]

The issues relating to pharmaceutical sector and public health considerations are dealt through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),the provisions under which require all WTO members to grant patents with a minimum term of twenty years for inventions in all fields of technology.[12] It is to be noted that until 1970 India followed the product patent regime, putting the country at per with the developed countries in terms of protecting innovation elsewhere. However, the Indian Patent Act 1970 allowed issue of process patents for inventions in the field of drugs, medicines, food and chemicals. As a result, India emerged as a major exporter of generic medicines, owing to the prevailing process patent regime (Chaudhuri, 2005). The export interest in generic drugs prompted India to participate actively at the WTO on the question of granting Compulsory Licensing (CL) and Parallel Imports (PI) on public health ground, particularly in the aftermath of the AIDS controversy in South Africa (Fisher and Rigamonti, 2005). However, in the post-2005

[8]On 28 January 2021, in his address to the Davos Dialogue, World Economic Forum the Prime Minister Mr. Narendra Modi announced that India has successfully controlled COVID-19.

[9] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19, WTO, Communication from India and South Africa.

[10] WTO. Available at: https://www.wto.org/english/docs_e/legal_e/final_e.htm, accessed 20 June 2021.

[11]WTO. Available at:https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#fntext-4, accessed 20 June 2021.

[12] In 1994, the push towards globally harmonized 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.

period, the country had to embrace the product patent framework, which incentivized R&D activities, thereby facilitating upward movement along the value chain (Ray Chaudhuri et al, 2019). As the tariff barriers in other countries came down, the need to address the existing non-tariff measures (NTMs) in the trade partners were strongly felt (GOI, 2008). The inherent cost advantages provide India an export opportunity in the post-Covid period (Dutta, 2021).

The recent Indian move, where 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, needs to be viewed in this wider context. The call by India and South Africa for an IPR waiver is based on the presumption that it will allow more firms to manufacture vaccines and medicines, leading to their availability at a cheaper price (FM'tHoen, 2002). However, the developed countries have strongly opposed the move and the waiver proposal is unlikely to sail through (Mukherjee, 2021). The current analysis attempts to judge the optimality of this approach to enhance the supply of COVID-19 vaccines, medicines and medical products and instruments. The analysis is organized as follows. Section 2 discusses the current context and Indian scenario. Section 3 deals with the framework and the data for analyzing India's comparative advantage in medicines (APIs and formulations), vaccines, and other COVID-19 related medical products. Section 4 summarizes the observed results, and link that up with India's trade policy framework in terms of policy outcomes such as tariffs and NTMs. Section 5 concludes.

2. Background

2.1 Need for an IPR waiver

Cheaper availability of vaccines, medicines, and other COVID-19 related medical items is a necessary condition for universal coverage. Earlier, India has successfully implemented polio vaccination program (Sutter, et al., 2014). However, at the peak of second COVID-19 wave during April 2021, a majority of the Indian population were not vaccinated. On 26 April 2021, out of India's 1.36 billion people, only 145 million received vaccination shots (Bhuyan, 2021).[13] On 8 April 2021, India reported stock of only 24 million vaccines, and during the earlier months were in fact exporting vaccines to other countries as part of vaccine diplomacy (*Ibid.*).[14] Supply-side disruptions such as border closures, lockdowns, interruption in vehicle movements and international trade, labor shortage, and the social distancing provisions in manufacturing facilities etc., only have opened other challenges. Given the short-run domestic supply challenges, India had to resort to importing vaccines, medicines, and other medical items. With control on vaccine exports, it is observed that up to September 2021 more than 790 million people have been vaccinated so far (BBC, 2021). It has been observed

[13] As on 13 August 2021, number of people who are vaccinated stands at 529 million. Real time update is available at: https://www.mohfw.gov.in/, accessed 13 August 2021.

[14] India has placed highest priority on advancing friendship and cooperation with her neighbours through its 'neighbourhood first policy,'. As part of this program, India began providing COVID-19 vaccines on a priority basis to Afghanistan, Bhutan, Bangladesh, Myanmar, Maldives, Nepal, and Sri Lanka. Between January and April 2021, India distributed a total of 19,542,000 vaccines to these countries, until it stopped further exports when the second COVID-19 wave hit India during April 2021.

that imports have relieved the pressure on excess demand in the domestic market, notably in case of liquid oxygen (Raghunandan, 2021). The question of IPR waiver did not arise in this context, as liquid oxygen is not covered by patent rights.

2.2 IPR waiver: necessary condition?

It can be argued that IPR waivers for COVID-19 vaccines and medicines may not specifically cause the much-anticipated downward spiral in prices in the India context, owing to the following reasons. First, the improved access for Covid-19 medicinal products in India, ensured through a series of reforms, needs to be highlighted. Out of the eight COVID-19 vaccines approved globally so far, five are already licensed or being produced in the country (Banik and Chakraborty, 2021; Reddy and Pai, 2021). For instance, Indian pharma companies, namely, Serum Institute of India, Dr. Reddy's Laboratories, Hetero Healthcare, and Biological E, obtained licenses from AstraZeneca, Gamaleya Institute, Novavax, and Johnson & Johnson respectively, for local production and in certain cases, exports. GOI is in discussion with Pfizer, leaving only Moderna and Sinovac Biotech, which presently do not have footprints in the country. The announcement from Moderna that it will not enforce its patent in case pharma majors were to manufacture vaccines may allow potential collaborations in India (Sagonowsky, 2020). Two other Indian firms, namely, Gennova Biopharmaceuticals and Cadila Healthcare are going through the phase-3 of clinical trials, with a potential to ease future shortage concerns (Sharma, 2021). Seven Indian pharma companies, namely: Cipla, Hetero Healthcare, Dr. Reddy's Laboratories, Cadila Healthcare, Jubilant Pharma, Mylan, and Syngene International obtained license for manufacturing Remdesivir from Gilead Sciences, an US firm. As evident from Table 1, the increased availability led to decline in the domestic price of Remdesivir. Further, on 12 June 2021, the Goods and Services Tax (GST) council, the GOI, slashed the GST rates on COVID-19 related items (except for vaccines), which means market price of these items will come down with a reduction in domestic taxes (Table 2).[15]

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	2800	899
Syngene International	RemWin	3950	2450

[15] The GST council is headed by the Union Finance Minister and is assisted by the Finance Ministers from all the states in India. The GST is an indirect tax on the supply of goods and services from the manufacture to the end consumer. GST is based on the principle of value addition, wherein credit of inputs taxes will be refunded at each stage and subsequent stages of value addition in the supply chain. The final consumer does not pay any indirect tax, except paying for the GST levied by the last supplier in the supply chain.

Jubilant Pharma	Jubi-R	4700	3400
Dr. Reddy's Laboratories	Redyx	5400	2700
Hetero Healthcare	Covifor	5400	3490
Mylan	Desrem	4800	3400
Cipla	Cipremi	4000	3000

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

Table 2: GST rates on COVID-19 related items (figures in %)

Medicines, and Medical Equipment	Before 12 June 2021	After 12 June 2021
Remedisivir	12	5
Tocilizumab	5	0
Amphotericin B	5	0
Anti-coagulant (Heparin and similar)	12	5
Any other drugs for COVID treatment	Applicable Rate	5
Pulse Oximeters	12	5
Hand Sanitiser	18	5
PPE Kit	18	5
N-95 mask	18	5
Triple Layer	18	5
Surgical Mask	18	5
Temperature check equipment	18	5
Covid test kits	12	5
Specified Inflammatory Diagnosis Kit (D-Dimer, IL-6 Ferritin and LDH)	18	5

Medical grade oxygen	12	5
Oxygen Concentrator/Generator	12	5
BiPAP machines	12	5
High flow nasal cannulas	12	5
Ventilators and ventilator masks	12	5
Vaccines	5	5

Source: Ministry of Finance, Government of India. GST rates were revised on June12, 2021.

With the entry of newer players, the market power of the pharmaceutical companies and their ability to adopt a monopoly pricing strategy (backed by patent rights) is expected to come down. Conversely, GOI dominate the pharma market as one of the largest buyers.[16] As per the new "liberalized and accelerated policy," announced by the GOI and implemented from 1 May 2021, Central Government decided to purchase 50% of the vaccines produced in the country directly from the manufacturers. These 50% vaccines shall continue to be administered by the states and Union Territories for vaccinating "45 and above" age group of population, alongside the COVID-19 frontline 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. Subsequently, in his address to the nation on 7 June 2021, Prime Minister Mr. Modi announced that the GOI is going to provide free vaccines to all citizens above 18 years of age. The GOI will now purchase 75% of the vaccines manufactured (increased from the earlier quota of 50%) and provide to all the states and union territories (UT), free of cost (Sharma, 2021). For the remaining 25%, the GOI has capped the prices at which vaccines can be sold at the private hospitals. This government intervention is likely to keep the corporate pricing strategies in check.

Second, GOI can already take recourse to Section 92 of the Indian Patent Act (1970) and grant CL for easing the shortage in the market. The WTO agreement permits the members to, "grant compulsory licences (paragraph 5(b)), wherein the government gives a third-party authorization to override a patent" (Cohen et al., 2005). CL allows governments to address public health needs by enabling domestic manufacture of patented drugs, at a cheaper price. Over the last two decades, a number of developing and less developed countries have taken recourse to CL (the majority for HIV medicines), on the ground of higher prices of the imported variety (Mohara et al., 2012). India used the CL provision only once in 2012 by granting Natco Pharma, to manufacture kidney and liver cancer drug sorafenib tosylate, patented by the German

[16]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, Orissa, and Uttar Pradesh, decided to float global tender to procure vaccines.

firm Bayer. The TRIPS provisions also create rooms for importing medicines from abroad, if a country lacks domestic manufacturing capacity through the PI route.[17]

During the Covid-19 pandemic waves, several developed (Canada, Germany) as well as developing (Chile, Ecuador) countries have already taken steps by using their patent acts to expedite issuance of CL (Syam, 2020). The Indian experience however goes contrary to this global trend. In India, Natco pharmaceutical applied for CL to manufacture Baricitinib, a COVID-19 drug, patented by Incyte Holdings Corporation with a license to Eli Lilly, the US-based pharma company (Barooah, 2021). Nevertheless, GOI explained its decision for not granting the CL through an affidavit filed before the Supreme Court by citing supply side bottlenecks (e.g., unavailability of raw materials and essential inputs) which even after issuance of CL will limit the supply of COVID-19 medicines (Ranjan, 2021). The Indian stance of not using the CL route to ease domestic availability of COVID-19 vaccines and medicines is inconsistent with its recent interests towards IPR waiver in WTO discussions. With granting of CL becoming improbable, the country has to rely on imports of COVID-19 medicines, vaccines, and other COVID-19 related medical products, to improve availability in the domestic market.

3. Comparative advantage for India's pharmaceutical products

3.1 Analytical framework

A shortage of vaccines and medicines in the domestic market can be linked to competitiveness, reflected through trade flows. Since the launch of the 'Make in India' initiative in 2014, India has introduced a series of fiscal, financial and tariff reforms to enhance the competitiveness to the pharma sector (Chakraborty and Banik, 2020). The inherent comparative advantages, couple with these supports, helped India to emerge as a major exporter of pharmaceutical products, ranging over generic medicines, bulk drugs, and formulations (Export Import Bank of India, 2016). However, the evidence on comparative advantage in India's key medicinal products and equipment exports, in the light of the pandemic, is scarce. Moreover, import tariffs imposed at the entry point necessarily lead to inflated end prices, as their effects are amplified and compounded along the distribution chain (Bauer, 2017). Likewise, several NTMs, including Technical Barriers to Trade (TBT), Port-Specific Entry Requirement, registration requirement for importers, Distribution and Traceability Requirement, and Packaging and Labelling Requirements, may result in higher price of the pharmaceutical products in general and Covid-19 medicines in particular. The present analysis, which attempt to compute comparative advantage for India's COVID-19 related pharmaceutical products, contribute to the existing literature by examining whether lower comparative advantage is a reason for India to embrace a protectionist trade policy.

[17] The so-called "paragraph 6 system" has been implemented only once to date, by Rwanda in 2007.

To judge the competitiveness of the Indian pharma and other medical product exports, the average Revealed Comparative Advantage (RCA) indices for the selected commodities are reported. The RCA has been calculated by the following formula:

$$RCA_i = \frac{\sum A_{iX} \,/\, \sum A_X}{\sum W_{iX} \,/\, \sum W_X}$$

where, $\sum A_{iX}$ and $\sum A_X$ represent export of a particular HS 6-digit product (i-th) and total exports from India respectively. $\sum W_{iX}$ and $\sum W_X$ depict exports of the i-th product by all countries and total global exports in that order. If the RCA index for this i-th product category is greater than unity, then the exporter country is enjoying comparative advantage in the same.

In addition, the analysis also presents the Revealed Comparative Disadvantage (RCDA) index, using the following formula, which is symmetric to the RCA index. However, instead of exports, imports data is used for computation of RCDA. If the RCDA index for an i-th product category is greater than unity, then the importer country might be suffering from comparative disadvantage.

$$RCDA_i = \frac{\sum A_{iM} \,/\, \sum A_{XM}}{\sum W_{iM} \,/\, \sum W_M}$$

The RCA-RCDA index results can be interpreted in the following manner. If the RCA and RCDA for a product are greater and lesser than unity respectively, a country can be called an ideal exporter of that product. Similarly, if the values of the RCA and RCDA are reversed, then the country would be an importer in nature. If both RCA and RCDA values are greater than unity, then simultaneous export and imports are taking place in the country, signifying presence of intra-industry trade (IIT) in that category. However, if both the RCA and RCDA are lesser than unity, then the country is likely to be self-sufficient in this commodity, as reflected from the low trade orientation.

3.2 Data

For the analysis we consider 41 different COVID-19 medical products spreading across six broad categories, namely: active pharmaceutical ingredients (10 products), vaccines and formulations (5 products), medical and non-medical wearables (12 products), disinfectants and sterilisation products (5 products), and medical devices and equipment (9 products). Trade data are based on HS Codes (at a six-digit level of HS Classification), which are obtained from the Trade Map database, International Trade Centre. A detailed reference of the products examined are reported in Annexure 1 in the Appendix. For the NTMs, we use Market Access Map (MACMAP) database provided by the ITC. This data reflects total number of NTMs which are in place for the year 2020. Tariffs data are sourced from World Integrated Trade Solution (WITS) database, World Bank; and Ministry of Commerce, GOI. The trade data is drawn over 2001-20. For observing the temporal perspective, the analysis is undertaken and compared over four sequential sub-periods, namely: 2001-05, 2006-10, 2011-15 and 2016-20, respectively. During the first period, that is, between 2001 and 2005, India adopted a cautious attitude by gradually embracing the product patent regime (from 1

January 2005, onwards). The second period (2006-10) was marked by India's entry into various Regional Trade Agreements (RTAs).[18] Thereafter, during the last two phases (2011-15 and 2016-20), Indian policymakers pursued a policy of self-reliance in manufacturing, initially with the 'Make-in-India' scheme introduced in 2014, followed by the 'Atmanirbhar Bharat Abhiyan' (i.e., Self-Reliant India) launched in 2020.

4. Competitiveness patterns: the results

Tables 3, bring out some interesting observations. As seen from Table 3, in general, India has a comparative advantage in manufacturing several active pharmaceutical ingredients (APIs), vaccines and formulations. On the contrary, the country lacks a comparative advantage in manufacturing other COVID-19 related medical items, such as medical and non-medical wearables, medical instruments, disinfectants and sterilization products.

Table 3: Competitiveness of India in select product categories

Sl. No.	HS Code	RCA				RCDA			
		2001-05	2006-10	2011-15	2016-20	2001-05	2006-10	2011-15	2016-20
Active Pharmaceutical Ingredients (APIs)									
1	293339	0.25	0.74	1.42	2.86	0.38	0.47	0.55	0.81
2	293349	0.40	0.38	2.58	6.52	0.08	0.14	0.57	1.15
3	293359	0.22	0.61	0.64	1.12	0.21	0.48	0.43	0.58
4	293399	0.06	0.16	1.28	3.03	0.04	0.12	0.33	1.44
5	293622	0.38	1.23	1.35	1.77	1.48	1.73	1.53	2.12
6	293625	0.07	0.01	0.04	0.08	1.44	1.08	1.34	1.41
7	293626	7.25	2.41	0.52	0.67	1.52	3.76	3.80	4.98
8	293627	0.03	0.03	0.17	0.29	0.41	0.31	0.29	0.54
9	294190	2.30	2.60	4.09	4.45	1.24	1.82	1.87	3.01
10	294200	84.57	64.50	43.68	39.02	45.03	24.06	20.53	13.97

[18]India signed 6 different RTAs, namely, (1) South Asian Free Trade Area in 2006, (2) India Bhutan Trade Agreement in 2006, (3) India Chile Preferential Trade Agreement (PTA)in 2007, (4) India MERCOSUR PTA in 2009, (5) India-ASEAN FTA in 2010, and (6) India South Korea Comprehensive Economic Partnership Agreement in 2010.

Vaccines and Formulations									
1	300220	2.01	1.11	1.21	1.55	0.88	0.34	0.41	0.46
2	300420	2.48	3.84	3.51	4.25	0.06	0.05	0.09	0.11
3	300439	0.28	0.21	0.25	0.20	0.11	0.10	0.11	0.09
4	300450	3.89	4.32	3.24	3.41	0.09	0.09	0.05	0.06
5	300490	0.88	0.92	1.74	2.44	0.09	0.11	0.08	0.10
Wearables (Raw Materials)									
1	560311	0.03	0.12	0.23	0.44	0.40	0.21	0.52	0.88
2	560312	0.01	0.44	0.93	1.18	0.21	0.18	0.18	0.23
3	560314	0.04	0.03	0.16	0.46	0.11	0.19	0.41	0.54
4	560391	0.03	0.02	0.11	0.07	1.13	0.29	0.55	0.71
5	560392	0.00	0.02	0.05	0.05	0.47	0.21	0.40	0.87
6	560393	0.01	0.01	0.07	0.17	0.57	0.26	0.27	0.43
7	560394	0.03	0.04	0.11	0.13	1.22	0.98	1.19	1.29
Medical and Non-medical wearables (Final Products)									
1	392690	0.39	0.50	0.54	0.56	0.41	0.45	0.50	0.55
2	401511	2.72	1.76	1.42	1.40	0.05	0.15	0.38	0.45
3	621790	0.24	0.72	0.70	0.56	0.10	0.14	0.10	0.15
4	630790	13.50	4.01	2.13	2.15	0.17	0.13	0.08	0.11
5	901850	0.17	0.26	0.23	0.32	2.62	1.48	1.57	1.41
Disinfectants and sterilisation products									
1	300215	-	-	-	0.04	-	-	-	0.05
2	380894	-	-	0.44	0.41	-	-	0.08	0.10
3	701010	1.84	2.29	2.31	3.00	0.39	0.47	0.62	1.52
4	701090	0.66	0.95	1.12	1.25	0.06	0.18	0.21	0.24

5	841990	0.79	1.11	0.87	0.90	1.15	1.24	0.91	0.85
Medical devices and equipment									
1	841920	0.13	0.47	0.51	0.43	1.06	1.10	1.16	1.55
2	901811	0.68	0.41	0.51	1.53	0.24	0.25	0.23	0.33
3	901812	2.00	0.45	0.64	0.39	1.49	1.00	0.83	1.19
4	901819	0.30	0.55	0.43	0.40	1.89	0.83	0.49	0.24
5	901839	0.26	0.30	0.43	0.54	0.59	0.47	0.36	0.36
6	901890	0.26	0.27	0.24	0.26	0.83	0.60	0.46	0.50
7	901920	0.03	0.04	0.03	0.05	0.53	0.34	0.43	0.67
8	902000	0.05	0.04	0.16	0.07	0.37	0.34	0.33	0.33
9	902212	0.13	0.02	0.03	0.15	1.11	1.01	1.01	1.10

Source: Computed by authors using trade data sourced from Trade Map (https://www.trademap.org/)

In the API segment, the RCA values increased over time for several product groups, indicating that India is consolidating its position as an exporter in this product category. Considering the items HS-293339 and HS-293349 (Hydroxychloroquine), initially, the RCA values were lesser than unity, but improved over time, crossing the competitiveness threshold value of one. While for the API items with an RCA value greater than unity India has a trade surplus, products characterized by RCA value less than one, India suffers from a trade deficit. For instance, in case of HS-293622 (vitamin B1), HS-293625 (vitamin B6), HS-293626 (vitamin B12), and HS-293627 (vitamin C), Indian manufacturers do not have comparative advantage and run trade deficit. Interestingly for HS-294190 (neomycin, rifampicin, and clindamycin salts) both the RCA and RCDA values are greater than unity, indicating presence of IIT.

Within the vaccines and formulations category, for all the items barring HS-300439 (formulations made of progesterone, oestrogen, etc.), RCA is greater than unity and RCDA is less than unity, which underlines the country's comparative advantage. In particular, for HS-300220 (all vaccines for human medicine, including COVID-19 vaccines), India displays a strong and time-invariant comparative advantage.

For most of the items falling under wearables (raw materials), medical and non-medical wearables (final products), disinfectants and sterilisation products, and medical devices and equipment sub-categories, India does not have comparative advantage. During 2016-20, only for HS-560312 (non-woven fabrics of 25-70 GSM), HS-401511 (surgical rubber or medical examination rubber gloves), HS-701010 (glass containers for vaccines), HS-901819 (pulse oximeters), andHS-901811 (electrocardiograph), RCA value is greater than unity. For all other items, RCA values were lesser than unity,

indicating absence of competitiveness. With the threat of COVID-19 wave looming large, India had to resort to import of some of these items. However, with time, production capacity in these products improved (ET, 2021).

It is further observed that India enjoys a lower RCA and RCDA values for capital-intensive medical items critical for treating COVID-19 patients such as HS-901920 (ventilators, oxygen humidifiers, CPAP, BIPAP, oxygen concentrators, etc.) and HS-902000 (other breathing appliances and gas masks, excluding protective masks having neither mechanical parts). In the pandemic period, import dependence of India increased for many of these product groups.

The higher RCA value (reflecting comparative advantage) also translates into a favourable trade balance across sectors, which are summarized in Table 4.

Table 4: Tariff (%) and trade balance ($ Million)

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, Metronidazole, Tinidazole, Acyclovir, Paracetamol, 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

Higher RCA scores tend to indicate comparative advantage and ideally may reflect trade surplus in favour of India. While the RCA-RCDA results jointly underline India's competitiveness patterns, the trade balance scenario is an indicator of evolving specialization. For example, in the vaccines and formulations category, India runs a trade surplus. Similar is the case with a few wearable items (raw materials), medical and non-medical wearables (final products), disinfectants and sterilization products, and medical device and equipment – items with higher RCA scores translating into a favourable trade balance for the country. However, irrespective of the RCA and RCDA results, India has followed a defensive trade regime, marked by the presence of higher trade-weighted average tariffs rates across APIs, vaccines, formulations, and other COVID-19 related product categories.

Table 5 attempts to summarize the observations of the paper in terms of RCA-RCDA (reflecting competitiveness) and import dependence on China, supplemented by trade balance and tariff protection related information. While the RCA-RCDA values have been used to gauge the trade opportunities, the average trade balance during 2016-20 has been considered as a benchmark. The average tariff barriers on the HS codes during 2016-19 are computed and reported in Table 5 under three distinct ranges. The current analysis defines the tariff protectionism as 'high', when the average tariff rates is more than 10%; 'moderate', when the average tariff rates is between 5-10%; and 'low', when the average tariff rates is less than 5%.

Table 5: India's Import Dependence on China

Sl. No	HS Code	Import Dependence of China				Dependence on China	Export Competitiveness	Import Threat	Trade Opportunity	Trade Balance	Tariff Protection
		2001-05	2006-10	2011-15	2016-20	% Share in Imports	RCA	RCDA	RCA-RCDA		Tariff Range
Active Pharmaceutical Ingredients (APIs)											
1	293339	28.2	46.5	65.8	76.8	High	Yes	No	Export	Positive	Modest
2	293349	50.4	75	64.3	69.2	High	Yes	Yes	IIT	Positive	Modest
3	293359	27.1	60.1	61.9	71.6	High	Yes	No	Export	Positive	Modest

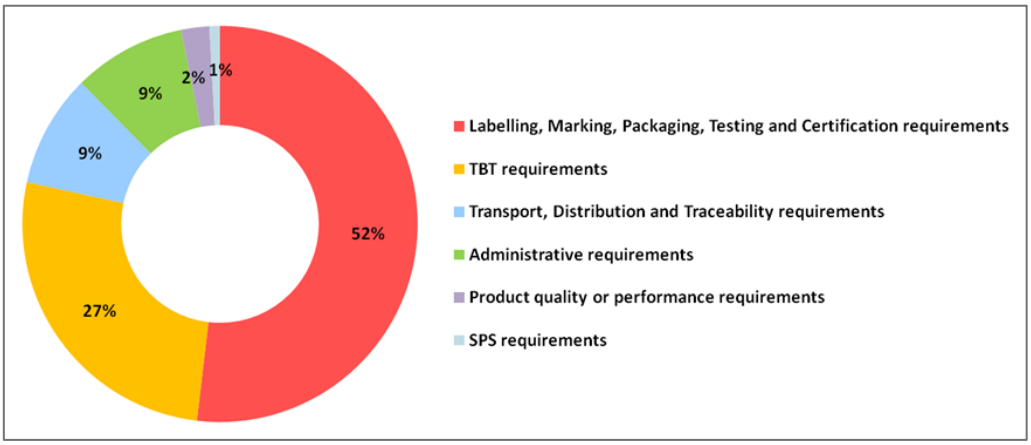
4	293399	33.8	50.9	64	71.9	High	Yes	Yes	IIT	Positive	Modest
5	293622	63.1	65.9	65.2	71.2	High	Yes	Yes	IIT	Negative	Modest
6	293625	57.2	78.8	80.6	77.8	High	No	Yes	Import	Negative	Modest
7	293626	81.3	85.1	90.5	95.1	High	No	Yes	Import	Negative	Modest
8	293627	24.6	52.5	71.8	77.6	High	No	No	Self-reliance	Negative	Modest
9	294190	41.3	68.7	74.1	76.9	High	Yes	Yes	IIT	Negative	Modest
10	294200	34.9	59.2	62.7	71	High	Yes	Yes	IIT	Positive	Modest
Formulation and Vaccines											
1	300220	1.4	3.6	6.9	8.3	Low	Yes	No	Export	Positive	Modest
2	300420	5.3	14.8	11.6	7.4	Low	Yes	No	Export	Positive	High
3	300439	4.1	5.9	7.4	1.6	Low	No	No	Self-reliance	Positive	Modest
4	300450	9.9	11.1	7.4	1.6	Low	Yes	No	Export	Positive	Modest
5	300490	1.6	1.1	3.4	2.3	Low	Yes	No	Export	Positive	Modest
Wearables (Raw Materials)											
1	560311	24.2	25	25.2	27.9	Modest	No	No	Self-reliance	Negative	Modest
2	560312	34.1	35.9	42.1	50.6	High	Yes	No	Export	Positive	High
3	560314	5.3	13.7	27.8	24.2	Modest	No	No	Self-reliance	Negative	High
4	560391	14.3	22.9	40	32	Modest	No	No	Self-reliance	Negative	Low
5	560392	27.4	39.1	35.5	38.8	Modest	No	No	Self-reliance	Negative	Modest
6	560393	19.3	35.5	33	35.2	Modest	No	No	Self-reliance	Negative	Modest
7	560394	16.2	41.5	34.8	42.3	High	No	Yes	Import	Negative	Modest
Medical and Non-medical wearables (Final Products)											
1	392690	7	18.9	30.6	34.3	Modest	No	No	Self-reliance	Negative	Modest
2	401511	1.8	3.4	2.5	1.3	Low	Yes	No	Export	Positive	Low
3	621790	18.6	33.2	43.9	58.1	High	No	No	Self-reliance	Positive	Modest
4	630790	74.1	57.4	38.2	55.8	High	Yes	No	Export	Positive	Modest
5	901850	0.7	3.5	6.4	8.4	Low	No	Yes	Import	Negative	Modest
Disinfectants and sterilisation products											
1	300215	-	-	-	0.1	Low	No	No	Self-reliance	Negative	Modest
2	380894	-	0.1	4.9	1.7	Low	No	No	Self-reliance	Positive	Modest
3	701010	5.7	62.3	80.3	88.3	High	Yes	Yes	IIT	Positive	Modest
4	701090	9.4	16.2	24.7	41.9	High	Yes	No	Export	Positive	Modest
5	841990	3	14.6	23	29.9	Modest	No	No	Self-reliance	Negative	Modest
Medical Devices and Equipment											
1	841920	0.8	8.5	13.3	12.1	Modest	No	Yes	Import	Negative	Modest
2	901811	1.4	8.7	60.7	47.4	High	Yes	No	Export	Positive	Modest
3	901812	3.8	10.5	23.2	24.6	Modest	No	Yes	Import	Negative	Low
4	901819	2	6.3	16.6	23.7	Modest	No	No	Self-reliance	Positive	Modest
5	901839	1.6	4.3	8.7	8.4	Low	No	No	Self-reliance	Positive	Modest
6	901890	1.5	5.3	10.6	14.3	Low	No	No	Self-reliance	Negative	Modest
7	901920	1	7.8	16.9	22.2	Modest	No	No	Self-reliance	Negative	Modest
8	902000	10	5.9	6.7	12.1	Low	No	No	Self-reliance	Negative	Modest
9	902212	17.5	19	31.7	40.6	High	No	Yes	Import	Negative	Modest

Source: Computed by authors from Trade Map data

From the perspective of tariff protection, interestingly, India adopts a defensive standpoint for several product categories, irrespective of the RCA and RCDA results. The defensive policy intervention in India towards pharma products can be linked to the fact that for many APIs the country is dependent on imports from China (Ahmed et al., 2020). For vaccines and formulation, India imposes a high vaccine tariffs of 10%, vis-à-vis the tariffs of 5% or lower elsewhere. Over 2001-18, the average global tariffs on medicines have fallen from 4.9% to 3.2%. While India has witnessed the biggest decline in average tariffs in percentage terms since 2001; several middle-to-high income countries (e.g. Nigeria, Ghana, Chile, Mongolia, Israel, and Bahrain) have eliminated tariffs over this period (Stevens and Banik, 2020). In addition, although average tariffs have fallen, number of dutiable tariff lines (tariffs coverage ratio) fluctuated in the country. For the pharmaceutical items (HS Code 3004) number of tariff lines increased from 18 in 2001 to 252 in 2018 (Stevens and Banik, 2020).[19]

Finally, Figure 1 reveals that the Indian market is characterized by several NTMs on pharmaceutical imports as well, where the data obtained from Market Access Map is summarized. It is observed that the TBT provisions and regulations on packaging and labelling are quite common across these products, which are crucial for the fight against Covid-19. As the compliance requirements may lead to cost escalation for the imported products, there is considerable scope for entering into mutual recognition agreements (MRAs) involving pharma products for improving public health outcomes.

Figure 1: Distribution of NTMs imposed by India during 2020



Source: Constructed by authors from Market Access Map data

The presence of high tariffs and NTM orientation in India, irrespective of the competitiveness patterns of the products, can be linked to the fact that for many APIs, wearables and other categories the country has a modest-to-high import dependence on China. Although tariffs on the API segment (HS-29) continued to remain high

(relative to the world average), a sharp reduction in trade-weighted average tariffs since 2005 helped the Indian vaccines and formulations manufacturers procure intermediate inputs at a cheaper price. This opportunity to access cheaper raw materials, in turn, helped India to considerably improve trade balance in the vaccines and formulations segment.

5. Conclusion

Given the comparative advantages in the medicine segment, aided by the cost advantages, India aspired to emerge as the vaccine hub of the world in early 2021. The second wave of the Covid-19 crisis however underlined the supply-side challenges and domestic price uncertainties, caused by acute shortage at home. India had to seek patent waivers on COVID-19 related medical products for the duration of the pandemic at the WTO. However, the current analysis reveals that even if India gets an IPR waiver, it is not going to make much difference as most of the leading players are already operating in India. The perception that the inability to get an IPR waiver is going to increase the price is also misleading, as the GOI has decided to make a majority of the COVID-19 vaccines available for its population free of cost. India is also not keen for using the CL provision, a legitimate WTO route, presumably anticipating that such a move may jeopardise in the ongoing negotiating with other COVID-19 vaccine manufacturers, namely, Pfizer and Moderna. Given the non-vaccinated population size and the short-run reliance of the country on foreign pharma corporates, this standpoint is unlikely to change in future.

For easing the domestic supply constraint in short run and enhance export in the medium-to-long runs, India needs to go for a tariff and NTM reforms. Despite a series of reforms, tariffs on medicines, vaccines and formulations, and other COVID-19 related medical items in India still remain high vis-à-vis global average, with the number of dutiable tariff lines in these categories increasing over 2001-19 period. Given that the majority of the patients in India have to pay out of their pockets for healthcare, these tariffs and NTMs, take a higher proportion of income from the poor than those higher up the income scale. Rather than seeking an IPR waiver India should try to reduce these tariffs and NTMs. With the pandemic continuing, reduction and elimination of tariffs and NTMs are desirable to facilitate smoother availability of medicinal goods in the domestic market and reduce the market price. On the other hand, a reduction in tariffs, by lowering the price of intermediate inputs can help the sector emerge competitively in the world market.

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Annex 1: Description of the products used for the analysis

Active Pharmaceutical Ingredients (APIs)		
Sl. No.	**HS Code**	**Description**
1	293339	Hydroxychloroquine
2	293349	Hydroxychloroquine
3	293359	Acyclovir, Piperazine Anhydrous for Anthelmintic Drugs
4	293399	Hydroxychloroquine
5	293622	Vitamin B1
6	293625	Vitamin B6
7	293626	Vitamin B12
8	293627	Vitamin C
9	294190	Neomycin, Rifampicin and Clindamycin Salts
10	294200	Diloxanide furoate, Cimetidine, Oxyclozanide, Famotidine, Ornidazole, etc.
Formulation and Vaccines		
Sl. No.	**HS Code**	**Description**
1	300220	All vaccines for human medicine, includingCOVID-19 vaccines
2	300420	Formulations made of Chloramphenicol, Erythromycin and Clindamycin Salts
3	300439	Formulations made of Progesterone, Oestogen, etc.
4	300450	Formulations made of Vitamin B1, B6, B12, Others Amino Acid / Protein preparations with or without Vitamins, Spirulina, etc.

5	300490	Formulations made of Neomycin, Ornidazole, Metronidazole, Tinidazole, Acyclovir, Paracetamol, Amphotericin B, Amphotericin B (Liposomal), Hydroxychloroquine, Flourate/Furazolidone/Antibacterial, Anthelmintic, Tocilizumab, etc., Antibacterial formulations, not elsewhere specified or included
Wearables (Raw Materials)		
Sl. No.	**HS Code**	**Description**
1	560311	Non-Woven Fabrics other than 25-70 GSM
2	560312	Non-Woven Fabrics of 25-70 GSM
3	560314	Non-Woven Fabrics other than 25-70 GSM
4	560391	Non-Woven Fabrics other than 25-70 GSM
5	560392	Non-Woven Fabrics of 25-70 GSM
6	560393	Non-Woven Fabrics other than 25-70 GSM
7	560394	Non-Woven Fabrics other than 25-70 GSM
Medical and Non-medical wearables (Final Products)		
Sl. No.	**HS Code**	**Description**
1	392690	Medical Coverall (PPE Kits), Nitrile / NBR Gloves
2	401511	Surgical rubber or medical examination rubber gloves
3	621790	Medical Coverall (PPE Kits), N 95 Masks, Medical Coverall (PPE Kits),
4	630790	Non-Medical Coverall (PPE Kits), Face Shields, N 95 Mask
5	901850	Medical Coverall (PPE Kits)
Supporting Framework (Medical Test kits/ Instruments, apparatus used in Diagnostic Testing		

Sl. No.	HS Code	Description
1	300215	COVID-19 Test kits (Blood, antisera, vaccines, toxins and cultures, Swabs)
2	380894	Alcohol-based hand sanitiser and other disinfectant preparations
3	701010	Glass containers for vaccines
4	701090	Glass containers for vaccines
5	841990	15 ml Falcon tube or Cryovials
Disinfectants and sterilisation products		
Sl. No.	**HS Code**	**Description**
1	300400	Alcohol based Sanitizers
2	300491	Hand Sanitiser
3	340130	Dettol Hand Sanitizers
4	340200	Ultra-moisturizing instant hand sanitizers
5	380894	Alcohol-based hand sanitiser
Medical devices and equipment		
Sl. No.	**HS Code**	**Description**
1	841920	Machinery, plant or laboratory equipment (Autoclave)
2	901811	Electrocardiograph
3	901812	Ultrasound machines
4	901819	Multiparametric Patient Monitoring devices/Pulse oximeters
5	901839	Medical and surgical instruments and apparatus
6	901890	Intubation kit

7	901920	Ventilators, Oxygen humidifiers / Flow Splitter/CPAP/BIPAP/Oxygen concentrators, Oxygen Therapy, medical ventilators (artificial respiration apparatus)
8	902000	Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts
9	902212	Medical and surgical instruments and apparatus (CT Scanners)

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