COMMENTARY ON INDIA'S

ECONOMY AND SOCIETY SERIES

21

THE ROLE OF INDUSTRIAL POLICY IN MARKET-FRIENDLY ECONOMIES

Case of COVID-19 vaccine R&D and its manufacturing in India and the USA

Sunil Mani

CDS
Thiruvananthapuram

India's Economy and indeed its society has been undergoing a major change since the onset of economic reforms in 1991. Overall growth rate of the economy has increased, the economy is getting increasingly integrated with the rest of the world and public policies are now becoming very specific compared over arching framework policies of the pre-reform period. Over the past few years, a number of important policies have been enunciated, like for instance the policy on moving towards a cashless economy to evolving a common market in the country through the introduction of a Goods and Services Tax. Issues are becoming complex and the empirical basis difficult to decipher. For instance the use of payroll data to understand growth in employment, origin-destination passenger data from railways to understand internal migration, Goods and Services Tax Network data to understand interstate trade. Further, new technologies such as Artificial Intelligence, Robotics and Block Chain are likely to change how manufacturing and services are going to be organised. The series under the "Commentary on India's Economy and Society" is expected to demystify the debates that are currently taking place in the country so that it contributes to an informed conversation on these topics. The topics for discussion are chosen by individual members of the faculty, but they are all on issues that are current but continuing in nature. The pieces are well researched, engages itself sufficiently with the literature on the issue discussed and has been publicly presented in the form of a seminar at the Centre. In this way, the series complements our "Working Paper Series".

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COMMENTARY ON INDIA'S ECONOMY AND SOCIETY SERIES – 21

The role of industrial policy in market-friendly economies

Case of COVID-19 vaccine R&D and its manufacturing in India and the USA[*]

Sunil Mani

CENTRE FOR DEVELOPMENT STUDIES
(Under the aegis of Govt. of Kerala & Indian Council of Social Science Research)
Thiruvananthapuram, Kerala, India

July 2021

[*]I am grateful to the comments received during an online seminar at CDS on July 2, 2021. The usual disclaimer holds good.

Abstract

Given the public good characteristics of new technologies and especially those contributing to improved health, there is a strong case for state support for R&D and indeed for converting those research results to commercialise products and processes. The state support to the market is even more vital in developing vaccines for the pandemic COVID-19, which has engulfed the whole world and has shattered the economies of countries and lives of ordinary citizens. The paper analyses how the state and the market have responded to the development of vaccines for this pandemic in two countries, India and the USA. India is chosen as it is one of the leading manufacturers of low-cost vaccines, and the USA is selected as it is the top country where systematic R&D on vaccines is carried out. Once again, the analysis drives home the strong case of state support to the market in developing crucial technologies and making them affordable so that a large section of the society can afford them. This is because new technologies also have natural monopoly characteristics as well. Furthermore, it underlines the importance of invoking industrial policy instruments to support R&D and manufacturing activities by the market. The case of vaccine R&D and manufacturing has given one more shot in the arm of industrial policy, the case for which had been renewed since the global financial crisis.

Keywords: COVID-19, coronavirus, vaccine, R&D, patents, advanced market commitment, technology transfer, industrial policy, India

JEL Classification: L52, O31, O32, 034, and O38

Introduction:

The 1990s saw a systematic paring down of industrial policy instruments, especially in the manufacturing sectors of several developing economies. The Indian economy was one of the major ones to embrace this change to a more market-friendly environment for investments in manufacturing. Despite this newfound euphoria for markets to be at the commanding heights of an economy, knowledge production characterised by well-known market failures was sought to be supported by the state, providing various sorts of even financial subsidies. However, the 2008-2009 global financial crisis showed that markets were not necessarily efficient. Indeed, there was a broad consensus that without decisive state intervention -- which included providing lifelines to specific firms and certain industries -- the market economies of the United States and Europe may have collapsed. A similar situation arose in 2020 with the onset of a devastating pandemic, which has affected the whole world so adversely that even the economies and societies of some of the wealthiest economies are affected. Life and economic activity have become very uncertain. The only credible solution to this crisis of unimaginable proportions is the invention and commercial production of vaccines for COVID-19. According to some estimates, about 290 R&D projects are in development across the world (WHO, 2021). Among all the countries, including India, where such action was being pursued on a feverish pitch, the USA was the first country to develop and commercialise a very highly effective and safe vaccine and that too using a hitherto not tried out new messenger RNA technology. The world had placed a relatively high optimism on India as one of the most credible sources of vaccine supply to an international partnership of donors, the COVAX, to distribute vaccines, especially to other developing countries. However, India has not successfully used its large installed capacity and considerable technological capability to manufacture and distribute vaccines in general and leverage this capability to make and diffuse COVID-19 vaccines in particular. Based on an analysis of the relevant data on the support to the market by the state for vaccine development and diffusion, we demonstrate in this paper that the contrasting experiences of two leading vaccine manufacturers could be attributed to how both countries have used industrial policy to drive vaccine development and production. The USA, which is characterised as a free market economy, did not hesitate to dust up and employ various industrial policy instruments gainfully. India, on the contrary, an economy long characterised by an extreme form of state control of economic activity, hesitated to intervene until at last fatality rates started mounting, leading even to the Supreme Court of the country to intervene, *suo moto*, and direct the authorities to put in place an effective vaccination policy. Finally, the Prime Minister announced an amended vaccine policy on the 7th of June 2021, outlining a more significant role by the state in vaccine production and distribution (Press Information Bureau, 2021). The paper thus makes out a strong case for industrial policy even in market-friendly economies and therefore adds to the renewed debate on industrial policy.

The paper is structured into five sections. Section 1 undertakes a brief survey of the renewed debate on the role of industrial policy the rationale for active intervention by the state in knowledge production. The second section discusses the two main research questions the paper seeks to unravel. It also maps out the current status of the landscape for coronavirus vaccine research and production and the rationale for selecting the two cases of the USA and India. The third section discusses how the USA government has intervened to strengthen the capacity of its market to produce vaccines. Likewise, the fourth section discusses the Indian case. Finally, the fifth section distils out the contrasts between the USA and Indian approaches of market strengthening by their respective federal governments and concludes the paper.

1. Renewed debate on the role of Industrial policy

Most economies of the world had used some instrument of industrial policy for growing their domestic manufacturing industry, especially in their catch-up phase. These industrial policy instruments manifested themselves in several ways. For example, India's licensing policy

gives preferential credit to new domestic ventures at subsidised interest rates, reserving specific industrial sectors exclusively for public sector enterprises and the small and medium scale sector. However, there was disenchantment with any form of state intervention in general. It was thought to encourage inefficiency and sloth, leading to suboptimal allocation of resources in some cases. This line of thinking culminated in the move towards economic liberalisation and privatisation in the 1990S across especially in the developing world, where the private sector soon began to replace state-owned enterprises as the commanding heights of the economy. The standard argument was that markets were efficient, so there was no need for the state to intervene either in the allocation of resources across sectors or in the choices of technique and even if markets were not efficient, governments were not likely to improve matters (Stiglitz, Lin, and Monga, 2013). According to Stiglitz, Lin and Monga (2013), the 2008-2009 global financial crisis dented one's faith in the efficiency of markets. Of course, before this, Cimoli, Dosi and Stiglitz (2009) had already rekindled this interest in the role of industrial policy in governing markets. Their study analyzed the impact of a collection of industrial policies, including those affecting the accumulation of technological knowledge, institutions supporting scientific and technological learning, competition and intellectual property rights, and trade policies.

Further, there was a broad consensus that without decisive state intervention -- which included providing lifelines to specific firms and certain industries -- the market economies of the United States and Europe may have even collapsed. This has led to a renewed debate on the necessity of having industrial policy even in so-called predominantly market-oriented economies (Lin, 2014). A systematic reading of literature reveals two broad strands of literature. The first one deals with government intervention to correct market failures in general. This literature questions the pervasive belief that market failures are exceptional, and there is a presumption of preference for free markets (Coyle, 2021). However, it is also a fact that the concept of efficiency is a fuzzy one difficult to be defined precisely in practical terms.

On the contrary, government intervention to correct market failures in having targeted industrial policies is also problematic. Very often, the industries targeted are not consistent with the comparative advantage of the country in question (Lin, 2014). Thus, the second strand in the literature that is more relevant for our purpose is dealing with the rationale for industrial and innovation policies for dealing with market failures in new technologies. Given the uncertainty of the potential returns to further knowledge, and given that exclusion is hard to enforce even with patents in place, Arrow (1962) and Nelson (1959) had demonstrated way back in the early 1960s that profit-oriented firms in a free market economy would tend to under-invest in R&D. Accordingly, both of them saw a clear case for public investment in the production of knowledge, such as the funding programs overseen by the U.S. Defence Advanced Research Projects Agency, the National Institutes of Health, and the National Science Foundation etc. Thus, there is a role for the state in the market economy as both an 'investor' and an 'insurer' (Aghion, Antonin, and Bunel, 2021). These arguments favouring state support for the market make eminent sense in vaccines for COVID-19 as the R&D in developing new vaccine technologies require enormous capital investments, especially at the testing phase.

Further, these R&D projects are characterised by high failure rates. Therefore, firms will require considerable capital subsidies and other forms of market interventions such as advanced market commitments[1] . The reluctant firms are encouraged to commit themselves to evolve new vaccines.

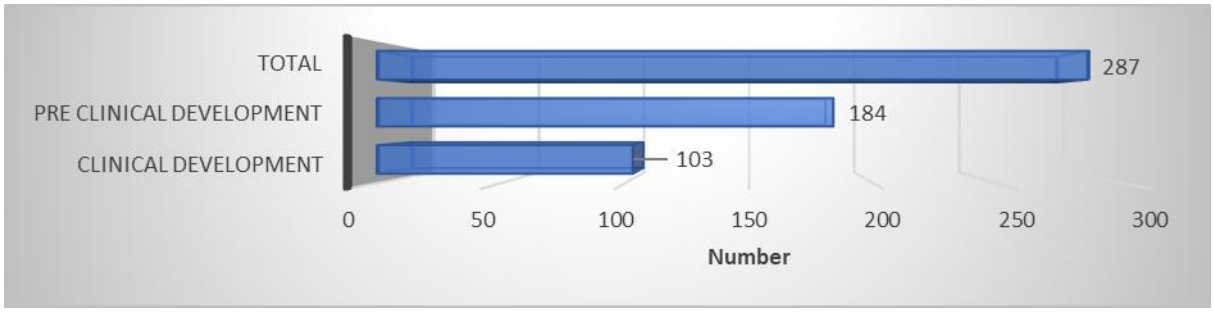
[1] According to the WHO, Advance Market Commitment for vaccines (AMC) is an innovative funding mechanism to incentivize vaccine makers to produce suitable and affordable vaccines needed especially in low-income countries. In an AMC, donors or governments commit funds to guarantee the price of vaccines once they have been developed. These financial commitments provide vaccine manufacturers with the incentive they need to invest in vaccine research and development, and to expand manufacturing capacity.

COVID-19 has once again prompted many free-market economies to dust up and use various public innovation and industrial policies to promote R&D and manufacture vaccines precisely. According to the WHO (2021), there are 287 vaccine R&D projects across ten different platforms in various countries (Figure 1). The USA, by far, has the most significant number of successful instances of technology development and its diffusion. The role being played by multiple state agencies towards vaccine development could fall into one or all of the following four categories. See Table 1.

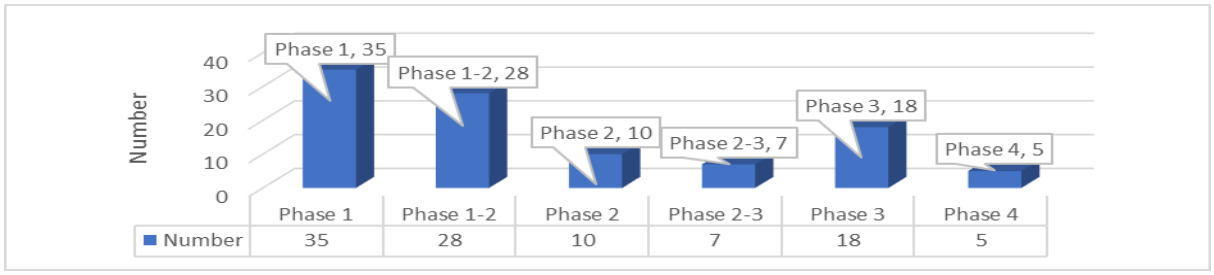
Table 1: The four roles which government may adopt for the development of COVID-19 vaccines

Roles	Instrument of support
1. As the lead customer	Public technology procurement
2. Reducing the risk of innovation by co-funding it	Direct funding of R&D through research grants, Advanced market commitments
3. Collaboration on R&D to support innovation	Joint R&D programmes with government research institutes
4. Using standards or regulations	Patent Policy, Regulatory policies for the use of drugs etc

Source: Mani (2002), Boghani and Jonash (1993)

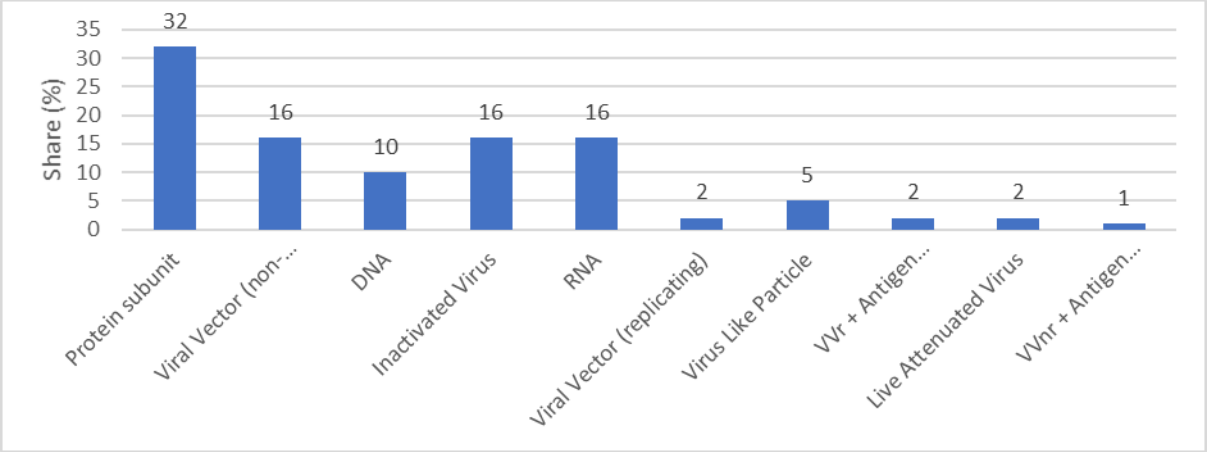


Total vaccine projects according to clinical or pre-clinical phase



Vaccine projects in the clinical phase- according to the testing phase

In exchange, companies sign a legally-binding commitment to provide the vaccines at a price affordable to developing countries in the long term. See WHO, Htts://www.who.int/immunization/newsroom/amcs/en/



Vaccines projects in clinical phase- according to platforms

Figure 1: Leading Vaccine R&D projects worldwide (as of the 22nd of June, 2021)

Source: WHO (2021)

In short, the coronavirus pandemic has shown the whole world that 'small governments can have big failures'. Therefore, the most credible way for economies battered by the coronavirus to return to some semblance of normality is by their governments intervening in vaccine production and distribution. Thus, the herd immunity required for opening the economies can be reached within the foreseeable future. This is the theme explored in detail in the present study. The contrasting experiences of the two countries, the USA and India, have attempted to develop vaccine technology by employing industrial policy instruments in varying degrees. The USA has traditionally believed in small governments, although it had always believed a vital role for the government as far as knowledge production is concerned (Mani, 2002, Bernanke, 2011).

2. Main research questions, the significance of the issues and rationale for the choice of the two causes

In this section, we spell out the main research questions that we seek to answer, the significance of those questions, and the rationale for choosing the two countries in two different stages of overall development and technological capability.

2.1 Research questions

The primary question that this paper is seeking to answer is to examine the role of industrial policy in so-called market-friendly economies. These economies are characterised by a systematic reduction in the discretionary part of governments concerning economic matters and promoting privatisation. Despite being wedded to free-market ideas; we argue that the USA has not hesitated to use industrial policy instruments of various sorts to strengthen the capacity of its private sector actors. We do this by examining the role that industrial policy instruments have facilitated the USA to successfully develop very highly effective vaccines for COVD-19 within a record period of eight months as against the usual period of several years (Figure 2). The quality and quantity of this intervention explain the USA's success in COVID-19 vaccine R&D and its production. The paper will map out the range of policy instruments the federal government in the USA has employed.

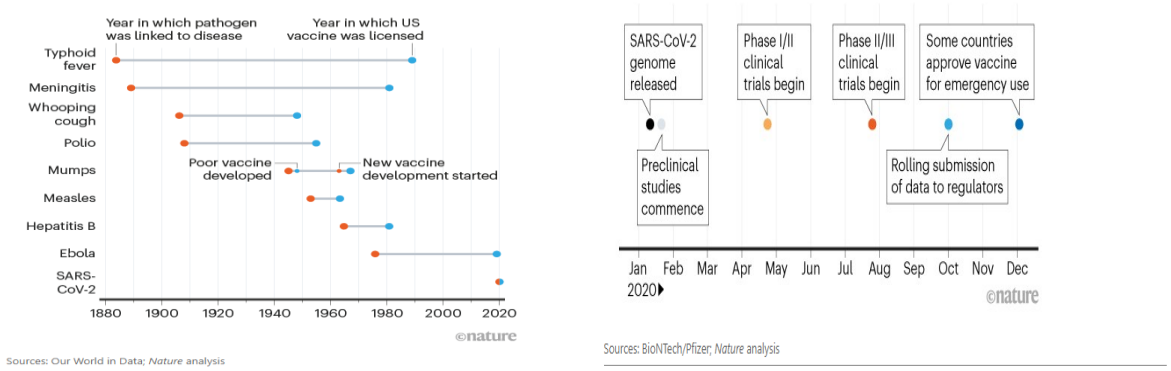


Figure 2: Time lags in vaccine development: COVID-19 vaccines vs all the rest

Source: Adapted from Ball (2020)

The second question that is dealt with in the paper is India's vaccine R&D and manufacturing performance. Although India has a long history of developing technological capability in vaccine research, manufacturing, and distribution, India is yet to emerge as a significant manufacturer of COVID-19 vaccines. However, it has a large installed capacity for manufacturing different kinds of vaccines. At least one domestic firm is rated as a significant low-cost manufacturer even in the world[2]. Further, it has one of the most extensive immunisation programmes globally and has the considerable institutional capacity to deliver this service very efficiently. The country also has a long history of using industrial policy instruments very successfully, especially for growing a range of high technology industries such as therapeutic drugs and aerospace (Chaudhuri, 2013, Mani, 2018). Chaudhuri (2013) showed that those industries such as the drugs and pharmaceuticals, which were supported through explicit industrial policy instruments, experienced positive trade balance even the economy was opened up. Imports were allowed compared to those like the telecommunications equipment industry, where government intervention was weakened or was substantially reduced. Despite all these positive aspects, the country has not been successful in emerging as a significant manufacturer of COVID-19, and its vaccination programme has floundered, leading to the Supreme Court intervening through a *suo moto* writ petition (Supreme Court of India, 2021). The paper will analyse how India has used various industrial policy instruments to affect domestic vaccine production.

2.2 Significance

The two questions are highly significant as the large scale vaccination is the only route to returning to normality. Other countries and especially the developing countries, are looking up to India for their vaccine supplies. In this way, the analysis of the two cases will present us with a range of convenient policy options for increasing vaccine production globally.

2.3 Rationale for the country cases

The following factors dictated our choice of the two country cases:

[2] Serum Institute of India, is the largest one in India and it produces the largest volume of vaccines and has the largest geographic scope vaccine manufacturers in India, with a relatively large pipeline, portfolio and revenue. Many of the vaccines it produces are for diseases recommended by WHO for routine immunisation for children. See Access to Medicine Foundation (2017). Also see Jadhav, Gautam and Gairola (2014)

(i) Both are prominent manufacturers of COVID-19 vaccines and exporters of different types of vaccines (as exports of COVID-19 vaccines are not easily available for the present). See Figures 3a and 3b.

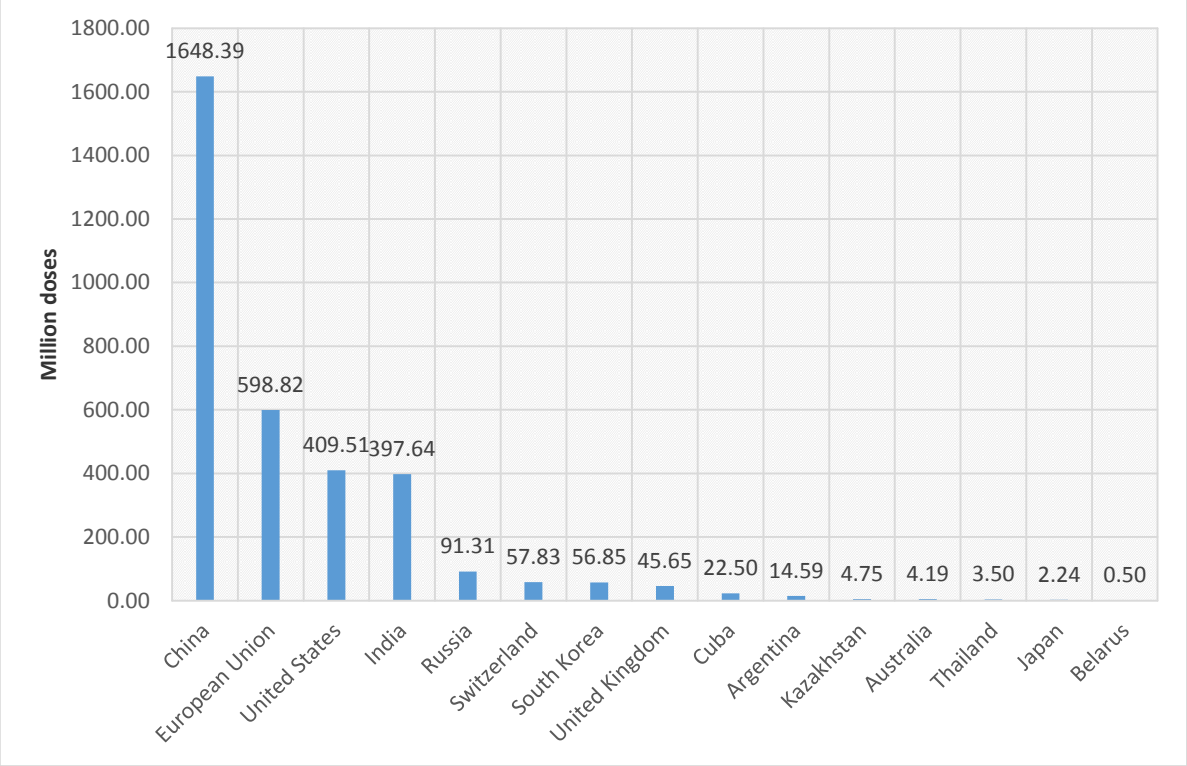


Figure 3a: Cumulative production of COVID-19 vaccines, November 2020-June 2021

Source: Global Commission for Post-Pandemic Policy (2021)

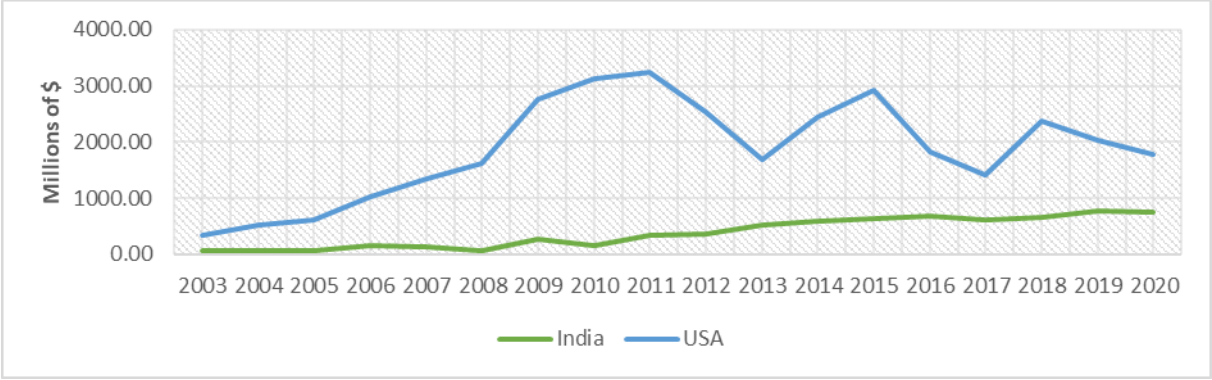


Figure 3b: Exports of vaccines from the USA and India (Millions of U.S. $)

Source: Extracted from U.N. Comtrade

(ii) The USA has a robust public R&D system in the form of the National Institutes of Health (NIH). It also has some of the major vaccine manufacturers in the world, such as Pfizer, Johnson&Johnson etc.,

(iii) India is well known as a low-cost manufacturer of vaccines and has one of the largest vaccine manufacturers in the world in terms of doses. Its total installed capacity for manufacturing different kinds of vaccines is about 8.15 billion doses per annum

(iv) Both countries have the highest caseloads and mortality figures due to COVID-19

2.4 Hypothesis

We hypothesise that the USA used industrial policy instruments much more in terms of its quality and quantity. In contrast, India has used such instruments sparingly and in an unstructured manner. The much better performance of the USA in vaccine R&D and its manufacture could be attributed to this rather generous usage of industrial policy instruments. Differences in income alone cannot explain this differential performance as the European Union countries and Japan have not done well on this front.

3. The case of the USA

The Chinese scientists sequenced the viral genome of SARS- CoV-2 on the 11th of January, 2020 and shared it with the WHO and other countries[3]. The worldwide R&D effort in finding a suitable vaccine candidate for dealing with COVID-19 commenced immediately afterwards. As seen in Figure 1 above, of the three vaccines authorised initially, two were from the USA. Table 2 summarises the main features of these vaccines.

Table 2: Leading Vaccine manufacturers for COVID-19

Vaccine manufacturer	Country	Platform	Number of countries where the vaccine is used	Timeline
Pfizer/BionNTech	USA	mRNA	105	TS: 24/04/20 TR: 09/11/20 EUA: 11/12/20
Moderna	USA	mRNA	55	T.S.: 27/07/20 T.R.: 30/11/20 EUA: 18/12/20
Oxford-AstraZeneca	The U.K.	Viral Vector (Non replicating)	178	T.S.: 28/08/20 T.R.: 23/11/20 EUA: 30/12/20
Johnson&Johnson	USA	Viral Vector (Non replicating)	27	T.S.: 07/09/20 T.R.: 29/01/21 EUA: 27/02/21
Sputnik V	Russia	Adenoviral vector	45	TS: 07/09/20 EUA: 23/12/20
Sinovac	China	Inactivated	32	T.S.: 21/07/20 EUA: 07/02/21
Sinopharm	China	Inactivated	40	July 2020 EUA: 31/12/20
Bharat Biotech	India	Inactivated	6	T.S: 20/06/20 T.R" 21/04/21 EUA: 03/01/21

Notes: T.S.: Trial Start, T.R.: Trial Result, EUA: Emergency Use Authorisation

Sources: Compiled from New York Times Vaccine Tracker, Bloomberg Vaccine Tracker

[3] See Xinhuanet (2020)

The USA is one of those countries where several government agencies, both at the federal and state levels, have supported medical R&D (Annexure 1). The federal government in the USA has used a variety of instruments to support both R&D on coronavirus vaccines and their eventual manufacture. These instruments are (i) strong support for basic research on vaccines for coronavirus in federal government laboratories; (ii) legislative changes to provide emergency support for vaccine development; (iii) enhancement of the institutional support for vaccine development by establishing new institutional arrangements specifically for vaccine development and by invoking old arrangements; (iv) provision of substantial financial support to vaccine manufacturers. These are discussed now in some detail.

3.1 Strong support for basic and applied development R&D for vaccines

One of the most exciting aspects of vaccine development was the development and commercialisation of very highly effective vaccines by the two USA manufacturers Pfizer-BioNTech and Moderna, and one U.K. manufacturer, Oxford- AstraZeneca, at a fraction of time compared to the usual time for vaccine development (See Figure 2 and Table 3). Several factors are supposed to have contributed to this. Most Scientific research is cumulative and path-dependent. *Standing on the shoulders of giants* is the commonly accepted metaphor to characterise scientific research. Previous vaccine research on coronaviruses like Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) helped researchers know where to begin and also advanced development of different types of vaccine approaches or platforms—which serve as a type of "template" for scientists to use in creating new vaccines. The former two companies were also the first to develop a vaccine for which a EUA was secured and use a new mRNA platform. The mRNA platform is considered a superior one for vaccines for two reasons (Jackson, Kester, Casimiro, et al., 2020). First, they are faster to design from the get-go to begin testing, which sped up the process to some degree. Second, they are easily scalable in terms of their manufacturing[4]. Both these traits are advantageous in vaccine development for COVID-19, where time and rapid manufacturing of billions of doses of the vaccine is the essence.

A narration of the cases of these two sets of firms will bring out the fact that they were able to develop the vaccines in record time as they were able to piggyback on fundamental research on newer types of vaccines that were going on at the National Institutes of Health (NIH) for many years. The vaccines made by Pfizer and Moderna, the first two companies to secure a EUA from the FDA, in particular, relied heavily on basic research on messenger RNA (mRNA) that emerged from two federally funded research:

(i) the viral protein designed by Dr Barney Graham and his colleagues at the Chief, Viral Pathogenesis Laboratory National Institute of Allergy and Infectious Diseases (NIAID}; and
(ii) the concept of RNA modification, first developed by Professor Drew Weissman and Katalin Kariko at the University of Pennsylvania.

The two scientists were working on this concept together as a team since 1997. Professor Katalin Kariko subsequently left the University of Pennsylvania and joined BioNTech (See Box 1). Needless to add, her presence at the firm must have significantly helped the firm familiarise itself with this new vaccine development technology.

[4] Recently (June 28, 2021) it was disclosed that the Pfizer-BioNTech and Moderna mRNAvaccines are likely to provide lifetime immunity to those who are vaccinated with these vaccines. See Mandavilli (2021).

A detailed network analysis of the patents for mRNA by Gaviria and Kilic (2021) reveals the following:

- The University of Pennsylvania exclusively licensed certain mRNA patents and applications to a company called CellScript and its affiliate, mRNA RiboTherapeutics, on the 20th of December, 2016. CellScript further entered into non-exclusive, worldwide sublicenses with Moderna[5] on the 26th of June, 2017 and with BioNTech on the 14th of July, 2017[6]. Although the patent and application numbers are censored, the Moderna sublicense agreement does explain that they relate to "technology which the two professors, Drew Weissman and Katalin Kariko, of the University of Pennsylvania developed.

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- The United States government-funded and has certain rights over at least some of the foundational Karikó and Weissman patents directed to mRNA discoveries.

Box 1: Press release from BioNTech announcing the joining of Professor Katalin Kariko

BIONTECH

PRESS RELEASE

Prof. Dr. Katalin Karikó Joins BioNTech Group

Mainz, Germany, February 2, 2014 – We are very proud to welcome Prof. Dr. Katalin Karikó at BioNTech.

Katalin Karikó leads the mRNA-based protein replacement program for BioNTech RNA Pharmaceuticals. She has more than 30 years of experience working with RNA. Prior to joining BioNTech RNA Pharmaceuticals, Dr. Karikó was on the faculty at the University of Pennsylvania Medical School for 25 years. There she investigated RNA-mediated immune activation and in a groundbreaking research she discovered that nucleoside modifications suppress immunogenicity of RNA. In 2006, she co-founded and served as CEO of RNARx. With the support of NIH, her team demonstrated in animals, including macaques the feasibility of using nucleoside-modified mRNA for protein replacement, thus opening a new field of therapy. She published more than 60 peer-reviewed papers and reviews many of them focusing on mRNA technologies. Dr. Karikó is co-inventor on mRNA-related patents, including the one awarded for RNA containing modified nucleosides.

Source:https://biontech.de/sites/default/files/2019-08/20140202_BioNTech_Katalin%20Kariko_ENG_final.pdf

It is seen that the firms Moderna, BioNTech, CureVac and GSK together own nearly half of the mRNA vaccine patent applications. Further, it is also noticed that the R&D that resulted in these patent applications were funded and in collaboration with federal laboratories and therefore can attract the provisions of the Bayh-Dole Act whereby federal agencies can license the basic research done by them to private sector firms who assume the entire risk of developing and commercialising these technologies. As seen from our subsequent discussion, the federal government has taken away even these risks from private sector companies by funding the R&D underlying the technology and providing advanced market commitments. In short, it is the strong support for basic and applied development research provided by the

[5] U.S Securities and Exchange Commission, https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473dex108.htm

[6] U.S Securities and Exchange Commission https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1015.htm

U.S. state that has resulted in the American firms swiftly releasing a highly effective and indeed safe vaccine for COVID-19.

But there have been some contrary views on the IPRs for these vaccines being licensed to the private firms in the USA. The NIH usually funds drug research and often invents essential scientific technologies later licensed and incorporated into drugs sold at massive profits by private sector firms. The NIH rarely claims ownership stakes or pursues patent rights, but that appears different from this coronavirus vaccine, apparently pursuing patent rights (Herman, 2020). On the contrary, one of the two firms, Moderna, has made a patent pledge that it will not impose its numerous patents for the coronavirus vaccine and will even licence it to other companies. See Box 2. However, some scepticism as usually patent pledges is taken as a public relations gimmick to build a company's reputation. However, rigorous empirical research by Ehrensperger and Tietze (2019) show that "driving technology diffusion and ecosystem and infrastructure building" is indeed the primary motive and confirms what the existing literature has suggested. However, it is also a fact that vaccine technology is complicated to be reverse engineered, unlike those in therapeutics. Once again, I will pick up this issue when I discuss I.P. suspension for vaccines that India and South Africa have been demanding.

According to Sachs (2021), the vaccine is a scientific success. It serves as a reminder that many of America's most significant technological breakthroughs result from collaborations between the market (private sector) and the state (federal government). In her book, *the Entrepreneurial State*, Mazzucato (2013) showed us convincingly that many new technologies ranging from the Internet to microwave ovens resulted from research done by scientific agencies in the federal government.

Box 2: A patent pledge by Moderna

As a company committed to innovation, Moderna recognises that intellectual property rights play an essential role in encouraging investment in research. Our intellectual property portfolio is an important asset that will protect and enhance our ability to continue to invest in innovative medicines.

Beyond Moderna's vaccine, other COVID-19 vaccines in development may use Moderna-patented technologies. However, we feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived I.P. barriers to vaccine development during the pandemic period, upon request, we are also willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period.

Moderna is proud that its mRNA technology is poised to be used to help end the current pandemic.

Source: Moderna website: https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

3.2 Legislative changes to provide emergency support

Despite some criticism for its dilatoriness on the government's part to respond to the COVID-19 catastrophe, the federal government was swift to respond with a piece of legislation known as the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020***.** This Act provided $8.3 billion in emergency funding for federal agencies to respond to the coronavirus outbreak. One of the most critical issues this Act address is developing, manufacturing, and procuring vaccines and other medical supplies. An essential aspect of this legislation was that spending on this was exempted from limits that are on discretionary spending. Of the $8.3 billion, $6.7 billion (81%) is designated for the domestic response and

$1.6 billion (19%) for the international response, and of this $6.7 billion, almost 94 per cent was devoted to health-related issues. The amount set apart for vaccine research and purchase was $2.3 billion- or 28 per cent of the total. This shows the extreme importance given by the federal government for vaccine development, although the amounts were mainly going to private sector enterprises.

3.3 Enhancement of the institutional support for vaccine development

There are essentially two components to this institutional support for vaccine development: First, setting up a specialised agency known as Operation Warp Speed (OWS). The second one was using the Defence Production Act to speed up its manufacturing within the country essentially. These two are discussed in some detail.

(a) Operation Warp Speed (OWS)

The programme was announced on the 15th of May, 2020, as part of the vaccine developed by the federal government. It is a partnership between public-private partnership like the Manhattan Project during the Second World War. The government agencies involved in OWS were the Department of Defence (DOD) and the Department of Health and Human Services (HHS). As stated on the HHS website, the goal was to produce 300 million doses of COVID-19 vaccines, with initial amounts available by January 2021. The HHS has obligated approximately $13 billion as of the 31st of December, 2020, to support the development, manufacture, and distribution of vaccines alone. To help achieve the goal, OWS supported multiple vaccine candidates to mitigate uncertainties associated with the safety or efficacy of developing just one or two vaccine candidates. The programme selected six manufacturers using three different platforms. See Table 3

Table 3: Vaccine manufacturers selected for sponsoring under the OWS

Vaccine platform	Vaccine manufacturers
mRNA	• Moderna (phase 3) • Pfizer/BioNTech phase 3)
Replication –defect- live- vector platform	• Janssen (phase 3) • AstraZeneca (phase 3)
Recombinant-subunit-adjuvanted protein platform	• Sanofi/GSK (phase ½) • Novavax (phase 1)

Source: Government Accountability Office (2020)

One of the tangible effects of the OWS has been a significant reduction in the timeline to develop vaccines. This used to be ten years or longer earlier, but now it has been brought down to just ten months. No doubt it is also since considerable basic research in developing vaccines for coronaviruses was already underway at the NIH (as discussed above), and the scientists at the NIH and some of the firms could also work together, due to the OWS, shortening the development time considerably. Further, according to Government Accountability Office, GAO (2020), the OWS addressed and solved three critical constraints to the speedy manufacturing of a voluminous dose of vaccines.

- **Limited manufacturing capacity**: Some companies are working on expanding production capacity. Biomedical Advanced Research and Development Authority (BARDA) helped them identify an additional manufacturing partner to increase their vaccine production. The U.S. Army Corps of Engineers is also overseeing construction projects to expand capacity at vaccine manufacturing facilities.

- **Disruptions to manufacturing supply chains**: The DOD assisted the companies with expediting procurement and delivery of critical manufacturing equipment. Additionally, officials from BARDA informed that their subject matter experts in developing and manufacturing vaccines worked with each of the six OWS vaccine companies to create a list of critical supply needs common across the six vaccine candidates. To address these essential needs of supply, DOD and HHS officials said that as of December 2020, they had placed prioritised ratings on 18 supply contracts for vaccine companies under the Defense Production Act. Furthermore, OWS officials stated that they have worked with U.S. Customs and Border Protection to expedite necessary equipment and goods coming into the United States.

- **Gaps in the available workforce with specialised skills**: OWS officials stated that they have worked with the Department of State to expedite visa approval supporting the arrival of key technical personnel, including technicians and engineers, to assist with installing, testing, and certifying critical equipment manufactured overseas. OWS officials also stated that they requested that 16 DOD personnel be detailed to serve as quality control staff at two vaccine manufacturing sites until the organisations can hire the required personnel.

The OWS was a sort of innovation in project implementation, although the basic idea for the project came from the Manhattan project of the late 1930s-early 1940s. But what is even more important is that the oversight institutions of the country, such as the GAO, provided the project with constructive suggestions for dealing with some of the constraints that it faced. As a result, through OWS, the U.S. could mobilise its entire vaccine R&D and manufacturing ecosystem. As a result, the country soon emerged to have a safe and effective vaccine for its citizens and the world. The three American vaccine manufacturers together account for about 30 per cent of the total vaccine production globally, although some of their production is done through contract manufacturers in Europe. See Table 4.

(b) Use of the Defence Production Act to facilitate the increase of vaccine production

The Defence Production Act (DPA) was enacted in 1950, and it gives the president of the USA powers to allocate "materials, services, and facilities" and award contracts that take priority over any other contract to "promote the national defence. In the COVID-19 case, the law is being used to defend the country against the virus. However, in extreme situations, the law can also prevent companies from exporting certain goods to keep them within the United States.

Table 4: Distribution of vaccine production by vaccine manufacturers worldwide
(Cumulative production in a million doses during November 2020 through the 30th of June 2021)

Manufacturer \country	China	United States	EU / EFTA	UK	Russia	Kazakhstan	Belarus	India	South Korea	Japan	Thailand	Australia	Argentina	Cuba	Total
Sinovac	905.6	null	null	null	null	null	null	null	null	null	null	null	null	null	905.6
Pfizer/BioNTech	null	222	501.3	null	null	null	null	null	null	null	null	null	null	null	723.3
Beijing/Sinopharm	677.9	null	null	null	null	null	null	null	null	null	null	null	null	null	677.9
University of Oxford/AstraZeneca	56.1	3	75.9	45.7	null	null	null	387.2	56.8	2.2	3.5	4.2	14.6	null	649.2
Moderna	null	161.4	57.8	null	null	null	null	null	null	null	null	null	null	null	219.2
Gamaleya Research Institute	null	null	null	null	88.3	4.7	0.5	null	null	null	null	null	null	null	93.5
J&J	null	23.1	21.7	null	null	null	null	null	null	null	null	null	null	null	44.8
CIGB	null	null	null	null	null	null	null	null	null	null	null	null	null	11.3	11.3
Finlay Vaccine Institute	null	null	null	null	null	null	null	null	null	null	null	null	null	11.3	11.3
Bharat/ICMR/ NIV	null	null	null	null	null	null	null	10.5	null	null	null	null	null	null	10.5
CanSino	5.3	null	null	null	null	null	null	null	null	null	null	null	null	null	5.3
Anhui Zhifei	3.5	null	null	null	null	null	null	null	null	null	null	null	null	null	3.5
VECTOR	null	null	null	null	3	null	null	null	null	null	null	null	null	null	3
RI for Biological Safety Problems	null	null	null	null	null	0.1	null	null	null	null	null	null	null	null	0.1
Total	**1648.4**	**409.5**	**656.7**	**45.7**	**91.3**	**4.8**	**0.5**	**397.7**	**56.8**	**2.2**	**3.5**	**4.2**	**14.6**	**22.6**	**3358.5**

Source: Global Commission for Post-Pandemic Policy (2021)

It has been observed that since the start of the pandemic, the federal government has used the law frequently in the crash programme to develop COVID-19 vaccines. According to the statement made by the then press secretary to the then president, Mr Trump, the DPA was used 18 times to aid vaccine development[7]. The Biden administration continues to use the Act and has even extended the DPA's use in the Pfizer contract, helping the company get equipment to expand its vaccine production. Thus, all six COVID-19 vaccines developed as

[7] https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-123020/

part of OWS have somehow benefited from the DPA[8]. The assistance ranged from help given to acquire equipment and access to scarce supplies and materials. In short, the DPA complemented OWS. This is yet again evidence to show that the USA has not ceased invoking even rarely used industrial policy instruments to jump-start and facilitate vaccine manufacturing.

3.4 Indemnity clauses to vaccine procurement contracts

The Federal government has thoroughly researched and put in place measures to deal with all legal issues that may arise in COVID vaccine development and its deployment (Hickey, Shen and Ward, 2020). This is contained in omnibus legislation called the COVID-19 PREP Act Declaration. The consensus is that so long as this declaration remains in force, COVID-19 vaccine manufacturers, distributors, and qualified health care providers are generally immune from any legal liability for losses relating to the use or administration of that vaccine. Instead, compensation through Counter Measures Injury Compensation Program (CICP) may be available for individuals who suffer Serious Adverse Events (SAE) resulting from receiving a COVID-19 vaccine. This legal remedy frees the vaccine manufacturers from paying compensation for SAEs emanating from vaccine usage and de-risk their manufacturing from substantial compensation payments. In any case, the existence of the CICP route and the fact that the two effective vaccines, both highly effective, have not reported any substantial adverse side effects, places the vaccine user also on a safe footing.

3.5 Financial support to vaccine manufacturers

As has been argued by Arrow (1962), private sector enterprises tend to underinvest in R&D as they fail to appropriate the full returns from their R&D efforts fully. This market failure is very acute in vaccine research, a complex technological activity fraught with severe failure rates and a long gestation period. Testing for the safety and efficacy of the vaccines is long drawn out and is very costly. This calls for direct intervention by the state to provide direct research grants and advance market commitments to the vaccine manufacturers. In light of this, the federal government has put in place two mechanisms. The first one is direct funding of R&D in the in-house R&D centres of vaccine manufacturers. The second one is advance market commitments, where the federal government pre-purchases several doses of the vaccine at pre-determined prices. Such pre-purchase agreements assure a ready market for the new vaccine. Both these financial support mechanisms make the vaccine manufacturers very venturesome in committing themselves to time and effort in this very uncertain project.

(i) R&D funding

The Global Health Centre has been compiling data on public investments in R&D for the COVID-19 vaccine and therapeutics. According to this database, public authorities' total investment (usually the federal/central government) is $ 5.8 billion, with the USA and Germany alone accounting for 63 per cent. Except for the Chinese government sources, none of the other developing or emerging country governments are in the picture. Apart from the public authorities, another 62 million dollars have been committed by philanthropic foundations such as the Gates Foundation. See Table 5

[8] See the Story by Lisa Simunaci, Office of the Secretary of Defence Public Affairs, https://www.dvidshub.net/news/386211/defense-production-act-shot-arm-warp-speeds-mission

Table 5: Public R&D funding for COVID-19 vaccine development
(Millions of USD)

	Public R&D Funding (Millions of USD)	Share (%)
USA	2327	38.80
Germany	1507	25.55
UK	500	8.48
European Union	327	5.54
Canada	283	4.80
Norway	262	4.44
Singapore	250	4.24
Australia	150	2.54
Saudi Arabia	150	2.54
Spain	87	1.47
Netherlands	58	0.98
France	18	0.31
Switzerland	10	0.17
China	8	0.14
Total	5937	100.00

Source: Global Health Centre (2021)

I cannot interpret the size of the R&D investment except that it is money committed just for a few enterprises (See Annexure 2 for a complete profile of public and private R&D in the USA). In addition to these, the companies have been spending their financial resources on R&D, and this data are not available. So the total R&D spending is those expended by the federal government agencies, the philanthropic organisations and those spent by the private sector. The detailed company-wise public and philanthropic funds committed to the COVID-19 vaccine is presented in Table 6.

Table 6: Company-wide public and philanthropic funds committed to R&D for COVID-19 vaccine
(Millions of USD)

	R&D Funding	Share (%)
Janssen	995.85	42.80
Moderna	956.3	41.10
Novavax	119.95	5.16
Biological E	3.4	0.15
Baylor College	1	0.04
Dynavax	3.4	0.15
HDT Bio Corp	8.2	0.35
Others	238.57	10.25
Total	**2326.67**	100.00

Source: Compiled from Global Health Centre data presented in Annexure 2

Almost 80 per cent of the funding has gone towards just two companies, and both have successfully got their vaccine candidates receiving a EUA from the USFDA. The third company, Novavax, has also, in the meantime, developed a very highly effective vaccine that

yet to receive a EUA[9]. Interestingly, the Indian vaccine company, Biological E, has received funding from the Gates Foundation as the company and Baylor College and Dynavax are developing a vaccine in India[10]. Finally, HDT Bio Corp has received funding from the federal government in co-developing an mRNA vaccine with another Indian company, Gennova. Thus US R&D investment is also facilitating vaccine development in India as well.

(ii) Advance market commitment

As seen earlier (see fn.1), governments commit funds to guarantee the price of vaccines once they have been developed. These financial commitments provide vaccine manufacturers with the incentive to invest in vaccine R&D and expand manufacturing capacity. So AMC is thus a well-established instrument of industrial specifically designed for vaccine development. The federal government has used this instrument of support rather extensively, as shown in Table 7. All the six vaccine manufacturers covered under the OWS have received substantial AMC to the tune of $ 24 billion. This hefty AMC would have encouraged and provided a credible line of support to do at risk- manufacturing of vaccines that were at that under various phases of testing.

Table 7: An advance market commitment by the federal government to USA vaccine manufacturers

(Millions of USD)

Vaccine manufacturer	APA
BioNTech/Pfizer	5973
Moderna Therapeutics	9499.56
Sanofi Pasteur/GSK	2072.78
Novavax	1600
University of Oxford/Astrazeneca	1200
Janssen	2029.48
AstraZeneca	1600
Merck and IAVI*	38.03
Total	**24012.85**

Note: *This product is no longer supported

Source: Biomedical Research and Development Authority (BARDA), https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine

The total financial support to the vaccine manufacturers works out to 26 billion dollars (Table 8). APA accounts for the lion share (91 per cent). The substantial financial support complemented the other instruments of support which has made the USA a success story in vaccine development.

[9] According to press reports, "Novavax says it may not seek emergency authorization from the Food and Drug Administration until the end of September 2021. And with a plentiful supply of three other authorized vaccines, it's possible that the agency may tell Novavax to apply instead for a full license — a process that could require several extra months". Also it is said that the company may secure EUA outside the USA in jurisdictions such as the UK, European Union, India and South Korea. See *New York Times*, https://www.nytimes.com/2021/06/14/health/covid-vaccine-novavax.html

[10] Corbevax, the vaccine jointly developed by these three organizations is currently in phase 3 trials

Table 8: Total federal funding to vaccine manufacturers through two routes of funding

(Millions of USD)

Vaccine manufacturer	Direct R&D Funding	APA	Total funding
BioNTech/Pfizer		5973	5973
Moderna Therapeutics	956	9500	10456
Sanofi Pasteur/GSK		2073	2073
Novavax	120	1600	1720
University of Oxford/AstraZeneca		1200	1200
Janssen	996	2029	3025
AstraZeneca		1600	1600
Merck and IAVI		38	38
Biological E	3		3
Baylor college	1		1
Dynavax	3		3
HDT Biotech	8		8
Others	239		239
Total	**2327**	**24013**	**26340**

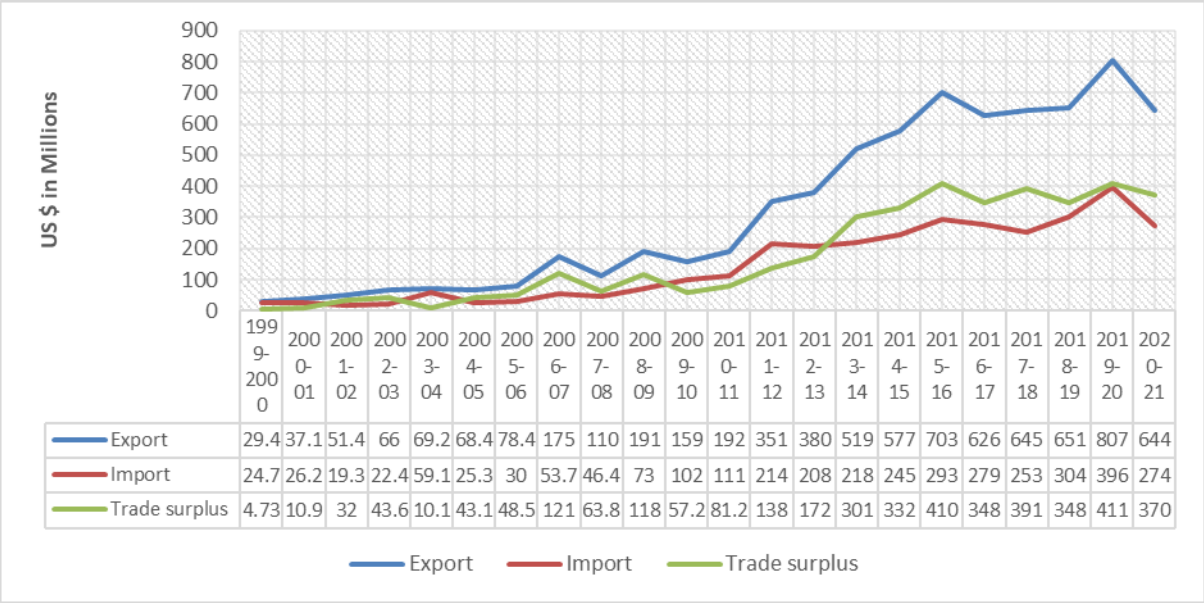
Source: Global Health Centre (2021), Biomedical Research and Development Authority (BARDA), https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine

3.6 Summing up the USA case

The USA is now the leading country in the world for both R&D and manufacturing in the vaccine for COVID-19. The basic R&D for the vaccine is mainly at the state-owned NIH. Still, a fair amount of applied developmental R&D is in large MNCs and new biopharmaceutical companies. The federal government has supported both vaccine research and manufacturing in a very significant way. This support has manifested in myriad forms like effecting legislative changes to promote emergency support for vaccine development, provision of substantial fiscal and institutional support and providing advanced market commitments. It is also significant that the state has also not enforced its patents for vaccine technology. In short, the USA case presents an ideal collaboration between state and markets. Thus it is a strong case in its use of industrial policy in an otherwise free-market economy. However, there have been some concerns over the nature of government intervention in vaccine development and its eventual distribution. One problem has been over the IPR of federally funded R&D projects. The issue is somewhat complex and is certainly beyond the scope of the present paper. Another concern has been on vaccine equity as the federal government has spent considerable public resources on vaccine development. Still, its fruits have not gone to all sections of the society as the cumulative vaccination rates among Black and Hispanic people continue to lag behind other ethnic groups in the country. Also, the USA has registered one of the highest mortality rates due to COVID-19 globally, although the fast pace of vaccinations has reduced the mortality trends. Further, it has also allowed the authorities to open the economy and for the citizens to return to some semblance of normality.

4 The case of India

As seen above, India is one of the leading vaccine manufacturers in the developing world and the world itself. It has an installed capacity of about 8 million doses of 29 different vaccines. One of the largest vaccine manufacturers globally is also in India. The country is a leading exporter of vaccines to the developing world and has been having a positive trade balance in the vaccine (Figure 4). So much earlier on in the vaccine development of COVID-19, hopes were placed on India to deliver large doses of vaccines at the lowest cost to the international vaccine partnership COVAX and other developing countries. But vaccine production in India has not been on expected lines, and her vaccination programme had been relatively slow. India has only one domestically produced vaccine and two other foreign vaccines manufactured in India under a voluntary license from their original developer. But the country is in the process of developing many new vaccines, and three of these are expected to be available during the August through December 2021 period.



	1999-2000	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21
Export	29.4	37.1	51.4	66	69.2	68.4	78.4	175	110	191	159	192	351	380	519	577	703	626	645	651	807	644
Import	24.7	26.2	19.3	22.4	59.1	25.3	30	53.7	46.4	73	102	111	214	208	218	245	293	279	253	304	396	274
Trade surplus	4.73	10.9	32	43.6	10.1	43.1	48.5	121	63.8	118	57.2	81.2	138	172	301	332	410	348	391	348	411	370

Figure 4: Exports, Imports and Trade Surplus in vaccines
Source: Compiled from U.N. Comtrade

4.1 Structure of COVID-19 vaccine production in India

India has a long history of vaccine manufacturing dating back to 1890[11]. During the period up to the independence, vaccine manufacturing was only in public sector research institutes mentioned in Table 9. The first private sector manufacturer of vaccines came up in 1953, followed by several other firms subsequently. Interestingly, the private sector domination of vaccine manufacturing commenced much earlier than 1991 when the country launched a policy of economic liberalization and privatisation. In other words, the decline of the share of the public sector in vaccine manufacturing started right through the 1950s when the public sector enterprises still occupied the economy's commanding heights.

[11] See Lahariya (2014) for a mapping of the history of vaccines and vaccination in India.

Table 9: Installed capacity for vaccine production in India, 2018-19

(in lakh doses)

Private Sector		**Public Sector**	
Name of firm	**Installed Capacity**	**Name of firm**	**Installed Capacity**
Serum Institute of India	32800	Human biological institute	5280
Bharat biotech International Ltd	13990	Haffkine	1176
Biological E.	10389	CRI, Kasauli	801
Biomed Pvt. Ltd,	7540	BCG vaccine	800
Panacea	5958	Pasteur institute of India	800
Dano Vaccine & Biological Pvt. Ltd.,	1600	BIBCOL	NA
Sanofi Pasteur India Pvt Ltd	321	HLL Biotech Ltd	NA
Chiron Behering	150	**Total public sector**	**8857**
Cadila healthcare	50		
Cadila Pharmaceuticals Ltd.	N.A.		
Green signal BioPharma Ltd	NA		
Ranbaxy Lab	NA		
Shantha Biotechnics Ltd	NA		
GSK Asia Pvt. Ltd	NA		
Total private sector	**72798**		
Total installed capacity	**81655**		

Source: Central Bureau of Health Intelligence (2021)

Detailed data on COVID-19 vaccine production is not available. But Global Commission for Post Pandemic Policy (2021) has estimated it to be 278.18 million doses of COVID-19 vaccines cumulatively up to the 31st of May, 2021. The domestically developed and produced COVAXIN is only about 10.5 million doses (just about 4 per cent). About 96 per cent of the vaccine produced in India is based on a foreign technology licensed, albeit voluntarily, by a foreign supplier. India's indigenous vaccine development is very little, and it can be attributed to India not having used industrial and innovation policy instruments to support vaccine R&D.

4.2 Vaccine R&D in India

As noted earlier, India has the reputation of being a significant vaccine manufacturer, and concerted efforts have been made by the Department of Biotechnology since its inception in 1986-87. One of the vital programmes that are currently underway is the Indo-US Vaccine Action Programme (VAP). The programme's primary objective is to develop novel and innovative vaccine technologies in priority areas such as dengue, enteric diseases, influenza (including avian influenza), malaria, and tuberculosis (T.B.). One of its significant achievements is the development lowest cost Rotavirus vaccine which became part of the universal immunisation programme. Further significant strides towards a vaccine for diseases like malaria and dengue have also been made. It is claimed that one out of every six children over the world receives vaccines manufactured in India.

Based on available research on the nature of R&D projects on vaccines, the following four issues characterise Indian vaccine research in general, and those on coronavirus in particular: (i) Much of the R&D projects on vaccines in India are devoted to the adaptation of already known vaccine technologies to specific Indian conditions; (ii) As a result of this, one of the main objectives of this adaptive R&D is to make large doses of the particular vaccine at the lowest cost possible; (iii) India has several technologically capable exclusive vaccine manufacturers (See Table 9) plus many pharmaceutical companies with vaccine development capabilities. Further, it has also some public laboratories and public sector enterprises to embellish its vaccine innovation system; (iv) The priorities for vaccine R&D is set out in the *National Vaccine Policy 2011*. The national focus is for manufacturing vaccines for locally prevalent diseases in India such as pneumonia, diarrhoea, and infections capable of spreading epidemics such as Japanese Encephalitis, Dengue, Cholera and Typhoid. Thus, India did not have any R&D projects on newer viral diseases such as those caused by coronaviruses, unlike in the USA. Nevertheless, immediately upon publication of the genome sequence of SARS-CoV-2, 9 Indian companies started R&D projects developing a vaccine for COVID-19 using a range of technologies. Seven out of these nine are with foreign technical collaboration either in voluntary licensing to manufacture the vaccine in India in large doses or strategic R&D partnership with foreign manufacturers. It is interesting to note that 5 of the seven foreign collaborators are from the USA. See Table 10.

From the above data table, India appears to have followed three technology strategies towards coronavirus vaccine development in hindsight. These are (i) voluntary licensing (in the cases of Covishield, Sputnik V, and NVX-CoV2373); (ii) Own R&D (in the cases of Covaxin and ZyCoV-D); and strategic R&D partnership with firms abroad (in the case of Corbevax, HGCO 19, inactivated rabies vector, and intranasal). Of the three, voluntary licensing seems to be the dominant mode. The choice of these three modes is more dictated by company strategies rather than by any specific designs. The fact that its R&D strategy is not that popular is an outcome of the low priority for vaccine R&D that the state has accorded despite the National Vaccine Policy, 2011 favouring it. It also points to the lack of support for domestic R&D with the right type of financial instruments. India's most important financial incentive for encouraging R&D is the R&D tax incentive (Mani, 2002). But it does not appear to be the appropriate one for promoting vaccine R&D where direct research grants and AMC are the more relevant instruments. This could also be seen in the case of the USA.

India did not have any public sector R&D projects devoted to an understanding coronaviruses that the domestic manufacturers could piggyback on. Hence the need for foreign collaboration of sorts, which they seem to have found on their own. Perhaps the liberalised foreign technology licensing agreement regime that was in force since 2009 may have helped. Unfortunately, there exists no other data on state support for this partnership, although it is very likely that some diplomatic channels may have been used to facilitate these crucial partnerships.

4.3 Legislative changes to provide emergency support for vaccine development

Unlike the USA, no specific legislative changes to vaccine development are available in India. The government of India announced a *Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy* in April 2021(Ministry of Health and Family Welfare, 2021a).

But this strategy is on actual vaccinations and not on vaccine development. Thus apart from the *National Vaccine Policy 2011*, there are no other specific policy document on COVID-19 vaccines. The Union Budget for 2021-22 has provided Rs 35000 crores for vaccine development (Ministry of Finance, 202, para 37, p. 7)1). But its actual distribution has not been spelt out anywhere, so much to say that the Supreme Court, in its order on the 30th of May, 2021, has ordered the union of India to submit an affidavit detailing how this amount is to be distributed for vaccine development.

Table 10: R&D projects on COVID-19 Vaccine in India

Sl. No.	Vaccine and technology	Indian Manufacturer	Collaborator	Current stage/(Expected doses available during August-December 2021) (million doses)
1.	Covishield (Viral Vector- Non replicating)	Serum Institute of India, Pune	Voluntary licensing from Oxford University/AstraZeneca, the U.K., to manufacture in India	EUA- large scale manufacturing- (500)*
2.	Covaxin (Inactivated Virus)	Bharat Biotech International Ltd, Hyderabad	Indian Council of Medical Research, ./National Institute of Virology	EUA- large scale manufacturing (400)*
3.	ZyCoV-D (DNA vaccine)	Cadila Healthcare Ltd, Ahmedabad (Zydus Cadila)	Dept. of Biotechnology, India- A grant-in-aid from Covid-19 Consortium supported the development of ZyCoV-D under National Biopharma Mission, Department of Biotechnology, Government of India, to Cadila Healthcare Ltd.	ZyCoV-D has completed Adaptive Phase I/II Clinical Trials; has started Phase III clinical trials in 30,000 volunteers- on June 30 2021, it has applied for a EUA (50)*
4.	Sputnik V (Adenoviral Vector)	Trialed and manufactured in India by Dr Reddy Lab, Also with Panacea Biotec	Voluntary licensing from Gamaleya National Center, Russia	EUA- large scale manufacturing/ (100)*
5.	NVX-CoV2373 (Protein subunit)	Serum Institute of India, Pune	Voluntary licensing to manufacture from Novavax, USA	Completed Phase III trials. May soon receive EUA in India –

6.	Corbevax- (Protein subunit)	Biological E Ltd, Hyderabad	In collaboration with Baylor College of Medicine, Texas, USA and Dynavax, USA	Currently in Phase 3 trials / (300)*
7.	HGCO 19 (mRNA)	Gennova, Pune	In collaboration with HDT Bio Corp, USA	Nil
8.	Inactivated rabies vector platform	Bharat Biotech International Ltd (BBIL), Hyderabad	Thomas Jefferson University, USA	BBIL and Thomas Jefferson University of Philadelphia have signed an exclusive deal to develop a new vaccine candidate for COVID-19 invented at Jefferson- completed preliminary tests in animal models
9	Intranasal Vaccine	BBIL	in collaboration with Precision Virologics, a startup incubated at the Washington University School of Medicine in St Louis, US.	Phase 1 trials in the USA and India- BBIL will subsequently manufacture the vaccine, having bought the rights to distribute the vaccine to all global markets except the USA, Japan and Europe- (100)*
10.	Vesiculo Vax Platform	Aurobindo Pharma Ltd, Hyderabad	Aurovaccine, USA	No information available in the public domain
11	Recombinant Adeno Associated Virus vector	Intas		No mention of this project on the company's website- The company has submitted its Environmental Health Risk Management Plan (EHRMP) for this project to the BIRAC
12	Virosome	Seagull Biosolutions		No information available in the public domain

Source: Adapted from Ministry of Health and Family Welfare (2020), p.19, Department of Biotechnology (2021), p.153, Supreme Court of India (2021a), p.54, Supreme Court of India (2021b)

*Figures in parentheses indicated millions of vaccine doses that the respective manufacturers promised to deliver during August through December 2021. The total of all these add up to 1350 million dose.

4.4 Institutional Support

The institutional support consists of two separate arrangements. The first one is more related to the promotion of vaccine R&D and its manufacturing, and the second is more focused on its distribution. The former is the *Mission COVID Suraksha to accelerate Indian COVID-19 Vaccine Development. T*he latter is the National Expert Group on Vaccine Administration (NEGVAC). In terms of the timing of its respective establishment, the NEGVAC was set up earlier in August 2020, whereas the Vaccine Suraksha mission was formed in November 2020.

(a) The NEGVAC

The NEGVAC implements India's vaccine policy. But none of its deliberations or recommendations is made public as yet. Changes in the vaccine policy that deals with its domestic manufacturing and distribution are announced from time to time by the Prime Minister or gleaned from occasional statements released by the Union Ministry of Health and Family Welfare. From whatever information that is available
The NEGVAC is more concerned with the immunisation programme rather than its domestic vaccine production. This is evident from its six objectives made known in its very first meeting. [12]

- **Conceptualisation and implementation mechanisms for creating a digital infrastructure** for the vaccine's inventory management and delivery mechanism, including tracking the vaccination process with a particular focus on last-mile delivery.
- **Deciding the broad parameters guiding the selection** of COVID-19 vaccine candidates for the country with inputs from the Standing Technical Sub-Committee of National Technical Advisory Group on Immunization (NTAGI).
- **Procurement mechanisms** for the COVID-19 vaccine include indigenous and international manufacturing and guiding principles for prioritising population groups for vaccination.
- **Financial resources required for procurement of COVID-19** vaccine and various options of financing the same.
- **Vaccine diplomacy**: The expert group discussed that India would leverage domestic vaccine manufacturing capacity and engage with all international players for the early delivery of vaccines in India and low and middle-income countries.
- **Advising the states on vaccine procurement:** The Committee also recommended that all the States not chart separate procurement pathways.

One could see two distinct phases in the operation of the NEGVAC in terms of its emphasis on domestic production. During the first phase of August 2020 through April 2021, the NEGVAC concentrated primarily on the diffusion of vaccination and in the second phase, which corresponds to the post-May 2021 period, it began to give relatively speaking more emphasis on the supply of vaccines as the success of diffusion crucially depends on the availability of vaccines. This change in focus could justifiably be attributed to the intervention in the form of a *Suo Moto* writ petition filed by the Supreme Court of India. In response to this petition, the affidavits filed on behalf of the Union of India has some facts about the operation of NEGVAC as far as augmentation of domestic supply of vaccines is concerned (Supreme Court of India, 2021a and b). This augmentation was to be achieved

[12] This is based on Ministry of Health and Family Welfare (2020b)

through two routes; the first route is through ramping up of domestic manufacturing capacity at two of the domestic manufacturers, and the second route through relaxing some of the conditions for the import of vaccines developed abroad and for which the relevant regulatory authorities have issued a EUA in the USA, U.K., Europe or in Japan or which are listed in WHO's Emergency Use Listing[13]. Thus unlike in the USA, where oversight bodies such as GAO have monitored the domestic production of vaccines, there was no such monitoring in India. Therefore, everything appears to be in a trial and error fashion.

(b) Mission COVID Suraksha to accelerate Indian COVID-19 Vaccine Development[14]

In April 2020, the union government set up a *Task Force for Focused Research on Corona Vaccine"* to encourage domestic R&D of Drugs, Diagnostics and Vaccines. This is the only institutional arrangement for encouraging domestic R&D for developing vaccines for COVID-19. It is part of the third stimulus package, *Atmanirbhar 3.0*, and the nodal agency for implementing this mission is the Department of Biotechnology (DBT). A dedicated Mission Implementation Unit at Biotechnology Industry Research Assistance Council (BIRAC), the existing activities under National Bio Pharma Mission (NBM) and Indo-CEPI Mission will provide complementary support to this mission. Phase-I of the COVID Suraksha Mission has been allotted Rs.900 Crore for 12 months, although the details of how this amount is allocated among the various projects is not available. Under the mission, a total of 11 vaccine candidate (see Table 10 above) have been supported by the DBT so far in both academia and industry. Three vaccine candidates are in human trials, with at least three more in advanced stages of preclinical to enter human trials shortly. The mission strategy is to leverage both national efforts and international partnerships in developing vaccines for COVID-19. Specific details of the vaccine R&D projects were already reported in Table 10. The only project that is in Phase 3 trials is the one by Biological E. The DBT has provided financial assistance in terms of grant-in-aid of over Rs 100 crore to this project and has also partnered with the firm to conduct all animal challenge and assay studies through the Translational Health Science Technology Institute (THSTI), Faridabad.

The mission is in operation for only seven months and shows some promise for developing vaccines that may be used during the August through December 2021 period. Further, the government has also signed an AMC for 300 million doses of the yet to be authorised vaccine from this specific firm. More on this will be discussed in the section on financial support.

From our discussion of the institutional support, it is clear that, at best, it has been in existence only for the last seven months or so. The government has steered clear itself from using any industrial policy instruments or instead used it sparingly to sound more like a knee jerk reaction rather than a well thought interventionist strategy. By and large, it has left the issue of R&D and manufacturing to private sector enterprises, occasionally intervening in response to specific criticisms by mainly the highest legal institution in the country. Although considerable vaccine capacity and technological capability exist in the public sector (see

[13] Ramping up domestic production consisted of the following three: (i) Serum Institute of India was to ramp up production from 50 million doses a month to 65 million doses a month and also further ramp it up by July 2021; (ii) Baharat Biotech, the only manufacturer of a domestically developed vaccine, was to increase its monthly production from 9 million to 20 million and then to 55 million by July 2021; and (iii) Production of the newly authorised Russian vaccine, Sputnik-V is to be increased from 3 million to 12 million by July 2021. Regarding the conditions for vaccines to imported, the government has done with the requirement of conducting bridging trials in India.

[14] The source of information for working out the ideas contained in this section are from Ministry of Science and Technology (2020) and Department of Biotechnology (2021).

Table 2 above), this does not appear to have been considered. Some commentators have even accused earlier governments of systematically destroying the capacity existing in public laboratories and enterprises (Bhushan, 2021, Abrol and Franco, 2021), But the issue is somewhat more complex. There are at least two significant constraints to involving the public sector in vaccine manufacturing in the short run, although this is a very credible strategy in the long run. First of all, India does not have readily usable vaccine technology developed in the public sector. However, it has now at least one vaccine (Covaxin) for which the central government can order the firm to issue voluntary licenses. In fact, according to a press statement from the Ministry of Health and Family Welfare (2021b) the government have already started involving certain public sector entities in vaccine production[15]. Second and most importantly, except for the Human Biological Institutes (HBI)[16], none of the other public sector enterprises and the labs have valid permits to manufacture vaccines issued by the regulator, the Central Drug Standard Control Organisation (CDSCO). See Table 11. For the licenses to be renewed, the public sector entities have to improve their manufacturing practices and bring them on par with current Good Manufacturing Practices (cGMP) prescribed by the CDSCO. Although this is doable, successive governments appear to be not interested in these public sector vaccine entities. The most important example of this lackadaisical attitude of the government is the hitherto non-completion of an effective vaccine manufacturing facility, the Integrated Vaccine Complex (IVC), which is currently part of a public sector enterprise HLL Biotech[17]. But as stated earlier, it is in the country's long term interests that these public sector entities, which between them have an installed capacity to manufacture 887.5 million doses of vaccine (Table 2 above), be made ready to manufacture and supply vaccines for COVID-19. They should be made the mainstay of the institutional support for vaccine development in the country.

[15] According to this report, two central government PSEs, Indian Immunologicals Ltd (IIL) and BIBCOL have entered into a voluntary technology transfer agreement with BBIL. Further, a state PSE , namely, Haffkine Institute, has also entered into a similar technology transfer agreement with BBIL The Union Government has also extended some financial assistance to all the above 3 undertakings although the exact amounts are not made public. Consequent to this, IIL will be in a position to start production of Covaxin from September 2021, while Haffkine Institute and BIBCOL will start production of the vaccine from November 2021. See Ministry of Health and Family Welfare (2021b).

[16] Indian Immunological Limited, the parent company of HBI has entered to a R&D collaboration with Griffith University in Australia to develop a Live Attenuated COVID-19 vaccine using the latest codon de-optimization technology. But there is no information on the progress of this R&D project in the company's website. See Kumar (2020).

[17] IVC was established in 2012 at an 'estimated' cost of Rs 594 crore and has a sanctioned staff strength of 408, of which nearly 251 posts are vacant. Between 2013 and 2019, IVC has generated a revenue of Rs 6.77 crore and incurred a loss of Rs 96.25 crore (based on a reply to an RTI inquiry). The cost overrun in project cost was 52 per cent- the project cost escalated from original Rs 594 crore in 2013 to Rs 904 crore in 2019. See Express News Service (2021).

Table 11: Validity of licenses issued to India's public sector vaccine entities

Sl. No.	Name of vaccine unit	License validity
1	BIBCOL	01.01.2012 to 31.12.2016 (Firm applied for renewal, i.e. 01.01.2017 to 31.12.2021, and the license is valid for the said period, till further orders are passed)
2	Haffkine	01.01.2012 to 31.12.2016 (Firm applied for renewal, i.e. 01.01.2017 to 31.12.2021, and the license is valid for the said period, till further orders are passed)
3	a. Human BiologicalInstitute, Hyderabad	17.04.2011 to16.04.2016 (Firm applied for renewal, i.e.17.04.2016 to 16.04.2021 and license is valid for the said period, till further orders are passed)
	b. Human Biological Institute, Udhagamandalam	01.01.2012 to 31.12.2016 (Firm applied for renewal, i.e. 01.01.2017 to 31.12.2021, and the license is valid for the said period, till further orders are passed)
	c. M/s Human Biologicals Institute, a Division of M/s. Indian Immunologicals Ltd., Mulugu Mandal	01.04.16 to 31.03.21
4	HLL Biotech Ltd.	31.05.14 to 30.05.2019
5	BCG vaccine	01.01.2008 to 31.12.2012 (Firm applied for renewal,i.e. 01.01.2013 to 31.12.2017, and the license is valid for the said period, till further orders are passed)
6	CRI Kasauli	01.01.2012 to 31.12.2016 (Firm applied for renewal i.e.01.01.2017 to 31.12.2021 and license is valid for the said period, till further orders are passed)
7	Pasteur Instituteof India, Coonoor	01.01.2008 to 31.12.2012 (Firm applied for renewal,i.e. 01.01.2013 to 31.12.2017, and the license is valid for the said period, till further orders are passed)

Source: Central Drugs Standard Control Organization (2021)

4.5 Financial support to vaccine manufacturers

Unlike the federal government in the USA, the central government in India has been very conservative in financing vaccine R&D and its manufacturing. The two routes of funding it, namely the R&D route and the AMC routes, have been used very sparingly. Nevertheless, based on our desk research, we have been able to construct a picture (Figure 5) of the total financial support for COVID-19 vaccine development, which works out to a total of Rs 9465.50 crores, of which Rs 946 crores is for R&D, Rs 4019.50 crores in the form of AMC and Rs 4500 crores in the form of bank credit to private sector vaccine manufacturers without requiring a bank guarantee from them. The detailed work out of these numbers is provided in Annexure 3.

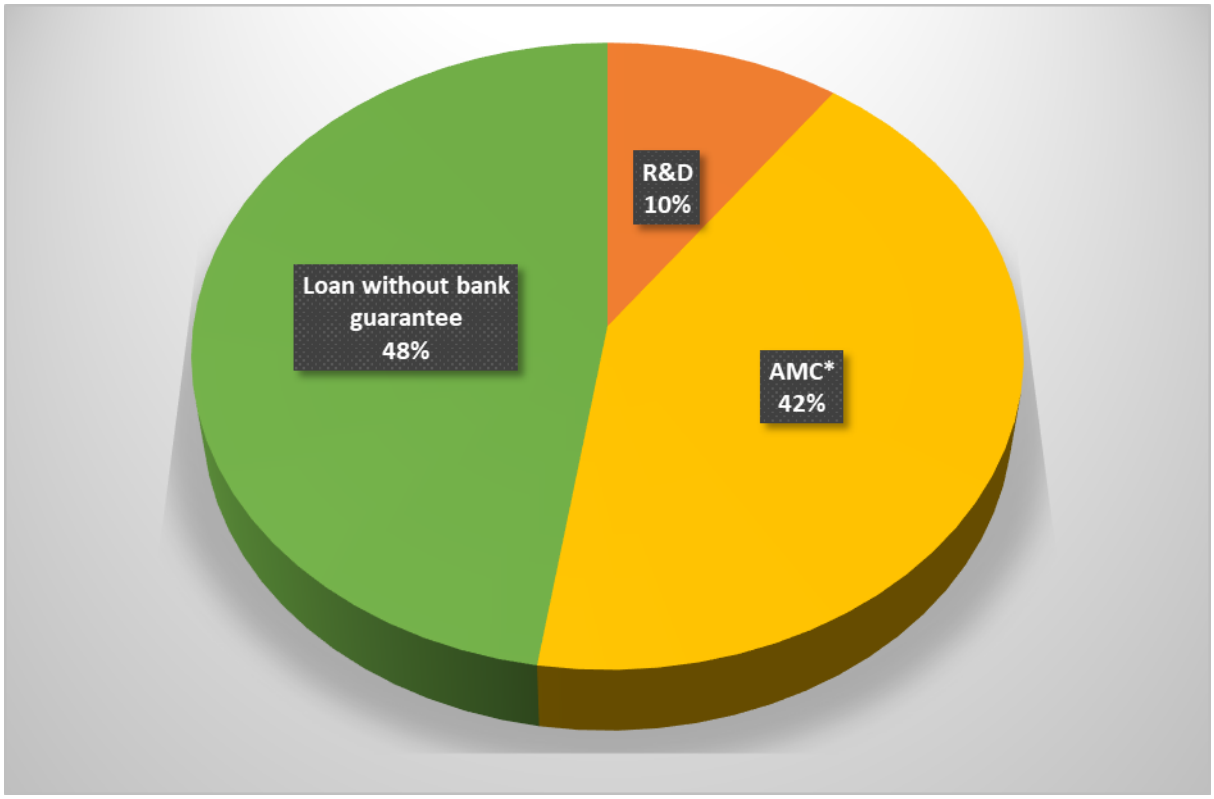


Figure 5: Distribution of financial support for COVID-19 vaccine development in India, 2020-21

Source: Annexure 3

The following points are to be noted while arriving at the total amount spent.

1. We have not included the Rs 35000 crores budgeted by the Finance Minister in her 2021-22 budget as the details have not been spelt out. In any case, it appears that much of this amount is to be used for purchasing and distributing vaccines than for R&D and manufacturing. The further affidavit submitted by the government to the Supreme Court on June 26, 2021 has given a figure of Rs 9381.83 crores as the procurement cost of vaccines (Supreme Court of India, 2021b, pp.46-47),
2. Hitherto, only about 50 per cent of the funds have actually been spent; the rest are commitments.

3. About a half of the funds are credit lines without bank guarantee extended to the vaccine manufacturers
4. Of the Rs 4019.50 denoted as AMC, only Rs 1500 crores (37 per cent) is strictly speaking AMC. The rest is amounted spent to procure locally made vaccines.

In short, India's financial support for vaccine R&D is very meagre compared to the substantial sums of money spent on vaccine development by the federal government in the USA. For some reason, the government in India appears to be more worried about breaching its fiscal deficit to GDP ratio rather than offsetting the natural inclination for private sector enterprises to underinvest in risky R&D as predicted by theory. Fiscal conservativism is a virtue in normal times. But it certainly is to be relaxed at all times in the arena of knowledge production.

4.6 Instruments for easing various constraints to vaccine production

A common philosophy that could be ascribed to public policies affecting industrialisation in the country is the government's concern and actions about removing the constraints of various sorts to manufacturing by improving the *ease of doing business*. In the case of vaccine R&D and manufacturing, there are some constraints that Indian manufacturers face, and the government can play an important role in sorting these constraints.

The design and manufacturing of vaccines are supposed to be more complex than standard therapeutics (Plotkin et al., 2017). However, among the various constraints that militate against its smooth manufacturing in late industrialising countries such as India, two limitations stand out. The first one is the access to its specialised proprietary knowledge, which manifests itself in patents and licensing. The second one is whether a country is inserted into the Global Value Chain for vaccine manufacturing as the manufacture of vaccines requires many raw materials and components. Here we will examine how India has addressed these constraints.

(a) Intellectual Property Right suspension and stand on compulsory licenses

Vaccines for COVID-19 developed by the USA and non-U.S. manufacturers are all covered by many patents. Although it is still early days, as far as most of the R&D projects are concerned, a surge in the number of patent applications for COVID-19 vaccine-related patents[18] is an excellent indication of the shape of things to come. It is seen that the existence of patents is one of the leading technological barriers to the widespread diffusion of technologies and especially innovations. So India, along with South Africa, has submitted a petition to the WTO to have the patents for vaccines suspended for a specified period (WTO, 2020). Many global health experts have sided with India and South Africa as the proposal has the backing of 100 of the WTO's 164 states. A panel on intellectual property is expected to discuss the issue in June 2021. Prominent among the supporters is the USA. As seen earlier, one of the leading U.S. vaccine developers has even made a patent pledge (see Box 2).

Moreover, since the vaccine R&D in most cases has been paid for by the national governments and philanthropic organisations, there is a strong case for I.P. suspension. But there has been strong opposition to this clamour for patent suspension by all developed countries such as the U.K., European Union, Canada, Japan, Switzerland, Norway and pharmaceutical companies themselves. In a sense, a mere waiving of patents unaccompanied by technology transfer is unlikely to be beneficial to vaccine manufacturers as vaccines are based on complex molecules, and therefore a mere waiving of patents will not result in

[18] EPO (2021)

reverse engineering of the technology for new vaccines (Kavanagh and Dollar, 2021). Further, the process technologies for vaccines are protected by trade secrets rather than by patents. However, well known medical NGOs such as the MSF have questioned this. MSF has referred to several instances in which aggressive patent strategies by leading vaccine manufacturers such as Pfizer has sued smaller foreign companies which have developed cost-effective and cheaper versions of high-cost vaccines (MSF, 2021). This has delayed the launch of more affordable versions. Further, the Third World Network has documented at least four cases where R&D projects on COVID-19 vaccine developments had to be abandoned (Third World Network, 2021).

In the absence of patent suspension, some have argued for national patent regimes to invoke a compulsory license provided under one of the flexibilities of the TRIPS Agreement. However, the central government is not for it. Its official view is clearly expressed in the Affidavit submitted by the Union of India to the Supreme Court wherein it is stated that "Government of India does not favour a compulsory license as it believes that "the main constraint is in the availability of raw materials and essential inputs" (Supreme Court of India, 2021, -p.68, paragraph 44). Instead, it believes that innovator companies will issue voluntary licenses given the growing market and the need to expand manufacturing capacity in the shortest possible time. India has been successful in getting three voluntary license deals. The first one is between Oxford/AstraZeneca and the Serum Institute of India. The second one is between the Russian Direct Investment Fund, Dr Reddy's laboratories, and Panacea Biotec. Among the two, it is only in the latter case that the government has intervened. The third one is between Novavax, USA and SII for a vaccine for which an EUA is yet to be issued either in the USA or in India.

Further, at home, there have been press reports of Bharat Biotech willing to share the code for its indigenously developed vaccine, *Covaxin,* with other domestic manufacturers. However, there is no evidence that it has done so. However, concerns have been expressed about the terms and conditions under which these voluntary licenses have been contracted, wherein some restrictive clauses may have been inserted.

The WHO had promoted the voluntary licensing of all kinds of technologies by setting up the COVID-19 Technology Access Pool (C-TAP). The C-TAP is to facilitate timely, equitable and affordable access to COVID-19 health products. But according to MSF (2021), this proposal has received a lukewarm reception from the MNC pharmaceutical firms.

In short, there is a strong case for a patent waiver, and India has taken a necessary and correct stand on this issue.

(b) Insertion into the Global Value Chain for Vaccine production

An essential aspect of COVID-19 vaccine manufacturing in the country is that domestic manufacturing involves an estimated 360 different input types that have to be imported from abroad. There is a Global Value Chain (GVC) for manufacturing vaccines, and just three countries, the USA, Germany, and China, are leading producers of these raw materials and components. India is not inserted into this GVC. Among the 12 items considered, India is a significant exporter of only preservatives. See Figure 6. The USA, Germany and China are the leading suppliers, and according to industry sources, India depends on the USA for most of its components and raw materials. India has been importing a number of these inputs from abroad. Using OECD (2021), I have derived India's imports of 16 key vaccine-making inputs (Table 12). It shows that the country imports a substantial quantity of these imports for the domestic manufacture of vaccines. To make matters even worse, India has clamped a high tariff of about 9.3 per cent on these vaccine inputs in contrast to the USA, which has a tariff of only 1.3 per cent on these items (Basu and Veeramani, 2021). Although there has been a

recent suspension of tariffs on imports of COVID-19 related products in general, including that on vaccines, the suspension is only for about three months.

Further, the USA's invocation of its DPA had erected a sort of export ban of these items to the Indian and other foreign-based manufacturers affecting their manufacturing timelines adversely. This de facto export ban is cited as another reason for vaccine production setbacks in India, leading to her vaccination schedule getting thrown out of gear. As hitherto, she has been able to vaccinate only 5 per cent of her population fully. Only about 20 per cent of the population has received at least one dose of the vaccine. There is, of course, no denying the fact that exports of domestically produced vaccines as part of India's vaccine diplomacy (accounted for 16 per cent of the exports up to the 29th of May, 2021), commercial exports (54 per cent), and those exported to COVAX (30 per cent) also contributed to the vaccine shortage[19].

Table 12: Imports of critical inputs for manufacturing vaccines
(Millions of USD)

HS 2017 Code	Vaccine input	2019-20	2020-21 (Apr- Feb)
285210	Thimerosal	0.42	0.39
283322	Aluminium Salts	0.02	0.02
290544	Sorbitol	8.50	7.49
291211	Formaldehyde	0.16	20.00
2941	Neomycin	1330.79	1364.77
290613	Sterols	16.81	8.66
701090	Vials	78.33	65.48
401699	Stoppers	237.79	211.43
4819	Insulated Cartons	81.43	60.07
901890	Vaccine Carriers	741.08	612.72
392310	Cold Boxes	50.62	34.19
841850	Refridgerators/ Freezer chests	36.16	30.35
841830	Freezers	65.51	35.01
281121	Dry ice	0.72	0.49
901831	Syringes	59.77	59.03
901839	Needles	299.96	170.76
Total imports of vaccine inputs		**3008.07**	**2680.86**

Source: Compiled from Export-Import Data Bank, Department of Commerce, Ministry of Commerce and Industry, Government of India

Note: The critical inputs and their HS codes are based on Annex B of OECD (2021)

[19] The source of this data is from Ministry of External Affairs (2021)

It appears that, towards the end of April 2021, the USA seems to have lifted the export ban on specific raw materials required by SII. The removal of this export ban was caused more by the devastation faced by India in the aftermath of the second COVID-19 wave rather than by any specific interventions by the state[20]. Nevertheless, it is a lesson for India with its *Make in India* strategy that the country needs to think through and map out the entire sectoral system of innovation for vaccines and put in place policies for jump-starting production of various inputs for vaccine making so that, at least, in the long run, it can emerge indeed as a significant supplier of vaccines. This is an important area where government intervention is required.

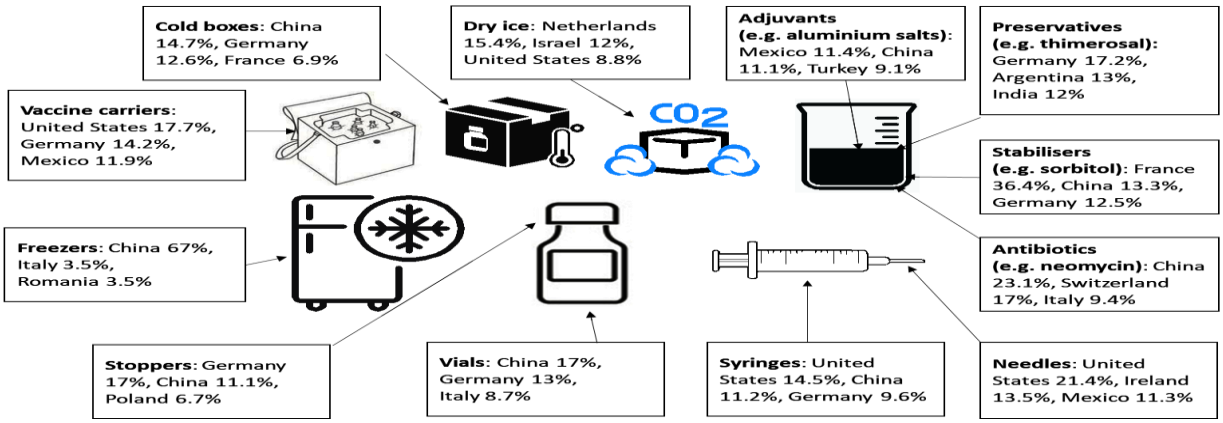


Figure 6: Top worldwide exporters of items needed in the production, distribution of vaccines

Note: The percentages referred to share in global exports in 2018

Source: OECD (2021)

4.7 Indemnity clauses to vaccine procurement contracts

Unlike in the USA, India has not given indemnity, or protection from legal liability, to any of its domestic manufacturers of coronavirus vaccines. But recently, the government, in its desire to augment the supply of vaccines, had decided to import vaccines from the two leading American manufacturers, Pfizer and Moderna. Of the two, Pfizer has insisted on an indemnity as one of its pre-conditions for supplying vaccines to India. Press reports indicate that the government, after some initial dithering, has finally approved Pfizer's request. The company has obtained indemnity in several countries where its vaccine is already in use, including the United States. Faced with the vaccine shortage, India has been on a vaccine import spree. It had already relaxed many conditions that it had earlier imposed on foreign vaccine suppliers, such as the need for bridging trials for vaccines that had already received a EUA in some of the jurisdictions abroad. Theoretically, this is not good news from the point of view of those likely to be adversely affected by the use of these vaccines. But in practical terms, this is not causing worry, primarily because the vaccines imported from the USA have not shown any adverse effect on the vaccine user[21]. Further, India has already some

[20] This is evident from the tweet by White House National Security Advisor, Mr Jake Sullivan. See his tweet at: https://twitter.com/JakeSullivan46/status/1386359529865162752

[21] According to the Centres for Disease Control and Prevention, USA, "Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults". But it also added that the

regulatory measures in the event of SAEs that may arise but only in clinical trials. According to a question answered in the Lok Sabha, 4735 people have died or had severe injuries due to clinical trials of drugs between 2008 through 2020 (Lok Sabha, 2018 and 2020). Clinical trials of new drugs are regulated under Rules 122 DA, 122DAB, 122DAC, 122DD, 122E and Schedule-Y of the *Drugs and Cosmetics Rules*, *1945*and the government has strengthened the regulatory provisions, including payment of compensation for SAEs due to clinical trials. However, this does not cover SAEs from drugs and vaccines that are authorised for use. Further, the compensation paid in the case of SAEs in India is very meagre: between 2014 and 2020, total compensation of just Rs 38.58 lakhs was paid (Lok Sabha, 2018 and 2020)

4.8 Summing up the Indian Case

India has focused more, relatively speaking, on vaccine distribution than its domestic production despite the fact there is an inevitable link between the two. Although a National Vaccine Policy 2011 was in place, it does not appear to have been implemented seriously over the years leading to a weak institutional structure for the support of domestic R&D and manufacturing of vaccines. Even now, the country does not appear to have a well thought out and anchored COVID-19 vaccine strategy in place. In a concerted manner, direct intervention by the government took place only in May 2021 after the decisive intervention by the Supreme Court of India. Given path dependence in innovation capability development, the country did not have any history of investments in basic research related to vaccines. The entire responsibility for developing vaccines for COVID-19 was left entirely to private sector firms to build it from scratch. None of the industrial and innovation policy instruments required to offset possible investments by private sector enterprises in R&D was put in place. The financial support for R&D was very meagre. There is also no strategy for using the substantial installed capacity available in public sector enterprises, although this should be only a long term strategy. There was also systematic identification of the constraints faced by domestic manufacturers as India is not effectively inserted into the GVC for vaccine production. It still has to depend on foreign markets, especially the USA, for R&D collaboration and for accessing crucial raw materials. But there is a silver lining in this otherwise dark cloud. India has lobbied for I.P. suspension in vaccines and has secured the support of many countries, including that of the USA.

Further, Indian private sector manufacturers have managed to secure voluntary licenses to manufacture vaccines developed abroad domestically. Additionally, some Indian manufacturers have partnered with American biotechnology firms to co-develop vaccines and manufacture them in India. Through specific industrial and innovation policy instruments, suppose the state can leverage this innovation capability; India has the potential to emerge as a significant manufacturer of very safe and effective vaccines for pandemics such as COVID-19 and that too at low cost. Not only India, but a large number of developing countries can indeed benefit from India's technological capability in vaccine development and manufacturing.

5 Contrast between the USA and Indian cases and the conclusions

The paper is all about the continued relevance and use of industrial policy instruments even in so-called market-friendly economies where economic liberalization and privatisation policies have sought to reduce the importance of state involvement, especially in the arena of industrialization. Given the possibility of market failures in knowledge production, state

patients have responded well to medications and rest. See https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

intervention to support the private sector activities is a very optimal policy. Our analysis of the two contrasting cases, the USA and India, supporting the R&D and manufacturing of COVID-19 vaccines lends considerable justification for the use of industrial policy instruments to arrive at successful outcomes. Table 13 summarises the contrast between the two economies.

Table 13: Contrast between India and the USA in vaccine R&D and production

Instrument of support	USA	India
Support for basic R&D on vaccine for coronavirus	Solid- long history- Federally-funded research	Weak- almost non-existent
Legislative changes	Emergency support for vaccine R&D- committed USD 2.3 billion	No strategy for vaccine development, but a system for vaccinations only- The union budget for 2021-22 has provided approximately 472 million USD equivalent but details not available
Institutional Support	Solid- Two institutional mechanisms • Operation Warp Speed • Use of the Defence Production Act	Not so strong • NEGVAC- more on the distribution of vaccines • Vaccine Suraksha Mission- focusing more on R&D
Financial Support	Two routes- • Funding R&D- USD 2.32 billion • AMC- USD 24.01 billion	Three routes- • Funding of R&D- USD 127.57 million • AMC- USD 542.5 million • Loan guarantee- USD 606.82
IPRs	• IP rights suspension for a brief period • Patent pledges by one of the manufacturer	• Lobbied for its waiver • Not favouring compulsory licenses • Preferring voluntary licenses
Indemnity clauses	Nil	Nil (?)
Federal/Central government's support for improving the ease of manufacturing	Substantial through the audit reports of GAO	Ambiguous- private sector enterprises left to fend for themselves
Overall opinion about the use of industrial policy instruments	Substantial	Limited- has proceeded in two phases: before and after intervention by the Supreme Court of India
Policy outcomes		
Number of vaccines approved/under testing	3- another three under various stages of testing	3- of which only one is based on indigenous technology- 2 are based on voluntary licenses from foreign vaccine manufacturers- another 6 are multiple stages of testing
Total vaccine production (in a million doses up to May 31, 2021)	369.45	279.18
Share of population that is vaccinated fully (in per cent as of June 24, 2021)	45.09	3.74
Total vaccinated per 100	95.4	21.26

Source: Own compilation, Global Change Data Lab (2021)

The USA is considered to be the home of the most virulent form of capitalism. This could be seen in the pride of place accorded to private sector enterprises in that country, and it is also the home of some of the largest and most innovative companies in a range of industries. In the area of medical R&D in general and in the development of vaccines, the federal government in the USA has worked very closely with the market. What they did is easily visible from a range of instruments that the federal government has invoked to jump-start the R&D and production of vaccines for a new and unknown disease. A survey

of these support instruments reveals that they have tried out every tool of state support available in the book. But the most important of which is the importance that the USA has given to fundamental research on vaccines, which eventually helped it develop highly effective vaccines within a brief period. The USA has now gone a step further in assigning a greater role for the government, even applied developmental research. This has manifested in the senate passing a new bill called *the United States Innovation and Competition Act of 2021* in early June 2021. This is an essential lesson for countries such as India that it must support basic research on vaccine development in one of its numerous public laboratories. The second lesson that the USA case has for us is the prime importance of involving the public sector. In the USA, this is confined to the performance and finance of R&D itself. In the case of India, the public sector must be involved not only in the performance and financing of R&D but also in the manufacturing of vaccines as considerable installed capacity exists in the industry.

Further, the public sector laboratories and institutes have a long history of manufacturing and supplying high-quality vaccines. They must be involved in vaccine production for COVID-19, even if it is only in the long run. In other words, the public and private sectors must complement each other. The government can play an essential role in crafting the sectoral system of innovation of the COVID-19 vaccine industry, just like what the USA has done it already. The third lesson for India is that the state must play an active and timely role in improving the availability of critical inputs for manufacturing and distributing vaccines in an industry whose value chain is globally distributed. The three issues more than indicate a more significant role for industrial policy than what is practised on an ad-hoc basis now. Recent events and discussions have shown that a historically free-market-oriented economy such as that of the USA is finding much relevance for a more significant role for industrial policy. In comparison, a historically state-directed economy such as India seems to be moving towards a more substantial role for the market with potential adverse consequences.

References

Abrol, Dinesh and Thomas Franco. 2021. 'Realistically, How Can India Expand COVID Vaccine Production Quickly? *The Wire*, https://thewire.in/government/realistically-how-can-india-expand-covid-vaccine-production-quickly

Access to Medicine Foundation (2017), 2017 *Access to Vaccine Index* https://accesstomedicinefoundation.org/media/uploads/downloads/5bc5eddd2d5ef_2017-Access-to-Vaccines-Index.pdf

Aghion, Philipe, Céline Antonin, and Simon Bunel. 2021. *The Power of Creative Destruction: Economic Upheaval and the Wealth of Nations*, Harvard University Press/Belknap Press.

Arrow, Kenneth. 1962. 'Economic Welfare and the Allocation of Resources for Invention, in National Bureau of Economic Research,' *The Rate and Direction of Inventive Activity: Economic and Social Factor*s, pp. 609-626, https://www.nber.org/system/files/chapters/c2144/c2144.pdf

Bagchi, Indrani. 2021. 'Vaccines and Supply Chains: A Perfect Storm?;' *The Economic Times* , *https://economictimes.indiatimes.com/news/india/vaccines-and-supply-chains-a-perfect-*storm/articleshow/82996690.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Ball, Philip. 2020. 'The Lightning-fast Quest for COVID Vaccines — and what it means for other Diseases', *Nature*, https://www.nature.com/articles/d41586-020-03626-1

Basu, A and C.Veeramani. 2021. 'Leveraging Global Supply Chains to Fight Covid-19', *Ideas for India*, https://www.ideasforindia.in/topics/trade/leveraging-global-supply-chains-to-fight-covid-19.html

Bernanke, Ben S. 2011. 'Promoting Research and Development: The Government's Role', *Issues in Science and Technology*, VOL. XXVII, NO. 4, https://issues.org/bernanke-research-development-government/

Boghani, Ashok B and Ronald S, Josh. 1993. 'The Role of Government in Fostering Innovation, https://www.adlittle.com/sites/default/files/prism/1993_q1_23-27.pdf

Bhushan, Bharat. 2021. 'Who destroyed India's vaccine self-sufficiency?', *The Busines Standard*, the 17th of May, https://www.business-standard.com/article/opinion/who-destroyed-india-s-vaccine-self-sufficiency-121051700112_1.html

Central Drugs Standard Control Organization. 2021. 'The List of Licensed Human Vaccine Manufacturing Facilities in India', https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/facilitiesLIST.pdf

Chaudhuri, Sudip. 2013. 'Manufacturing Trade Deficit and Industrial Policy in India', *Economic and Political Weekly*, Vol.48, Issue No: 8.

Cimoli, Mario, Giovanni Dosi, and Joseph E.Stiglitz. 2009. *Industrial Policy and Development: The Political Economy of Capabilities Accumulation*, New York: Oxford University Press.

Coyle, Diane. 2020. *Markets, State and People*, Princeton: Princeton University Press.

Department of Biotechnology. 2021. *Annual Report 2020-21*, Ministry of Science and Technology, Government of India, p.153.

Dolgin E. 2019. Unlocking the Potential of Vaccines Built on Messenger RNA. *Nature.* 574(7778): S10-S12. doi: 10.1038/d41586-019-03072-8. PMID: 31619807.
Drug Database (2021), *Government Agencies that fund medical R&D,* http://drugdatabase.info/government-agencies-that-fund-medical-rd/

Express News Service . 2021. 'Nine Years on, no Production in Centre's Integrated Vaccine Complex in Tamil Nadu, RTI finds', *The New Indian Express*, the 21st of April, https://www.newindianexpress.com/states/tamil-nadu/2021/apr/26/nine-years-on-no-production-in-centres-integrated-vaccine-complex-in-tamil-nadu-rti-finds- 2294824.html
Global Commission for post-pandemic policy (2021), https://globalcommissionforpostpandemicpolicy.org/vaccine-production-april-2021/

EPO. 2021. 'Number of Patent Applications Worldwide', Fighting Coronavirus, Vaccines, https://www.epo.org/news-events/in-focus/fighting-coronavirus/vaccines-and-therapeutics.html

Gaviria, M., Kilic, B. 2021. 'A Network Analysis of COVID-19 mRNA Vaccine Patents.' *Nature Biotechnology,* Vol. 39, pp. 546–548, https://doi.org/10.1038/s41587-021-00912-9

Global Change Data Lab. 2021. *Our World in Data, https://ourworldindata.org/covid-vaccinations*

Global Commission for Post-Pandemic Policy. 2021. 'Covid-19 Vaccine Production, to June 30th, 2021', https://globalcommissionforpostpandemicpolicy.org/covid-19-vaccine-production-to-june-30th-2021/

Global Health Centre. 2021. COVID-19 Vaccines R&D Investments. Graduate Institute of International and Development Studies. Retrieved from: knowledgeportalia.org/covid19-r-d-funding

Government Accountability Office. 2020. *Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations,* Report to Congressional Addressees, GAO-21-207.

Herman, Bob. 2020. 'The NIH claims joint ownership of Moderna's Coronavirus Vaccine', https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html

Hickey, Kevin J, Weng W.Shen and Erin H.Ward. 2020. *Legal Issues in COVID-19 Vaccine Development and Deployment*, Congressional Research Service, https://crsreports.congress.gov/product/pdf/R/R46399

Jackson, N.A.C., Kester, K.E., Casimiro, D. *et al* .2020. The Promise of mRNA Vaccines: a Biotech and Industrial Perspective. *npj Vaccines* **5,** 11 https://doi.org/10.1038/s41541-020-0159-8

Jadhav, S, M. Gautam, S. Gairola. 2014. 'Role of Vaccine Manufacturers in Developing Countries Towards Global Healthcare by Providing Quality Vaccines at Affordable Prices,' *Clinical Microbiology and Infection*, Vol. 20, Supplement 5, pp 37-44.

Kavanagh, Matthew M and David Dollar. 2021. *We are a long way from Vaccinating the World. Could a Patent Waiver Help?* Dollar and Sense Podcast, The Brookings Institution, https://www.brookings.edu/wp-content/uploads/2021/06/DollarAndSense_Transcript_MatthewMKavanagh.pdf

Kumar, Ravi N. 2020. 'Indian Immunological and Australia's Griffith University tie-up for COVID-19 Vaccine Research', *The Hindu*, the 20th of April, http://indimmune.com/images/iil-news/Covid.pdf

Lahariya, Chandrakant. 2014. 'A Brief History of Vaccines and Vaccination in India', *Indian Journal of Medical Research,* Vol. 139, No: 4, pp, 491-511.

Lin, J Y. 2014. 'Industrial Policy Revisited: A New Structural Economics Perspective', *China Economic Journal*, 'Vol.7, pp. 382-39.

Lok Sabha. 2018. 'Deaths due to Clinical Trials', Unstarred question no: 6486, http://loksabhaph.nic.in/Questions/QResult15.aspx?qref=68532&lsno=16

Lok Sabha. 2020. 'Illegal Clinical Trials', Unstarred question no: 965, http://164.100.24.220/loksabhaquestions/annex/174/AU965.pdf

Mani, Sunil (2002) *Government, Innovation and Technology Policy, An International Comparative Analysis, New Horizons in Economics of Innovation Series,* Cheltenham, UK and Northampton, USA: Edward Elgar Publishing: Edward Elgar

Mandavilli, Apoorva. 2021. 'Pfizer and Moderna Vaccines Likely to Produce Lasting Immunity, Study Finds', *The New York Times*, June 28.

Mani, Sunil. 2018. 'One Size Does Not Fit All: An Analysis of The Importance of Industry-Specific Vertical Policies for Growing High Technology Industries in India', in S. Mahendra Dev (ed.), *India Development Report 2017*, New Delhi: Oxford University Press, pp. 224-245.

Mazzucato, M. 2013. *The Entrepreneurial State: Debunking Public vs Private Sector Myths*, Anthem Press, London, http://marianamazzucato.com/the-entrepreneurial-state/.

Ministry of External Affairs. 2021. 'Vaccine Supply', https://mea.gov.in/vaccine-supply.htm

Ministry of Health and Family Welfare (2020a), COVID-19 Vaccines, Operational Guidelines, Government of India, https://www.mohfw.gov.in/covid_vaccination/vaccination/dist/images/documents/COVID19VaccineOG111Chapter16.pdf.

Ministry of Health and Family Welfare (2020b), *National Expert Group on Vaccine Administration for COVID-19 deliberates on strategy to ensure COVID-19 vaccines' availability and its delivery mechanism*, Press Release, https://pib.gov.in/PressReleasePage.aspx?PRID=1645363

Ministry of Health and Family Welfare (2021a), *Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy, https://www.mohfw.gov.in/pdf/LiberalisedPricingandAcceleratedNationalCovid19VaccinationStrategy2042021.pdf*

Ministry of Health and Family Welfare (2021b), 'Union Government consistently and proactively working to secure and enhance the Availability of COVID Vaccines', https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1718332

Ministry of Finance. 2021. *Union Budget Speech 2021-22*, https://www.indiabudget.gov.in/doc/Budget_Speech.pdf

Ministry of Science and Technology. 2020. *Government Launches Mission COVID Suraksha to accelerate Indian COVID-19 Vaccine Development*

MSF. 2021. *WTO COVID-19 TRIPS waiver proposal, https://msfaccess.org/sites/default/files/2020-12/COVID_TechBrief_MSF_AC_IP_TRIPSWaiverMythsRealities_ENG_Dec2020.pdf*

Nelson, Richard. 1959. 'The Simple Economics of Basic Scientific Research, *Journal of Political Economy*, Vol. 67, No: 3, pp. 297-306 https://www.journals.uchicago.edu/doi/abs/10.1086/258177

OECD. 2021. 'Using Trade to Fight COVID-19: Manufacturing and Distributing Vaccines,' *OECD Policy Responses to Coronavirus (COVID-19)*, OECD Publishing, Paris, https://doi.org/10.1787/dc0d37fc-en.

Plotkin, Stanley James M. Robinson, Gerard Cunningham, Robyn Iqbal, and Shannon Larsen. 2017. 'The Complexity and Cost of Vaccine Manufacturing – An Overview', *Vaccine*. 2017 the 24th of July; 35(33): 4064–4071.

Press Information Bureau. 2021. 'Government of India to Provide Free Vaccine to all Indian Citizens above 18 Years of Age', https://www.pib.gov.in/PressReleasePage.aspx?PRID=1725113 (accessed on the 8th of June 2021)

Sachs, Jeffrey D. 2021. 'Share the Intellectual Property on COVID-19', *Project Syndicate*, https://www.project-syndicate.org/commentary/covid19-intellectual-property-waiver-is-a-moral-imperative-by-jeffrey-d-sachs-2021-04

Stiglitz, Joseph E.; Lin, Justin Yifu; Monga, Célestin. 2013. 'The Rejuvenation of Industrial Policy', Policy Research Working Paper; No. 6628. World Bank, Washington, DC.: World Bank.

Supreme Court of India. 2021a. *Affidavit dated 09.05.2021 on behalf of Union of India*, Suo Moto Writ Petition (Civil) No: 3 of 2021 In Re: Distribution of essential services and supplies Services during pandemic

Supreme Court of India. 2021b. *Further affidavit dated 26.06.2021 on behalf of Union of India*, Suo Moto Writ Petition (Civil) No: 3 of 2021 In Re: Distribution of essential services and supplies Services during pandemic

Third World Network (2021), *TWN series on intellectual property and covid-19 vaccines*, https://twn.my/title2/briefing_papers/covid19_vaccines_series.htm

WHO. 2021. COVID-19 vaccine tracker and landscape, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

WTO. 2021. *Waiver from specific provisions of the TRIPS agreement for the prevention, containment and treatment of covid-19*. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

Xinhuanet. 2020. 'Reality Check of U.S. Allegations Against China on COVID-19', http://www.xinhuanet.com/english/2020-05/10/c_139044103.htm

Sunil Mani is Director and Professor, RBI Chair, Centre for Development Studies, Trivandrum.

E-mail: mani@cds.edu.

Annexure 1: Government Agencies that Fund Medical R&D across countries

United States of America

- Department of Health and Human Services
    - National Institutes of Health (NIH)
    - Biomedical Advanced Research and Development Authority (BARDA)
    - Centres for Disease Prevention and Control (CDC)
    - Food and Drug Administration (FDA)
- Department of Defense (DoD)
    - Congressionally Directed Medical Research Programs (CDMRP)
    - Walter Reed Army Institute of Research (WRAIR)
- Department of Veterans Affairs
- State-level
    - California Institute for Regenerative Medicine (CIRM)

India

- Indian Council of Medical Research (ICMR)
- Council for Scientific and Industrial Research (CSIR)
- Department of Biotechnology
- Department of Science and Technology
- Ministry of Health and Family Welfare

United Kingdom

- National Institute for Health Research (NIHR)
- U.K. Medical Research Council (UKRI)
- Scotland
    - Chief Scientist Office (CSO)
- Wales
    - Health and Care Research Wales
- Northern Ireland
    - Health and Social Care Research and Development Directorate (HSC R&D)

Canada

- Canadian Institutes of Health Research (CIHR)

New Zealand

- Health Research Council of New Zealand (HRC)

Australia

- National Health and Medical Research Council (NHMRC)

Brazil

- National Council for Scientific and Technological Development (CNPq)

Argentina

- National Scientific and Technical Research Council (CONICET)

Mexico

- National Council on Science and Technology (CONACYT)

Peru

- National Council for Science, Technology, and Innovation (CONCYTEC)

European Union

- European Commission Health Research and Innovation Projects
- European Medicines Agency (EMA)

Belgium

- Belgian Federal Science Policy Office (belspo)

The Netherlands

- Dutch Research Council (NWO)

France

- National Centre for Scientific Research (CNRS)
- National Institute of Health and Medical Research (Inserm)

Norway

- The Research Council of Norway

Japan

- Agency for Medical Research and Development (AMED)

South Korea

- National Research Foundation of Korea (NRF)

Singapore

- National Medical Research Council (NMRC)

Source: Drug Database (2021)

Annexure 2: R&D funding for COVID-19 vaccine development by the Federal Government and Philanthropic Organisations in the USA

	Funder_lvl_1	Recipient_country	Recipient_lvl_2	Recipient_lvl_1	R&D Funding (Million)
United States of America	US government DOD	United States of America	Industry	SAB Biotherapeutics	27.00
United States of America	US government BARDA/ASPR	France/United Kingdom	Industry	Sanofi Pasteur/GSK	30.78
Gates Foundation	Gates Foundation	United States of America	Industry	Inovio Pharmaceuticals	5.00
United States of America	U.S. government DOD	United States of America	Industry	Ology Bioservices	11.90
United States of America	US government BARDA/ASPR	Belgium	Industry	Janssen	456.24
United States of America	US government BARDA/ASPR	United States of America	Industry	Moderna Therapeutics	430.30
Gates Foundation	Gates Foundation	India	Industry	Biological E Limited	4.02
Gates Foundation	Gates Foundation	Australia	Academics and other research institutions	Melbourne Children's Trials Centre	7.05
Love, Tito's	Love, Tito's	United States of America	Academics and other research institutions	Baylor College of Medicine	1.00
Gates Foundation	Gates Foundation	South Korea	Industry	SK Biosciences	3.60
Vivo Capital	Vivo Capital	China	Industry	SinoVac	7.50
United States of America	US government BARDA/ASPR	United States of America	Industry	Moderna Therapeutics	53.00
United States of America	US government BARDA/ASPR	United States of America	Industry	Merck	38.03
United States of America	U.S. government DOD	United States of America	Industry	Novavax	60.00
United States of America	U.S. government DOD	United States of America	Industry	Novavax	21.95
United States of America	US DOD	United States of America	Industry	Inovio Pharmaceuticals	71.00
ADX Foundation	ADX Foundation	Norway	PDPs	CEPI	0.10
United States of America	US government BARDA/ASPR	United States of America	Academics and other research institutions	Colorado State University	0.70
United States of America	US government BARDA/ASPR	United States of America	Industry	Verndari	0.70

United States of America	US government BARDA/ASPR	United States of America	Industry	Moderna Therapeutics	472.00
United States of America	US government BARDA/ASPR	United States of America	Industry	Esperovax, Inc	0.61
United States of America	US government BARDA/ASPR	United States of America	Industry	Vaxess Technologies	0.75
Gates Foundation	Gates Foundation	United States of America	Industry	Dynavax	3.40
Gates Foundation	Gates Foundation	United States of America	Industry	Novavax	15.00
United States of America	US government BARDA/ASPR	United States of America	Academics and other research institutions	University of Connecticut	0.43
United States of America	U.S. government DOD	United States of America	Industry	Adaptive Phage Therapeutics (APT)	9.80
United States of America	U.S. government HHS	Belgium	Industry	Janssen	85.30
United States of America	U.S. government NIH	United States of America	Industry	HDT Bio Corp	8.20
Gates Foundation	Gates Foundation	South Korea	Other	IVI	1.50
Gates Foundation	Gates Foundation	Norway	PDPs	CEPI	20.00
United States of America	U.S. government HHS	Belgium	Industry	Janssen	454.31
Dolly Parton COVID-19 Research Fund	Dolly Parton COVID-19 Research Fund	United States of America	Industry	Moderna Therapeutics	1.00
United States of America	U.S. government DOD	United States of America	Industry	Novavax	23.00
United States of America	U.S. government NIH	United States of America	Industry	Soligenix	1.50
Total					**2,326.67**

Source: Global Health Centre (2021)

Annexure 3: Financial support for COVID-19 vaccine R&D and manufacture in India

	Details of expenditure	Rs. in Crores
1.	**Mission COVID Suraksha- the India COVID-19 Vaccine Development Mission- as part of the third stimulus package- DBT is the nodal agency**	900
2.	**Funds provided by ICMR for the development of COVAXIN and these have been given for conducting clinical trials** - Isolation of the virus, bulk production of virus and characterisation of the vaccine strain at NIV. • Preclinical studies of the vaccine strain in hamsters and monkeys. • Quality control samples of small animal studies and phase 1 and phase 2 serum samples. • Phase 3 clinical trial (full funding). • Assessing the effectiveness of COVAXIN against variant strains of SARS-CoV-2 (U.K. variant, Brazil variant, South African variant and Indian double mutant strain)	35
3.	**Funds provided by ICMR for testing the vaccine COVISHIELD in India:** • The bridging studies of COVISHIELD in 1600 participants in India were supported by ICMR in partnership with Serum Institute of India (SII). No funds were provided to SII. Instead, funds were transferred to 14 clinical trial sites. • ICMR also supported laboratory studies on the characterisation of immune response related to COVISHIELD at ICMR-National AIDS Research Institute (NARI), Pune.	11
4.	One hundred per cent advance payment for doses of vaccine during May- July 2021)- • SII- 110 million doses • BBIL- 50 million doses • Biological E- 300 million doses	 1732.50 787.50 1500.00
5.	Credit without a bank guarantee • SII • BBIL	 3000 1500
	Total	**9465.50***

Source: Own compilation based on Department of Biotechnology (2021), Supreme Court of India (2021)

Note: *This does not include the amounts the government have sanctioned to three PSEs for manufacturing the indigenously developed Covaxin through a voluntary license between them and the technology supplier, BBIL

Centre for Development Studies
(Under the aegis of Govt. of Kerala & Indian Council of Social Science Research)
Prasanth Nagar, Ulloor
Thiruvananthapuram 695 011
Kerala, India

Phone : 0471 - 2774200, 2448881, 2442481, 2448412
Fax: 0471 - 2447137
Website: www.cds.edu