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INDIA'S ROLE IN FRUGAL INNOVATIONS IN HEALTH-RELATED TECHNOLOGIES TO DEAL WITH COVID-19 OPPORTUNITIES AND CONSTRAINTS

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ABSTRACT

There are a number of instances of successful frugal innovations in India's health-related technology industry consisting of vaccines, drugs and medical devices of various types. COVID-19 offers an opportunity for these domestic technological capabilities to be expressed systematically as it will be immensely useful not just for India but for the world at large in managing or even getting rid of the pandemic itself. However, it also raises the role of the state in supporting this research and manufacturing activity by designing financial instruments for financing the innovation and manufacturing activities and removing the barriers imposed by a very restrictive and stifling patent regime and by reducing lack of coordination between government policies and agencies.

Keywords: COVID-19, Coronavirus, SARS-CoV2, health related technologies, frugal innovation, pharmaceutical, medical devices, financing of innovation, patents, India

JEL Classification: H12, I18, L52, L65, O31, O34, O38

India's Role in Frugal Innovations in Health-Related Technologiesto Deal with COVID-19 Opportunities and Constraints

COVID-19, which is sweeping the world so rapidly and with much ferocity has not spared India either. Although strictly going by health metrics such as the density of cases and death per million, India, fortunately, has been spared the worst scenario. The spread of coronavirus has been very uneven across the sub-continent but the government has responded to it with one of the most stringent lockdowns[1] in the world.

An important aspect of the SARS-CoV-2 virus which causes COVID-19 is the fact that there are at the moment no known vaccines for its complete eradication, no therapeutic drugs for its treatment and medical devices, personal protective equipment for its management and containment of its spread are either too costly or are in short supply. However, in all these cases, fast-tracked R&D projects and clinical trials are in progress the world over. In fact, according to WHO (2020), there are as on April 23, 2020, 6 candidate vaccines in clinical evaluation and 77 candidate vaccines in pre-clinical evaluation. In fact, at the time of writing, one of the 6 candidate vaccines in clinical evaluation has made much progress. Regarding therapeutic drugs, two existing anti-viral drugs have been shortlisted and one among them is showing some early results, based on US National Institute of Allergy and Infectious Diseases (NIAID) trials, that it can speed recovery in infected patients. An important characteristic of all the health-related technologies whether it is a vaccine, a therapeutic drug or a medical device, is the fact that it will have to be manufactured and made available at a very low price that it can be afforded by public health systems the world over. This is where India can come in, as it has built up considerable technological and manufacturing capabilities to manufacture and distribute large quantities of these

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1 See University of Oxford, Coronavirus Government Response Tracker, https://www.bsg.ox.ac.uk/research/research-projects/coronavirus-government-response-tracker(last accessed on May 2, 2020).

technologies at prices which are significantly lower than is available at present across the world including that of China. Three such areas that may be highlighted where India's response has been noticed internationally is in vaccine research and its manufacturing, preparedness and ability to manufacture generic versions of the so-called game-changer drugs and frugal engineering in designing and manufacturing medical devices such as invasive ventilators and N95 equivalent masks. Further, some of the states in India has shown that it is possible to contain the pandemic in a short period, provided that the government can win the trust of the civil society, in general, to comply fully with the various stringent measures like a complete lockdown and that the governments in question place paramount importance to the technical advice provided by their respective public health authorities. These are explained in some more specific details below:

(i) Vaccine research and manufacturing: There are 6 Indian firms which are active in research on a vaccine for COVID-19. The details of these are in Table 1. Among, all these, the Serum Institute of India is one of the more interesting ones, as it is considered to be the world's largest vaccine maker by several doses produced and sold across the world. The company is 53 years old, employs 7000 persons and operates from plants in India, the Netherlands and the Czech Republic. A lion's share of the 20 different vaccines that it manufactures is exported to 165 countries at an average price of US 0.50 cents a dose, earning it the reputation of being the cheapest vaccine manufacturer in the world which makes it eminently eligible for participating in the quest for a cheap vaccine against coronavirus. Its partnership with Oxford Vaccine Group for a promising under-trial COVID-19 vaccine aims to have the vials ready for commercial use by September-October 2020 as the Oxford vaccine has become the bellwether with success being reported from the US National Institute organized trials on the rhesus macaque.

(ii) Therapeutic drugs: The two drugs that are presumed to be effective in treating COVID- 19 are Hydroxychloroquine and Remdesivir. The former, after some initial trials, are now considered to be not effective, although the largest manufacturer of this drug in the world, accounting for about 70 per cent is an Indian pharmaceutical company, Zydus Cadila. The latter drug has now passed some trials in the USA, has received an emergency use authorisation (EUA)[2] from the U.S Food and Drug Administration (USFDA) as reported above. The drug, remdesivir, in recent clinical trials, has shown to shorten recovery time for seriously ill COVID-19 patients. The National Institutes of Health (NIH) began a randomized controlled trial of the drug for the treatment of COVID-19 patients. The details of the trial are not available, but what is available is only an announcement by NIH on its website. But the website also mentions that more detailed information about the trial results, including more comprehensive data, will be available in a forthcoming report.[3]

2 See USFDA (2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment (last accessed on May 1, 2020).

3 See National Institute of Health (2020), https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19 (last accessed on May 2, 2020).

Table 1: Indian pharmaceutical companies active on COVID-19 vaccine research (as on April 30, 2020)

Company	Number	Details
Zydus Cadila	2	• The company announced that it has initiated an accelerated research programme with multiple teams in India and Europe developing a vaccine for COVID-19 based on two approaches: • The first approach is cantered on the development of a DNA vaccine against the major viral membrane protein which is responsible for the cell entry of the novel coronavirus. • The second approach focuses on developing a vaccine against COVID-19. This will use a live attenuated recombinant measles virus, designed to induce long-term specific neutralising antibodies.
The Serum Institute of India	1	• Has partnered with American biotechnology firm Cadagenix to develop such a vaccine, and expects it to be ready by early 2022 and with Oxford Vaccine Group to manufacture the vaccines being developed by them. • The company is aiming to manufacture 4-5 million doses
Biological E	1	
Bharat Biotech	1	• Bharat Biotech and the US-based FluGen along with virologists at the University of Wisconsin-Madison have begun the development and testing of a unique vaccine against covid-19 called CoroFlu.
Indian Immunological	1	• Has entered into a research collaboration agreement with Australia's Griffith University to develop a lead vaccine candidate for coronavirus. • As part of the cross-continental collaboration, scientists from IIL and the University will develop a 'Live Attenuated SARS-CoV-2 vaccine' or COVID-19 vaccine using the latest codon de-optimization technology.
Mynvax	1	• Startup developed by IISc, Bangalore

Source: Biswas (2020), WHO (2020), Economic Times, April 16, 2020, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/six-indian-companies-working-on-covid-19-vaccine-many-challenges-in-finding-a-preventive-experts/articleshow/75160500.cms?from=mdr (last accessed on May 2, 2020).

Some important domestic pharma companies including Cipla, Glenmark and Dr Reddy's, according to the industry sources, have started working on the development of the drug which is under patent protection until 2035[4]. The companies are hoping that Gilead, which owns the drug patent, will grant them licensing provisions as it did with hepatitis C drug Sovaldi in 2014, so that domestic manufacturing can then commence. For the present, according to the "Bolarexemption[5]", the companies are allowed to formulate the drug, strictly for the R&D purposes. It is understood that key pharma companies have started the process to develop the drug's active pharmaceutical ingredients (APIs).

A public laboratory belonging to the CSIR network of laboratories, the Indian Institute of Chemical Technology (IICT) has developed a convenient and cost-effective synthetic process for producing the antiviral drug Favipiravir[6]. IICT has transferred the entire process and significant quantities of pharma-grade API of Favipiravir to one of the largest domestic pharma companies, Cipla. The company has approached the regulatory authority for conducting clinical trials for treating COVID-19

(iii) Medical devices: India has at present at least one domestic manufacturer, AgVa, of invasive ventilators who can supply it for 20 per cent of the going international price of these ventilators. In more recent times, a startup, Nocca Robotics (NR), which is incubated by Indian Institute of Technology, Kanpur (IITK) is in the process of commercialising a low-cost ventilator which according to the developers will cost only about 6 per cent of going international price of ventilators. A US-based engineering simulation company, Ansys, has entered into an agreement with the IIT Kanpur led consortium to assist in its development. NR is expected to manufacture about 30000 ventilators by May 2020 although more recent information about the progress of this project is not forthcoming. Apart from ventilators, there are some other devices such a diagnostic test kit has been developed by a public laboratory, Sree Chitra Tirunal Institute of Medical Sciences and Technology(SCTIMST). The product called Chitra GeneLamp-N can confirm COVID-19 in two hours or so, at a low cost of

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4 https://www.businesstoday.in/latest/trends/coronavirus-gilead-to-partner-with-local-firms-for-remdesivir-production-in-india/story/401387.html (last accessed on May 5, 2020).

5 The exemption enables generic drug manufacturers to use an inventor's pharmaceutical drug before the patent expires, which not only aids in the early launch of generic versions of the drug once the innovator drug's patent term ends, but also promotes further R&D. In India, the exemption is set out in Section 107A of the Patents Act and is comparatively broader than its US equivalent.

6 Preliminary results of favipiravir's (viral RNA polymerase inhibitor) moderate antiviral effect on COVID-19 have emerged from a study in China, although the parent company of the drug (Fujifilm Pharmaceuticals, Japan) has not confirmed the drug's efficacy.Favipiravir (Avigan) is approved in Japan and China for influenza and is investigational for use in COVID-19.

less than INR 1000 per test. SCTIMIST has also developed very cost effective swabs for collecting oral and nasal specimens for COVID-19 suspected persons and also for developing a viral transport medium which is designed to retain the virus in its active firm during its transportation from the collection point to the lab[7] and these technologies have been successfully transferred to manufacturing firms in Kerala and Gujarat. Still another example of a COVID related frugal innovation is an N95 equivalent mask developed by an Indian Institute of Technology, Delhi (IITD) incubated startup, ETEX. The *KAWACH*, developed by ETEX, the mask is at par with N95 in terms of proper fitting, and engineered filtration layer that could provide up to 98% filtration efficiency and costs less than INR 45 per piece. In short, India's manufacturing sector has responded very well in terms of developing a whole host of COVID related, but frugal technologies that are at the same time affordable.

What we have mapped out above is by no means an exhaustive list of frugal medical devices. These are the more important ones which are immediately required for COVID-19 detection and its management and they confer two important advantages to the country. First, they increase the supply of quality medical devices which are immediately required for COVID-19 management at extremely affordable prices. Second, such efforts reduce our dependence on importation of medical devices of questionable quality and exorbitant prices.[8]

The three factors that can hamper India's technological response COVID-19 is its ability to identify new ways of financing R&D projects in this area and also in effecting changes in the international governance rules concerning Intellectual Property Rights and especially patents which makes it easier for domestic technology development in this crucial fight against COVID-19 and finally reducing the lack of coordination between government policies.

(a) Financing of innovation: Innovations to contain COVID-19 are of two types. Those relating to vaccines and therapeutic drugs, and those relating to various types of medical devices. The former type (say Type 1) of innovations may involve, relatively speaking, more formal R&D even if it is for generic versions of already introduced drugs. The latter type (Type 2) of devices may not require formal R&D and it will in most cases involve some form of reverse engineering of the already existing type of devices. In terms of financing innovation, Type 1 will require both R&D tax incentives and research grants. While in Type 2, research grants and sometimes even equity financing will be the right type of instrument: equity finance is required for establishing new startups. However, in both cases, public technology procurement will be a very useful instrument that can assure a market for the newly developed technology. One of the main modes of financing innovation in the country has been

7 See the Press Release, Ministry of Science and Technology (2020).

8 The recent controversy over imports of rapid antibody test kits is an illustration of such difficulties. See, https://www.bbc.com/news/world-asia-india-52378265 (last accessed on May 3, 2020).

through offering a very generous R&D tax regime (Mani, 2014), although the generosity of which has been reduced over time. Studies (Mani, 2018) have shown that the empirical evidence on the effectiveness of this incentive to spur additional investments in R&D, in general, has been questionable. Estimates on revenue loss on account of this incentive computed and presented by the Union Ministry of Finance in its receipt budgets have shown that it has increased from Rs 2839 crores in 2005-06 to Rs 8309.95 crores in 2019-20. We argue that given its performance record as an incentive for enabling firms to commit more resources to R&D and also given the urgency dictated by the pandemic, the government should consider either targeting the tax incentives only to health-related technologies or convert it to a research grant system whereby projects in this priority area are funded with some less stringent conditions on outcomes. Whatever is the policy decision on this suggestion, as Gans (2020) has argued that governments need to bear in mind the following two important aspects while designing their policy instruments for financing innovations to find effective solutions in health-related technologies. They are (i) ''the usual way of rewarding innovative activity breaks down because governments and donors will put pressure on innovators to reduce the price;" and (ii) "the urgent nature of the crisis means that governments need to failure-tolerant in pursuing a wide variety of approaches to solve a given problem". According to Gans (2020), the most tried and tested method or policy instrument that encompasses both (i) and (ii) types of failures is the instrument of public technology procurement where the public health authorities offer a credible commitment to purchase all of the innovations at a pre-determined price that is remunerative enough for the innovators.

(b) Governance rules on Intellectual Property Rights: An important area where much clarity is required is on the role of IPRs and especially patents which if it is not allowed to be reformed very quickly can stand in the way of many of these frugal innovations not reaching the masses in the shortest possible time. This is because the pharmaceutical industry and indeed the digital industry are the two that are most affected, either positively or negatively, by the TRIPS compliant patent regime that was put in place in India since 2005. Even within the short window of time, one could see the negative effect of patents. We could cite four recent incidents during the coronavirus pandemic to buttress our concern.

First, is the case of the American MNC pharmaceutical company, Gilead, whose drug, remdesivir, has received a EUA[9] from USFDA. According to Gilead itself,the company has in early March 2020, sought and was subsequently granted an orphan drug designation for the remdesivir as a potential treatment for COVID-19. Orphan drug designation is granted by the USFDA in situations where the disease affects fewer than 200,000 patients in the United States, although the numbers involved even in the US was significantly higher. The orphan drug status confers many benefits to the recipient such as generous

9 See the press statement by the company, https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-to-rescind-remdesivir-orphan-drug-designation (last accessed on May 2, 2020).

tax concessions and it also results in a waiver of the requirement to provide a paediatric study plan before the submission of a New Drug Application – a process that can take up to 210 days to review.

But subsequently, the company has submitted a request to the USFDA to rescind the orphan drug designation it was granted, for the investigational antiviral remdesivir, for the treatment of COVID-19 and is waiving all benefits that accompany the designation. Further, Gilead is planning to give away free of charge 1.5 million vials of the drug which is currently available with it as the drug was developed earlier for treating another viral disease, Ebola. But according to the USA based advocacy group, Initiative for Medicines, Access & Knowledge (I-MAK)[10], Gilead is a company with a poor reputation for charging very high prices in drugs for treating rare diseases. This could be seen in the context of pricing of hepatitis C where the company bought the drug that cured hepatitis C of a small company, and then charged exorbitant prices which put that medicine beyond the reach of the public health system[11]. It is also important to realise that the remdesivir was developed and tested by two US universities, Vanderbilt and Emory and its recent field trial for its efficacy for treatment of COVID-19 was publicly funded. All these, will naturally necessitate it to be priced very cheaply. Given Gilead's poor record and the company applying for an orphan drug status, I am not sure whether the company will allow the Indian drug manufacturers to make generic versions of the drug while the remdesivir still has a valid patent. However, the Indian patent office could issue a compulsory license to deal with this issue as it has done once in the past. This will of course, crucially, depend on the price which Gilead is planning to charge for a dose of the drug.

Second, is the case of N95 face masks where again the monopoly position for its manufacturing is held by the US MNC, 3M. While 3M is not the only producer of N95s, it is the largest domestic manufacturer accounting for over 70 per cent of the market. The company holds 441 patents[12] in the US that mentions 'N95' or 'respirator and the latest respirator-related patent granted to 3M was approved just on April 7, 2020[13]. It is this fact of patents that explains the shortage of this crucial personal protective equipment that is exposing the front line health workers to the dangerous effects of this highly contagious virus. The IITD incubated startup ETEX with its *Kawach* mask does appear to have circumvented this problem although the Damocles sword of a patent infringement litigation is very much hanging on its head.

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10 See I-MAK, https://www.i-mak.org/2017/10/25/first-ever-us-patent-challenges-gilead-hepatitis-c/ (last accessed on May 2, 2020).

11 The source of this information is from press statement by Professor Aaron Seth Kasselheim, Professor of Medicine at Harvard Medical School. The Kasselheim statements are to be found in Kolata (2020).

12 See https://docs.google.com/spreadsheets/d/1SCCCKsGBNC8NmbsydtJfag3wwBl384Fc6hvFMntQfT0/edit#gid=689748996 (last accessed on May 2, 2020) also Stiglitz, Jayadev and Prabhala (2020).

13 See https://www.healthpolicy-watch.org/the-netherlands-joins-covid-19-ip-pool-initiative-kentucky-governor-requests-3m-release-n95-patent/ (last accessed on May 2, 2020).

Third, is the scandal of sorts that has erupted in the development of convalescent plasma therapy. There is now some consensus that once a patient recovers from Covid-19, his or her blood contains antibodies in its plasma that can fight the virus. Those antibodies can be extracted from a donor's blood and given to a severely ill patient via transfusion, with the hope that the donor's antibodies will help the patient recover.The therapy needs blood samples taken from recovered COVID-19 patients. Given the competition for these samples has resulted in a shortage of sorts. A Mumbai-based Indian company specialising in the development of polyclonal antibodies is supposed to have charged USD 50000 for just a millilitre of blood and acted as a middleman to a California based biopharmaceutical company, specialising in the manufacturing of antibodies (Bradley, 2020).

Fourth, instead of lessening the hold of patents, the United States continues to treat India as a country where the patent system is very weak, especially as far as pharmaceuticals and medical devices are concerned and have continued to place India in its Priority Watch List. The recently released report by the Office of the United States Trade Representative (2020) gives solid expression to this long-standing concern of the US. It is surprising that despite the explicit recognition of the stifling effect of patents, the US has continued with its oft-repeated efforts and calls for further strengthening the IPR regime in India. See Box 1 for the details. As the Box reveals, the US continues to campaign for repealing of Section 3(d) of the Indian Patent Act which places a higher bar on the inventiveness criteria for especially pharmaceutical drugs and also has managed to water down one of the most unique features of our patent system namely the requirement of a working patent.

Time is now ripe for a complete rethinking on the policy on patents in general and those for health related technologies in particular. Systematic recent analysis (Boldrin and Levine, 2008, 2012) has shown that the patent system appears to have broken down and companies use patents as a strategic instrument for maintaining or creating barriers to entry to new firms so that they can continue to maintain their monopoly and also to make excessive profits. A stricter patent regime which has been carved out by TRIPS compliance has led to a bourgeoning of patent ligations. In fact Jaffe and Lerner (2011) has shown the fact that many companies and especially those from the USA make much more revenue through patent litigation rather than earning royalties through licensing their patents. In fact the market for disembodied technologies and especially those related to health related technologies have become very imperfect over the years. The COVID-19 has brought to focus the IPR scene. There are now many positive developments which are purely voluntary efforts by universities and advocates of an open science or patent pool movement. Companies too have changed their rigid or sometimes even unacceptable stands on patents because of strong opposition from especially the media. Table 2 summarises a selection of the more important ones reported in the press recently.

Table 2: The state of flux in the patenting arena in the context of COVID-19

Company or organization	Name of drug	Actions
AbbVie	Kaletra- antiviral drug thought to be effective as a therapeutic drug for COVID-19	• Relinquished its patent right but only after the Israeli government issued a compulsory license to manufacture a generic version of the drug.
Biotechnology Innovation Organization https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus	Vaccine for COVD-19	• More than a third of its 1000 members are now working on coronaviruses· • New collaborations between arch rivals Glaxo Smith Kline of UK and Sanofi, France
Labrador Diagnostics	Diagnostic tests for detecting COVID-19	• Filed a patent lawsuit against US start-up Bio Fire for developing diagnostic tests for detecting COVID-19 • Consequent to very strong opposition to this from the media have backtracked
Gilead	Remdesivir- the drug that is now received an EUA for treating COVID-19 patients	• Made a U- turn in its attempt to secure an 'orphan drug" status for its drug so that it could have enjoyed tax concessions
Open Covid Pledge https://opencovidpledge.org/pledge/	All companies having technologies for dealing with COVD-19	• Companies could make pledge to make their respective IPs free of charge
Fighting coronavirus together at the University College London, UK https://covid19research.uclb.com/	All companies having technologies for dealing with COVD-	• At present UCL itself has made its Venture breathing aid (CPAP) free of charge. This involves a design and manufacturing package

Source: Compiled from Palmer and Mancini (2020), Pearcey (2020)

It is essential that to ensure effective and quick development of vaccines and therapeutic drugs and indeed the type of medical devices that are required for dealing with COVID-19, we require as Mazzucato and Torreele (2020) has argued, (a) a mission oriented public-private partnership in achieving clearly defined common goals; and (b) in order to maximize efficiency of R&D projects in this area, given the fact that all the skill sets that are required for a successful launch of a vaccine, drug or device are not available, an open collaboration straddling firms and nations are required. Fortunately in vaccine development, one is able to see elements of both (a) and (b).

Box 1: United States' reasons for continue to putting India in the Priority Watch List

- Patent issues continue to be of particular concern in India as long-standing issues remain for innovative industries. The potential threat of compulsory licenses and patent revocations, and the narrow patentability criteria under the India Patents Act, burden companies across different sectors.
- Patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements.
- India is moving forward on trying to resolve burdensome patent reporting requirements by issuing a revised Manual of Patent Office Practice and Procedure and considering revisions to Form 27 on patent working.
- The pharmaceutical industry reports concerns as to India's continued use of the threat of compulsory licensing to coerce right holders to lower pharmaceutical prices. Right holders also reported growing concerns over the expansive application of patentability exceptions to reject pharmaceutical patents.
- In the pharmaceutical sector, Section 3(d) of the India Patents Act also remains problematic. One implication of its restriction on the patent-eligible subject matter is the failure to incentivize innovation that would lead to the development of improvements with benefits for Indian patients.
- India maintains extremely high customs duties directed to IP-intensive products such as medical devices, pharmaceuticals, Information and Communications Technology (ICT) products, solar energy equipment, and capital goods.

Source: Office of the United States Trade Representative (2020).

(**c**) **Improving coordination between government policies**: And still another constraint to domestic technology development especially in a fast track mode which COVID-19 demands are to reduce the contradictions in public policies. An all too frequent instance of this lack of coordination is

between domestic manufacturing policies especially phased manufacturing requirements and trade policies. The existence of some free trade agreements (FTA) has further complicated this issue. A recent case in point is in the domestic manufacturing of mobile phones which continues to depend heavily on imported inputs from partners in south-east Asian with whom India has an FTA. A further issue that requires careful analysis is the practice of allowing importation of the technology which the state has supported to be developed or even in the process of being developed. So when domestic R&D projects are about to reach its logical conclusion, the government allows importation of the very same technology, often enough on weighty on technological considerations. The recent experiences of telecommunications equipment and the case of the semi high-speed train are cases to illustrate this. However, there appears to be some coordination of all S&T work towards COVID-19 coordinated by the Office of the Principal Scientific Adviser to Government of India[14].

Summing up: There are very many instances of successful frugal innovations in India's health-related technology industry consisting of vaccines, drugs and medical devices of various types. COVID-19 offers an excellent opportunity for these domestic technological capabilities to be expressed systematically as it will be immensely useful not just for India but for the world at large in managing or even getting rid of the pandemic (if the vaccines that are being developed proves to be effective in immunising the population) itself. However, it also raises the role of the state in supporting this research and manufacturing activity by designing financial instruments for supporting the innovation and manufacturing activities and removing the barriers imposed by a very restrictive and stifling patent regime and by reducing lack of coordination between government policies and agencies. India could thus carve out an important niche as the true pharmacy to the world in this extraordinary time.

14 This could be found here: https://vigyanprasar.gov.in/covid19-newsletters/ (last accessed on May 3, 2020)

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