

Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Valuation
- M & A
- IP Policy
- Technology Transfer
- Innovation Research
- Patent Law
- Licensing
- Data Management
- Copyright
- Collaborations
- Balance for Rights & Obligations

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### Editorial

While the entire world is looking forward to the affordable access of an effective vaccine against Covid-19, it is heartening to note that India will be part of the vaccine initiative, since Serum institute of India, Pune (Dr. Cyrus Poonawala) is the largest vaccine manufacturer in the world. All India Radio Kozhikode (Calicut- Kerala) Mr. K.M. Narendran (KMN) interviewed Mr. Purushothaman C Nambiar (PCN), Director of Serum Institute of India. The interview was in Malayalam. I am taking this privilege and liberty of translating the public domain broadcasted discussions of the interview from Malayalam for the benefit of CIPROM audience.

Q: (KMN):- Serum institute has become globally famous now. Today whole world is watching what Serum Institute is doing for vaccine against Covid-19. Could you please explain what Serum is doing for vaccine against COVID? What is the nature of your relationship with Oxford vaccine project? What are the stages of your progress in this field? (And other questions subsequently thereafter)

Ans: (PCN):- Serum institute of India commenced production in 1966. It was founded by Dr. Cyrus Poonawala. Serum institute of India is the largest vaccine manufacturer in the world. However, being in pharma industry, we do not advertise or publicize about our activities. 2 out of 3 children born anywhere in the world are (statistically) being immunized with vaccines made by Serum institute of India.

As regards vaccines against COVID-19 are concerned, we have planned to make 5 to 6 vaccines. These are in various stages of development. The most important one is based on the cell-bank made available to us by the Oxford University, UK. The Oxford vaccine is undergoing trials in various locations of the world. These trials are presently moving into Phase 3, involving thousands of volunteers in different locations. Based on the original cell-bank received by us, we have already manufactured 20 lakhs doses of vaccines for Oxford. This is under various stages of trials. From October 2020, we will start human trials, based on which we may get permission from the Indian Regulatory Authorities, if the human trials are promising.

Over and above this, our own vaccine is also under trials, which may come up for human trials in September 2020. We are also working on other vaccines of our own. The Oxford vaccine was originally planned against Malaria. This is presently being tested for Covid-19. The Covid-19 virus itself is mutating by itself. Our own vaccines, other than the Oxford vaccine, are being developed based on the Covid-19 virus in India specifically. By October, the quantity of vaccines made by Serum institute of India is expected to be about 60 lakhs. Our planned production of vaccines for Covid-19 is around 20 lakhs per month. By end of September, we expect our vaccines to be available. The approximate cost of the vaccine is expected to be about Rs. 4,500/-. Moreover our company's policy is to offer the vaccine to the needy population at the lowest possible price. Serum institute of India is globally famous for providing quality vaccines at lowest prices. For example, when vaccines

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made by others are priced at Rs. 595/- our own vaccine is priced at Rs. 55/-. This is our reputation in affordable pricing. By October 2020, we hope to make available about 60 lakh vaccines. We will continue to make the vaccines at the rate of about 10 to 15 lakhs per month. About 60 % of Indian population fall under the category of 35 years or younger. As far as the Indian population is concerned, we are proposing to make the vaccine available to older population (30-35%) and the very young. However, we may focus on the containment zones declared by the government, initially after obtaining clearance from the government. Presently, we are concentrating on preventive vaccines as discussed above.

Our immunization dose is a single dose which may be effective for three years. Our strain is different from that of Oxford. Presently 13 projects are in progress all over the world. However, most of them or at least some of them will need to come to us for manufacture, formulation and filling. We work on contract manufacturing or on our own marketing basis. When we market the product for Asia and Africa, we will price the product as per our strategy. Mostly we will be working on marketing arrangement for Asia and Africa. Once the trial data is ready and is positive, we will approach ICMR who is the regulatory authority for granting clearance for marketing. ICMR and Bharat Serum are working on another vaccine (BCG) originally meant for TB. However, I cannot comment on that.

We expect a vaccine to be ready by October 2020. Most of the other vaccines are already under schedule. Most probably the vaccine for Covid-19 will also come under immunization schedule by next year, 2021. Indian population and density is high. However the recovery rate is about 69-70%. Our mortality rate is only about 0.5%, compared to Europe and USA, whose mortality rates are extremely high. India is very much better off, even as on date. Even in India, we have slums in Mumbai and suburbs, where, social distancing is virtually impossible. In spite of that, India has successfully controlled the mortality rate compared to countries with lower population and density. Vaccines will be made available both through the government as well as private marketing. Since our operations are confidential, we are not disclosing on our website. However, we are keeping the government of India updated every day. The office of the PM is monitoring our progress, through our daily reports which we make available at 3 AM every day. We have made a commitment to the Government and to the PMO to this effect. Serum Institute of India is already exporting vaccines to 170 countries. We have 5500 employees in Serum institute on 120 acre area. There are nearly 200 scientists working in our R&D. We are, by and large, unaffected by the Covid-19 in our campus. We have also used our Covid-19 vaccine, on a few employees from containment zones and they have remained safe. We are also working on a product for administration to those who are already infected. This is in early stage of development. Corona virus has a spike. We are targeting /isolating the spike, while developing this product.

Mr. Narendran concluded the interview by wishing Serum institute of India and those associated with these efforts, all success.

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## TASK FORCE ON REPURPOSING OF DRUGS FOR COVID19

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### Assessment of Patent related barriers for Indian manufacturers

The TFORD-COVID19-India has commissioned M/s Gnanlex Hermeneutics Private Limited (Gnanlex) to carry out patent searches and provide their opinion on the patent landscape in India for the drug candidates considered by the TFORD-COVID19-India and also provide insights into the the freedom-to-operate status for Indian manufacturers. Thanks to Gnanlex for providing timely assistance. This section is edited by Dr Vidula Walimbe (TechEx.in at Venture Center).



Reports from Gnanlex Hermeneutics Pvt Ltd (Released on 28 June 2020)

Source: <https://nclinnovations.org/covid19/patents/>

### India's first COVID-19 vaccine candidate COVAXIN gets DCGI approval

India's first COVID-19 vaccine candidate COVAXIN has received the approval of drug regulator DCGI for phase I and II of human clinical trials. The drug has been developed by Bharat Biotech. Human clinical trials are scheduled to start across India in July 2020.

Source: <https://www.cnbcvt18.com/healthcare/indias-first-covid-19-vaccine-candidate-covaxin-gets-dcgi-approval-6226931.htm>

### Dexamethasone, favipiravir, plasma therapy - how India's Covid care has evolved in 5 mths

From antiretrovirals to steroids, from focussing on ventilators to now looking for oxygen, a lot has changed in the standard of care for Covid-19 over the past five months in India. On Saturday, the Ministry of Health and Family Welfare issued revised treatment guidelines including dexamethasone, the inexpensive and easily available steroid, in treatment protocols.

Source: <https://theprint.in/health/dexamethasone-favipiravir-plasma-therapy-how-indias-covid-care-has-evolved-in-5-months/451703/>

### Madras university gets a patent for finding anti-cancer compound

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Source: <https://timesofindia.indiatimes.com/city/chennai/madras-univ-gets-a-patent-for-finding-anti-cancer-compound-in-sapota-leaves/articleshow/76698427.cms>

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## Indian Jugaad against COVID-19



The bike is the brainchild of Partha Saha of Aralia village near Agartala. In times of social distancing and in keeping with guidelines issued by the WHO, the electric bike has a one-metre distance between each seat.

Source: <https://indianexpress.com/article/north-east-india/tripura/tripura-coronavirus-bike-social-distancing-6380370/>



Milkman using a funnel and a long pipe to channel the milk into the container held by the customer, thus practising social distancing

Source: <https://twitter.com/AwanishSharan/status/1258377884650967040> and <https://www.readersdigest.in/features/story-in-the-times-of-coronavirus-5-ideas-that-celebrate-indian-jugaad-125710>



Researchers at National Institute of Technology Karnataka Develop Disinfection Chambers To Fight Coronavirus. "ZERO-COV," the disinfection chamber, made out of an old fridge, can destroy 99.9% of microorganisms present in the surface of the items

Source: <https://www.ndtv.com/karnataka-news/karnataka-researchers-develop-disinfection-chambers-to-fight-coronavirus-2212619>

## Coronavirus related Patents

**US10700151** granted to Apple Inc. for Synthetic Group Selfies, Allowing Users to Take Virtual Group Selfies Remotely Apple's synthetic group selfie feature allows users to rearrange the position of the members after the selfie has been generated.

Source: <https://gadgets.ndtv.com/apps/news/apple-granted-synthetic-group-selfies-patent-remote-virtual-photos-individual-iphone-2242799>

**US10689716** filed on March 19, 2020 and granted to University Of Miami on June 23, 2020 for test kits and methods for detecting the presence of Coronavirus polynucleotides in a biological sample.

Source: <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi/html%2FPTO%2Fsearch-adv.htm&r=1&f=G&l=50&d=PTXT&S1=coronavirus.TI.&QS=TTL/coronavirus&RS=TTL/coronavirus>

**EP0640096A1** filed on May 7, 1993 by Smithkline Beecham Corp For universal vaccine useful to protect different species of animals against infection by different host-specific coronaviruses (Universal Coronavirus Vaccine).

Source: <https://worldwide.espacenet.com/patent/search/family/025380027/publication/EP0640096A1?q=pn%3DEP0640096A1>