

(Petition filed under section 8 of Kerala High Court Act)

**BEFORE THE HONOURABLE HIGH COURT OF KERALA
AT ERNAKULAM**

W.P.(civil) No. / 2021

Petitioner

Gopakumar G.K

Vs-

Respondents

1. Union of India
Ministry of Health & Family Welfare,
Nirman Bhawan, C-Wing, New Delhi – 110011
Represented by its Secretary
2. Drug Controller General of India (DCGI),
FDA Bhawan, Kotla Road,
New Delhi 110002.
3. The Controller General of Patents, Designs and Trade Marks
Office of the Controller General of Patents, Designs
and Trademarks,
Boudhik Sampada Bhawan,
S.M.Road, Antop Hill, Mumbai 400 037
4. The State of Kerala represented by its Chief Secretary
Government Secretariat, Trivandrum-695001
5. The Secretary
Health and Family Welfare Department
State of Kerala,
Government Secretariat, Trivandrum-695001

**MEMORNDUM OF WRIT PETITION (CIVIL) FILED UNDER
ARTICLE 226 OF THE CONSTITUTION OF INDIA**

Address for service of all process and notices etc on the petitioner may be served to his Counsel **M/s. Abdul Raof.P, K.R. Avinash, Raj Carolin V** Advocates, MK Associates, and to the respondents are as shown above.

STATEMENT OF FACTS

1. This writ petition is filed seeking a direction against the respondents to permit the capable vaccine manufacturers in India, to manufacture Covid vaccines, over riding the intellectual property rights, either by invoking the compulsory licensing or through any other means or modes in the wake of second wave of Covid-19 Pandemic all over the world in general and particularly in India,
2. The petitioner is a citizen of India. The petitioner is a social worker and an Advocate by profession. This writ petition is filed in the larger interest of the general public and not for any personal interest of the petitioner. The petitioner has not filed any other writ petition seeking identical or similar reliefs.
3. It is submitted that from the dawn of 2020, the world is facing the greatest threat ever seen in the history of mankind due to the COVID-19 pandemic. The pandemic is being affected in most sophisticated and developed nations to the most backward and remotest corners of the world. The mankind has been searching to find a way out to escape from this crises to save the human life. By this time the pharmaceutical companies and universities were able to invent various types of vaccine to abate and resist this pandemic, to a great extent.

4. But, unfortunately, the scarcity of vaccine as well as the required medicines are causing great set back in the attempt of the nations to successfully resist this challenge. Though the developed and rich nations were able to produce and vaccinate considerable portions of their citizens, more than ninety percent of the world population is still under the threat of this pandemic. The non-availability of vaccine and medicines to the majority of the world population is due to the shortage in production as well as the high cost of the vaccine and the medicines. The experts in this field are of the unanimous opinion that the only way out is to vaccinate at least seventy percent of the world population and thereby acquire herd immunity.
5. But still it is unreachable for majority of the nations. All the vaccine for Covid -19 are developed by multi-national pharmaceutical companies or the Universities. As far as the medicines developed by the Universities, they have given the right to produce and market the vaccine to pharmaceutical companies as the Universities are lacking infrastructures for large scale production of medicines.
6. As per the existing legislations governing the intellectual properties and patents, the producers as well as the companies are having exclusive right of production of such vaccines and medicines. As per the 'TRIPS' agreement, most of the countries have agreed to grant patent protection for pharmaceutical products. Therefore in spite of the invention of dozens of vaccine and medicines against the COVID-19, most of the nations and a majority of the world population are still unable to access or procure the vaccine or medicines. Even the countries like India, which is considered as the pharmacist of the world, is facing acute shortage of vaccine in spite

of having sufficient infra-structure to cater major portion of the requirement of the world.

7. It is submitted that India is producing two vaccines. One is by Serum Institute, with trade name of COVISHIELD. It is an intellectual property of AstraZeneca, British Swedish collaboration and the said vaccine is developed by University of Oxford. The second one is COVAXIN developed by Bharath Biotech. The pricing of these vaccines are comparatively high and the quantum of production is much lower, even insufficient to meet the requirements of India.
8. The main obstacle before the authorities and the Governments are the rigors of the legislation about the intellectual properties. But the human life is more important than commercial rights of anyone. So, it is the duty of the Governments to find out the ways to provide medicines in the form of vaccines at an affordable price. If required the Government should disregard the intellectual property right to save the life the citizen.
9. Considering the pandemic situation in the country, vaccines are on top of India's wish list. There are more than 3,000 pharma companies in India. Together they run 10,500 manufacturing facilities. It's an industry valued at more than 30 billion dollars. There are 16 other licensed manufacturers in India producing human vaccine and 8 in public sector. Out of this, the public sector are having capacity to cater the requirement of the lion population of the world. However, Serum Institute and Bharat Biotech are the only two companies out of that are producing vaccines. The rest don't have licenses. The lack of license is because of the patents/protection to the intellectual property rights.

10. The production protocol, clinical trial details, the ingredients and the ratio are trade secrets of vaccine manufacturers. Their recipes are locked away. Pharma giants are unwilling to publicly share knowledge. So a handful of companies are doing all the heavy lifting and are producing all the vaccines with their limited capacity.
11. This pandemic has taught us that global solidarity exists only in theory. Is compulsory licensing an option? This is basically an override of patents. Regulators can authorise companies to produce a patented product without the patent owner's permission. All vaccines are trade secrets (undisclosed in formations)by their makers. It is the government's job to protect these patents. But sometimes during emergencies, governments themselves can override these patents. The rigors of protection of intellectual property right as per the TRIPS agreement has already been relaxed with respect to life saving medicines, in case of national emergency in Doha Summit WTO as early as 2001.
12. It is submitted that in India, compulsory licensing is permitted under the patents act of 1970. Specifically, Section 92 of the act empowers the Central government to issue compulsory licenses. But there are three conditions.
 - a) there must be a national emergency.
 - b) the requirement must be extremely urgent.
 - c) it must be for public non-commercial use.

A deadly virus, killing 4,000 plus Indians a day, does qualify for all three. So theoretically India can do this. India can even override patents on Pfizer and AstraZeneca and other vaccines.

13. All capable Indian companies can be allowed to produce Covid-19 vaccines. This practice is approved by the World Trade Organisation (WTO). Countries are free to issue compulsory licenses during emergencies. They are also free to decide what constitutes an emergency. The patent owner must be suitably compensated. So there is no scope of a backlash from Geneva. Even the Supreme Court of India is asking the Centre to consider this option.
14. If the government does opt for compulsory licensing, a good start would be Bharat Biotech's Covaxin. It is a homegrown job. So making it available to other producers would set a great example for the world. AstraZeneca's vaccine is patented. But India's Serum Institute has been producing it by the millions. This is because Astrazeneca has issued a voluntary license for their job.
15. They have shared their formula with Serum Institute. Sputnik-V has done the same with Panacea Biotech. Voluntary licenses save time and money. To step up vaccine production, two things need to happen. (1), Indian pharma companies must reach out for licenses. They can't sit out this vaccination drive. And (2), foreign job makers need to loosen the reins. Either make their formulas public or issue more voluntary licenses. These are decisions that usually involves a lot of haggling. But India needs to make these decisions right now. To get a better appraisal of how India is struggling with the number of Covid cases and Vaccination a detailed table is appended below:

COVID CASES		
	TOTAL	DEATHS
WORLD	15.6 CRORE	32.6 LAKHS
INDIA	2.19 CRORE	2.38 LAKHS(4187 on 07.05.21)
KERALA	18.2 LAKHS	5683 (54 - on -07.05.21)
VACCINATION		
	1 ST DOSE(as on -07.05.21)	2 ND DOSE(on - 07.05.21)

INDIA	16,49,73,058	3,28,85,234
KERALA	76,95,855	15.67,209

16. The threat of COVID-19 is not only a national issue, but is an international threat and the threat to the whole humankind. It is much above than the national emergency. Hence it is high time to the Our government to open the doors for all the manufactures to enable them to produce the vaccines and the medicines either by disregarding the intellectual property rights or by taking over this rights by compensating the intellectual property right holders and facilitate to produce maximum quantity of vaccine at an affordable price and cater it to the people on war-footing basis. Since the life of millions of people are at stake, the state cannot simply sit as spectators and they are bound to protect the interest of the general public by adopting appropriate measures to protect the life of the people which is guaranteed under the constitution of India. In the circumstances it is only appropriate to direct the respondent to issue compulsory licensing to all the willing pharmaceutical companies to manufacture Covid -19 Vaccine

Hence the petitioner is left with no other remedy other than approaching this Hon'ble Court on the following among other

G R O U N D S

A. As per the study report of Director of All India Institute of Medical Science, Mr. Randeep Guleria and other experts have warned that without much delay the 3rd phase of covid pandemic will occur and it will affect the younger section of the society and it will be more devastating considering the mutation of the virus. Hence it is high

time to produce more vaccines in short span of time to save the life of people. A true copy of the news item published in online news portal of 'News Tree' dated 06.05.2021 is herewith produced and marked as **Exhibit P1**

- B. Certain variants like "N .440K" Covid is fifteen times more lethal than the present version and the only way out is to vaccinate the people at the earliest. Though there are fanciful claim with respect to the vaccination drive, the percentage of the polity immunised till date is very meagre.
- C. Though India is considered as the pharmacy of the world and the global leaders in vaccine coverage, as far as Covid - 19 vaccine is concerned the coverage is poor and there is remarkable mismatch between the target and availability. Though target up to **30 April 2021** is to vaccinate **28.62** crores, that is ,health care and front line workers, the person above the age of 45 years with comorbidity ,the vaccination coverage is only **12.7** cores. **44%** of targeted population alone could be vaccinated. Only **13.5%** of population above 18 years and **9.2%** total population.
- D. At that time USA have covered 50.4%, UK 43.3%, Germany 26.7% and Brazil 13.7%. The main reason is the shortage of vaccine. The present production capacity of both manufacturers that is, Serum Institute of India and Bharath Biotech is only 25.3 Lakhs dose per day. Even if they may able to produce 38 lakhs per day by the end of this month, as per their claim it is insufficient for requirement of Nation. To vaccinate everyone above 18 years by January 2022, India would make at least 69 lakhs dose per day.

- E. The present production capacity covers only 30 percentage of the requirement. In the current rate it will be able to vaccinate all the person above age of 18, will take at least by the end of 2023 and still youngsters under the age of 18 will be under threat. A true copy of the article published in this regard in online news portal of The New Indian Express dated 06.05.2021 is herewith produced and marked as **Exhibit P2**
- F. In case of health emergency, all civilised nations of the world have made statutes to disregard the Intellectual Property Rights and to grant compulsory licence to pharma products. A true copy of the article published in the website of International Bar Association dated 30.6.2020 is herewith produced and marked as **Exhibit P3**
- G. Section.84 to 92 of the Patent Act governs the provision for compulsory licence. Compulsory licence can be obtained by an applicant on satisfy certain conditions. But it is a time consuming and lengthy procedure. But under section. 92 of the Patent Act the Controller General can Suo-moto issue compulsory licence in pursuance of a notification issued by a Central Government, If there is either national emergency or extreme urgency or in case of public non-commercial use. True copies of the articles published on the subject of Compulsory licensing dated 18.1.2019 and 19.12.2019 are herewith produced and marked as **Exhibit P4 and P5**
- H. It is submitted that the entire world is under the emergency and it is uptime to permit the manufactures to produce vaccines especially the nation like USA ,France, and the World Trade Organisation have assented for a go bye of the “Trips Agreement” and the Intellectual Property Rights with respect to the Covid vaccines and the required Medicines. True copy of the statement of Ambassador of US dated

5.5.2021 is herewith produced and marked as **Exhibit P6**. True copy of the articles published on the subject in the New India Express online edition dated 6.5 2021 is herewith produced and marked as **Exhibit P7**

- I. The Governments can very well rely on the precedent made in **Bayer CORPORATION Vs Union of India** in which the Controller has given compulsory licence to Natcopharma for generic production of a life saving medicine used for treating livers and kidney cancer. The price of the medicine Bayer Corporation was 2.8 lakhs per month. NatcoPharma offered to sell it around Rs.9000/- on granting compulsory licence Natco Pharma was direct to pay 6% of royalty from the total sale amount to Bayer corporation.
- J. At present none of the Covid vaccines are patented. Hence, it may not be technically possible to rely on the provisions regarding the compulsory licencing in Patent Act. At the same time the Intellectual Property Right is a **trade secret(Un disclosed information)** and the details of the production Protocol, clinical file, data etc. are available with the concerned Drugs Control Authority. At present such information's are entitled for data protection. That protection can be relaxed considering the present scenario. The nation has to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the "prevention, containment or treatment of COVID-19, until widespread vaccination is in place globally, and the majority of the world's population has developed immunity.
- K. Moreover in the absence of registration, the holders of the Intellectual Property Rights are having only the right of **passing off**. The passing off rights should not have better protection than the Patented Rights

especially in the health emergency. In no event should IP rights become legal obstacles to ensuring early access to affordable medicines for everyone in the world during a pandemic that has already killed more than a million people worldwide and threatens to kill millions more. But also, in no event should WTO members act in ways that would eliminate the incentives that are essential to inspire the innovations that make new medicines possible.

For the reasons stated above and other reasons to be canvassed at the time of hearing it is most humbly prayed that this Hon'ble Court may be pleased to

P R A Y E R

- (i) Declare that the compulsory licensing is permissible for vaccines and medicines for the treatment of Covid -19 in India in the light of emergency situation caused by the second wave of Covid-19 Pandemic and increasing number of Covid cases and consequent surge in death rate.
- (ii) Issue writ of mandamus or any other writ or order directing the respondents to issue compulsory license or grant permission to the pharmaceutical companies to manufacture Covid-19 vaccine within a time frame, over riding the provisions of intellectual property legislations and International covenants.
- (iii) grant such other relief's as this Hon'ble Court may deem fit and proper as on the facts and circumstances of the case.

Dated this the day of May 2021

Counsel for the Petitioner

Interim Relief Sought for:

For the reasons stated in the Writ Petition (civil) and the affidavit, it is most humbly prayed that this Hon'ble Court may be pleased to direct the respondents to issue compulsory license to the pharmaceutical companies to manufacture Covid-19 vaccine within a time frame overriding the provisions of intellectual property legislations and International covenants, pending disposal of the above Writ Petition (civil).

Dated this the day of May 2021

Petitioner

Counsel for the Petitioner

(Petition filed under section 8 of Kerala High Court Act)

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Gopakumar Gk : Petitioner

Vs.

Union of India and others : Respondents

AFFIDAVIT

I, Gopakumar GK, do hereby solemnly affirms and state as follows:

1. I am petitioner in the above Writ Petition (civil). I know the facts of the case.
2. The facts of the case are fully and correctly stated in the Writ Petition (civil) and I submit that the same may be treated as part of this affidavit.
3. Exhibits produced in the Writ Petition (civil) are the true copies of its original documents.

4. The petitioner is not a wayfarer or interloper, filed this writ petition (civil) with bonafides and have no personal or private interest in the matter other than the interest as a public
5. The petitioner files this petition with bonafides that the public money should be handled and utilized by the persons accountable to the authorities.
6. That there is no authoritative pronouncement by the Supreme Court or the High Court on the question raised and the result of the litigation shall not lead to any undue gain to me or anyone associated with me.
7. I have not filed any other petition seeking similar and identical relief's in the same subject.

All the facts stated above are true.

Deponent

Solemnly affirmed and signed before me by the deponent on this the day of in my office at Ernakulam.

Abdul Raoof.P
Advocate

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SYNOPSIS

Points to be urged:

This writ petition is filed in public interest seeking a direction against the respondents to permit the capable vaccine manufacturers in India, to manufacture Covid vaccines over riding the intellectual property rights, either by invoking the compulsory licensing or through any other means or modes in the wake of second wave of Covid-19 Pandemic all over the world in general and particularly in India,

It is submitted that to combat the pandemic though vaccines were invented, the scarcity of vaccine as well as the required medicines are causing great set back in the attempt of the nations to successfully resist this challenge. The experts in this field are of the unanimous opinion that the only way out is to vaccinate at least seventy percent of the world population and thereby acquire herd immunity.

As per the existing legislations governing the intellectual properties and patents, the producers as well as the companies are having exclusive right of production of such vaccines and medicines. Even the countries like India, which is considered as the pharmacist of the world, is facing acute shortage of vaccine in spite of having sufficient infra-structure to cater major portion of the requirement of the world.

It is submitted that India is producing two vaccines. One is by Serum Institute, with trade name of COVISHIELD. It is an intellectual property of AstraZeneca, British Swedish collaboration and the said vaccine is developed by University of Oxford. The second one is COVAXIN developed by Bharath Biotech. The pricing of these vaccines are comparatively high and the quantum of production is much lower, even insufficient to meet the requirements of India. The present production capacity covers only 30 percentage of the requirement. In the current rate it will be able to vaccinate all the person above age of 18, only by the end of 2023 and still youngsters under the age of 18 will be under threat

The main obstacle before the authorities and the Governments are the rigors of the legislation about the intellectual properties. But the human life is more important than commercial rights of anyone. So, it is the duty of the Governments to find out the ways to provide medicines in the form of vaccines at an affordable price. If required the Government should disregard the intellectual property right to save the life the citizen.

It is submitted that in India, compulsory licensing is permitted under the patents act of 1970. Specifically, Section 92 of the act

empowers the Central government to issue compulsory licenses. But there are three conditions.

- d) there must be a national emergency.
- e) the requirement must be extremely urgent.
- f) it must be for public non-commercial use.

A deadly virus, killing 4,000 plus Indians a day, does qualify for all three. So theoretically India can do this. India can even override patents on Pfizer and AstraZeneca and other vaccines.

Hence in this writ petition, the petitioner seeks appropriate direction to permit all capable Indian companies to produce Covid-19 vaccines thereby uphold the constitutional right to life guaranteed under the constitution of India.

Date	Events
January 2021	Vaccine for Covid 19 is invented
April 2021	The second wave of Covid 19 reported in India
5.5.2021	U.S. waived patent right on Covid-19 vaccine

Counsel for the Petitioner

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Counsel for the Petitioner

Pre On 10/5/2021

SUB: PUBLIC INTEREST LITIGATION: Seeking a direction to issue compulsory license or grant permission to the pharmaceutical companies to manufacture Covid-19 vaccine, over riding the provisions of intellectual property legislations and International covenants.

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ARTICLE 226 OF THE CONSTITUTION OF INDIA**

Abdul Raof. P.

K.R. Avinash (Kunnath)

Raj Carolin.V

ADVOCATES

MK ASSOCIATES,

Appendix

Petitioner's Exts

