IN THE HON'BLE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

I.A. NO. _____ OF 2021

IN

SUO MOTU WRIT PETITION (C) NO. 03 OF 2021

IN THE MATTER OF:

RE: DISTRIBUTION OF ESSENTIAL SUPPLIES & SERVICES DURING PANDEMIC

AND IN THE MATTER OF:

JAN SWASTHYA ABHIYAN ...APPLICANT(S)

VERSUS

UNION OF INDIA & OTHERS …RESPONDENT(S)

APPLICATION FOR DIRECTIONS

[For Index, please see inside]

ADVOCATE FOR APPLICANT: ASTHA SHARMA

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APPLICATION FOR DIRECTION

TO,
THE HON'BLE CHIEF JUSTICE OF INDIA
AND HIS COMPANION JUSTICES OF
THE HON'BLE SUPREME COURT OF INDIA

THE HUMBLE APPLICATION OF
THE APPLICANT ABOVENAMED

MOST RESPECTFULLY SHOWETH:

1. This Hon'ble Court vide its Order dated 22.04.2021, in light of the grim situation prevailing in the country on account of the Covi-19 Pandemic, was pleased to issue notice to the Central Government, State/Union Territories Governments and the parties, who appeared to have approached the Hon'ble High Courts to show cause why uniform orders be not passed by this Hon'ble Court in relation to the following –

(i) Supply of Oxygen;

(ii) Supply of Essential Drugs;

(iii) Method and Manner of Vaccination; and

(iv) Declaration of Lockdown.

2. The Applicant herein has preferred an Application seeking intervention in the present matter and the contents thereof may be read as part and parcel of the present application and the same are not being reiterated for the sake of brevity and to avoid prolixity.

3. The Applicant herein – *Jan Swasthya Abhiyan ("**JSA**"),* Mumbai, is a network of organisations and individuals, including feminist organisations, academics, activists, service delivery networks, trade unions, whose members are citizens of India, collectively working towards health issues in. JSA Mumbai is a part of the the Indian regional circle of the global People's Health Movement (PHM). The Applicant, has been involved in efforts towards realizing the right to health and healthcare as basic human rights for all the people residing in the Mumbai Metropolitan Region.

4. It is most respectfully submitted that during the Covid-19 crisis, the Applicant herein, has been closely monitoring and working with government health officials, non-governmental organizations and networks to help ordinary citizens and their families to gain access to health care at both public and private facilities. Many of these persons/ families have faced financial hardships in paying for treatment in private hospitals.

5. The Applicant herein had earlier filed a writ petition before the Hon'ble Bomaby High Court titled "*Jan Swasthya Abhiyan & Anr. vs. State of Maharashtra & Ors.*" [ADHOC NO. PIL (ST) NO. 21 OF 2020], *inter alia* seeking direction to the Respondent authorities therein, in relation to enlisting/ sequestering Private Health facilities for Covid care by notifying a clear protocol with regard to such referrals; and ensuring that private/ charitable hospitals assign required bed capacity for the poor during the period of the lockdown; and provision of free Covid-19 treatment in private hospitals. The matter had been finally argued decided by the Hon'ble Bombay High Court vide its final order dated 12.06.2020.

6. The Applicant is preferring the present Application, without any vested or personal interest, and the present Application is being preferred, solely in public interest.

7. It is well known that the Union of India is implementing its second phase of vaccination wherein there is a plan to vaccinate all those above the age of 18. However it is also a matter of public knowledge that the vaccines are in short supply and many states have already made a demand for supply of additional doses of the vaccine.

8. It is submitted that one of the primary reasons for the shortage in the vaccines is the limited number of manufacturers. There are also issues of procurement and the pricing of the vaccine as in view of the approach taken by the Union of India, the manufacturers have applied their

own pricing to the vaccine. On the other hand, some states are vaccinating the pubic free of cost.

9. Yet another aspect which is a hurdle to widespread manufacture of vaccines is the grant of patents to the manufacturers i.e. Bharat Biotech and Oxford University (on behalf of Astra-Zeneca). In view of the patents granted in respect of the vaccines, the other manufacturers are unable to step in and manufacture the product

10. Vide the present Application the Applicant, is seeking certain urgent directions :

    A) Scaling up the production of vaccines against coronavirus ;

    B) Single Procurement window of the vaccines by the Central Government;

    C) Allocation of vaccines to the States by the Central Government;

    D) Distribution of the vaccines to the States.

    E) Ceiling prices of vaccines against Covid 19.

BRIEF FACTUAL MATRIX

11. Corona viruses are a family of zoonotic virus, known to cause illnesses that could range from common cold to severe respiratory disease. One of the major infections caused by coronaviruses (CoV) is the severe acute respiratory syndrome (SARS)-CoV. COVID-19 is the most recent of this family that has severely affected populations across the world.

12. On December 31, 2019, China informed the World Health Organization (WHO) about cases of pneumonia of unknown aetiology detected in Wuhan city, Hubei province of China, which was reported to the WHO.

13. Taking note of the sudden death of people in China and the unprecedented rise in the number of cases, and noting its quick spread, the Director-General WHO, after several internal consultations, declared COVID-19 outbreak as Public Health Emergency of International Concern (PHEIC).

14. In India, the first wave of COVID-19 infection started in March 2020 when the cases rose steadily from a mere 40 to 8000 and then reached its crescendo by September 2020 when more than 97,000 patients had got affected. It had taken 108 days for the cases to rise from 8,000 on June 2, 2020, to 97,894 on September 17, 2020, during the first wave of the pandemic. The wave started to show some signs of decline thereafter, though the pandemic was not over at all.

15. However, now, recently from March 2021 onwards, India is witnessing a second wave of the Corona virus or Covid-19 pandemic. It has taken 63 days for cases to rise from 8,000 on February 2, 2021 to 1,03,558 as of April 5, 2021. As of April 24, 2021, India had reported total of 24,28616 cases with a cumulative of 186920 deaths of COVID-19. In one day alone, April 26 2021 over 3.2 lacs cases of Covid 19 were reported and deaths crossed over 2,000 over seven days running. This is the second wave the Corona virus

infection in the country which is turning out to be much more virulent and infectious than the first wave that started in India in March 2020. In the second wave, in 2021 the number of cases is also rising more rapidly than in the first wave.

HEALTH EMERGENCY, PRODUCTION, IMPORT, PROCUREMENT AND PRICING OF VACCINES

16. India has a population of about 1.35 billion or 135.5 crore people. Originally the policy was to inoculate only those above the age of 65 years. Later on those above 45 years were also included. Now, from the 1st of May 2021 all over 18 years of age would be inoculated. Ultimately it is reasonable to assume that the whole population would have to be inoculated.

17. It is an admitted position that in order to reach herd immunity at least would kick in if at least of 70 percent of the population are inoculated. 70 percent adult population is about 650 million adults working out nearly 1.4 billion doses. 70 percent of the total population is about 980 million persons. It is estimated that at the rate that two inoculations for 70 percent of the populations will take a very long time.

18. With only two manufacturers in the market today, namely Serum Institute of India (SII) producing the vaccine, *Covishield*, and Bharat Biotech's Covaxin. Their combined production capacity is 60 million a month (SII) and 5 million a month (Bharat Biotech). Bharat Biotech is planning to ramp up its capacity to 700 million doses a year.

The total annual production from both would be about 1400 million doses a year.

19. However, with the passage in the last three months only 30 percent of the 40 crores of the persons above the age of 65 years have been inoculated with the first dose. It is estimated that in the last 100 days 14.19 crores inoculations have taken place. Of these about 2.4 crores have taken the 2nd dose. This is roughly 1.8% of the total population.

20. Apart from the two existing producers, Sputnik vaccine, developed by the Russian entity, Gamaleya Research Institute of Epidemiology and Microbiology and promoted by Russian Direct Investment Fund (RDIF) is likely to imported from May 2021 onwards through RDIF. Later in collaboration with Dr Reddy's Laboratories and its partners, including Gland Pharma, Hetero, Strides Pharma Science etc, it is proposing to make available 250 million doses in the next 12 months. Other two companies viz Panacea Laboratories and Virchow also signed the license to produce 100 million and 200 million doses respectively. This conglomerate will also manufacture the Sputnik vaccine for the rest of the world. The three would be able to produce about 1900 million doses. However, there is no clarity with regard to how many of these doses are available to the Indian market because these agreements are contract manufacturing license to supply to RFID.

21. It is not known how long the immunity lasts. If it lasts one year after a full dose administration (one or two doses) this might mean that every person has to be inoculated every

year. In that case the need may be about 1.35 billion doses annually. Therefore capacity has to be ramped up accordingly.

22. In any event it is necessary that the Respondent No. 1 must transparently disclose its plan about the persons who need to be vaccinated the anticipated need and the local production capacity and how it proposes to ramp it up.

23. Unfortunately the Respondent No. 1 did not realize the need to invite other vaccine manufacturers to ramp up the capacity of vaccine production in the country early enough. However that has changed and now. The Respondent No. 1 has recognised that there is a need to increase the local production capacity and accordingly sought to invite other vaccine producers internationally to get market authorization to produce locally in India. Towards this purpose the Department of Biotechnology facilitated financial grant to produce Bharath Biotech's Covaxin through three public sector units. However, there is no clarity when the products from these facilities will be available in market and projected number of doses.

24. Further It has to be recognized that there should be other sources, apart from the existing three, in India. However the Government has turned only to the manufacturers abroad and invited them with fast track approvals. Though that cannot be faulted with, it is necessary that India does not find itself in the same position again. For that it is necessary that local production be encouraged, both in the public sector and in the private sector. Public sector units must be

provided with funds to ramp up their capacities. The Respondent No. 1 must disclose its plans to increase production capacities of vaccines of public sector units and how much investment it is proposing to make in the public sector units.

PRODUCTION, PROCUREMENT AND DISTRIBUTION

25. The Respondent No. 1 has announced some decisions and a and a new strategy titled Liberalised Pricing and Accelerated National Covid19 Vaccination Strategy. First, that 50 percent of the production in India would be for the Government, the balance 50% will be for sale in the open market. Second, the private companies would set their own prices. Third, the Respondent No. 1 stopped the availability of vaccine in the private sector for people aged 45 and above for Rs 250. Fourth, the Respondent No. 1t announced a transfer a total of Rs 4500 crores to two vaccine companies SII and Bharat Biotech. Fifth, the individuals aged between 18 and 45 are eligible for vaccination from either a State government scheme or private sector. Sixth, bridging studies for marketing approval is done away with. The third issue is not being addressed here.

26. As to the first, it is not clear what is the production for the Government is for, for the Central Government and/or the States, and on what terms. Is it for foreign obligations and if so what percentage and on what terms? It further appears that out of the Government quota the States have to privately negotiate with the producers. Already the States are complaining that they are not getting any responses from

either SII or Bharat Biotech about when they would be able negotiate with them to supply the vaccines. This is a serious situation.

27. For the last 70 years the Indian vaccine procurement system was worked on the basis that Respondent No. 1 procures all the vaccines from public manufacturers and distributes it through the States to all free of charge as a part of the immunization programme. For the first time in the history of India there is a differentiation between the States and the Government of India to procure diagnostics, therapeutics or vaccines. The money for purchasing the vaccines and medicines comes from direct and indirect taxes and from international assistance and does not brook any difference between the States and the Central Government.

28. This is not only strange but contrary to the obligation of the Respondent No. 1 under Entry 29 of the List III of the Seventh Schedule to control interstate spread of infectious diseases. Thus the Respondent No. 1 is obliged and duty bound to assist the States to combat the spread of Covid 19. This has been the underlying reason why the Respondent No. 1 has been procuring diagnostics, therapeutics and vaccines centrally and distributing to the States. The success of that has been seen in all vaccines national infectious diseases in (e.g. Polio, TB and HIV) programmes. The Respondent No. 1, rather than complying with it's duty, is abdicating its Constitutional responsibilities bestowed upon it.

29. Moreover, the central procurement has the advantage of the buyer's purchasing strength. Being a monopoly buyer, and being able to buy huge quantities and negotiate with the sellers in a single window system, it can beat down the prices of the sellers. This huge advantage has been frittered away by the Respondent No. 1, unilaterally and thereby compelling the State Governments to negotiate with sellers individually, whether in India or abroad. From the buyer's market the Respondent No, 1 has made it into a sellers' market. The sellers are laughing their way to the bank, literally. No wonder they are not even negotiating the prices with the States. Thus private companies are being allowed to set their prices at their whims and fancies only to make unconscionable profits.

30. Moreover it is submitted that it is necessary to ensure that ultimately all persons take the vaccine shots, one or two as per the protocols. However if the States are forced to purchase them, they might be tempted to sell the vaccines to their constituents and not make them available free of charge to those who cannot afford them. It is to be noted that it is upto the States to make them available free or for a price. The result could well be that richer States will make the vaccines available free of charge and other, poorer, States charge for them. Resultantly some persons may not get the vaccine administered, defeating the purpose of the programme. It is therefore necessary that vaccines must be available to all free of charge through Government centres. This doesn't mean that those who can afford should not be able to access them at private entities for an affordable fee.

31. The decision of the Respondent No. 1 promotes inequities and ultimately infringes rights of citizens under Articles 14 and 21 of the Constitution of India. It implies that richer States can go to the market and purchase the vaccines and poorer and smaller states will be left to the arbitrary whims and fancies of the private companies. This would mean that some citizens in India would be able to get the vaccines early and others may not get it at all. Further by pushing people between 18-45 years to vaccines at the financial health of state or at high price in the private sector is arbitrary and results in the denial of vaccines. The decision is therefore in violation of Articles 14 and 21 of the Constitution of India. Therefore the Respondent No. 1 should be forthwith directed to revert to the original procedure of central procurement of all vaccines and distribute them through the States free of charge.

32. The decision of the Respondent no. 1 to stop procuring the vaccines centrally and set the prices itself is to the detriment of the interests of the States and ultimately the citizens of India who have a fundamental right to access essential medicines to protect their health. Nay the Respondent No. 1 has a duty to ensure that the rights of all people in India to health and life are protected. The decision is arbitrary with no rational purpose and defeats the object of procuring vaccines for the people to protect their health. This is being negated by the decision of the Respondent No. 1 stop procuring itself and set the procurement price itself and thus

PRICES AMOUNTS TO PROFITEERING BY THE VACCINE PRODUCERS

33. SII and Bharat Biotech have both announced their prices. SII is going to sell its vaccine Rs. 150 to the Central Government and Rs. 400 for State Governments, which it reduced to Rs. 300 per dose. It will sell at Rs. 600 per dose in the private market. In contrast Bharat Biotech will sell its vaccine at Rs. 150 per dose to the Central Government, Rs. 600 per dose the state governments and Rs. 1200 per dose in the private market. Shockingly this is more than what is being paid abroad. The SII vaccine is available in the European market at (USD 2.15) Rs. 160 per dose , at (USD 2.10) Rs 210 per dose for GAVI, at (USD 30) Rs. 222 in the UK and at (USD 4) Rs 297 in the US. Sputnik will be selling its vaccine at Rs. 750 per dose.

34. It is respectfully submitted that the above decision allows profiteering at the cost of lives of the citizens of India.

35. On its own admission, even the sales at Rs. 150 per dose that the SII is selling to the Central Government, it makes a modest profit. Thus the prices it has set for the State and private market are super profits. It is submitted that private pharmaceutical companies cannot be allowed to profiteer at the expense of the lives and the health of the people of India.

36. The intellectual property and the technology developed by Oxford University is public funded.

37. It must be noted that SII did not get the intellectual property rights and technology of manufacturing of *Covishield* at market rates from Oxford-Astra Zeneca. From some reports it appears that it got it free. The idea was for SII to make it available the vaccine to people in India and the developing world at low and affordable rates. Even if the intellectual property rights was obtained by SII at cost it did not have to spend a substantial amounts on the same. Further, SII received USD 300 million from the Gates Foundation as a grant to establish the manufacturing facility for vaccines against Corona virus. Apart from a short bridging study SII did not take any development work for the marketing authorization of *Covishield*. Unfortunately, what it got to as a public good make it available for the poor is now being converted by SII to profiteer from. That cannot be countenanced.

38. From the reports Bharat Biotech spent about Rs. 350 crores. For that reason it appears that it selling *Covaxin* at higher rates than SII.

39. That apart the Respondent No 1 is proposing to pay pre purchase agreements and paying the amounts to the tune of Rs. 3,000 crores to SII and Rs. 1,500 crores to Bharat Biotech. The Respondent No. 1 has got a grant from GAVI of USD 300 million (about Rs. 22,000 crores), which it has already received, to expand production of vaccine production. Despite this pre purchase down payments the rates of vaccines both by SII and Bharat Biotech are exorbitant.

INTELLECTUAL PROPERTY AS A BARRIER

40. There are two vaccine manufacturers in India, namely Serum Institute of India (SII) producing the vaccine, *Covishield,* and Bharat Biotech. SII is manufacturing Covishield under license from Oxford University the original developers of the vaccine. It appears that Oxford University has licensed the patent to SII. It has filed several applications before the Patent Controllers The applications are pending.

41. Other companies who are intending to produce other vaccines. The patent applications filed in India and pending are set out in the table below.

Corona Vaccine: Patent Applications in India

OXFORD/ASTRA/SII - COVISHIELD

Serial. No.	Applicant	Application No. and Patent No.	International No.	Date of filing	Claims Coverage	Patent Expiry
1	ISIS Innovation Limited	9960/CHENP/2013 IN318021	PCT/GB2012/000467 WO/2012/172277	12.12.13	Claims cover adenovirus vector comprising capsid derived from chimpanzee adenovirus AdY25.	12 December 2032
2	ISIS Innovation Limited Okairos AG	2087/MUMNP/2009 IN263933	PCT/GB2008/001175 WO/2008/122769	09.11.09	Claims cover immunogenic composition or vaccine with simian adeno virus vector.	9 November 2028
IDENTIFIED INDEPNDENTLY – APPLICATIONS COVERING ADENOVIRUS VECTOR USED IN COVISHIELD VACCINE OF OXFORD ASTRAZENECA						
3	**OXFORD**	201817047327	PCT/GB2017/051851	14.12.18	Claims	

	UNIVERSITY INNOVATION LIMITED	Awaiting Examination			cover ChAdOx2 vector derived from ChAd68/ C68/ Pan6/ sAd25 adenovirus.	
4	**OXFORD UNIVERSITY INNOVATION LIMITED**	202147007710 Awaiting Examination	PCT/EP2019/073181	24.02.21	Claims cover recombinant simian adenovirus ChAdOx1	

TRADE SECRETS SHOULD BE MADE AVAILABLE

42. Apart from the patent protection vaccine companies are using the trade secret protection to keep the manufacturing process and cell lines as a secret. The CDSCO insists the non-originating vaccine manufacturer to prove the safety and efficacy through clinical trials. This is a time and resource consuming requirement. In the current pandemic, it is important to share these trade secrets to scale up the production through diverse manufactures. Unlike the compulsory licence provisions in the Patents Act there is no legal mechanism in India to disclose the trade secret to protect public health. The urgent intervention of the Hon'ble Court is required to facilitate the sharing of the trade secret to scale up the production of vaccines.

DCGI BE DIRECTED TO ISSUE APPROVALS IN ACCORDANCE WITH LAW

43. It is pertinent to note that there are several companies who have the capacity to manufacture cannot do so due to the fear of legal action against them by the patentee even at the stage of merely filing regulatory approval dossier. In fact, as a matter of practice the Respondent No. 4 (Drug Controller

General of India) been refusing drug licence/approval to any company who does not have a licence from Bharat Biotech or Astra Zeneca as the case may be as the vaccine is covered by various patents. This has led to a situation of today where the vaccine is in short supply. In fact it is doubtful whether those who received the first round of the vaccine will receive the second dose at all.

44. There is no warrant for this under the Patent Act, and in fact is contrary to Section 107A of the Patents Act, which allows license for market authorization which does not amount to infringement. This has been interpreted by the Delhi High Court to permit what is known as "patent linkage" and not permitted under the judgments of ***Bayer v Union of India*** 2010 SCC Online 541] and ***Bayer v Natco*** [2017 SCC OnLine Del 7378 (Single Judge) and 2019 SCC OnLine Del 8209 (Appeal Court)]

45. In order to respond to the demand of these vaccines, across the country, there is a need to rapidly upscale production, which can only happen when there are more companies manufacturing the drugs.

46. This is possible by issuing authorization for Government use or orders for compulsory license for public non-commercial use in respect the patents covering the vaccines.

PRICES SHOULD BE SET UNDER THE DRUG PRICE (CONTROL) ORDER

47. Yet another aspect is that the prices of these vaccines be controlled and the maximum upper limit be fixed so as to

make them affordable and accessible to realise the right to health and life for all person in India. This should be done by the National Pharmaceutical Pricing Authority under the Drug Price Control Order (DPCO). However, the Respondent no. 1 is unable to fix prices on account of an order issued by it under the Essential Commodities Act dated 3-June 2019, in particular vide para 2(ii) (A) by which the Paragraph 32 (i) has been substituted: -

> *"Para 32 (i) 'a manufacturer producing a new drug patented under the Indian Patents Act 1970 (Act 39 of 1970), for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country"*

48. As a result of this, the Respondent No. 1 is unable to fix the prices of patented vaccines for a period of 5 years from the date of commencement of its commercial marketing by the manufacturer of the drug in the country. It is submitted that Respondent No. 1 cannot fix the prices of the patented vaccines for a period of 5 years from the date of first commercial marketing of the patented vaccines in the country. Paragraph 19 of the DPCO 2013 empowers the NPPA to fix the celling price or retail price of any medicines including vaccines in the public interest.

49. The Applicant further submits, that the objective of the Essential Commodities Act and DPCO is to fix prices of all drugs which are essential commodities to realise the right to health and life under Article 21. By granting an exemption by virtue of para 32(i) of the DPCO, exactly the opposite is done. Patent being a monopoly, monopolist prices are

permitted to be fixed by the impugned amendment. This defeats the objective of the DPCO and the Essential Commodities Act. Therefore, the impugned amendment is *ultra vires* the Essential Commodities Act 1955. It is also in violation of Article 14 reads with Article 21of the Constitution. The *intelligible differentia* has no rational nexus to the object sought to be achieved by the Essential Commodities Act.

50. The Applicant, therefore approaches this Hon'ble Court for the reliefs prayer for herein, as several persons affected by COVID-19 who could have been saved are losing their lives owing to the acute shortages of vaccines. The rising numbers in Covid Deaths, across the Country calls for utilising all possible provisions in the law to remove intellectual property barriers to health and COVID-19 related treatment, on the following grounds which are without prejudice to one another: -

I. ***<u>That lack of or limited availability and accessibility of medicines for treatment of COVID-19 violates the Constitutional Right to Health And Life guaranteed under Article 21 of the Constitution of India</u>***

(i) That the right to health is an inherent part of right to life guaranteed under Article 21 and has been recognised by the this Hon'ble Court in a catena of cases, including ***Vincent Panikurlangara v. Union of India***, (1987) 2 SCC 165; ***Consumer Education & Research Centre v. Union of India***, **(**1995) 3 SCC 42; ***Dr Ashok v. Union of India***, **(**1997) 5 SCC 10 amongst others.

(ii) That the Right under Article 21 is not merely a right but also an obligation on the state as recognised in by the Hon'ble Supreme Court in ***State of Punjab and Others v. Ram Lubhaya Bagga***, **(**1998) 4 SCC 117.

(iii) That the Hon'ble Supreme Court in ***Paschim Banga Khet Mazdoor Samity v. State of W.B.;*** (1996) 4 SCC 37 held that Article 21 imposes an obligation on the state to safeguard right to life of every person which included ensuring access to medical treatment. The Hon'ble Court further noted at Para 16 that, "…*it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done.…Court has held that the State cannot avoid its constitutional obligation in that regard on account of financial constraints...*".

(iv) That this Hon'ble Court in ***Rakesh Chandra Narayan v. State of Biha****r*, (1989) Supp (1) SCC 644, has further held that a welfare State like ours, it is the obligation of the Government to provide medical attention to every citizen.

(v) That supporting the increase of production of vaccines cannot be evaded citing any reason but can be scaled up by utilising provision in the Patents Act and allowing other companies to manufacture these patented drugs;

(vi) That this Hon'ble Court while issuing notice and adjudicating the *suo moto* Writ Petition (C) No. 07 of 2020, in Re: ***The Proper Treatment of Covid 19 Patients and Dignified Handling of Dead Bodies in***

the Hospitals etc, has recognized that the Right to health is guaranteed and includes access to affordable treatment, which is a duty of the state under Article 21 of the Constitution.

(vii) That lack of access to affordable vaccines violates the right to health of persons affected by COVID-19 violates the fundamental rights of persons in India under Article 21 of the Constitution of India.

(viii) That India is also a signatory to the International Covenant of Economic Social and Cultural Rights (ICESCR), whereby it is obligated to ensure the highest attainable standard of physical and mental health of all persons enshrined in Article 12 of ICESCR;

(ix) That India is obligated to follow the principles recognised in Article 25.1 of the Universal Declaration on Human Rights iterating right to a standard of living adequate for the health and well-being of themselves including food, clothing, housing and medical care;

(x) That these rights recognised in the international instruments have been recognised and incorporated in India's local laws including through the Protection of Human Rights Act, 1993 which recognises *human rights* to include rights relating life, liberty, equality and dignity embodied in international covenants;

(xi) That right to health includes the availability, accessibility, acceptability and quality of health good and services, as also recognised by the General Comment 14 of the Committee on Economic, Social and Cultural Rights (CESCR);

(xii) That right to accessibility of health includes access that is based on non-discrimination, physical accessibility, affordability and access to information;

(xiii) That the accessibility to COVID-19 vaccines is well within the right to health of any person;

II. ***<u>The vaccine distribution program of the Government should make vaccines available to all free of charge</u>***

(i) That Article 47 read with Article 21 of the Constitution obligates the State to improve and protect public health. That fulfilment this obligation requires utilising existing legal and policy tools;

(ii) That providing access to essential, life-saving vaccines to all persons in a public health crisis of COVID-19 is an obligation of the State under Articles 21 and 14 of the Constitution;

(i) That ensuring availability and accessibility to COVID-19 vaccines is an obligation of the state.

(ii) That in order to ensure that Covid 19 epidemic is combated it is undisputable that all persons in India should be inoculated with the full course of Covid Vaccine, one or two shots, as the case may be.

(iii) It is submitted that the vaccination program of the Government of India should not be limited to those above age of 18;

(i) Ultimately, in order that all are safe from Covid 19, it is necessary that all in India should be vaccinated;

(ii) It is clear that with all the three vaccines producers, SII's *Covishield*, Bharat Biotech's *Covaxin* and RIDF's *Sputnik* will not be able to cater to the needs of the Indians who require the first full course of 2.7 billion doses as also those that are required to be sent abroad under international obligations;

(iii) Therefor there is an imperative need ramp up capacity to cater for the emergent, medium and long term need of vaccines;

(iv) The Respondent No. 1 should be directed to disclose its plans to increase production capacities of vaccines of public sector units and how much investment it is proposing to make in the public sector units;

(v) In order that all are vaccinated it is necessary that vaccine/s are available free of charge from the Government hospitals and centres;

(vi) This does not mean that the vaccines are not made available at private hospitals and centres for a fee;

III. *The decision of the Respondent No. 1 not to procure all the vaccines required for free distribution through the States violates the right to health and life of citizens of India*

(i) For more than seventy years all diagnostics, therapeutics and vaccines have been centrally procured by the Respondent No. 1 and allocated to the States for distribution through the local networks;

(ii) The said system has worked well and there is no need to change it;

(iii) It allows the Respondent No. 1, being a huge and a monopoly buyer to negotiate the best price from the seller;

(iv) Moreover, it fosters equity between the rich and poorer States in India;

(v) It guarantees that all who need the diagnostics, therapeutics and vaccines gets them in accordance with Articles 14 and 21 of the Constitution of India;

(vi) It also ensures that the Respondent No 1 complies with its obligations under Entry 29 of List III of the Seventh Schedule;

(vii) The new system introduced by the Respondent No. 1 has put the States at the mercy of the vaccine sellers and producers forcing them to compete against each other, with rich States faring well and poorer States losing out;

(viii) Already the States are complaining that they are not getting any responses from either SII or Bharat Biotech about when they would be able negotiate with them to supply the vaccines. This is a serious situation.

(ix) Consequently there is a great risk that in people in poorer States may not get the vaccines;

(x) Ultimately the Fundamental Rights of the people of India under Article 14 and 21 are liable to be infringed;

IV. *The vaccines should be subject to price control under the Drug Price Control Order issued under the Essential Commodities Act*

(i) On its own admission, even the sales at Rs. 150 per dose of Covishield that SII is selling to the Central Government, it makes a modest profit;

(ii) Therefore the prices of Rs. 300, 600 and 1200 per dose are super profits.

(iii) There is good reason that in order to save lives that prices of vaccines be controlled and the regime of fixing prices under the DPCO issued under the Essential Commodities Act be utilized

(iv) Therefore it is necessary that a direction be issued that National Pharmaceutical Pricing Authority fix the prices of vaccines.

V. *That COVID-19 is a public health emergency and the government is obligated to issue an order of Government authorization under Section 100 or a Compulsory license for non-commercial public use under Section 92(1), of Patents Act to respond to national emergency and ensure continued access to the vaccines*

(i) That the Hon'ble Supreme Court of India vide its order dated 22.04.2021 in the present Suo Moto Writ Petition, took cognisance of lack of COVID-19 resources and further directed that the essential services and supplies have to be down in an even-handed manner taking into account the local availability of resources.

(ii) That the supply of both vaccines over the past few days has been declining; there is no guarantee that those who received the vaccine the first time would be able to receive the second dose of the vaccine ;

(iii) The third parties apart from the Bharat Biotech and Serum Institute are excluded from manufacture of the vaccine due to active patent on the vaccine;

(iv) That the supply of the vaccine in India is solely dependent on manufacture by Bharat Biotech and

Serum Institute of India and RDIF through Dr. Reddy's Laboratories;

(v) That reliance on limited to provide the vaccine in the market, that too through imports, have laid bare the major shortage for this vaccine;

(vi) That to ensure better availability of this vaccine, there is a need for more companies to produce the vaccine ;

(vii) That the Patents Act under Section 100 empowers the Respondent No, 1 to authorize any person in writing to use any invention to the purposes of the government;

(viii) Additionally, the Patents Act under Section 92 empowers the Respondent No. 1 to issue a Compulsory License in case of a national emergency, extreme urgency or in case of public non-commercial use.

(ix) That these provisions has been included in the Patents Act pursuant to Article 31 of the TRIPS Agreement allowing states to authorise use of an invention without permissiSon of the right holder in situation of national emergency, extreme urgency, and public non-commercial use;

(x) That such exception to patent right is to be read in a manner that supports the right of the country to protect public health. Such reading has also been iterated by member states of the WTO at the 2001 Doha Declaration on TRIPS and Public Health and the Resolution A/HRC/RES/12/24 of the Human Rights Council of the UN;

(xi) That the Respondent No. l has moved the TRIPS Council to waive intellectual property rights for Covid 19 related diagnostics, therapeutics and vaccines.

(xii) The Respondent No. 1 is expected to be consistent at the domestic and international level in its response.

(xiii) That Hungary, Israel have issued government use authorisation for use of patents related to COVID-19 treatments to protect public health of their population;

VI ***<u>The impugned amendment vide order dated 3rd January 2019 being para 32 of the DPCO is violation of art 14 and 21</u>***

(i) Impugned Amendment in Para 32(i) vide order dated 3 January 2019 has no rational basis for the intelligible differentia between the patented and non-patented drugs;

(ii) The objective of the Essential Commodities Act and DPCO is to ensure availability and accessibility of diagnostics therapeutic and vaccines, including those for the treatment of Covid-19, to be available to all to realise the right to health and protect the right to life;

(iii) There is no rational nexus between intelligible differentia between patented and non-patented drugs and the object sought to be achieved under the Essential Commodities Act and the DPCO ;

51. The Applicant herein has not approached any other Court or this Hon'ble Court, with any other petition/application in respect of the subject matter of his application.

52. In light of the above, it is most respectfully submitted, that the present application on behalf of the Applicant herein is *bona fide* and filed in the interest of public in the present

situation and an order allowing the present Application shall meet the ends of justice.

PRAYERS

In the premises stated above, it is, therefore, respectfully prayed, that this Hon'ble Court may be pleased to:

a. Direct the Respondent No. 1 to disclose its plans to increase production capacities of vaccines of private and public sector units and how much investment it is proposing to make in the public sector units;
b. Direct the Respondent No. 1 and all the States to ensure that that the full course of vaccine/s are available free of charge to all at Government hospitals and centres who access them with a further order to allow vaccines to be made available at private hospitals and centres at affordable rates;
c. Direct the Respondent No. 1 to continue the current scheme of providing vaccines for people aged 45 and above the full course of vaccine/s are available for RS 250 at the private sector.
d. Quash the decision of the Respondent No. 1 not to procure the vaccines at a central level with the further direction to the Respondent No. 1 to procure all the vaccines at central level and distribute them to the States in accordance with their requirements as has been done for the past 70 years;
e. Direct the Respondent No. 1 to ascertain if any vaccine is covered by any patent/s, and if so, issue government authorization under section 100 or compulsory licence section 92 of the Patents Act in respect thereof with a further direction to the Drugs controller General of India

(DCGI) through Respondent No 1 to take measures to share the trade secrets related manufacturing process of vaccines to scale up the production of vaccines;

f. Direct the National Pharmaceutical Pricing Authority to fix the prices of the vaccines in accordance with law;

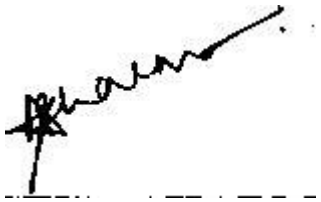
g. Pass such further and other orders as this Hon'ble Court may deem fit in the interest of Justice.

AND FOR THIS ACT OF KINDNESS THE APPLICANT AS IN DUTY BOUND EVER PRAY.

Drawn By –
Ms. Rajeshwari Hariharan & Ms. Nupur Kumar, Advocates

Settled By –
Mr. Anand Grover,
Senior Advocate

FILED BY



(ASTHA SHARMA)
Advocate for the Applicant

New Delhi

Dated: 29.04.2021

IN THE HON'BLE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

IA NO. _____ OF 2021

IN

SUO MOTU WRIT PETITION (C) NO. 3 OF 2021

IN THE MATTER OF:
RE: DISTRIBUTION OF ESSENTIAL SUPPLIES & SERVICES DURING PANDEMIC

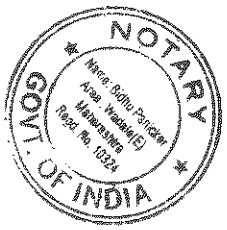
AND IN THE MATTER OF:
JAN SWASTHYA ABHIYAN ...APPLICANT(S)

VERSUS

UNION OF INDIA & ORS. ...RESPONDENT(S)

AFFIDAVIT

I, Ms. Brinelle DeSouza, aged 52, D/o Noel Desouza, Co-convenie Jan Swasthya Abhiyan, having its registered office at 417-18, Mahinder Chambers, Opposite Dukes Factory, Chembur, Mumbai, Maharashtra, do hereby solemnly affirm and state as under:



1. That I am the Co-Convenie of the Applicant in the present Petition and as such I am fully conversant with the facts and proceedings of the case.

2. That I have read the contents of the accompanying IAs and I say that the contents therein are true to my personal knowledge & belief.

3. That the present affidavit is of the same or subsequent date of the drafting of the petition/application.

4. That the Annexures are true copies of the originals thereof.

DEPONENT

VERIFICATION

I, the deponent above named, do hereby state on solemn affirmation that the contents of Para No. 1 to 4 herein above are true and correct to my own knowledge and that nothing material has been concealed there from.

Verified at Mumbai this 27th day of April, 2021.

DEPONENT

BEFORE ME

BIDHU PANICKER
B.Com. LL.B.
ADVOCATE HIGH COURT
NOTARY (Govt. of India)
Res: 303, Sandeep Apt., Plot No. A/197,
Sector-20, Near Balaji Temple,
Nerul (W), Navi Mumbai, Maharashtra.

Notary Reg. Sr. No. 3178/2021
In Book No. III