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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ FAO(OS) (COMM) 81/2020

UNION OF INDIA ..... Appellant

Through: Mr.Tushar Mehta, SGI with Mr.Balbir Singh, ASG with Ms.Monikabenjamin Mr. Bhagavn Swarup Shukla, CGSC, Mr. Rajesh Ranjan, Mr.Joel, Mr.Shyam Gopal and Mr.Sarvan Kumar, Advs.

versus

PANACEA BIOTEC LIMITED ..... Respondent

Through: Mr.Sandeep Sethi, Sr. Adv. with Mr.Kawal Nain, Mr.Bhavya Nain, Mr.Rohit Dadwal and Ms.Kavita Sharma, Advs.

% Date of Decision: 04th June, 2021

CORAM:
HON'BLE MR. JUSTICE MANMOHAN
HON'BLE MR. JUSTICE NAJMI WAZIRI

MANMOHAN, J. (ORAL)

J U D G M E N T

C.M.No. 16526/2021

1. Present application has been heard by way of video conferencing.

FACTS

2. The present appeal has been filed by the Appellant challenging the judgment and order dated 18th March, 2020, passed by learned Single Judge whereby the application filed by the Appellant herein under Section 34 of

the Arbitration and Conciliation Act 1996 (hereinafter referred to as "the Act 1996") was rejected on the ground of delay terming it as merely a '*bunch of papers*' and that by the time it was re-filed along with a copy of the Award, the period of limitation had expired, although the initial application had been filed with the registry within the period of limitation.

3. On 22nd July, 2020, learned counsel for the Respondent-Applicant had stated that the Respondent-Applicant, in the meantime, would not prosecute the execution proceedings instituted by it before the learned Single Judge.

4. Subsequently, present application being CM Appl.16526/2021 was filed by the Respondent-Applicant seeking modification of the interim order dated 22nd July, 2020 as well as for a direction to the Appellant to release the awarded amount along with interest to the Respondent-Applicant within two weeks.

5. It was averred in the application that the Respondent-Applicant had manufactured trial batches of COVID-19 vaccine Sputnik V in collaboration with Russian Direct Investment Fund (for short 'RDIF') and the process of manufacturing scale-up batches is on. It was further averred that if the awarded amount is not released by the Appellant to the Respondent-Applicant, the whole process of manufacturing of vaccine may get derailed and delayed which would not be in the larger interest of the country.

6. When the application was taken up for hearing on 18th May, 2021, learned ASG appearing for Appellant/non-applicant had stated that manufacture of Sputnik V vaccine by the Respondent-Applicant would not benefit the country as its manufacture is to be for global supply by RDIF and it cannot be used for domestic use in India.

7. As this Court was of the *prima facie* opinion that as there is an acute shortage of COVID-19 vaccines in India and the collaboration between the Respondent-Applicant and the RDIF may give India a window of opportunity to ensure that the vaccines manufactured by the Respondent-Applicant are used in India, it issued notice in the present application, as well as asked the Appellant/non-applicant to examine the present application from the aforesaid perspective and also asked the parties to complete the pleadings. However, as there has been no amicable resolution of the disputes, the application has been taken up for hearing.

ARGUMENTS ON BEHALF OF RESPONDENT-APPLICANT

8. The learned senior counsel for the Respondent-Applicant states that technology has been granted to the Respondent-Applicant for manufacture of Sputnik V vaccine by RDIF of Russia through its affiliate company “LLC Human Vaccines” of Russia ("HV"). He further states that as per the terms of Agreement, HV has granted an advance amount against supply of Sputnik-V vaccine to meet the partial fund requirement for fulfilling its obligations pursuant to the Agreement, including towards capital expenditure and the cost of materials & other expenses to be incurred in connection with transfer of technology, production of initial proof of concept/trial batches, validation/registration batches and initial commercial batches production. To safeguard the interest of the Appellant, he states that the Respondent-Applicant shall deposit twenty per cent of the sale proceeds of the Sputnik V vaccine with the Registry of this Court till the said awarded amount along with interest is fully secured, subject to the outcome of the present appeal.

ARGUMENTS ON BEHALF OF APPELLANT-NON APPLICANT

9. In rebuttal, the learned ASG states that no modification of the order dated 22nd July, 2020 passed by this Court can be prayed for having regard to the fact that the Respondent-Applicant by way of the present application is trying to bring a fresh prayer for release of the entire disputed awarded amount '*in disguise'*, which if granted would render the appeal proceedings before this Court infructuous as it would receive the entire disputed awarded amount without adjudication.

10. He further states that the issue pertaining to the awarded amount in dispute in the present appeal cannot be integrated with and made subject to the unrelated issue of the Respondent-Applicant's need for funds for manufacturing the Sputnik V vaccine. He states that the Respondent-Applicant is already being privately financed and funded by RDIF for whom it is manufacturing the Sputnik V vaccine under a private contract. He contends that the arrangement of the Respondent-Applicant with a foreign government (Russian) investment fund by the name of RDIF is entirely a private contractual financing arrangement and that the Government of India has nothing to do with the same. Therefore, where the Respondent-Applicant itself has admitted obtaining finances from RDIF, a foreign government investment fund, for manufacture of Sputnik V vaccine, it cannot be stated by the Respondent-Applicant that it lacks funds for said manufacture.

11. The learned ASG also states that the Respondent-Applicant, as of today, is still far away from manufacturing the COVID-19 vaccine, as its samples are pending approval with the statutory authorities. In support of his

contention, he relies upon paragraphs 6 and 7 of the rejoinder-affidavit filed by the Respondent-Applicant to the present application. The said paragraphs are reproduced hereinbelow:-

> *"6. Regulatory Pathway for Obtaining Manufacturing License of vaccine in India is as under:-*
>
> > *i. Application in form CT-10 to seek DCGI permission on form CT-11 to manufacture new drug or investigational new drug for clinical trial, bioavailability or bioequivalence study or for examination, test and analysis;*
> >
> > *ii. Test license on Form-29 from State Licensing Authority to manufacture new drug or investigational new drug for clinical trial, bioavailability or bioequivalence study or for examination, test and analysis;*
> >
> > *iii. Manufacturing and testing of 3 pre licensure consistency batches for Test and Analysis purpose*
> >
> > *iv. Submission of sample from 3 consistency batches to CDL for testing and release;*
> >
> > *v. Submission of dossier and CDL, Kasauli, release report to DCGl for seeking clinical trial permission/Manufacturing permission for sale and distribution purpose;*
> > *vi. Grant of manufacturing permission from DCGI on Form CT-23;*
> >
> > *vii. Submission of form CT-23, Dossier and form 27-D to State Licensing authority to seek manufacturing license on Form 28-D for Sputnik V vaccine; and*
> > *viii. Grant of Manufacturing license from State Licensing Authority on form 28-D.*
>
> *7. Pursuant to the above said collaboration agreement, the respondent has taken the steps as mentioned in para 6 (i) to (iv)*

and samples and lot summary protocols of the validation batches of both the components of combined vector based vaccine against. SARS-CoV-2 (Gam-COVID-Vac) have been furnished to CDL, Kasauli for testing and release purpose on parallel basis."

12. He lastly contends that the entire issue of procurement, manufacturing, distribution and payments of all available vaccines, including Sputnik V, are pending before the Hon'ble Supreme Court of India in Suo Moto Writ Petition No. 3/2021 and therefore, this Court should restrain itself from passing any order in the present application.

REJOINDER ARGUMENTS ON BEHALF OF RESPONDENT-APPLICANT

13. In rejoinder, the learned senior counsel for the Respondent-Applicant clarifies that the amount advanced by RDIF meets only a part of the overall fund requirement including working capital and capital expenditure and the Respondent-Applicant needs additional funds for capital expenditure as well as for securing supply of key raw materials, packaging materials, consumables, etc. from its suppliers which will help it to expedite and to ramp-up the commercial production of Sputnik V vaccine. He emphasises that release of the money as prayed for in the present application would help the Respondent-Applicant to place orders well in time on its suppliers for the said purposes, so that the vaccine can be made available in India at the fastest pace, which will be in the larger public interest.

14. In response to a pointed query by this Court, learned senior counsel for Respondent-Applicant candidly admits that the Respondent-Applicant has no unencumbered asset in its possession to offer as security against the release of the awarded sum.

15. He emphasises that the Sputnik-V vaccine to be manufactured by the Respondent-Applicant is nothing but a replica of the vaccine that has been manufactured in Russia and imported in India by Dr. Reddy's laboratory under an emergency use authorisation granted by the Union of India vide Notification dated 01st June, 2021. Consequently, according to him, the Respondent-Applicant is also entitled to emergency use authorisation forthwith, as well as approval to manufacture Sputnik-V vaccine in India. The said Notification dated 01st June, 2021 is reproduced hereinbelow:-

> *"In light of the huge vaccination requirements in India in the wake of the recent surge of COVID-19 cases and the need for increased availability of imported vaccines to meet the national requirements even though the domestic manufacturing of COVID-19 vaccines is getting augmented, in partial modification of this office Notice of even number dated 15.4.2021, as per recommendation of NEGVAC, it has been decided that for approval of COVID-19 vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) and which are well established vaccines from the stand point that millions of individuals have already been vaccinated with the said vaccines, the requirements of conducting post approval bridging clinical trials and the requirements of testing of every batch of vaccine by the Central Drugs Laboratory (CDL), Kasauli can be exempted, if the vaccine batch/lot has been certified and released by National Control Laboratory of Country of Origin.*
>
> *However, scrutiny and review of their Summary Lot Protocol & Certificate of analysis of Batch/Lot shall be undertaken by CDL Kasauli for Batch release as per the standard procedures and the requirements of assessment on the first 100 beneficiaries for 7 days for safety outcomes before the vaccine is rolled out for further immunization programme, along with other procedures for filing of applications and timelines for processing of the applications, etc. as laid down in the notice dated 15.4.21 shall remain the same."*

SUPPLEMENTARY ARGUMENTS ON BEHALF OF APPELLANT

16. At this stage, the learned ASG states that Government of India has decided to procure Sputnik V vaccine from Dr. Reddy's Laboratory alone. He emphasises that the Respondent-Applicant is at least one month away from the commercial production inasmuch as the efficiency and ethnic test are yet to be complied with, as there is no emergency waiver under Section 26B read with Rule 122B of the Drugs Rules, 1945 (as amended by Cosmetics Rules, 2020 (13th Schedule)Vide GSR 763 (E), dt. 15-12-2020 w.e.f. 15-12-2020) [hereinafter referred to as 'Rules, 1945'] as has been granted to the imported Sputnik V vaccine vide Government of India Notification dated 01st June, 2021. Section 26B of the Drugs and Cosmetics Act, 1940, (hereinafter referred to as 'Act 1940') and the Rules 122-A, 122-B framed thereunder are reproduced hereinbelow:-

A) Section 26B of the Act, 1940:-

> ***"26B. Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest****. —Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug."*

B) Rules 122-A, 122-B of Rules, 1945:-

> ***122-A. Application for permission to import new drug****.- (1) (a) No new drug shall be imported, except under, and in accordance with, the permission granted by the Licensing Authority as defined in clause (b) of rule 21.*

(b) An application for grant of permission to import a new drug shall be made in Form 44 to the Licensing Authority, accompanied by a fee of fifty thousand rupees:

Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with new claims, is made, the fee to accompany such application shall be fifteen thousand rupees.

Provided further that any application received after one year of the grant of approval for the import and sale of new drug, shall be accompanied by a fee of fifteen thousand rupees and such information and data as required by Appendix I or Appendix I A of Schedule Y, as the case may be.

(2) The importer of a new drug when applying for permission under sub-rule (1), shall submit data as given in Appendix I to Schedule Y including the results of local clinical trials carried out in accordance with the guidelines specified in that Schedule and submit the report of such clinical trials in the format given in Appendix II to the said Schedule :

Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest decide to grant such permission on the basis of data available from other countries:

Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenic studies, Perinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.

(3) The Licensing Authority, after being satisfied that the drug if permitted to be imported as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, may issue an import permission

in Forms 45 and/or Form 45 A, subject to the conditions stated therein:

Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission, could be considered.

122-B. Application for approval to manufacture new drug

(1)(a) No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in clause (b) of rule 21.

(b) An application for grant of approval to manufacture the new drug and its formulations shall be made in Form 44 to the Licensing Authority as defined in clause (b) of rule 21 and shall be accompanied by a fee of fifty thousand rupees:

Provided that where the application is for permission to import a newdrug (bulk drug substance) and grant of approval to manufacture its formulation/s, the fee to accompany such application shall be fifty thousand rupees only.

Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with new claims, is made, the fee to accompany such subsequent application shall be fifteen thousand rupees. Provided further also that any application received after one year of the grant of approval for the manufacture for sale of the new drug, shall be accompanied by a fee of fifteen thousand rupees and such information and data as required by Appendix I or Appendix I A of Schedule Y, as the case may be.]

(2) The manufacturer of a new drug under sub-rule (1) when applying for approval to the Licensing Authority mentioned in the said sub-rule, shall submit data as given in Appendix I to Schedule Y including the results of clinical trials carried out in the country in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in the format given in Appendix II to the said Schedule.

(2A) The Licensing Authority as defined in clause (b) of rule

21 after being satisfied that the drug if approved to be manufactured as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, shall issue approval in Form 46 and/or Form 46A, as the case may be, subject to the conditions stated therein:

Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered.

(3) When applying for approval to manufacture a new drug under sub-rule (1) or its preparations, to the State Licensing Authority, an applicant shall produce along with his application, evidence that the drug for the manufacture of which application is made has already been approved in the name of the applicant] by the Licensing Authority mentioned in Rule 21:

Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority in Rule 21 may, in public interest decide to grant such permission on the basis of data available from other countries:

Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenic studies, Perinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.

17. Rule 80 (7) of New Drugs and Clinical Trials Rules, 2019 (which came in force w.e.f. 19th March, 2019) is relevant and is reproduced hereinbelow:-

"Rule 80. Application for permission to manufacture new drug for sale or distribution.—

xxxx xxxx xxxx xxxx

(7) The local clinical trial may not be required to be submitted along with the application referred to in sub-rule (1) if,-

(i) *the new drug is approved and marketed in countries specified by the Central Licencing Authority under rule101 and if no major unexpected serious adverse events have been reported; or*

(ii) *there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and*

(iii) *the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the Central Licencing Authority:*

Provided that the Central Licencing Authority may relax this condition, where the drug is indicated in life threatening or serious diseases or diseases of special relevance to Indian health scenario or for a condition which is unmet need in India such as XDR tuberculosis, hepatitis C, H1N1, dengue, malaria, HIV, or for the rare diseases for which drugs are not available or available at a high cost or if it is an orphan drug."

COURT'S REASONING

COURT ALWAYS HAS THE POWER TO VARY OR MODIFY ANY INTERIM ORDER FOR GOOD AND COGENT REASON.

18. It is settled law that the Court always has the power to vary or modify any interim order for good and cogent reason. In any event, in the present case, the Respondent-Applicant had made a voluntary statement that, in the

meantime, it would not prosecute its execution application. It is always open to the Respondent-Applicant to file an application, as has been done in the present instance, to withdraw its statement for good reason.

COURT CLARIFIES THAT IT IS NOT EXAMINING THE GOVERNMENT'S POLICY WITH REGARD TO COVID 19 VACCINES

19. This Court clarifies that in the present proceedings it is not examining the Government of India's procurement, manufacture and distribution policy of COVID 19 vaccines. In any event, there is no stay by the Supreme Court of India of the present proceedings. Accordingly, this Court has no option but to proceed ahead with the matter.

PRESENT APPEAL WOULD NOT BE INFRUCTUOUS IF THE PRESENT APPLICATION IS ALLOWED.

20. This Court is also of the view that the present appeal would not be infructuous if the present application is allowed because if the appeal were to be allowed, the Respondent-Applicant would be liable to refund the entire amount received by it along with interest.

RESPONDENT-APPLICANT IS ENTITLED TO AND THERE IS NO LEGAL BAR IN DIRECTING RELEASE OF THE AWARDED SUM SUBJECT TO THE CONDITION THAT IT OBTAINS PERMISSION FROM THE APPELLANT TO MANUFACTURE VACCINES.

21. It is further settled law that filing of an application to set aside the Arbitral Award under Section 34 of the Act 1996 would not by itself render the said Award as unenforceable. Though it is open to the Court under Sections 34 and 36 of the Act 1996 to stay the operation of the Award, yet

while considering such an application the said court has to treat it as an application for stay of money decree under Code of Civil Procedure, 1908.

22. In the present matter, the Respondent-Applicant's case stands on a higher pedestal inasmuch as it has not only an Arbitral Award in its favour but the Appellant's Section 34 petition has been dismissed by the learned Single Judge at the threshold stage holding it to be '*a mere bunch of papers*' instead of an appropriate application under Section 34 of the Act 1996. Further, it is not the Appellant's case that the Award has been induced or affected by fraud or corruption.

23. Consequently, the Respondent-Applicant is entitled to release of the Awarded sum and there is no legal bar in directing release of the Awarded sum to the Respondent-Applicant subject to the condition that it obtains permission from the Appellant to manufacture Sputnik V vaccines in India. Even otherwise, the Respondent-Applicant in the present case is willing to safeguard the interest of the Appellant by depositing twenty percent (20%) of the sale proceeds with the Registry of this Court till the Awarded amount along with interest is fully secured. It is pertinent to mention that accounts in the present case would not be an issue as the vaccines sought to be manufactured by the Respondent-Applicant shall be primarily sold to the Appellant or the State Governments.

IN VIEW OF THE SPECIFIC DENIAL BY THE RESPONDENT-APPLICANT. THIS COURT CANNOT PRESUME THAT IT HAS BEEN ADVANCED THE ENTIRE FUNDS AND THE RAW MATERIALS BY RDIF.

24. Further in the absence of any documentary proof by the Appellant and in view of the specific denial by the Respondent-Applicant in his rejoinder

that it has not been entirely funded by RDIF, this Court, while deciding the present application, cannot presume that the Respondent-Applicant has been advanced the entire funds and the raw materials by RDIF to facilitate manufacture of Sputnik V vaccine in India.

DURING AN EPIDEMIC EVERY COUNTRY UNDER ARTICLE XX OF GATT HAS THE RIGHT TO RESTRICT THE EXPORT OF PARTICULAR PRODUCTS.

25. In fact, the stand of the Union of India, to put it mildly, has been '*evolving*' from time to time. While on the first date of hearing i.e. 18th May, 2021, this Court was informed that manufacture of vaccine by the Respondent-Applicant was for global supplies purposes, in the reply affidavit dated 29th May, 2021 it was averred that '*CDSCO has not granted any manufacturing license or license for conducting clinical trials to the respondent for Sputnik V vaccine allegedly sought to be manufactured by it in India*' and further that '*the appellant does not have any information regarding readiness or availability of Sputnik V vaccine allegedly claimed to have been manufactured by the respondent*'(para18 of reply). Subsequently, on 01st June, 2021 it was stated that three sample vaccines had been received from the Respondent-Applicant and the same were yet to undergo efficiency and ethnic test under the Act 1940.

26. This Court is of the view that during an epidemic every country under Article XX of General Agreement on Tariffs and Trade (GATT) has the right to restrict the export of particular products. The relevant portion of the said Article is reproduced hereinbelow:-

"General Exceptions:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

...

(b) necessary to protect human, animal or plant life or health;....

(i) involving restrictions on exports of domestic materials necessary to ensure essential quantities of such materials to a domestic processing industry during periods when the domestic price of such materials is held below the world price as part of a governmental stabilization plan; Provided that such restrictions shall not operate to increase the exports of or the protection afforded to such domestic industry, and shall not depart from the provisions of this Agreement relating to non-discrimination;

(j) essential to the acquisition or distribution of products in general or local short supply; Provided that any such measures shall be consistent with the principle that all contracting parties are entitled to an equitable share of the international supply of such products, and that any such measures, which are inconsistent with the other provisions of the Agreement shall be discontinued as soon as the conditions giving rise to them have ceased to exist. The CONTRACTING PARTIES shall review the need for this sub-paragraph not later than 30 June 1960."

27. Consequently, to state that the production of vaccine being carried out by the Respondent-Applicant is for global supplies, which cannot be used for domestic use even during the time of an epidemic, is untenable in law.

IN COVID-19 PANDEMIC, TO GO BY THE RULE BOOK APPLICABLE IN NORMAL TIMES COULD MEAN JEOPARDISING A FEW HUMAN LIVES. THIS IS NOT THE TIME TO FEEL COWED-DOWN BY AUDITS AND INVESTIGATIONS.

28. This Court also takes judicial notice of the fact that till date, there have been about two crore eighty five lakhs seventy four thousand three hundred fifty (2,85,74,350) coronavirus cases in India due to the COVID-19 epidemic. It will not be an exaggeration to say that the human race, in general is facing an existential crisis.

29. Though according to the Government of India, one of the best ways to fight against the pandemic is to vaccinate the public, yet there is shortage of vaccines in India. Government of National Capital Territory of Delhi (GNCTD), in recent past, has been issuing repeated public statements curtailing its vaccination drive with regard to either the number of Vaccination Centres or categories of persons to be vaccinated.

30. Furthermore, from the contents of the present application, in particular its Annexure R-3 dated 05th April, 2021 at page 25, it is apparent that there is lot of '*untapped capacity*' (of the 'installed capacity' of the domestic vaccine manufacturing industry) by way of infrastructure for manufacture of vaccines within the country. However, there is nothing on record to show that officers of the Appellant had sought to augment the much-needed vaccine production or handheld the Indian vaccine manufacturers and acted as facilitators for use of this untapped infrastructure. Even when a foreign fund house has tapped into this untapped infrastructure for manufacture of vaccines, the officials of the Appellant, despite being asked for advance monies, have refused to make

use of this opportunity to ensure that the vaccines so manufactured are made available for use in India as soon as the Respondent-Applicant is '*supply ready*'.

31. In this extraordinary situation, to go by the rule book applicable in normal times would mean an opportunity to save a few human lives may be in jeopardy. These are not normal times. One has to look at the '*big picture*'. At this moment, '*alacrity*', '*flexibility*' and '*agility*' has to be the "mantra". This is not the time to feel cowed-down by audits and investigations. Any official of the Respondent-Applicant, who, due to fear of subsequent investigation, refuses to act in the present pandemic, may open himself/herself to charge of offences affecting the human body. This Court is of the opinion that allowing of the application in the present facts cannot be construed by any reasonable authority as favouring a particular entity as by doing the same, one would be making an effort to protect human lives.

THIS COURT IS OF THE VIEW THAT THE APPELLANT SHOULD EXAMINE WAIVING BRIDGE TRIALS IN LIGHT OF VACCINE POSITION IN THE COUNTRY AND IN ACCORDANCE WITH LAW

32. In any event, this Court, with the assistance of the counsel for the parties, has examined Section 26B of the Act 1940 and the Rules framed thereunder and also Rule 80 (7) of New Drugs and Clinical Trials Rules, 2019. This Court finds that sub-rule 2 of Rule 122-A and sub-rule 3 of Rule 122-B of the Rules, 1945 and sub-rule 7 of Rule 80 of New Drugs and Clinical Trials Rules, 2019 are *pari materia* as they grant power to the Union of India to exempt the manufacturer or the importer, as the case may be, from submitting results of local clinical trials in certain circumstances.

33. The Respondent-Applicant also relies upon Circular (Notice) of the Government of India dated 15th April which envisages a corollary grant of licence to manufacture a Covid-19 vaccine, in cases where the identical product has been permitted for import and use in India, without clinical/ethnicity trials under the said Rules. The relevant portion of the Circular reads as under:

"X-11026/07/2020-PRO
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Relation Office)

FDA Bhawan, Kotla Road
New Delhi, 110002
Dated: 15 April, 2021

NOTICE

Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL)....

- *The Covid vaccines already approved by the DCGI for restricted use in emergency situation in India, and proposed to be fill finished at a site within the country different from the manufacturing site, by receiving bulk of the approved vaccine, will also be approved by CDSCO based on inspection & CDL release....."*

34. This Court is of the view that the Appellant should examine waiving bridge trials in light of vaccine position in the country. However, as no specific prayer has been sought in the present proceedings with regard to waiver of bridge trials, this Court directs the Appellant to consider

Respondent-Applicant's application for emergency use and authorisation under Section 26B of the Act 1940 read with relevant Rules and OM's/Policies/Schemes framed thereunder in accordance with law.

RELIEF

35. Consequently, the present application is allowed and the Appellant is directed to release the Awarded sum along with interest as directed by the learned Arbitrator to the Respondent-Applicant (who was successful before the learned Arbitrator and the learned Single Judge) subject to the condition that it obtains permission from the Appellant to manufacture Sputnik V vaccines in India. This release of money shall also be subject to the express undertaking given by learned senior counsel for the Respondent-Applicant (which is accepted by this Court) that it would deposit twenty percent (20%) of the sale proceeds of the Sputnik V vaccine with the Registry of this Court till the said Awarded amount along with interest is fully secured, subject to the outcome of the present appeal.

FAO(OS)(COMM) 81/2020

List the appeal before the regular Roster Bench.

The order be uploaded on the website forthwith. Copy of the order be also forwarded to the learned counsel through e-mail.

MANMOHAN, J

NAJMI WAZIRI, J

JUNE 04, 2021
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