DISTRICT: KOLKATA

## IN THE HIGH COURT AT CALCUTTA CONSTITUTIONAL WRIT JURISDICTION

#### APPELLATE SIDE

W. P. No. (W) Of 2020

Subject matter relating to

Under Group **IX** Head of the Classification List

#### **CAUSE TITLE**

Kanishk Sinha

.....Petitioner

Versus

Shri Harsh Vardhan & Others

.....Respondents

For Petitioner (In - Person)

KanishK sil

Kanishk Sinha, MSc,

LLB, HM PLAZA, 8, Acharya Jagdish Chandra Bose Road, Kolkata – 700 017, Mobile: - 9830647300

/ 7044598246

DISTRICT: KOLKATA

#### IN THE HIGH COURT AT CALCUTTA

#### CONSTITUTIONAL WRIT JURISDICTION

#### APPELLATE SIDE

W. P. No. (W) Of 2020

Kanishk Sinha

.....Petitioner

Versus

Shri Harsh Vardhan & Others

.....Respondents

#### INDEX

S1.No.	Particulars of Papers	Annexure	Page
1.	List of Dates		
2.	Points of Law		
3.	Writ Petition	***************	
4.	Copy of the Form – 1 Application for grant of Patent dated: 27.03.2020.	P – 1	
5.	Copy of the Form – 2, Complete Specification dated: 27.03.2020.	P - 2	
6.	Website copy of the order dated: 01.04.2020 passed in W.P. 5325 (W) of 2020 by this Hon'ble Court.	P – 3	
7.	Website copy of the order dated: 08.04.2020 passed in W.P. 5325 (W) of 2020 by this Hon'ble Court.	P – 4	
8.	Scanned copy of the representation dated: 09.04.2020 issued by the petitioner.	P – 5	

9.	Scanned copy of the impugned letter dated: 27.04.2020 issued by Government of India, Ministry of Health and Family Welfare.	P – 6	
10.	Scanned copy of the impugned letter dated: 11.05.2020 issued by the Indian Council of Medical Research, New Delhi.	P – 7	
11.	Copy of the proposal dated: 20.05.2020 by email to the Department of Bio Technology, Government of India, New Delhi.	P – 8	

#### LIST OF DATES

Dates	:	Events					
27-03-2020	:	The petitioner has readied one patent application for a					
		invention of vaccination of Novel Coronavirus in the form					
		of Form - 1 AND 2 before the Kolkata Patent Office,					
		Government of India.					
27-03-2020	:	Petitioner tried to file and upload the same before the					
		Patent Office, Kolkata through their e – module viz: -					
		www.ipindia.nic.in but due to error in their website the					
		same cannot be filed and / or uploaded.					
01-04-2020	:	This Hon'ble Court upon hearing the writ petition being					
		W.P. 5325 (W) of 2020 has been pleased to pass					
		interim order "As an interim order this Court directs					
		that considering the extraordinary circumstances created					
		by the lock down, the respondent authorities shall very					
		actively consider the prayer of the writ petitioner as made					
		in prayer (a) of the writ petition and take a decision in the					
		matter by 7th April, 2020 to be communicated to this					
		Court keeping in view the fact that no valuable right of the					
		writ petitioner is lost by virtue of this unusual situation."					
08-04-2020	:	This Hon'ble Court upon hearing the writ petition being					
		W.P. 5325 (W) of 2020 has been pleased to dispose of					
		the writ petition directing inter alia " Learned counsel					

for the respondents submits that the application of the petitioner for grant of patent has been accepted online. This substantially redresses his grievance in this writ application. His further prayer is for an order upon the government to allow him to do research work in connection with the invention of a vaccine to prevent or combat the COVID 19 virus. For this purpose, he may make a proper application before the appropriate authority. The said authority, upon consideration of the petitioner's eligibility and his fulfillment of other necessary conditions may consider such application for doing research in accordance with law by making a decision within four weeks of communication of this order."

09-04-2020

Petitioner submitted the application as per this Hon'ble Court judgment / order dated: 08-04-2020 passed in W.P.5325 (W) of 2020 before the Secretary, Ministry of Health and Family Welfare, Government of India stating inter alia "....That, since due to the lockdown and / or extraordinary circumstances I cannot arrange for a private laboratory as such I seek limited assistance to use any of the available Government of India laboratory facility exclusively with proper security and instruments / apparatus to develop the COVID 19 vaccine rest we

will take care of the investment and project costs as it is a commercial project and I apprehend that, if I take government funding then I have to share and / or give its exploitation rights to the Government u/s 102 of the Patents Act, 1970 HENCE our demand is only confined to use any of the available government laboratory facility exclusively with proper instruments / apparatus only for which I am ready to pay the fees also as directed by the authority concerned.

That, I also seek blood samples / swab samples of the infected / recovered COVID 19 patient.

That, after development of the vaccine I would be requiring the volunteers to clinically test the said vaccine.

That, I also seek PPEs for all our team members at the time of research.

That, the team members of this classified project will be solely decided by the undersigned without interference of the Government of India.

FURTHERMORE, I pray for a hearing opportunity through video conferencing at the time of deciding the instant application by the authority through WhatsApp or Microsoft Teams application whichever is possible and / or available or else any adverse decision taken by the authority will be treated as an ex facie.

It imperative to state herein that, the Hon'ble Court has granted the Government of India four weeks time to

		decide my application but I would like to state that, it is				
		a race against time and each minute delay are causing				
		casualties so it would be appreciated if the same is				
		decided on priority basis so that, I can come up with the				
		vaccine at an early date.				
27-04-2020	:	The Secretary, Ministry of Health and Family Welfare,				
		Government of India assigned the matter to the Director				
		General of Indian Council of Medical Research, New				
		Delhi for taking decision on the application dated: 09-				
		04-2020 made by the petitioner.				
11-05-2020	:	Indian Council of Medical Research, Government of				
		India, New Delhi vide his letter dated: 11-05-2020 has				
		stated as follows;				
		"I am directed to refer to the above mentioned case				
		on the subject and to say that in compliance of the				
		Order dated 08.04.2020 passed by the Hon'ble High				
		Court at Calcutta at Kolkata in W.P. (C) No. 5325 of				
		2020 (Shri Kanishk Sinha – Vs – Union of India &				
		others), representation dated 09.04.2020 has been				
		received in Indian Council of Medical Research (ICMR),				
		New Delhi for consideration and the replies are as				
		follows:-				
		ICMR believes in working in close partnership with				
		various stakeholders. While ICMR is actively engaged in				
		formulating research projects on epidemiology,				

		operational research, clinical studies and diagnostics,					
		the research group on vaccines has been dissolved as					
		DBT has taken a lead on vaccines.					
		BIRAC (DBT) and SERB (DST) have already placed a call					
		for proposals in the area of COVID – 19 vaccines.					
		In view of this, ICMR has decided not to invite proposals					
		on vaccine development, Hence, the representation					
		09.04.2020 submitted by Shri Kanishk Sinha has been					
		considered in ICMR and disposed of to the above effect.					
		This issues with the approval of competent authority.					
20-05-2020	:	Petitioner submitted his proposal before the BIRAC					
		(DBT) for sponsorship.					
23-05-2020	:	HENCE THIS WRIT PETITION.					

#### POINTS OF LAW

- Whether the impugned in action on the part of respondents authorities are wholly illegal, arbitrary, malafide and against the principles of Natural Justice.
- 2. Whether, the Respondent authorities failed to consider as per article 21 of the Constitution of India it is their duty to protect the life and property of your petitioner and by refusing to allow the application for doing research in connection with invention namely Vaccine for Novel Coronavirus is highly prejudicial for the society at large.
- Whether, the respondents have acted illegally in exercise of the power conferred by the statute.
- Whether, as per Article 14 which depicts equality and equal protection before law, the activities of the respondent authorities are highly discriminatory.



DISTRICT: KOLKATA

#### IN THE HIGH COURT AT CALCUTTA

#### CONSTITUTIONAL WRIT JURISDICTION

#### APPELLATE SIDE

W. P. NO: (W) OF 2020

In the Matter of:

An application under Article 226 of the Constitution of India;

-And-

In the Matter of

Kanishk Sinha, son of Shri Bimal Bihari Sinha, Patentee having its office at HM PLAZA, 8, A.J.C. Bose Road, Kolkata — 700 017.

.... Petitioner

-Versus-

 Shri Harsh Vardhan, Member of Parliament C/o Office of the Hon'ble Minister of Health and Family Welfare, Ministry of Health and

Family Welfare, Government of India, Nirman Bhawan, New Delhi – 110 011;

- The Secretary, Ministry of Health and Family Welfare, Emergency Medical Response Division,
   Government of India, Nirman Bhawan, New Delhi 110 011;
- The Secretary (BIRAC), Ministry of Science and Technology,
   Government of India, Department of Bio Technology, 6th 8th Floor,
   Block 2, CGO Complex, Lodhi
   Road, New Delhi 110 003; AND
- The Director General, Indian
   Council of Medical Research, V.
   Ramalingaswami Bhawan, P. O. Box
   No: 4911, Ansari Nagar, New
   Delhi 110 029.

.... Respondents

То

The Hon'ble Thottathil B. Radhakrishnan, Chief Justice and His Companion Justices of the said Hon'ble Court

#### The humble petition of the petitioners

#### above-named

MOST RESPECTFULLY SHEWETH:

- That, your petitioner is a law abiding citizen of India and also having the fundamental rights protected as enshrined in Part - III of the Constitution of India. That, it maybe pertinent to mention herein that, petitioner is the patent holder various inventions including eco - friendly battery operated e - rickshaws and many other in the field of renewable energy resources.
- That, petitioner has approached before the respondent no: 2 for allowing
  his application for facilitating suitable research facility for further
  development of the low cost vaccination of Novel Coronavirus.
- The petitioner has invoked extraordinary jurisdiction of this Hon'ble Court under article 226 of the Constitution of India praying for issuance of following writs: -
  - (i) A writ in the nature of Mandamus directing the respondent no: 3 rescind / cancel / withdraw the impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination;
  - (ii) A writ in the nature of Certiorari calling the entire records from the respondent no: 3 in connection with impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 and on being so certified quash the impugned order dated: 11-05-2020 refusing to providing

suitable research facility for further development of the practically feasible low cost vaccination;

- (iii) a writ in the nature of mandamus directing the respondent no: 3 to allow the application dated: 20-05-2020 for grant of sponsorship forthwith;
- (iv) a writ in the nature of mandamus directing the respondent no:

  3 to disclose the details of the funds allotted, procedure, timeline and
  projects sponsored by them so far for developing the COVID 19 vaccine
  and status of the said projects so far; and
- (v) In corollary to the prayers made hereinabove in the event respondents failed to allow the petitioner to do the research for developing a vaccine for combating covid 19 vaccine and / or sponsor the petitioner project, declare, the respondent no: 3 calling for the proposal scheme as a scam and saddle the responsibity of all deaths upon the respondent no: 1 to 4 for not allowing effective research activities.
- 4. That your petitioner submit that, he is in possession of a application for a invention of vaccination of Novel Coronavirus in the form of Form - 1 AND 2 filed before the Kolkata Patent Office, Government of India.

Copy of the Form - 1, application for grant of patent dated 27-03-2020 is annexed herewith and marked as Annexure P - 1.  That your petitioner submit that he is in possession of complete specification in Form – 2 for "Vaccine of Novel Coronavirus"

Copy of the Form – 2, Complete Specification dated: 27-03-2020 is annexed herewith and marked as Annexure P - 2.

 That, your petitioner submit that, this Hon'ble Court upon hearing the writ petition being W.P. 5325 (W) of 2020 has been pleased to pass an interim order;

"....As an interim order this Court directs that considering the extraordinary circumstances created by the lock down, the respondent authorities shall very actively consider the prayer of the writ petitioner as made in prayer (a) of the writ petition and take a decision in the matter by 7th April, 2020 to be communicated to this Court keeping in view the fact that no valuable right of the writ petitioner is lost by virtue of this unusual situation."

Website copy of the order dated: 01.04.2020 passed in W.P. 5325 (W) of 2020 by this Hon'ble Court is annexed herewith and marked as Annexure P - 3.

 That, your petitioner submit that, this Hon'ble Court upon hearing the writ petition being W.P. 5325 (W) of 2020 has been pleased to dispose of the writ petition directing inter alia; "..... Learned counsel for the respondents submits that the application of the petitioner for grant of patent has been accepted online. This substantially redresses his grievance in this writ application. His further prayer is for an order upon the government to allow him to do research work in connection with the invention of a vaccine to prevent or combat the COVID 19 virus. For this purpose, he may make a proper application before the appropriate authority. The said authority, upon consideration of the petitioner's eligibility and his fulfillment of other necessary conditions may consider such application for doing research in accordance with law by making a decision within four weeks of communication of this order."

Website copy of the order dated: 08.04.2020 passed in W.P. 5325 (W) of 2020 by this Hon'ble Court is annexed herewith and marked as Annexure P - 4.

- 8. That, your petitioner submit that, he has submitted the application as per this Hon'ble Court judgment / order dated: 08-04-2020 passed in W.P.5325 (W) of 2020 before the Secretary, Ministry of Health and Family Welfare, Government of India stating inter alia;
  - "....That, since due to the lockdown and / or extraordinary circumstances I cannot arrange for a private laboratory as such I seek limited assistance to use any of the available Government of India

laboratory facility exclusively with proper security and instruments / apparatus to develop the COVID 19 vaccine rest we will take care of the investment and project costs as it is a commercial project and I apprehend that, if I take government funding then I have to share and / or give its exploitation rights to the Government u/s 102 of the Patents Act, 1970 HENCE our demand is only confined to use any of the available government laboratory facility exclusively with proper instruments / apparatus only for which I am ready to pay the fees also as directed by the authority concerned.

That, I also seek blood samples / swab samples of the infected / recovered COVID 19 patient.

That, after development of the vaccine I would be requiring the volunteers to clinically test the said vaccine.

That, I also seek PPEs for all our team members at the time of research.

That, the team members of this classified project will be solely decided by the undersigned without interference of the Government of India.

FURTHERMORE, I pray for a hearing opportunity through video conferencing at the time of deciding the instant application by the authority

through WhatsApp or Microsoft Teams application whichever is possible and / or available or else any adverse decision taken by the authority will be treated as an ex facie.

It imperative to state herein that, the Hon'ble Court has granted the Government of India four weeks time to decide my application but I would like to state that, it is a race against time and each minute delay are causing casualties so it would be appreciated if the same is decided on priority basis so that, I can come up with the vaccine at an early date.

Scanned copy of the representation dated: 09.04.2020 issued by the petitioner is annexed herewith and marked as Annexure P – 5.

9. That, your petitioner submit that, the Secretary, Ministry of Health and Family Welfare, Government of India assigned the matter to the Director General of Indian Council of Medical Research, New Delhi for taking decision on the application dated: 09-04-2020 made by the petitioner.

Scanned copy of the impugned letter dated: 27.04.2020 issued by Government of India, Ministry of Health and Family Welfare is annexed herewith and marked as Annexure P – 6.

That, your petitioner submit that, Indian Council of Medical Research,
 Government of India, New Delhi vide his letter dated: 11-05-2020 has
 stated as follows;

"....I am directed to refer to the above mentioned case on the subject and to say that in compliance of the Order dated 08.04.2020 passed by the Hon'ble High Court at Calcutta at Kolkata in W.P. (C) No. 5325 of 2020 (Shri Kanishk Sinha – Vs – Union of India & others), representation dated 09.04.2020 has been received in Indian Council of Medical Research (ICMR), New Delhi for consideration and the replies are as follows:-

ICMR believes in working in close partnership with various stakeholders. While ICMR is actively engaged in formulating research projects on epidemiology, operational research, clinical studies and diagnostics, the research group on vaccines has been dissolved as DBT has taken a lead on vaccines.

BIRAC (DBT) and SERB (DST) have already placed a call for proposals in the area of COVID – 19 vaccines.

In view of this, ICMR has decided not to invite proposals on vaccine development, Hence, the representation 09.04.2020 submitted by Shri Kanishk Sinha has been considered in ICMR and disposed of to the above effect.

This issues with the approval of competent authority."

Scanned copy of the impugned letter dated: 11.05.2020 issued by the Indian Council of Medical Research, New Delhi is annexed herewith and marked as Annexure P-7.

 That, your petitioner submit that, he has submitted his proposal before the BIRAC (DBT) for sponsorship.

Copy of the proposal dated: 20.05.2020 by email to the Department of Bio Technology, Government of India, New Delhi is annexed herewith and marked as Annexure P – 8.

- 12. That, the acts and actions of the respondent authorities are highly condemned and for the benefit and betterment of the society at large his application for doing research along with sponsorship must be allowed forthwith.
- 13. That your petitioner submit that the respondent authorities are simply avoiding the prayers of the petitioner without any rhyme and reason.
- 14. That your petitioner submit that the acts and actions of the respondent authorities are not only impermissible in the eye of law but it is bad and illegal also and therefore should be condemned and direct them to act in accordance with law.

- 15. That your petitioner submits that the respondent authorities has acted arbitrarily, whimsically, illegally and mala fide manner to deprive the petitioner.
- 16. Being aggrieved by the overt actions and/or inactions on the part of the Respondent Authorities by passing the impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination; and to not allowing the application dated: 20-05-2020 for grant of sponsorship forthwith; and for directing the respondent no: 3 to disclose the details of the funds allotted, procedure, timeline and projects sponsored by them so far for developing the COVID 19 vaccine and status of the said projects so far, the petitioner herein beg to prefer the instant application before this Hon'ble Court under Article 226 of the Constitution of India on the following amongst other:-

#### GROUNDS

- I. FOR THAT the impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination at the cost of the petitioner was permissible in the eye of law.
- II. FOR THAT, is the respondent no: 1 and 2 can be held liable for the deaths so far due to refusal of the application of the petitioner for

development of low cost vaccination at the cost of the petitioner when he is so far not been able to successfully develop the vaccination to combat covid 19 pandemic and on other hand not even sponsoring proposals for development of the said vaccination is highly discriminatory under article 14 of the Constitution of India.

III. FOR THAT, the said omission is preventing the populace of the State of West Bengal as well as the entire country from accessing a infection free environment, thereby infringing Articles 21, 48A and 51A(g) of the Constitution of India.

- IV. FOR THAT The virus has also shone a light on another fatal weakness in our health system: the profit-driven pharmaceutical innovation model that we rely upon to develop life-saving vaccines and medicines. Because the President of United States Mr Donald Trump in G7 summit has sought to buy up the exclusive rights to a promising Covid-19 vaccine from a German biotech firm has been greeted with anger. During a global crisis, when all of humanity is at risk, our sense of fairness and our own self-interest makes this shameless attempt to buy the right to life (with little regard for those it excludes) seem immoral.
- V. FOR THAT the Government of India must have allowed the petitioner to do the research without acting as an stumbling block should have been allowed to conduct the research at this emergent

situation when whole world scientific community is in a hunt for the vaccine of Novel Coronavirus HENCE is totally arbitrary.

- VI. FOR THAT the action of the respondent authorities is otherwise bad in law;
- VII. FOR THAT such arbitrary and illegal conduct on the part of the Respondent Authorities be taken into judicial notice and, as such, This Hon'ble Court may consider to intervene in this issue in exercise of its high prerogative Writ Jurisdiction so as to protect the petitioner from being prejudiced at the hands of the Respondent Authorities and to safeguard its rights guaranteed under the Constitution of India and in view of such arbitrary and oppressive conduct on the part of State Authority;
- VIII. FOR THAT being aggrieved by the inactions at the hands of respondent authorities, the petitioners are before This Hon'ble Court for ends of justice.
- IX. FOR THAT the acts and actions of the respondent authorities are arbitrary, mala fide and with fullest of ill motive;
- 17. Thus the petitioners submit that the concerned Respondent Authorities ought to be directed by this Hon'ble Court (i) A writ in the nature of

Mandamus directing the respondent no: 3 rescind / cancel / withdraw the impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination; (ii) A writ in the nature of Certiorari calling the entire records from the respondent no: 3 in connection with impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 and on being so certified quash the impugned order dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination; (iii) a writ in the nature of mandamus directing the respondent no: 3 to allow the application dated: 20-05-2020 for grant of sponsorship forthwith; (iv) a writ in the nature of mandamus directing the respondent no: 3 to disclose the details of the funds allotted, procedure, timeline and projects sponsored by them so far for developing the COVID - 19 vaccine and status of the said projects so far; and (v) In corollary to the prayers made hereinabove in the event respondents failed to allow the petitioner to do the research for developing a vaccine for combating covid 19 vaccine and / or sponsor the petitioner project, declare, the respondent no: 3 calling for the proposal scheme as a scam and saddle the responsibity of all deaths upon the respondent no: 1 to 4 for not allowing effective research activities, failing which the petitioner shall suffer from irreparable loss and injury.

 That if no Order is passed in the instant Writ application, your petitioner will suffer irreparable loss and injury.

- 19. That the records pertinent to the instant writ application are lying within the Appellate Side Jurisdiction of This Hon'ble Court.
- 20. That the petitioner submit that on the self-same cause of action, the petitioners have not made any other application before any Court of Law.
- 21. That the petitioner submit that there is no other alternative efficacious speedy remedy excepting moving an application under Article 226 of the Constitution of India before This Hon'ble Court.
- 22. That, the petitioner prays for exemption from filling duly affirmed affidavit in the prevailing circumstances.
- 23. That, the petitioner undertakes to file the deficit court fees within 48 hours from the moment of opening of the High Court, after attaining normalcy.
- 24. That the balance of convenience in the instant case is very much in favour of the petitioners for an interim order as prayed.
- 25. That the instant application is made bona fide and for the ends of justice.

Under the aforesaid circumstances

mentioned hereinabove, the petitioners

most humbly prays that Your Lordships

may be graciously pleased to –

- i. A writ in the nature of Mandamus directing the respondent no: 3 rescind / cancel / withdraw the impugned order issued by letter no: 435/Legal Cell/2020, dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination;
- ii. A writ in the nature of mandamus directing the respondent no: 3 to allow the application dated: 20-05-2020 for grant of sponsorship forthwith; and
- iii. A writ in the nature of mandamus directing the respondent no: 3 to disclose the details of the funds allotted, procedure, timeline and projects sponsored by them so far for developing the COVID 19 vaccine and status of the said projects so far.
- iv. A writ in the nature of Certiorari calling
  the entire records from the respondent
  no: 3 in connection with impugned order
  issued by letter no: 435/Legal

Cell/2020, dated: 11-05-2020 and on being so certified quash the impugned order dated: 11-05-2020 refusing to providing suitable research facility for further development of the practically feasible low cost vaccination;

- v. In corollary to the prayers made
  hereinabove in the event respondents
  failed to allow the petitioner to do the
  research for developing a vaccine for
  combating covid 19 vaccine and / or
  sponsor the petitioner project, declare,
  the respondent no: 3 calling for the
  proposal scheme as a scam and saddle
  the responsibity of all deaths upon the
  respondent no: 1 to 4 for not allowing
  effective research activities;
- vi. Grant exemption to the petitioner from filling duly affirmed affidavit in the prevailing circumstances.
- vii. Grant exemption to file the deficit court fees within 48 hours from the moment of

opening of the High Court, after attaining normalcy.

- viii.Issue a Rule NISI in terms of the above prayers (i), and (iv) above;
- ix. Grant an interim order in terms of prayer (i) and (ii) made hereinabove
- x. An order for costs incidental to this application shall be borne by the Respondents.
- xi. Such further order or orders and/or direction or directions as Your Lordship may deem fit and proper.

And for the act of kindness, Your petitioners, as in duty bound, shall ever pray.

Kuishk sil

#### AFFIDAVIT

I, Kanishk Sinha, son of Dr Bimal Bihari Sinha, aged about 41 years, by faith - Hindu, by occupation - Scientist and Entrepreneur having its Principal place of business at HM PLAZA, 8, AJC Bose Road, Kolkata - 700 017 and resident of 122 Bidhanpally, Kolkata - 700 084 do hereby solemnly affirm and swear as follows :-

- 1. That I am the Petitioner in the instant writ petition and as such I am well conversant with the facts and circumstances of this case and competent to swear this affidavit on my behalf.
- 2. That the statements made in paragraphs and are true to my knowledge, those made in paragraphs to are my information derived from records which I verily believe to be true and rests are my humble submissions before This Hon'ble Court.

KanishK sil

Prepared in my Office

The Deponent is known to me

Clerk to:

Advocate

Solemnly affirmed before me on

this day of May, 2020

I hereby certify that annexure

are legible.

In Person

COMMISSIONER

"FORM 1		(F	OR OFFI	CE USE ONLY)				
THE PATENT								
THE PATENT								
APPLICATIO	APPLICATION FOR GRANT OF PATENT							
(See section	7, 54 and 135 a	ind sub-rule (1	1) of rule 20)					
			Application	No.				
			Filing date:			-		
	×		Amount of	f Fee				
			paid:					
			CBR No:					
			Signature:					
1. APPLICAI	NT'S REFERENCE	[/				,		
IDENTIFICA	TION NO. (AS AI	LLOTTED BY						
OFFICE)	*							
2. TYPE OF APPLICATION [Please tick (✓) at the appropriate category]								
Ordinary (V Convention ( )			()	PCT	PCT-NP()			
Divisional	Patent of	Divisional	Patent of	Divi	sional	Patent of Addition ()		
()	Addition ( )	()	Addition ( )	()				
3A. APPLIC	ANT(S)	•		•				
Name in I	Full	Nationality	Country of	Add	ress of t	he Applicant		
-			Residence					
				Hou	se No.	122		
	1.7 7 1 41 11 11	INDIAN	INDIA	Stree	et	Bidhaupally		
KANISE	IK SINHA	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		City		Kolkata		
				State	9	West Bengal		
				Cour	ntry	India		
				Pin c		700084		
3B. CATEGO	ORY OF APPLICA	NT [Please tic	k (✓) at the a	pprop	riate cat	egory]		
Natural P	erson ()	Other tha	an Natural Pers	on				
		Small Ent	ity()	St	artu	Others ( )		
					_p (			
					)			
4. INVENTO	OR(S) [Please tic	k ( $\checkmark$ ) at the a	ippropriate ca	tegory	/]			
Are all th			No ( )					

same a	s the applica	int(s)						<u> </u>	
	furnish the d	 etails of the ir	ventor(s						
	,		•	<i>'</i>					
Name	in Full	Nation	ality	Countr		Addres	ss of th	ne Inventor	
				Resider	nce				
		-, -				House	No.		
		B 43	1		<u> </u>	Street			
		The same	-61	- mental	a week	City			
						State			
						Count			
						Pin co	de		
5. TITLE	OF THE INVE	NTION \	IACC	INE	F	OR NO	VEL	_ CORONAVIR	US
6. AUTH	ORISED REGI	STERED PATE	VT		N/PA	No			
AGENT	(S)								
				ſ	Name				
					Mobil	e No.			
	RESS FOR SEF	RVICE OF APP	PLICANT	IN I					
INDIA					Postal	Address			
		٠			eleph	one No.			
	_				Mobil				
					ax No				
					-mail				
	CASE OF APPI TRY, PARTICUL					APPLICATI	ON FI	LED IN CONVENTI	ON
Country	Application	Filing date	Name o	f the	Title	e of the	IPC (	as classified in the	
	Number		applicar	nt	inve	ention		ention country)	
	_		/	_					
9. IN	CASE OF PC	T NATIONAL	PHASE	APPLIC	ATION	N, PARTICI	JLARS	OF INTERNATION	NAL
APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)									
International application number International filing date									
10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION									
					· ·	1			
Original (first) application No.				Date of filing of original (first) application					

### 11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main application/patent No.

Date of filing of main application

#### 12. DECLARATIONS

#### (i) Declaration by the inventor(s)

(In case the applicant is an assignee: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

I/We, the above named inventor(s) s/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

- (a) Date
- (b) Signature(s)
- (c) Name(s)

#### (ii) Declaration by the applicant(s) in the convention country

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

- (a) Date
- (b) Signature(s)
- (c) Name(s) of the signatory

(iii) Declaration by	the applicant(s)	-							
	(s) hereby declare(s) th								
☐ I am/ We are in possession of the above-mentioned invention.									
The provisional/complete specification relating to the invention is filed with thi									
application.									
The inver	The invention as disclosed in the specification uses the biological material from India								
and the	and the necessary permission from the competent authority shall be submitted by								
me/us be	me/us before the grant of patent to me/us.								
There is a	There is no lawful ground of objection(s) to the grant of the Patent to me/us.								
	are the true & first inve								
	,	al representative of true	& first inventor(s).						
	_	•	ılars of which are given in						
			untry/countries in respect of						
	nvention(s).								
☐ I/We clai	im the priority from th	e above mentioned app	lication(s) filed in convention						
			protection in respect of the						
			ore that date by me/us or by						
	on from which I/We de								
☐ My/our	application in India is	s based on internation	al application under Patent						
Coopera	tion Treaty (PCT) as me	ntioned in Paragraph-9.							
☐ The app	lication is divided out o	of my /our application pa	articulars of which is given in						
Paragrap	h-10 and pray that this	application may be trea	ted as deemed to have been						
filed on	DD/MM/YYYY under se	ction 16 of the Act.							
☐ The said	invention is an improv	ement in or modification	of the invention particulars						
of which	are given in Paragraph	-11.							
13. FOLLOWING ARI	E THE ATTACHMENTS W	VITH THE APPLICATION							
(a) Form 2									
Item	Details	Fee	Remarks						
Complete/	No. of pages								
provisional	17	- 11							
specification)#			,						
No. of Claim(s)	No. of claims and								
27	No. of pages 2								
Abstract	No. of pages								
No. of Drawing(s)	No. of drawings and		,						
2	No. of pages								

- # In case of a complete specification, if the applicant desires to adopt the drawings filed with his provisional specification as the drawings or part of the drawings for the complete specification under rule 13(4), the number of such pages filed with the provisional specification are required to be mentioned here.
- (b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).
- (c) Sequence listing in electronic form
- (d) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).
- (e) Priority document(s) or a request to retrieve the priority document(s) from DAS (Digital Access Service) if the applicant had already requested the office of first filing to make the priority document(s) available to DAS.
- (f) Translation of priority document/Specification/International Search Report/International Preliminary Report on Patentability.
- (g) Statement and Undertaking on Form 3
- (h) Declaration of Inventorship on Form 5
- (i) Power of Authority

W		
.,	Total fee ₹in Cash/ Banker's Cheque /Bank Draft bearing No	Dateon
	Bank.	
	I/We hereby declare that to the best of my/our knowledge, information	and belief the fact
	and matters slated herein are correct and I/We request that a patent r	may be granted to
	me/us for the said invention.	

Signature:

Name:

To.

The Controller of Patents

The Patent Office, at. Kolkata

Note: -

\* Repeat boxes in case of more than one entry.

Dated this 2 7th day of March 20.20

- \* To be signed by the applicant(s) or by authorized registered patent agent otherwise where mentioned.
- \* Tick (✓)/cross (x) whichever is applicable/not applicable in declaration in paragraph-12.
- \* Name of the inventor and applicant should be given in full, family name in the beginning.
- \* Strike out the portion which is/are not applicable.
- \* For fee: See First Schedule";

# FORM 2 THE PATENT ACT, 1970 (39 of 1970) COMPLETE SPECIFICATION

#### Title

#### "VACCINE FOR NOVEL CORONAVIRUS"

Applicant: Kanishk Sinha, 37/F, Shivalaya, Modern Park, 2<sup>nd</sup> Road, Near Sarada Ashram, Kolkata ⇒ 700 075, State of West Bengal, India Email: - kanishksinha28@yahoo.in An Indian Citizen

The following specification particularly describes and ascertains the nature of this invention and the manner in which it is to be performed.

2

#### Field of the Invention

This invention is related to the vaccine of Novel Coronavirus. In particular, it relates to advanced immunotherapy.

#### Background of the Invention and Related Prior Art

Due to its extensive history of safety as well as availability in multiple tumor types, lethal iy irradiated tumor cell vaccines engineered to secrete GM-CSF (GVAX) is one vaccine platform that has potential for combinatorial therapy with immune checkpoint blockade antibodies. However, local GM-CSF secreted by GVAX can mobilize myeloid precursors into macrophages and dendritic cells, but this cytokine may not induce their activation. Thus, a major limitation of GVAX is in the activation of antigen presenting cells (APC) necessary for optimal tumor antigen presentation in the afferent arm of the immune system. One simple strategy that phenocopies the robust immunological responses seen in vaccines against infectious agents is to combine multiple TLR agonists with a Novel Coronavirus cell - based vaccine. Clinically, multiple adjuvants have been developed for cancer patients to augment the potency of cancer vaccines, and many of these adjuvants are typically TLR agonists.

One real concern with non-targeted TLR stimulation is the procarcmogenic consequences of chronic TLR stimulation in the tumor cells. Stimulation of TLR4 receptors expressed on tumor cells has shown to promote carcinogenesis. TLR signaling in the hematopoietic compartment, however, has been shown to elicit antitumor responses, which have translated into multiple clinical trials. In order to target the dendritic cells in the tumor microenvironment and test whether TLR4 stimulation in the

microenvironment can induce a procarcmogenic effect in vivo, our group injected LPS formulated GVAX intratumorally and found that intratumoral injection of TLR4 ligand absorbed GVAX improved the local anti-tumor response in vivo in three different murine models.

There is a continuing need in the art to obtain safer and more effective treatments of mutating range of Novel Coronaviruses.

The history of human coronaviruses began in 1965 when Tyrrell and Bynoe<sup>1</sup> found that they could passage a virus named B814. It was found in human embryonic tracheal organ cultures obtained from the respiratory tract of an adult with a common cold. The presence of an infectious agent was demonstrated by inoculating the medium from these cultures intranasally in human volunteers; colds were produced in a significant proportion of subjects, but Tyrrell and Bynoe were unable to grow the agent in tissue culture at that time. At about the same time, Hamre and Procknow<sup>2</sup> were able to grow a virus with unusual properties in tissue culture from samples obtained from medical students with colds. Both B814 and Hamre's virus, which she called 229E, were ether-sensitive and therefore presumably required a lipid-containing coat for infectivity, but these 2 viruses were not related to any known myxo- or paramyxoviruses. While working in the laboratory of Robert Chanock at the National Institutes of Health, McIntosh et al<sup>3</sup> reported the recovery of multiple strains of ether-sensitive agents from the human respiratory tract by using a technique similar to that of Tyrrell and Bynoe. These viruses were termed "OC" to designate that they were grown in organ cultures.

Within the same time frame, Almeida and Tyrrell<sup>4</sup> performed electron microscopy on fluids from organ cultures infected with B814 and found particles that resembled the infectious bronchitis virus of chickens. The particles were medium sized (80–150 nm), pleomorphic, membrane-coated, and covered with widely spaced club-shaped surface projections. The 229E agent identified by Hamre and Procknow<sup>2</sup> and the previous OC viruses identified by McIntosh et al<sup>3</sup> had a similar morphology (Fig. 1).

Coronavirus OC16. Reprinted with permission from Proc Natl Acad Sci USA. 1967;57;933–940.

In the late 1960s, Tyrrell was leading a group of virologists working with the human strains and a number of animal viruses. These included infectious bronchitis virus, mouse hepatitis virus and transmissible gastroenteritis virus of swine, all of which had been demonstrated to be morphologically the same as seen through electron microscopy.<sup>5,6</sup> This new group of viruses was named coronavirus (*corona* denoting the crown-like appearance of the surface projections) and was later officially accepted as a new genus of viruses.<sup>7</sup>

Ongoing research using serologic techniques has resulted in a considerable amount of information regarding the epidemiology of the human respiratory coronaviruses. It was found that in temperate climates, respiratory coronavirus infections occur more often in the winter and spring than in the summer and fall. Data revealed that coronavirus infections contribute as much as 35% of the total respiratory viral activity during epidemics. Overall, he proportion of adult colds produced by coronaviruses was estimated at 15%.8

In the 3 decades after discovery, human strains OC43 and 229E were studied exclusively, largely because they were the easiest ones to work with. OC43, adapted to growth in suckling mouse brain and subsequently to tissue culture, was found to be closely related to mouse hepatitis virus. Strain 229E was grown in tissue culture directly from clinical samples. The 2 viruses demonstrated periodicity, with large epidemics occurring at 2- to 3-year intervals. Strain 229E tended to be epidemic throughout the United States, whereas strain OC43 was more predisposed to localized outbreaks. As with many other respiratory viruses, reinfection was common. In Infection could occur at any age, but it was most common in children.

Despite the extensive focus placed exclusively on strains 229E and OC43, it was clear that there were other coronavirus strains as well. As shown by Bradburne, 11 coronavirus strain B814 was not serologically identical with either OC43 or 229E. Contributing to the various strain differences in the

family of coronaviruses, McIntosh et al<sup>12</sup> found that 3 of the 6 strains previously identified were only distantly related to OC43 or 229E.

Epidemiologic and volunteer inoculation studies found that respiratory coronaviruses were associated with a variety of respiratory illnesses; however, their pathogenicity was considered to be low.<sup>2,8,13,14</sup> The predominant illness associated with infections was an upper respiratory infection with occasional cases of pneumonia in infants and young adults.<sup>15,16</sup> These viruses were also shown to be able to produce asthma exacerbations in children as well as chronic bronchitis in adults and the elderly.<sup>17–19</sup>

While research was proceeding to explore the pathogenicity and epidemiology of the human coronaviruses, the number and importance of animal coronaviruses were growing rapidly. Coronaviruses were described that caused disease in multiple animal species, including rats, mice, chickens, turkeys, calves, dogs, cats, rabbits and pigs. Animal studies included, but were not limited to, research that focused on respiratory disorders. Study focus included disorders such as gastroenteritis, hepatitis and encephalitis in mice; pneumonitis and sialodacryoadenitis in rats; and infectious peritonitis in cats. Interest peaked particularly regarding areas of encephalitis produced by mouse hepatitis virus and peritonitis produced by infectious peritonitis virus in cats. Pathogenesis of these disease states was various and complex, demonstrating that the genus as a whole was capable of a wide variety of disease mechanisms.20 Human and animal coronaviruses were segregated into 3 broad groups based on their antigenic and genetic makeup. Group I contained virus 229E and other viruses, group Il contained virus OC43 and group III was made up of avian infectious bronchitis virus and a number of related avian viruses.<sup>21</sup>

## EMERGENCE OF THE SEVERE ACUTE RESPIRATORY SYNDROME (SARS) CORONAVIRUS

Given the enormous variety of animal coronaviruses, it was not surprising when the cause of a very new, severe acute respiratory syndrome, called SARS, emerged in 2002–2003 as a coronavirus from southern China and

spread throughout the world with quantifiable speed.<sup>22–24</sup> This virus grew fairly easily in tissue culture, enabling quick sequencing of the genome. Sequencing differed sufficiently from any of the known human or animal coronaviruses to place this virus into a new group, along with a virus that was subsequently cultured from Himalayan palm civets, from which it presumably had emerged.<sup>25</sup>

During the 2002-2003 outbreak, SARS infection was reported in 29 countries in North America, South America, Europe and Asia. Overall 8098 infected individuals were identified, with 774 SARS-related fatalities.<sup>26</sup> It is still unclear how the virus entered the human population and whether the Himalayan palm civets were the natural reservoir for the virus. Sequence analysis of the virus isolated from the Himalayan palm civets revealed that this virus contained a 29-nucleotide sequence not found in most human isolates, in particular those involved in the worldwide spread of the epidemic.<sup>25</sup> In the animal viruses, this nucleotide sequence maintains the integrity of the 10th open reading frame (ORF); whereas in the human strains, the absence of this motif results in 2 overlapping ORFs. The function of the ORFs in the animal and human isolates is unknown, and it is unclear whether the deletion of the 29-nucleotide sequence played a role in the transspecies jump, the capacity of the epidemic strain to spread between humans or the virulence of the virus in humans. Curiously data from seroepidemiologic studies conducted among food market workers in areas where the SARS epidemic likely began indicated that 40% of wild animal traders and 20% of individuals who slaughter animals were seropositive for SARS, although none had a history of SARS-like symptoms.<sup>25</sup> These findings suggest that these individuals were exposed through their occupation to a SARS-like virus that frequently caused asymptomatic infection. Infection control policies may have contributed to the halt of the SARS epidemic. The last series of documented cases to date, in April 2004, were laboratory-acquired.

The SARS epidemic gave the world of coronaviruses an enormous infusion of energy and activity that contributed to the large amount already known

about the virology and pathogenesis of coronavirus infections from the expanding area of veterinary virology.<sup>21</sup>

## CORONAVIRUS GENOME AND STRUCTURE

Coronaviruses are medium-sized RNA viruses with a very characteristic appearance in electron micrographs of negatively stained preparations (Fig. 1). The nucleic acid is about 30 kb long, positive in sense, single stranded and polyadenylated. The RNA is the largest known viral RNA and codes for a large polyprotein. This polyprotein is cleaved by viral-encoded proteases to form the following: an RNA-dependent RNA polymerase and an ATPase helicase; a surface hemagglutinin-esterase protein present on OC43 and several other group II coronaviruses; the large surface glycoprotein (S protein) that forms the petal-shaped surface projections; a small envelope protein (E protein); a membrane glycoprotein (M protein); and a nucleocapsid protein (N protein) that forms a complex with the RNA. The coding functions of several other ORFs are not clear. The strategy of replication of coronaviruses involves a nested set of messenger RNAs with common polyadenylated 3-ends. Only the unique portion of the 5-end is translated.<sup>21</sup> Mutations are common in nature. In addition, coronaviruses are capable of genetic recombination if 2 viruses infect the same cell at the same time.

All coronaviruses develop in the cytoplasm of infected cells (Fig. 2), budding into cytoplasmic vesicles from the endoplasmic reticulum. These vesicles are either extruded or released from the cell within the same time frame, and then the cell is destroyed.

Strain 229E in WI-38 cells. Reprinted with permission from J Virol. 1967;1:1019–1027.

All group I coronaviruses, including 229E, use human aminopeptidase N as their cellular receptor.<sup>27</sup> Mouse hepatitis virus, a group II coronavirus, uses a member of the carcinoembryonic antigen family as its receptor.<sup>28</sup> The receptor for OC43 is not known, but it may be 1 of several cell surface molecules, including 9-O-acetylated neuraminic acid and the HLA-I

molecule.<sup>29</sup> The SARS coronavirus uses angiotensin-converting enzyme II as its cellular receptor.<sup>30,31</sup>

## NEWLY IDENTIFIED GROUP I HUMAN CORONAVIRUSES

Since 2003, 5 new human coronaviruses have been discovered (<u>Table 1</u>). Three of these are group I viruses that are closely related and likely represent the same viral species. In 2004, van der Hoek et al<sup>32</sup> reported the discovery of a new human coronavirus, NL63, isolated from a 7-month-old girl with coryza, conjunctivitis, fever and bronchiolitis. Using a novel genomic amplification technique, these investigators were able to sequence the entire viral genome. Phylogenetic analysis demonstrated that this virus was a group I coronavirus related to 229E and transmissible gastroenteritis virus, a virus of pigs. Screening of 614 respiratory specimens collected between December 2002 and April 2003 turned up 7 additional individuals who tested positive for NL63. All had upper or lower respiratory tract disease or both.

TABLE 1. Recent Discoveries of Human Coronaviruse				
Virue	Location	Group	Year	Reference
SARS	China	IV?	2003	22-24
NL63*	Netherlands		2004	32
NL*	Netherlands	1	2004	33
HCeV-NH*	New Haven, CT		2005	34
HKU1	Hong Kong	11	2005	35

## Recent Discoveries of Human Coronaviruses

Shortly after, Fouchier et al<sup>33</sup> reported the identification of a coronavirus, named NL, isolated from an 8-month-old boy with pneumonia and grown from a clinical specimen that was obtained in April 1988. Genomic amplification techniques, based on arbitrarily primed reverse transcriptase-polymerase chain reaction (RT-PCR), were used to identify viral sequences. Full genomic sequence analysis of NL showed that this virus was also a group I coronavirus and closely related to NL63. Four of 139 (2.9%) respiratory specimens collected from November 2000 to January 2002 tested positive for NL.<sup>33</sup> Respiratory tract disease was observed in these 4 children whose ages ranged from 3 months to 10 years. The discovery of both NL63 and NL depended on the propagation of the viruses in cell culture.

With the use of molecular probes that targeted conserved regions of the coronavirus genome, months later, Esper et al found evidence of a human respiratory coronavirus in respiratory specimens obtained from children younger than 5 years of age, which was designated the New Haven coronavirus (HCoV-NH). This approach was based on the theory that the gene for the viral replicase of all coronaviruses has conserved genetic sequences that encode indispensable, essential functions and that these sequences could be targeted for virus identification and discovery. This approach did not require propagation of the virus in cell culture, organ cultures or experimental animals and could be performed directly on respiratory secretions. After the initial identification of novel sequences of HCoV-NH, specific probes were used to screen respiratory specimens collected between January 2002 and February 2003 from children younger than 5 years of age whose respiratory specimen tested negative for respiratory syncytial virus, influenza, parainfluenza and adenoviruses. Of 895 children, 79 (8.8%) tested positive for HCoV-NH by RT-PCR, a majority of whom were sampled in the winter and spring seasons.<sup>34</sup> Sequence and phylogenetic analysis based on the replicase gene showed that HCoV-NH was closely related to both NL63 and NL, although the full genomic sequence of HCoV-NH has not been completed. Cough, rhinorrhea and tachypnea were present in more than one-half of the children infected with HCoV-NH. Eleven children were in the newborn intensive care unit at the time of their sampling and had been hospitalized since birth, suggesting either nosocomial infection or a less likely cause of vertical transmission.

One child, a 6-month-old who tested positive for HCoV-NH, also carried a diagnosis of Kawasaki disease, a vasculitis of early childhood. In a subsequent case-control study, 8 of 11 (72.7%) children with Kawasaki disease tested positive for HCoV-NH while only 1 of 22 (4.5%) age- and time-matched controls tested positive for HCoV-NH (P = 0.0015). By correlating these findings, Graf<sup>37</sup> detected the presence of a peptide corresponding to the spike glycoprotein of NL63, the closely related virus identified in the Netherlands, in tissue from individuals with Kawasaki disease. The summation of these findings suggests that HCoV-NH may play a role in the

pathogenesis of Kawasaki disease. Further research is necessary to determine whether HCoV-NH is the cause of Kawasaki disease.

## NEWLY IDENTIFIED GROUP II HUMAN CORONAVIRUSES

In January 2001, a 71-year-old man who had recently returned from Shenzhen, China, a previously SARS-endemic area, presented in Hong Kong with a fever and productive cough. Although his SARS screening was negative, a novel group II coronavirus sequence was amplified by RT-PCR from his respiratory specimen with the use of primers that targeted conserved regions of the viral replicase gene. This novel virus, designated HKU1, was genetically distinct from OC43, the other known human group II coronavirus. This virus could not be propagated in cell culture. Seroepidemiologic studies, based on antibodies reacting with a recombinant HKU1 nucleocapsid, suggested that human infection with HKU1 might be common. However, it is unclear whether the enzyme-linked immunosorbent and Western blot assays used to detect HKU1 antibody were also detecting cross-reactive antibody to OC43 or other human coronaviruses.

## Summary of the Invention

According to one aspect of the invention a composition is provided which may be used for treating Novel Coronavirus patients. The composition comprises (a) cytokine-expressing, proliferation incompetent, whole Novel Coronavirus cells; (b) an anti-PD-1 antibody that specifically binds to human Programmed Death 1 (PD-I); and (c) a TLR (toll like receptor) agonist; wherein the whole Novel Coronavirus cells are formulated with the TLR agonist.

According to another aspect of the invention a method is provided. Agents are administered to a Novel Coronavirus patient. The agents are: (a) cytokine-expressing, proliferation incompetent, whole Novel Coronavirus cells; (b) an anti-PD-1 antibody that specifically binds to human Programmed Death 1 (PD-1); and (c) a TLR (toll like receptor) agonist; wherein the whole Novel Coronavirus cells are formulated with the TLR agonist. The whole Novel Coronavirus cells are formulated with the TLR agonist.

According to another aspect of the invention a kit is provided which comprises the agents: (a) cytokine-expressing, proliferation incompetent, whole Novel Coronavirus Cells; (b) an anti-PD-1 antibody that specifically binds to human Programmed Death 1 (PD-1); and (c) a TLR (toll like receptor) agonist; wherein the whole Novel Coronavirus cells are formulated with the TLR agonist. Optionally the whole Novel Coronavirus cells are formulated with the TLR agonist.

The field of coronavirology has advanced significantly in recent years. The SARS epidemic was a dramatic reminder that animal coronaviruses are potential threats to the human population, although the exact mechanism of species-to-species spread of the SARS coronavirus remains obscure. NL63 has been identified in many countries. This virus and the related viruses NL and HCoV-NH are likely the cause of a substantial proportion of respiratory tract disease in infants and children. The impact of HKU1 is not yet known. It seems clear that the coronaviruses infecting humans and causing respiratory disease are heterogeneous and quite widely distributed among groups I and II. It may be that some of the newer coronaviruses represent strains similar to the original B814 and OC strains that could not be further characterized in the 1960s. Additional human coronavirus strains will very likely be discovered, which stresses the need for further investigation into the virology and etiology of these infectious organisms.

### **Detailed Description of the Invention**

We have developed in vivo evidence that optimally formulated Novel Coronavirus vaccines combined with PD-1 blockade can be used therapeutically for treating Novel Coronavirus. We have collected evidence demonstrating that the combination regimen can be effective agamst established tumors that are poorly immunogenic. All the components of this combinatorial regimen have been individually tested in patients and found to be clinically safe. The disclosed treatment strategy may work by adaptive immune evasion, although applicants do not intend to be bound by any proposed mechanism of action.

[23] Patients having a variety of Novel Coronavirus may be treated with the combination regimen.

This process are used to cure cancers include colorectal cancer, an aerodigestive squamous cancer, a lung cancer, a brain cancer, a liver cancer, a stomach cancer, a sarcoma, a leukemia, a lymphoma, a multiple myeloma, head-and-neck cancer, an ovarian cancer, cervical cancer, a uterine cancer, a breast cancer, a melanoma, a prostate cancer, a pancreatic carcinoma, and a renal carcinoma. This list is meant to be illustrative rather than limiting. [24] Whole cancer ceils may be allogeneic, syngeneic, or autologous to the treatment recipient. Typically they may be treated to make them proliferation incompetent by a technique which preserves preserve their immunogenicity and their metabolic activity. One typically used technique is irradiation. Such ceils. Typically the same general type of tumor cell is used that the patient bears. For example, a patient suffering from melanoma will typically be administered proliferation incompetent melanoma cells. The cells may express and secrete a cytokine naturally or by transfection with a nucleic acid which directs such expression and secretion. One suitable cytokine is GM-CSF. For example, the tumor cell may express a transgene encoding GM-CSF as described in U.S. Pat. Nos. 5,637,483, 5,904,920, 6,277,368 and 6,350,445, as well as in US Patent Publication No. 20100150946, each of which is expressly incorporated by reference. One example of a GM-CSFexpressing, genetically modified cancer ceil for the treatment of pancreatic cancer is described in U.S. Pat, Nos. 6,033,674 and 5,985,290, both of which are expressly incorporated by reference herein. Other cytokines can be used. Suitable cytokines which may be used include cytokines which stimulate dendritic ceil induction, recruitment, and/or maturation. Such cytokines include, but are not limited to, one or more of GM-CSF, CD40 ligand, IL-12, CCL3, CCL20, and CCL21. Granulocyte- macrophage colony stimulating factor (GM-CSF) polypeptide is a cytokine or fragment having immunomodulatory activity and having at least about 85% amino acid sequence identity to GenBank Accession No. AAA52122.1.

[25] According to one alternative embodiment, cytokines are delivered by inactivated bystander cells which express and secrete one or more

cytokines. The bystander cells may provide all of the cytokines which stimulate dendritic cell induction, recruitment, and/or maturation, or may supplement cytokines secreted by the inactivated tumor cells. Immunomodulatory cytokine-expressing bystander cell lines are described in U.S. Pat. Nos. 6,464,973, and 8,012,469, Dessureault et al., Ann. Surg. Oncol. 14: 869-84, 2007, and Eager and Nermmaitis, Mol. Ther. 12: 18-27, 2005, each of which is expressly incorporated by reference.

[26] Antibodies which are suitable for use in the treatment regimen and compositions and kits include any which specifically bind to Programmed Death 1 (PD-1). Exemplary types of antibodies which may be employed include without limitation human, humanized, chimeric, monolclonal, polyclonal, single chain, antibody binding fragments, and diabodies. Typically antibodies are substantially encoded by an immunoglobulin gene or immunoglobulin genes, or fragments thereof. Antibodies are capable of specifically binding an antigen or epitope. See, e.g. Fundamental Immunology, 3rd Edition, W.E, Paul, ed,, Raven Press, N.Y. (1993); Wilson (1994; J. Immunol, Methods 175:267-273; Yarmush (1992) J. Biochem. Biophys, Methods 25:85-97. An antibody typically specifically binds to an antigen or epitope. Specific binding occurs to the corresponding antigen or epitope even in the presence of a heterogeneous population of proteins and other biologies. Specific binding of an antibody indicates that it binds to its target antigen or epitope with an affinity that is substantially greater than binding to irrelevant antigens The relative difference in affinity is often at least 25% greater, more often at least 50% greater, most often at least 100%. The relative difference can be at least 2x, at least 5x, at least 10x, at least 25x, at least 50x, at least IOOx, at least IGOOx, for example.

Toll like receptors (TLR) are a family of proteins that sense a microbial product and/or initiates an adaptive immune response. TLR activate a dendritic cell (DC). TLRs are conserved membrane spanning molecules containing an ectodomain of leucine-rich repeats, a transmembrane domain and an intracellular TIR. (Toil/IL-IR) domain. TLRs recognize distinct structures in microbes, often referred to as "PAMPs" (pathogen associated molecular patterns). Ligand binding to TLRs invokes a cascade of intra-

cellular signaling pathways that induce the production of factors involved in inflammation and immunity.

Exemplary agonists which may be used for these receptors include, without lipoproteins. lipopolypeptides, peptidoglycans, limitation lipopolysaccharide, neisseria! porins, flageilin, profiilin, galactoceramide, muramyl dipeptide, giucopyranosyl lipid A (GLA), and resiquimod (R848). Peptidoglycans, lipoproteins, and lipoteichoic acids are cell wall components of Gram-positive. Lipopolysaccharides are expressed by most bacteria. Flageilin is the structural component of bacterial flagella that is secreted by pathogenic and commensal bacterial. A Galactosylcerami.de (a-GalCer) is an activator of natural killer T (NKT) cells. Muramy! dipeptide is a bioactive peptidoglycan motif common to all bacteria. Such agonists mediate innate immune activation via Toll-like Receptors. Specific binding of an agonist for its cognate receptor is often expressed in terms of an affinity. The ligands of the present invention may bind with affinities of between about 104 M"1 and about  $10^{\rm s}$  M<sup>"1</sup>. Affinity is calculated as  $\frac{3}{4} = k_{\rm off}/k_{\rm c}$ ,  $(k_{\rm ol}-f)$  is the dissociation rate constant, 035 is the association rate constant and K4 is the equilibrium constant). Single or multiple agonists may be used.

In humans, ten TLR have been identified. TLRs that are expressed on the surface of cells include TLR- 1,-2,-4,-5, and -6, while TLR-3, -7/8, and -9 are expressed with the ER compartment. Human dendritic cell subsets can be identified on the basis of distinct TLR expression patterns. By way of example, the myeloid or "conventional" subset of DC (mDC) expresses TLRs 1-8 when stimulated, and a cascade of activation markers (e.g. CD80, CD86, MHC class I and II, CCR7), pro-inflammatory cytokines, and chemokmes are produced. A result of this stimulation and resulting expression is antigenspecific CD4+ and CD8+ T cell primmg. These DCs acquire an enhanced capacity to take up antigens and present them in an appropriate form to T ceils. In contrast, the plasmacytoid subset of DC (pDC) expresses only TLR7 and TLR9 upon activation, with a resulting activation of NK cells as well as T-eells. As dying tumor cells may adversely affect DC function, it has been suggested that activating DC with TLR agonists may be beneficial for priming anti-tumor immunity in an immunotherapy approach to the treatment of

cancer. It has also been suggested that successful treatment of breast cancer using radiation and chemotherapy requires TLR4 activation.

TLR agonists known in the art and useful in the present invention include, but are not limited to, the following:

Pam3Cys, a TLR- 1/2 agonist;

CFA, a TLR -2 agonist;

MALP2, a TLR-2 agonist; Pam2Cys, a TL -2 agonist;

FSL-1, a TLR-2 agonist; Hib-OMPC, a TLR-2 agonist; polyribosinic ;polyribocyticlic acid (Poly I:C), a TLR-3 agonist; polyadenosine-polyuridylie acid (poly AU), a TLR-3 agonist;

Polyinosinie-Polycytidylic acid stabilized with poiy-L-lysine and carboxymethylcelitilose (Hiltonol©), a TLR-3 agonist; monophosp oryl lipid A (MPL), a TLR-4 agonist;

LPS, a TLR-4 agonist; bacterial flagelim, a TLR-5 agonist; sialyl-Tn (STn), a carbohydrate associated with the MUC1 mucin on a number of h uman cancer cells and a TLR-4 agonist; imiquimod, a TLR-7 agonist; resiquimod, a TLR-7/8 agonist; loxoribine, a TLR-7/8 agonist; and unmethylated CpG dinucleoti.de (CpG-ODN), a TLR-9 agonist. Formulation of the Novel Coronavirus cells with the TLR agonist appears to be a contributing factor to enhanced efficacy. Formulations can be incubated together for periods of times such as ¼, ½, 1, 2, 3, 5, 10, 24 hours, at temperatures such as 4 degrees C. Alternatively, binding in the presence of a lipophilic agent or an emulsifying agent can be employed. Such agents are well known in the art.

V arious dosing schedules may be envisioned, with simultaneous or staggered timing, with single or multiple agents, single cycle or multiple cycles.

Methods of administering treatment agents to cancer patients vary. Exemplary methods include without limitation subcutaneous, intravenous,

intramuscular, intraarterial, intradermal. intrathecal. intratumoral, intraperitoneal, sublingual, and epidural administrations. Administration may be to a human, mammal, mammalian subject, animal, veterinary subject, placebo subject, research subject, or experimental subject. Typically an agent such as an exogenous ligand, reagent, placebo, small molecule, pharmaceutical agent, therapeutic agent, diagnostic agent, or composition is contacted with the subject in an appropriate anatomical location. Administration may be for the purposes of therapy, pharmacokinetic study, diagnostic assay, research, placebo, or experimental method. Agents according to the invention may be, but not need not be, administered as a single composition. Although administration as a single composition is contemplated by the present invention, agents may be delivered to a single subject as separate administrations, which may be at the same or different time, and which may be by the same route or different routes of administration. In some cases, the agents may in fact contact each other within the subject's body, forming a composition in vivo.

The above disclosure generally describes the present invention. All. references disclosed herein are expressly incorporated by reference. A more complete understanding can be obtained by reference to the following specific examples which are provided herein for purposes of illustration only, and are not intended to limit the scope of the invention.

## I claim:

- 1. A composition comprising:
- a cytokine-expressing, proliferation incompetent, whole Novel Coronavirus cells;
- an anti~PD~I antibody that specifically binds to human Programmed Death 1 (PD-1); and
- a TLR (toll like receptor) agonist;
- wherein the whole Novel Coronavirus cells are formulated with the TLR agonist.
- 2. The composition of claim 1 wherein the cytokine is GM-CSF (granulocyte money t cell stimulating factor).

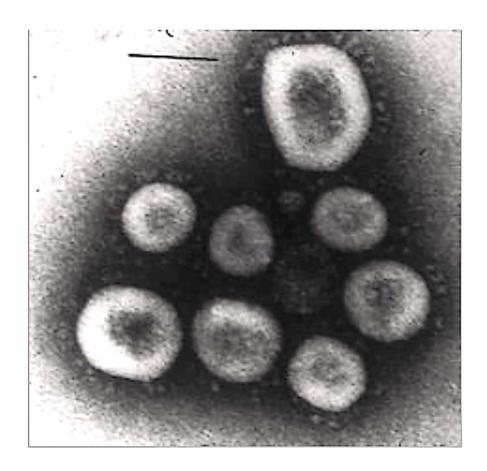
- 3. The composition of claim 1 wherein the whole Novel Coronavirus cells are autologous to the patient.
- 4. The composition of claim I wherein the whole Novel Coronavirus cells are formulated with a TLR7/8 agonist.
- 5. The composition of ciaim 1 wherein the whole Novel Coronavirus cells are formulated with a TLR4 agonist.
- 6. The composition of ciaim 1 wherein the whole Novel Coronavirus cells are formulated with a TLR4 and a TLR7/8 agonist.
- 7. The composition of claim 1 wherein the TLR. agonist is selected from the group consisting of GLA, R848, and a combination thereof.
- 8. The composition of claim 1 wherein the Novel Coronavirus cells are melanoma cells.
- 9. The composition of claim 1 wherein the TLR agonist and whole infected cells are formulated with an emulsion vehicle.
- 10. The composition of claim 1 wherem the TLR agonist and whole infected cells are formulated with Lipofectamine™.
- 11. The composition of claim 1 wherem the TLR agonist and whole infected ceils are formulated with a cationic lipid.
- 12. A method comprising:
- administering to a Novel Coronavirus patient immunotherapeutic agents: cytokine-expressing, proliferation incompetent, whole Novel Coronavirus cells; an anti-PD-1 antibody that specifically binds to human Programmed Death 1 (PD- 1); and a TL (toll like receptor) agonist; wherein the whole Novel Coronavirus cells are formulated with the TLR agonist.
- 13. The method of claim 12 wherein the cytokine is GM-CSF (granulocyte moncyte cell stimulating factor),
- 14. The method of claim 12 wherein the whole Novel Coronavirus ceils are autologous to the patient.
- 15. The method of claim 12 wherein the Novel Coronavirus cells are formulated with a TLR7/8 agonist.
- 16. The method of claim 12 wherein the whole cancer ceils are formulated with a TLR4 agonist.
- 17. The method of claim 12 wherein the whole cancer ceils are formulated with a TLR4 and a TLR7/8 agonist.

- 18. The method of claim 12 wherein the TLR agonist is selected from the group consisting of GLA, R848, and a combination thereof.
- 19. The method of claim 12 wherein the Novel Coronavirus cells are melanoma cells.
- 20. The method of claim 12 wherein the TLR agonist and whole tumor cells are formulated with an emulsion vehicle.
- 21. The method of claim 12 wherein the TLR agonist and whole tumor cells are formulated with Lipofectamine™.
- 22. The method of claim 12 wherein the TLR agonist and whole tumor cells are formulated with a cafiomc lipid.
- 23. A kit comprising agents:
- cytokine-expressing, proliferation incompetent, Novel Coronavirus cells; an a ti-PD-I antibody that specifically binds to human Programmed Death 1 (PD-1); and
- a TLR (toll like receptor) agonist.
- 24. The kit of claim 23 further comprising instructions for administering and/or formulating the agents.
- 25. The kit of claim 23 further comprising an emulsion vehicle.
- 26. The kit of claim 23 further comprising Lipofectamine™.
- 27. The kit of claim 23 further comprising a cationic lipid.

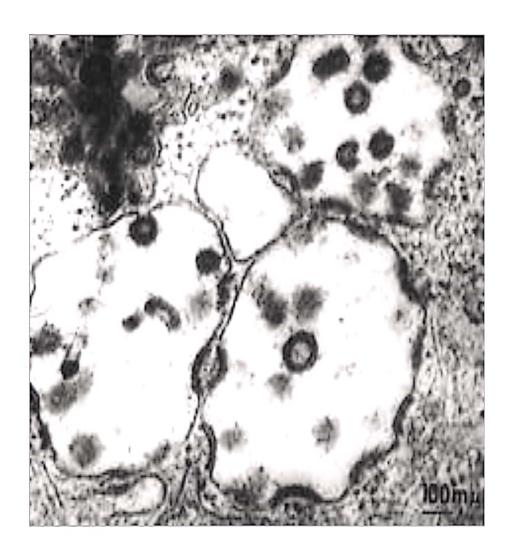
[KANISHK SINHA]

INVENTOR

## FIGURE - 1



## <u>FIGURĒ - 2</u>



1

01.04.2020

(S1, 2)

[via video conference] (S. Banerjee)

W.P. 5325(W) of 2020

Kanishk Sinha Versus Union of India & Ors.

Mr. Kanishk Sinha

... Petitioner in person

This application is entertained on the express undertaking of the petitioner to comply with all formalities regarding filing including stamping and punching of the petition immediately upon resumption of normal court business.

Leave is granted to the petitioner to serve notice of the writ petition and the application by e-mail on the respondents.

The writ petition and the connected application are taken up together.

The respondents are not represented for lack of proper notice.

List the writ petition along with the connected application being C.A.N 3000 of 2020 on 8th April, 2020.

As an interim order this Court directs that considering the extraordinary circumstances created by the lock down, the respondent authorities shall very actively consider the prayer of the writ petitioner as made in prayer (a) of the writ petition and take a decision in the matter by 7<sup>th</sup> April, 2020 to be communicated to this Court keeping in view the fact that no valuable right of the writ petitioner is lost by virtue of this unusual situation.

(I. P. Mukerji, J.)

## W. P. No.5325 (W) of 2020 Kanishk Sinha v. Union of India & Ors. in CAN No.3000 of 2020

08.04.2020 S1-01 Via video conference (S.R.)

Mr. Kanishk Sinha ... petitioner-in-person.

Mr. Avinash Kankani ... for the respondent nos.1 & 2.

Mr. Provash Ch. Sadhuka ... for the respondent no.3.

This application is entertained on the express undertaking of the petitioner to comply with all formalities regarding filing including stamping and punching of the petition immediately upon resumption of normal court business.

Learned counsel for the respondents submits that the application of the petitioner for grant of patent has been accepted online. This substantially redresses his grievance in this writ application. His further prayer is for an order upon the government to allow him to do research work in connection with the invention of a vaccine to prevent or combat the COVID 19 virus.

For this purpose, he may make a proper application before the appropriate authority. The said authority, upon consideration of the petitioner's eligibility and his fulfillment of other necessary conditions may consider such application for doing research in accordance with law by making a decision within four weeks of communication of this order.

The writ application (W.P. No.5325 (W) of 2020 and the connected application CAN No.3000 of 2020) are disposed of by this order.

All parties are to act on a server copy of this order on the usual undertakings.

(I.P. Mukerji, J.)

KANISHK SINHA, MSc, LLB, HM PLAZA, 8, Acharya Jagadish Chandra Bose Road, Kolkata – 700 017, Mobile: - 9830647300 / 7044598246 Email: - kanishksinha28@yahoo.in

## **MOST URGENT**

To,

The Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, Near Udyog Bhawan Metro Station, Maulana Azad Road, New Delhi – 110 011.

DATED: - 09-04-2020, Kolkata

SUB: - W. P. NO: 5325 (W) OF 2020

WITH

C. A. N. NO: 3000 OF 2020

Kanishk Sinha

Versus

The Union of India & Ors

Dear Madam / Sir,

Most humbly and respectfully I am to submit that, the entrepreneurs namely Kanishk Sinha and Mrs Lipika Das Sinha in the year 2005 has been granted patent for invention of Electric rickshaws (also known as electric tuk-tuks or e-rickshaws) which have been become more popular in some cities since 2008 as an alternative to auto rickshaws and pulled rickshaws because of their low fuel cost, and less human effort compared to pulled rickshaws. They are being widely accepted as an alternative to petrol / diesel / CNG auto rickshaws. They are 3 wheelers pulled by an electric motor ranging from 650 - 1400 Watts. They are mostly manufactured in India and China, only a few other countries manufacture these vehicles. Battery - run rickshaws could be a low - emitter complementary transport for the low - income people, who suffer most from a lack of transport facility, if introduced in a systematic manner according to experts. (The copy of the Letter of patent dated: 28.12.2012 w.e.f. 02.05.2005 issued by the Government of India and Judgment / order dated:

KANISHK SINHA, MSc, LLB, HM PLAZA, 8, Acharya Jagadish Chandra Bose Road, Kolkata – 700 017, Mobile: - 9830647300 / 7044598246 Email: -

<u>kanishksinha28@yahoo.in</u>
24.02.2020 passed in Title Suit No: 27 of 2018 by the Learned 13<sup>th</sup>
Additional District Judge, South 24 Parganas are annexed herewith and
marked as <u>Annexure – 1</u> to the instant application collectively).

That, they have also invented the water driven hydrogen powered car which was successfully tested by Japanese Prime Minister. The Hon'ble High Court of Judicature at Patna directed ".....We have heard learned counsel for the respondents and find that in view of the communication dated 28th April, 2010, it cannot be said that the application of the appellant was incomplete and the return of the application thus, cannot be sustained. Consequently, we set aside the communication dated 26<sup>th</sup> June, 2013 and direct the respondents-patent office to continue with the process after the letter dated 28th April, 2010 in accordance with law." (Judgment / order dated: 07.02.2017 Letters Patent Appeal No.1609 of 2016 Arising out of Civil Writ Jurisdiction Case No. 23851 of 2013 by the Hon'ble High Court of Judicature at Patna is annexed herewith and marked as Annexure — 2 to the instant application).

That, the Hon'ble Calcutta High Court upon hearing a writ petition being W.P. 5325 (W) OF 2020 with C.A.N.No: 3000 OF 2020 vide its judgment / order dated: 08.04.2020 has been pleased to direct ".....For this purpose, he may make a proper application before the appropriate authority. The said authority, upon consideration of the petitioner's eligibility and his fulfillment of other necessary conditions may consider such application for doing research in accordance with law by making a decision within four weeks of communication of this order." Website copy of the judgment / order dated: 08.04.2020 passed in W. P. NO: 5325 (W) OF 2020 WITH C. A. N. NO: 3000 OF 2020 by the Hon'ble High Court at Calcutta is annexed herewith and marked as Annexure – 3 to the instant application).

That, since due to the lockdown and / or extraordinary circumstances I cannot arrange for a private laboratory as such I seek limited assistance to use any of the available Government of India laboratory facility exclusively

51

KANISHK SINHA, MSc, LLB, HM PLAZA, 8, Acharya Jagadish Chandra Bose Road, Kolkata – 700 017, Mobile: - 9830647300 / 7044598246 Email: -

with proper security and instruments / apparatus to develop the COVID 19 vaccine rest we will take care of the investment and project costs as it is a commercial project and I apprehend that, if I take government funding then I have to share and / or give its exploitation rights to the Government u/s 102 of the Patents Act, 1970 HENCE our demand is only confined to use any of the available government laboratory facility exclusively with proper instruments / apparatus only for which I am ready to pay the fees also as directed by the authority concerned.

That, I also seek blood samples / swab samples of the infected / recovered COVID 19 patient.

That, after development of the vaccine I would be requiring the volunteers to clinically test the said vaccine.

That, I also seek PPEs for all our team members at the time of research.

That, the team members of this classified project will be solely decided by the undersigned without interference of the Government of India.

FURTHERMORE, I pray for a hearing opportunity through video conferencing at the time of deciding the instant application by the authority through WhatsApp or Microsoft Teams application whichever is possible and / or available or else any adverse decision taken by the authority will be treated as an ex facie.

It imperative to state herein that, the Hon'ble Court has granted the Government of India four weeks time to decide my application but I would like to state that, it is a race against time and each minute delay are causing casualties so it would be appreciated if the same is decided on priority basis so that, I can come up with the vaccine at an early date.

Thanking you

Yours faithfully

Kais WK 5. V

[KANISHK SINHA]

Inventor / Patentee

# No.C-18018/7/2020-EMR/PH Government of India Ministry of Health & Family Welfare EMR Division

Nirman Bhawan, New Delhi-110011 Dated the th April, 2020

To

The Director General, Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India

Subject: Compliance of Order dated 08.04.2020 of Hon'ble Calcutta High Court in W.P. No. 5325 (W) of 2020 with CAN No.3000 of 2020-reg

Sir,

I am directed to forward herewith a representation dated 09.04.2020 received from Shri Kanishk Sinha, petitioner in pursuance of order dated 08.04.2020 passed by the Hon'ble Calcutta High Court in W.P. No. 5325 (W) of 2020 with CAN No.3000 of 2020 for consideration and taking a decision within four weeks of the order. Copies of the order and WP are also enclosed.

Encl: As above.

Yours faithfully,

(S. Nayak)

Deputy Secretary to the Government of India

Tel: 011-23061288

e-mail: sdnnayak@yahoo.com

Shri Kanishk Sinha, H.M. Plaza, 8, Achanga Jagadish Chandra Bosc Road, Kolkata-708017. Email: - Kanishksinha 28@yahoo.in 1h.-7044598246 53 Annexure P - 7



भारतीय आयुर्विज्ञान अनुसंधान परिषद रयास्थ्य अनुसंधान विमाग, स्वास्थ्य और परिवार कल्याण मञ्जालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No. 435/Legal Cell/2020

SPEED POST COURT MATTER Dated: 11.05.2020

Sh. Kanishk Sinha PLAZA, 8, Acharya Jagadish Chandra Bose Road, Kolkata-700017

<u>Sub</u>: Compliance of Order dated 08.04.2020 passed by the Hon'ble High Court of Calcutta at Kolkata in W.P. (C) No. 5325 of 2020 filed by Shri Kanishk Sinha –Vs- Union of India & others-regarding.

Sir,

I am directed to refer to the above mentioned case on the subject and to say that in compliance of the Order dated 08.04.2020 passed by the Hon'ble High Court of Calcutta at Kolkata in W.P. (C) No. 5325 of 2020 (Shri Kanishk Sinha –Vs- Union of India & others), representation dated 09.04.2020 has been received in Indian Council of Medical Research (ICMR), New Delhi for consideration and the replies are as follows:-

ICMR believes in working in close partnership with various stakeholders. While ICMR is actively engaged in formulating research projects on epidemiology, operational research, clinical studies and diagnostics, the research group on vaccines has been dissolved as DBT has taken a lead on vaccines.

BIRAC (DBT) and SERB (DST) have already placed a call for proposals in the area of COVID-19 vaccines.

In view of this, ICMR has decided not to invite proposals on vaccine development. Hence, the representation 09.04.2020 submitted by Shri Kanishk Sinha has been considered in ICMR and disposed of to the above effect.

This issues with the approval of competent authority.

Yours faithfully,

Dr. R Lakshminardyanan ADG (Admn.)

#### Copy to:-

- 1. Registrar, Hon'ble High Court of Calcutta.
- 2. PS to DG/PS to Sr. D.D.G. (Admn.).

Annexure P - 8

## SUBMISSION OF INNOVATION FOR FAST TRACKED REVIEW & FUNDING SUPPORT - REGARDING:

From: Kanishk Sinha (kanishksinha28@yahoo.in)

To: sped4.birac@nic.in

Date: Wednesday, 20 May, 2020, 12:19 am IST

### To, The BIRAC

Sub: SUBMISSION OF INNOVATION FOR FAST TRACKED REVIEW & FUNDING SUPPORT - REGARDING;

Dear Sir / Madam,

I am Kanishk Sinha, MSc, Physics and LLB and holder of several patents in the field of renewable energy segments.

That, I have invented the vaccine for COVID - 19 for which patent has been accepted (copy attached).

That, I am approaching to Your good self (BIRAC) in view of suggestion given by ICMR vide their letter dated: 11-05-2020 (Copy attached).

That, I have two folded ideas for fighting this pandemic i.e., 1st to develop the full fledged vaccine depending upon my patent and 2nd is my last claim of my amended specification dated: 15-05-2020 filed before the patent office to make out a compound of ".....The antiprotozoal Ivermectin with Doxycycline an antibiotic will act as an effective compound for curing COVID - 19"

That, I request for approval of the said idea and sponsoring the same at the earliest so that, we can deploy the same for public purpose at the earliest.

I request for your good self response as early as possible.

Yours truly Sd/-Kanishk Sinha, MSc, LLB Shivalaya, 37/F, Second Street, P.S. Survey Park, Kolkata - 700 075 West Bengal, IN Mobile:- 9830647300 / 7044598246 Mail:- kanishksinha31@gmail.com Viz: - www.jaspermotors.in



FORM 2.doc 83kB



FIGURE - 1.doc 45.5kB



FIGURE - 2.doc 46kB





FORM 13, 15-05-2020.pdf 211.5kB



CBR\_6541\_Dated 03042020.pdf 91.7kB



CBR\_6541\_Dated 03042020.pdf 91.7kB



ORDER 01.04.2020.pdf 94.7kB



Judgment 08.04.2020.pdf 57.5kB

## DISTRICT: KOLKATA IN THE HIGH COURT AT CALCUTTA CONSTITUTIONAL WRIT JURISDICTION APPELLATE SIDE

W.P. (W) OF 2020

In the matter of:

Kanishk Sinha

.....Petitioner

-Vs.-

Shri Harsh Vardhan & Others

.....Respondents

## WRIT PETITION

Kanishk Sinha, MSc, LLB, HM PLAZA, 8, Acharya Jagdish Chandra Bose Road, Kolkata – 700 017, Mobile: -9830647300 / 7044598246