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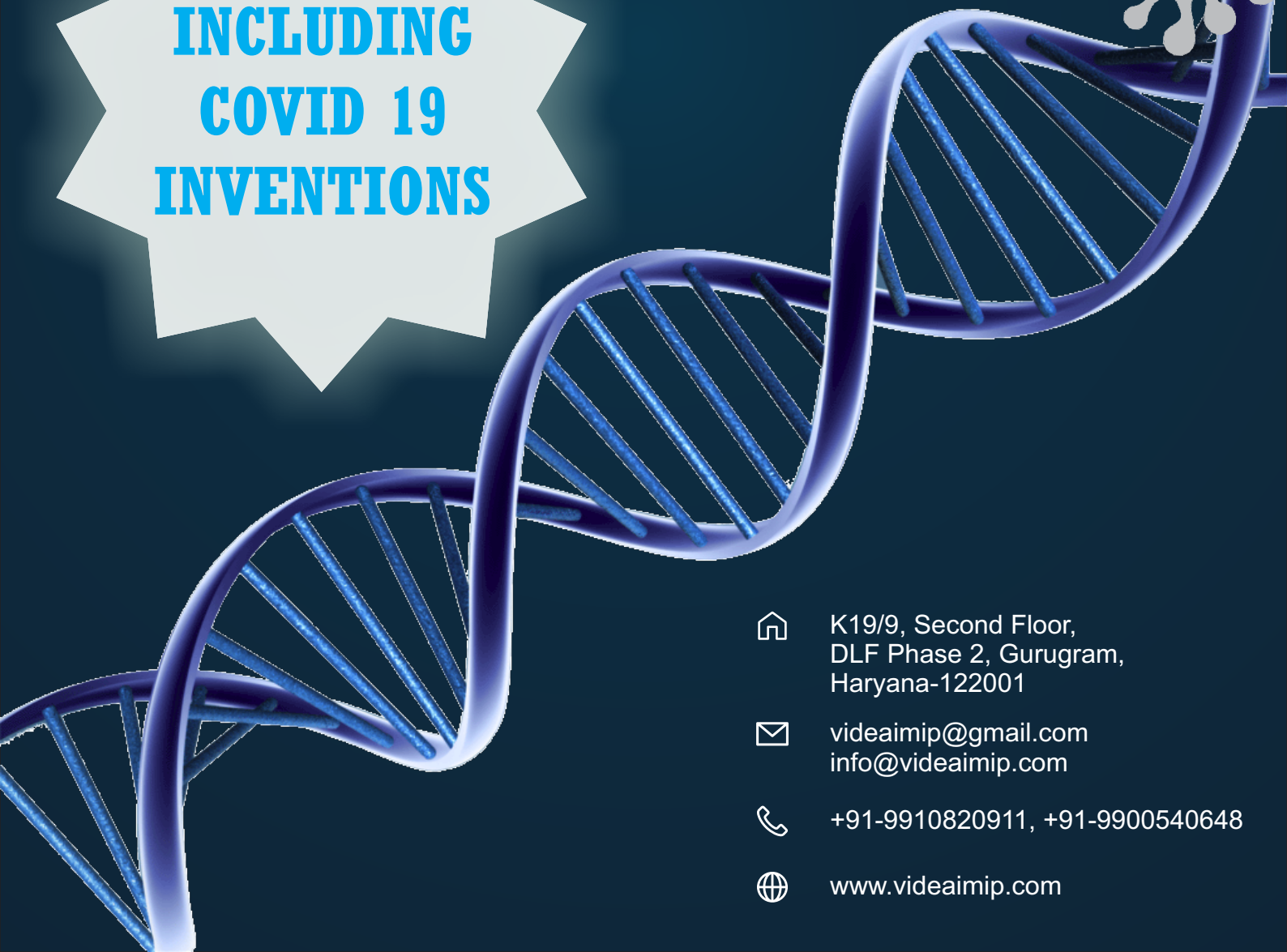
INNOVATION AND PATENT TRENDS IN DEALING INFECTIOUS VIRUSES

INCLUDING COVID 19 INVENTIONS



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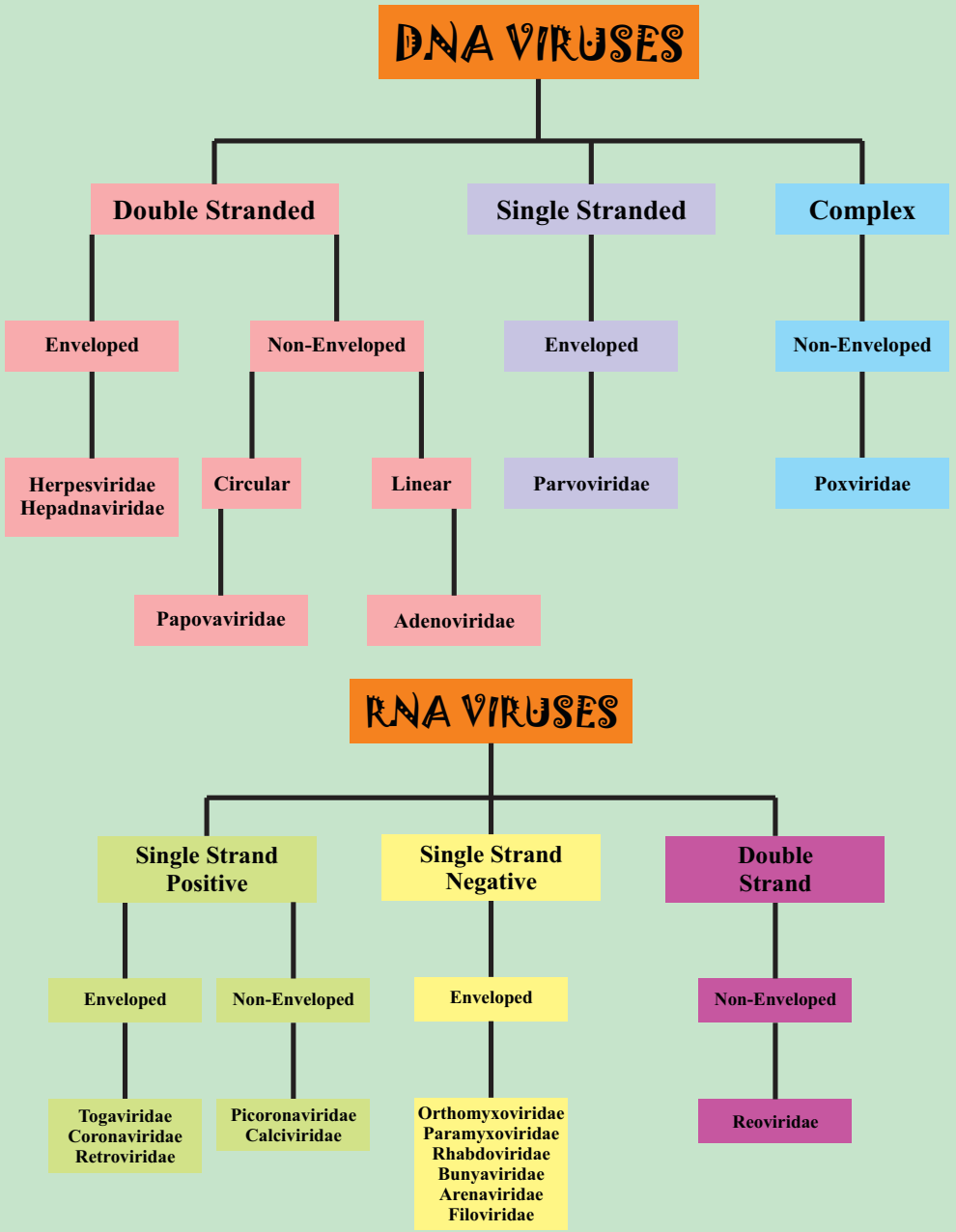
INNOVATION AND PATENT TRENDS : CORONA VIRUS

INTRODUCTION

Viruses are microscopic infectious particles or parasites also referred to as virion which contain a RNA genome or a DNA genome. The virions contain genetic blueprint but cannot independently read or decode it and hence it requires host machinery to replicate. This implies that in order for virions to transform into a infectious particle to enter and attach to the target cells, and more importantly use host cell mechanisms to produce self-structures or reactions (mRNA, proteins, copies of genome), and assemble (translation and transcription) into progeny virion particles.

CLASSIFICATION OF VIRUS BASED ON GENOME

Depending on the virus type, the nucleic acid is single-stranded or double-stranded, linear, circular or segmented. Single-stranded RNA and DNA genomes can have the same polarity or different polarity when compared to messenger RNA. A single-stranded genome that has the same polarity as the messenger RNA is referred to as a positive sense or plus strand.



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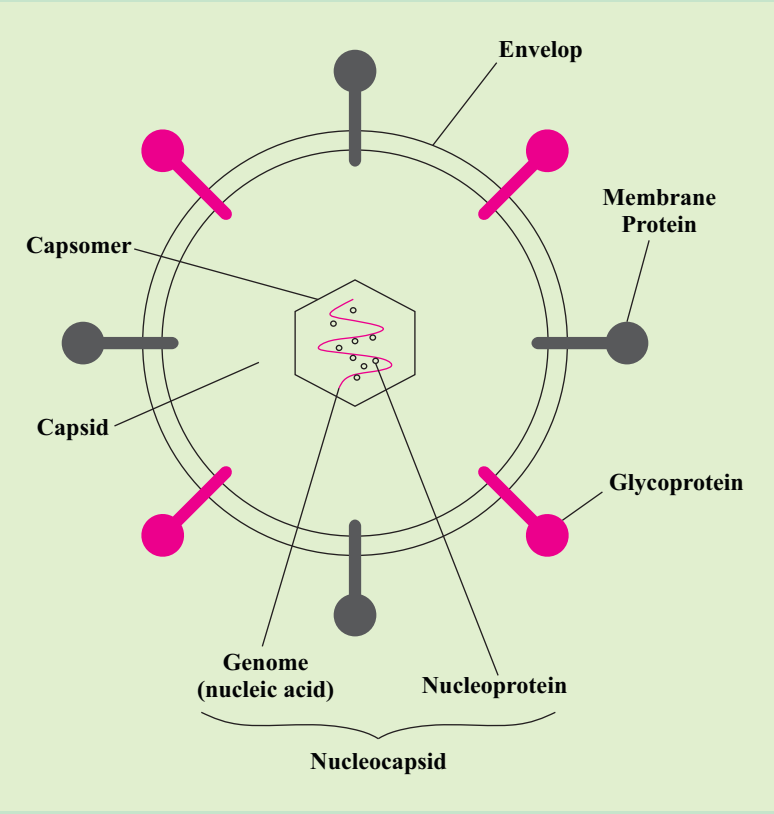
NOVEL CORONA VIRUS

Coronaviruses (CoVs) are a group of highly diverse, enveloped, positive-sense, and single-stranded RNA viruses, causing diseases of respiratory, enteric, hepatic, and neurological systems in both humans and animals. Coronaviruses are zoonotic, i.e. can be transmitted between animals and people.

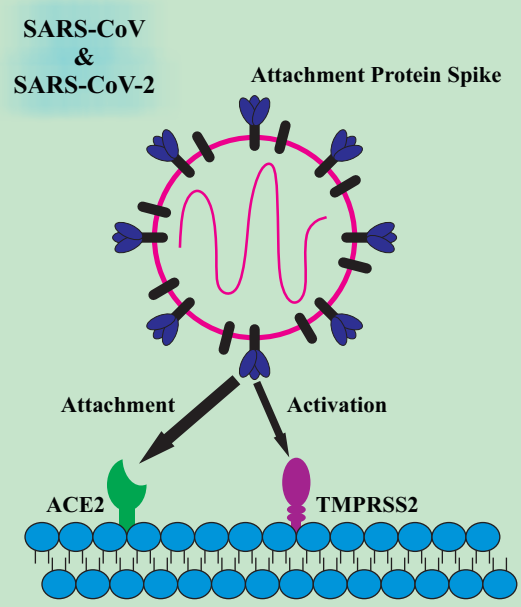
Human CoV infections have traditionally caused a low percentage of annual respiratory infections. Over the past 2 decades, two novel CoVs, severe acute respiratory syndrome CoV (SARS-CoV) and Middle East respiratory syndrome CoV (MERS-CoV), have emerged and cause severe human diseases resulting in epidemics/pandemics.

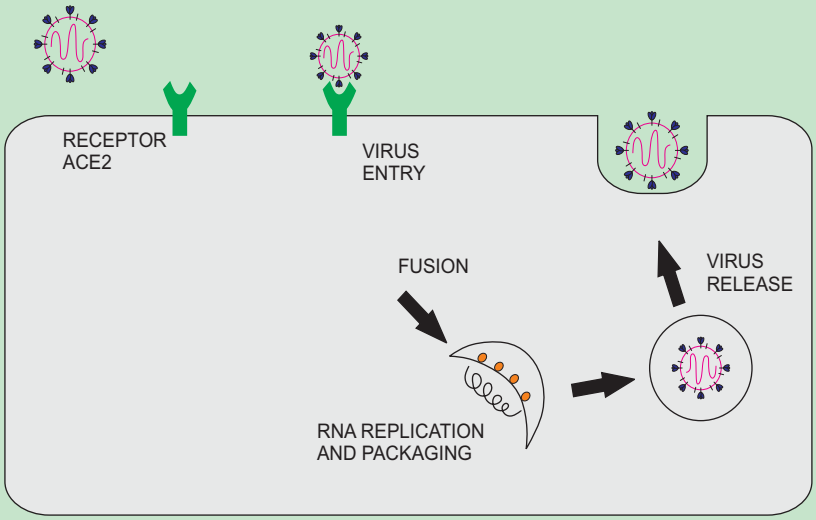
SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) which causes **COVID 19** is the seventh member of the family of CoVs that infects humans.



PATHOGENETIC STEPS IN HUMANS

➔ SARS-CoV-2 access inside of a host's body through respiratory passages, eyes, and open wounds. The virus needs special receptors to enter the cells, so that the reaction (mRNA, proteins, copies of genome), and assembly (translation and transcription)process may commence. The specific receptor that is required is theACE2 (the angiotensin-converting enzyme 2), an attachment protein found on the surface of the lungs. SARS-CoV-2 binds to ACE2 via its spike protein.





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- After the virus enters the host, it un-coats and the genome is transcribed, and proteins translated. Then these proteins are assembled in the cell membrane and the genomic RNA is incorporated forming mature virion particles, which may leave the host cell in one of two ways:
  - break the host cell open (lysis) and destroy the host cell or after the lysis from the cell – non-encapsulated viruses; or
  - pinch out from the cell membrane and break away (budding) with a piece of the cell membrane surrounding them;this is how enveloped viruses leave the cell, and in this way, the host cell is not destroyed.

DIAGNOSIS

The diagnosis of viral infections is based on

A. the recognition of a distinct clinical syndrome such as fever, tiredness, dry cough, aches and pains, nasal congestion, runny nose, sore throat, diarrhoea; and

B. the laboratory generated reports based on blood, body fluids, lesion scraping, tissue to diagnose anti-nfection.

PATENT AND COVID 19

There has been a rapid recent increase in patenting activity broadly referring to the SARS-CoV-2, in the context of vaccines especially, but also relating to diagnosis and treatment. The subject matter of these patents and patent applications covers recombinant gene sequences, other extracts and derivatives from the virus genome, new genetic constructs making use of such material, diagnostics, and more general platform technologies for the production of vaccines and treatments that make use of genetic inputs from the virus.

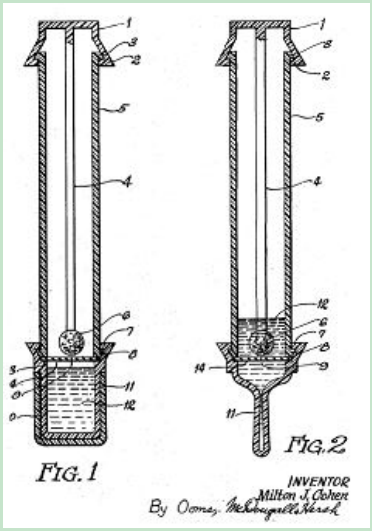
We have illustrated with the help of few examples the patent activity around Viruses, diagnostics etc, elucidating the progression of patent technology and strategies of patenting.

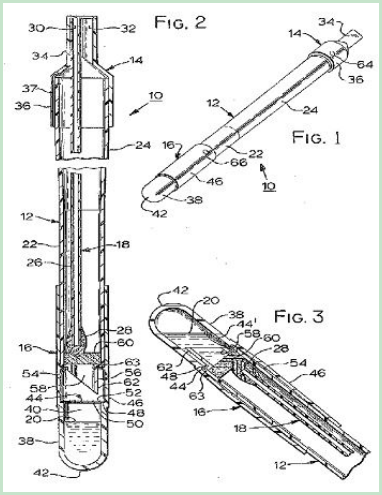
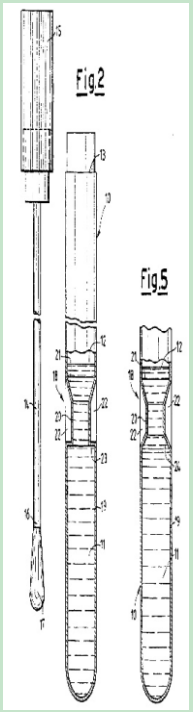
The activity has been categorised under:

I. Collection Devices
II. Vaccine formulations
III. Anti-Viral Drugs
IV. Molecular diagnostics

Collection Device: Swabs are globally and extensively used in the field of clinical and diagnostic analyses for collection of biological samples/specimens. A swab is basically a cylindrical rod with a collection end with fibre material, such as rayon or a natural fibre such as cotton. The collection end has hydrophilic properties to allow rapid absorption of specimen to be collected and tested.

Examples of Patents/Patent applications in the field of Viral Specimen collection:

Patent /Application No.	Date of Filing	Status	Brief Description	Figures
US3163160A (Milton J Cohen)	15-11-1962	Granted and expired	A combination consisting of a disposable sample swab and culture medium device, comprising a tubular container open at both ends, a cover at one end, means for removably securing said cover to said one end, an applicator rod, a sterile swab attached to said rod whereby said swab is held suspended within said container when said cover is secured in place, a flexible receptacle, means for securing said receptacle at the other end of said container, a slitted self-sealing valve secured adjacent said other end and separating the interior of said receptacle from the interior of said container, and a liquid culture medium disposed within said receptacle, whereby said swab and cover can be removed from said container for application of a sample to said swab, and whereby said swab and cover can be thereafter resecured to said container, said culture medium can be forced through said slit by collapsing the walls of said receptacle, and whereby said combination can be discarded when bacterial growth within the device is completed.	

Patent /Application No.	Date of Filing	Status	Brief Description	Figures
US4353868A (Covidien AG, Tyco Group SARL)	02-05-1981	Granted and expired	A specimen collecting and transporting device is provided which includes a container, a swab in the container connected to a closure cap closing one end of the container, and a reservoir attached to the other end of the container and containing a liquid culture-sustaining medium sealed in a chamber of the reservoir. The bottom end of the container has an opening covered by an absorbent pad and which is in contact with the swab tip. The container has a projection which when moved relatively toward the reservoir, pierces the chamber seal to allow the medium to flow through the opening to the pad and swab tip.	
EP0643131B1 (Copan Italia SpA)	09-09-1993	Granted and expired	Device for sample collection and in vitro transport for diagnostic use, of the type comprising a test-tube with culture medium in gel form and a rod carrying at one end a stopper for sealing the test-tube and at the opposite end means for collecting said specimen, for example a wad of fibre wrapped around the tip of the rod, to be dipped into the culture medium. Said test tube has an essentially cylindrical shape interrupted by a neck situated under the level reached by the free surface of the transport medium inside the test tube.	

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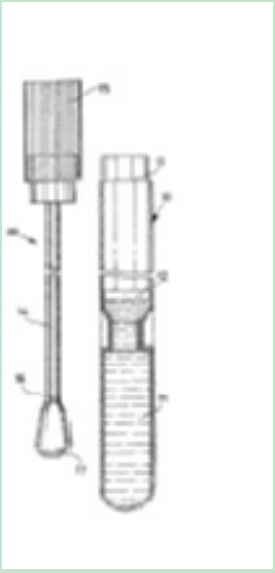
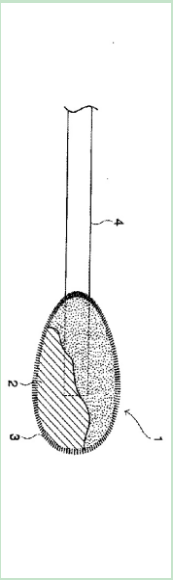
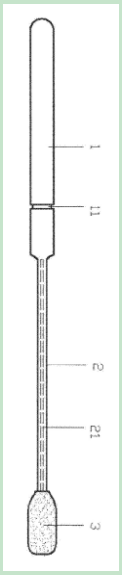
Patent /Application No.	Date of Filing	Status	Brief Description	Figures
WO2004086979A (Copan Innovation Limited)	2003-04-01	Worldwide litigation filed	The citation describes Swab for collecting biological specimens of the type consisting of a rod terminating in a tip covered with fibre with hydrophilic properties to allow absorption of said specimens, characterised in that said fibre covers said tip in the form of a layer deposited by flocking. Swab is characterised in that said layer of said fibre (17) has a thickness between 0.6 and 3 mm.	
JP2011234666A (Sanyo Co., Ltd.)	2010-05-10	Pending	The citation describes a cotton swab wherein a cotton lump is provided at one or both ends of a shaft, and a flocking layer is provided on the surface of the cotton lump by flocking short fibers in a brush shape. An adhesive layer is disposed partially or entirely on the surface of the fiber lump portion, and a flocked layer covering the adhesive layer is disposed by flocking fiber thereon in a brush shape.	
CN201939387U (Shenzhen Mairuikelin Technology Co., Ltd.)	2011-01-26	Granted and active till 2031	The citation describes a swab constructed to collect and release a biological sample comprising a flock fiber tipped applicator wherein the flock fibers are sea-island bicomponent fibers, the bicomponent fibers being structurally stable in water and the sea component of the bicomponent flock fibers being intact, wherein said bicomponent fibers comprise 10-3000 island parts per fiber.	

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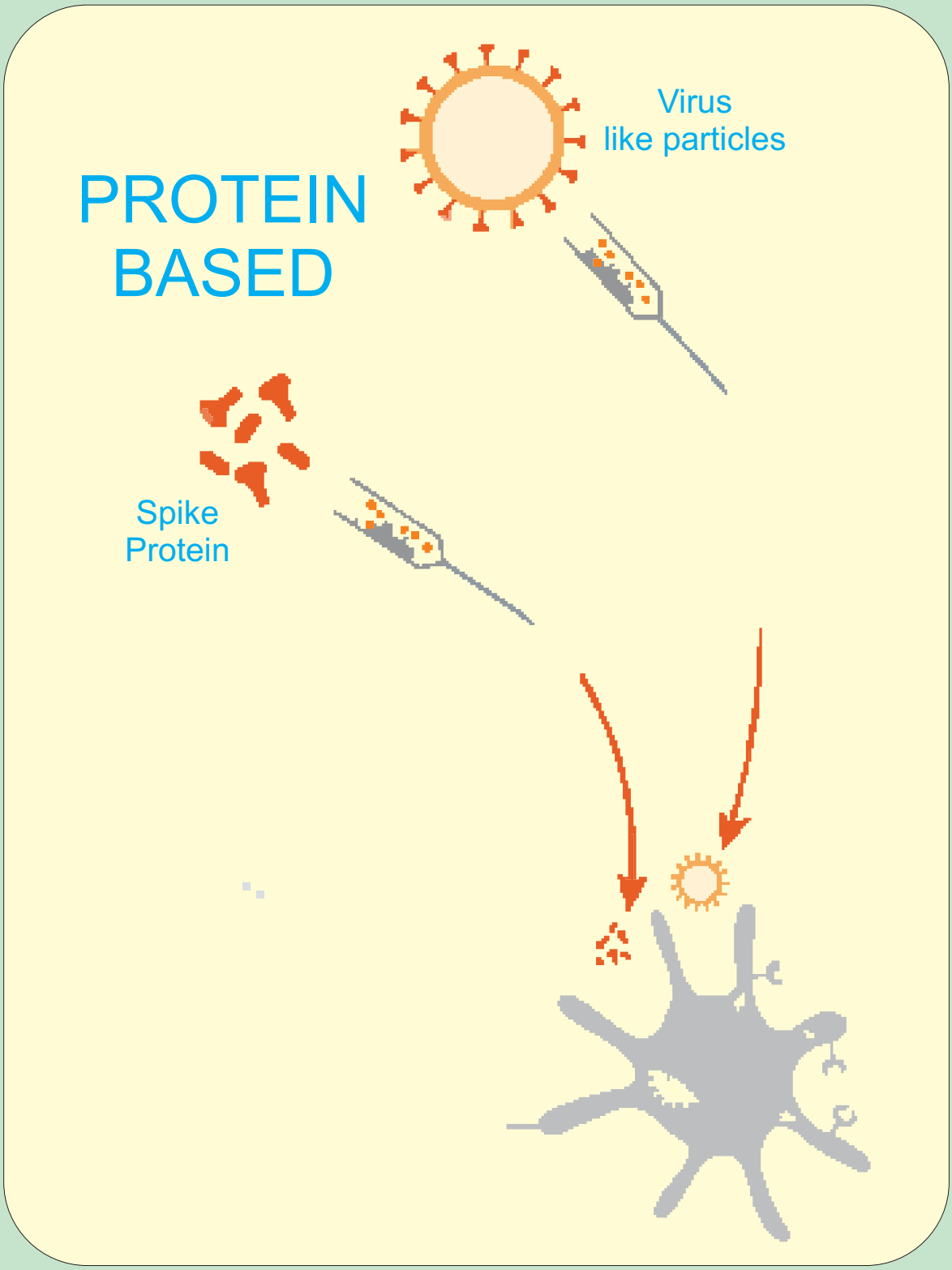
Protein and Virus Like Particle Vaccine formulations: The protein-based vaccines utilises Spike protein and M protein, on the other hand Virus like particles are empty virus shells that mimic virus structure and are not infectious as they lack genetic material. However, both of them trigger strong immune response.



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INNOVATION AND PATENT TRENDS : CORONA VIRUS

Patent /Application no.	Brief Description
US3060094A 07-04-1959	**Preparation of virus vaccines without significantly impairing the antigenic properties thereof**; The method in which the suspension of virus microorganisms is influenze.(1) heating a sample of a suspension of virus microorganisms by a heat-exchanger at various different relatively high temperatures in about a fraction of a second; (2) testing the microorganisms after heating at each temperature to determine the infectivity thereof; (3) continuing the heating of samples of suspensions of virus microorganisms as described in step 1 so long as the sample stall exhibits infectivity.
US6974577B2 04-02-2001	**Inactivated bovine scours vaccines, processes and method of preventing bovine scours** A combination bovine rotavirus and coronavirus vaccine capable of inducing immunity in bovine animals without serious side effects, the combination vaccine comprising a vaccinal amount of a plurality of inactivated bovine rotavirus strains, at least one inactivated bovine coronavirus strain, and at least one vaccinal bacteria.
US7838006B2 Immunitor USA Inc 24-08-2000	**Viral vaccine composition, process, and methods of use:** The composition comprises viral pathogen-infected cell or tissue, or malignantly or immunologically aberrant cells or tissues which has been reduced and/or denatured. The preferred composition is administered across a mucosal surface of an animal suffering or about suffer from infection. The composition is administered as preventive or therapeutic vaccine.
AU2009201478B2 Novartis Vaccines and Diagnostics Inc 10-04-2003	**The severe acute respiratory syndrome coronavirus.** The invention relates to nucleic acids and proteins from the SARS coronavirus. These nucleic acids and proteins can be used in the preparation and manufacture of vaccine formulations, diagnostic reagents, kits, etc. The invention also provides methods for treating SARS by administering small molecule antiviral compounds, as well as methods of identifying potent small molecules for the treatment of SARS.
JP2017524339A 23-05-2014	**Middle East respiratory syndrome-human antibody against coronavirus spike protein.** The present invention provides monoclonal antibodies that bind to the Middle East Respiratory Syndrome-Coronavirus (MERS-CoV) spike protein and methods of use. In various embodiments of the invention, the antibody is a fully human antibody that binds to the MERS-CoV spike protein. In certain embodiments, the antibodies of the invention are useful for inhibiting or neutralizing MERS-CoV activity, thereby providing a means to treat or prevent MERS infections in humans. In certain embodiments, the invention provides a combination of one or more antibodies that bind to a MERS-CoV spike protein for use in the treatment of MERS infection. In certain embodiments, the one or more antibodies bind to distinct non-competitive epitopes contained in the receptor binding domain of the MERS-CoV spike protein.
EP1618127B1 Novartis Vaccines and Diagnostics Inc 09-04-2004	**Immunogenic composition comprising a spike protein of the SARS coronavirus.** An immunogenic composition comprising an isolated or purified polypeptide comprising a) the Severe Acute Respiratory Syndrome (SARS) virus Spike polypeptide amino acid sequence SEQ ID NO: 6042, or b) an amino acid sequence having >80% sequence identity to SEQ ID NO: 6042, or c) a fragment of at least 10 consecutive amino acids of SEQ ID NO: 6042; with the proviso that the polypeptide is not MFIFLLFLTLTSGSDLDRCTTFDDVQAP.
JP6643239B2 19-09-2013	Immunogenic middle east respiratory syndrome coronavirus (MERS-CoV) compositions and methods. MERS-CoV nanoparticles comprising a Middle East Respiratory Syndrome Coronavirus (MERS-CoV) antigen, wherein the antigen comprises a baculovirus-expressed full-length spike polypeptide in trimeric form. the spike polypeptide is the only polypeptide in the nanoparticles, the nanoparticles; and (ii) support Ponin based adjuvant; An immunogenic composition comprising: an immunogenic composition capable of inducing a high affinity neutralizing antibody against MERS-CoV.

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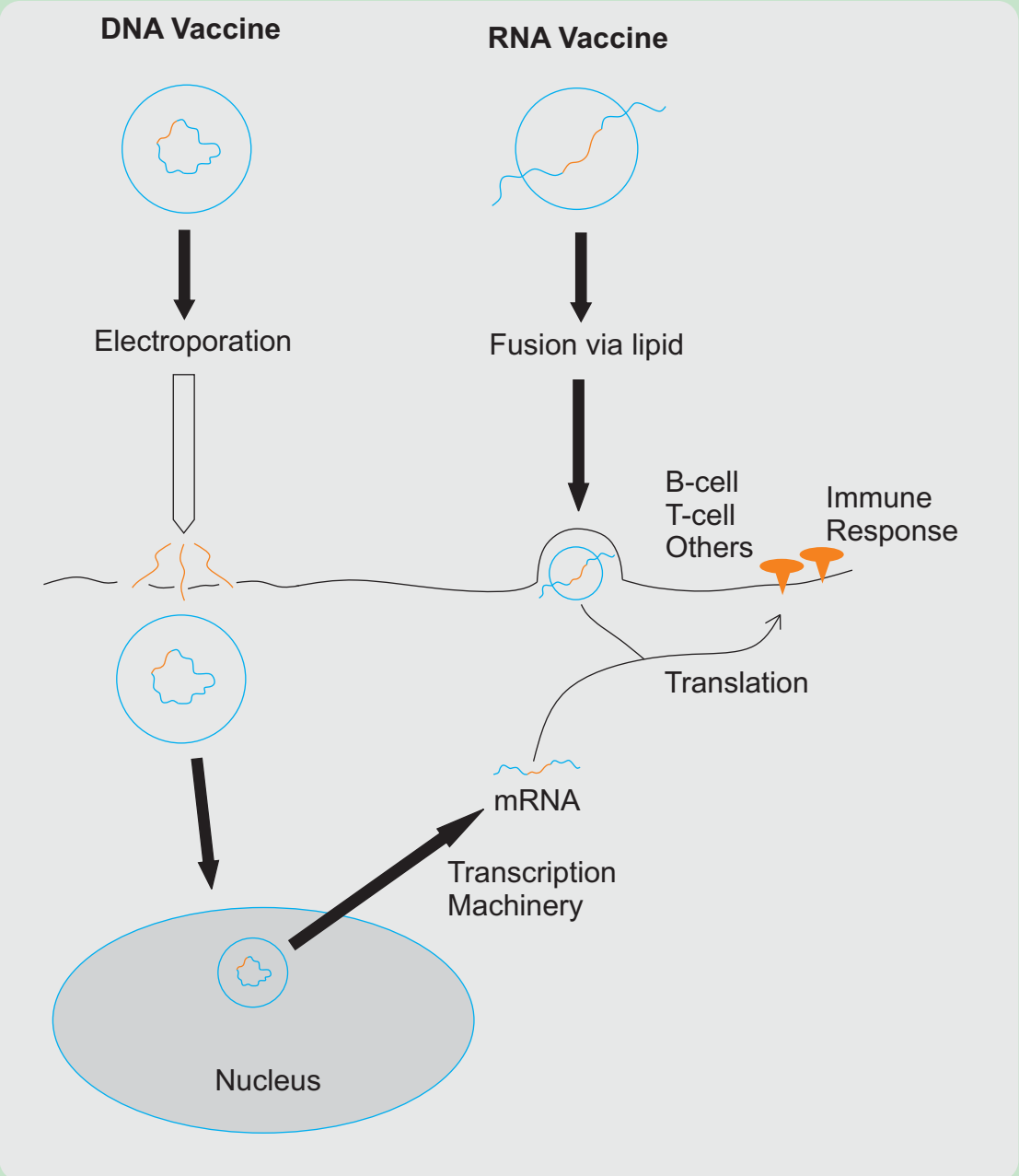
Antiviral Drugs: Targets for antiviral drugs

(i) fusion of the virion with the cell membrane, as required for virus penetration and release;
(ii) virus un-coating, which may also require the interaction of virus and cellular membranes;
(iii) proteolytic cleavage of viral precursor proteins, which is an essential step in the assembly of virion;
(iv) synthesis of viral DNA or RNA, which is often achieved by virus-specific DNA polymerases or RNA polymerases;
(v) maturation of viral mRNA (5'-capping, methylation, 3'-adenylation) which may impose greater demands on the cell than the maturation of cellular mRNA; and
glycosylation of viral proteins, which is required for the assembly of enveloped viruses

Nucleic Acid Vaccines:



INNOVATION AND PATENT TRENDS : CORONA VIRUS

Appl./Patent No.	Brief Description
US4945050A 13-11-1984	**Method for transporting substances into living cells and tissues and apparatus therefor**Inert or biologically active particles are propelled at cells at a speed whereby the particles penetrate the surface of the cells and become incorporated into the interior of the cells. The process can be used to mark cells or tissue or to biochemically affect tissues or tissue in situ as well as single cells in vitro. Apparatus for propelling the particles toward target cells or tissues are also disclosed. A method for releasing particles adhered to a rotor device is also disclosed.
US20140242152A1 06-07-2011	**Immunogenic compositions and uses thereof -**This invention generally relates to immunogenic compositions that comprise an RNA component and a polypeptide component. Immunogenic compositions that deliver antigenic epitopes in two different forms—a first epitope from a pathogen, in RNA-coded form; and a second epitope from the same pathogen, in polypeptide form—are effective in inducing immune response to the pathogen. The invention also relates to a kit comprising an RNA-based priming composition and a polypeptide-based boosting composition. The kit may be used for sequential administration of the priming and the boosting compositions.
US20190010469A1 30-03-2007	**Attenuated viruses useful for vaccines**. This invention provides an attenuated virus which comprises a modified viral genome containing nucleotide substitutions engineered in multiple locations in the genome, wherein the substitutions introduce synonymous deoptimized codons into the genome. The instant attenuated virus may be used in a vaccine composition for inducing a protective immune response in a subject. The invention also provides a method of synthesizing the instant attenuated virus. Further, this invention further provides a method for preventing a subject from becoming afflicted with a virus-associated disease comprising administering to the subject a prophylactically effective dose of a vaccine composition comprising the instant attenuated virus.
US8080642B2 Vical Inc 16-05-2003	**Severe acute respiratory syndrome DNA compositions and methods of use.** The present invention is directed to raising a detectable immune response in a vertebrate by administering in vivo, into a tissue of the vertebrate, at least one polynucleotide comprising one or more regions of nucleic acid encoding a SARS-CoV protein or a fragment, a variant, or a derivative thereof. The present invention is further directed to raising a detectable immune response in a vertebrate by administering, in vivo, into a tissue of the vertebrate, at least one SARS-CoV protein or a fragment, a variant, or derivative thereof. The SARS-CoV protein can be, for example, in purified form. The polynucleotide is incorporated into the cells of the vertebrate in vivo, and an immunologically effective amount of an immunogenic epitope of a SARS-CoV polypeptide, fragment, variant, or derivative thereof is produced in vivo. The SARS-CoV protein is also administered in an immunologically effective amount.

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INNOVATION AND PATENT TRENDS : CORONA VIRUS

Molecular diagnostics:

Isolation of virus: Most diagnostic laboratories only use tissue culture for virus isolation. A specific cytopathic effect or induction of a characteristic function (e.g., hemagglutination) can indicate the growth of viruses in tissue culture. This can be confirmed with virus specific antisera applied to the tissue monolayer to neutralize the cytopathic effect or the hemagglutination reaction.

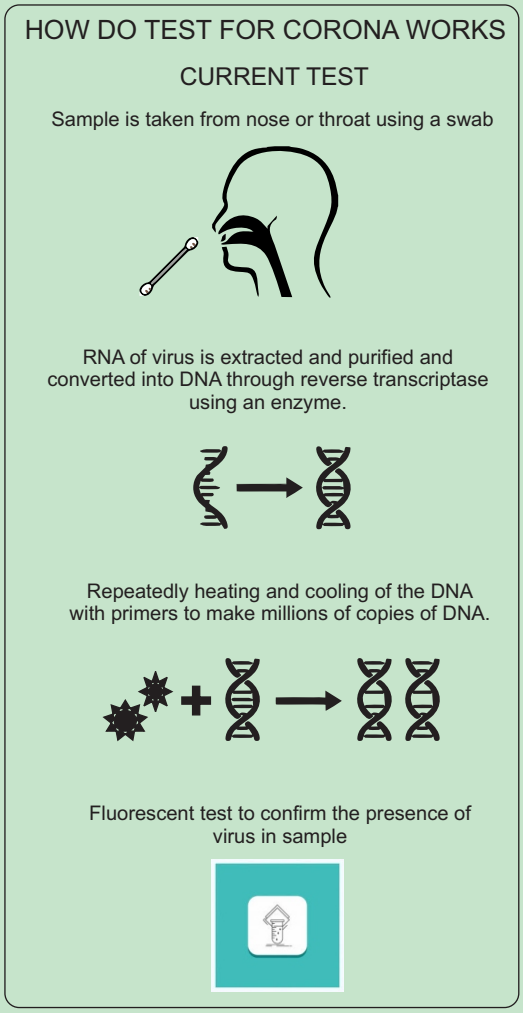
Antigen detection in body fluids: The sample collection is made from the respiratory tract for isolating the respiratory viruses with specific immune sera linked to fluorescence or enzyme immunoassay detection.

Nucleic acid Detection: Blood samples or tissue samples can be analysed by PCR amplification and/or nucleic acid probes to detect viral nucleic acid in body fluids or tissues.

Antibody detection: IgM antibody detection can assist with acute diagnosis.

Detection via Microscope: Examination of tissue samples by light microscopy for viral induced cytopathology and antigen detection by immunohistochemical staining.

Examination of body fluids or tissues by electron microscopy: This is not an efficient method and is dependent upon sufficient numbers of virions being present to permit detection.



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INNOVATION AND PATENT TRENDS : CORONA VIRUS

CN1806175A 10-06-2003	Method of diagnosing SARS corona virus infection. The present invention relates to methods of detecting the presence or absence of antibody to SARS coronavirus in a sample, based on the discovery that the S, M, E, N and U274 proteins of SARS coronavirus are antigenic. Such methods may be used to diagnose whether a patient has been infected by or exposed to SARS coronavirus. Antibodies directed against S, M, E, N and U274 proteins of SARS are also provided.
CN102732638A 07-04-2011	Method for single-tube multiplex fluorescent polymerase chain reaction (PCR) detection of human coronavirus OC43, 229E, NL63, HKU1 and SARS, and primers, probes and kit adopted by the method. The invention provides a method for single-tube multiplex fluorescent polymerase chain reaction (PCR) detection of human coronavirus OC43, 229E, NL63, HKU1 and SARS. The method adopts primers having sequences of SEQ ID NO: 1-10, and probes having sequences of SEQ ID NO: 11-15. The invention also provides a kit for single-tube multiplex fluorescent PCR detection of human coronavirus OC43, 229E, NL63, HKU1 and SARS. The kit contains the primers and the probes. The method provided by the invention adopts the primers which are specific primers of OC43, 229E, NL63, HKU1 and SARS, and the probes which are Taqman probes, utilizes TAMRA/CY5/FAM/ROX/JOX multiple fluorescein labeling, realizes single-tube multiplex detection of human coronavirus OC43, 229E, NL63, HKU1 and SARS, and has the advantages of strong specificity, high sensitivity, fast detection speed, simple and convenient operation and low cost. The primers and the probes can be used as detection reagents for a scientific research and clinical application.
US46404903P 17-04-2003	Compositions and methods for determining the presence of SARS coronavirus in a sample. The present invention relates to oligonucleotides useful in determining the presence of SARS coronavirus in a test sample. The oligonucleotides of the present invention may be incorporated into detection probes, capture probes and amplification oligonucleotides, or used in various combinations thereof
US20040229211A1 13-05-2003	Sensitive diagnostic testing methodology using multiplex real time PCR with one dye (MOD) and its use as in severe acute respiratory syndrome (SARS)
CN1557838A 10-02-2004	SARS coronavirus nucleocapsid protein monoclonal antibody, hybridoma for producing the same, detection agent containing the same and use thereof. The present invention discloses the specific monocloneal antibody of SARS-CoV nuclear capsid protein, hybrid tumor producing the antibody, reagent containing the monocloneal antibody and reagent kit therewith. The monocloneal antibody is secreted and produced with the cell line including hybrid tumor 1E8A11 of preservation number of CCTCC-C200401, hybrid tumor 1E8A17 of preservation number of CCTCC-C200402, hybrid tumor 10E4A4 of preservation number of CCTCC-C200403, and hybrid tumor 14A3A3A19 of preservation number of CCTCC-C200404. The reagent kit established with the monocloneal antibody may be used in early diagnosis of SARS-CoV infection and has the features of simplicity, convenience, fastness, high sensitivity, powerful specificity, etc.

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INNOVATION AND PATENT TRENDS : CORONA VIRUS

MOST RECENT AND IMPORTANT DEVELOPMENTS RELATED TO CORONA VIRUS

VACCINE DEVELOPMENT

Live Attenuated Vaccine:

Pirbright Institute of UK has developed a traditional live attenuated form of coronavirus. EP3589731A1 provides variant replicase gene encoding polyproteins comprising a mutation in non-structural protein (nsp)-14 for which a patent has been granted for the application.

Loyola University Chicago US Department of Agriculture,EP3589731A1has recently developed a live, attenuated coronavirus comprising a variant replicase gene encoding polyproteins comprising a nsp-15, the replicase gene encoding the nsp15 and causes any change, including mutations and/or deletions, that affects the stability or activity of the nsp15.

Protein and Virus Like Particle Vaccine formulations:

The most recently granted US patent application US201562219926 filed by Tel Aviv University of Israel for a vaccine that targets the coronaviruses' Receptor Binding Motif (RBM), a critical structure that enables the virus to bind to and infect a target cell. The patent provides polypeptides derived from the coronaviruses (CoVs) Spike protein (S) characterized by high affinity and specificity the S receptor and its neutralizing antibodies. The invention specifically provides an amino acid sequence of reconstituted Receptor Binding Motif (RBM) of the viral Spike protein comprising of one linker and one fragment of the native RBM of 30 to 200 amino acid sequence comprised within the Receptor Binding Domain (RBD) of said Spike protein forming a binding interface that interacts with the viral receptor. These polypeptides compose the vaccines, and vaccine-based therapies targeting CoVs, and SARS and MERS viruses.

DRUG DISCOVERY/DEVELOPMENT

Patent application WO2017049060A1 byGilead Sciences, a US biopharmaceutical company, describes use of the drug Remdesivir in infections caused by viruses of the Coronaviridae family, to which corona viruses belong.

Patent application WO2019053696A1 by Alios Biopharma, Inc. describes novel nucelosides and nucleotides which have potential to be used as drugs to treat infection caused by Coronaviridae family.

US based AIM ImmunoTech Inc., immuno-pharma company has announced that it has filed patents (unpublished) related to its drug candidate Ampligen for treating corona virus infections.

DIAGNOSTIC TOOLS

The earliest approvals for use of in vitro diagnostic (IVD) kits and point-of-care devices was given only to devices manufactured by the Centre for Disease Control and Prevention (CDC) and the Wadsworth Centre - both of which are government agencies.

Roche's cobas SARS-CoV-2 assay kit was the first approval given to a private player. This was followed by approvals to kits provided by manufacturers like Thermo Fisher, PerkinElmer Inc., Abbott Diagnostics Scarborough Inc., and several others.

The American company Co-Diagnostics, Inc.,of Utah, USA, a molecular diagnostics company, has developed a patented technology for the development of diagnostic tests for SARS-CoV-2.CoSara Diagnostics Pvt. Ltd., (Ahmedabad, India) is a joint venture between Co-Diagnostics Inc. and Ambalal Sarabhai Enterprises of India which is the first to get licenseto manufacture coronavirus test kits from the Central Drugs Standards Control Organization (CDSCO).

KEY OPPORTUNITIES

Intellectual property plays an important role throughout the development of a vaccine, antiviral drug, or diagnostic kits. Key opportunities for creation and protection of intellectual property in relevant area of research are listed below:

Vaccine: One can protect

a) the genomic sequence of the isolated virus with modifications to serve as the basis for the development of the vaccine,
b) the production processes of the viruses,
c) the production methods of antigens for vaccines, and,
d) adjuvants, compositions and dosages of the product.

Antivirals: One can protect

a) novel drugs; and
b) the dosage form and their medical uses.

Diagnostic kits: One can protect

a) the specific novel recombinant primers apart from the naturally occurring sequences for detection and kit thereof;
b) the recombinant antibodies and kit thereof; and
c) novel technique for detection (including novel nanoparticles, dyes etc) and kit thereof.

Conclusion:

Viruses have been around forever, and they have made us aware of their presence via infectious diseases, sometimes taking the form of epidemic or pandemic. The last major viral pandemic was Flu Pandemic during 1918-1919. It is estimated that about 500 million people or one-third of the world's population became infected with this virus.

The times have changed, and the modern technology has enabled us to sequence virus and come up with new formulations and vaccines, that are being tested and are due to be launched very soon.

However, the recent developments in the field of vaccine development have mostly relied on the traditional methods of development of live attenuated vaccines for immunity and polypeptide for development of new vaccines. Keeping this in mind it should also be noted that there are several key common proteins between SARS-CoV, MERS-CoV and SARS-CoV-2 that may serve as drug targets as the protein share similar sequence, such as coronavirus main protease, spike glycoprotein (S protein) etc. Therefore, many countries including India is trying to treat COVID 19 with New Use of a Known Compounds such as Sepsivac a leprosy drug, Favipiravir an antiviral drug to treat influenza, Interferon, the antiviral, which can boost immune response against pathogens etc.. Hence, it can be safely concluded that strategies adopted by the development of vaccines in SARS and MERS could also use in the development of COVID-19 vaccines, and patented as elucidated the recent grants of patent covering mRNA based protein in US.