Saving the World with Patents:
Is the TRIPS Waiver helping or hurting innovation?

June 15, 2021

**Technology Relevance™**
- Worldwide citations received from later patents, adjusted for age, patent office practices and technology field
- Average value: 1

**Market Coverage™**
- Market size protected by active patents and pending patent applications on a certain invention
- Value of granted US patent: 1

**Competitive Impact™**
- (Individual patent strength)
- The relative business value of a patent family

**Patent Asset Index™**
- Innovative strength of a company or portfolio (ability to achieve competitive advantage)!
Today’s speakers

Brian Arthur Pomper
Akin Gump

Melissa Brand
Biotechnology Innovation Organization (BIO)

Dr Sarbani Chattopadhyay
LexisNexis PatentSight

Gene Quinn
IPWatchdog
Vaccine

• A substance used to stimulate the production of antibodies and provide immunity against one or several diseases, prepared from the causative agent of a disease, its products, or a synthetic substitute, treated to act as an antigen without inducing the disease

• Prophylactic vaccines are for prevention of disease

https://medlineplus.gov/ency/article/002024.htm
Overview of the Field
A zoonosis is an infectious disease that has jumped from a non-human animal to humans. Zoonotic pathogens may be bacterial, viral or parasitic, or may involve unconventional agents and can spread to humans through direct contact or through food, water or the environment. (WHO)
Top 20 companies, as per PatentSight®, in the field of antivirals related to Corona virus family and related virus families (broad overview)
Coronaviridae family

Subunit vaccine (optional: with adjuvants)

Vector based vaccine

Conjugate vaccine

Nucleic acid vaccine

Inactivated vaccine

Source: WHO: https://www.who.int/health-topics/coronavirus#tab=tab_1
Compositions against sars-coronavirus and uses thereof

The present invention provides compositions of binding molecules specifically binding to a coronavirus such as SARS-CoV and capable of neutralizing an infection caused by the virus. The compositions are suitable for diagnosing, preventing and/or treating a condition resulting from a coronavirus such as SARS-CoV. (Source: EP1812067.A1, equivalent)
Settings for recombinant adenoviral-based vaccines

The present invention provides new uses of recombinant adenoviral vectors in vaccination regimens, such as prime/boost set-ups and subsequent vaccinations and applications for gene therapy. Moreover, the invention provides new assays to determine the best regimen for applying the most suitable recombinant viral vector in a vaccination or gene ther...

1. An improvement in a method of delivering a nucleic acid sequence of interest to a subject using an adenoviral delivery vehicle, the method comprising:

   administering to the subject a recombinant adenovirus vector of a first serotype having a nucleic acid sequence of interest, wherein the first serotype is selected from the group consisting of A511, A252, A504, A635, A645, and A649; and

   administering to the subject, subsequent to administering the recombinant adenovirus vector of the first serotype, a recombinant adenovirus vector of a second serotype having a nucleic acid sequence of interest, wherein the second serotype is different from the first serotype.

6. The method according to claim 5 wherein the viral antigen is selected from the group consisting of an Ebola virus antigen, a measles virus antigen, and a West Nile virus antigen.
Background document on the Janssen Ad26.COV2.S (COVID-19) vaccine

Background document to the WHO Interim recommendations for use of Ad26.COV2.S (COVID-19) vaccine
17 March 2021


The Janssen COVID-19 Vaccine is a replication-incompetent adenovirus type 26 (Ad26)-vectorized monovalent vaccine encoding the SARS-CoV-2 spike (S) protein from the Wuhan-Hu-1 isolate (GenBank accession number MN908947), stabilized in its prefusion conformation. The vector cannot replicate in human cells because the E1 gene was deleted from the genome. To manufacture vaccines that are based on replication incompetent adenoviral vectors, a specific cell line is used that complements the missing E1 gene. This cell line is derived from a single human primary cell, obtained in 1985 from fetal retina tissue (at 18 weeks of gestation adhering to the Dutch laws that were in effect). The cell line was established by transformation of the primary cells using the Adenovirus E1 gene which resulted in a cell line that constitutively expresses E1, and that is thus able to complement the adenoviral vector that misses E1, allowing the vector to replicate during the manufacturing process. Another consequence of the E1 transformation is that the cell line can be propagated indefinitely and as a result, there is no need to go back to the primary cells in any part of the scientific discovery or manufacturing process. The Ad26 vector expressing the S protein is grown in PER.C6G TetR cell line, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.
Novavax


- Immunogenic middle east respiratory syndrome coronavirus (mers-cov) compositions and methods

Novavax

Discovered herein are nanoparticles containing MERS virus proteins in polymer structures, and compositions containing the nanoparticles formulated for administration as immunogenic compositions. Also provided herein are vectors constructs encoding the proteins, and host cells containing the vector constructs. The disclosure also includes methods of making the nanoparticles and administering them to vertebrates, including methods of inducing immune responses to MERS that reduce or prevent infection by the virus. (Source: EP046579.A1, equivalent)

No drawing available.

Inventors: Gale Smith, Liu Ye, Massare Michael

Applicant: Novavax Inc.
Immunogenic middle east respiratory syndrome coronavirus (MERS-CoV) compositions and methods

Disclosed herein are nanoparticles containing MERS virus proteins in polymer structures, and compositions containing the nanoparticles formulated for administration as immunogenic compositions. Also provided herein are vector constructs encoding the proteins, and host cells containing the vector constructs. The disclosure also includes methods of making the nanoparticles and administering them to vertebrates, including methods of inducing immune responses to MERS that reduce or prevent infection ...

Source: original

Abstract

1. An immunogenic composition comprising

(i) a MERS-CoV nanoparticle, wherein the nanoparticle comprises a MERS CoV antigen, wherein the antigen consists of baculovirus Spike polyepitope in trimer form, and wherein the Spike polyepitope is the only polyepitope in the nanoparticle, and

(ii) an adjuvant, wherein the adjuvant consists of two ISCOM matrix particle types wherein the first particle type comprises a lipid from Quillaja Saponaria Molina, and the second particle type comprises a lipid and saponin Fraction C from Quillaja Saponaria Molina;

wherein the composition is capable of inducing neutralizing antibodies against MERS-CoV.

Matrix-M™ adjuvant

Induces the influx of antigen-presenting cells (APC), which enhance activated T cell, B cell, and APC populations.

https://www.novavax.com/our-unique-technology
Novavax to Present at International Society for Vaccines Virtual Congress COVID-19 Vaccine Update

Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial

Jan 28, 2021 at 4:05 PM EST

First to Demonstrate Clinical Efficacy Against COVID-19 and Both UK and South Africa Variants

coronavirus spike (S) protein and is adjuvanted with Novavax' patented saponin-based Matrix-M™ to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.
Family of US2013216566.A1 et al.

Vectors expressing SARS immunogens, compositions containing such vectors or expression products thereof, methods and assay...

Sanofi

First filing in family 6/21/2004
First publication in family 3/10/2005

SARS (severe acute respiratory syndrome virus, a coronavirus) immunogens, antigens, or epitopes, nucleic acid molecules encoding such immunogens, antigens, or epitopes; vectors containing such nucleic acid molecules, e.g., viral vectors such as baculovirus vectors, DNA vectors, such as DNA plasmid vectors, e.g., DNA plasmids that express a nucleic acid molecule in a mammalian cell, uses for such immunogens, antigens or epitopes and vectors, e.g., as an active component immunogenic, immunological or vaccine compositions, or to generate antibodies, such as monoclonal antibodies, and methods for making, and using such immunogens, antigens or epitopes, vectors, antibodies, including in methods for eliciting an immunological or immunogenic or vaccine response, as well as i...
GlaxoSmithKline
Use of an influenza virus and an oil-in-water emulsion adjuvant to induce CD4 T-cell and/or improved B-memory cell response

GlaxoSmithKline

The present invention relates to influenza vaccine formulations and vaccination regimes for immunising against influenza disease, their use in medicine, in particular their use in augmenting immune responses to various antigens, and to methods of preparation. In particular, the invention relates to multivalent influenza immunogenic compositions comprising an influenza antigen or antigenic preparation thereof from at least two influenza virus strains, at least one strain being associated with a pandemic outbreak or having the potential to be associated with a pandemic outbreak, in combination with an oil-in-water emulsion adjuvant. (Source: EP1861120.A1, equivalent)
USE OF AN INFLUENZA VIRUS AND AN OIL-IN-WATER EMULSION ADJUVANT TO INDUCE CD...

The present invention relates to influenza vaccine formulations and vaccination regimes for immunising against influenza disease, their use in medicine, in particular their use in augmenting immune responses to various antigens, and to methods of preparation. In particular, the invention relates to multivalent influenza immunogenic compositions Co...

Source: equivalent

AS03

AS03 (for "Adjuvant System 03") is the trade name for a squalene-based immunologic adjuvant used in various vaccine products by GlaxoSmithKline (GSK). It is used, for example, in GSK's AH1N1 pandemic flu vaccine Pandemrix. It is also in Arepanrix and the Q-pran for H5N1 influenza [1]

A dose of AS03 adjuvant contains [2]

- 10.69 mg squalene
- 11.86 mg DL-α-tocopherol
- 4.86 mg polysorbate 80

In the 2009 influenza pandemic, vaccines containing AS03 delivered a stronger immunogenic response against pandemic H1N1 influenza than non-adjuvanted vaccines, despite their containing lower levels of viral antigen. [3]
Summary

Background

CoV2 preS dTM is a stabilised pre-fusion spike protein vaccine produced in a baculovirus expression system being developed against SARS-CoV-2. We present interim safety and immunogenicity results of the first-in-human study of the CoV2 preS dTM vaccine with two different adjuvant formulations.

Methods

This phase 1–2, randomised, double-blind study is being done in healthy, SARS-CoV-2-seronegative adults in ten clinical research centres in the USA. Participants were stratified by age (18–49 years and ≥50 years) and randomly assigned using an interactive response technology system with block randomisation (blocks of varying size) to receive one dose (on day 1) or two doses (on days 1 and 22) of placebo or candidate vaccine, containing low-dose (effective dose 1·3 μg) or high-dose (2·6 μg) antigen with adjuvant AF03 (Sanofi Pasteur) or AS03 (GlaxoSmithKline) or unadjuvanted high-dose antigen (18–49 years only). Primary endpoints were safety, assessed up to day 43, and immunogenicity, measured as SARS-CoV-2 neutralising antibodies (geometric mean titres), assessed on days 1, 22, and 36 serum samples. Safety was assessed according to treatment received in the safety analysis set, which included all randomly assigned participants who received at least one dose. Neutralising antibody titres were assessed in the per-protocol analysis set for immunogenicity, which included participants who received at least one dose, met all inclusion and exclusion criteria, had no protocol deviation, had negative results in the neutralisation test at baseline, and had at least one valid post-dose serology sample. This planned interim analysis reports data up to 43 days after the first vaccination; participants in the trial will be followed up for 12 months after the last study injection. This trial is registered with ClinicalTrials.gov, NCT04537208, and is ongoing.
mRNA Based Vaccines
mRNA Based Vaccines
Thank you.

www.patentsight.com

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Appendix
Other Entities with Know How
Focused Search for Patents Regarding *Coronaviridae* Spike Protein

Keywords specific to Spike proteins searched in Title and/or Abstract in combination with related IPC/CPC classes.
Orangutans and bonobos at US zoo get experimental COVID-19 vaccine

March 04, 2021

Nine great apes at the San Diego Zoo are the first non-human primates to receive an experimental COVID-19 vaccine.

In February, four orangutans and five bonobos at the zoo each received two doses of the vaccine, which was developed by the veterinary pharmaceutical company Zoetis, according to National Geographic.

The zoo reached out to Zoetis after several of the gorillas at their safari park tested positive for COVID-19 in January, and the company responded by providing a small supply of their vaccine, according to a statement from Zoetis.

The vaccine is still experimental and hasn’t yet been approved for use in animals in the US.