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Analysis of COVID-Related Patents for Antibodies and Vaccines

Kausalya Santhanam

SOUTH CENTRE

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173

ANALYSIS OF COVID-RELATED PATENTS FOR ANTIBODIES AND VACCINES

Kausalya Santhanam*

SOUTH CENTRE

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* Kausalya Santhanam is an Independent Consultant based in India.

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South Centre
International Environment House 2
Chemin de Balexert 7–9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

This paper provides an analysis of patents covering selected antibodies and vaccines used in the treatment or prevention of COVID-19. The aim of the report is to support national patent offices and interested parties in developing countries with information that can serve as guidance for the examination of the claims contained in relevant patents or patent applications. The antibody combination considered for the patent analysis in this paper are Casirivimab and Imdevimab. The vaccines considered for the patent analysis are mRNA-1273, Sputnik, ChAdOx1 nCoV-19 vaccine (AZD1222). The analysis was completed in May 2022.

Este documento proporciona un análisis de algunas patentes que cubren anticuerpos y vacunas utilizados en el tratamiento o la prevención de la COVID-19. El objetivo del informe es apoyar a las oficinas nacionales de patentes y a las partes interesadas de los países en desarrollo con información que pueda servir de orientación para el examen de las reivindicaciones contenidas en las patentes o solicitudes de patentes pertinentes. La combinación de anticuerpos considerada para el análisis de patentes en este documento son Casirivimab e Imdevimab. Las vacunas consideradas para el análisis de patentes son ARNm-1273, Sputnik, vacuna ChAdOx1 nCoV-19 (AZD1222). Este análisis finalizó en mayo de 2022.

Ce document fournit une analyse des brevets couvrant une sélection d'anticorps et de vaccins utilisés dans le traitement ou la prévention du COVID-19. L'objectif de ce rapport est de fournir aux offices nationaux des brevets et aux parties intéressées dans les pays en développement des informations pouvant servir de guide pour l'examen des revendications contenues dans les brevets ou les demandes de brevets pertinents. Les combinaisons d'anticorps considérées pour l'analyse des brevets dans ce document sont le Casirivimab et l'Imdevimab. Les vaccins pris en compte pour l'analyse des brevets sont le mRNA-1273, le Sputnik, le vaccin ChAdOx1 nCoV-19 (AZD1222). Cette analyse a été achevée en mai 2022.

TABLE OF CONTENTS

1. CASIRIVIMAB AND IMDEVIMAB ANTIBODY COMBINATION 1
2. MRNA VACCINE: MRNA-1273 5
3. SPUTNIK VACCINE 9
4. CHADOX1 NCOV-19 VACCINE (AZD1222) 12

1. CASIRIVIMAB AND IMDEVIMAB ANTIBODY COMBINATION

Background

The Casirivimab and imdevimab antibody combination received an emergency use authorization for treatment of COVID-19 from the FDA in November 2020 and is generically referred to as REGEN-COV2. Apart from the United States (US), the combination is either under trials or authorized in the United Kingdom, Japan, India and European Union.

US10787501 Family (Assignee: Regeneron Pharma)
Estimated Expiry: 25 June 2040

The patent disclosure provides recombinant antibodies and antigen-binding fragments that specifically bind to coronavirus spike proteins.

The claims provide an isolated antibody or antigen-binding fragment thereof that binds a SARS-CoV-2 spike protein comprising the amino acid sequence set forth by a specific protein sequence (SEQ ID NO. 832) comprising three heavy chain complementarity determining regions (CDRs) (HCDR1, HCDR2 and HCDR3) contained within a heavy chain variable region defined by specific protein sequence (SEQ ID NO. 202) and three light chain complementarity determining regions (CDRs) (LCDR1, LCDR2 and LCDR3) contained within a light chain variable region (LCVR) comprising the amino acid sequence set forth by specific protein sequence (SEQ ID NO. 210).

A second therapeutic agent which is a second antibody or an antigen-binding fragment thereof, that binds a SARS-CoV-2 spike protein comprising the amino acid sequence set forth in SEQ ID NO: 832 is also claimed.

The second antibody or antigen-binding fragment is defined by three heavy chain CDRs (HCDR1, HCDR2 and HCDR3) containing within an HCVR comprising the amino acid sequence set forth in SEQ ID NO: 640, and three light chain CDRs (LCDR1, LCDR2 and LCDR3) containing within an LCVR comprising the amino acid sequence set forth in SEQ ID NO: 646.

The above patent covers the combination of casirivimab and imdevimab antibody cocktail.

US10975139
Estimated Expiry: 25 June 2040

This patent claims the polynucleotide encoding the antibody, HCDRs and the LCDRs that are claimed in **US10787501**.

US10954289
Estimated Expiry: 25 June 2040

The patent disclosure provides recombinant antibodies and antigen-binding fragments that specifically bind to coronavirus spike proteins.

The patent provides a vector comprising a polynucleotide encoding a heavy chain variable region (HCVR) of an antibody or antigen-binding fragment thereof that binds a SARS-CoV-2 spike protein comprising the amino acid sequence set forth by a specific protein sequence (SEQ ID NO: 832), wherein said HCVR comprises three heavy chain complementarity determining regions (CDRs) (HCDR1, HCDR2 and HCDR3), wherein said HCDR1 comprises the amino acid sequence set forth by a specific protein sequence (SEQ ID NO: 680), said HCDR2 comprises the amino acid sequence set forth by a specific sequence (SEQ ID NO: 682), and said HCDR3 comprises the amino acid sequence set forth by a specific protein sequence (SEQ ID NO: 684).

Similarly, a vector comprising a polynucleotide encoding a light chain variable (LCVR) of an antibody with specific sequence is also claimed

The patent also claims a lipid nanoparticle comprising a polynucleotide encoding a light chain variable region (LCVR) of an antibody or antigen-binding fragment thereof that binds a SARS-CoV-2 spike protein comprising specific amino acid sequence.

The polynucleotide in the above claims can either be a DNA or an RNA.

This patent does not particularly cover the drug.

Patent Summary:

Substantive (Related to patent grants)

- The PCT application WO2021045836 consists of a total of 80 claims and broadly covers isolated antibody or antigen-binding fragment thereof that binds a SARS-CoV-2 spike protein comprising the amino acid sequence set forth in SEQ ID NO: 832 comprising 3 heavy chain complementarity determining regions (CDRs) contained within a heavy chain variable region (HCVR) comprising the amino acid sequence set forth in SEQ ID NO: 202, and three light chain complementarity determining regions (CDRs) (LCDR1, LCDR2 and LCDR3) contained within a light chain variable region (LCVR) comprising the amino acid sequence set forth in SEQ ID NO: 210. There are also claims to the above antibody and a second therapeutic agent. The second therapeutic agent is an antimalarial agent (chloroquine or hydroxychloroquine) or anti-inflammatory agent which is an antibody (sarilumab, tocilizumab, or gimsilumab) or specific proteins defined by SEQ ID NO.s (Table 2 provides exemplary antibody combinations).
- A method of treating or preventing coronavirus is claimed and the said coronavirus is selected from the group consisting of SARS-CoV-2, SARS-CoV, and MERS-CoV.
- All the patents filed so far are likely to expire by June 2040. US10787501 may have patent term extension (PTE) once the regulatory approvals come through.
- While data (enablement) is provided with regard to the working of claimed antibodies, there is no convincing data with regard to combinations although combination claims are granted in the US (US10954289)

Timeline and other details

- Considering that the first application (Provisional) in this family was filed in the US in Apr 2020 and the Utility (complete) application was filed on 25 June 2020, the patent grant was fast-tracked for issuance by September 2020.

- It is noted that a PCT application is on record filed on 25 June 2020 and has entered the National Phase in many countries before the 30 or 31 months deadline. These countries include Argentina, India, Israel, New Zealand, Columbia, Singapore, Canada, Mexico, EA (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russian Federation, Tajikistan, Turkmenistan), Brazil, Chile, Indonesia, Thailand, South Africa and Australia.
- It is interesting to note that Regeneron/Roche have not entered the EU yet. But it could also be in a grey period where the application has entered EU but is yet to be published.
- The National Phase entry deadline runs till Oct/Nov 2022 and thus there is plenty of time for the Applicant to enter any PCT signatory countries including EU.
- Roche is collaborating with Regeneron for global supply of REGEN-COV2 (Ex: In India, Roche is collaborating with Cipla for production).
- Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") has filed suits alleging patent infringement by three companies racing to develop COVID-19 countermeasures. Regeneron, Pfizer, and BioNTech are each charged with directly infringing on U.S. Patent No. 10,221,221, assigned to Allele. The patent covers monomeric fluorescent proteins, coined "mNeonGreen," that are "among the brightest known in [their] class and have exceptional utility as a biomarker and/or protein fusion tag."
- According to Allele's complaint filed in the Southern District of New York, Regeneron used mNeonGreen while creating its COVID-19 "antibody cocktail,"
- Allele's suit however is not directly concerned with Regeneron's combination patents in any way.

Notes on Patentability

Analysis of the specification

- The granted patent **US10787501** is taken as a reference to examine patentability issues.
- Antibody claims (claims 1-14).
- Antibodies can be claimed as:
- antibody itself, compositions containing one or more antibodies, methods of generating the antibody (process) and/or therapeutic use of an antibody depending on the jurisdiction
- For patentability purposes, an antibody may be claimed as **(a) specifically referring to an antigen-binding region or (b) by providing the specific sequences of heavy chain and light chain domains or (c) as a hybridoma cell line, in order to get grant on the composition. While these are some possibilities to define an antibody, it should be noted that these should be substantiated by written description as well as enablement for grant of the claims.**
- The above patent from Regeneron defines an antibody by complementarity determining regions (CDRs). By this, it means that specific heavy chain complementarity determining regions, for example HCDR1, 2, 3 contained within a heavy chain variable region set forth by SEQ ID NO. 202 is claimed. Similarly, three light chain complementarity determining regions contained within a light chain variable region (LCVR) set forth by SEQ ID NO. 210 is claimed.
- This is one of the ways of defining an antibody which is **precise/specific and passes the inventiveness step requirement of patentability** which is a higher bar for protein drug invention as against novelty.
- This is however, **specific and thus narrow** as compared to defining an antibody only by an antigen or an epitope.

- The **written description** herein is satisfied primarily by the elucidation of CDR-H1, CDR-H2, and CDR-H3 and CDR-L1, CDR-L2, and CDR-L3 given in Table 4.
- The broadest antibody claim is **enabled** by characterization of hybridoma supernatants (Example 3) and binding of the antibody to SARS-CoV-2-S virus (Example 4). Further characterization has been done via antibody dependent cell mediated toxicity (ADCC) assay (Example 6). In addition, structure determination of antibody-bound spike protein is done in Example 16 which adds more credibility to the patentability of the composition, that is, the antibody.

Combination Claims

- A **second therapeutic agent** is claimed as a dependent claim from claims 14-20. Claim 15 provides that the second therapeutic agent is an anti-inflammatory agent or an antimalarial agent. There are no working examples to establish the synergy of the antibody (of claim 1 to 14) and a second therapeutic agent which is either an inflammatory agent or an antimalarial agent. Thus, this claim is not enabled.
- While a list of antibody combinations is claimed, only Figures 10A and 10B present results of neutralization capacity of antibody combinations. It is also intriguing that **there is no synergistic neutralization activity in the combinations** (Figure 10B).
- **The combination claims fulfill written description requirement but are shaky on the grounds of enablement requirements. Thus, it can be deduced that the application, at the outset, should be rejected.**

It is emphasized that while analyzing a protein drug (biotech patent applications), it is not only important to check for novelty and inventive step of the composition, but it is also equally important to check whether every claim is (a) adequately described in the disclosure and (b) supported in the form of data.

In this context, the following case laws in the last decade throw some light on the Written Description requirement:

Antibody genus is often claimed with reference to functional characteristics (binding affinities or binding locations or blocking ability). But to adequately support a genus claim, a patent must disclose either a representative number of species, or structural features common to all members of the genus. *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.,* 759 F.3d 1285, 1299 (Fed. Cir. 2014). Else, the genus claim should be rejected.

Similarly, in *Nuvo Pharmaceuticals v. Dr. Reddy's Laboratories*, 923 F.3d 1368 (Fed. Cir. 2019) a patent for a non-steroidal anti-inflammatory drug was invalidated as "effective amount to raise the gastric pH of [a] patient to at least 3.5" was not adequately described to establish possession.

Lack of written description was upheld in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc*., 941 F.3d 1149, 1153 (Fed. Cir. 2019) with regard to Hepatitis C drug.

2. mRNA Vaccine: mRNA-1273

Background

The mRNA-1273 vaccine is a lipid nanoparticle–encapsulated mRNA-based vaccine that encodes the prefusion stabilized full-length spike protein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes Covid-19. Some of the Companies that have developed lipid nanoparticle encapsulated mRNA-based vaccine includes Moderna Therapeutics, Acuitas Therapeutics Inc., The Trustees of the University of Pennsylvania/National Institutes Of Health (NIH), the U.S. Department of Health and Human Services (DHHS), U.S. Government.

Relevant Patent applications filed after 2015

1) WO2017070626 (Assignee: Moderna Therapeutics, 16 family members)
National phase entry into AR (ABD), EP, Taiwan and the United States
Granted patents in the US: US10702600, 10702599, 10272150, 10064934)
Application pending in EP (EP3364984)
Estimated Expiry: 21 October 2036
Analyzed patent US10702600

The patent family provides respiratory virus ribonucleic acid (RNA) vaccines and combination vaccines.

Claims: The patent claims a composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.

Claim 1 is very broad that claims the mRNA comprising ORF encoding BetaCoV S protein or its subunit formulated in a lipid nanoparticle.

The dependent claims provide other known aspects. Claim 8 provides that the mRNA comprises a chemical modification which a 1-methylpseudouridine modification or a 1-ethylpseudouridine modification (claim 9).

Claims 16 and 24 are specific independent claims establishing the mRNA + lipid nanoparticle. Claim 16 describes the specific mRNA encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle that comprises 20-60% ionizable cationic lipid, 5-25% neutral lipid, 25-55% cholesterol, and 0.5-15% PEG-modified lipid.

Claim 24 further provides the actual structure of the lipid nanoparticle as compound 25. This limits the formulation to just compound 25 and not a total of 233 lipid nanoparticles whose structures are provided in the specification.

Notes on Patentability

- Many embodiments are provided (from 1-97) that describe too many permutations and combinations. This does not necessarily mean that they are enabled.
- For each of the independent claims in the application, other than applying the patentability test of novelty and inventive step, it is important to check for adequacy of

enablement. Most often, the application may satisfy the extrinsic patentability criteria (novelty and inventive step) but may lack the application requirements of written description and enablement.
- Patent offices to take note of enablement requirement and go with claims that provide actual formulation with defined specifics which are substantiated with data points to support the said formulation.

2. WO2015164674 (Assignee: Moderna Therapeutics, 22 family members)
National phase entry into AU, BR, CA, CN, EP, IN, JP, RU, SG & US
Granted patents in the US: US10709779, US 9,872,900, US 10,022,435
Granted in Russia RU2746406
Estimated Expiry: 23 October 2035

This application claims a nucleic acid vaccine, comprising: one or more messenger RNA (mRNA) polynucleotides having an open reading frame encoding an antigenic polypeptide, and a cationic lipid nanoparticle having a molar ratio of 20-60% cationic lipid: 5-25% non-cationic lipid: 25-55% sterol; and 0.5-15% PEG-modified lipid.

The subject matter is mainly on a generic nucleic acid (DNA) vaccine formulated as a cationic lipid nanoparticle. However, the dependent claims indicate that the encoding antigenic polypeptide is specific for influenza virus.

In EP the related application **EP3134131** is in condition for allowance (July 2021, intention to grant). But it is pertinent to note that the applicants have restricted the antigenic polypeptide to strain of Influenza A and B or combinations but there is no mention of coronavirus.

IN201617039870 (pending Indian patent application with the same subject matter)

The Indian application claiming a nucleic acid vaccine, comprising: one or more messenger RNA (mRNA) polynucleotides having an open reading frame encoding an antigenic polypeptide, and a cationic lipid nanoparticle having a molar ratio of 20-60% cationic lipid: 5-25% non-cationic lipid: 25-55% sterol; and 0.5-15% PEG-modified lipid and a total of 54 claims is currently (as of 26/10/2021) opposed (under pre-grant opposition) by Indian Pharmaceutical alliance.

The claims are opposed under all grounds given in Sec 25(1)(a-k) (grounds for pre-grant opposition) of The Indian Patent Act.

Based on the Patent Application disclosure and the prior art, the claims will be restricted to specific antigenic polypeptide. It is also important to note, once the claims are restricted the patent will have no relevance to coronavirus vaccine.

Notes on Patentability

- The broadest claim talks only about a generic nucleic acid (DNA) vaccine formulated as a cationic lipid nanoparticle. This means, once granted, it can be used for formulating any nucleic acid molecule.
- During examination, it is imperative to limit the claim to a single or a group of related nucleic acid (DNA) vaccine so as to restrict the applicant claim monopoly for any number of unrelated vaccines.
- For now, the to-be-granted European application **EP3134131 examination should serve as a guideline for this application.**

3. WO2017099823 (Assignee: Moderna Therapeutics, 11 family members)
National phase entry into AU, CA, EP, JP & US
Estimated Expiry: 10 December 2036
Analyzed patent US10207010

The patent claims a lipid nanoparticle (LNP) comprising a PEG-lipid, an ionizable lipid that is an ionizable amino lipid, a helper lipid, and a structural lipid, wherein the PEG-lipid comprises a

compound of Formula (V): or a pharmaceutically acceptable salt thereof, wherein: R^3 is —OR^O ; R^O is hydrogen, optionally substituted alkyl or an oxygen protecting group; r is an integer between 1 and 100, inclusive; and R^5 is optionally substituted C_{10-40} alkyl; and wherein the ionizable amino lipid has the structure of compound 18: or a pharmaceutically acceptable salt thereof.

US10556018, US10485885, EP 3386484A

The US granted patent provides a method for delivering a therapeutic level of a protein of interest to a subject, the method comprising: administering to the subject at least two doses of lipid nanoparticles (LNPs) comprising an mRNA coding for the protein of interest, wherein the LNPs comprise an ionizable lipid, a helper lipid, a structural lipid, and a PEG-lipid, wherein

the PEG-lipid is a compound of Formula (V—OH): or a pharmaceutically acceptable salt thereof, wherein: r is an integer between 1 and 100, inclusive; and R^5 is optionally substituted C_{10-40} alkyl; and wherein said LNPs result in a reduced anti-PEG IgM response in the subject as compared to LNPs lacking a PEG-lipid of Formula (V—OH).

Notes on Patentability

The patent application most likely will not be granted in developing countries as a method of delivery as a stand-alone claim is not a patentable subject matter in many countries including India.

4. WO2021030701 (Acuitas Therapeutics, Inc) (due for entry into National Phase by 14/2/2022)
Estimated Expiry: 14 August 2040

The application provides a method for delivering a nucleic acid to a primate in need thereof, comprising administering a lipid nanoparticle (LNP) to the primate, the LNP comprising: i) a nucleic acid, or a pharmaceutically acceptable salt thereof, encapsulated within the LNP; ii) a cationic lipid; iii) a neutral lipid; iv) a steroid; and v) a polymer-conjugated lipid, wherein a plurality of the LNPs has a mean particle diameter ranging from 40 nm to 70 nm.

There are several embodiments with regards to the cationic lipids, neutral lipids, steroids and polymer-conjugated lipid.

Notes on Patentability

The method of delivering or administering a LNP comprising i) a nucleic acid, or a pharmaceutically acceptable salt thereof, encapsulated within the LNP; ii) a cationic lipid; iii) a neutral lipid; iv) a steroid; and v) a polymer-conjugated lipid is claimed.

The method of delivery of LNP as such is not inventive unless the said combination provided and supported by data is found inventive.

It is to be noted that there are six examples. Preparation of lipid nanoparticle is supported by reference and brief description. For all the embodiments that are claimed, it is important to check whether there is supportive data. This would help in establishing enablement.

Also, to be noted, that a “method of delivery” claim as such is not an allowable subject matter in a developing country like India.

Summary

Four families are analyzed for m-RNA vaccine-related patent applications/patents (m-RNA 1273). Although there are many more family members provided,, the above four families have either entered or possibly could enter developing countries in the National Phase.

3. SPUTNIK VACCINE

Background

The Sputnik V (Gam-COVID-Vac) vaccine is an adenoviral-based, two-part vaccine against the SARS-CoV-2 coronavirus. Initially produced in Russia, Sputnik V uses a weakened virus to deliver small parts of a pathogen and stimulate an immune response.

It is a vector vaccine based on adenovirus DNA, in which the SARS-CoV-2 coronavirus gene is integrated.

Relevant Patent applications/patents
1) WO2021/002776 (Assignee: FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY)
Estimated Expiry: 13 July 2040

There are a total of 10 claims out of which claims 1-6 are composition claims and claims 7-10 are Method (process) claims.

Claim 1 provides an immunobiological agent for the prevention of diseases caused by severe acute respiratory syndrome virus SARS-CoV-2 based on recombinant human adenovirus serotype 5 or recombinant human adenovirus serotype 26, containing optimized for the expression in mammalian cells the sequence of S protective antigen of the SARS-CoV-2 virus with gene C'-terminal deletion of 18 amino acids (SEQ ID NO:2).

Claim 2 provides all of claim 1 but with SEQ ID NO: 3 (in place of SEQ ID NO: 2) which is human IgGl Fc-fragment sequence.

Claim 3 provides similar elements as claim 1 containing the expression in mammalian cells the SARS-CoV-2 virus S protein receptor-binding domain sequence with the viral leader peptide sequence (SEQ ID NO:4).

Claim 4 provides similar elements as claim 1 containing the expression in mammalian cells the SARS-CoV-2 virus protein S receptor-binding domain sequence with the transmembrane domain of vesicular stomatitis virus glycoprotein (SEQ ID NO:5).

Claim 5 provides an Immunobiological agent for the prevention of diseases caused by the severe acute respiratory syndrome (SARS-CoV-2) virus based on recombinant human adenovirus serotype 5, or recombinant human adenovirus serotype 26, containing optimized for the expression in mammalian cells the SARS-CoV-2 virus S protein receptor-binding domain sequence with the leader peptide sequence and the human IgGl Fc-fragment sequence (SEQ ID NO:6).

The application entered National Phase in Eurasian Patent Office (EA) and was granted in June 2021. It was granted in Russia in February 2021.

The following countries are covered under EA: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan.

Notes on Patentability

- The subject matter was carved out post COVID-19 pandemic and thus is specific for providing immunity (vaccination) against SARS-CoV-2.
- As seen in the claims, the immunological agent is developed against recombinant human adenovirus serotype 5 or 26 by expression of S protective antigen of SARS-CoV-2 virus with gene C' – terminal deletion of 18 amino acids (SEQ ID NO: 2).
- Also provided in the claims are combinations of the adenovirus serotype 5 or 26 with SEQ ID NO: 3, 4, 5 or 6.
- While adenoviral based vaccines are known in the art, the specific combinations of serotypes bring novelty to the invention.
- Similarly, unique and specific combination of serotype 5 or 26 with specific sequences establish inventive step. These compositions are also supported by data.
- Thus, novelty and inventive steps are established by specific serotypes and also by deletion.
- Written description is satisfied by providing the sequences.
- The claims are enabled as the effectiveness of the immunization with the immunological agent of the invention is provided by Fig. 1 to Fig. 5 (animal studies).

2) WO2021/076010 (Assignee: FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY)
Estimated Expiry: 9 November 2040

The patent application provides claims for a pharmaceutical agent for the induction of specific immunity against severe acute respiratory syndrome virus SARS-CoV-2, which contains component 1, comprising an agent in the form of expression vector based on a genome of recombinant human adenovirus serotype 26, wherein the E1 and E3 regions are deleted from the genome and the ORF6-Ad26 region replaced by ORF6-Ad5, with a placed expression cassette selected from SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, and which also contains component 2, comprising an agent in the form of expression vector based on a genome of recombinant human adenovirus serotype 5, wherein the E1 and E3 regions are deleted from the genome, with a placed expression cassette selected from SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3.

Furthermore, the claims also cover the liquid or lyophilized (freeze-dried) formulation of the pharmaceutical agent.

The liquid formulation contains, mass percentage of: tris from 0.1831 to 0.3432 sodium chloride from 0.3313 to 0.6212 sucrose from 3.7821 to 7.0915 magnesium chloride hexahydrate from 0.0154 to 0.0289 EDTA from 0.0029 to 0.0054 Polysorbate-80 from 0.0378 to 0.0709 ethanol 95% from 0.0004 to 0.0007 water in the remaining part.

The lyophilized (freeze-dried) formulation contains, mass %: tris from 0.0180 to 0.0338 sodium chloride from 0.1044 to 0.1957 sucrose from 5.4688 to 10.2539 magnesium chloride hexahydrate from 0.0015 to 0.0028 EDTA from 0.0003 to 0.0005 Polysorbate-80 from 0.0037 to 0.0070 water the remaining part.

The patent is granted in Russia since September 2020.

The patent is granted in the following countries covered under the Eurasian Patent Office (EA) since March 2021: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan.

Notes on Patentability

- The subject matter was carved out post COVID-19 pandemic and thus is specific for providing immunity (vaccination) against SARS-CoV-2).
- The composition claims 1-3 which claim the pharmaceutical agent is very specific and has limitations that will render novelty as well as inventive step.
- The expression cassette is provided in Figure 1 satisfying written description and enablement (since it is known in the art on how to make the expression cassette once the specific target and promoter genes are given)
- The working of the pharmaceutical agent is provided in Figures 2–15 (proliferation experiment and more). Herein the liquid and lyophilized formulations are used (satisfying enablement for the formulations).
- Formulations claims are specific as the amount of excipients are clearly indicated. Thus, the formulation claims are narrow but will pass the novelty test. Inventiveness is always an issue for formulation.
- While some countries are generous in granting formulation claims, it is important to adhere to and evaluate the inventive step, have discussions with the inventor/agent before granting such formulation claims.

3) WO2021/076009 (Assignee: FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY)
Estimated Expiry: 6 November 2040

The application claims expression vector containing the genome of recombinant human adenovirus serotype 26, wherein the E1 and E3 regions are deleted, and the ORF6-Ad26 region is replaced by ORF6- Ad5, with an integrated expression cassette selected from SEQ ID NO:l, SEQ ID NO:2, SEQ ID NO:3.

There is one method of use claim that claims the use of the said vector for creating an immunobiological agent for the induction of specific immunity against severe acute respiratory syndrome virus SARS-CoV-2.

The patent is granted in Russia.

The patent is granted in the following countries covered under EA as of Mar 2021: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan.

Notes on Patentability

- Since the vector is linked to the expression cassette as defined by the specific sequences designated as SEQ ID NO: 1, 2 and 3, it is not difficult to establish novelty and inventive step. This is supported by the view that linking a vector to specific expression cassette (hitherto unknown) designated by sequence IDs will render novelty. The inventive step herein, is supported by data as provided below.
- Production of the expression vector containing the genome of the adenovirus serotype 26 is elaborated in Examples and thus written description and enablement is fulfilled for the application.

VaxPal shows the presence of three more applications for which PCT filing is due in 2022. These are not available for evaluation as they are yet to be published.

4. ChAdOx1 nCoV-19 Vaccine (AZD1222)

Background

The ChAdOx1 nCoV-19 vaccine (AZD1222) was developed at Oxford University (now assigned to AstraZeneca) and consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene.

Clinical trials for this vaccine are done in the United Kingdom, Brazil, and South Africa. Accordingly, AZD1222 is being distributed for vaccination in more than 100 countries across six continents and has been administered to hundreds of millions of persons.

Relevant Patent applications
1) WO2012172277
Assignee: University of Oxford

The invention provides simian adenovirus and adenoviral vectors. In particular, the invention provides an adenovirus vector comprising a capsid derived from chimpanzee adenovirus AdY25, wherein said capsid encapsidates a nucleic acid molecule comprising an exogeneous nucleotide sequence of interest.

National phase entry: AU, BR, CA, CN, EP, IN, RU, SG, ZA and the US

Granted in AU, CA, CN, EP (2 patents granted), IN, JP, US (2 granted, 1 pending) and ZA. Stands abandoned in RU and BR.

Granted claims of EP2714916B1

The patent provides claims for an adenovirus vector comprising a capsid, wherein said capsid comprises the capsid proteins from wildtype chimpanzee adenovirus AdY25 and encapsidates a nucleic acid molecule comprising an exogeneous nucleotide sequence of interest operably linked to expression control sequences which direct the translation, transcription and/or expression thereof in an animal cell and an adenoviral packaging signal sequence, wherein the nucleotide sequence that encodes the wildtype chimpanzee adenovirus AdY25 is SEQ ID NO: 1, wherein said vector lacks a functional E1 locus, and wherein the vector comprises at least one heterologous E4 open reading frame from another adenoviral serotype.
This is the patent that covers the vaccination product.

The claim provides adenovirus vector comprising a capsid, wherein said capsid comprises the capsid proteins from wildtype chimpanzee adenovirus AdY25 and encapsidates a nucleic acid molecule comprising an exogeneous nucleotide sequence of interest operably linked to expression control sequences.

The specificity of the adenovirus is provided by the following recitation: “the wildtype chimpanzee adenovirus AdY25 is SEQ ID NO: 1, wherein said vector lacks a functional E1 locus, and wherein the vector comprises at least one heterologous E4 open reading frame from another adenoviral serotype”.

This patent is having claims directly related to the vaccine product of AstraZeneca and is also protected by supplementary protection certificate in many EU countries (DE, IE, ES, SE, CH, DK, GB, etc.) as of 2021.

Granted patent **US9714435** mirrors similar claims.

Note on patentability:

The chimpanzee adenoviral vector is specifically covered in the patent but the nucleotide sequence that is operably linked to this adenovirus is left open ended to accommodate any nucleotide from any disease area. In short, by providing "encapsidates a nucleic acid molecule" wherein the nucleic acid molecule is not defined by any SEQ ID, it is gathered that any nucleic acid molecule pertaining to any disease area can be used alongside the said adenoviral vector.

The wildtype chimpanzee adenovirus AdY25 is identified by specific sequence which renders novelty.

Granted claims in EP3321367B1

The invention claims an adenoviral vector other than AdHu5, suitable for driving expression of a heterologous transgene in a host cell, comprising an adenoviral genome, wherein the E40rf4, E40rf6 and E40rf6/7 coding regions have been replaced with heterologous AdHu5 E40rf4, E40rf6 and E40rf6/7 coding regions, whilst comprising the native E40rfl, E40rf2 and E40rf3 coding regions, and wherein said adenoviral genome lacks an E1 and an E3 locus. The adenoviral vector is derived from AdY25 or AdCh68 (dependent claim).

The transgene (given in the broadest claim) encodes a **molecule of interest**, and wherein the molecule of interest is a protein, polypeptide or nucleic acid molecule of interest, and optionally, wherein the transgene encodes one or more, two or more or three or more molecules of interest. The molecule of interest is further provided as proteins and polypeptides comprising antigens, molecular adjuvants, immunostimulatory proteins or recombinases.

Note on patentability:

Specificity (limitations) to claims provided in terms of coding regions of adenoviral genome. By leaving it as molecule of interest, it is open ended, and the molecule can be any molecule (belonging to any disease area) which can be expressed by specific adenoviral vector.

By providing "encapsidates a nucleic acid molecule" wherein the nucleic acid molecule is not defined by any SEQ ID, it is gathered that any nucleic acid molecule pertaining to any disease area can be used alongside the said adenoviral vector.

US2020360533

The above pending US application presents a vaccine comprising an adenovirus vector comprising a capsid, wherein said capsid comprises one or more capsid proteins from chimpanzee adenovirus AdY25 and encapsidates a nucleic acid molecule comprising an exogenous nucleotide sequence of interest operably linked to expression control sequences which direct the expression thereof in an animal cell and an adenoviral packaging signal

sequence, and wherein the nucleotide sequence that encodes the wild-type chimpanzee adenovirus AdY25 is SEQ ID NO: 1.

The exogenous nucleotide sequence of interest is an antigen, a molecular adjuvant, an immunostimulatory protein or a recombinase. The antigen is a self-antigen expressed by a tumour cell.

The exogenous nucleotide sequence of interest is a microRNA (miRNA) or an immunostimulatory RNA sequence.

The nucleotide sequence of interest encodes an antigen specific to cancer or a tumor associated antigen (TAA) from a pathogen involved in cancer immunopathogenesis and the pathogen is selected from human papilloma virus (HPV), hepatitis B (HBV), or Epstein Barr virus (EBV).

Notes on Patentability

Although the nucleotide sequence of interest is open ended (by providing “encapsidates a nucleic acid molecule” wherein the nucleic acid molecule is not defined by any SEQ ID, it is gathered that any nucleic acid molecule pertaining to any disease area can be used alongside the said adenoviral vector), specificity is rendered in dependent claims and the patent claims are clearly tied to cancer and tumor associated antigen (TAA) from a pathogen involved in cancer immunopathogenesis.

2) WO2020043869
Assignee: Oxford University Innovation Ltd.

The invention relates to methods for generating a recombinant adenovirus comprising a nucleotide sequence encoding a heterologous gene of interest for use as a vaccine comprising the steps of inserting the heterologous gene of interest into the adenovirus genome by recombining terminal protein complexed adenovirus genomic DNA (TPC-Ad gDNA) with a polynucleotide comprising a nucleotide sequence encoding the gene of interest and having 5' and 3' ends that are homologous to the insertion site sequence of the adenovirus genomic DNA in an in vitro recombination reaction, transfecting cells growing in individual vessels with a dilution of the in vitro recombination reaction mixture from (i) such that a number of such individual vessels contain a single cell that is infected by a recombinant adenovirus comprising the nucleotide sequence encoding the heterologous gene of interest, and identifying those individual vessels in which a single cell has been infected by the recombinant adenovirus comprising the nucleotide sequence encoding the heterologous gene of interest.

The application describes a method/process for generating the recombinant adenovirus comprising a nucleotide sequence encoding a heterologous gene of interest as provided in the 2013 application for use as a vaccine.

National phase entry: AU, CA, CN, EP, IN, MX, KR and SG. Examination pending in all countries.

Notes on patentability

The method of generating a recombinant adenovirus comprising a nucleotide sequence encoding a heterologous gene is not a new subject matter and thus not inventive. The International Search Report (ISR) also points out that a high-throughput system for generating

recombinant adenovirus is disclosed in the Journal of Biotechnology, 162:246-252, 2012 (D1) and vaccination to conserved influenza antigens using a novel simian adenovirus vector is provided in PLOS ONE, 8:e55435, 2013 (D2). International Search Report (ISR) also indicates a novel chimpanzee adenovirus vector with low seroprevalence is disclosed in PLOS ONE, 7:e40385 (D3) and an article in Expert Review of Vaccines, Expert Reviews Ltd, GB, 16: 1241-52, 2017 (D4) discusses chimpanzee adenoviral vectors as vaccines and its challenges.

In view of the above prior art documents, it will be difficult to establish the inventive step of the method/process that is claimed in WO2020043869 unless the applicants provide new substantial data to show the enhanced efficacy of the adenovirus vector of the invention.

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SOUTH CENTRE

International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

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