

## IP Trends on COVID-19 vaccine-related patents

There has been a growing dire need for developing effective COVID-19 vaccines to minimize the further spread of the pandemic and contain the virus. The World Health Organization (WHO) has announced that thirty-five vaccines are now under clinical trial and another 145 are in a preclinical evaluation stage (as of September 9, 2020). Generally, when it comes to vaccine development, pharmaceuticals and research institutes go-head-to-head with each other to become a front runner in the vaccine race. Early patent obtainment and exclusive sales and production are key to placing a company in a favorable position under such fierce competition. However, the coronavirus pandemic has triggered the industry to prioritize cooperation within an international framework so that as many countries as possible can get access to patents owned by pioneering drug makers. The Japanese government has reached a deal on the supply of a COVID-19 vaccine with Pfizer and Astra Zeneca respectively in order to secure inoculation for all nationals. In this report, we will introduce and analyze patents related to promising COVID-19 vaccines.

### Patent information on promising COVID-19 vaccines

Thirty-five candidate vaccines, which are under clinical trial on the WHO list, are broken into the following vaccine platform categories. The number of vaccines in each category is shown in brackets.

- Non-replicating Viral Vector (7)
- mRNA (6)
- DNA (4)
- Protein Subunit (11)
- Virus-like particle (VLP) (1)
- Inactivated (6)

We featured two promising COVID-19 vaccines under clinical trials from data “*DRAFT landscape of COVID-19 candidate vaccines – 9 September 2020*”.

#### ① **Developer/manufacturer: University of Oxford/AstraZeneca**

Vaccine platform: Non-Replicating Viral Vector

Type of candidate vaccine: ChAdOx1-S (AZD1222)

Viral vector vaccine is a non-pathogenic or a weakened viral vector that antigen protein genes are genetically introduced into the vector. Adenovirus and retrovirus are used as viral vectors. For the SARS-CoV-2 vaccine, a viral vector vaccine having a gene encoding a spike protein, which plays a crucial role in infection, is mainly being developed.

Patent information: WO2012-172277 (PCT Publication number) / 2014-516536

(Japanese Publication Number)

Title of Invention : Simian adenovirus and hybrid adenoviral vectors

Filing History :

- Priority application (GB) in May, 2011
- PCT application in May, 2012 (WO2012-1722)
- US Patent Granted in June, 2017 (9714435)

**Japanese Patent Number: 6230527**

[Claim 1]

An adenovirus vector comprising a capsid ,wherein the capsid contains one or more capsid protein derived from wild type 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 translation, transcription and/or expression thereof in an animal cell and an adenoviral packaging signal sequence, wherein nucleotide sequence coding the wild type chimpanzee adenovirus AdY25 is sequence number 1.

[Noteworthy point]

In the present invention, the prevalence rate of the vector-neutralizing antibodies in human serum is low, and the vector, which has a target antigen, induces a sufficiently high immune system. There is no limitation in the claims to the antigen of SARS-CoV-2. Any adenovirus vector comprising one or more capsid derived from wild type chimpanzee adenovirus AdY25 would be within the claim scope. Since the present invention does not specify a target antigen, the invention could not stand out from competitors if the aforementioned vector is of no use.

② **Developer/manufacturer: Moderna/NIAID**

Vaccine platform: RNA vaccine

Type of candidate vaccine: LNP-encapsulated mRNA

mRNA vaccine against SARS-CoV-2 is engineered as following steps: first, an artificial mRNA strand encoding a coronavirus gene is produced. Second, the mRNA is encapsulated by lipids, which are nanoparticles. Third, once the vaccine is injected into a human body, mRNAs are translated into virus proteins (virus antigen) and then, they cause the immune system to react which subsequently creates antibodies. Compared with conventional vaccines, mRNA vaccines are available in a shorter manufacturing time and are less cumbersome tasks in culturing the virus. In recent years, mRNA vaccine has been actively developed.

Patent information : No. 10702600 (US Patent Registration number / Registration date: July 7, 2020)

Title of Invention: Betacoronavirus mRNA vaccine

Currently, there is no corresponding Japanese application. Below is excerption from the US patent gazette.

[Claim 1]

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.

[Noteworthy point]

BetaCoV recited in Claim 1 covers novel coronavirus (SARS-CoV2). The composition including mRNA encoding coronavirus S proteins within liquid nanoparticles, is covered in a scope of claims in the present invention. An example of the present invention describes the result that the mRNA vaccine coding MERS CoV spike protein was into immunized rabbits and successfully induced neutralizing antibody.

Most of the promising vaccine candidates in the WHO list have not yet to be disclosed patent publication. That said, most developers have leveraged their existing technologies and owned patents so as to apply them to coronavirus vaccine development. Holding a core patent at earlier stage is essential so that it could help boost further drug discovery in the unprecedented situation.

Next, we introduce another anti-coronavirus vaccine patent which is lately granted by the JPO.

**A latest patent related to coronavirus vaccine issued at the JPO**

**③ Developer/manufacturer: Loyola University Chicago**

This is a type of conventional protein subunit vaccine.

Patent information: WO2018-160977 (PCT Publication number) / 2020-513845 (Japanese Publication number)

Title of Invention: Coronaviruses, vaccines comprising the same, and methods for preventing disease

Filing History:

- Priority application (US) in March, 2017
- PCT application in March, 2018 (PCT/US2018/020678)
- Japanese publication in May, 2020 (2020-513845)
- Filing a request for Amendment to the JPO in June, 2020

The aforementioned applications has not yet to be granted. Below is excerption from the Japanese publication.

[Claim 1]

A live, attenuated coronavirus comprising a variant replicase gene encoding polyproteins comprising a non-structural protein (nsp)-15, the replicase gene encoding the nsp 15 and causing any change, including mutations and/or deletions, that affects

the stability or activity of the nsp 15.

[Noteworthy point]

The present invention is aimed at utilizing an attenuated vaccine by introducing mutation into nsp 15 which makes nsp15 unstable. Non-structural protein (nsp)-15 is also existing in SARS-CoV-2.

### Summary

Currently, various types of vaccine are under clinical trials. The aforementioned three vaccines have taken different approaches in development, and it is highly expected that more vaccines will pass clinical tests. Coronavirus vaccine development has just taken off, and we should maintain this momentum. Not only drug makers, but also companies from all walks of life could be hopefully dedicated to becoming actively engaged in drug recovery.

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Dr. Iida has extensive experience in handling patent prosecution in the field of biotechnology and pharmaceuticals on behalf of pharmaceutical companies, universities, and research institutions and has over 7 years' experience as a patent attorney. His expertise covers patent prosecution, trials for invalidation, and suits against trial decisions.

He has also detailed knowledge of genome editing and gave a lecture on notes of caution for patent maps and strategies for patent applications on genome editing at a seminar entitled "The Drug Development which Genome Editing has been Changing" organized by Nikkei Biotechnology & Business in October 2015. Dr. Iida has been asked to contribute articles to medical magazines based on his wide knowledge and experience in both biotechnology and the IP field. In 2019, he was selected for IAM Patent 1000 2019: The World's Leading Patent Professionals (Intellectual Asset Management).