

# IP monopoly problem in the fields of vaccines

March 10, 2022

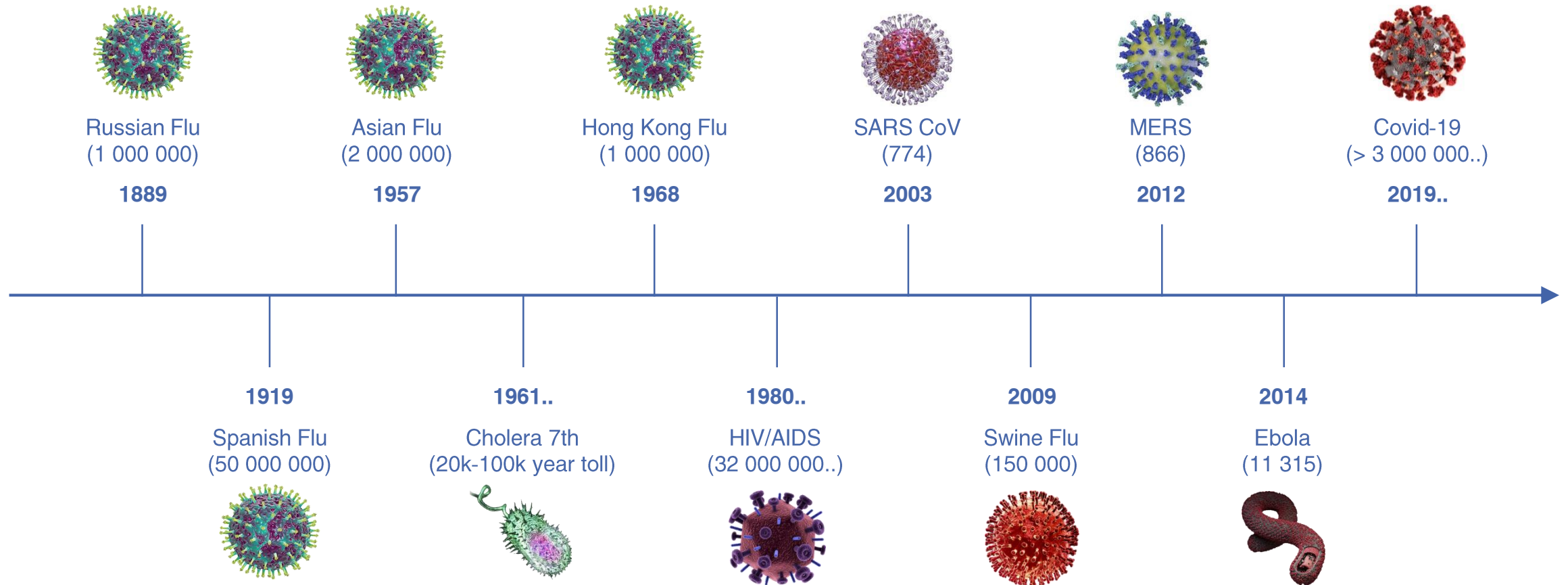
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PATENT AND TRADEMARK  
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# 20<sup>TH</sup>-21<sup>ST</sup> CENTURY PANDEMICS

Pandemic: epidemic of infectious disease spreading to other countries and affecting many people



# **SCIENTIFIC OPINION HISTORICALLY PROVED**

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**It is impossible to predict what next virus  
hits humans**

# STATISTICS ON VACCINE PATENTING

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- What can we see implementing patent statistics?
  - Does vaccine patenting look occasional?
  - What steady tendencies does it show (e.g. growth)?
  - What specific features (e.g. spikes) does it have?
    - Can we interpret them?
    - When do they appear?

# SEARCH STRATEGY

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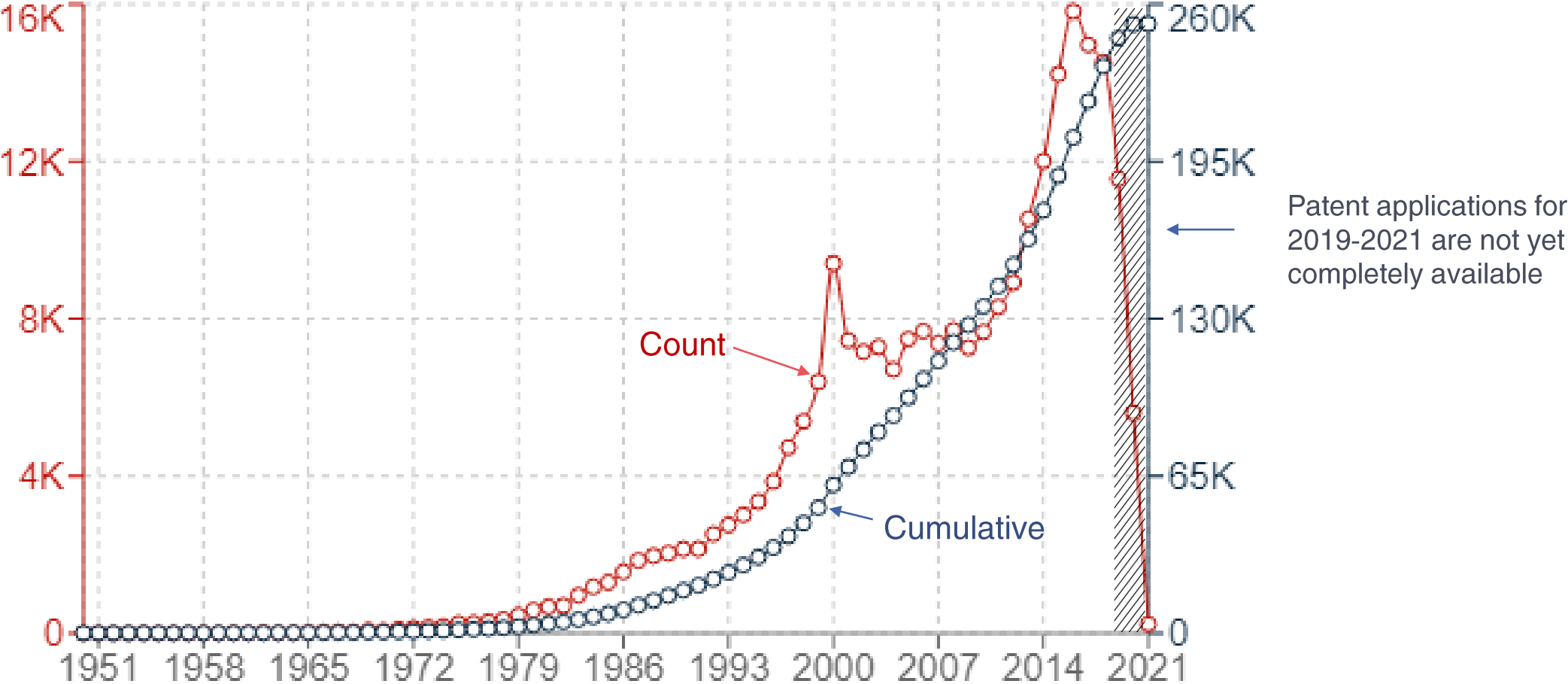
- **Whether and how pandemics are reflected in patenting activities for vaccines?**
- **How continuously do new vaccine developments appear?**

Patent Database: Espacenet

Date range: 1950-2021

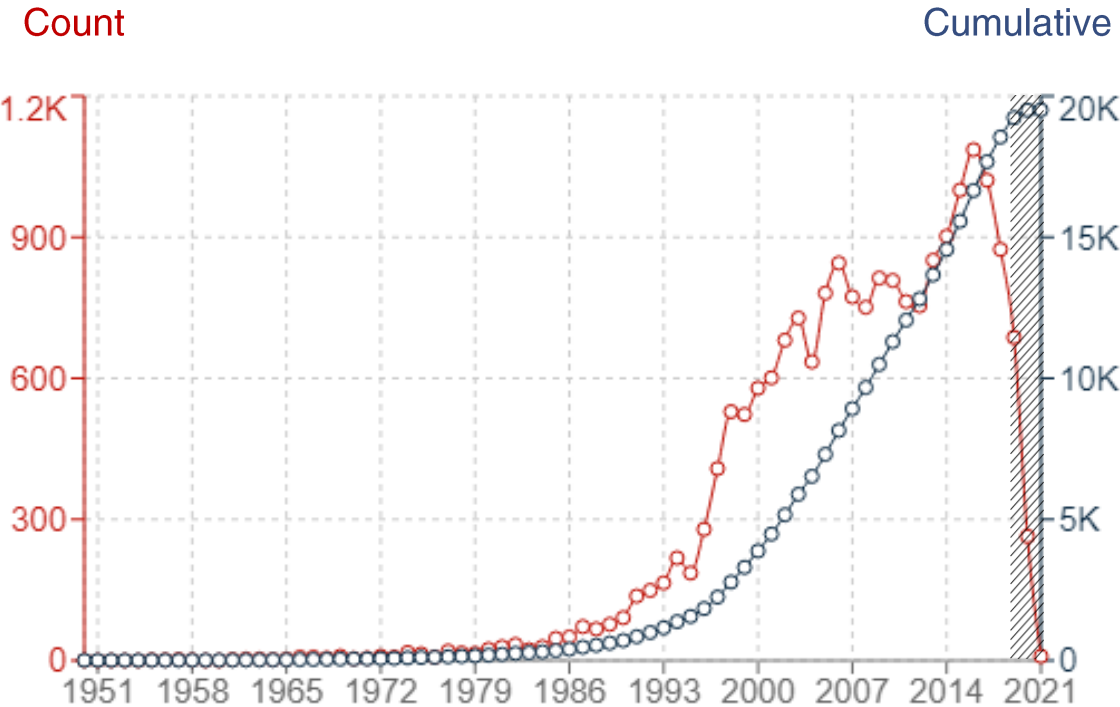
Keywords :  
✓ vaccin\*, immun\*, human  
✓ influenza, flu, swine, pdm09, H1N1  
✓ coronavirus, SARS\*, MERS\*

# VACCINES PATENTING

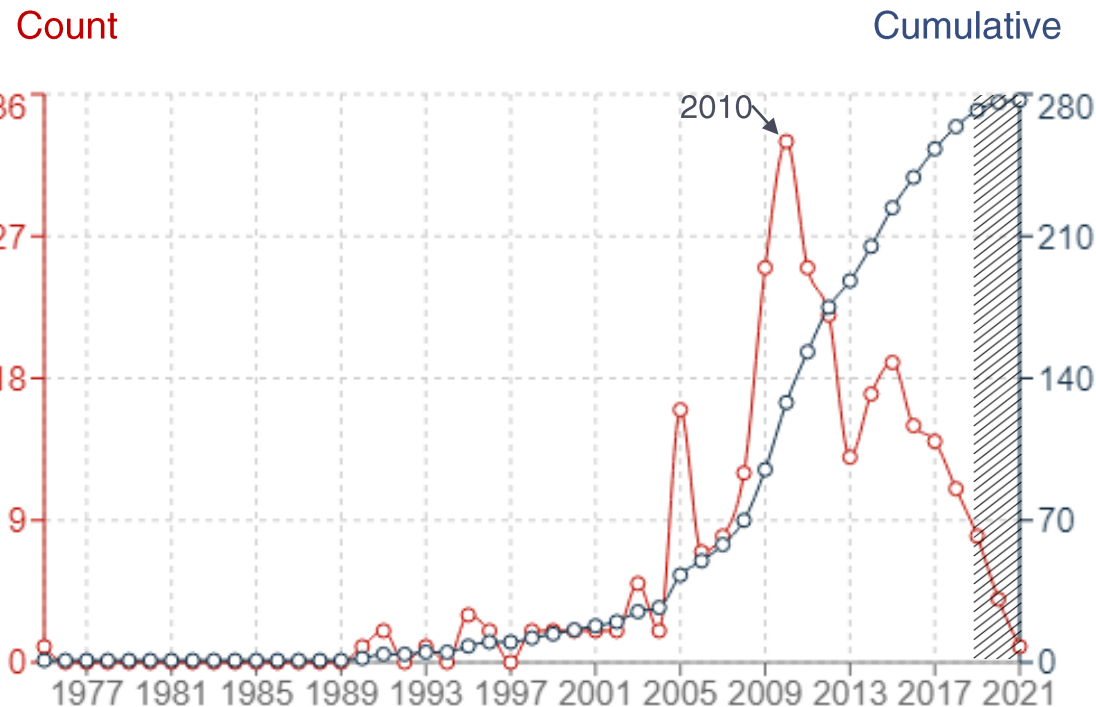


# INFLUENZA VACCINES PATENTING

Influenza vaccines



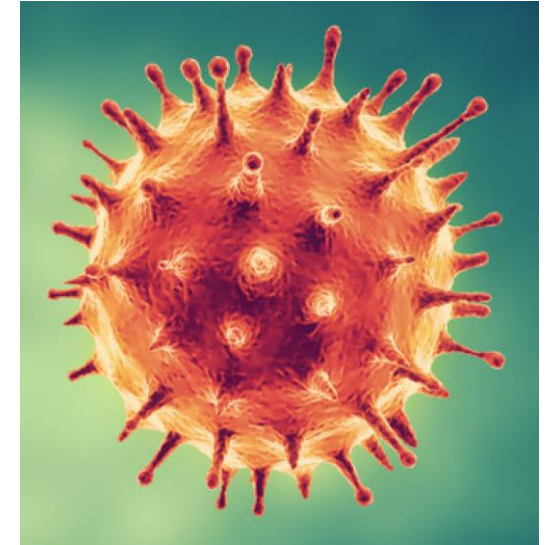
Swine influenza virus vaccines



# CORONAVIRUSES

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- subfamily of Coronaviridae family; enveloped RNA viruses
- particles have spikes (S-glycoprotein) reminiscent of solar corona
- respiratory infections in mammals and birds
- 4 known genera of coronaviruses: alpha, beta, gamma and delta
- 7 human coronaviruses, which belong to
  - alphacoronavirus (HCoV-NL63 and HCoV-229E) and
  - betacoronavirus (HCoV-OC43, HCoV-HKU1, SARS, MERS and CoV-2)
- originate from birds/animals
- 3 large-scale outbreaks in the last two decades: SARS-CoV in 2002, MERS-CoV in 2012 and SARS-CoV2 (COVID-19) in 2019



# CORONAVIRUS VACCINES IN PRE-COVID-19 ERA

## SEVEN HUMAN CORONAVIRUSES

- Human coronavirus 229E (HCoV-229E)
- Human coronavirus NL63 (HCoV-NL63)
- Human coronavirus OC43 (HCoV-OC43)
- Human coronavirus HKU1 (HCoV-HKU1)
- Middle East respiratory syndrome-related coronavirus (MERS-CoV)
- Severe acute respiratory syndrome coronavirus (SARS-CoV-1)
- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)



## LIST OF EXAMPLES OF PATENTS:

**SU924951** (VNII GRIPPA) of 19.05.1980 (Strain of corona virus LP (Leningrad) 2/77 for analysis of Corona Virus Infections)

**EP1526175B1** (Versitech Limited) of 18.08.2004 (the invention provides a vaccine in particular against HCoV-NL63)

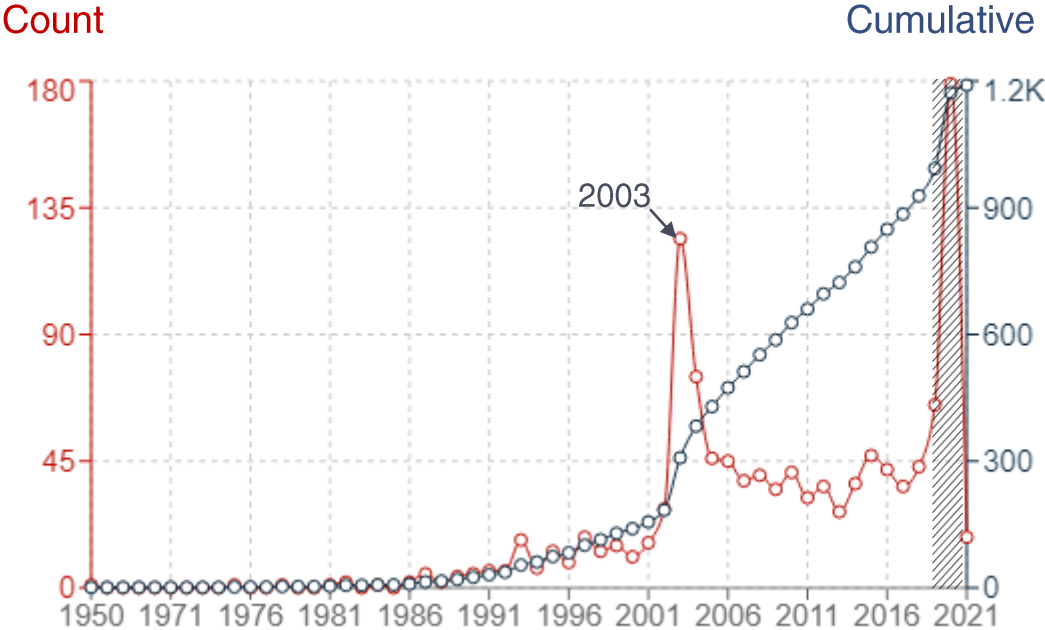
**US8092994B2** of 21.07.2004 (the invention provides a complete genomic sequence of CoV-HKU1 or a part thereof and a composition comprising them).

**RU2332457** (Bioleaders Corporation, M.D. LAB, Bioleaders Japan Corp., Korea Research Institute of Bioscience and Biotechnology) of 04.06.2004 (the invention provides a surface protein expression vector comprising any one or two or more of pgsB, pgsC and pgsA genes encoding poly-gamma-glutamic acid synthase complex and a gene encoding a spike antigen protein or a nucleocapsid antigen protein of SARS coronavirus, a microorganism transformed by the expression vector, and a vaccine for prevention of SARS virus comprising the spike antigen protein or the nucleocapsid antigen protein).

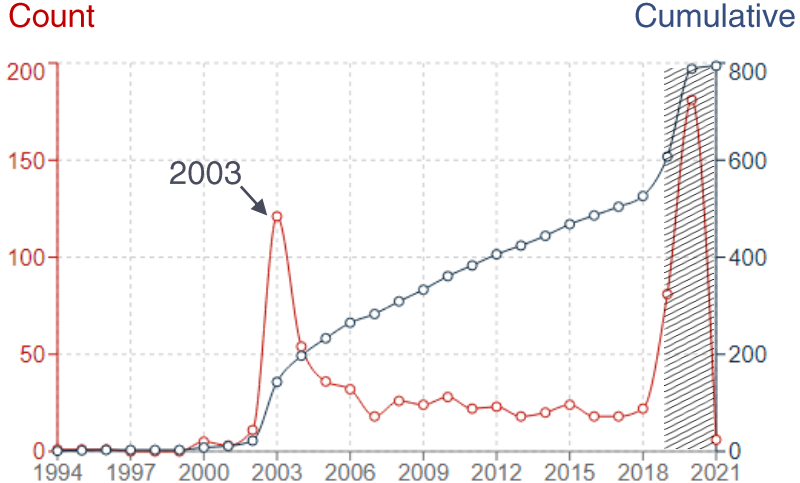
**RU2709659** (the Gamaleya National Center) of 06.09.2018 (the invention provides an immunobiological agent based on human recombinant adenovirus serotype 5 or recombinant human adenovirus serotype 26, comprising optimized for expression in mammalian cells the consensus sequence of complete protective antigen S of MERS virus on the basis of protein S gene sequences of modern MERS virus strains of 2015-2017 years with sequence SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 or SEQ ID NO: 5).

# CORONAVIRUS VACCINES PATENTING

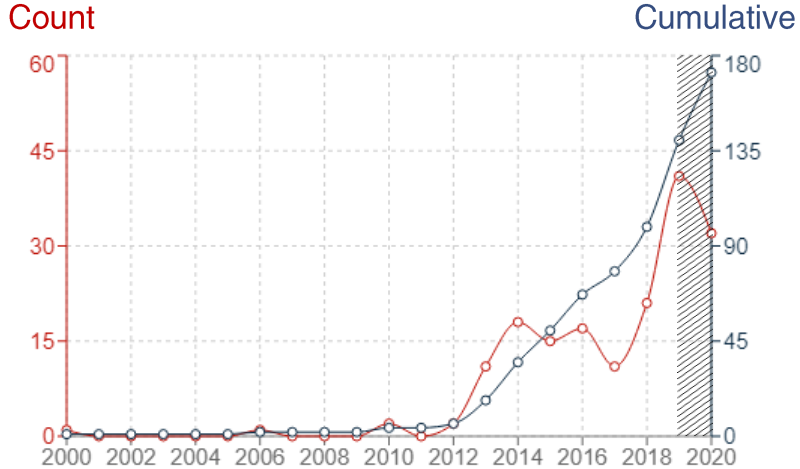
Coronavirus vaccines



SARS-CoV vaccines

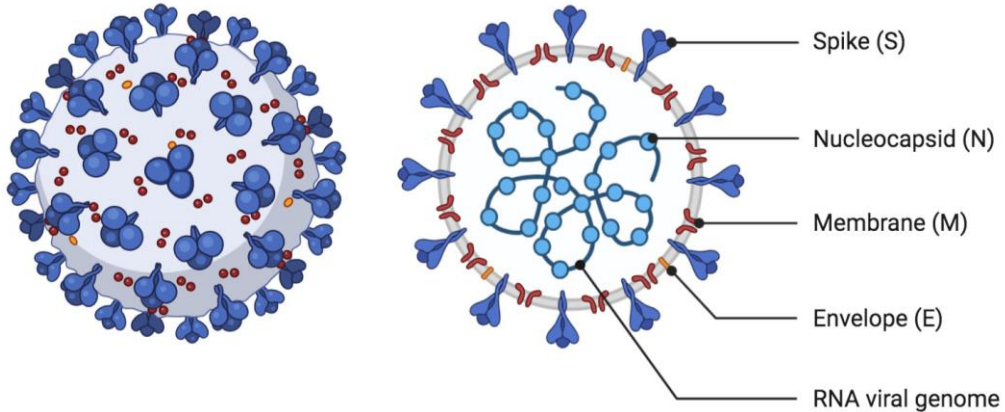


MERS-CoV vaccines



# CORONAVIRUS DISEASE 2019 (COVID-19)

## SARS-CoV-2



<https://natsci.msu.edu/news/scientists-focus-on-fundamental-virology-and-therapeutics-in-covid-19-fight/>

### Variants of SARS-CoV-2 recognized by the WHO:

Alpha: Lineage B.1.1.7 emerged in the United Kingdom in September 2020 (and B.1.1.7 with E484K mutation).

Beta: Lineage B.1.351 emerged in South Africa in May 2020.

Gamma: Lineage P.1 emerged in Brazil in November 2020.

Delta: Lineage B.1.617.2 emerged in India in October 2020.

### Severe acute respiratory syndrome coronavirus 2

(SARS-CoV-2) is a causative agent of COVID-19. The virus shows a great similarity with SARS-CoV and bat SARS-like coronaviruses.

The first known case of COVID was identified in Wuhan, China in **December 2019**.

The WHO declared a global pandemic on **11 March 2020**.

The most common symptoms are fever, cough, and shortness of breath. Additional symptoms include weakness, headache, nausea, changes to taste and smell.

### COVID-19 is highly transmissible viral infection:

- SARS-CoV-2 has structure differences from previously known coronaviruses.
- Transmission of SARS-CoV-2 occurs primarily via respiratory droplets from face-to-face contact, besides, it can be via contaminated surfaces.
- Infection can be spread by asymptomatic and presymptomatic carriers.
- Lack of pre-existing human SARS-CoV-2 immunity and specific antiviral medicaments.

# **REACTION ON COVID-19 BY PATENT WORLD**

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**Fast examination tracks**

**Debates on “free access”**

**Compulsory licensing or even Free use**

# FAST-TRACK PATENT EXAMINATION: HOW IT WORKS

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For applications related to:

*April 2020 – program of accelerated patent examination for inventions on treatment of viruses and accompanying illnesses (pneumonia)*

- *Antiviral medicals*
- *Diagnostics of viral diseases (including diagnostic test systems)*
- *Medical devices (including artificial lung ventilation devices, inhalers, intubation tubes)*
- *Protective equipment (including medical masks, respirators, protective suits)*
- *Sterilizing and disinfecting agents*

(1) Acceleration procedure is applied automatically without any additional fee, and

(2) The first substantive examination action is issued within 2 months from the date of completion of the formal examination

# FAST TRACK IN ACTION: PATENT PENDENCY TIME

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- **The Gamaleya National Center**

- RU2720614 – *6 business days*
- RU2731342 – *7 business days*
- RU2731356 – *7 business days*
- EA 37291 - 5 months
- EA 37297 - 5 months
- EA 37903 – 11 months

RU2745626 (**SUVOROV**) - 4 months

- **State Research Center of Virology & Biotechnology VECTOR**

- RU2743595 – 2,5 months
- RU2733831 – 3 months
- RU2733832 – 1,5 months
- RU2733834 – 1,5 months
- RU2738081 – 1 month 3 weeks

RU2747762 (**DUKHOVLINOV**) – 13 months

# ACCESS TO VACCINE PATENTS – BROADENED DEFINITION?

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- Reasonable licensing opportunities with compulsory licensing on exceptional basis
- Availability of scientific data
- Availability of technical specifications for key important equipment
- Access to research materials
- Access to virus strains
- Publicly available and easy accessible educational materials

Covid-19 story tends to add to this list

- ***Access to any needed technology by limiting patent rights for it***

# IS IP A BARRIER?

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**Dr. Francis Gurry**, Ex-Director General of WIPO

“Some Considerations on Intellectual Property, Innovation, Access and COVID-19”

*“It may be noted that there **does not appear to be any evidence that IP is a barrier** to access to vital medical preventive measures, such as vaccines, or to treatments or cures”*

*“An effective strategy or approach to encouraging innovation must ensure that the right incentives are in place to encourage the major funders and performers of R&D to deliver results. **IP is a central part of those incentives**”.*

# COMPULSORY LICENSING AND FREE USE

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**Can they help?**

**In short perspective?**

**In long perspective?**

## **CONCLUDING**

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**Recent pandemic of COVID–19 in no way diminished value of IP but rather showed how important the IP system moved on by only human creativity**

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