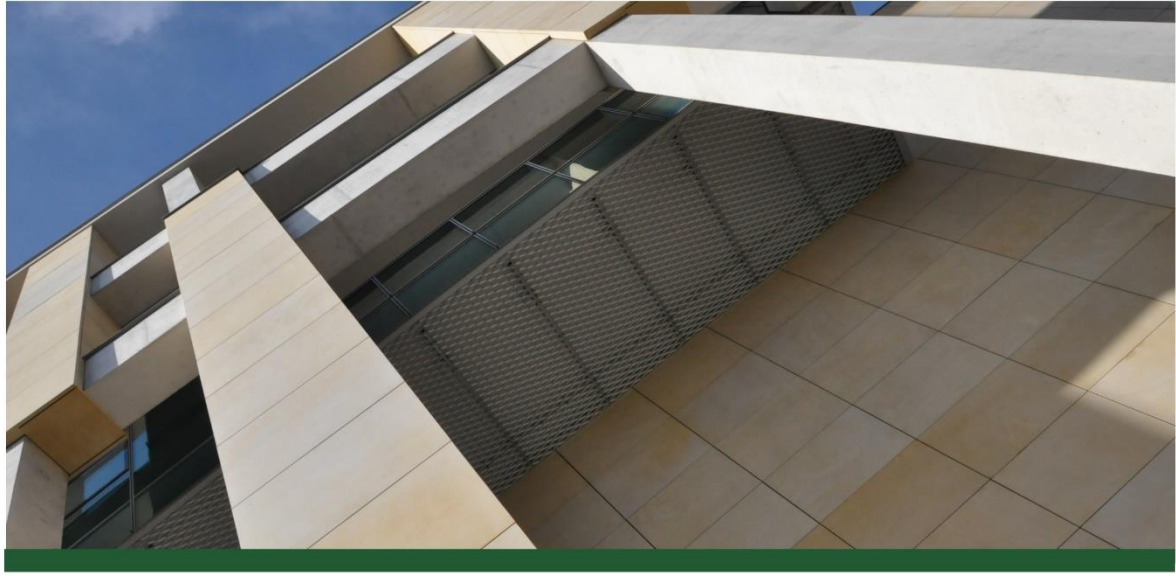
UNIRIO
Universidade Federal do Estado do Rio de Janeiro

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS



The Pfizer-BioNTech COVID-19 vaccine development – case study

RICARDO SICHEL, MAŁGORZATA MACUDA

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

INTRODUCION / AIM

By the beginning of the XXI Century a new challenge has appeared – a new pandemic at an international level without no treatment or vaccine available – the SARS CoV-2 virus.

The countries started to adopt measures related to social distance, the application of lock-down, which had a direct impact on the economy. There was no health crisis with this dimension, since the Spanish flu pandemic, in 1918.

The purpose of the paper is to analyse the development of a new vaccine, considering the protection of Intellectual Property (IP) rights, the investment made and how the knowledge of managing accountability enabled this company to develop and produce the vaccine, that is used at an international level. The paper looks at the BioNTech case, which produces a vaccine together with the US pharma industry Pfizer Inc.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

INTELLECTUAL PROPRIETY

Intellectual property protection is used by the major pharmaceutical laboratories, with purpose to ensure rights of its intangible assets.

Considering the major companies, as Pfizer, BioNTech and Sinovac and taking the data from the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO), the following result appears:

- at the USPTO (2021) Pfizer and BioNTech have each filed 50 patent applications and Sinovac has filed 15 patent applications;
- at the EPO (2021), the figures are 50 patent applications applied by Pfizer and the same number for BioNTech and Sinovac.

Considering COVID-19, there have been 341 patent applications at the EPO and 318 applications at the USPTO. The importance of those applications is related to the value of the intangible asset. It is not just a question of obtaining an exclusive right, but the possibility of licensing rights and technology know how.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

INTELLECTUAL PROPRIETY PROTECTION

The trade of technology also means a conception of political strategy of a certain nation. It handles the knowledge of technological information as part of its national security.

Nowadays, the information related to the production of the COVID-19 vaccine may be included in this concept, since the pandemic has been affecting not only the public health but likewise the international and national economies. It means that the trade partners should be aware of how granted the protection of a certain technology is. The uncertainty at the procedure of granting an IP right, or even in enforcing it may hinder the opportunity of having a deal done.

The concept of exclusive rights conferred by patent protection should not be more important than the public interest, especially when the community health is involved. In the case of COVID-19 vaccines, the World Health Organisation - WHO is engaged with a program called Covax Facility, which has the objective to distribute the immunization to the poorest countries of the world.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

INTELLECTUAL PROPRIETY PROTECTION

The legal protection of new vaccine is a result of the application of the national patent legislation. Patents are granted to inventions, not to discoveries. Patent protection should be available for all inventions and should also grant protection for a minimum period of 20 years counted from the filling date. The price of the new pharmaceutical products has been considered a major problem for several countries in order to grant better treatment through the public health system and also enabling its budget to afford them.

BioNTech, which has developed the COVID-19 vaccine has a strong commitment to IP protection. It is possible to certify that IP protection is also used to enable the enterprise's activities, not only for products that are no used, but it includes product that are being researched and still in development. It is important to consider the patent protection as an intangible asset, which enables its owner to trade it.

Pfizer, in collaboration with BioNTech, was the first company to receive emergency use authorization (EUA) from the Food and Drug Administration for its vaccine (FDA, 2020). It received the EUA in December 2020.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

BioNTech's COVID-19 VACCINE

BioNTech's COVID-19 vaccine is based on the Company's proprietary mRNA technology and to date has been granted either an emergency use authorization, temporary use authorization or conditional marketing authorization in over 65 countries and regions. The mRNA-based COVID-19 vaccine will be marketed under the brand name COMIRNATY® in the EU, where BioNTech has received the appropriate conditional marketing authorization.

BioNTech and Pfizer are working with governments and health ministries around the world that are arranging the vaccine's distribution during the pandemic, subject to the approval or authorization of the particular country and the terms of supply agreements. To date (March 2021), supply agreements have been contracted for 1.4 billion doses worldwide.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

INVESTMENT IN R&D

The investment made in R&D does not grant the result to be obtained. There is a possibility, that by the end of the investigation, nothing valuable might be obtained, but the risk is a part of this procedure, as a way to foment technological innovation.

Several countries, according to the OECD has been investing an expressive percentage of their GDP in R&D. The COVID-19 pandemic has demonstrated how important this form of investment R&D is. It is not limited to production of vaccines, but also the investigation of new form of treatments.

It is perhaps the first time in history of mankind that a vaccine was developed in such a short time of period. It is a result of investment made by the public and private sectors of several countries.

In the fiscal year 2020, BioNTech received a government funding commitment for government grants totaling €375.0 million.

POZNAŃ UNIVERSITY OF ECONOMICS AND BUSINESS
UNIRIO Universidade Federal do Estado do Rio de Janeiro
Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

BioNTech

BioNTech was founded in 2008. For more than ten years, the Company operated as a research and development company with small scale production for clinical trials only. With increasing organic and inorganic growth and commercial vaccine production starting in 2020, the requirements for environmental management have increased. BioNTech has been addressing its corporate responsibility strategically since late 2019. Since then, the basic structures for professional sustainability management have been consistently created.

The COVID-19 vaccine has put BioNTech in the spotlight of public attention. In the financial year 2020, BioNTech entered into two strategic collaborations with major pharmaceutical companies in connection with the BNT162 vaccine program “Lightspeed”: Pfizer Inc. of New York, USA; and Fosun Pharmaceutical Industrial Development Co. Ltd. of Shanghai, China.

A few months after the first vaccine doses were delivered, the first BioNTech sustainability report provides structured answers to a wide range of questions about corporate responsibility. The Sustainability Report is a first milestone for a company (prepared in accordance with the GRI Standards: Core option).

Al. Niepodległości 10
61-875 Poznań, Poland
phone +48 61 856 90 00
www.ue.poznan.pl/en

BioNTech

With the first emergency use or conditional approval of the COVID-19 vaccine worldwide on December 2, 2020, and its commercial production, society's perception of BioNTech has changed significantly. With that comes new expectations for the company:

- people's expectation of an effective and safe vaccine;
- investors' expectations of a risk-adjusted return that also takes sufficient account of the environmental, social and governance (ESG) dimensions;
- the expectation of employees and business partners to shape the company's growth in a fair and sustainable way
- the expectations, especially of the younger population, that the company's growth will be in line with the Paris climate goals;
- and the expectation of many non-governmental organizations campaigning for fair and equitable global access o COVID-19 vaccines to contain the global pandemic effectively.