

ALMA MATER STUDIORUM UNIVERSITÀ DI BOLOGNA

TRADE SECRETS, INTELLECTUAL PROPERTY **AND VACCINES**



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a) it is secret, in the sense that it is not, in the configuration and assembly precise Of its components, generally known or easily accessible to people within the environments that normally deal with the type of information in question;

Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of **undisclosed know**how and business information (trade secrets) against their acquisition, unlawful USe and

disclosure







(b) has commercial value as a secret;

has been subject to reasonable security **(C)** measures by the person who has legitimate control of the information, to keep it secret



The pharmaceutical industry is affected by the illegal practice of trade secret theft

Following COVID-19 pandemic, virus several vaccines have developed. been During the vaccine development process, intangible information is obtained that is protected by trade secret

TRADE SECRETS CANNOT BE PROTECTED BY PATENT



The EU Ombudsman considers that, in general, clinical data cannot be defined **Confidential Business Information (CCI)**

the clinical reports must be anonymised to prevent

The TRIP's agreements have governed Intellectual property since 1994

One hundred academics have proposed a derogation from these Agreements to allow access to vaccines and treatment even in low income COUNTRIES (Least Developed Countries LDC)

The European Parliament with the resolution of 10/06/2021 expressed in favor of a **temporary modification of the** Agreement

NO AGREEMENT HAS BEEN **REACHED BETWEEN PARTIES**

and professionals who participated patients in clinical trials from being identified

	BNT162b2 2.5 Clinical Overview		
	Lymphadenopathy		
	Two participants 5 to <12 years of age had cases of lymphadenopathy up to the data cutoff $\sqrt[3]{e}$ date.		
	 1 PPD participant 8 years of age in the 20-µg group had Grade 1 bilateral cervical and inguinal lymphadenopathy with onset at 21 days post-Dose 2 and reported as ongoing at the time of the data cutoff. This event was considered by the investigator as not related to study intervention. 		
	 1 PPD participant 8 years of age in the 30-µg group as assigned (ie, received both doses of 30 µg), had Grade 1 left axillary lymphadenopathy with onset at 3 days post-Dose 2 and reported as resolved 17 days after onset. This event was considered by the investigator to be related to study intervention. 		
	2.5.5.2.1.4. Safety Conclusions – Phase 1		
H (GMT)	High frequencies of reactogenicity to the 20 and 30 µg dose levels in participants 5 to <12 years of age contributed to the decision to select a lower dose of 10 µg as the final dose level of BNT162b2 to proceed to Phase 2/3 for this age group. The dose level selection decision for this age group was based on Phase 1 safety and immunogenicity results. BNT162b2 at 10 µg was well tolerated in participants 5 to <12 years of age based on available Phase 1 safety results representing follow up to approximately 3 months after Dose 2.		
ct-2021 01:41 (GMT)	Safety results from Phase 1 dose level groups supported the Phase 2/3 dose level selection (refer to Section 2.5.5.2.1.5).		
ct-2	2.5.5.2.1.5. Dose Selection from Phase 1 Data		

During the COVID-19 pandemic, the European Medicines Agency (EMA) has implemented exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that have been approved or are under evaluation. Trial data have been published on Clinical





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Know-how is a set of intangible techniques and practices characterized by secrecy such as to provide the holder with an economic advantage. Although this definition is not sufficient to ensure patent coverage, trade secrets can nonetheless be protected under law. EU Directive 2016/943 establishes that trade secrets constitute any information that is: a) secret in the sense that "it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question"; b) has commercial value because it is secret; (c) has been "subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret". The Covid-19 pandemic caused by a new coronavirus confronted the scientific community with a major challenge: developing a vaccine. An immense effort led to the development and subsequent availability of several effective vaccines and therapies, which, however, are not accessible to the entire world population, especially those in middle and low income countries. Since research into and development of a new drug entails intangible knowledge and processes protected by trade secret regulations, one hundred international intellectual property specialists have petitioned for a temporary derogation from the TRIPs agreements protecting intellectual property. With its resolution of 10 June 2021, the European Parliament has also come out in favour of a temporary modification to the TRIPs agreements. However, the parties involved have yet to reach a consensus. This study looks at the possible ways in which the parties could achieve an agreement that would protect their rights.

- DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance)

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- Parlamento Europeo, https://www.europarl.europa.eu/doceo/document/RC-9-2021-0306_IT.html ; consulted on 15/05/2022.

