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Can you patent the sun?

The Covid-SARS-19 Vaccine as a chance to rethink the relationship between Intellectual Property and Commons

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Abstract

This work argues that the Covid-19 vaccine should be considered as a Commons, something that is managed and owned by the public at large, and not as private property – exclusivity - of pharmaceutical companies.

The reasons of such a strong argument – in particular the conspicuous public funding contribution and the search for a human and equity-oriented Global Health Security - are investigated in this work through a methodological approach which analyzes legislation, case-law and secondary sources, mostly in relation to the United States and the European Union, but also focusing on the international community as a whole.

Although there are different forms of intellectual property, the main focus of this work is on patents and, in a smaller part, trade secrets, considering that these are the main instruments through which pharmaceuticals, such as vaccines, are protected. It is true that, from a legal perspective, vaccines can be patented, leading to questionable practices in the pharmaceutical industry, such as patent thickets and strategic accumulations, and they can be covered by trade secrets, whose owners do not seem inclined to consider the disclosure as an option, even when this would benefit the public at large.

However, an alternative path, which would result in the theorization of a Commons for the vaccine, can be pursued. Indeed, it is noted that this invention would satisfy the two requirements that every Commons should have to be defined as such: being potentially owned in a private way; being managed more efficiently by the public at large.

In particular, considering that the actual types of Commons in the intellectual property law field - the public domain, exceptions/limitations to patents, or open innovation instruments such as IP pledges – present some issues in relation to enforceability, this dissertation, building on the work of the author Dusollier, advances the idea that from the inclusivity, which is the typical feature of every Commons, an inclusive right can be envisaged and applied in the context of the vaccine, while rethinking the relationship between intellectual property and Commons. Although this is - for now - a theoretical speculation without proper legal grounds, it can provide inputs to the current discussion about the waiver of IP rights that has been proposed at the WTO level and has been already the object of attention of the civil society at large.

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Introduction

When in 1955 the journalist Edward R. Murrow asked Jonas Salk, the inventor of the polio-vaccine, who owned the patent for that pharmaceutical product, the scientist replied “The people, I would say. There is no patent. Could you patent the sun?”[1]. This sentence sums up the main argument of this work: the Covid-19 vaccine should be considered as a Commons, something that is managed and owned by the public at large, and not as private property – exclusivity - of pharmaceutical companies.

The reasons of such a strong argument will be investigated in this work through a methodological approach which analyzes legislation, case-law, and secondary sources, mostly in relation to the United States and the European Union, given the influence of these regions and the impact of their pharmaceutical industries worldwide, but also focusing on the international community as a whole. Indeed, the pandemic that we are currently living has global implications, and the “miraculous” vaccines that have been developed in such a small amount of time must be administered in every corner of the world to have a chance of defeating the Covid-19 virus, or at least, end this emergency situation.

Although there are different forms of intellectual property, the main focus of this work will be on patents and, in a smaller part, trade secrets, considering that these are the main instruments through which pharmaceuticals, such as vaccines, are protected. In particular, it will be argued that, at least in relation to the Covid-19 vaccine, a renovated balance between Intellectual Property and the Commons Theory must be pursued.

As this work itself recognizes, it is true that for now, from a legal perspective, vaccines can be patented or covered by trade secrets, but this does not mean that the law cannot be modified. Indeed, it should be remembered that law must keep pace with the society. Therefore, if the needs of the society change – as it has occurred in this pandemic – law must change and evolve as well, and this work can offer a theoretical direction to follow.

The work is structured as follows. The first chapter sets the indispensable grounds that will be developed later on. In particular, the first section reports an history of vaccines, considering the 20th Century, and focusing not on the medical aspects, but more on the institutions that were involved in these events. It will be underlined that, despite the fact that at the early stages of vaccine production in

[1] B. Palmer, *Jonas Salk: Good at Virology, Bad at economics* (April 13, 2014) http://www.slate.com/articles/technology/history_of_innovation/2014/04/the_real_reasons_jonas_salk_didn_t_patent_the_polio_vaccine.html (last visited Sep 8, 2021).

the 20th Century, a consistent part of the vaccine Research & Development (R&D) was controlled by the public, such as the US government, at the end of the century a shift occurred towards the private multinational companies and their hegemony.

The second section explains the reasons for which the private sector started to be predominant, and why, instead, a collaboration between the public and private sectors to develop vaccines is desirable, although it will be clear, through different examples, how this collaboration is extremely difficult to achieve.

The third and last section of this chapter introduces the pharmaceutical products in the context, first of all, of their cumbersome authorization processes respectively implemented by the US Food and Drug Administration (FDA), and the European Medicines Agency (EMA). Eventually, the most relevant form of protection for pharmaceuticals in the US and the EU – patents – will be mentioned, and it will be underlined how for the pharmaceutical companies themselves this Intellectual Property Regime does not seem to provide enough incentives, and other forms of protection are being sought.

The second chapter addresses, on the one hand, the relationship between vaccines – with special focus to the innovative mRNA technology - and intellectual property in relation to the current pandemic of Covid-SARS-19, and on the other hand, the relationship between Big Pharma and intellectual property.

In particular, the first section describes how vaccines can be patented. Although this work is not expected to discuss biology or natural sciences issues, the mRNA technology, which is at the basis of some of the most relevant vaccines against Covid-19 that have been developed in the last year, is introduced as the main example and case-study in order to assess the patentability of vaccines in general.

The second and third sections explore specific issues related to patents in the context of the pharmaceutical industry, which are patent thickets and strategic accumulations of patents. Further reflections and suggested solutions to such issues, including, for the first one, an interesting analogy with the Anticommons Theory and, for the second one, the recourse to Competition Law, are taken into account.

The fourth and last section considers the instrument of trade secret, whose significance has been growing consistently in the last few years, leading to the implementation of specific laws both in the EU and the US. It will be underlined, given its importance, that trade secret could be a relevant instrument in the current pandemic, although the effectiveness of its disclosure relies on the private initiative of the owners.

The third chapter explores further perspectives on vaccines and intellectual property, in the context of the pandemic, including the proposal for the EU Unitary Patent System, that would stand united and firm within the international community.

More specifically, the first section underlies the Trade-Related Aspects of Intellectual Property Rights Agreement's significance, specifically in relation to the compulsory license. Indeed, it will be considered that this is not a suitable instrument to face the challenges that rise in the patent field during this pandemic,

such as the patentability of Covid-19 vaccines, but also diagnostics and treatments against the virus.

The second section shifts the attention to the EU former attempts in the implementation of a European Patent System, mostly impaired by issues of national sovereignty. It will be underlined that nowadays the situation might change, thanks to the Unitary Patent Package, and specifically the European Patent with Unitary Effect, that may ensure a harmonization in this field of law, through the support and the improvement of the European Patent Convention (EPC).

The third and final section shows that this goal is linked to the Unified Patent Court Agreement that should guarantee the enforcement of the Unitary Patent. In this context, the reluctancy of the Member States to entrust a supranational court to enforce the patent rights in the EU may represent a major obstacle.

Following the analysis of vaccines in light of the intellectual property subject, conducted in the second and third chapters, the fourth and last chapter argues that the vaccine against Covid-SARS-19 should be considered a Commons.

In particular, the first section addresses the first reason behind the aforementioned argument. Although the governments all around the world have invested substantial public funding in the R&D of treatments, diagnostics, and vaccines against Covid-SARS-19, the pharmaceuticals derived from that R&D belong to the private companies. Considering the lack of international and EU legal instruments in this regard, some US initiatives that attempt to solve this contradiction will be analyzed, although their effects seem not so encouraging.

The second section illustrates the second reason why vaccines should be Commons, which is the achievement of an efficient Global Health Security (GHS) system, that is human and equity-oriented, and not focused only on the wealth and security of each country nationals. It will be stated that there are many instruments through which this GHS can be implemented, and one of them is exactly a waiver of intellectual property rights, which would result in the theorization of vaccines as Commons.

The third section introduces the Theory of Commons, through a juxtaposition with the Theory of Anticommons which represents the private property. Though some authors consider the commons as a “tragedy” - something to avoid because of its inefficiency - it will be discussed that at the end the Commons Theory is a “comedy”, in the sense that it is efficient and beneficial for the public at large.

The fourth section addresses the same theory in the field of intellectual property, stating that the Commons in this subject matter can assume three different connotations: public domain, exceptions/limitations to copyright and patent, and open innovation. These three types of Commons will be illustrated by underlying their respective advantages and disadvantages.

The fifth and last section applies this Theory of Commons in the context of the vaccine against Covid-19, and it highlights all the benefits that would derive from it. Eventually it will be underlined that, from a theoretical perspective, an effective way to implement, manage, and enforce such a Commons is the “inclusive right”, whose main features will be illustrated, and it will be explained that this right can constitute a good starting point for the implementation of legislation related to the vaccine as a Commons.

Chapter 1: Preliminary remarks

1.1 A brief history of vaccines, between the public and private sectors

"No single medical advance had a greater impact on human health than vaccine"[2]. Indeed, since the end of 18th Century vaccines proved very helpful in contrasting the mass dissemination of diseases such as rabies, cholera, tuberculosis and eventually contributed to their eradication. In particular, the first mass vaccination occurred against smallpox – a virus responsible to have killed more than 500 million people in total– after 1796 the scientist Edward Jenner inoculated with vaccinia virus (cowpox) a 13-yeard old boy, and he demonstrated immunity against the virus[3].

In the USA, at the end of World War II, that can be considered the starting point of this brief history of the vaccine system, the pharmaceutical industry was not interested in this type of medical remedies, given the emergence of sophisticated antibiotics[4]. For example, in the 1940s the development of a vaccine against pneumonia was not extensively recognized, since the treatment of this disease with a new penicillin and sulphonamide was considered a better solution[5]. The pharmaceutical industry was focusing its resources in other therapeutical areas which seemed to be more profitable than vaccines[6].

However, while new methods for culturing viruses started to be studied, the scientist Maurice R. Hilleman – later considered the most important developer of vaccines in the 20th Century - had been hired by the newly merged company Merck, Sharp & Dohme, in order to establish and run an innovative vaccine research initiative. This included every step that would lead to the creation of a vaccine: basic research, development, and clinical research[7].

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[2] P. A. Offit, *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis* (New Haven, Yale University Press, 2005) xi.

[3] The Immunization Advisory Centre, *A brief history of vaccination* (2020) https://www.immune.org.nz/vaccines/vaccine-development/brief-history-vaccination (last visited Sep 27, 2021).

[4] S. Blume, *Towards a history of "the vaccine innovation system," 1950-2000*, in C. Hannaway (ed.), *Biomedicine in the twentieth century: Practices, policies, and politics* (2008) 257.

[5] ibid.

[6] ibid.

[7] L. Galambos, with J. E. Sewell, *Networks of Innovation: Vaccine Development at Merck, Sharp & Dohme, and Mulford, 1895-1995* (Cambridge University Press 1995) 79-99.

Hilleman, who had a massive support in the company, started an ambitious program directed especially at treating major diseases of children, such as measles[8]. Notably, although patent protection for vaccines at that time was either absent or weak, innovation in this sector started to increase anyway, since there was a scientific enthusiasm about the multiple possibilities that vaccines would offer. Most importantly, the federal government of the United States started to promote the use of selected vaccines, such as the notorious polio vaccine[9]. Hence, in the late 1950s the manufacture of vaccines in the US was consistent.

The pharmaceutical industry lost interest in the vaccine market once again in the 1970s. One primary reason could be a series of disasters occurred during the 1976 swine influenza[10]. In particular, the US government, in order to preserve public health[11], decided that the entire population would have to be vaccinated. This led to delays in the production of the vaccine, and the unwillingness of the pharmaceutical company to assume responsibility for the damages caused by the vaccine. Thus, between the mid-1960s and the end of 1970s, there was a significant decrease of licensed vaccine manufacturers and products[12].

The Office of Technology Assessment (OTA) of the US Congress expressed concerns on this matter[13], since at that time the US was highly dependent on one main pharmaceutical company for the production of vaccines, and there was a high risk that even this company could leave the market. This is what happened already, for instance, in the mid-1970s when the pharmaceutical company Eli Lily realized that the development of an experimental pneumococcal vaccine was too expensive and required an exaggerate amount of testing required by the federal regulations[14].

Given all these difficulties, the idea of a more active role by the federal government in stimulating and coordinating R&D for vaccines began to take hold among relevant vaccine spokesmen, but unfortunately no concrete initiative followed[15]. Indeed, the so-called National Vaccine Program (NVP) established by the Congress in 1986, that was supposed to achieve the aim of coordinating all the vaccine-related activities between the federal institutions and the private firms, faced several issues of insufficient funds, and thus could not operate properly[16].

Therefore, in the 1980s more pharmaceutical companies left the vaccine market, and by the mid-1990s only two US firms were actively developing new pediatric vaccines.[17] Dramatic changes in the vaccine industry did not occur only

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[8] ibid.
[9] Blume (n. 4) 258.
[10] ibid.
[11] D. J. Sencer and J. D. Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12(1) Emerging
Infectious Diseases 29-33 (2006) 33.
[12] Office of Technology Assessment (OTA), *Review of Federal Vaccine and Immunization Policies* (U.S. Government Printing Office, 1979).
[13] ibid at 27.
[14] ibid at 35.
[15] Blume (n. 4) 259-260.
[16] R. Nowak, *U.S. National Program is Going Nowhere Fast*, 265(5177) Science 1375 (1994) https://link.gale.com/apps/doc/A15828312/AONE?u=glasuni&sid=bookmark-AONE&xid=8e4614ff (last visited Aug 30, 2021).
[17] Blume (n. 4) 260.

in the US. This means that the failure of vaccines at that time was not only based on the ineffective policies implemented by the US federal government, but they were related to other factors that involved every country and affected the entire vaccine market globally[18].

In particular, the first important aspect that drove the radical change of industry worldwide was the complex scientific and technological assets that started to be required[19]. Secondly, the technological ownership to produce vaccines shifted from the public, as it was, for instance, forty years before when the first polio vaccine was discovered, to the private sector, and thus to the large industrial laboratories managed by private entities[20]. The third aspect that changed the vaccine enterprise was the increasing globalization of commerce, in the sense that, as the author Blume noted, in 1998 the global industry was owned by a few private multinational companies, instead of involving the smaller, public and state-controlled production of vaccines[21]. Lastly, the international standards for the vaccine production became much more stringent and difficult to implement[22].

Hence, as it can be noticed, the vaccine market was dramatically changing everywhere. It is true that these changes were strictly dependent on the country that is considered. For instance, despite the scarce presence of public funding in this field, in both China and India the growth and expansion of private companies was occurring alongside the pre-existent public funding[23]. Moreover, in Netherlands, the attempts of the private sector to eliminate the public one had never been entirely successful[24].

Within these changes, since private companies were gaining control of the R&D, the knowledge necessary to develop new vaccines started to be noticeably privatized and not freely exchangeable as it was in the past. For example, in 1983 a survey among the US manufacturers of vaccines stated that only two patents had been granted for twenty-seven different products. Ten years later, one firm had to obtain fourteen patents to produce its hepatitis-B vaccine[25]. Thus, despite the important role that governments played in the past, granting public funds for the vaccine R&D, by the 90s the private sector had acquired more power to decide whether and in which ways research could be translated into vaccine products[26].

It must be considered that, on the one hand, through the incentive of obtaining patents, since they could allow companies to gain monopolies in the pharmaceutical market, the vaccine research and manufacture increased considerably, leading to a multiplication of vaccines offered to children in the US

[18] ibid.
[19] S. Shin, *The Global Vaccine Enterprise: A Developing World Perspective*, 4(5) Nature Medicine 503, Vaccine Supplement (1998) 503-4.
[20] ibid.
[21] ibid.
[22] ibid.
[23] Blume (n. 4) 262.
[24] ibid.
[25] D. C. Mowery and V. Mitchell. *Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives*, 20(4) Journal of Health Politics, Policy and Law 973 (1995) 976.
[26] P. Freeman and A. Robbins, *The Elusive Promise of Vaccines*, The American Prospect 80-90 (1991).

and, thanks to the World Health Organization Expanded Program of Immunization, in several parts of the world[27]. On the other hand, the new vaccines were more expensive, in the sense that, thanks to the administration of vaccine through the involvement the public sector, an injection could cost $ 33,70 for each child, instead through the private companies the price of the product increased to $ 517,12[28].

This brief overview has presented how, in this problematic balance between the public and private sector, since the end of the 20th Century until now, the private sector has acquired a predominant position. In the following section it will be underlined, by offering examples, that there are still opportunities for the collaboration between these two opposite interests.

1.2 The opportunities of the collaboration between the public and private sector in the vaccines production

Over the last decades there has been a reduction of the public sector involvement for vaccine R&D[29]. In particular, a few so-called developed countries started to switch to the privatization of vaccines R&D, while until that moment this occurred in publicly funded research centres, many of which eventually were acquired by multinational companies[30].

For instance, the notorious Pasteur Institute, founded in 1887 by the scientist Louis Pasteur in order to not only conduct basic and applied research but also to develop and produce vaccines, was acquired by the private-owned Institut Mérieux. The latter, after a series of mergers and acquisitions, resulted in the establishment of the multinational company Sanofi[31]. A similar situation occurred in Italy where the Sclavo Institute in Siena, born with the aim of improving public health technologies, was privatized and then acquired by the Swiss company Novartis,[32] Also in the Netherlands, one of the few countries that tried to resist the privatization of the public-owned vaccine sector, as observed in 1.1, the National Vaccine Institute (NVI) was sold to the private Serum Institute of India Ltd (SIIL)[33].

These examples show the incompatibility of this vaccine privatization with an important argument, according to which the public sector has the responsibility

[27] Blume (n. 4) 270.
[28] A. R. Hinman, W. A. Orenstein, J. M. Santoli, et al., *Vaccine Shortages: History, Impact, and Prospects for the Future*, 27(1) Annual Review of Public Health 235-259 (2006) 240.
[29] M. A. Stevenson, *Geneva-Seattle Collaboration in Support of Developing Country Vaccine Manufacturing*, 13(4) Global Public Health 426-441 (2018) 428.
[30] ibid.
[31] Sanofi. Biotechnics, S. A. S, *Industry Watch. Asia-Pacific*, 13 Biotech News 29-40 (2009).
[32] P. M. Danzon & N. Sousa Pereira, *Vaccine supply: Effects of regulation and competition*, 18(2) International Journal of the Economics of Business 239–271 (2011).
[33] K. Kulkarni, *Serum Institute of India buys Dutch vaccine maker for $40.3 mln*, Reuters (2012) http://in.reuters.com/article/serum-institute-bilthoven-biologicals-idINDEE8630A220120704 (last visited Aug 31, 2021).

and obligation to provide goods and services in order to benefit each population, and most importantly, the vulnerable ones, which are usually the ones that are found in developing countries[34]. This same argument considers that the role of private sector is to give priority to products that would be beneficial for the companies' investments and profits, and this means to not take into high account the aspect of innovation, especially in the developing countries[35].

Authors argue that this opposition between private and public sector, and the predominance of the first one, inevitably led to, first, the excessive costs of the products that could not be afforded by the poorest countries, and second, the lack of priority and interest on the side of the private sector in R&D to treat diseases in developing countries[36].

Instead of having a radical contrast between these two interests, the private and public ones, it is important to address the opportunities for collaboration between the private and public sectors in the development of vaccines, that can lead to the sustainability of the production in developing countries. The first attempt can be traced back to the work of the World Health Organization (WHO), which tried to assist both manufacturers and governments of developing countries in, respectively, meeting the strict international quality standards for health products and strengthening the capacity of regulating domestic vaccine production[37].

In particular, in 1987 the WHO entered into an agreement with the United Nations Children's Fund (UNICEF) in order to establish the safety and effectiveness of products, and to support National Regulatory Authorities (NRAs) to accomplish their aims[38]. The process is the following: manufacturers submit their product applications to the WHO, which decides whether those products are prequalified (PQ), i.e. eligible for an international distribution[39]. To avoid that smaller manufacturers are endangered from the fact that NRAs must apply the same standards to grant the pre-qualification, in 2000 the WHO elaborated a comparative scoring system that provides an indicator of each NRA functionality, according to the minimum international standards for vaccine production. Thus, manufacturers can proceed with their PQ applications only when the NRAs have passed the assessment and are declared functional[40].

Severe issues related to helping governments to establish appropriate regulatory standards highlight the flaws of the WHO system. With the regulatory capacity-building strategy (the so-called "5-step capacity building approach") established in 1998, the WHO started to develop an assessment tool in order to address each country on an individual basis. WHO identified gaps and created

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[34] R. T. Mahoney, A. Pablos-Mendez, & S. Ramachandran, *The introduction of new vaccines into developing countries: III. The role of intellectual property*, 22(5) Vaccine 786–792 (2004).
[35] P. Trouiller, E. Torreele, P. Olliaro, N. White, S. Foster, D. Wirth & B. Pécoul, *Drugs for neglected diseases: A failure of the market and a public health failure?* 6(11) Tropical Medicine and International Health 945–951 (2001).
[36] Mahoney et al (n. 34) 788.
[37] J. Milstien, A. Costa, S. Jadhav, & R. Dhere, *Reaching international GMP standards for vaccine production: Challenges for developing countries*, 8 Expert Review of Vaccines 559–566 (2009).
[38] N. Dellepiane & D. Wood, *Twenty-five years of the WHO vaccines pre qualification programme (1987-2012): Lesson learned and future perspectives*, 33 Vaccine 52–61 (2015).
[39] ibid.
[40] N. Dellepiane, personal communication (March 18, 2015) in Stevenson (n. 29) 433.

country-specific Institutional Development Plans (IDPs) in collaboration with each government [41]. Finally, after fulfilling those plans, countries were ready for a reassessment. However, since resources to implement this system were limited, the needs of certain countries were prioritized in - sometimes - an arbitrary way. In particular, the criteria through which countries are divided in three different groups (A, B, C), which correspond to different layers of assistance, are not entirely clear. In addition, maintaining this system required the full collaboration of the governments of these countries and the contribution of external donors[42], something extremely difficult to reach and preserve.

Another way to offer an assistance to produce vaccines in developing countries, and to avoid that every aspect of the market is in the hands of private firms, is through private philanthropic organizations, among which the most notorious can be considered the Bill and Melinda Gates Foundation (BMGF). In particular, the latter underwrote and supported the Global Alliance for Vaccine and Immunization (GAVI) in 2001, which offered a mechanism of development assistance, consisting in the introduction of expensive pediatric vaccines in developing countries, and raising political support for the aim of immunization.[43]

It can be reputed that BMGF managed to quantify in the South of the world the diseases that could be prevented by the vaccine, helped to improve clinical trials and product procurement for poor countries, and gave a sort of market stability for vaccine producers, leading to an increase of PQ demand from manufacturers in developing countries[44]. The work of BMGF was definitely beneficial in terms of providing pharmaceuticals in a developing country, considering that studies have shown that usually it can take 10-15 years from the first licensure in a developed country before the same vaccine is introduced in a developing one[45].

Interestingly, the Foundation put its energy also in directly supporting the capacity of individual manufacturers of developing countries. For instance, together with the efforts of the Seattle-based non-profit organization called PATH, that was the promoter of the Meningitis Vaccine Partnership of 2001, BMGF brought together the private firm SIIL, WHO, United States' National Institutes of Health and Food and Drug Administration (FDA), and an Amsterdam-based company, with the aim of producing a new less expensive meningococcal vaccine that could be given to sub-Saharan African Countries[46].

Although the described initiatives can be considered an effective way to pursue the harmonization between the public and private sectors, probably they are insufficient, since there is still an obstacle that, despite every effort of

[41] ibid.
[42] M. Laforce, personal communication (November 26, 2014) in Stevenson (n. 28) 434.
[43] Bill and Melinda Gates Foundation, *Bill and Melinda Gates Foundation announces $750 million gift to speed delivery of life-saving vaccines* (1999) http://www.gatesfoundation.org/Media-Center/Press-Releases/1999/11/Global-Alliance-for-Vaccines-and-Immunization (last visited Sep 1, 2021).
[44] Stevenson (n. 29) 434; Dellepiane & Wood (n. 38) 57.
[45] R. T. Mahoney & J. E. Maynard, *The introduction of new vaccines into developing countries*, 17(7) Vaccine 646–652 (1999) 646.
[46] D.M. Bishai, C. Champion, M.E. Steele & L. Thompson, *Product development partnerships hit their stride: Lessons from developing a meningitis vaccine for Africa*, 30(6) Health Affairs 1058–1064 (2011) 1058.

collaboration, does not give the possibility to optimize the aforementioned balance between publicity and privatization. This obstacle is represented by intellectual property and more specifically patents, of which an overview in the pharmaceutical industry will be offered in the next and last section of this chapter, after having underlined the complexity of the authorization processes for pharmaceuticals implemented in both the US and the EU.

1.3 The pharmaceuticals in the context of authorization processes and protection regimes

It seems opportune to provide the overview in the pharmaceutical industry, focusing on the US and the EU ones, because of their importance worldwide, by providing every year several innovative technologies and essential drugs to people[47].

It must be understood that pharmaceutical companies that want to bring a new drug into the market, must go through a multistep process that requires both patent grant by the US Patent and Trade Mark Office and FDA approval, if the refence is made to the US market, and the patent grant by the European Patent Office and the EMA approval in the European context. This process is generally reputed expensive and of long duration[48].

In particular, the FDA approval process can take between ten and twelve years[49], since the authority must assess whether the product is safe and effective to be made commercially available[50]. The process within the EMA, often referred to as "centralized procedure"[51], appears to be shorter, considering that the time limit for the evaluation of a drug should amount to 210 days, before the agency sends its opinion to the European Commission for the approval[52]. However, such time limit can be extended if additional questions need to be addressed[53], and this can lead to longer approval times.

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[47] A. Fachler, *The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift towards Regulatory Exclusivities*, 24(4) Fordham Intellectual Property, Media & Entertainment Law Journal 1059 (2014) 1063.

[48] V. J. Roth, *Will FDA Data Exclusivity Make Biologic Patents Passe*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 249 (2013) 251.

[49] D. Fernandez, J. Huie & J. Hsu, *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 969 (A. Krattiger et al. eds., 2007).

[50] 21 U.S.C. § 355.

[51] See Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[52] European Commission, *Authorization procedures- the centralized procedure* https://ec.europa.eu/health/authorisation-procedures-centralised_en (last visited Nov 4, 2021).

[53] ibid.

Therefore, if pharmaceutical companies keep developing drugs, they need an effective system of incentives, and this system can perhaps be offered by patent protection. Indeed, patent law is defined sometimes as "the legal embodiment of innovation"[54], and the pharmaceutical industry is the one that relies the most on patent protection[55]. When companies create new pharmaceutical drugs to be sold in the market, they are motivated by the fact that, thanks to the grant of the patent, they would be compensated for the investments in R&D, and that they could profit from the exclusivity in the market conferred by the patent itself[56].

Under Title 35 of the US Code, entitled "Patents", if the invention has as its object a "composition of matter" that is "new and useful"[57], it is "novel"[58], and "non-obvious"[59], and the patent-holder fully discloses how the invention works in the patent application[60], a patent is granted for twenty years from the date the application itself is filed[61].

In a very similar way, according to the EPC, if the invention falls within one of the patentable ones[62], and it fulfils the requirements of "novelty"[63], "inventive step"[64], and "industrial application"[65], it can be granted a patent that usually lasts for twenty years from the date of application[66]

It seems important to underline a few issues regarding patents in the pharmaceutical sector.

First, in relation to the US context, there is evidence that patents are issued quite early during the product development, specifically before the clinical trial testing that is required to receive the FDA approval[67]. Therefore, the effective patent life is generally reduced to approximately fourteen years, or the patent may be expired even before the product is introduced into the market[68].

A second issue is related to the European context. In particular, as explained in further detail in section 3.2, the EPC does not grant a unitary patent that is protected in each of the 38 countries that ratified that treaty. It is true that the patent authorization process is managed only by the EPO, which is in fact the centralized body before which a patent application is made. However, it is also true that the Office grants a bundle of national patents, in the sense that it will

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[54] A. Lewin, *Medical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 HARV. J.L. & TECH. 403 (2012) 412.

[55] In the software industry there seems not to be such a strong reliance on patents as a method to prevent free-riding on inventive activity: W. Landes & R.A. Posner, *The economic structure of intellectual property law* (2003) 312.

[56] Fachler (n. 47) 1066.

[57] 35 U.S.C. § 101.

[58] 35 U.S.C. § 102.

[59] 35 U.S.C. § 103.

[60] ibid.

[61] 35 U.S.C. § 154.

[62] EPC, Art. 52.

[63] EPC, Art. 54.

[64] EPC, Art. 56.

[65] EPC, Art. 57.

[66] EPC, Art. 63.

[67] R. S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007) 348.

[68] ibid; H. G. Grabowski & M. Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491 (2007) 492.

offer the protection of an invention in the countries the patent holder has specifically indicated in her patent application[69]. Hence, a patent will not receive uniform protection throughout all the European territory, and this can constitute a disincentive for the pharmaceutical company that would incur in an extremely cumbersome process.

A last aspect regards the difficulty of applying the patent requirements in the pharmaceutical industry. In particular, since applications for patents are made very early in the product development, it is impossible to assess properly the "useful" requirement[70]. Moreover, it can be argued that the strict "novel" and "non-obvious" requirements fail to recognize the real importance and value of this type of products, which is not the information underlying the invention, but consists in the benefits that such invention can offer to the public at large, since pharmaceuticals are made abstractly to fulfil public health purposes, and not just for the goals of curiosity and inventiveness as such[71].

Considering all these issues, it can be stated that the patent system does not provide the optimal incentive to innovation[72], at least in the pharmaceutical industry. As a result, many authors have started to think about different systems of protection and incentives for pharmaceutical products, including vaccines.

The works of Wright and Kapczynski seem particularly relevant in this respect, because these authors, by questioning the role of intellectual property, confirm the idea explored in the present dissertation, in particular in Chapter 4, that intellectual property is not always the only way to efficiently manage the "products of the mind".

For instance, although no concrete reforms at the legislative level have been implemented for now, economists have started to think about direct government funding and prize systems as a better way to provide incentives for pharmaceutical companies and, as a consequence, better welfare for the public at large[73]. Since, as discussed above, most of the times patent requirements – utility, novelty and inventive step - set a ban to innovative and useful drugs because of their formal lack of patentability, a reward-based incentive program could promote the usage of certain drugs because of their high social value[74].

Another effective system that could replace patent protection in the US is the application of regulatory exclusivities enforced by FDA. It was already stated that patent exclusivity is already partially running while the FDA approval is in progress. Considering also that FDA already plays a part in granting patent extensions - the so-called "pseudo-patents" – in order to remedy the ineffectiveness of the original patent term[75], it is proposed that FDA could administer all the regulatory exclusivities in a way that may finally boost

[69] EPC, Art. 64(1).
[70] Fachler (n. 47) 1077.
[71] B. N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009) 516.
[72] B. D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983) 691.
[73] A. Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005) 1045.
[74] Fachler (n. 47) 1091.
[75] Eisenberg (n. 67) 360-61.

innovation in the pharmaceutical industry[76]. Indeed, these FDA regulations would be designed to offer periods of exclusivity to the innovators of the industry, as it would occur with intellectual property[77]. The advantage of this proposal is to solve the overlap between the patent grant and FDA approval, since FDA itself would grant the exclusivity.

Considering the current attempts to find alternative incentives for innovation in the pharmaceutical industry, it can be concluded that intellectual property is not always the optimal solution. This idea will be developed further in the following chapter, that investigates the protection of vaccines within intellectual property more closely, in the light of the current pandemic of Covid-SARS-19.

[76] ibid at 348.
[77] Fachler (n. 47) 1094.

Chapter 2: Vaccines and intellectual property in the context of the pharmaceutical industry and the current pandemic

2.1 Vaccines and patents: the mRNA technology as a case-study

Before assessing whether the mRNA technology can be patentable, an overview of the patentability of vaccines in general must be provided. First, if the international context is taken into account, it can be noticed that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, whose members are the 161 countries - almost every country of the world - which constitute the World Trade Organization (WTO), provides that any inventions can be patentable as long as "they are new, involve an inventive step, and are capable of industrial application"[78], as already stated for the US and the EU context in 1.3.

There is not a definition of invention in this legislation, though there is a list of subject matter that member states can decide to exclude from patentability under their national law. In particular, according to Art. 27 of TRIPS, among this subject matter, there are "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes"[79].

The problem is that not even in this case a definition of animal or microorganism or a clarification about gene patenting has been provided. Therefore, it can be said that states are left on their own in terms of choosing and interpreting this possible limitation to patentability[80].

If the attention shifts now on a regional level, the context is even more unclear. For the US, the reference is to Title 35 of the US Code which deals with Patent Law. In particular, what constitutes patentable subject matter in the US is described in a general clause, referring to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"[81].

[78] TRIPS, Art. 27(1).
[79] TRIPS, Art. 27(3)(b).
[80] E. Siew-Kuan Ng, *Intellectual Property in Vaccine Innovation: Impact of Recent Patent Developments*, 1404 Methods in Molecular Biology 835 (2016) 838.
[81] 35 U.S.C. § 101.

By contrast, in art. 52(2) of the EPC, a list of non-patentable subject matter is offered, and it includes "(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information"[82]. It is however clarified that the subject-matter mentioned in that list should be excluded from patentability "only to the extent to which a European patent application or European patent relates to such subject-matter […] as such"[83]. Although there are doubts about what can be considered a non-patentable subject matter as such[84], the EPC is sufficiently clear in considering specific genes products and DNA sequences as patentable, as long as these products have an industrial application, since they are not listed among the non-patentable subject matter.

In the US, some guidance in identifying the exact scope of a patentable invention has been offered by the case-law of the Supreme Court, by crossing a crucial evolution with the *Myriad* decision, in 2013, which clarified the patentability of genes products and DNA sequences.

Initially, to the question whether microorganisms may be considered patentable subject matter, the Court replied that patents can be granted for "anything under the sun that is made by man"[85]. In particular, the relevant distinction in order to assess the patentability is not between living and inanimate things, but between products of nature and human-made inventions[86].

After this decision, the US Patent and Trade Mark Office (USPTO) adopted a very expansive approach in granting patents to a wide range of engineered DNA molecules and claimed cDNA molecules in combination with other genetic materials[87]. Only in 2009, this practice adopted by a "patent-happy"[88] USPTO was challenged by medical researchers, advocacy groups, medical doctors, and patients, in the abovementioned *Myriad* decision[89].

Here, the Supreme Court terminated this liberal tendency of granting patents related to genes and genomic DNA sequences. Indeed, focusing on the idea of product of nature, Justice Thomas - who delivered the opinion for the court - stated that there is an implicit exception to patentable subject matter as generally described in 35 U.S.C. § 101, that is laws of nature, natural phenomena, and abstract ideas, because otherwise patents would restrict the use of these basic tools of technology, and innovation would be impaired[90].

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[82] EPC, Art. 52(2).
[83] EPC, Art. 52(3).
[84] This involves the analysis of other patentability requirements: in this regard c.f. the "technical contribution" approach adopted in UK with *Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371, and the "technical character" approach by the EPO in *Programs for computers* G3/08 [2010] EPOR 36.
[85] *Diamond v Chakrabarty* [1980] 447 U.S. 303, 309.
[86] ibid.
[87] Brief for the United States as amicus curiae in the Association for *Molecular Pathology v Myriad Genetics* (in the US Supreme Court).
[88] J. Bravin, *Justices wary on gene patents*, The Wall Street Journal (2013) http://www.wsj.com/articles/SB10001424127887324485004578424782830965300 (last visited Sep 8, 2021).
[89] *Association for Molecular Pathology v Myriad Genetics* [2013] 12 U.S. 398.
[90] ibid.

Although every invention is the concretization and implementation of laws of nature, phenomena and idea, a balance must be struck between incentives to creation and discovery, and the correct flow of information towards the public[91], as already underlined in 1.3. Therefore, on that occasion the patentability of genomic DNA was held to be invalid.

This approach seems to be more coherent to the already described EPC's limitations to patentable subject matter, since *Myriad* basically affirmed that a product of nature can be patented only when it serves some "human" purposes, meaning that it solves a certain technical problem and is implemented in an artificial way.

With the success of the very recent mRNA vaccines manufactured by Moderna and BioNTech/Pfizer against Covid-SARS-19, the mRNA technology gained a huge attention worldwide, although this method in producing vaccines is not so recent.

Indeed, the idea of genetic - DNA and RNA - vaccines started to be developed many years ago, but until the late 2000s there was not so much trust in using RNA, because of its instability, the inefficiency in *vivo* delivery and the risks of having substantial inflammatory responses[92].

Lately, from 2010 onwards, some fundamental innovations in the study of RNA made possible the solution of the problems that have been just mentioned. In particular, the progresses are related to the ability of engineering mRNA sequences, the enactment of effective methods that lead to the safe and reliable production of mRNA, and the improvement of techniques to efficiently deliver mRNA vaccines[93].

These innovative nucleic acid vaccines are an improvement of the former recombinant vector vaccines[94], considering that, instead of inserting the DNA plasmid into a bacterial or mammalian cell to then purify the antigenic result, these new vaccines can be immediately administered into the patient where the antigen is produced in her own cells[95]. This viral antigen, that is produced by the patient's cells *in situ*, stimulates an immune response. Therefore, on the one hand immunity against the original virus is generated, and on the other hand, the security of the vaccine recipient is not compromised[96].

Moreover, in terms of the manufacturing process, these mRNA vaccines are easier and faster to produce than the recombinant vector vaccines, and this is an extremely important aspect in the current pandemic, where the timing of the virus response to the vaccine must be reduced as much as possible. Indeed, when the sequence that encodes an immunogen is discovered, the vaccines can be

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[91] ibid.

[92] N. Pardi, M. J. Hogan, and D. Weissman, *Recent Advances in mRNA Vaccine Technology*, 65 Current Opinion in Immunology 14 (2020) 14.

[93] ibid.

[94] A vaccine against Covid-SARS-19, manufactured through a recombinant vector, is the Vaxzevria Vaccine (former Astrazeneca).

[95] W. Jiskoot, G. F. A. Kersten, E. Mastrobattista, B. Slutter, *Vaccines*, in: D. J. A. Crommelin, R. D. Sindelar, B. Meibohm (Eds), *Pharmaceutical Biotechnology*, Springer Nature (2016) 381-304.

[96] E. H. Pilkington, E. J. A. Suys, N. L. Trevaskis, et al., *From Influenza to COVID-19: Lipid Nanoparticle mRNA Vaccines at the Frontiers of Infectious Diseases*, 131 Acta Biomaterialia 16-40 (2021) 17.

produced within few weeks[97]. This can be useful specifically in case a new virus strain has been identified, or a new mutation has occurred in a known virus.

Another relevant characteristic is that multiple mRNAs encoding different antigens can be combined in a single immunization, leading to a multi-antigenic approach that constitutes an optimal solution to assemble multimeric protein complexes directly in the host cells, and thus to obtain a universal vaccine against influenza[98].

Given the importance of this ground-breaking technology, it should come as no surprise that every time an invention related to it has been developed is immediately patented. For instance, Moderna has been patenting every mRNA technology and delivery instrument that is essential for mRNA therapeutics and vaccines[99].

If this discussion about patentable subject matter is transposed in the context of vaccines, it must be said that their patentability largely depends on their composition, given that these products can have many forms[100]. Perhaps the ingenious vaccine against smallpox, already mentioned in 1.1, which was realized through an injection of pus from a milk maid that had been exposed to cowpox, would not deserve patentability, according to the current patent legislation and jurisprudence, because of its natural connotation[101].

However, nowadays, there are vaccines that contain living or nonliving matter that have been altered to have a synthetic result suitable for inoculation, such as the recombinant vectors. It can be said that, following the criteria established in *Myriad*, since they contain modified pathogens or modified DNA, this type of vaccines can be patentable.

For instance, the flu vaccine, which is deemed to need regular updates every year, requires months of work made by highly prepared scientists, and even though some of its parts are based on nature, it is something created in state-of-the-art laboratories[102]. The same should apply for mRNA vaccines manufactured in the current pandemic.

It is true that they are based on something that it is naturally present in the human body – mRNA - and the viral antigen in this case is produced in the cells of the patient. However, the final product involves, as it has been already underlined, years of experimentation and development to engineer mRNA sequences, and to allow them to function in a way that they are useful for human purposes. This is the reason why it is defined mRNA technology, with this last term indicating something that is in fact artificial.

Therefore, it can be stated that vaccines, although they are generally based on a product of nature, are not to be considered as such, other than the fact that they are industrially applicable. This means that under US and EPC law most of them are patentable. However, the reflection that this work sets out to make, based on the wider objective of the theorization of a Commons for the Covid-19

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[97] ibid.
[98] ibid.
[99] Moderna, *Moderna's Patent Estate: Messenger RNA Technologies (mRNA) & Delivery Technologies* (2021) https://www.modernatx.com/mrna-technology/modernas-intellectual-property (last visited Sep 8, 2021).
[100] Ng (n. 80) 843.
[101] Palmer (n. 1).
[102] ibid.

Vaccine, as it will be argued in Chapter 4, is the following: is it fair and reasonable that vaccines are patentable? In order to answer this question, it is important to address first, in the next two sections, the phenomena of patent thickets and strategic accumulations, as two keys to further investigate the relationship between vaccines and patents in the pharmaceutical industry.

2.2 Patent thickets in complex technologies: a vicious cycle

Innovation nowadays is reputed to be cumulative in its nature[103]. This is evident if innovation is seen as a scientific pyramid, where each scientist adds a block to a certain creation[104]. In R&D, typically, the new inventor cannot simply recognize credits to the previous one in form of citation, but patents would require each new manufacturer to demand a license to the patent holder[105]. In this context, it is possible to identify a specific phenomenon called "patent thickets"[106].

Interestingly, in the legal literature, this term is often linked to the Anticommons Theory elaborated by Professor Michael Heller in the field of real property. According to this theory, the Anticommons issue arises whenever there is an excessive fragmentation of different owners' interests in the same piece of land[107]. In particular, according to Heller, who elaborated this theory to offer an explanation about the riddle of empty storefronts and full kiosks in Moscow, this Anticommons is "a type of property regime that may result when initial endowments are created as disaggregated rights rather than as coherent bundles of rights in scarce resources"[108].

This phenomenon of Anticommons is considered to be symmetrical to the one of Commons[109]. Indeed, while in the Theory of Commons each person has the right to use a given resource and, at the same time, no one has the right to exclude another one from that resource, in the Anticommons each owner is attributed the right to exclude others from the use of a resource, but no one has the tools to implement this right[110]. Hence, using that resource becomes problematic.

Although this work considers the Commons Theory in more details in Chapter 4, this analogy between Anticommons and patent thickets offers an idea about how the theories related to real property can often be applied in the context

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[103] O. Gurgula, *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features*, 48(4) IIC - International Review of Intellectual Property and Competition Law 385 (2017) 387.

[104] C. Shapiro, *Navigating the patent thicket: cross licenses, patent pools, and standard-setting*, in: A. B. Jaffe et al (eds) *Innovation policy and the economy*, 1 National Bureau of Economic Research 120 (2001) 120.

[105] ibid.

[106] ibid.

[107] M. Heller, *The tragedy of the anticommons: property in the transition from Marx to markets*, 111 Harv L Rev 621 (1998).

[108] ibid at 623.

[109] ibid.

[110] ibid at 622.

of intellectual property. In line with the Anticommons Theory, patent thickets can be understood as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology"[111]. As it can be noticed, this definition fits with the complex technology issue[112].

Thickets are in fact usually applied to offer patent protection of parts of a technology that is defined modular and complex, in the sense that different components of that technology can be assembled to result in different products ("modular"), and these products consist of a multitude of these different components ("complex")[113]. Given this complexity, as there are overlaps in the functionality of different components, there is an overlap in the patents granted for those components, and if the patents are granted to different firms, the patent thickets issue arises[114].

There are two substantial factors that lead to the phenomenon: institutional gaps and business strategies. The first one is connected to the flaws that can affect the work of the patent offices. In particular, the lack of resources in these institutions causes a poor examination of the patent application, that in turn results in granting weak patents with overlapping claims or claims whose scope is uncertain[115].

The issue of business strategies can be explained referring to the reasons why big companies decide to patent in complex industries. These reasons are the following: to prevent rivals from patenting related inventions ("patent blocking"), since otherwise the first company would not have the exclusivity for that specific technology; to use the patent in the negotiation with other owners that have patented different technologies; to avoid patent infringement lawsuits[116].

A relevant problem is that patent thickets are reputed to trigger a vicious cycle. In particular, it has been shown that, due to patent thickets, in certain industries, it is difficult to identify all the patents that have been granted, to assess the claims in every patent, and to avoid the overlaps, and the owners of these technologies have no intentions to arrest the production of innovative products[117]. The consequence is that companies are prompt to filing hundreds of patents each year to avoid patent infringement and to be in a more convenient trade position when negotiation takes place. The result is more patent thickets.

Biotechnology, which includes vaccine R&D, is one of the industries that mostly involve patent thickets[118]. It has been already noticed in 2.1 that vaccines can be included among the complex technologies, and although that they are based on natural elements, such as mRNA, they require the human intervention

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[111] Shapiro (n. 104).
[112] Gurgula (n. 103) 388.
[113] B. H. Hall et al., *A study of patent thicket*, UK Intellectual Property Office (2013) 7.
[114] ibid.
[115] ibid at 8.
[116] W. M. Cohen, *Protecting their intellectual assets: appropriability conditions and why US manufacturing firms patent (or not)*, NBER Working Paper, Cambridge, MA 7552 (2000) 7552.
[117] Federal Trade Commission, *Report to promote innovation: the proper balance of competition and patent law and policy* (2003).
[118] ibid at 32: other technologies that can generate this phenomenon are semiconductors, computer software, the Internet and nanotechnology.

for every step that leads to their production. Indeed, different patents are granted for one vaccine to protect this technology on different levels[119].

A finalized vaccine product is constituted by various components, and each of them may be covered by different patents. In particular, a vaccine can be formed by an antigen, an adjuvant, and an excipient, that are respectively covered by more than one patent[120]. For instance, when a novel antigen is identified, there can be the patentability of the nucleic acid level, the protein level, and the expression technology, that would receive a distinctive protection than the one towards adjuvants and vehicle technologies[121].

Moreover, not only the vaccine *per se*, but also its medical application can receive patent protection[122], such as for a new delivery device, a novel vaccine combination with various substances, a new dosage, or a different target group[123]. Given these circumstances, it can be easily understood that one single manufacturer of the vaccine is not the holder of all the patents for that product and the relative medical applications.

This inevitably leads to a "war" of in-, out-, and cross-licensing that is even more common than in other sectors of the pharmaceutical industry[124]. Therefore, there is once again a run by the pharmaceutical companies to apply for several patents related to the different components of a vaccine, resulting in more patent thickets.

The question is how the problem of patent thickets can be solved in complex technologies, mostly for the benefit of the smaller companies that have consistent difficulties to entry a particular sector where there are complex technologies, without the risk to be involved in expensive lawsuits or in non-favorable licensing negotiations.

According to some authors, such as Jacob, this problem of patent thickets is a direct and natural malfunctioning of the patent system, and thus nothing can really be done to solve it if the patent system itself is not improved in some ways[125]. Indeed, in a certain way, it is patent law itself that authorizes the application of patent thickets. As explained in the section 2.1, both in the EPC and the US legislation, every single invention can be patentable, as soon as it is

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[119] M. M. M. Mertes & G. Stötter, *Managing the patent thicket and maximizing patent lifetime in vaccine technology*, 6(10) Human Vaccines 860 (2010) 860.

[120] ibid.

[121] ibid.

[122] This is legally possible according to the EPO, *Guidelines for Examination* (Part G, Chapter IV, 7.1): "Where a substance or composition is already known to have been used in a "first medical use", it may still be patentable under Art. 54(5) for any second or further use in a method according to Art. 53(c), provided that said use is novel and inventive" https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm (last visited Oct 15, 2021). In the US there is not an exclusion of patentability of methods for medical treatment, as it is instead provided in Art. 53(c) EPC. Therefore, the US is even more permissible than the EPC in this regard. See for further details C. Ducimetière, *Second Medical Use Patents - Legal Treatment and Public Health Issues*, 101 Research Paper (South Centre, 2019).

[123] Mertes (n. 119) 860.

[124] ibid.

[125] R. Jacob, *Patent thickets: a paper for the European Patent Office Economic and Scientific Advisory Board Meeting*, 8(3) J Intellect Prop Law Pract 206 (2013).

new[126], non-obvious[127], and industrially applicable[128], and the "size" and the contribution of these inventions in relation to the composition of a complex technology is not relevant.

Other authors, including Gurgula, are more optimists and believe that there has been at least one example in history where the patent thickets issue has been solved through private mechanisms, that is the sewing machine war[129].

In the 19th Century, the sewing machine was considered a complex technology and, as such, was not made by one manufacturer. Indeed, many inventors made a lot of experimentation and were granted hundreds of patents for each essential component of that invention[130]. This led to the so-called "Sewing Machine War" of the 1850s, since it became impossible to manufacture one of these machines without incurring in patent infringements[131].

Now, this problem was not overcome by new laws concerning the patent system, but by the patent holders exercising in a more collaborative way the rights of use and disposition attributed through their patents, resulting in one of the first patent pools in history called "Sewing Machine Combination"[132]. Therefore, Gurgula contends that there is the need of coordination among patent owners, in the forms of patent pools, cross-licensing, and standard setting mechanisms[133].

The problem is that these mechanisms have not resulted to be particularly effective, since their implementation is left to the will of the patent holders, that most of the time are not inclined to collaborate with their competitors, as it will be seen also in relation to the disclosure of trade secrets in section 2.4. Hence, a different solution can be proposed in the following terms.

Considering the analogy between the patent thickets and the Anticommons Theory, it can be said that if the vaccine becomes a Commons, as it is discussed in Chapter 4, at least for the relative complex technology the patent thickets would not be an issue anymore. Therefore, instead of focusing on a collaboration between patent holders, or on a reformation of the patent system, which, especially in the pharmaceutical industry, has not proved particularly effective, and indeed other types of incentives have been discussed in section 1.3, such as a system of rewards, the solution to avoid patent thickets could be to abolish the patent system for this technology through the introduction of Commons, which will be the central argument of Chapter 4.

[126] EPC, Art. 54; 35 U.S.C. § 102.
[127] EPC, Art. 56; 35 U.S.C. § 103.
[128] EPC, Art. 57; 35 U.S.C. § 103.
[129] Gurgula (n. 103) 392.
[130] A. Mossoff, *The rise and fall of the first American patent thicket: the sewing machine war of the 1850s*, 53 Ariz Law Rev. 165 (2011) 194.
[131] ibid.
[132] ibid.
[133] Gurgula (n. 103) 392.

2.3 The strategic accumulation of patents

Patent thickets must be distinguished from the so-called strategic accumulation of patents, that is a phenomenon strictly related to the pharmaceutical industry, through which pharmaceutical companies are able to extend their monopoly in the market[134].

Although its implementation has global relevance, this practice has been particularly detected and assessed by the European Commission which identified two underlying goals that allow the competitors in the market to keep their monopoly and have the broadest protection: to guarantee the protection of their product at least until the end of the monopoly of the base patent; to extend the exclusivity period even if the base patent has expired[135].

To achieve the first aim, the competitors will try to file hundreds of patent applications that cover every commercially valuable aspect of their products such as different processes, formulations, pharmaceutical indications, resulting in multiple levels of protection for the company, especially in cases other competitors attempt to invalidate the base patent during its exclusivity period[136]. In this way, these competitors, that are generic companies, namely companies that produce and sell drugs whose patents have already expired, would have serious difficulties to enter the market because of the strategic accumulation of secondary patents by the first competitor, defined as the originator[137].

Moreover, if the originator company obtains numerous secondary patents, the product is still protected after the expiration of the base patent, achieving the second aim mentioned above, and generic companies are kept outside the market[138]. The result of all these accumulation practices is the creation of a web of patents, namely a portfolio of patent rights that protects the different components of a single product[139].

A way through which this portfolio may grow is also the use of pending applications, in the sense that the originator competitor can increase the number of applications by filing for divisional patent applications, which will have a procedure of their own, although they were supposed to be part of a unique application[140].

As mentioned before, patent thickets in complex technologies and strategic accumulation of patents in the pharmaceutical industry are two different practices[141]. Although the second has some similarities with the first one, considering that they both constitute a dense web of overlapping patents, and they both depend mainly on institutional flaws, as it has been seen in relation to

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[134] ibid at 394.
[135] European Commission, *Pharmaceutical sector inquiry: final report*, Pharm Sect Inquiry (2009) 184, para 475.
[136] ibid at 189, para 491.
[137] ibid at 184, para 476.
[138] ibid at 185, para 477.
[139] ibid at 189, para 492.
[140] ibid at 187, para 481.
[141] Gurgula (n. 103) 399.

patent thickets in section 2.2, there are many aspects in which the two practices differ.

First, the strategic accumulation is made by only one company - the originator -, instead the patent thickets – and this is their main characteristic – are managed by different patent holders for the same complex technology[142].

Secondly, the strategy of accumulation attempts to protect the base patent of the originator, which has a noticeable commercial value, and to extend this protection beyond the base patent itself, meanwhile in the patent thickets this underlying motivation is not identified[143].

Thirdly, the originator maintains always exclusive rights over the patent portfolio[144].

The fourth reason why the two practices are different is related to the aspect of intention. Indeed, while patent holders do not want to implement patent thickets as peculiar business strategies, in the pharmaceutical industry the accumulation of patents is strategic, and thus intentional, since there is the aim to prevent generic companies from entering the market[145].

Lastly, if patent owners do not solve the patent thickets problem, there will be damages for everyone involved, since at one point it will be impossible to use a certain feature of a complex technology without the risk to violate a certain patent, as observed in 2.2. By contrast, the strategic accumulation is something that the originator does not want to end, because it can keep competitors off the market[146].

Therefore, it can be stated that this second phenomenon – typical of the pharmaceutical industry – is more dangerous and challenging than the one of patent thickets, and it would require regulatory solutions not only in terms of patent law – that for now are completely absent - but also in relation to competition law. Indeed, such a strategic behavior of pharmaceutical companies that want to extend their patent monopoly should be sanctioned by competition authorities.

Competition Law has the correct instruments to face such practices, since the latter would be dealt with under Art. 102 of the Treaty on the Functioning of the European Union (TFEU) which prohibits “any abuse by one or more undertakings of a dominant position”, also the ones related to intellectual property rights[147].

An example in this regard is the *Perindopril* case[148], where the EU Commission identified and condemned the practice of strategic accumulation for the first time. In particular, in 2014 the Commission found that a French pharmaceutical company abused its dominant position, violating EU competition law, by engaging in massive patent acquisitions with respect to the successful and notorious drug Perindopril, since its aim was to prevent the entry of other companies in the market.

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[142] ibid.
[143] ibid.
[144] ibid.
[145] ibid.
[146] ibid.
[147] See for the US context 15 U.S.C. § 2 which similarly refers to “monopolization or attempt to monopolize”.
[148] Case AT.39612 – *Perindopril (Sevier)* [2016].

As a matter of fact, this generic entry should have happened after the expiration of the base patent. Instead, the entry occurred with a 4-year delay[149], because of the strategy through which the company accumulated many secondary patents throughout the years, in addition to the ones related to the basic compounds and processes of production of the drug.

The Commission reached the conclusion that the multiple patents and patent applications led the potential entrants to an impossibility in determining the scope of the originator's patent protection and, consequently, in developing a product that would allow them to enter the market[150].

However, the Commission clarified that these practices would not necessarily constitute infringement of competition law, although they were both part of the comprehensive strategic accumulation put in place by the pharmaceutical company[151].

This case shows how this type of difficult relationship between intellectual property and pharmaceutical companies can be contrasted thanks to the described inputs from Competition Law.

Naturally, regarding vaccines, the strategic accumulation would be contrasted in an even more efficient way if patent rights in this context were not present. This points to the application of the Commons Theory in the pharmaceutical industry, and specifically in the vaccine's sector, which is the idea explored in Chapter 4.

Now there is one last aspect of this relationship between intellectual property and vaccines that must be addressed: the trade secret.

2.4 Vaccines and trade secrets

A trade secret has been described in the literature as "an item of information - commonly a customer list, business plan, or manufacturing process - that has commercial value and that the firm possessing the information wants to conceal from its competitors in order to prevent them from duplicating it"[152].

It is important to clarify that until 2015/2016, and thus before the enactment of two important pieces of legislation in the US and the EU, there was not an exclusive right that the possessor was entitled to exercise to protect that trade secret. Indeed, if the latter had been revealed, the law would have not provided for a specific remedy, but, for instance from a common law perspective, the protection was offered through remedies such as breach of contract – e.g. committed by a former employee – or tort of trespass[153].

In 2016, both in the EU and the US two important acts related to the trade secret were implemented, respectively defined as EU Trade Secrets Directive

[149] ibid at para 4.
[150] ibid at para 2770.
[151] ibid at para 4.
[152] D. D. Friedman, W. M. Landes, and R. A. Posner, *Some Economics of Trade Secret Law*, 5(1) Journal of Economic Perspectives 61 (1991) 61.
[153] ibid.

2016/943 (from now on “Directive”) and Defend Trade Secrets Act 2016 (DTSA), although TRIPS already contained some foundational provisions in this regard[154].

Therefore, before addressing exactly the role that trade secrets can play in the current pandemic, it is important to underline some aspects of these two pieces of legislation, that try to offer a direction that companies should follow when they have the intention to enforce trade secret rights and to defend their assets against misappropriation[155].

Both the DTSA and the Directive aim to protect confidential commercial information and in doing so they provide similar definitions of what information can be considered a trade secret, that is almost every type of confidential business and technical information[156]. In particular, both provisions require that the information must be kept secret and there is an economic value that derives properly from the fact that the specific information is not known by the public at large.

Moreover, both legislations do not only protect the object where the information is contained – such as a document – but the information itself, namely the underlying formula, design, process, procedure, etc. However, usually the document is always needed to prove that there is a trade secret, and thus the distinction between the memorialization of the information and the information itself is not so clear and relevant[157].

Even the requirement of misappropriation is conceived in a similar way in both acts. Indeed, a violation can occur when there is wrongful acquisition, wrongful use, and wrongful disclosure, that respectively are considered acquisition of a trade secret through a conduct that goes against honest commercial practices, and use or disclosure of a trade secret by a person who obtained that trade secret in an unlawful way[158].

In addition, independent development and reverse-engineering are usually considered lawful practices, except when it is otherwise established in a contract[159].

A noticeable difference between the DTSA and the Directive concerns the identification of the person legitimated to pursue a civil misappropriation action. In particular, the DTSA provides that the owner of the trade secret is the one that can bring this type of action[160], in a situation which is similar to the one where only the patentee is supposed to bring a patent infringement action[161].

Given this circumstance, in a trade secret case, a defendant could potentially argue that the standing is not conferred on plaintiffs that own or have

[154] See Section 7: protection of undisclosed information.
[155] A. B. Patel, J. Pade, V. Cundiff, et al., *The Global Harmonisation of Trade Secret Law: The Convergence of Protection for Trade Secret Information in US and EU*, 38(12) European Intellectual Property Review 738 (2016) 738.
[156] 18 U.S.C. §1839(3); 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, Art.2(1).
[157] Patel et al. (n. 155) 739.
[158] 18 U.S.C. §1839(5)(6); Directive, Art.4(2)–(4).
[159] 18 U.S.C. §1839(6)(B); Directive, Art. 3.
[160] 18 U.S.C. §1836(b)(1).
[161] 35 U.S.C. §281.

a license to less than all the rights derived from the trade secret[162], since in a patent case it has been stated that only the patent owner or an exclusive licensee may pursue an infringement action, and not a non-exclusive licensee[163].

By contrast, according to the Directive, an action for misappropriation can be requested by a "trade secret holder" that is defined as "any natural or legal person lawfully controlling a trade secret"[164]. In this way it can be argued that not only the trade secret owner or an exclusive licensee has the standing to sue, but also a non-exclusive one that is in control of the trade secret. This leads to an extension of the legitimacy to pursue a misappropriation action under the Directive, as compared to the DTSA[165].

Lastly, with regards to remedies, both legislations provide in a complete way for monetary and equitable relief, which includes royalties, lost profits, and injunctive relief[166]. In addition, the DTSA states that if the trade secret has been "willfully and maliciously misappropriated" or "the claim of misappropriation is made in bad faith", the court may award "exemplary damages" and "reasonable attorney's fees to the prevailing party"[167]. The same act also establishes *ex parte* seizure by a federal law enforcement officer of property "necessary to prevent the propagation or dissemination of the trade secret that is the subject of the action"[168].

By contrast, the Directive, considering that it must always take into account the internal market as one of the most important objectives of the EU[169], states that remedies should be granted in a way that is always proportionate, barriers to the trade in the internal market must be avoided, and safeguards for abuses must be established[170].

As it can be immediately noticed, there is a substantial overlap between the DTSA and the Directive in terms of definitions and requirements for liability in order to enforce a trade secret infringement. The variant in this context is how the Directive is implemented by the EU member states over the years, given that this type of EU legislation does not generally aim to a full harmonization, but more to a convergence among legal rules of different countries[171].

If, in the EU, national laws have different requirements for what can identified as the same action of misappropriation, it may be expected that the US will play a more considerable role, since, in a certain way, this legal system will offer more certainty for those companies and individuals that would like to bring this action before a court.

However, the illustration of these two pieces of legislation help to comprehend that, compared to a few years ago, trade secret has a considerable importance worldwide and, whether in the US or in the EU, companies should take these new legal rules into high consideration, evaluating the various

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[162] Patel et al. (n. 155) 740.
[163] *Prima Tek II LLC v A-Roo Co* [Fed. Cir. 2000] 222 F. 3d 1372, 1377.
[164] Directive, Art. 2(2).
[165] Patel et al. (n. 155) 740.
[166] 18 U.S.C. §1836(b)(3)(B) and §1836(b)(3)(A); Directive, Art. 14(1)-(2) and Art. 12(1)-(2).
[167] 18 U.S.C. §1836(b)(3)(C)–(D).
[168] 18 U.S.C. §1836(b)(2)(A)(i).
[169] See Treaty on the European Union (TEU), Art. 3.
[170] Directive, Art. 7.
[171] Patel et al. (n. 155) 744.

requirements, remedies, and defenses for misappropriation, to have their intellectual property rights protected.

It must be assessed whether trade secrets play a role in the Covid-19 pandemic, in a more efficient way than patents, especially in the context of vaccine development.

It can be said that from providing information such as genomic data, to biological resources, and manufacturing know-how, trade secrets have a role in this pandemic[172]. In other words, finding a vaccine against Covid-19 includes trade secrets operating alongside patents, trademarks, copyrights, working all together as incentives for the manufacture of that particular product[173].

A fundamental argument is that, and this work has already underlined this aspect, sharing certain trade secret information related to the vaccine development in the context of the pandemic would be beneficial for the world, leading to a more rapid development and an expansion in supply capacity of not only vaccines, but also treatments and diagnostics against the virus[174].

In particular, there are three public health priorities that would suggest that this is the right answer: speed, adequacy of supply and affordability. Considering that the pandemic has already made millions of victims worldwide and generated an unprecedented economic crisis, speed would be the first aspect to consider. The only way to balance this priority and the safety and efficacy in producing vaccines is through trade secrets about the vaccine development process that should be shared with competitors, researchers, and governments[175].

It is true that presumably, although there is not a certain empirical evidence in this regard, this sharing would lead to a less consistent overall revenue for the pharmaceutical company or an individual manufacturer. However, sharing this information means the development of various vaccines and treatments that would be safer and more effective than an isolated product, generating a higher trust and demand in a world that naturally will need every vaccine dose and treatment to defeat the virus[176].

In addition, from a more moral and ethical perspective, there would be an obligation to ensure vaccines and treatments affordable for all people and not just for wealthy countries, considering that for now “an international effort to acquire vaccines for low- and middle-income countries is struggling to gain traction”[177], as it will be further underlined in section 4.2.

To reach this important purpose of public interest, which is indirectly envisaged in the EU Directive[178], the optimal proposal would be a compulsory

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[172] D. S. Levine, *COVID-19 TRADE SECRETS AND INFORMATION ACCESS: AN OVERVIEW*, InfoJustice.org (July 10, 2020) http://infojustice.org/archives/42493 (last visited Sep 18, 2021).

[173] D. S. Levine, *Trade Secrets and the Battle Against Covid*, 15(11) Journal of Intellectual Property Law & Practice 849 (2020) 849.

[174] ibid.

[175] ibid.

[176] ibid.

[177] E. Callaway, *The unequal scramble for coronavirus vaccines — by the numbers*, Nature (August 27, 2020) https://www-nature-com.ezproxy.lib.gla.ac.uk/articles/d41586-020-02450-x (last visited Sep. 18, 2021): “Wealthy countries have struck deals to buy more than two billion doses of coronavirus vaccine in a scramble that could leave limited supplies in the coming year”.

[178] See Directive, Art. 1(2)(b): “This Directive should not affect […] the application of Union or national rules requiring trade secret holders to disclose, for reasons of public interest, information,

trade secret license where owners are compensated for what they have invested and shared. However, if this can appear too cumbersome to be implemented, another proposal includes the voluntary effort by civil society groups, public officials, and the public itself to persuade manufacturers and scientists to share this information in the name of public health[179].

It can be argued that if these voluntary and compulsory trade secret sharing are implemented, they would be beneficial not only right now but also in the future to face challenges such as climate change, energy scarcity and the next pandemic, becoming an important instrument in pursuit of an open innovation policy[180].

This is in line with the theory and strategy of vaccines as Commons, whose fundamental premises and characteristics will be investigated in Chapter 4. Instead, in the following one, the international and the European contexts will be assessed, in order to offer further perspectives on vaccines and intellectual property, although they do not seem to be particularly promising as an answer to this pandemic.

including trade secrets, to the public or to administrative or judicial authorities for the performance of the duties of those authorities".

[179] Levine (n. 173) 850.

[180] ibid.

Chapter 3: Further perspectives on vaccines and intellectual property: the TRIPS agreement and the EU Unitary Patent System

3.1 Considering the international context: the ineffectiveness of the TRIPS agreement and the compulsory license instruments

There is a consistent number of authors, *inter alia* Dinwoodie and Dreyfuss, according to which the significance of the TRIPS Agreement is decreasing internationally[181], due to the following indicators: the response to emerging technological trends offered by new intellectual properties treaties, such as the World Intellectual Property Organizations (WIPO) Treaties; the new free trade agreements (FTAs), concluded by the US and the EU, whose provisions usually deviate considerably from the TRIPS rules; the US intention of retaliation in case the implementation of TRIPS is too consistent; and the limited use of the WTO dispute settlement system to deal with TRIPS-generated disputes[182].

In particular, with regard to the first indicator about the incapacity of TRIPS to implement a "digital agenda", only two years after its adoption, the WIPO adopted the WIPO Copyright Treaty (WCT)[183], which was particularly useful to clarify existing rules on digital technology, or to enact new provisions in order address the increasing issues of the digital environment[184].

At the same time, WIPO adopted the WIPO Performances and Phonograms Treaties (WPPT)[185] that provided rights for the storage and transmission of works in digital environment. Hence, TRIPS can be considered outdated in relation to the digital environment.

In addition, the US and the EU started to stipulate FTAs with developing countries in order to establish the so-called "TRIPS-plus" standards, namely IP provisions that deviate from TRIPS flexibilities, such as in relation to data

[181] G. B. Dinwoodie & R. C. Dreyfuss, *Designing a Global Intellectual Properly System Responsive to Change: The WTO, WIPO and Beyond*, 46 Hous. L. Rev. 1187 (2009) 1188.
[182] D. Harris II, *TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J Intell Prop L 367 (2011) 371.
[183] Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 65 (1997).
[184] Harris (n. 182) 371.
[185] Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 76 (1997).

protection and, as it will be seen later, to the instruments of compulsory licensing[186].

Moreover, the US have threatened to retaliate against the implementation of certain instruments provided in TRIPS, such as the compulsory license, through the Special 301 Mechanism. Section 182 of the Trade Act 1994 allows for a possible retaliatory trade action against countries that do not offer protection to the intellectual property rights of the US. In particular, the Office of the US Trade Representative (USTR) is required to prepare a report concerning intellectual property-related practices of foreign countries[187]. This Special 301 report is an annual review of the global intellectual property protection and enforcement around the world[188].The countries that in these reports are identified as consistent violators of the intellectual property rights of the US, constitute a "Priority Watch List", becoming the focus of attention for the US[189].

Although countries that have been subjected to this mechanism thought that with the enactment of TRIPS the US would have stopped to issue these reports, the latter are still in use, especially to function as a preliminary procedure before triggering an IP case through the WTO Dispute Settlement Understanding (DSU), and to address issues that are not covered by the TRIPS[190]. This resulted in a shift from a centralized enforcement system offered by the DSU to a unilateral enforcement under the Special 301[191].

Another aspect that negatively influenced the enforcement of TRIPS through the DSU is related to the Anti-Counterfeiting Trade Agreement (ACTA)[192], that with its four substantive sections provides for the enforcement of intellectual property rights[193]. One of the most relevant concerns about this legislation is that this is an attempt to overcome TRIPS and the DSU enforcement system in order to create not an accepted agreement between several countries, but to impose a certain global standard for copyright infringement, without addressing the specificities of each country through an effective multilateral process[194].

All these indicators are evidence of the fact that TRIPS is losing relevance. With regards to patents and vaccines – the main focus of this work – there seems to be an additional problem: the inefficiency of the compulsory license instruments provided in Artt. 31-31bis of TRIPS.

"A compulsory license is a state-granted license issued to a third party to manufacture and produce a patented invention without the patent owner's

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[186] J. F. Morin, *Multilateralising TRIPS-plus Agreements: Is the US Strategy a Failure*?, 12 J. WORLD INTELL. PROP. 175 (2009).
[187] See e.g. Office of the United States Trade Representative, Special 301 Report, Annex 1 (2010) http://www.zeropaid.com/wp-content/uploads/2010/05/1906.pdf (last visited Oct 7, 2021).
[188] Harris (n. 182) 372.
[189] Special 301 Report (n. 187): in this report, for instance, the Priority Watch List included: Algeria, Argentina, Canada, Chile, China, India, Indonesia, Pakistan, Russia, Thailand, and Venezuela.
[190] J. Pauwelyn, *The Dog that Barked but Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1(2) J. INT'L Disp. SETTLEMENT 389 (2010) 389.
[191] ibid at 429.
[192] ACTA (Dec. 3, 2010) https://ustr.gov/acta (last visited Oct 7, 2021).
[193] Morin (n. 186).
[194] C. R. McManis, *The Proposed Anti-Counteifeiting Trade Agreement (ACIA): Two Tales of a Treaty*, 46 Hous. L. Rev. 1235 (2009) 1236-37.

consent"[195], and this instrument was one of the main controversial issues for the ratification of TRIPS. On the one side, developed countries required stronger protection for patented inventions[196]. On the other side, developing countries wanted easier access to patented technologies, and thus a wider application of compulsory licenses[197].

The final compromise can be found in Art. 31 entitled "Other Use Without Authorization of the Right Holder" which gives the countries ample discretion in using compulsory license. However, there are some conditions that must be respected to apply this instrument, including, most relevantly: (a) that the authorization of this instrument should be assessed on its specific merits; (b) that the government and the right holder should attempt to negotiate a voluntary license on reasonable commercial terms, although in a situation of emergency – such as the current pandemic - this condition can be waived, provided that nevertheless the patent holder is notified as soon as reasonably possible; (f) that the license must be "predominantly for the supply of the domestic market"; (h) that the government must grant "adequate remuneration" to the patent owner[198].

The second type of compulsory license, based on Art. 31bis, should be considered a waiver of the instrument contained in Art. 31, by enabling countries that do not have the capacity to produce generic substitutes of patented pharmaceuticals, under the domestic compulsory licenses, to import the substitutes from countries that have the capacity to manufacture them, without risking the intrusion of the patent holder[199].

It was the AIDS pandemic in South Africa that led to the adoption by the WTO Ministerial Conference of the Doha Declaration on the TRIPS Agreement and Public Health[200] which recognized that "WTO Members with insufficient or no manufacturing capacities [of pharmaceuticals] could face difficulties in effective[ly] us[ing] compulsory licensing under the TRIPS Agreement"[201]. Hence, the amendment to Art. 31 was enacted to improve access to essential medicines worldwide.

Notwithstanding great expectations for the use of compulsory licenses to address public health problems that mostly affected developing countries, only a few countries issued these licenses under Art. 31, and there was only one application of Art. 31bis[202]. The reasons for this failure, identified by Harris, are mainly three.

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[195] Harris (n. 182) 383, note 72. See also P. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes*, TECHNICAL REP. SER. (1981) who defined the compulsory license as "an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state".

[196] D. Gervais, *The TRIPS Agreement: Drafting History and* Analysis (1st ed. 1998) 15.

[197] ibid at 16.

[198] TRIPS, Art. 31.

[199] TRIPS, Art. 31bis.

[200] WT/MIN(01)/DEC/1 (2002).

[201] ibid at para 6.

[202] Harris (n. 182) 387.

First, the instrument contained in Art. 31bis, that, as already mentioned, should operate as a waiver of the classic compulsory license regime in Art. 31, is considered not flexible for both the exporting and importing countries[203].

In particular, the only case in which this waiver was implemented has been the one where Canada and Rwanda were respectively the exporting and importing countries[204]. Apotex, which was the manufacturer of the generic AIDS medicine destinated to Rwanda, declared that the process was too cumbersome and involved huge costs with few incentives[205]. Most part of the complication was caused by the long negotiations between Apotex and the patent holders[206]. From this example, it can be noted that, if the rightsholders themselves are not involved and do not receive consistent incentives for the concession of IP rights, the obligations of the countries can be ineffective.

The second reason why these instruments are reputed to be ineffective is that some countries fear retaliation from other countries and pharmaceutical companies[207]. For instance, when in Thailand the national government decided to issue a compulsory license under Art. 31 to produce antiretroviral drugs (ARVs), the United States and the European Union censored the country as one to be concerned about[208], and the pharmaceutical company Abbott decided to not license some of its products in Thailand[209]. This demonstrates that countries and IP owners can be reluctant to see developing countries issuing compulsory licenses. This situation worries states, that, on the one hand, do not want to antagonize pharmaceutical companies that bring jobs and investment in their territories, and, on the other hand, prefer to not destabilize political relations with major regions of the world, such as the US and the EU, that have strong economic power and political influence worldwide[210].

Last reason for the inefficiency and scarce application of Artt. 31 and 31bis is interestingly the same that it has been addressed with regard to the inefficiencies of TRIPS in general; namely, the obligations contained in bilateral agreements between States may limit the application of the compulsory license mechanisms[211].

As an example, the US stipulated several free trade agreements[212], and the correspondent provisions permit the use of compulsory licenses to obtain generic medications only when certain conditions are met. These include the exclusivity of the data generated by the patent holder to the holder herself, or a prior

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[203] ibid at 390-91.
[204] H. P. Hestermeyer, *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines,* AM. Soc'Y INT'L L. (2007).
[205] Press Release, Apotex, *Life Saving AIDS Drug for Africa Gets Final Clearance* (2007).
[206] ibid; *TRIPs Mechanism Set to Fail as Apotex Ships ARV*, Pharma Letter (2008).
[207] Harris (n. 182) 392.
[208] *WTO Must Support Access to Medicines for Poor Countries,* Oxfam East Asia Blog (2009).
[209] K. Alcorn, *Abbott to Withhold New Drugs from Thailand in Retaliation for Kaletra Compulsory License,* Nam Aids Map (2007).
[210] Harris (n. 182) 392-393.
[211] ibid at 393.
[212] See Office of the United States Trade Representative, *Bilateral Trade Agreements* (2011) https://ustr.gov/issue-areas/labor/bilateral-and-regional-trade-agreements (last visited Oct 9, 2021).

notification to or a consent by the patent owner in order to issue the compulsory license for her invention[213].

As it can be noticed, the TRIPS started to lose relevance not only on a general basis but also in relation to the compulsory license, that several developed countries advocated as the only instrument able to face the current pandemic in terms of access and distribution of pharmaceuticals on a global scale, as it will be noted in section 4.2. Moving from the international context back to the EU context, the next section will address the attempts of patent harmonization throughout the European Integration, culminating in the European Patent with Unitary Effect.

3.2 Towards the implementation of a Unitary Patent System in the EU

Since the beginning of the European Integration project there have been several attempts to establish a European Patent System that could harmonize the national systems in this specific field, in order to fulfil the most important objective of the European Union, namely the promotion and maintenance of the internal market[214].

Indeed, the European Patent has been defined as "an old and vexing problem"[215] by Pila, who in turn borrowed that expression from some authors of the 60s, such as Spencer, that had already underlined this issue[216].

The Post Second World War patent initiatives – the Strasbourg Patent Convention (SPC) of 1963, the Community Patent Convention (CPC) of 1975, and the still existing EPC of 1973 - were impaired by several issues that were substantive, procedural, political, and constitutional[217].

In particular, there was the question on how to harmonize national patent systems that were considerably different in terms of national laws, traditions, and procedures, or how to manage in a unitary way a huge complexity of technical information (the so-called "prior art")[218].

In addition, the European institutions had to deal with the issue about how to enforce such a supranational system, either by leaving this aspect to the national courts and authorities, with the risk that there would have been differences in the enforcement of patent rights – as it partially occurred with the EPC whose enforcement is mostly left to each country -, or by establishing a supranational court and office[219].

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[213] Chuan-feng Wu, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law,* 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141 (2010).
[214] TEU, Art. 3(3).
[215] J. Pila, *The European Patent: An Old and Vexing Problem*, 62(4) The International and Comparative Law Quarterly 917 (Cambridge University Press, 2013).
[216] R. Spencer, *A European Patent: An Old and Vexing Problem*, 45 ABAJ (1959) 1157-9.
[217] Pila (n. 215) 921.
[218] ibid.
[219] ibid.

These aspects affected the enactment of the initiatives to institute a European Patent System. A first initiative, the SPC, promoted by the Council of Europe and mentioned above, was aimed at harmonizing national laws on patentability, especially in relation to its rigorous novelty standard[220], the progressive definition of patentable subject matter[221], and the role and importance of patent claims[222].

However, this Convention left several gaps, among which the most relevant are related to the procedure for obtaining the patents, the specification of their content and ownership, and indications of restrictions for their exploitations, since these were all matters on which the countries could not reach a consensus[223].

Although the six founders of the European Economic Community (EEC) – Belgium, France, Italy, Luxemburg, Germany, and Netherlands - had a more ambitious agenda than the Council of Europe, by being committed to homogeneously realize the objectives of the Treaty of Rome (1957), the CPC of 1975 is not to be considered a great success either[224].

The EEC Six were convinced that the supranational system established by the CPC would have co-existed with the national systems, leading to the issue of the simultaneous protection of national and Community patents[225]. Moreover, the countries did not conceive the system as autonomous, but believed that national courts and authorities should have played an important role in solving conflicts of entitlements, infringement, and hypothetical compulsory license instruments[226]. Therefore, the CPC resulted in an uncomplete and unsatisfactory patent system that did not last until today.

The only European Patent System that is still in force, and thus can be considered the most successful, is the EPC of 1973. While the EPC provided for the harmonization of patent requirements[227], as it has been seen in sections 1.3 and 2.1, and procedural aspects[228], it has to be considered that the EPO grants a bundle of national patents, whose enforceability is still left to national courts and patent offices. This means that the EPC does not provide for any relevant enforcement provision, proving the important issue that the national sovereignty of each country in this technical but economically relevant field of law is still prevalent.

These difficulties in establishing a European Patent System can be linked to the reason why the European Commission initially failed in the negotiations with the pharmaceutical companies to acquire the vaccine against Covid-19.

It is common knowledge that at the beginning of the vaccine distribution at the end of January 2021, companies such as Pfizer and Astrazeneca reduced

[220] SPC, Art. 4
[221] SPC, Artt. 1-2
[222] SPC, Art. 8
[223] Pila (n. 215) 922.
[224] ibid at 923.
[225] General Secretariat of the Council of the European Communities, *Records of the Luxembourg Conference on the Community Patent 1975* (Office for Official Publications of the European Communities 1982) (CPC travaux) para 248-50.
[226] G. Finniss, *Will National Industrial Property Rights Disappear?*, Industrial Property 148 (1961) 162.
[227] See EPC, Chapter I.
[228] See EPC, Part III.

supplies to Europe due to the most disparate reasons[229], despite several statements such as the one made by European Council President Charles Michel[230], and the practical difficulties related to the massive production and distribution of the vaccines.

One of the reasons for the lack of the Commission's authority to ensure that pharmaceutical companies respected the terms of the contracts, could be properly that in the EU there has never been a proper patent harmonization, that would have worked as a deterrent against potential misbehavior of pharmaceutical companies. For instance, if the latter had not respected the terms of the contracts, the EU could have had advanced the use of harmonized compulsory licenses, that would work more effectively than a compulsory license applied by only one or a few Member States. However, such an important instrument can be safely enforced only if there is a proper patent system that regulates it in detail.

Therefore, there is the need of a proper patent system at the European level that can finally not enhance harmonization in this field of law, but also allow the EU to gain that authority and responsibility towards pharmaceutical companies and the international community.

This scenario can probably benefit from the Unitary Patent Package, that was approved by 25 EU member states and consists of three elements: the EU Regulation 2012/1257 on the Unitary Patent[231], the EU Regulation 2012/1260 on the official languages for this new patent[232], and the Agreement which institutes a Unified Patent Court that will be further investigated in the next section.

It is important to clarify that this "European patent with unitary effect", once granted, provides uniform protection and has equal effects in all the participating Member States[233]. This feature departs considerably from the aforementioned system of the EPC, since the EPO grants a bundle of national patents. Indeed, when applying before the EPO, the patentee must choose in which country she wants protection of the patent[234]. By contrast, within the unitary system, the patent would be protected throughout all the member states[235]. It must be considered also that the bundle of national patents granted according to the EPC would not be replaced by the unitary patent, but these systems would co-exist, alongside each other. Therefore, a patent holder can choose to apply whether for the EPC "traditional" system, or for the unitary patent.

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[229] C. Pailliez and G. De Clercq, *EU says it will make vaccine companies respect supply contracts*, Reuters (2021) https://www.reuters.com/article/us-health-coronavirus-eu-vaccines-idUSKBN29T090 (last visited Oct 12, 2021): Pfizer declared that it was slowing supplies to perform manufacturing changes that would strengthen production; Astrazeneca said that the initial deliveries were problematic due to a production glitch.

[230] ibid: "We plan to make the pharmaceutical companies respect the contracts they have signed ... by using the legal means at our disposal".

[231] Regulation (EU) 2012/1257 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection.

[232] Council Regulation (EU) 2012/1260 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements.

[233] Regulation 2012/1257, Art. 3(2).

[234] EPC, Art. 64(1).

[235] Regulation 2012/1257, Art. 4(1).

Interestingly, the Unitary Patent seems more akin to the registered EU Trade Mark (EUTM) that has equal effects throughout the EU[236]. However, despite this similar characteristic, these two instruments cannot be more different.

In particular, the EUTM, in order to be granted, must satisfy certain substantive requirements that are contained in the Regulation itself, while the unitary patent - this is its second relevant aspect – would comply with the substantive law of the EPC, and the authority that should decide whether the patent can be granted is the EPO itself[237].

This aspect is not necessarily to be considered as negative, since the EPC provides a more than decent harmonized system in terms of patentability requirements and validity, and the patent holders are already familiar with this legislation. A controversial issue is that, as already mentioned, this law seems not to provide for the proper enforcement against patent infringement, and so does the Regulation on the Unitary Patent. However, it will be further discussed in section 3.3 that it is the Unified Patent Court (UPC) which should be responsible to enforce both the European Patent and the European Patent with Unitary Effect[238].

Regarding the Regulation 2012/1260, it must be said that this legislation would result particularly helpful, since it allows the patentee to apply only in one of the official languages of the EPC, and no other translations are required[239]. This is a less cumbersome obligation, than in the EPC which states that the European patent application, if filed in any other language than the official ones, should be translated in two of them, otherwise that application can be withdrawn[240].

Therefore, as it can be noticed from the analysis of its features, this European Patent with Unitary Effect can introduce a consistent supranational patent system where patents would find recognition in all the EU member states, resulting in a more cohesive system of intellectual property. The major issue is still related to the enforcement of this new patent, and in the next and last section of this chapter it will be underlined how the solution offered by the UPC does not seem to be entirely effective.

3.3 The Unified Patent Court as an obstacle to the European Unitary Patent system?

The UPC that, as already mentioned, should be responsible to enforce the European Patent and the EU Patent with Unitary Effect[241], was established via an intergovernmental treaty, and not through the usual EU legislative procedures,

[236] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark, Art. 1(2).
[237] Regulation 2012/1257, Art. 2(b).
[238] UPC Agreement, Art. 32.
[239] Regulation 2012/1260, Art. 3(1).
[240] EPC, Art. 14(6).
[241] UPCA, Art. 32.

because there were some concerns among the states that the institution of such a court was not compatible with EU law.

This idea was bolstered by the Court of Justice's opinion 1/09 about a predecessor of the UPC[242]. More specifically, when it was asked whether a draft agreement that was meant to establish a unified patent litigation system was compatible with EU law, the CJEU replied that this agreement would have deprived courts of the member states of the possibility to interpret and apply EU law, and the CJEU itself to reply through preliminary ruling, according to Art. 267 TFEU, to questions referred by the national courts[243].

This situation would have altered "the essential character of the powers which the Treaties confer on the institutions of the European Union and on the Member States and which are indispensable to the preservation of the very nature of European Union law"[244]. Therefore, the agreement was considered to not be compatible with EU law.

However, in the same opinion the Court clarified that Art. 262 TFEU is a proper legislative base that potentially allows to extend the jurisdiction of EU courts to European acts that establish intellectual property rights[245]. Consequently, there is not a monopoly of the CJEU in the field of IP and there is the possibility to introduce a new judicial system that would deal with controversies in that field of law[246]. Hence, there was the attempt to establish again such a system, but this time through an international treaty.

Inevitably, although the UPC is defined as a common court of the member states[247] with an obligation of applying EU law in its entirety[248], there are some grey areas and tensions in some aspects of this treaty, properly for its mixed nature of international, European, and national law[249].

For instance, since the agreement does not specify what can occur if a member state decides to leave the EU or withdraw from the UPCA itself, it is not clear whether to rely on the Vienna Convention on the Law of the Treaties and/or on EU law[250]. This can be relevant in the context of Brexit. Indeed, the UK has decided to withdraw from the Agreement, since it does not want to be bound to any EU obligation[251], including the CJEU and its jurisdiction that would still play a role in the context of the UPC. The latter is in fact entitled to make preliminary references under Art. 267 TFEU, and the decisions of the CJEU are binding on the UPC[252].

As it can be noticed, there is still an issue of national sovereignty that clearly shows how advances in the harmonization of the patent field have been minimal,

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[242] Opinion 1/09 [2011] ECR I-1137.
[243] ibid at para 88-89.
[244] ibid.
[245] ibid at para 61.
[246] ibid.
[247] UPCA, Art. 1.
[248] UPCA, Art. 24(1)(a).
[249] A. Plomer, *The Unified Patent Court and the Transformation of the European Patent System*, 51 IIC 791–796 (2020) 791.
[250] ibid.
[251] IAM, *The UK will not be part of the UPC, government confirms to IAM* (2020) https://www.iam-media.com/law-policy/uk-no-upc (last visited Oct 16, 2021).
[252] UPCA, Art. 21.

since all three patent initiatives that have been described in the present chapter failed in relation to the aspect of supranational enforcement, which is now debated with regards to the UPCA.

Therefore, although nowadays, after the entry into force of the Treaty of Lisbon, Art. 118 TFEU clearly provides for a specific competence of the EU in the context of intellectual property, it can be said that the idea, linked to the strong national sovereignty, according to which patents granted in a certain country cannot be revoked by courts of another country, is still present.

This concern of national sovereignty is even more evident when it is noted that the UPCA does not facilitate completion of the single market[253], as its purpose should be, but it fragments the European patent integration between the 25 participating member states (24 actually, as the UK is not included anymore), and the 3 non-participating states - Spain, Croatia and Poland -, as well as the participating countries that have not ratified the agreement yet[254].

As an example, only on 7 August 2021 Germany ratified the UPCA, after years of constitutional concerns related to the ratification bill. Indeed, at first the German Constitutional Court (GCC) declared the process through which the agreement was adopted unconstitutional[255]. In particular, according to the court, in order to implement Art. 118 TFEU, there was the need of unanimity, since the legal basis should have been Art. 262 TFEU. Given that unanimity was not reached in the EU, member states "changed the integration program of Lisbon and chose a functional alternative to a proper Union court – alongside the EU"[256]. Therefore, for the GCC, the creation of the UPC was a replacement of the proper EU legal basis that was Art. 262 TFEU[257]. Considering all this, the GCC concluded that this consistent reallocation of judicial functions, that would have superseded German Courts, was an amendment to the Constitution in substantive terms, by requiring 2/3 majority vote in the parliament[258].

Another concern raised by the GCC, which deserves attention, is about the adequate protection of fundamental rights that the UPCA can offer. In particular, the UPC would have certain powers to produce evidence, seize goods, and inspect premises[259], and this could result in an "encroachment of fundamental rights" in the jurisdictions of the member states[260]. These civil remedies under the UPCA should be compatible with the fundamental rights provided in the EU Charter of Fundamental Rights (EUCFR), such as rights to privacy[261], good administration[262], access to documents[263], justice and fair trial[264]. All these rights expressly derive from the European Convention on Human Rights (ECHR)[265],

[253] TUE, Art. 3.
[254] Plomer (n. 249) 792.
[255] Case No. BvR 739/17.
[256] ibid at para 145.
[257] ibid at para 154.
[258] Plomer (n. 249) 793.
[259] UPCA, Artt. 59-60.
[260] BvR 739/17 (n. 255) at para 158.
[261] EUCFR, Art. 7.
[262] EUCFR, Art. 41.
[263] EUCFR, Art. 42.
[264] EUCFR, Art. 47.
[265] ECHR, Artt. 6-8.

that all the EU member states must comply with since they are all part of the Council of Europe.

A relevant aspect is that the ECHR is not even mentioned in the UPCA; the Charter is cited only in the Preamble and is not listed in the binding section of the agreement as an applicable source of law[266]. Therefore, it is legitimately questionable how much weight is given by the UPC to the protection of fundamental rights[267], if it also considered that one of the reasons why the EU Parliament notoriously rejected the EU ratification of the ACTA was properly the potential far-reaching IP enforcement measures on some fundamental rights[268].

Last aspect to consider is that the UPC risks fracturing in a consistent way the only existing European patent system - the EPC. Although it was conceived as a temporary measure before reaching the full harmonization of the enforcement of patents in the EU, the EPO started to assume the connotation of a quasi-judicial body, especially through its consistent interpretation and implementation of the patentability requirements[269]. This led to a gradual increase of patents granted by the EPO not only to EPC companies, but also to foreign companies[270]. Hence, the EPO became in a way the "guarantor" of European patents, and perhaps a fragmentation due to the UPC intervention would not be so desirable, considering the recognition, trust, and credibility that the EPO gained worldwide.

In light of the above, it is sufficiently clear that the presence of a supranational court is the most relevant aspect of a supranational patent system. For instance, a hypothetical compulsory license implemented by the EU itself, as hypothetically assumed in section 3.2, can be enforced only through the intervention of a court. Naturally, in the long run, the UPC implementation will depend upon the stability of the EU, recently disrupted by Brexit and the pandemic, and as long as that judicial body does not find such implementation, the "dream" of having an integrated European Patent System that can prove effective in standing united and firm against the pharmaceutical companies is far from reached.

Hence, in the next and last chapter it will be seen that another solution can be implemented to face the current pandemic worldwide: the vaccine against Covid-19 as a Commons.

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[266] UPCA, Art. 24.

[267] Plomer (n. 249) 794.

[268] See D. Matthews and P. Zikovska, *The Rise and Fall of the Anti-Counterfeiting Trade Agreement (ACTA): Lessons for the European Union*, 44 IIC 626 (2013) 638: in its report of 2009 the Parliament raised concerns related to the implication of ACTA for some important fundamental rights, such as the rights to privacy and data protection, identified as core values for the respect of private and family life.

[269] A. Plomer, *The EPO as patent law-maker in Europe*, 25(1) European Law Journal 57–74 (2019).

[270] See EPO, *Annual Report of Granted Patents 2018* https://www.epo.org/about-us/annual-reports-statistics/annual-report/2018/statistics/granted-patents.html (last visited Oct 18, 2021).

Chapter 4: The Covid-19 Vaccine in the light of the Commons Theory

4.1 The great paradox: public funding but private properties

There are two main reasons why the vaccine against Covid-19 should be considered a Commons. The first one, investigated in this section, is the public funding contribution.

In particular, the current pandemic resulted in drastic economic and social dislocation[271]. Given this unprecedented situation, countries all around the world – *inter alia* the EU, United Kingdom, Germany, Canada, and US - started to accelerate the development and manufacture of treatments and vaccines, by allocating in total $ 9 billion of research funding from the beginning of the pandemic to the half of 2020, most of the times to private companies[272].

Looking at the US example only, it can be immediately understood how the public funding have been and still are extremely important for the R&D of every instrument (vaccines, therapeutics, etc…) needed to defeat the virus. Indeed, the US has contributed with 35% of all the public funding, focusing it mostly on a domestic level, through large grants allocated in US-based pharmaceutical companies[273].

Even before the pandemic, the public commitment in pharmaceutical R&D has always been consistent in the US. There is proof that the federal government publicly funded the development of several drugs from 2010 to 2016[274]. With an annual budget of $ 30 billion, the US National Institute of Health (NIH) is the world's largest single funder research in the life sciences, providing one-third of the biomedical R&D in the US overall, and most of the funding for the basic biomedical research[275].

Despite the substantial investment made by the government, and ultimately by the public at large as taxpayers, the property of the vaccines and treatments

[271] A. Kapczynski, *Realizing Public Rights Through Government Patent Use*, 49 Journal of Law, Medicine & Ethics 34 (2021) 34.
[272] COVID-19 R&D Tracker Update: 6 Aug. 2020, Policy Cures Research, https://bit.ly/38W5JQD (last visited Sep. 20, 2021).
[273] ibid.
[274] D. Li, P. Azoulay, and B. N. Sampat, *The Applied Value of Public Investments in Biomedical Research*, 356(6333) Science 78 (2017).
[275] ibid; H. Moses 3rd, E. R. Dorsey, D. H. M. Matheson, S. O. Thier, *Financial anatomy of biomedical research,* 294 JAMA 1333–1342 (2005).

still belongs to the pharmaceutical companies that allegedly developed them. For instance, with regard to the mRNA technology implemented for now in the vaccines manufactured by Moderna and BioNTech/Pfizer that own the relative patents, as observed in section 2.1, the NIH publicly funded 174 publications in PubMed (PMID) in relation to this type of vaccines, a number which equals to 23% of the total amount of 767 PMID[276].

Another example is the anti-viral drug remdesivir, sold by the company Gilead Sciences, but developed through the contribution of public funding and research collaboration[277]. In particular, the US government funded the Phase III trial of the drug and its earlier development, when the pharmaceutical company entered into a research agreement with the US Army Medical Research Institute for Infectious Disease to scan some molecules of the company's library for treatments against Ebola, among which remdesivir was identified[278].

Considering this deep public commitment, the US government could have claimed rights over this drug, such as co-ownership of the key patents, but none of such rights has been implemented or recognized[279]. Indeed, only Gilead has been granted patents for this invention, leading to a monopoly in terms of making, using, selling, and importing the drug in the US. Therefore, surely the collaboration between the public sector and the private companies should be incentivized, as it has been underlined in section 1.2, but fair recognition about each contribution to a particular invention must be given.

Despite the total lack of international and EU legal instruments to address this issue, as evidenced in Chapter 3, there is one legislative example - it will be seen whether it is effective or not - through which the public efforts in developing and manufacturing pharmaceuticals can be recognized in the US: the Bayh-Dole Act, approved by the Congress in 1980 to facilitate the US technological innovation[280]. This legislation allows the government to apply so-called "march-in" rights, that in turn entail the possibility of granting a license to a company to develop an invention protected by patents but financed through public funding, even against the will of the patent holder[281].

In particular, at first the government can require the contractor or successors in title to grant a "nonexclusive, partially exclusive, or exclusive license"[282]. If the patent owner refuses to grant it, the government will grant the

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[276] A. E. Kiszewski, E. G. Cleary, M. J. Jackson, F. D. Ledley, *NIH funding for vaccine readiness before the COVID-19 pandemic*, 39(17) Vaccine 2458 (2021) 2460: see Table 1.

[277] C. Rowland, *Taxpayers Paid to Develop Remdesivir But Will Have No Say When Gilead Sets the Price*, Washington Post (May 26, 2020) https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/ (last visited Sep. 20, 2021).

[278] A. Sarpatwari, A. Kaltenboeck, and A. S. Kesselheim, *Missed Opportunities on Emergency Remdesivir Use*, 324(4) JAMA 331 (2020) https://doi.org/10.1001/jama.2020.11932 (last visited Sep. 20, 2021).

[279] J. Krellenstein, C. J. Morten, *The U.S. Government's Apparent Co-Ownership of Patents Protecting Remdesivir* (2020) https://www.prep4all.org/news/remdesivir (last visited Sep. 20, 2021).

[280] P.L. 96- 517, Amendments to the Patent and Trademark Act (94 Stat. 3015).

[281] J. R. Thomas, *March-In Rights Under the Bayh-Dole Act*, Congressional Research Service (Aug. 22, 2016) 7 https://fas.org/sgp/crs/misc/R44597.pdf (last visited Sep. 20, 2021).

[282] 35 U.S.C. §203(a).

license itself[283]. The issue is in the strict criteria that must be complied with if the government wants to implement this "march-in" mechanism.

Indeed, these rights can only cover inventions that are "conceived or first actually reduced to practice in the performance of work under a funding agreement"[284]. However, most of the government contributions do not directly fund the specific technology, since there is often an indirect contribution to the drug development, by for instance identifying bio-makers or analysing certain diseases[285].

In addition, there are four circumstances under which these march-in rights can be exercised, the most relevant of which states that the action must be taken when there is a necessity "to alleviate health or safety needs"[286]. This provision seems to be quite broad and unclear, and some authors, such as Kapczynski, have observed that it does not solve the problem of excessive pricing, which is the phenomenon that occurred, for example, with the drug remdesivir[287].

This Act would only prevent a potential failure in commercializing the product[288], something unlikely in the current pandemic, where the demand of medical help is high. Therefore, it is no surprise that these march-in rights have never been properly applied in the 35-year history of the Bayh-Dole Act, and the main reason of the various denials was exactly that the drug pricing was not so excessive as to trigger the march-in mechanism[289].

In view of the ineffectiveness of this legislative act, the question now is whether there is a more effective way to recognize the government contribution to the development of vaccines and treatments against Covid-19. If a system of fair pricing should be implemented, some authors believe that one of the most important factors in defining such fair price is the accounting of the public funding, and once again the US context is relevant in this regard, since the most important reform proposals adopted this approach[290]. For instance, through the proposed Medicare Negotiation and Competitive Licensing Act[291], private sector research and expenditures would be taken into consideration to calculate the price of a drug, resulting in an indirect indication of public funding.

Naturally, public funding can be considered also directly in reducing the drug price, in the sense that, once the government has reduced R&D cost and risk, its investment is directly part of the input in the development of the drug, and the price should represent such input[292].

An enacted law in this regard, perhaps more effective than the Bayh-Dole Act, could permit the government to override a patent and purchase the invention covered by that patent at a competitive price[293]. Patent holders are naturally

[283] ibid.
[284] 35 U.S.C. § 201(e).
[285] Kapczynski (n. 271) 35.
[286] 35 U.S.C. §203(a).
[287] Kapczynski (n. 271) 35.
[288] B. Bayh and R. Dole, *Our Law Helps Patients Get New Drugs Sooner*, Washington Post (April 11, 2002) at A28.
[289] Thomas (n. 281) 8-9.
[290] Kapczynski (n. 271) 36.
[291] H.R. 1046 (2019).
[292] Kapczynski (n. 271) 36.
[293] 28 U.S.C. §1498.

entitled to receive compensation, but not for all the lost profits[294]. Royalties should in fact be established taking into account a variety of aspects, *inter alia* existing license terms (if any) and R&D investments made by the patent holder itself[295].

This provision §1498 has been applied by the federal government, mostly when there was the need to procure defence instruments by obtaining a fair price and avoiding the difficulties related to the evaluation of patent claims[296]. In the pharmaceutical context, this instrument has been used in 2001, when, during the anthrax scare after the 9/11 terroristic attack, a proposal was made to import generic versions of the antibiotic ciprofloxacin, and this led the patent holder in that situation, the company Bayer, to cut its price[297]. Therefore, this provision allows the government to have a consistent leverage for the reduction of a drug price, either through voluntary agreement or generic procurement[298].

Although this legal instrument seems to have a better effect in terms of recognizing the public funding contribution than the Bayh-Dole Act, there are some aspects which remain quite debatable.

It is true that the process is straightforward, and patent holders cannot prevent the federal procurement agents to accept bids to contracts without considering the patent status of the drug. However, the rightsholders are entitled to sue for compensation before, at the first instance, the Court of Federal Claims[299], and this would definitely pose a first obstacle to the process[300].

Another complexity could derive from the various drug regulatory requirements that should in any case be assessed by the FDA[301], and it has been already noticed in section 1.3 how this assessment can often be long and expensive. Hence, this regulatory deadlock would frustrate the efficacy of the provision.

Lastly, from a more political point of view, it is highly difficult to imagine that the US government would implement this mechanism by going systematically against the interests of the patent holders. Hence, as Bayh-Dole Act, this provision has not been recently applied in the pharmaceutical context, except as a threat during the anthrax scare in 2001 mentioned before.

Perhaps a more radical intervention would be needed, especially in an emergency such as the one that the entire world is experiencing right now. A Theory of Commons for the vaccines could represent that more radical and better solution. But before delving into such topic, in the next section another reason why a total shift from property to non-property at least in relation to vaccines is needed will be discussed.

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[294] H. Brennan, A. Kapczynski, C.H. Monahan, and Z. Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale Journal of Law and Technology 275 (2016) 311.
[295] ibid.
[296] Rowland (n. 277).
[297] Brennan et al. (n. 294) 303.
[298] ibid.
[299] 28 U.S.C. §1498.
[300] Kapczynski (n. 271) 36.
[301] ibid.

4.2 The search for an effective Global Health Security

The second most relevant reason why the theorization of a Commons for the Covid-19 vaccine should be pursued is the so-called Global Health Security (GHS). The latter has not a proper definition, but it has always been approached from two opposite perspectives: on the one hand, the one of state and national security which prioritizes national safety, and on the other hand, with a more holistic point of view, the one of security of the entire humanity, beyond national borders[302].

This lack of clarity is shown in how the world was highly unprepared to face the Covid-SARS-19 virus and all the consequences that derived from it[303]. Therefore, there is the need to take a position in relation to what GHS really means.

This can be done by critically assessing two aspects of this pandemic that amplified issues of inequality, nationalism, and private interests: the restrictive measures commonly defined as lockdowns (including stay-at-home orders, shelter-in-place orders, economic shutdown)[304], and the vaccine's development and distribution.

The first phenomenon involved more than 3.9 billion people in more than 90 countries[305]. The impact of the restrictive measures has been highly dependent on the specific typology of country involved. The most drastic effects can be found in Low- and Middle-Income Countries (LMICs) where the lockdown led to a limitation of access to essential public health services, such as the treatment of HIV[306].

Moreover, considering that all the health facilities were deeply focused on testing, treating, and preventing Covid-19, in those LMICs there has been a 10% decline of sexual and reproductive health (SRH) services only in 2020, specifically in relation to use of contraceptives, services for pregnancy-related and new-born care, and abortions[307].

Other than these serious health issues, there is evidence that state authorities started to use intimidation, violence, and imprisonment against part of

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[302] A. B. Šehović, *Towards a new definition of health security: A three-part rationale for the twenty-first century*, 15(1) Global Public Health 1 (2019).

[303] A. B. Šehović & K. Govender, *Addressing COVID-19 vulnerabilities: How do we achieve global health security in an inequitable world*, 16(8-9) Global Public Health 1198 (2021) 1198.

[304] WHO, *Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19* (2020) https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19 (last visited Sep. 21, 2021).

[305] Euronews, *Coronavirus: Half of humanity now on lockdown as 90 countries call for confinement* (2020) https://www.euronews.com/2020/04/02/coronavirus-in-europe-spain-s-death-toll-hits-10-000-after-record-950-new-deaths-in-24-hou (last visited Sep. 21, 2021).

[306] WHO, *WHO: Access to HIV medicines severely impacted by COVID-19 as AIDS response stalls* (2020) https://www.who.int/news/item/06-07-2020-who-access-to-hiv-medicines-severely-impacted-by-covid-19-as-aids-response-stalls (last visited Sep. 21, 2021).

[307] T. Riley, E. Sully, Z. Ahmed & A. Biddlecom, *Estimates of the potential impact of the COVID-19 pandemic on sexual and reproductive health in low-and middle-income countries*, 46 International Perspectives on Sexual and Reproductive Health 73 (2020).

the population, not due to violations of the restrictive measures, but only because they were political opponents and marginalised communities[308].

Lastly, it is true that in every part of the world these lockdowns have had consistent socio-economic effects especially on marginalised parts of the population, that had difficulties to or could not access to financial and economic support[309]. It is also true that in LMICs, namely countries in Africa, with large informal economies, the situation has only worsened[310].

The only instrument that could put an end to all the restrictive measures and their devastating consequences is the vaccine, that was finally introduced at the end of 2020, but the real success of this pharmaceutical depends only on its equitable access and rapid distribution on a global scale, and unfortunately this is not what it is happening right now.

Since the end of 2020, thirteen vaccines against Covid-19 have been authorised in different parts of the world, and this rapid development was almost seen as an improvement of GHS. However, problems related to efficacy, storage, administration, pricing and, most importantly, equitable access and distribution have complicated the situation[311].

Indeed, although all the vaccines seem to be effective against the virus, there are some differences in terms of efficacy in preventing symptomatic Covid-19: the mRNA Pfizer and Moderna vaccines were shown to have 94-95% efficacy[312], while the recombinant vector vaccine Vaxzevria (former Astrazeneca) around 60-70%[313].

Also, while all the vaccines, except Johnson & Johnson, require two shots to allow the body to have an immunity response, Pfizer and Moderna vaccines result particularly complicated to store, since they need a cold chain to be distributed[314].

In addition, there are significant price differences. The two mRNA vaccines are sold at $ 15 per dose (Moderna) and $ 20 per dose (Pfizer), being in this way the most expensive vaccines, while the recombinant vector vaccine Vaxzevria Vaccine (former Astrazeneca) is less expensive ($ 4 per dose)[315].

Another consistent issue is that the ambitious plan launched at the beginning of the pandemic by the WHO, the Access to COVID Tools-Accelerator

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[308] R. A. Aborisade, *Accounts of unlawful use of force and misconduct of the Nigerian police in the enforcement of COVID-19 measures*, Journal of Police and Criminal Psychology 1–13 (2021).
[309] World Bank, *World Bank's response to COVID-19 (Coronavirus) in Africa* (2020).
[310] ibid.
[311] Šehović & Govender (n. 303) 1200-1201.
[312] P. Olliaro, *What does 95% COVID-19 vaccine efficacy really mean?*, The Lancet (2021).
[313] Paul-Ehrlich-Institut, *Safety and efficacy of the COVID-19 Vaccine AstraZeneca* (2021) https://www.pei.de/EN/newsroom/hp-news/2021/210218-safety-efficacy-covid-19-vaccine-astra-zenaca-information-pei.html (last visited Sep 21, 2021).
[314] Šehović & Govender (n. 303) 1201.
[315] K. Zaiets, J. Borresen & K. Weintraub, *Comparing the COVID-19 vaccines. Three vaccines are authorized for use in the United States and another two are coming soon. Here is a closer look at what we know so far*, USA Today (2021) https://www.usatoday.com/in-depth/graphics/2021/03/27/comparing-covid-19-vaccines/6806600002/ (last visited Sep. 21, 2021).

(ACT-A), which had the initial aim of making the vaccines accessible to everyone, remained just a figment of imagination[316].

By contrast, a sense of vaccine nationalism took over at the end of 2020, with all the wealthy countries that started to pre-order vaccine quantities beyond their own needs, arriving to cover 300% of the population[317]. Developing countries, notwithstanding the fact that their own citizens have been part or are taking part right now to the trials for Covid-19 vaccines, have being automatically excluded from this massive distribution, and thus it is unlikely that their own populations will be able to get vaccinated in the near future[318].

As it can be easily noticed, in this moment the goal of ensuring a GHS that is human security-centric and equity-based, especially in terms of equitable access and distribution of vaccines, is far from being accomplished.

Unfortunately, even the international community, that should ensure, if not the total accomplishment, at least a contribution in reaching a GHS for the vaccines, has proven to be not particularly sensitive in this regard. In particular, the proposal by India and South Africa to internationally waive obligations of TRIPS, namely all the intellectual property rights, in order to make Covid technologies - especially vaccines - publicly available for all the world, did not receive a positive respond, and was blocked at first in October 2020[319].

When the two proposing countries renewed this request of a general waiver of patent rights in March 2021, this time supported by over 80 developing countries, the richer WTO members, such as US, EU, Japan, Canada, and Switzerland continued to block it, asserting that the existing compulsory licenses mechanisms provided in TRIPS[320] are suitable to guarantee enough supply of vaccines and treatments around the world[321]. However, in section 3.1 it has been already noted that this cannot be considered entirely true in light of the issues related to the intricacy of the procedures, the fear of retaliation, and the derogations imposed by various bilateral agreements.

Only very recently, in May 2021, the US changed its policy, when it announced support to the proposed temporary waiver of intellectual property rights on Covid-19 related technologies that was being discussed at the WTO[322]. However, it is still extremely unclear how this technology transfer will be implemented in a practical way[323].

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[316] Šehović & Govender (n. 303) 1201; D. G. Legge & S. Kim, *Equitable Access to COVID-19 Vaccines: Cooperation around Research and Production Capacity Is Critical*, 4(1) Journal for Peace and Nuclear Disarmament 73-134 (2021) 79-81.

[317] ibid.

[318] BusinessTech, *South African firm to help develop COVId-19 vaccines for the rest of Africa* (2021) https://businesstech.co.za/news/government/469958/south-african-firm-to-help-develop-covid-19-vaccines-for-the-rest-of-africa/ (last visited Sep. 21, 2021).

[319] K. M. Gopakumar & C. Rao, *TWN info service on UN sustainable development* (2021).

[320] Artt. 31-31bis.

[321] EUROACTIV, *Rich countries block push by developing nations to waive COVID vaccine patent rights* (2021) https://www.euractiv.com/section/economy-jobs/news/rich-countries-block-push-by-developing-nations-to-waive-covid-vaccine-patents-rights/ (last visited Sep. 21, 2021).

[322] B. Ito, *Impacts of the vaccine intellectual property rights waiver on global supply*, VOXEU (2021) https://voxeu.org/article/impacts-vaccine-intellectual-property-rights-waiver-global-supply (last visited Sep. 21, 2021)

[323] ibid.

Another international instrument through which developing nations could obtain access to vaccines is the facility called COVAX at the WHO, funded in an attempt of showing multilateral solidarity. However, even in this case the practical difficulties are consistent.

First, COVAX is committed to ensure a vaccine contingent of 20% cover of each country's population, which is a quantity extremely lower than the one required to reach herd immunity and protect the entire world from the virus[324].

Secondly, there is still the issue of bilateral agreements and Memorandum of Understanding (MoUs), between developed countries, LMICs and vaccine manufacturers, that allow the latter to overcome the legal guarantees and requirements of COVAX.

Third weakness is the lack of funding[325]. Considering all these aspects, it can be noticed how this pandemic has shown once again the controversial links between global health, GHS, and global inequities, and how the latter must be reduced in order to achieve this GHS that is more human and equity-oriented[326].

There are different interventions that can be done to pursue this perspective of GHS. The first one could be prioritizing Covid-19 in health programming[327]. Indeed, the prevention and vaccine programs against the virus require the implementation of efficient and strong universal systems, in terms of primary health care (PHC) oriented public health services[328]. Interestingly, practical hints to create such a system can be taken from LMICs that implemented efficient public health strategies, such as integrated programming, contact tracing, and door to door health care, for instance during the epidemic response to Ebola in West Africa[329].

Second, there is the need of human rights instruments, especially the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) and the International Covenant on Civil and Political Rights (ICCPR, 1976)[330]. These international treaties can enforce important rights and state obligations related to the access of life-saving drugs[331]. The specific approach to follow would be, on the one hand, a temporary IP exception, and on the other hand, a pressure on the states to comply with their international obligations of promoting the right to health and the extension of financial and technical resources to LMICs[332].

Third intervention that can be made to pursue GHS is the use of an equity focus in the International Health Regulations (IHR) of the WHO[333]. This treaty

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[324] A. Green, *At WTO, a battle for access to COVID-19 vaccines* (2020) https://www.devex.com/news/at-wto-a-battle-for-access-to-covid-19-vaccines-98787 (last visited Sep. 21, 2021).
[325] Šehović & Govender (n. 303) 1202; Legge & Kim (n. 316) 79-81.
[326] ibid.
[327] ibid at 1204.
[328] ibid.
[329] ibid.
[330] ibid at 1203.
[331] See ICESCR, Art. 12 which establishes the right of everyone to the highest attainable standard of physical and mental health.
[332] J. Dugard, J. Handmaker & B. Porter, *Mobilising human rights to address coronavirus vaccine apartheid*, Opinio Juris (2021) http://opiniojuris.org/2021/02/18/mobilising-human-rights-to-address-coronavirus-vaccine-apartheid/ (last visited Sep. 22, 2021).
[333] Šehović & Govender (n. 303) 1203.

requires each country to prepare and adhere to pandemic guidelines, but its core requirements have not received a huge implementation in most countries, especially the poor and developing ones[334]. The implementation of the IHR framework, that can allocate global and local accountability, would be central to deal with the inequities of the world.

Lastly, there is probably the most relevant intervention for this dissertation, that is technology and knowledge transfer[335], and the recent US statement of adherence to the waiver of intellectual property rights at the WTO level seems to pave the direction to it.

However, it has been already stated that for now it is not entirely clear how this transfer would occur, and it is unlikely that IP owners would implement this transfer of knowledge spontaneously, for instance by disclosing trade secrets, as noticed in 2.4, or by sharing the information in relation to a certain patent. In this regard, support for the waiver is increasing among unions and civil society organizations, such as Free The Vaccine Campaign, that call for the remove of obstacles such as intellectual property[336], and the declaration of vaccines as public goods[337]. It is exactly this last aspect, the Commons and their application in the context of the Covid-19 Vaccine, that will be the focus of the next sections.

4.3 From the Tragedy to the Comedy of the Commons

Since the advent of the classical economics in the 18th Century, it has been commonly accepted that the world functions in a better way when it is divided among different private properties[338]. Indeed, it has often been stated that the right to exclude others is the most important characteristic of the private property[339], since it allows the owner of a certain property to acquire the full value of his investment, providing an incentive to spend time and labor for the development of valuable resources[340].

This conception of property directly derives from the thought of the 17th Century British Philosopher John Locke who notoriously stated that "every man has a property in his own person. […] The labour of his body, and the work of his hands, we may say, are properly his. Whatsoever then he removes out of the

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[334] G. Bartolini, *The failure of 'core capacities' under the WHO International Health Regulations*, 70(1) International & Comparative Law Quarterly 233 (2021).
[335] ibid.
[336] European Public Service Union, *Trade rules must not impede access to COVID-19 vaccines and medical supplies* (2021) https://www.epsu.org/article/trade-rules-must-not-impede-access-covid-19-vaccines-and-medical-supplies (last visited Sep 22, 2021).
[337] Mail & Guardian, *Towards a people's vaccine campaign: A call to action* (2021) https://mg.co.za/special-reports/2021-01-15-towards-a-peoples-vaccine-campaign-a-call-to-action/ (last visited Sep 22, 2021).
[338] C. Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53(3) The University of Chicago Law Review 711 (1986) 712.
[339] W. Blackstone, *Commentaries* *2.
[340] ibid at *4 and *7.

state that nature hath provided, and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property"[341]. Therefore, everyone should be recognized the fruits of their labor in the form of private property.

In addition, exclusive control of the private property allows owners to identify other owners, and to exchange their products (the fruits of their labors), until there will be a high recognition of all the private things for the final benefit of the society as a whole[342]. Hence, exclusive property is something to be pursued as the only way to boost the well-being of a community, by giving a method to control, use, and exchange that property.

A direct consequence of this argument is what Garrett Hardin defined as the "Tragedy of the Commons"[343]. In particular, this author argues that when things are left to the use of the public, they are destined to be overused or underused. Considering that these public goods are not owned and managed by someone, no one would invest in them, knowing that all the efforts put in those goods can be completely lost[344].

Hence, the feature of exclusivity, typical of private property, should be preferred to the one of inclusivity of the public goods, at the point that the basic social and commercial interactions that we constantly have would not be practicable if property rights were not consistent or poorly defined[345].

Considering all the above, it would be difficult even to imagine an idea of "public property". Instead, this notion has been present in the law of the western world since the Romans, that deeply influenced the later European and American law[346]. Indeed, the current western legal doctrine debates about some kinds of property that do not have a single owner but are open to the public at large, being subjected to what the Romans called the *jus publicum*, i.e., the "public right"[347].

The current academic and judicial discussion is in fact focusing on the issue. For instance, in the US there has been the adoption of a "inherent publicness" argument in a series of cases related to waterfront property[348]. At the beginning, public property was considered only the land between low and high tides[349]. More recently, the public easement for navigational and fishing purposes has been extended from the tidelands to the dry sand areas landward of the high-tide sign[350].

An interesting position related to the Commons in the European context is the one assumed in Italy where the common goods "have mostly represented a battleground for economic and social change"[351]. In particular, a proper common

[341] J. Locke, *The Second Treatise of Government* (1689) Chapter 5**.**
[342] C. G. Holderness, *A Legal Foundation for Exchange*, 14 J. Legal Stud. 321 (1985) 321-22.
[343] G. Hardin, *The Tragedy of the Commons*, 162 Science 1243 (1968).
[344] ibid.
[345] Holderness (n. 342) 344.
[346] Rose (n. 338) 713.
[347] ibid.
[348] ibid.
[349] See e.g. *Martin v. Waddell* [1842] 41 U.S. 366.
[350] See e.g. *City of Daytona Beach v. Tona-Rama, Inc.* [1974] 294 So. 2d 73.
[351] M. R. Marella, *The Commons as a Legal Concept*, 28(1) Law and Critique 61 (2017) 66.

goods movement in Italy is strongly against some enclosures, regarding common spaces and resources, that have been established to promote private profit[352].

There is an exemplary case that can help to understand this idea according to which common goods can be anything and can "emerge" according to the specific circumstances of a situation[353]. Cinema Palazzo, a private theatre located in Rome, after its closure, was given to a company that wanted to convert it into a casino. However, many artists, students, and residents contrasted this plan by occupying the cinema, and eventually by transforming it into a Commons. When the company legally claimed that some of the occupants were responsible for the dispossession that it had suffered, the Court rejected this argument, by stating that the occupy movement was a "pacific multitude", and these people were motivated by a genuine objective, notably saving the cultural use and purpose of the building[354]. Therefore, in that specific situation the establishment of the Commons was lawful.

There has been consistent criticism towards this expansion of the public property notion, since it has been stated that uncertainty about property rights induces conflicts and impairs resources. According to this argument, if the waterfront property or Cinema Palazzo are transformed into Commons, no one has an incentive to invest in them, but there is only an interest in consuming them, before others do the same, leading to a deterioration and waste of those goods[355].

It must be admitted that this commons theory considerably contrasts the classical 18th Century economic thinking and most of the legal theories informed by the exclusivity of private property. Indeed, this different kind of property has as its hallmark the public access and its inclusivity.

However, the author Rose in her elaboration of the "Comedy of the Commons" – widely shared by this work – demonstrates that the Commons Theory can be reliable[356]. Indeed, if the question whether any property must have the feature of being exclusive, the answer would be negative, since in our reality there are exceptions to private and exclusive property rights[357].

The first exception is the one of "plenteous goods", things that are either so abundant or so unbounded that there is not even the need to establish for them a system of resource management. Examples of plenteous goods are the ocean and air, since they are so plentiful and almost impossible to reduce at private property that they are left to the public at large, without a system that administers them in a certain way[358].

However, this is not a relevant exception for the purpose of this work, which instead focuses on those goods that theoretically can be privatized, but it is a better choice not to. These things correspond to the second exception to private properties: the "public goods"[359], since, as it will be further specified, one of their

[352] S. Bailey and U. Mattei, *Social movements as constituent power*, 20 Indiana Journal of Global Legal Studies 965 (2013).
[353] Marella (n. 351).
[354] Tribunale di Roma, VII Sez. Civ. [8 February 2012].
[355] N. A. Roberts, *The Efficiency of the Common Law and Other Fairy Tales,* 28 UCLA L. Rev. 169 (1980) 177-80.
[356] Rose (n. 338) 717.
[357] ibid.
[358] ibid at 718.
[359] ibid.

most important features is properly the capability of being privatized, such as a vaccine that can be patented.

Actually, this category of goods has found recognition since the advent of classical economics in the 18th Century, when it has been stated that there are instances of "market failure" where the notorious Adam Smith's "invisible hand"[360] does not work properly. This inefficiency is in fact particularly envisaged, *inter alia*, in public goods, natural monopolies, and externalities, since in these cases private resources fail to reach their optimal social use, or – better to say - the social efficiency in their exclusivity[361].

Indeed, public goods cannot be managed by collective agreements among the owners since they are costly and, when a consistent number of parties is involved, private collective action is not an efficient option. Hence, the only optimal solution to manage public property seems to be governmental management, in the sense that the government assumes total or partial ownership and control over the property, and in this way, it can try to correct the market failure[362].

However, the governmental management is not the only way to enforce Commons. It could be an error to think that according to the classic paradigm of neoclassical economics and modern microeconomy theory, either ownership is vested in private parties, or the property is owned by a state, suggesting that markets are always based on private rights. Since the Middle Ages a different phenomenon from the private property and government-controlled property can be detected, the so-called "inherently public property", which is property "collectively owned and managed by the society at large"[363].

Hence, this is what can be defined as Commons, which must not be seen as something "tragic". By contrast, considering that these regimes of properties achieve the highest value when they can be accessed by the public at large, as it will be shown soon, it is more appropriate to refer to a Comedy of the Commons, intended as "a story with a happy outcome"[364].

With regard to the proper Commons - the "inherently public property" -, there are clarifications to be made. First, the public in this case is the "public at large", that is not only the one that acts through the intervention of an organized government which manages that particular property, but most importantly it is a public that manages that Commons through customs and habits that are radicalized in a certain civilized society[365].

Moreover, two aspects are essential for the public in order to claim that property as a Commons: the property has to be capable of being monopolized by private owners, and the claim of the public should be stronger than the one of private people, in the sense that this particular good would be more efficient and valuable if used by an indefinite and unlimited number of people[366].

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[360] See e.g. A. Smith, *The Theory of Moral Sentiments* (1759) Part IV, Chapter 1.
[361] Rose (n. 338) 718-19
[362] ibid at 719.
[363] ibid at 720.
[364] ibid at 722-23.
[365] ibid at 774.
[366] ibid.

If a purpose of the Commons should be identified, it can be stated that the main object of this inherent public property is the protection of commerce[367]. As a matter of fact, commerce becomes more valuable as the number of participants increases, since markets create thousands of opportunities, and people become richer in the moment that they start to "truck, barter, and exchange"[368]. Hence, this notion of Commons results compatible and not in contrast with the classic economic thinking.

On this point, it can be added that according to a few authors that have elaborated a particular conceptualization of the commerce, the latter should be seen not only as an interactive practice, but also as a socializing and educating institution[369]: as James Madison and recent political economists thought, since it is supposed to make everyone richer, commerce would reduce social contrasts, and the trade context would distract people from personal problems[370].

Lastly, commerce entails that people's attention is focused on the desires of other people[371]. This is linked to the Commons features and scope, since, in a certain way, the Commons, as the commerce, aim at allowing people to be sociable and socializing – to be with each other - and these are probably the most important "returns to scale" that such a practice can obtain[372].

Therefore, as mentioned before, the inefficiency - "tragedy" - of the commons is not a sustainable concept. By contrast, commons are efficient and effective - "comedy" - in supporting social activities in general, not just limited to commerce, such as education, good manners, commemorative practices[373]. The more an activity is socializing, the more it can receive the Commons Protection.

It should be added that it is the Anticommons - the exclusivity of private property - that ultimately experiences a "tragedy", since, as it was pointed out in section 2.2 by referring to the work of Heller, if there are many owners that are supposed to have the right to exclude others from the use of a resource, this resource is inclined to be underused[374]. Hence, private property is sometimes unable to provide its full efficiency that, at the beginning of this section, it was assumed it had, while the Commons and their inclusivity seem to enhance sociability.

After having offered this introduction to the Commons characteristics and advantages, in the next section this theory will be addressed in the field of a specific type of intellectual property.

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[367] ibid.
[368] A. Smith, *The Wealth of Nations* (Modern Library ed. 1937) 13.
[369] A. Hirschman, *The Passions and the Interests* (1977) 49-66: 18th century thinkers thought that human avarice was the basis of our sociability.
[370] M. Diamond, *The Federalist*, in L. Strauss & J. Cropsey, History of Political Philosophy 573 (1963) 590-92.
[371] Hirschman (n. 369) 58-63.
[372] Rose (n. 338) 777.
[373] ibid at 777-78.
[374] Heller (n. 107) 624.

4.4 The Commons in the Intellectual Property Law field

The Commons Theory has gained noticeable interest in all types of property, among which intellectual property is the most peculiar and the most interesting to debate on. In particular, the question that the legal literature has been asking right now is whether, in the light of the Commons, the idea of property is still needed to increase creation and innovation, the two most important aspects that justified intellectual property in the first place.

Indeed, until now, there was no doubt that intellectual property was the only mean in order to achieve creation and innovation. Through a reasoning that is extremely similar to the one elaborated in 4.3 about the rationale of private property in general, it has been stated that, without intellectual property, the creation would result in intellectual products which are non-exclusive and non-rival.

In particular, users would access the product without paying its price, i.e. free-riding on it (non-exclusivity), and the resource would be used without depriving anyone else of such a use (non-rivalry)[375]. In this way the creator is contributing to the welfare of the entire society, but if she cannot recoup her investment, there would be a lack of incentive that ultimately results in a block of innovation and creation.

To avoid that something like this can occur, intellectual property is introduced by attributing to the author or inventor the fruits of her labor. Therefore, intellectual property, as private property in general, is introduced to correct the market failure that would derive from the use of only public goods.

It is true that in case of intellectual products there would not be that depletion of physical resources that Garrett in his "The Tragedy of the Commons" was referring to. However, according to this line of thought, without incentives given by intellectual property, there would be an under-production of works and inventions, that is always an inefficiency of the market.

It has been already assessed in 4.3 that this type of argument should not be accepted anymore, and this is also valid in the intellectual property context, where Commons, that are intended as resources that lack exclusivity, are already widespread, as evidenced by the author Dusollier[376]. It is exactly her work about "Commons as a reverse intellectual property" that is the focus of this and the following section. In particular, Dusollier states that Commons in the IP field can derive from the delineation of the exclusivity granted by copyright and patent, which is mostly public domain and exceptions/limitations[377].

In addition, considering that sometimes authors and inventors decide to opt-out entirely from exclusivity to encourage the sharing and dissemination of their

[375] R. Watt, *Copyright and Economic Theory – Friends or Foes?* (Cheltenham: Edward Elgar, 2000) 4-5.
[376] S. Dusollier, *The commons as a reverse intellectual property – from exclusivity to inclusivity*, in J. Griffiths, *Concepts of Property in Intellectual Property Law* (H. Howe ed. Cambridge University Press 2013) 258.
[377] ibid.

intellectual products[378], Commons can be the result of private ordering initiatives, such as open-source software, Creative Commons or open-source patenting[379].

The issue is that, since the instruments listed above are completely different from each other, in the sense that, for instance, the public domain is a non-right situation, meanwhile patent pools – as open-source patenting – are more rights-based, if the same expression "Commons" is used for all of them, there can be confusion in relation to what is a proper Commons in IP[380]. Hence, it is better to clarify these different categories of Commons before moving forward.

The first Commons is the public domain, that covers those intellectual resources that are not protected, or no longer protected by IP, and in this way, it lacks any exclusivity[381], resulting in a Commons at the highest grade. In particular, in patents – IP of interest for this work – public domain results in abstract ideas, discoveries[382], inventions that do not satisfy the patentability requirements, excluded subject matter[383], as observed in section 2.1, inventions that are no longer under patent protection, and unregistered inventions.

By contrast, inventions that are not patentable on the grounds of *ordre public* or morality, or because they are products of nature[384], as always noticed in 2.1, cannot be considered part of the public domain, since they cannot be exploited in general, and thus their aspect of inclusivity would not be acceptable[385]. Interestingly, this aspect is connected to one of the Commons' main features, described in section 4.3, notably that property can potentially become private, as in this case the invention in abstract must be patentable. Therefore, it can be already noticed that the fundamental features of the Commons Theory mentioned above should be present in all the different types of property where this theory is applied.

Another way to conceive Commons in IP is when there is not a total non-property, as in the case of public domain, but when non-property – whose main aspect is inclusivity - coexists with spaces of property – characterized by exclusivity -[386]. This is related to exceptions and limitations in patents, when, for instance, in the case of private use of the invention there is a general entitlement of inclusivity, or according to the research exception, there is a Commons reserved to some specific categories of people.

It has been argued that these exceptions and limitations can be also included in the public domain itself, if the latter is divided in two connotations. In particular, there is a structural public domain that encompasses works and inventions that are not covered by copyright and patent at all, and a functional public domain that is the one that includes the exceptions and limitations, since

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[378] ibid.
[379] N. Elkin-Koren, *What Contracts Cannot Do: The Limits of Private Ordering in Facilitating a Creative Commons*, 74 Fordham Law Review 375 (2005) 398.
[380] Dusollier (n. 376) 266.
[381] ibid at 267.
[382] See EPC, Art. 52(2); although, as it has been already noticed (see 2.1), in the US a proper list of non-patentable subject matter is not provided, see 35 U.S. Code § 101.
[383] ibid.
[384] See EPC, Art. 53.
[385] Dusollier (n. 376) 268.
[386] ibid.

in this case the openness and the degree of Commons is dependent not on the type of work and invention, but on the circumstances of the single situation[387].

The last form of inclusivity in the IP context is the most recent one and defined as the open innovation movement[388]. The first type of open innovation that gave origin to all the others is the open software, which is based on "the freedom to run and use a program and to copy, modify, improve and redistribute it"[389]. Moreover, it has as one of its main "commandments" the free redistribution of the software's source code to everyone[390].

This open-source concept found acknowledgement, other than in the copyright field[391], in the patent one. One of the most prominent examples is the Biological Open Source (BiOS) License, created by the Centre for Applications of Molecular Biology in International Agriculture (CAMBIA), which establishes a worldwide, non-exclusive and royalty free right to develop and apply the technology of two patents owned by the centre[392].

Another example of open innovation in the patent field, that is extremely recent, is the IP pledges which, although they assume various forms and labels, have as their main goal to make IP freely available to the public, and they have proved to be particularly helpful during the current pandemic of Covid-SARS-19[393].

In particular, IP owners started to gather in organizations and make available their IP rights to users all around the world, without the latter being at risk of committing a patent infringement. These pledges are usually royalty-free, and in some cases – such as the Open Covid Pledge – self-executing, meaning that anyone who is interested can immediately use the IP without additional negotiation or formalities[394]. In addition, when there is the risk that the users may charge excessive price for the products that result from the IP freely available to anyone, some pledges - such as the Harvard-Mit-Stanford Pledge - require that users must demand "fair" or no more than "cost-plus" prices[395].

All these open innovation instruments, from open software to patent pledges, can be considered Commons, in the sense that they are inclusive in sharing and using a specific resource[396]. However, this category of Commons is different than the ones of public domain and exceptions/limitations. Indeed, in the

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[387] S. Dusollier, *Scoping Study on Copyright and Related Rights and the Public Domain*, WIPO (2010) 8–9.
[388] K. Walsh, A. Wallace, M. Pavis et al, *Intellectual Property Rights and Access in Crisis*, 52 IIC 379-416 (2021) 386.
[389] Dusollier (n. 376) 269.
[390] Open Source Initiative, *Open Source Definition* (2007) first commandment: https://opensource.org/osd (last visited Sep 27, 2021).
[391] See the Creative Commons project invented and developed by Lawrence Lessig: https://creativecommons.org (last visited Sep 27, 2021).
[392] See CAMBIA, The CAMBIA BIOS Initiative https://cambia.org/bios-landing/the-cambia-bios-initiative/ (last visited Sep 27, 2021).
[393] J. L. Contreras et al., *Pledging intellectual property for COVID-19*, Nature Biotechnology (2020) 1.
[394] ibid.
[395] ibid at 2; IP pledges database available at http://www.pijip.org/non-sdo-patent-commitments/ (last visited Oct 20, 2021).
[396] Dusollier (n. 376) 270.

open innovation instruments there are some exclusive rights, that are, instead, completely absent in the public domain[397].

For instance, the IP pledges have as their main object information most of the times covered by patents. Therefore, the inclusivity generated by this particular Commons derives from the exclusivity that the patent owner obtained through patentability. This is not a contradiction, since exclusivity, on which intellectual property is based, is something different than exclusion[398]. Exclusivity in a certain invention does not entail exclusion of others from using that invention. Hence, open innovation instruments are ultimately contracts where the patent owner or the author of a certain work decides willingly to create inclusive entitlements that are beneficial to the users of that invention or work[399].

Some authors, such as Elkin-Koren, criticized such recourse to contracts, explaining that this means to make intellectual property rely on private-ordering norms – contracts – potentially resulting in the impairment of the balance of different IP regimes[400]. The specific concern is that market players that own IP would make their assets available to the users under very restrictive terms, probably more restrictive than normal licenses, under the false assumption of open innovation[401].

It can be said that, although the risk is definitely tangible, most open innovation instruments aim to make any margin of exclusivity impossible, by having a proper "self-binding Commons"[402] that would not allow IP owners to change terms of the contracts in a more restrictive way whenever they wish to.

The legal mechanism that would apply in this context is the so-called "copyleft" – also defined in the patent context as grant-back - which originated from its opposition to the word copyright, as a play in words: copyright would represent the feature of exclusion, typical of IP, meanwhile copyleft refers to the waiver of copyright in a more inclusive perspective[403]. Through this copyleft mechanism, if someone wants to improve or modify a specific work or invention, she is required to distribute the modified work or invention under conditions of inclusivity. Hence, any modified work or invention would be included under an open innovation scheme, resulting in a total correspondence between the contract and the IP resource itself[404].

This mechanism would solve another issue related to open innovation which is the lack of enforceability of the privileges granted to the users against other users, since the copyleft clause would provide, for any user of a specific invention, a right against the world and not only against the licensor or patent owner[405].

After assessing each Commons, Dussollier offers an overview of their specific advantages and disadvantages. It can be underlined that the Commons that is the furthest away from exclusivity would be the public domain, that on the

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[397] ibid.
[398] ibid.
[399] ibid.
[400] Elkin- Koren (n. 379).
[401] ibid.
[402] Kapczynski et al (n. 73) 1072.
[403] Dusollier (n. 376) 271.
[404] S. Dusollier, *Sharing Access to Intellectual Property*, 82(3) Chicago- Kent Law Review 1391 (2007) 1414–16.
[405] Dusollier (n. 376) 271.

one hand allows anyone to use a specific creation unconditionally, but on the other hand, this unlimited use is almost impossible to enforce, since no one that is part of the public could claim and protect her privilege through a legal remedy[406].

A similar situation can be found in the context of copyright and patent exceptions, where an exclusive right is not enforceable because of the binding force of the legislation which provides for a specific limitation. The difference with the public domain is that the inclusive privilege enjoyed by users for the exceptions is enforceable only through defence when there is a case of copyright or patent infringement[407].

Lastly, open innovation instruments, which originate from exclusive rights, create enforceable contractual rights against the licensor or the IP owner, but only on the condition that the freedoms granted by these Commons are perpetuated through the copyleft or grant-back mechanism[408].

After having addressed the different Commons in the intellectual property field, it is time to deal with the theoretical possibility to include the vaccine against Covid-19 among them.

4.5 The vaccine against Covid-SARS-19 as a Commons: the inclusive right

As already mentioned in 4.2, across the world there have been important campaigns related to the issue of vaccine access and allocation, such as the Free The Vaccine initiative which demands that "Covid-19 diagnostic tools, treatments, and vaccines must be available to everyone everywhere"[409], or academics, including Boschiero, who have stated the nature of vaccines as "global common/public goods", despite being currently regulated as "private market goods"[410]. The question to be answered now is how this desirable shift to a Commons Regime can be realized.

The vaccine against Covid-19 should be considered a Commons, since it is compatible with the two important and general features that every Commons should have to be defined as such, as explained in section 4.3.

First, a vaccine is capable of being monopolized by private owners. Indeed, it has been already noticed how every pharmaceutical company tries to patent the vaccine. This is possible from a legal perspective because, although the starting point can be something natural such as mRNA, ultimately in order to develop and produce a vaccine there is the implementation of a complex

[406] ibid at 277.
[407] ibid.
[408] ibid.
[409] See Free The Vaccine campaign https://freethevaccine.org (last visited Sep 29, 2021).
[410] N. Boschiero, *COVID-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management*, Global Jurist 1-54 (2021) 16.

technology which is made by humans, and vaccines can be granted different patents, as explored mostly in 2.1 and 2.2.

The second aspect which suggests that a vaccine can become a Commons is that this good would be more beneficial if used by the public at large. The reasons behind this benefit are countless, and the most important ones, that have been already deeply investigated in the previous sections of this chapter, especially while discussing the GHS, are listed below.

First, only if this vaccine is administered in every part of the world there is a chance to defeat the virus once and for all. Indeed, there is the need to reach a herd immunity and avoid that some new strains imperil the efficacy of the vaccine itself in the future. As affirmed in an impactful way by Meijer, "In a pandemic, nobody is safe until everyone is safe"[411].

Secondly, an equitable access and allocation of vaccines towards the public at large would contribute to institute a GHS that is human and equity-oriented and not just focused on the nationals' safety. The establishment of such a system would also allow to face future pandemics or serious global issues, such as climate change, in a more efficient and responsible way.

Thirdly, it would simply be fair to recognize the efforts that the public itself put in developing and producing these vaccines, since it has been seen in section 4.1 that most of R&D in this pandemic – but also beyond - received public funding, and thus the contribution of taxpayers.

Fourthly, the vaccine as a public good perhaps would constitute a symbol against the nationalisms and xenophobia that have been spreading around the world also in this context, considering that in this moment some wealthy countries that have large supplies of vaccines are refusing to vaccinate migrants and asylum seekers, and they are prioritizing just their nationals[412].

Now that it has been clarified that the vaccine meets the conditions to be considered a Commons, it seems opportune to assess which particular category of IP Commons it belongs to, and in this assessment the advantages and disadvantages of each Commons, provided by the author Dusollier in her "Commons as a reverse intellectual property"[413] – referred to extensively in 4.4 - must be considered.

If the vaccine was part of the public domain, no IP holder would have an exclusive right in it, resulting in an unconditional freedom to use the vaccine. However, there would be an issue of enforceability, since the public domain is without controls and legal enforcement, and this would lead to a risk of underuse or overuse of this resource.

A similar situation would arise if the vaccine was recognized as an exception/limitation to the patent regime. On the one hand, there would not be any exclusivity. On the other hand, the enforceability would be implemented only as a defence against an alleged patent infringement. Therefore, the cases where this Commons is enforceable would be extremely limited.

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[411] M. Meijer, *COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-how and Technology*, European Journal of Public Health (2021) 1.

[412] M&G (n. 337).

[413] Dusollier (n. 376).

Lastly, perhaps the most suitable Commons for the vaccine would an open innovation instrument, such as IP pledges or patent pools, that have been already implemented in this pandemic for some diagnostics and treatments against Covid-19, as observed in section 4.4. Indeed, this Commons would be enforceable against the licensor or IP holder.

However, these instruments are based on private ordering, and thus on the will of the IP holder herself. It is far from certain that the owner of patents related to the vaccine would be willing to share such a technology with everyone in the form of a binding pledge. Therefore, also this Commons does not seem to be the best solution for the vaccine against Covid-19.

There is one last option in order to obtain a proper enforceability and management of the vaccine as a Commons. It is now sufficiently clear that, at least in the intellectual property field, "there is no grand unified theory of Commons"[414]. However, all commons have one constant feature which is inclusivity, and this should be taken into high consideration[415].

It has been already ascertained that until now intellectual property has always been focused on exclusivity, and not on the spaces of inclusivity that anyway have been present in the IP context as public domain, exceptions/limitations, and open innovation instruments.

This perspective should change, in the sense that the private and public dichotomy, which has constituted the foundation of IP, should be replaced with a more complex combination of rights and privileges[416]. This does not mean to abolish IP completely, but to achieve a harmonisation between IP and the Commons, as a proper balance should be pursued between the public and private sectors.

If this harmonization should be achieved, the author Dusollier advances the idea that the inclusivity feature must be conceived not only as a static aspect of a Commons, but as something that is normatively relevant[417]. Hence, it should have normative consequences.

In particular, users of a work or invention, whether it is in the public domain, it constitutes an exception/limitation to copyright or patent law, or it is delivered through an open innovation instrument, should always be able to enforce and manage that Commons, properly in the form of inclusivity[418]. Therefore, the main idea proposed by Dusollier is that there should be an actual "inclusivity right" that would constitute an effective remedy or enforcement. This right would be extremely useful for the public domain and exceptions/limitations that are almost impossible to implement, but also in the open innovation schemes where usually the users' rights are enforceable only against the licensor or IP holder[419].

Usually when there is a right, a correspondent duty arises. Indeed, the correlative of the inclusivity right would be a duty on everyone else to not interfere

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[414] Y. Benkler, *Between Spanish Huertas and the Open Road: A Tale of Two Commons?* (2011) 1.
[415] Dusollier (n. 376) 279.
[416] J. E. Cohen, *Copyright, Commodification, and Culture: Locating the Public Domain*, in L. Guibault and P. Bernt Hugenholtz (eds.), *The Future of the Public Domain –Identifying the Commons in Information Law* (The Hague: Kluwer Law International, 2006) 165.
[417] Dusollier (n. 376) 279-80.
[418] ibid at 280.
[419] ibid.

with the inclusivity. This would solve another relevant issue in IP, that is a lack of a proper immunization of the public domain or exceptions/limitations from other people's rights, contracts, or technological measures, that in a certain way can frustrate all the inclusivity granted by these Commons[420].

Considering all the aforementioned aspects, Dusollier provides that an inclusive right should have the following characteristics:

1. It shall never exclude another person enjoying the same inclusive right;
2. It shall preserve the resource – object of the inclusive right itself - and its collective use;
3. It must be enforced in order to defeat any claim of exclusivity that could hamper the common use;
4. Any court judgement that recognizes the inclusive right against some claim of exclusivity shall automatically benefit all individuals enjoying a similar inclusive right in the work or invention;
5. Any legal regime of inclusive rights would be assessed and implemented according to the particular situation concerned[421].

These features would be perfectly compatible if the Commons was the vaccine against Covid-19. The inclusive right for this Commons would have as its main object the distribution, management, and administration of the vaccine against Covid-19.

In particular, this inclusive right shall never be exercised in a way that can potentially exclude others that should enjoy the same right. By contrast, it should be exercised in a way that preserve the Commons itself – the vaccine – and its collective use.

Moreover, this right can be enforced in order to defeat any exclusivity that could hamper the common use of the vaccine. In addition, in relation to court judgements, these should serve not only as an example of enforcement of this right, but, most importantly, these decisions should automatically benefit all individuals enjoying a similar right in that vaccine.

Lastly, this inclusive right should be implemented according to the particular situation concerned. However, it is important to clarify that, whether the vaccine is recognized as a public domain, as an exception/limitation, or as an open innovation instrument, the features of this inclusive right, that have been just assessed, should never be derogated, but they would find application in any circumstance.

This represents a valuable suggestion regarding the enforceability and management of the vaccine against Covid-19 as a Commons. Despite being theoretical, this argument represents an indication and starting point to have a practical application of such a Commons in terms of legislative reforms and courts' decisions, or in relation to the IP waiver proposed at the WTO level, and to pursue this proper balance between intellectual property and the Commons, in a way that does not completely antagonize these two juridical phenomena.

[420] ibid.
[421] ibid.

Conclusion

This work has attempted to assess the delicate equilibrium which exists between intellectual property – as an expression of exclusivity – and the Commons – whose main feature is inclusivity – in the context of the current pandemic and in relation to the vaccine against Covid-19.

Starting with providing an historic overview of the relationship between the public and private sectors in the development of vaccines, with a predominance of the second one from the end of 20th Century onwards, it has been underlined how the attempts of offering a better balance between the private and public interests have not been entirely successful. In the meantime, it has been addressed that the system of incentives provided by the instrument of patent has started to show inefficiencies in the pharmaceutical industry, strictly linked to the cumbersome procedures for authorizing pharmaceuticals, so that other solutions are opportune to consider.

Subsequently, with a specific focus on the vaccine and its most recent and innovative mRNA technology, it has been explained that vaccines can be patented from a legal perspective. However, the patentability leads to questionable practices in the pharmaceutical industry, such as patent thickets and strategic accumulations of patents, which in turn result in a damage not only for the patent holders themselves and the generic companies, but for the public at large. With regard to trade secrets, which is another effective instrument to protect the knowledge related to vaccines, it has been underlined that IP owners do not seem inclined to consider disclosure as an option, even when this would benefit the public at large.

Moving to the international level as relevant to the regulatory context of patents and vaccines in the pandemic, the international one, it has been noted that, considering the TRIPS agreement, the instruments of compulsory license, that some developed countries still claim to be effective, showed a consistent number of flaws in their implementation. Moreover, considering the European context, issues of national sovereignty have always impaired the implementation of a proper EU patent system which would stand united and firm within the international community. Despite the proposal of the EU Unitary Patent System, there is a major obstacle, namely the UPC Agreement, which does not seem to offer an optimal mechanism of enforcement of the related rules.

On this basis, this work has tried to point to an alternative solution, at least in relation to the Covid-19 vaccine, which is the theorization of a Commons for such invention. The first reason why this direction should be followed is that, since the public funding for the development of the vaccine – as for every other

treatment against the virus - has been consistent, and there are not proper legal instruments that would recognize such public effort in the context of the privatized pharmaceutical industry, it could be fair to attribute to the public at large the ownership of such a product.

Secondly, there is the need, now more than ever, to pursue a GHS that is human and equity-oriented, considering that this pandemic has exacerbated inequalities around the world, that are being showed also by the fact that only the richer and developed countries have enough quantities of vaccine. In order to seriously leave this pandemic behind us, the entire population of the world must be vaccinated, and this shall be done quickly. Therefore, it has been noted that this vaccine would satisfy the two requirements that every Commons should have to be defined as such: being potentially owned in a private way; being managed in more efficient by the public at large.

Lastly, this work has addressed which exact form of IP Commons this vaccine should have: the public domain, exceptions/limitations – in this case - to patents, or open innovation instruments such as IP pledges. Considering that all these three types of Commons present some issues, especially in relation to the aspect of enforceability, this dissertation, building on the work of Dusollier, has advanced the idea that from the inclusivity, which is the typical feature of every Commons, an inclusive right can be envisaged and applied in the context of the vaccine, while rethinking the relationship between intellectual property and Commons. Although this remains - for now - a theoretical speculation without proper legal grounds, it can represent a starting point to implement legislations in this regard. In particular, it can provide inputs to the current discussion about the waiver of IP rights that has been proposed at the WTO level and has been already the object of attention of the civil society at large, as evidence of the fact that the society itself is becoming more sensitive to this issue.

In conclusion, law should change according to the new needs of the society, and it should offer, as every other science, its contribution in order to solve problems, especially when they have global implications. This must be specifically done through the involvement of legal researchers, legislators, judges, and all the other actors that can offer legal solutions to complex issues, by not only applying the current juridical categories and concepts, but also by changing them according to the concrete situation that has been addressed. Will law succeed in this objective? Time and research will tell.

References

Legislation

- (Proposed) Medicare Negotiation and Competitive Licensing Act.
- 15 U.S.C. “Commerce and Trade”.
- 18 U.S.C. “Crimes and Criminal Procedure”.
- 21 U.S.C. “Food and Drugs”.
- 28 U.S.C. “Judiciary and Judicial Procedure”.
- 35 U.S.C. “Patents”.
- Agreement on the Unified Patent Court.
- Agreement on Trade-Related Aspects of Intellectual Property Rights.
- Anti-Counterfeiting Trade Agreement.
- Bayh-Dole Act.
- Community Patent Convention.
- Council Regulation (EU) 2012/1260 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements.
- Defend Trade Secrets Act.
- 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.
- EU Charter of Fundamental Rights.
- European Convention on Human Rights.
- European Patent Convention.
- International Covenant on Civil and Political Rights.
- International Covenant on Economic, Social and Cultural Rights.
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Regulation (EU) 2012/1257 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection.
- Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark.
- Strasbourg Patent Convention.
- Trade Act.

- Treaty on the European Union.
- Treaty on the Functioning of the European Union.
- WHO International Health Regulations.
- WIPO Copyright Treaty.
- WIPO Performances and Phonograms Treaties.

Case law

- *Association for Molecular Pathology v Myriad Genetics* [2013] 12 U.S. 398.
- BvR 739/17 [2017].
- Case AT.39612 – *Perindopril (Sevier)* [2016].
- *City of Daytona Beach v. Tona-Rama, Inc.* [1974] 294 So. 2d 73.
- *Diamond v Chakrabarty* [1980] 447 U.S. 303.
- *Martin v. Waddell* [1842] 41 U.S. 366.
- Opinion 1/09 [2011] ECR I-1137.
- *Prima Tek II LLC v A-Roo Co* [Fed. Cir. 2000] 222 F. 3d 1372.
- Tribunale di Roma, VII Sez. Civ. [8 February 2012].

Literature

- Aborisade R. A., *Accounts of unlawful use of force and misconduct of the Nigerian police in the enforcement of COVID-19 measures*, Journal of Police and Criminal Psychology 1–13 (2021).
- Alcorn K., *Abbott to Withhold New Drugs from Thailand in Retaliation for Kaletra Compulsory License,* Nam Aids Map (2007).
- Bailey S. and Mattei U., *Social movements as constituent power*, 20 Indiana Journal of Global Legal Studies 965 (2013).
- Bartolini G., *The failure of 'core capacities' under the WHO International Health Regulations*, 70(1) International & Comparative Law Quarterly 233 (2021).
- Bayh B. and Dole R., *Our Law Helps Patients Get New Drugs Sooner*, Washington Post (April 11, 2002).
- Benkler Y., *Between Spanish Huertas and the Open Road: A Tale of Two Commons?* (2011).
- Bill and Melinda Gates Foundation, *Bill and Melinda Gates Foundation announces $750 million gift to speed delivery of life-saving vaccines* (1999) http://www.gatesfoundation.org/Media-Center/Press-Releases/1999/11/Global-Alliance-for-Vaccines-and-Immunization (last visited Sep 1, 2021).
- Bishai D. M., Champion C., Steele M. E. & Thompson L., *Product development partnerships hit their stride: Lessons from developing a meningitis vaccine for Africa*, 30(6) Health Affairs 1058 (2011).
- Blackstone W., *Commentaries*

- Blume S., *Towards a history of "the vaccine innovation system," 1950-2000*, in C. Hannaway (ed.), *Biomedicine in the twentieth century: Practices, policies, and politics* (2008).
- Boschiero N., *COVID-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management*, Global Jurist 1-54 (2021).
- Bravin J., *Justices wary on gene patents*, The Wall Street Journal (2013) http://www.wsj.com/articles/SB10001424127887324485004578424782830965300 (last visited Sep. 8, 2021).
- Brennan H., Kapczynski A., Monahan C. H., and Rizvi Z., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale Journal of Law and Technology 275 (2016).
- BusinessTech, *South African firm to help develop COVId-19 vaccines for the rest of Africa* (2021) https://businesstech.co.za/news/government/469958/south-african-firm-to-help-develop-covid-19-vaccines-for-the-rest-of-africa/ (last visited Sep. 21, 2021).
- Callaway E., *The unequal scramble for coronavirus vaccines — by the numbers*, Nature (August 27, 2020) https://www-nature-com.ezproxy.lib.gla.ac.uk/articles/d41586-020-02450-x (last visited Sep 18, 2021).
- CAMBIA, The CAMBIA BIOS Initiative https://cambia.org/bios-landing/the-cambia-bios-initiative/ (last visited Sep 27, 2021).
- Cohen J. E., *Copyright, Commodification, and Culture: Locating the Public Domain*, in Guibault L. and Bernt Hugenholtz P. (eds.), *The Future of the Public Domain –Identifying the Commons in Information Law* (The Hague: Kluwer Law International, 2006).
- Cohen W. M., *Protecting their intellectual assets: appropriability conditions and why US manufacturing firms patent (or not)*, NBER Working Paper, Cambridge, MA 7552 (2000).
- Contreras J. L. et al., *Pledging intellectual property for COVID-19*, Nature Biotechnology (2020).
- COVID-19 R&D Tracker Update: 6 Aug. 2020, Policy Cures Research, https://bit.ly/38W5JQD (last visited Sep. 20, 2021).
- Creative Commons https://creativecommons.org (last visited Sep 27, 2021).
- Danzon P. M. & Sousa Pereira N., *Vaccine supply: Effects of regulation and competition*, 18(2) International Journal of the Economics of Business 239 (2011).
- Dellepiane N. & Wood D., *Twenty-five years of the WHO vaccines pre qualification programme (1987-2012): Lesson learned and future perspectives*, 33 Vaccine 52 (2015).
- Diamond M., *The Federalist*, in Strauss L. & Cropsey J., History of Political Philosophy 573 (1963).
- Dinwoodie G. B. & Dreyfuss R. C., *Designing a Global Intellectual Properly System Responsive to Change: The WTO, WIPO and Beyond*, 46 Hous. L. Rev. 1187 (2009).

- Doha Declaration on the TRIPS Agreement and Public Health WT/MIN(01)/DEC/1 (2002).
- Dugard J., Handmaker J. & Porter B., *Mobilising human rights to address coronavirus vaccine apartheid*, Opinio Juris (2021) http://opiniojuris.org/2021/02/18/mobilising-human-rights-to-address-coronavirus-vaccine-apartheid/ (last visited Sep. 22, 2021).
- Dusollier S., *Scoping Study on Copyright and Related Rights and the Public Domain*, WIPO (2010).
- Dusollier S., *Sharing Access to Intellectual Property*, 82(3) Chicago- Kent Law Review 1391 (2007).
- Dusollier S., *The commons as a reverse intellectual property – from exclusivity to inclusivity*, in Griffiths J., *Concepts of Property in Intellectual Property Law* (H. Howe ed. Cambridge University Press 2013).
- Eisenberg R. S., *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007).
- Elkin-Koren N., *What Contracts Cannot Do: The Limits of Private Ordering in Facilitating a Creative Commons*, 74 Fordham Law Review 375 (2005).
- EUROACTIV, *Rich countries block push by developing nations to waive COVID vaccine patent rights* (2021) https://www.euractiv.com/section/economy-jobs/news/rich-countries-block-push-by-developing-nations-to-waive-covid-vaccine-patents-rights/ (last visited Sep. 21, 2021).
- Euronews, *Coronavirus: Half of humanity now on lockdown as 90 countries call for confinement* (2020) https://www.euronews.com/2020/04/02/coronavirus-in-europe-spain-s-death-toll-hits-10-000-after-record-950-new-deaths-in-24-hou (last visited Sep. 21, 2021).
- European Commission, *Authorization procedures- the centralized procedure* https://ec.europa.eu/health/authorisation-procedures-centralised_en (last visited Nov 4, 2021).
- European Commission, *Pharmaceutical sector inquiry: final report*, Pharm Sect Inquiry (2009).
- European Patent Office, *Annual Report of Granted Patents 2018* https://www.epo.org/about-us/annual-reports-statistics/annual-report/2018/statistics/granted-patents.html (last visited Oct 18, 2021).
- European Patent Office, *Guidelines of Examination* https://www.epo.org/law-practice/legal-texts/html/guidelines/e/index.htm
- European Public Service Union, *Trade rules must not impede access to COVID-19 vaccines and medical supplies* (2021) https://www.epsu.org/article/trade-rules-must-not-impede-access-covid-19-vaccines-and-medical-supplies (last visited Sep 22, 2021).
- Fachler A., *The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift towards Regulatory Exclusivities*, 24(4) Fordham Intellectual Property, Media & Entertainment Law Journal 1059 (2014).
- Federal Trade Commission, *Report to promote innovation: the proper balance of competition and patent law and policy* (2003).

- Finniss G, *Will National Industrial Property Rights Disappear?*, Industrial Property 148 (1961).
- Free The Vaccine campaign https://freethevaccine.org (last visited Sep 29, 2021).
- Freeman P. and Robbins A., *The Elusive Promise of Vaccines*, The American Prospect 80 (1991).
- Friedman D. D., Landes W. M., and Posner R. A., *Some Economics of Trade Secret Law*, 5(1) Journal of Economic Perspectives 61 (1991).
- Galambos L., with Sewell J. E., *Networks of Innovation: Vaccine Development at Merck, Sharp & Dohme, and Mulford, 1895-1995* (Cambridge University Press 1995).
- General Secretariat of the Council of the European Communities, *Records of the Luxembourg Conference on the Community Patent 1975* (Office for Official Publications of the European Communities 1982) (CPC travaux).
- Gervais D., *The TRIPS Agreement: Drafting History and* Analysis (1st ed. 1998).
- Gopakumar K. M. & Rao C., *TWN info service on UN sustainable development* (2021).
- Grabowski H. G. & Kyle M., *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491 (2007).
- Green A., *At WTO, a battle for access to COVID-19 vaccines* (2020) https://www.devex.com/news/at-wto-a-battle-for-access-to-covid-19-vaccines-98787 (last visited Sep. 21, 2021).
- Gurgula O., *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features*, 48(4) IIC - International Review of Intellectual Property and Competition Law 385 (2017).
- Hall B. H. et al., *A study of patent thicket*, UK Intellectual Property Office (2013).
- Hardin G., *The Tragedy of the Commons*, 162 Science 1243 (1968).
- Harris II D., *TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J Intell Prop L 367 (2011).
- Heller M., *The tragedy of the anticommons: property in the transition from Marx to markets*, 111 Harv L Rev 621 (1998).
- Herper M., *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, FORBES (Aug 11, 2013) http://www.forbes.com/sites/matthewherper/2013/08/11 /how-the-staggering-cost-of-inventing-new-drugs-is-shapingthe-future-of-medicine (last visited Sep 2, 2021).
- Hestermeyer H. P., *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines,* AM. Soc'Y INT'L L. (2007).
- Hinman A. R., Orenstein W. A., Santoli J. M. et al., *Vaccine Shortages: History, Impact, and Prospects for the Future*, 27(1) Annual Review of Public Health 235 (2006).
- Hirschman A., *The Passions and the Interests* (1977).

- Holderness C. G., *A Legal Foundation for Exchange*, 14 J. Legal Stud. 321 (1985)
- IAM, *The UK will not be part of the UPC, government confirms to IAM* (2020) https://www.iam-media.com/law-policy/uk-no-upc (last visited Oct 16, 2021).
- Ito B., *Impacts of the vaccine intellectual property rights waiver on global supply*, VOXEU (2021) https://voxeu.org/article/impacts-vaccine-intellectual-property-rights-waiver-global-supply (last visited Sep. 21, 2021)
- Jacob R., *Patent thickets: a paper for the European Patent Office Economic and Scientific Advisory Board Meeting*, 8(3) J Intellect Prop Law Pract 206 (2013).
- Jiskoot W., Kersten G. F. A., Mastrobattista E., Slutter B., *Vaccines*, in: Crommelin D. J. A., Sindelar R. D., Meibohm B. (Eds), *Pharmaceutical Biotechnology*, Springer Nature (2016).
- Kapczynski A. et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005).
- Kapczynski A., *Realizing Public Rights Through Government Patent Use*, 49 Journal of Law, Medicine & Ethics 34 (2021).
- Kiszewski A. E., Cleary E. G., Jackson M. J., Ledley F. D., *NIH funding for vaccine readiness before the COVID-19 pandemic*, 39(17) Vaccine 2458 (2021).
- Krellenstein J., Morten C. J., *The U.S. Government's Apparent Co-Ownership of Patents Protecting Remdesivir* (2020) https://www.prep4all.org/news/remdesivir (last visited Sep. 20, 2021).
- Kulkarni K., *Serum Institute of India buys Dutch vaccine maker for $40.3 mln*, Reuters (2012) http://in.reuters.com/article/serum-institute-bilthoven-biologicals-idINDEE8630A220120704 (last visited Aug 31, 2021).
- Landes W. & Posner R. A., *The economic structure of intellectual property law* (2003).
- Legge D. G. & Kim S., *Equitable Access to COVID-19 Vaccines: Cooperation around Research and Production Capacity Is Critical*, 4(1) Journal for Peace and Nuclear Disarmament 73-134 (2021).
- Levine D. S., *COVID-19 TRADE SECRETS AND INFORMATION ACCESS: AN OVERVIEW*, InfoJustice.org (July 10, 2020) http://infojustice.org/archives/42493 (last visited Sep 18, 2021).
- Levine D. S., *Trade Secrets and the Battle Against Covid*, 15(11) Journal of Intellectual Property Law & Practice 849 (2020).
- Lewin A., *Medical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 HARV. J.L. & TECH. 403 (2012).
- Li D., Azoulay P., and Sampat B. N., *The Applied Value of Public Investments in Biomedical Research*, 356(6333) Science 78 (2017).
- Locke J., *The Second Treatise of Government* (1689)**.**
- Mahoney R. T. & Maynard J. E., *The introduction of new vaccines into developing countries*, 17(7) Vaccine 646 (1999).

- Mahoney R. T., Pablos-Mendez A., & Ramachandran S., *The introduction of new vaccines into developing countries: III. The role of intellectual property*, 22(5) Vaccine 786 (2004).
- Mail & Guardian, *Towards a people's vaccine campaign: A call to action* (2021) https://mg.co.za/special-reports/2021-01-15-towards-a-peoples-vaccine-campaign-a-call-to-action/ (last visited Sep 22, 2021).
- Marella M. R., *The Commons as a Legal Concept*, 28(1) Law and Critique 61 (2017).
- Matthews D. and Zikovska P., *The Rise and Fall of the Anti-Counterfeiting Trade Agreement (ACTA): Lessons for the European Union*, 44 IIC 626 (2013).
- McManis C. R., *The Proposed Anti-Counteifeiting Trade Agreement (ACIA): Two Tales of a Treaty*, 46 Hous. L. Rev. 1235 (2009).
- Meijer M., *COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-how and Technology*, European Journal of Public Health (2021).
- Mertes M. M. M. & Stötter G., *Managing the patent thicket and maximizing patent lifetime in vaccine technology*, 6(10) Human Vaccines 860 (2010).
- Milstien J., Costa A., Jadhav S., & Dhere R., *Reaching international GMP standards for vaccine production: Challenges for developing countries*, 8 Expert Review of Vaccines 559 (2009).
- Moderna, *Moderna's Patent Estate: Messenger RNA Technologies (mRNA) & Delivery Technologies* (2021) https://www.modernatx.com/mrna-technology/modernas-intellectual-property (last visited Sep. 8, 2021).
- Morin J. F., *Multilateralising TRIPS-plus Agreements: Is the US Strategy a Failure*?, 12 J. WORLD INTELL. PROP. 175 (2009).
- Moses 3rd H., Dorsey E. R., Matheson D. H. M., Thier S. O., *Financial anatomy of biomedical research,* 294 JAMA 1333–1342 (2005).
- Mossoff A., *The rise and fall of the first American patent thicket: the sewing machine war of the 1850s*, 53 Ariz Law Rev. 165 (2011).
- Mowery D. C. and Mitchell V., *Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives*, 20(4) Journal of Health Politics, Policy and Law 973 (1995) 976.
- Nowak R., *U.S. National Program is Going Nowhere Fast*, 265(5177) Science 1375 (1994) https://link.gale.com/apps/doc/A15828312/AONE?u=glasuni&sid=bookmark-AONE&xid=8e4614ff (last visited Aug 30, 2021).
- Office of Technology Assessment (OTA), *Review of Federal Vaccine and Immunization Policies* (U.S. Government Printing Office, 1979).
- Office of the United States Trade Representative, *Bilateral Trade Agreements* (2011) https://ustr.gov/issue-areas/labor/bilateral-and-regional-trade-agreements (last visited Oct 9, 2021).
- Office of the United States Trade Representative, Special 301 Report, Annex 1 (2010) http://www.zeropaid.com/wp-content/uploads/2010/05/1906.pdf (last visited Oct 7, 2021).
- Offit P. A., *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis* (New Haven, Yale University Press, 2005).

- Olliaro P., *What does 95% COVID-19 vaccine efficacy really mean?*, The Lancet (2021).
- Open Source Initiative, *Open Source Definition* (2007) https://opensource.org/osd (last visited Sep 27, 2021).
- P. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes*, TECHNICAL REP. SER. (1981).
- Pailliez C. and De Clercq G., *EU says it will make vaccine companies respect supply contracts*, Reuters (2021) https://www.reuters.com/article/us-health-coronavirus-eu-vaccines-idUSKBN29T090 (last visited Oct 12, 2021).
- Palmer B., *Jonas Salk: Good at Virology, Bad at economics* (April 13, 2014) http://www.slate.com/articles/technology/history_of_innovation/2014/04/the_real_reasons_jonas_salk_didn_t_patent_the_polio_vaccine.html (last visited Sep. 8, 2021).
- Pardi N., Hogan M. J., and Weissman D., *Recent Advances in mRNA Vaccine Technology*, 65 Current Opinion in Immunology 14 (2020).
- Patel A. B., Pade J., Cundiff V., et al., *The Global Harmonisation of Trade Secret Law: The Convergence of Protection for Trade Secret Information in US and EU*, 38(12) European Intellectual Property Review 738 (2016).
- Paul-Ehrlich-Institut, *Safety and efficacy of the COVID-19 Vaccine AstraZeneca* (2021) https://www.pei.de/EN/newsroom/hp-news/2021/210218-safety-efficacy-covid-19-vaccine-astra-zenaca-information-pei.html (last visited Sep 21, 2021).
- Pauwelyn J., *The Dog that Barked but Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1(2) J. INT'L Disp. SETTLEMENT 389 (2010).
- Pila J., *The European Patent: An Old and Vexing Problem*, 62(4) The International and Comparative Law Quarterly 917 (Cambridge University Press, 2013).
- Pilkington E. H., Suys E. J. A., Trevaskis N. L., et al., *From Influenza to COVID-19: Lipid Nanoparticle mRNA Vaccines at the Frontiers of Infectious Diseases*, 131 Acta Biomaterialia 16-40 (2021).
- Plomer A., *The EPO as patent law-maker in Europe*, 25(1) European Law Journal 57–74 (2019).
- Plomer A., *The Unified Patent Court and the Transformation of the European Patent System*, 51 IIC 791–796 (2020).
- Press Release, Apotex, *Life Saving AIDS Drug for Africa Gets Final Clearance* (2007).
- Riley T., Sully E., Ahmed Z. & Biddlecom A., *Estimates of the potential impact of the COVID-19 pandemic on sexual and reproductive health in low-and middle-income countries*, 46 International Perspectives on Sexual and Reproductive Health 73 (2020).
- Roberts N. A., *The Efficiency of the Common Law and Other Fairy Tales,* 28 UCLA L. Rev. 169.
- Roin B. N., *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009).

- Rose C., *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53(3) The University of Chicago Law Review 711 (1986).
- Roth V. J., *Will FDA Data Exclusivity Make Biologic Patents Passe*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 249 (2013).
- Rowland C., *Taxpayers Paid to Develop Remdesivir But Will Have No Say When Gilead Sets the Price*, Washington Post (May 26, 2020) https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/ (last visited Sep. 20, 2021).
- Sanofi Biotechnics, S. A. S, *Industry Watch. Asia-Pacific*, 13 Biotech News 29 (2009).
- Sarpatwari A., Kaltenboeck A., and Kesselheim A. S., *Missed Opportunities on Emergency Remdesivir Use*, 324(4) JAMA 331 (2020) https://doi.org/10.1001/jama.2020.11932 (last visited Sep. 20, 2021).
- Šehović A. B. & Govender K.*, Addressing COVID-19 vulnerabilities: How do we achieve global health security in an inequitable world*, 16(8-9) Global Public Health 1198 (2021).
- Šehović A. B., *Towards a new definition of health security: A three-part rationale for the twenty-first century*, 15(1) Global Public Health 1 (2019).
- Sencer D. J. and Millar J. D., *Reflections on the 1976 Swine Flu Vaccination Program*, 12(1) Emerging Infectious Diseases 29 (2006).
- Shapiro C., *Navigating the patent thicket: cross licenses, patent pools, and standard-setting*, in: Jaffe A. B. et al (eds) *Innovation policy and the economy*, 1 National Bureau of Economic Research 120 (2001).
- Shin S., *The Global Vaccine Enterprise: A Developing World Perspective*, 4(5) Nature Medicine 503, Vaccine Supplement (1998).
- Siew-Kuan Ng E., *Intellectual Property in Vaccine Innovation: Impact of Recent Patent Developments*, 1404 Methods in Molecular Biology 835 (2016).
- Smith A., *The Wealth of Nations* (Modern Library ed. 1937).
- Spencer R., *A European Patent: An Old and Vexing Problem*, 45 ABAJ (1959).
- Stevenson M. A., *Geneva-Seattle Collaboration in Support of Developing Country Vaccine Manufacturing*, 13(4) Global Public Health 426 (2018).
- The Immunization Advisory Centre, *A brief history of vaccination* (2020) https://www.immune.org.nz/vaccines/vaccine-development/brief-history-vaccination (last visited Sep 27, 2021).
- Thomas J. R., *March-In Rights Under the Bayh-Dole Act*, Congressional Research Service (Aug. 22, 2016) https://fas.org/sgp/crs/misc/R44597.pdf (last visited Sep. 20, 2021).
- *TRIPs Mechanism Set to Fail as Apotex Ships ARV*, Pharma Letter (2008).
- Trouiller P., Torreele E., Olliaro P., White N., Foster S., Wirth D. & Pécoul B., *Drugs for neglected diseases: A failure of the market and a public health failure?* 6(11) Tropical Medicine and International Health 945 (2001).
- Walsh K., Wallace A., Pavis M. et al, *Intellectual Property Rights and Access in Crisis*, 52 IIC 379-416 (2021).

- Watt R., *Copyright and Economic Theory – Friends or Foes?* (Cheltenham: Edward Elgar, 2000).
- World Bank, *World Bank's response to COVID-19 (Coronavirus) in Africa* (2020).
- World Health Organization, *Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19* (2020) https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19 (last visited Sep. 21, 2021).
- World Health Organization, *WHO: Access to HIV medicines severely impacted by COVID-19 as AIDS response stalls* (2020) https://www.who.int/news/item/06-07-2020-who-access-to-hiv-medicines-severely-impacted-by-covid-19-as-aids-response-stalls (last visited Sep. 21, 2021).
- Wright B. D., *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983).
- *WTO Must Support Access to Medicines for Poor Countries,* Oxfam East Asia Blog (2009).
- Wu Chuan-feng, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law,* 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141 (2010).
- Zaiets K., Borresen J. & Weintraub K., *Comparing the COVID-19 vaccines. Three vaccines are authorized for use in the United States and another two are coming soon. Here is a closer look at what we know so far*, USA Today (2021) https://www.usatoday.com/in-depth/graphics/2021/03/27/comparing-covid-19-vaccines/6806600002/ (last visited Sep. 21, 2021).

Summary in Italian - Riassunto in lingua italiana

Quando nel 1955 il giornalista Edward R. Murrow chiese a Jonas Salk, l'inventore del vaccino contro la poliomielite, chi fosse il proprietario del brevetto per quel prodotto farmaceutico, lo scienziato ha risposto "Le persone, direi. Non c'è brevetto. Si può brevettare il sole?". Questa frase riassume l'argomentazione principale di questo lavoro: il vaccino contro il Covid-19 dovrebbe essere considerato un Bene Comune, qualcosa che è gestito dalla collettività, e non una proprietà privata – connotata dal carattere della esclusività – delle case farmaceutiche.

Le ragioni di una così forte argomentazione sono ampiamente investigate in questo lavoro, attraverso un approccio metodologico che analizza legislazione, giurisprudenza e letteratura, principalmente in relazione agli Stati Uniti e all'Unione Europea, data l'influenza di queste aree geografiche e l'impatto delle loro aziende farmaceutiche a livello mondiale, ma anche concentrandosi sulla comunità internazionale nel suo complesso. Infatti, la pandemia che stiamo vivendo in questo momento ha implicazioni globali, e i "miracolosi" vaccini che sono stati sviluppati in così poco tempo devono essere somministrati in tutti gli angoli del mondo affinché si possa avere un'occasione di sconfiggere il virus Covid-19 o, per lo meno, far cessare questa situazione emergenziale.

Nonostante ci siano varie forme di proprietà intellettuale, questo lavoro si concentra principalmente su brevetti e, in misura minore, sui segreti industriali, considerando che questi sono i principali strumenti attraverso cui i prodotti farmaceutici, come i vaccini, sono protetti. In particolare, come accennato prima, viene argomentato che, almeno in relazione al vaccino contro il Covid-19, dev'essere ricercato un rinnovato equilibrio tra Proprietà Intellettuale e Beni Comuni.

Come riconosce questo stesso lavoro, è vero che al momento, da un punto di vista giuridico, i vaccini possono essere brevettati o protetti dal segreto industriale, ma ciò non vuol dire che la legge non possa essere modificata. D'altronde, bisogna sempre ricordare che il diritto deve tenere il passo della società in cui trova applicazione. Dunque, visto che i bisogni di una società cambiano – come è avvenuto in questa pandemia – il diritto deve fare altrettanto evolvendosi, e questo lavoro può offrire una direzione per lo meno teoretica da perseguire.

Il primo capitolo fissa le basi indispensabili che vengono approfondite nei capitoli successivi. In particolare, il primo paragrafo illustra una storia dei vaccini, tenendo in considerazione il XX Secolo, e concentrandosi non sugli aspetti strettamente clinici, ma soprattutto sulle istituzioni che erano coinvolte in questi eventi. Viene specificamente evidenziato come, nonostante all'inizio della produzione vaccinale nel XX secolo una parte consistente di Ricerca e Sviluppo fosse controllata dal settore pubblico, come ad esempio il governo statunitense, alla fine del secolo scorso è avvenuto uno cambiamento in favore delle private multinazionali e la loro egemonia.

Il secondo paragrafo spiega le ragioni per cui il settore privato iniziò ad essere predominante, e come invece sarebbe desiderabile una collaborazione fra settore pubblico e privato per sviluppare vaccini, anche se, attraverso alcuni esempi, viene dimostrato come questa collaborazione sia molto difficile da raggiungere.

Il terzo e ultimo paragrafo di questo capitolo introduce i prodotti farmaceutici nel contesto, innanzitutto, dei loro processi di approvazione, implementati, rispettivamente, dalla US Food and Drug Administration e dall'Agenzia Europea del Farmaco. Successivamente, viene illustrata la più rilevante forma di proprietà per i medicinali, ossia i brevetti, e viene evidenziato come per le stesse aziende farmaceutiche questa proprietà intellettuale non sembri essere particolarmente incentivante, e dunque iniziano ad essere pensate altre forme di protezione ed incentivi, come ad esempio il sistema a premi (rewards system).

Il secondo capitolo affronta, da un lato, la relazione tra vaccini – con particolare attenzione alla innovativa tecnologia a mRNA – e proprietà intellettuale con riferimento alla attuale pandemia, e dall'altro lato, la relazione tra la c.d. "Big Pharma" – l'industria farmaceutica – e la proprietà intellettuale.

Più specificamente, il primo paragrafo descrive come i vaccini vengono brevettati. Nonostante questo lavoro non intenda discutere temi di biologia o scienze naturali, è introdotta la tecnologia a mRNA, che è alla base di alcuni dei più rilevanti vaccini contro il Covid-19 sviluppati nell'ultimo anno, come principale esempio e caso da analizzare per comprendere la brevettabilità dei vaccini negli Stati Uniti – in particolare dopo il caso *Myriad Genetics* – e in Europa con la Convenzione sulla Concessione dei Brevetti Europei (European Patent Convention).

Il secondo e il terzo paragrafo esplorano specifiche problematiche in relazione ai brevetti nel contesto farmaceutico, che sono i c.d. "cespugli di brevetti" (patent thickets) e la c.d. "accumulazione strategica dei brevetti" (strategic accumulation of patents). Vengono considerate soluzioni per entrambi i problemi, ricorrendo specificamente ad un'analogia con la teoria degli Anti-Beni Comuni (Anticommons) per quanto riguarda i cespugli di brevetti, e al diritto della concorrenza con riferimento all'accumulazione strategica.

Il quarto e ultimo paragrafo considera lo strumento del segreto industriale, la cui importanza è cresciuta notevolmente negli ultimi anni, portando all'implementazione di specifiche leggi nell'UE - Direttiva (UE) 2016/943 del Parlamento europeo e del Consiglio, dell'8 giugno 2016, sulla protezione del know-how riservato e delle informazioni commerciali riservate (segreti commerciali) contro l'acquisizione, l'utilizzo e la divulgazione illeciti – e negli USA – Defend Trade Secrets Act 2016. Viene evidenziato come, vista la sua importanza, il segreto industriale possa essere uno strumento rilevante nell'attuale pandemia nel momento in cui le informazioni da esso protette vengono rese note per fini pubblici, nonostante la sua efficacia dipenda principalmente dall'iniziativa privata del proprietario di detto segreto.

Il terzo capitolo esplora prospettive ulteriori sul rapporto tra vaccini e proprietà intellettuale, nel contesto della pandemia, soprattutto con riferimento alla proposta del Brevetto Unico Europeo, che potrebbe finalmente permettere all'UE di essere compatta e unita nella comunità internazionale.

In particolare, il primo paragrafo critica la rilevanza dell'accordo TRIPs (Trade-Related Aspects of Intellectual Property Rights), specificamente in relazione allo strumento della licenza obbligatoria, previsto negli artt. 31-31bis. Viene sottolineato come quest'ultimo non sia uno strumento appropriato per affrontare le sfide del settore dei brevetti nella pandemia, come soprattutto la brevettabilità del vaccino, ma anche in generale trattamenti e metodi diagnostici contro il Covid-19.

Il secondo paragrafo si concentra sui passati tentativi – in particolare la Strasbourg Patent Convention e la Community Patent Convention - da parte dell'UE di implementare un Sistema Europeo dei Brevetti, principalmente contrastato da istanze di sovranità nazionale. Viene rilevato che la situazione adesso potrebbe cambiare, grazie allo Unitary Patent Package, e in particolare il Regolamento (UE) n. 1257/2012 del Parlamento europeo e del Consiglio, del 17 dicembre 2012, relativo all'attuazione di una cooperazione rafforzata nel settore dell'istituzione di una tutela brevettuale unitaria. Questo European Patent with Unitary Effect potrebbe assicurare un'armonizzazione anche in questo settore del diritto, attraverso un supporto e un miglioramento della EPC e il suo European Patent Office (EPO).

Il terzo e ultimo paragrafo mostra che questo obiettivo è strettamente collegato all'Accordo sulla Unified Patent Court, l'istituzione giudiziaria che dovrebbe garantire l'esecuzione (enforcement) del Brevetto Unico. Però, in questo contesto, la riluttanza degli Stati Membri a fidarsi di una corte sovrannazionale rappresenta un grosso ostacolo per l'adozione del Sistema Europeo dei Brevetti.

Il quarto e ultimo capitolo giunge ad argomentare che il vaccino contro il Covid-19 dovrebbe essere considerato un Bene Comune (Commons).

Specificamente, il primo paragrafo illustra la prima ragione per sostenere tale argomento. Nonostante molti governi in tutto il mondo – tra cui UE, USA, Canada, Regno Unito, Giappone, Germania – abbiano investito notevoli fondi pubblici in ricerca e sviluppo di trattamenti, metodi diagnostici, e vaccini contro il Covid-19, i prodotti farmaceutici derivanti da quell'importante R&D appartengono alle aziende farmaceutiche. Considerata l'assenza di strumenti a livello internazionale o europeo in questo ambito, viene menzionato qualche esempio di legislazione statunitense che cerca di risolvere questa contraddizione, senza però ottenere grandi risultati.

Il secondo paragrafo illustra la seconda ragione per cui il vaccino dovrebbe essere considerato un Bene Comune, cioè il perseguimento di una Sicurezza Sanitaria Globale (Global Health Security) che sia orientata verso l'umanità e l'uguaglianza, e non focalizzata soltanto sul benessere e la sicurezza di ciascun cittadino di un certo Paese. Viene affermato in particolare che vi sono parecchi strumenti attraverso cui questa prospettiva di Global Health Security può essere implementata, uno fra tutti è la deroga all'applicazione dei diritti della proprietà intellettuale, proposta da alcuni Paesi in via di sviluppo nell'ambito dell'Organizzazione Mondiale del Commercio (WTO), che porterebbe proprio alla teorizzazione dei vaccini come Beni Comuni.

Il terzo paragrafo introduce proprio la Teoria dei Beni Comuni (Theory of Commons), attraverso una giustapposizione con la Teoria dei Beni Privati (o Anti-Beni Comuni) che rappresenta la proprietà privata. Nonostante alcuni autori, tra

cui Hardin, considerano i Beni Comuni come una “tragedia” – data l’inefficienza economica che si può creare per il loro uso incontrollato – l’autrice Carol Rose afferma che in realtà la Teoria dei Beni Comuni è una “commedia” nel senso che questi beni, nonostante siano suscettibili di essere gestiti da soggetti privati, sono più efficienti e utili nel momento in cui la loro titolarità appartiene alla collettività.

Il quarto paragrafo illustra la medesima teoria nell’ambito della proprietà intellettuale, basandosi sul lavoro dell’autrice Dusollier, la quale afferma che i Beni Comuni in questo specifico campo del diritto possono assumere tre diverse forme: il pubblico dominio, le eccezioni/limitazioni al diritto d’autore e ai brevetti, e gli strumenti di open innovation. Questi tre distinti tipi di Commons vengono illustrati, evidenziando i rispettivi vantaggi e svantaggi.

Il quinto e ultimo paragrafo applica questa Teoria dei Beni Comuni nel contesto del vaccino contro il Covid-19, mostrando (e riassumendo) tutti i vantaggi che deriverebbe da questa scelta. Anziché però individuare un particolare tipo di Commons tra quelli illustrati nel paragrafo precedente, dato che tutti e tre sembrano presentare dei grossi problemi di esecutività (enforceability), viene introdotto il concetto di “inclusive right”, mutuato anch’esso dal lavoro di Dusollier, che sarebbe l’unico modo per efficacemente implementare, gestire e rendere esecutivo il Bene Comune del vaccino. Nonostante si tratti di uno spunto prettamente teoretico, questo inclusive right potrebbe costituire un ottimo punto di partenza per discutere di eventuali legislazioni che si occuperebbero di rendere esecutivo questo Commons, come ad esempio nell’ambito della deroga all’applicazione dei diritti della proprietà intellettuale, che è stata proposta, come già accennato, da Paesi in via di sviluppo membri dell’Organizzazione Mondiale del Commercio, e che magari potrebbe essere concretizzata proprio attraverso l’applicazione dell’inclusive right.

In conclusione, il diritto dovrebbe mutare in base ai nuovi bisogni di una società, e, come qualunque altra scienza, dovrebbe offrire il suo contributo per risolvere problemi, specialmente quelli che hanno una portata globale. Ciò può essere concretamente realizzato attraverso il coinvolgimento di ricercatori, legislatori, magistrati, e tutti gli altri “attori” che possono offrire soluzioni a problemi complessi, non solo applicando gli attuali concetti giuridici, ma anche cambiandoli e riconsiderandoli alla luce della situazione specifica che viene affrontata. Riuscirà il diritto a realizzare questo obiettivo? Solo il tempo e la ricerca saranno in grado di stabilirlo.