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Patents for vaccines: Biden's (many) reasons

The pandemic has forced us to reconsider the relationship between public and private research. The question it poses is whether, over the next 20 years, governments' only negotiating position on technologies that are the basis of vaccines, which were created with the contribution of the same governments, will be to sign one purchase contract after another.

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President Biden's surprise move on his possible support for the suspension of patents for Covid-19 vaccines has had considerable resonance¹. Many, starting with the pharmaceutical firms themselves, hastened to say that by doing so governments would destroy any stimuli for innovation, there would be no increase in available doses, it would create confusion on the stock market, governments should instead stop restricting exports, that this is in fact a geopolitical move by Biden, and so on. In a book soon to be published in Italy by Laterza Editori («The privatization of knowledge. Three proposals against the new oligopolies») I argue that the pandemic forces us to reconsider the relationship between public and private research.

It would be useful to reflect on five facts:

1) Firstly, Biden knows that some patents related to mRNA vaccines are crucially linked to two fundamental findings of publicly-backed research: the concept of mRNA modification (undertaken by Weissman and Karikò at the University of Pennsylvania)² and, above all, the technology for treating viral spike proteins by Graham et al.³, at the National Institutes of Health, in particular at the NIAID, the institute headed by Fauci (see Prefusion Coronavirus Spike Proteins and Their Use, U.S. Pat: 10,960,070 issued 2021-03-30)⁴. In an official statement, the NIH announced that «NIAID scientists have created stabilized spike proteins⁵ for the development of vaccines against coronaviruses, including SARS COV-2 ... », it claimed to have filed patents in this regard «to protect the rights of government concerning these inventions» and to have adopted a non-exclusive licensing approach in favour of several private companies, including Moderna⁶ (NIH Statement to Axios)⁷. As it turns out, Biontech and other firms⁸ have also obtained this licence (conditions are unknown). As is often the case, knowledge, innovation and intellectual property are closely interlinked.

2) According to the Bayh-Dole Act (the law that governs the subject of patents obtained with the assistance of the US federal government)⁹, if the price of the drug or other conditions are not "reasonable", the government can recover its rights and enter the market directly ("march-in" clause)¹⁰

¹ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>

² <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>

³ <https://patents.justia.com/inventor/jason-mclellan>

⁴ <https://www.ott.nih.gov/technology/e-234-2016>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4860016/>

⁶ <https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html> , <https://www.citizen.org/article/the-nih-vaccine/>

⁷ <https://www.documentcloud.org/documents/6956323-NIH-Statement-to-Axios>

⁸ «According to correspondence with NIAID in December of 2020, the following companies have licenses to this invention: Medigen Vaccine Biologics Corp.; Noachis Terra, Inc.; OncoSec Medical Incorporated; BioNTech AG; N4 Pharm UK Limited; Dynavax Technologies; RNAceuticals, Inc.; Sanofi Pasteur; GlaxoSmithKline Biologicals SA; Adimmune Corporation; Vaxess Technologies; Meso Scale Diagnostics, LLC; The Binding Site Group Ltd.; ReiThera Srl; GeoVax, Inc.; ExcellGene SA; and Thermo Fisher Scientific Inc.» <https://www.keionline.org/35746>

⁹ https://en.wikipedia.org/wiki/Bayh%E2%80%93Dole_Act#References

¹⁰ <https://fas.org/sgp/crs/misc/R44640.pdf>

with its own initiatives. This option, not mentioned by Biden, but common knowledge amongst insiders¹¹, would be far more radical than the temporary suspension of patents. Discussions about this have also been disclosed by the New York Times (March 21, 2021 and May 7, 2021)¹² and confirmed by other authoritative sources.

3) Thirdly, in the case of Moderna the downstream development of the research was funded by another federal agency (BARDA, Biomedical Advanced Research and Development Authority)¹³ to the tune of over a billion dollars, which amply covered the costs. It is no coincidence that Moderna¹⁴ is often referred to as a vaccine co-developed with the NIH¹⁵, that is, with the public sector. But other vaccines, too, would not have been possible without the unprecedented intervention in scale and speed of public research infrastructures and perhaps without the over ten billion dollars that they paid out.

4) Furthermore, the de-risking in favour of the private sector was also decisive, with public purchases for billions of dollars even before receiving authorisations (with large profit margins for Moderna and Pfizer, which were abundantly reflected in their share values)¹⁶.

5) Lastly, authorisation times on the part of the Food and Drug Administration (and other pharmaceutical agencies) were shorter than a year because of the emergency. Since the patents last for 20 years, this would leave the planet dependent on some private companies' legal monopoly on vaccines for perhaps 19 years, almost a whole generation. The technology legally protected by these patents (and by others based on more conventional approaches, but also supported almost entirely by public funds, as in the case of the Oxford AstraZeneca carrier virus)¹⁷ will, in all probability, also serve for future campaigns in the presence of variants, the emergence of which is in turn fostered by the extremely slow uptake of vaccines in developing countries, as reported by the World Health Organization. Hence, we have been talking about something fundamental for many years. Biden has every reason to raise the issue of intellectual property. As varied as the practical and legal solutions may be in the short term, Biden's administration, with Anthony Fauci the key player in the vaccine strategy as a consultant, and Eric Lander of MIT (one of the most renowned geneticists in the world) at the head of the Federal Government's Office of Science and Technology, has at its disposal massive public infrastructures in the biomedical field, such as the NIH and BARDA. These operate on a scale that we dare not even dream of in Europe (the NIH's annual budget is 40 times that of CERN, to have a yardstick). So Biden certainly doesn't need to be told by Pfizer's CEO or by the industry press releases that producing a vaccine is a complex matter from the point of view of raw materials, machinery and professionalism. The issue it raises is whether the only negotiating position of governments over the next 20 years on the technologies that underlie vaccines, which were created with contributions from the same governments, will be that of signing one purchase contract after another with an oligopoly, which would have enormous power as regards prices, delivery times and control of the value chain without, however, being able to guarantee the vaccination of the entire planet¹⁸. More generally, from my point of view, it raises the issue of the privatisation of knowledge, which begins upstream as a public good and is incorporated downstream into share values (the subject of my next book).

¹¹ <https://crsreports.congress.gov/product/pdf/LSB/LSB10422>

¹² <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>

¹³ <https://public3.pagefreeser.com/browse/HHS%20%E2%80%93%20About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>

¹⁴ <https://www.modernatx.com/patents> , <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/>

¹⁵ https://www.eurekalert.org/pub_releases/2021-04/bu-cvd042121.php

¹⁶ <https://theconversation.com/us-backed-vaccine-patent-waiver-pros-and-cons-explained-160480>

¹⁷ <https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1>

¹⁸ <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreele-on-waiving-covid-patents>

Biden has blown everyone away because the US government knows it has strategic levers and it plans to use them to sit at the table of the WTO (where patents could be suspended formally via a very complex procedure) and to negotiate from a position of strength in other forums. We can do without the textbook lesson on the role of patents in stimulating innovation, which is cited by many, if those patents are also based on other patents that result from public research, if private research was co-financed by taxpayers, if the business risk was shifted to governments, if clearances from public agencies were granted in record time in an emergency, and if we fail to beat mutant strains in a timely fashion and on a planetary scale. It is not “business as usual” and pharmaceutical firms would do better to hire external relations consultants who would suggest that they say: «Mr. President, let’s talk about this».

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References

Allen A., Kaiser Health News, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, Scientific American, November 18 2020. <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>

Ardizzone K., *License to NIH Spike Protein Technology Needed in COVID-19 Vaccines Demonstrates “Available to the Public on Reasonable Terms” Requirement*, Knowledge Ecology International, March 30 2021. <https://www.keionline.org/35746>

Bokhari F., *US-backed vaccine patent waiver: pros and cons explained*, The Conversation, May 6 2021. <https://theconversation.com/us-backed-vaccine-patent-waiver-pros-and-cons-explained-160480>

Cross S., Rho Y., Reddy H. *et al.*, 2021, *Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology*, doi: <https://doi.org/10.1101/2021.04.08.21255103>

Gebrekidan S., Apuzzo M., *Rich Countries Signed Away a Chance to Vaccinate the World*, The New York Times, Published: March 21, 2021, Updated: May 7, 2021. <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>

Kirchdoerfer R.N., Cottrell C.A., Wang N. *et al.*, 2016, *Pre-fusion structure of a human coronavirus spike protein*, Nature, 531(7592): 118–121. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4860016/>

Rizvi Z., *The NIH Vaccine*, Public Citizen, June 25 2020. <https://www.citizen.org/article/the-nih-vaccine/>

Shores D., *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?*, IPWatchdog, November 11 2020. <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/>

The Economist, *Mariana Mazzucato, Jayati Ghosh and Els Torreale on waiving covid patents*, April 20 2021. <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreale-on-waiving-covid-patents>