Intellectual Property and Innovation American Inn of Court

Tuesday, May 25, 2021

Joint Inn Meeting

Co-Hosted with the Alan D. Lourie Intellectual Property American Inn of Court

CLE Materials

Topic

IP- and Privacy-Related Implications of the COVID-19 Vaccine

Facilitated By

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Contents

Vaccine Intro

Available Vaccines

- ***Pfizer-BioNTech***
- ***Moderna***
- ***Johnson & Johnson/Janssen***
- ***AstraZeneca and Novavax***
  - As of February 27, 2021, these vaccines are the subject of in-progress or planned large-scale clinical trials.

BioNTech Patents

Number	Title	Filing Date	Issue Date
US10808242	METHOD FOR REDUCING IMMUNOGENICITY OF RNA	Aug. 24, 2016	Oct. 20, 2020
US10576146	PARTICLES COMPRISING A SHELL WITH RNA	Mar. 15, 2018	Mar. 3, 2020
US10485884	RNA FORMULATION FOR IMMUNOTHERAPY	Mar. 25, 2013	Nov. 26, 2019
US9950065	PARTICLES COMPRISING A SHELL WITH RNA	Sep. 26, 2013	Apr. 24, 2018
US2020/0155671	PARTICLES COMPRISING A SHELL WITH RNA	Jan. 22, 2020	Pending
US2020/0197508	METHODS AND COMPOSITIONS FOR STIMULATING IMMUNE RESPONSE	Mar. 21, 2018	Pending
US2019/0153428	METHOD FOR REDUCING IMMUNOGENICITY OF RNA	Feb. 26, 2018	Pending
US2018/0263907	LIPID PARTICLE FORMULATIONS FOR DELIVERY OF RNA AND WATER-SOLUBLE THERAPEUTICALLY EFFECTIVE COMPOUNDS TO A TARGET CELL	Mar. 30, 2016	Pending
US2017/0273907	STABLE FORMULATIONS OF LIPIDS AND LIPOSOMES	Sep. 17, 2015	Pending

Moderna Patents

Number	Title	Filing Date	Issue Date
US10703789	MODIFIED POLYNUCLEOTIDES FOR THE PRODUCTION OF SECRETED PROTEINS	Jun. 12, 2019	Jul. 7, 2020
US10702600	BETACORONAVIRUS MRNA VACCINE	Feb. 28, 2020	Jul. 7, 2020
US10577403	MODIFIED POLYNUCLEOTIDES FOR THE PRODUCT OF SECRETED PROTEINS	Jun. 12, 2019	Mar. 3, 2020
US10442756	COMPOUNDS AND COMPOSITIONS FOR INTRACELLULAR DELIVERY OF THERAPEUTIC AGENTS	Dec. 18, 2017	Oct. 15, 2019
US10266485	COMPOUNDS AND COMPOSITIONS FOR INTRACELLULAR DELIVERY OF THERAPEUTIC AGENTS	Jun. 11, 2018	Apr. 23, 2019
US10064959	MODIFIED NUCLEOSIDES, NUCLEOTIDES, AND NUCLEIC ACIDS, AND USES THEREOF	Apr. 21, 2017	Sep. 4, 2018
US9868692	COMPOUNDS AND COMPOSITIONS FOR INTRACELLULAR DELIVERY OF THERAPEUTIC AGENTS	Mar. 31, 2017	Jan. 16, 2018

Johnson & Johnson Patents

Number	Title	Filing Date	Issue Date
US9701718	ADENOVIRUS SEROTYPE 26 AND SEROTYPE 35 FILOVIRUS VACCINES	Dec. 14, 2011	Jul. 11, 2017
US2018/0080010	METHOD FOR THE PRODUCTION OF AD26 ADENOVIRAL VECTORS	Nov. 27, 2017	Mar. 22, 2018

Expedited Examination

- ***Patent Prosecution Highway***
  - Allows for expedited examination when an applicant has allowable claims from another participating patent office.
- ***Track One Prioritized Examination***
  - Allows for expedited examination with payment of a fee.
- ***Petition to Make Special***
  - Advances an application out of turn under certain conditions, including if the invention will materially enhance the quality of the environment, contribute to the development or conservation of energy resources, contribute to countering terrorism, or for other reasons of importance, if accompanied by a fee.

COVID-19 Prioritized Examination Pilot Program

- ***Requirements***
  - Application contains 1+ claim to a product or process related to COVID-19.
  - Claimed product or process is subject to an applicable FDA approval for COVID-19 use.
  - Applicant qualifies for small or micro entity status.
- ***Benefits***
  - Prioritized examination without paying associated prioritized examination and processing fees.

Vaccine IP ‘Waiver’ and TRIPS

The high-level debate: should IP rights give way to a public health emergency?

- ***Proponents:***
  - Global inequities in vaccine/therapeutics/testing/PPE distribution would be helped by temporary waivers of IP restrictions
  - Patents are designed to protect inventors from unfair competition; a pandemic is not an economic competition

- ***Opponents***
  - Current inequities not caused by IP and won't be helped by waivers
  - Diminishes incentive to innovate in future pandemics
  - Risk of IP theft outside narrow scope of pandemic (e.g. mRNA technology)
  - Constitutional concerns

TRIPS

- 1994 agreement among 164 member nations of WTO
- Establishes minimum standards of IP protection (e.g., copyrights, 20-year patents, trade secrets, etc)
- Violations give rise to trade penalties among nations (not private right of action)
- 2001 Doha Declaration introduced some flexibility for HIV/AIDS and future public health emergencies — principally endorsement of compulsory licenses
- Modifications require unanimous consensus

TRIPS – October 2020 Waiver Proposal

- *October 2020:* India and South Africa propose temporary waiver — option not to enforce any IP (patents, trade secrets, copyrights) involving any COVID-related technology (vaccines, therapeutics, diagnostics, PPE)

- Supported by ~100 WTO members

- Opposed by US, EU, Japan, and others

Biden Administration Statement on TRIPS

This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved.

US Trade Representative Katherine Tai
May 5, 2021

Impact of U.S. TRIPS Statement

- India/South Africa expected to present new proposal in coming weeks
- Ongoing debate in Europe — Germany still opposes
- WTO conference in November/December 2021

- IP beyond vaccines? Beyond patents?
  - Note — much of know-how remains trade secret

- If waiver enacted by WTO…
  - Interplay with other international trade agreements?
  - How will U.S. apply it?
  - Expiration?

- Supply chain and manufacturing challenges remain

Privacy Concerns

Debate: Confidentiality of Protected Health Information (PHI) v. Public Health

- ***Benefits of Collecting/Sharing Vaccination Data***
  - Monitor vaccination progress
  - Report adverse reactions
  - Compare vaccine efficacy in different populations
  - Keep track of who needs second dose
- ***Concerns***
  - Personal privacy
  - Trust in government's ability to safely maintain data
  - Misuse of data by government

Protected Health Information (PHI) Under HIPAA

- COVID-19 infection history and vaccination status are PHI under Health Insurance Portability and Accountability Act (HIPAA)
- HIPAA bars certain “covered entities” from disclosing PHI in some circumstances
  - Healthcare providers
  - Private insurance companies
  - Government healthcare programs (Medicare, Medicaid, Veterans Affairs healthcare, etc.)
  - “business associates” of covered entities (billing, practice management, etc.)

Some Disclosures Permitted Under HIPAA

- When disclosure is necessary to provide treatment
  - *E.g.*, nursing home can disclose COVID-19 infection to EMTs who are providing treatment
- When required by state law
  - *E.g.*, state law may require reporting of confirmed or suspected cases
- To notify public health authority authorized to receive PHI
  - *E.g.*, CDC, state or tribal public health departments
- To protect first responders
- Disclosures to law enforcement / correctional facilities with custody over an individual

COVID-19 Data Already Being Shared

- Some states have signed “Data Use and Sharing Agreement” with federal government to share vaccination data
  - Data that is shared includes identifying information (name, address, DOB)
  - Some states allow opting out of sharing information
- Information is stored in CDC’s COVID-19 Data Clearinghouse.
- Identifying info supposed to be removed before export
- Concern that data in clearinghouse can use based for other purposes, *e.g.* deportation
  - Electronic Frontier Foundation has filed suit in D.D.C. under FOIA on behalf of immigrants’ rights groups seeking information on how data is stored and used

What Disclosure Should Be Required?

- HIPAA does not prohibit ***asking*** someone about their COVID history or vaccine status.
- EEOC guidance says that employers can ask about vaccination status and require vaccinations
  - Subject to federal laws regarding accommodations for, *e.g.*, disability or religious belief
- State laws
  - Some states have "vaccine passport"-like systems, *e.g.*, New York's Excelsior Pass
  - Other states have banned business and/or state agencies from requiring proof of vaccination for service, *e.g.* Florida and Texas

Discussion

PATENTS

A network analysis of COVID-19 mRNA vaccine patents

A preliminary network analysis highlights the complex intellectual property landscape behind mRNA-based COVID-19 vaccines.

The COVID-19 pandemic has had a substantial impact on global health and highlighted the importance of international cooperation to effectively combat SARS-CoV-2. Since the discovery and publication of the virus's genome in January 2020, scientists have rushed to develop vaccines, therapeutics and diagnostics on an unprecedented timescale. To date there are 80 vaccines in clinical trials and 70 more in clinical development, setting the stage for some of the fastest vaccine development and testing in modern history[1]. The vaccine technology platforms used by the most promising vaccine candidates range from viral vector–based and protein-based technologies to mRNA and lipid nanoparticle technology. Despite these impressive scientific achievements, barriers such as the vaccine cold chain and multiple forms of intellectual property (IP) protection stand in the way of equitable access and fair allocation.

Webs of intellectual property claims underpin the marketing of many vaccines. For example, the underlying technology used to develop a vaccine can be protected by patents, while manufacturing methods and techniques (know-how) can be protected by trade secrets. Therapeutic development programs tend to consist of an intricate relationship between an inventor and an innovator[2]. The foundational technology needed to develop a vaccine could have been invented in an academic lab setting or startup research firm, protected through patents, and subsequently licensed out to a larger entity for further development and commercialization. These larger entities are designated as innovators because they transform the foundational technology into the final market product.

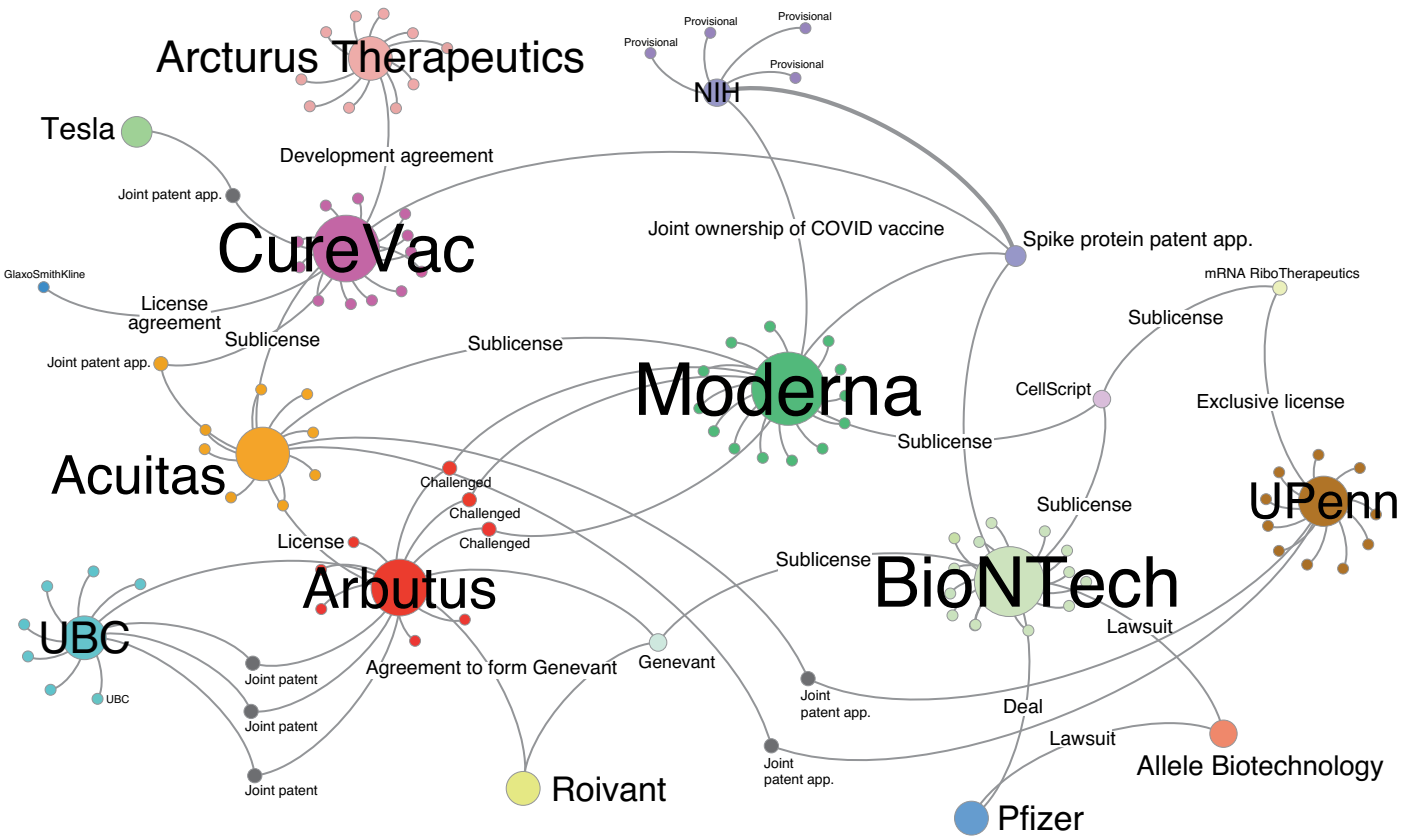

Fig. 1 | Patent network analysis of mRNA-based vaccine candidates for COVID-19. Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology (Supplementary Information). The network analysis was developed using Gephi[23]. UPenn, University of Pennsylvania; UBC, University of British Columbia; app., application.

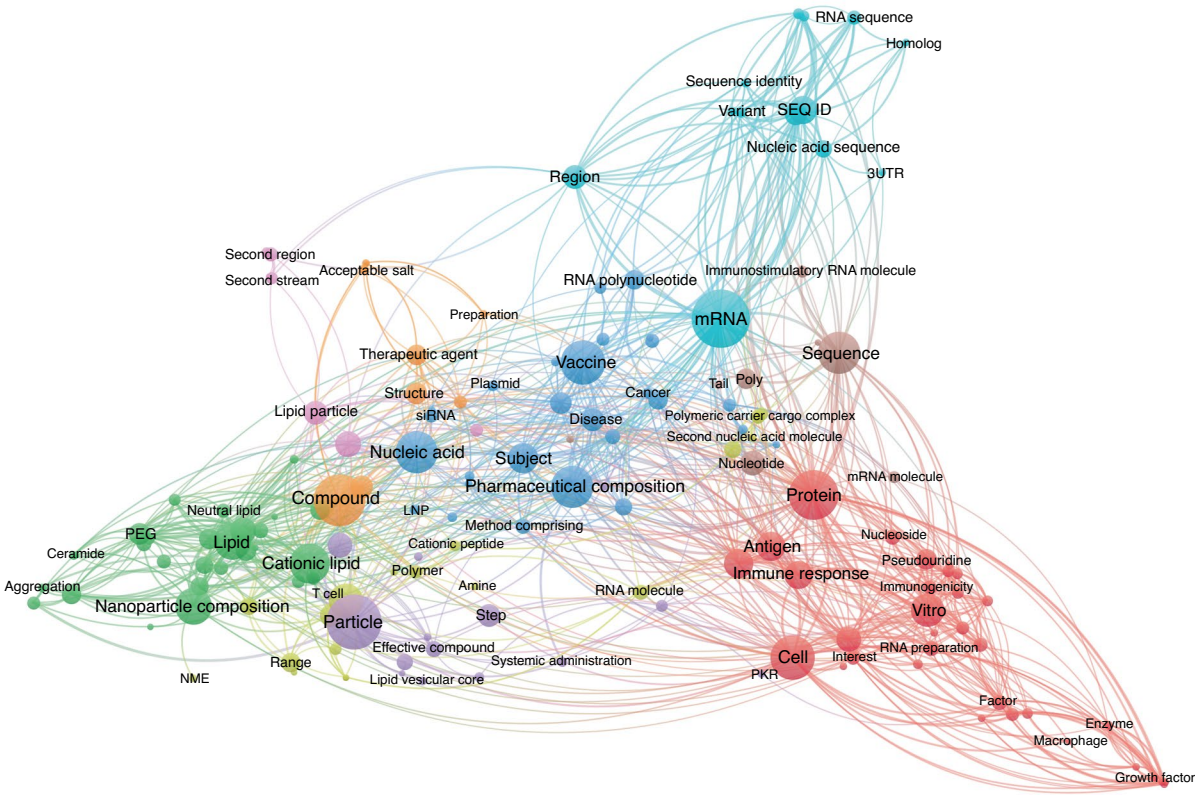

Fig. 2 | Landscape of scientific terms found in all of the abstracts and claims of the patents and applications that were identified as relevant to mRNA vaccine technology. The scientific landscape was developed using VOS Viewer. LNP, lipid nanoparticle; NME, new molecular entity; PEG, polyethylene glycol; PKR, protein kinase R; SEQ ID, sequence identifier; 3UTR, 3′ untranslated region.

In an attempt to demonstrate the complexity involved in IP protections and licensing deals surrounding COVID-19 vaccine technology, we developed a preliminary patent network analysis. We identified patents that were relevant to various vaccine technology platforms and used US Securities and Exchange Commission (SEC) filings to highlight pertinent licensing deals. A visualization of the landscape is shown in Fig. 1.

Moderna, Pfizer and BioNTech, CureVac and Arcturus have all developed mRNA-based vaccine candidates for COVID-19. This vaccine technology platform uses mRNA technology, lipid nanoparticle technology and delivery system technology to achieve a desired biological response. A lipid nanoparticle must be used to deliver the mRNA to the cells to avoid mRNA degradation, which makes it a key aspect of the vaccine's technology. After the mRNA is delivered to a cell, it instructs the cell to produce the SARS-CoV-2 spike protein, thereby eliciting an immune response[3,4].

Scientists have studied the use of mRNA as a novel therapeutic since the early 1990s[5]. However, it wasn't until 2005 that a group of researchers at the University of Pennsylvania published findings on mRNA technology that have since been deemed critical to the development of mRNA based therapies[6]. SEC filings highlighted by Knowledge Ecology International reveal a series of sublicenses for mRNA-related patents that stem from the University of Pennsylvania to both Moderna and BioNTech[7–9]. The 2017 filings indicate that the University of Pennsylvania exclusively licensed their patents to mRNA RiboTherapeutics, which then sublicensed them to its affiliate CellScript. CellScript proceeded to sublicense the patents to Moderna and BioNTech; however, the patent numbers are redacted in all the filings, making it difficult to determine which are relevant to the production of COVID-19 vaccines.

Another key aspect of an mRNA vaccine platform is the ability to deliver the mRNA to a cell using a lipid nanoparticle. Some early work on lipid nanoparticles was done jointly by the University of British Columbia and Arbutus Biopharmaceuticals in 1998. SEC filings show that patents relating to this early technology were solely assigned to the University of British Columbia and then licensed back to Arbutus[10].

Further analysis reveals that in 2012 Arbutus licensed a set of patents relating to the delivery of nucleic acids to Acuitas Therapeutics. In 2016, Acuitas entered into a development and option agreement with CureVac, which included access to patents on lipid nanoparticle technology[11]. Acuitas also granted a sublicense to Moderna; however, in 2016 Arbutus declared that Acuitas's sublicense to Moderna was improper and took to the Canadian legal system for remedy[10]. The litigation in Canada was eventually settled, but in 2018 Moderna began filing inter partes reviews (IPR), a procedure for challenging the validity of a US patent before the US Patent and Trademark Office, on three of Arbutus's patents, which concluded with the cancellation of claims in two of the three challenges[12]. Moreover, Arbutus also entered into an agreement with Roivant to spin out Genevant, which received a license for the patent portfolio on lipid nanoparticles[13]. Genevant sublicensed the patents to BioNTech, who then entered into an agreement with Pfizer to develop a COVID-19 vaccine[14–16]. It is also important to note that the US National Institutes of Health (NIH) and Moderna entered

into an agreement in 2019 to co-develop coronavirus vaccines; however, this was before the identification and spread of SARS-CoV-2[17,18].

The mRNA vaccine platform for COVID-19 relies on the production of the coronavirus spike protein to elicit an immune response. Moderna, CureVac, Pfizer and BioNTech have all disclosed that the mRNA used in their vaccine candidates encodes a stabilized version of the spike protein that was developed by the NIH. A report by Public Citizen identified a pending patent application on this modified spike protein that was filed by the NIH[19]. The NIH also has four other provisional patent applications on a novel coronavirus vaccine as disclosed in a recent publication[17]. This complex matrix of patents, licenses and agreements between these entities highlights the intricacies involved in biopharmaceutical development. Since patent numbers are redacted in all the SEC filings, we decided to develop our own patent landscape for the respective entities. Patents and patent applications that are relevant to the respective vaccine technology platform and owned or assigned to any of the entities discussed were identified and highlighted (Supplementary Information)[20,21]. A visual representation of the science encompassed in the patents and applications is shown in Fig. 2 [22].

The success of mRNA vaccines in clinical trials highlights the potential of mRNA technology to be the future of medicine. The rapid development and clinical success of COVID-19 mRNA vaccines can be credited to the relationship between inventors and innovators. As evidenced by our network analysis, key technological advancements were invented in academic labs or small biotech companies and then licensed to larger companies for product development. Despite this success, patents, trade secrets and know-how owned by or assigned to larger companies may impede future research and development of mRNA technology by creating legal barriers that limit access to this technology.

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References

1. Zimmer, C., Corum, J. & Wee, S.-L. Coronavirus vaccine tracker. *The New York Times* https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (2020).
2. Kiliç, B. *Boosting Pharmaceutical Innovation in the Post-TRIPS Era* (Edward Elgar Publishing, 2014).
3. Walsh, E. E. et al. *N. Engl. J. Med.* **383**, 2439–2450 (2020).
4. Corbett, K. S. et al. *Nature* **586**, 567–571 (2020).
5. Wolff, J. A. et al. *Science* **247**, 1465–1468 (1990).
6. Karikó, K., Buckstein, M., Ni, H. & Weissman, D. *Immunity* **23**, 165–175 (2005).
7. Abinader, L. G. Foundational mRNA patents are subject to the Bayh-Dole Act provisions. *Knowledge Ecology International* https://www.keionline.org/34733 (2020).
8. CellScipt & Moderna. Patent sublicense agreement. EX-10.8. https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473dex108.htm (2017).
9. CellScipt & BioNTech. Patent sublicense agreement. EX-10.15. https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1015.htm (2017).
10. Arbutus Biopharma Corporation. Annual report. https://www.sec.gov/Archives/edgar/data/1447028/000162828018003276/arbutus10k2017.htm (2017).
11. CureVac. Registration form F-1. https://www.sec.gov/Archives/edgar/data/1809122/000110465920086354/tm2016252-11_f1.htm (2020).
12. Silbersher, Z. Does Moderna Therapeutics' pipeline depend upon its patent dispute with Arbutus Biopharma over mRNA delivery? *Markman Advisors* https://www.markmanadvisors.com/blog/2018/12/17/does-moderna-therapeutics-pipeline-depend-upon-its-patent-dispute-with-arbutus-biopharma-over-mrna-delivery (2018).
13. Arbutus Biopharma Corporation. Form 8-K. https://www.sec.gov/Archives/edgar/data/1447028/000117184318002661/f8k_041218.htm (2018).
14. BioNTech and Genevant. License and co-development agreement. EX-10.17. https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1017.htm (2018).
15. Pfizer & BioNTech. Research collaboration and license agreement. EX-10.18. https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1018.htm (2018).
16. BioNTech. Registration form F-1. https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm (2020).
17. Herman, B. The NIH claims joint ownership of Moderna's coronavirus vaccine. *Axios* https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html (2020).
18. Rizvi, Z. The NIH vaccine. *Public Citizen* https://www.citizen.org/article/the-nih-vaccine/ (2020).
19. Rizvi, Z. Leading COVID-19 vaccine candidates depend on NIH technology. *Public Citizen* https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/ (2020).
20. Gaviria, M. & Kilic, B. mRNA-1273 vaccine patent landscape (for NIH-Moderna vaccine). *Public Citizen* https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/ (2020).
21. Gaviria, M. & Kilic, B. BioNTech and Pfizer's BNT162 vaccine patent landscape. *Public Citizen* https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/ (2020).
22. van Eck, N. J. & Waltman, L. VOSViewer: visualizing scientific landscapes. https://www.vosviewer.com (2010).
23. Bastian, M., Heymann, S. & Jacomy, M. Gephi: an open source software for exploring and manipulating networks. *Int. AAAI Conf. Weblogs and Social Media* https://gephi.org/publications/gephi-bastian-feb09.pdf(2009).

Competing interests

The authors declare no competing interests.

Additional information

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/s41587-021-00912-9.

PUBLICCITIZEN

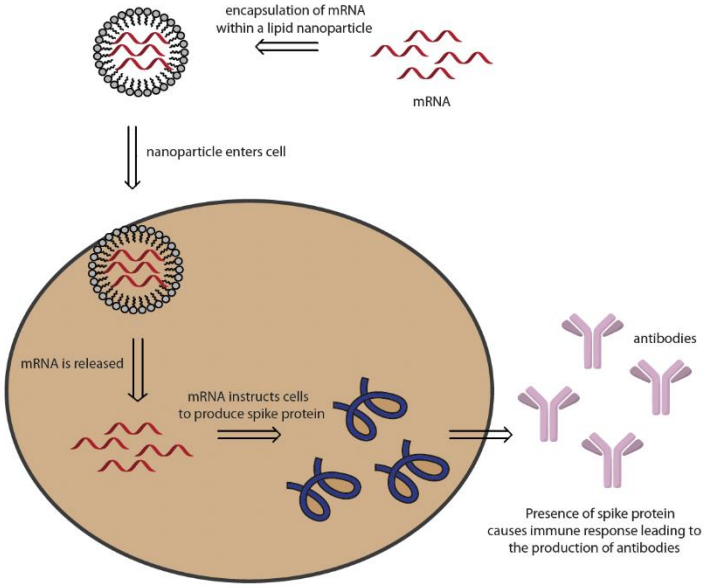
BioNTech and Pfizer's BNT162 Vaccine Patent Landscape

By Mario Gaviria and Burcu Kilic[1]

November 12, 2020

Safe and effective vaccines are key to combating the Covid-19 pandemic; however, patents and other intellectual property claims directed at vaccine technologies create legal barriers for equitable access and fair allocation. No corporation produces at scale to supply the world. Providing timely global access will depend in significant part on increasing supply, including by transferring technology to qualified manufacturers. Much of this technology is claimed as patented, proprietary, or confidential in nature.

German company BioNTech and its U.S. partner Pfizer's[2] vaccine candidate, BNT162 SARS-CoV-2, employs the use of lipid nanoparticle (NP) technology to deliver mRNA to cells. Once the lipid nanoparticle is injected into a patient, it travels into the cells and instructs them to produce the SARS-CoV-2 spike protein. The presence of this coronavirus protein is thought to trigger an immune response leading to the production of antibodies.[3] If the patient is infected with coronavirus, the antibodies will identify and bind to the virus, which triggers a series of events resulting in the elimination of the virus.



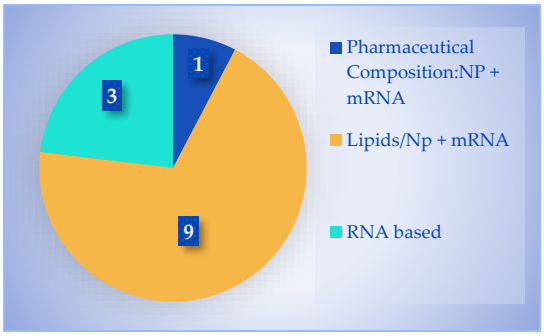
[1] Public Citizen's Access to Medicines Program

[2] All patents and patent applications identified in this study were claimed by BioNTech indicating that they are the inventor of the relevant vaccine technology, while Pfizer is acting as the innovator and leading the large-scale manufacturing, development, and regulatory approval process.

[3] https://www.nejm.org/doi/10.1056/NEJMoa2027906

BNT162 is in Phase 3 clinical trials. Pfizer announced promising but preliminary trial results on November 9th.[4]

We identified several patents claimed by BioNTech relating to the pertinent vaccine technologies.[5] We placed them in three groups based on their description and their primary independent claim:



- Patents directed at RNA
- Patents directed at Lipids/NP + mRNA
- Patents specifically directed at pharmaceutical compositions involving lipid NP + mRNA.

Below is our non-exhaustive list. In a recent financial statement, BioNTech suggested that its patent claims extend to mRNA structure, formulations, and manufacturing, and relies on trade secrets and confidential know-how to protect aspects of mRNA manufacturing technologies.[6]

Patent/Published Application	Applicant/Assignee	Filing Date	Status	Invention Type
US 10,576,146	BioNTech	March 15, 2018	Active	Lipids/NP + mRNA
US 10,485,884	BioNTech	March 5, 2013	Active	Lipids/NP + mRNA
US 9,950,065	BioNTech	September 26, 2013	Active	Lipids/NP + mRNA
US2020/0155671	BioNTech	January 22, 2020	Pending	Lipids/NP + mRNA
US2020/0197508	BioNTech	March 21, 2018	Pending	RNA immune response
US2019/0153428	BioNTech	August 24, 2016	Pending	RNA immunogenicity
US2019/0321458	BioNTech	July 14, 2017	Pending	PC: Lipids/NP + mRNA
US2018/0263907	BioNTech	March 30,2016	Pending	Lipids/NP + mRNA
US2017/0273907	BioNTech	September 17, 2015	Pending	Lipids/NP + mRNA
US2014/0030808	BioNTech	December 2, 2011	Pending	RNA expression
WO2016/156398	BioNTech	March 30,2016	Published	Lipids/NP + mRNA
WO2015/043613	BioNTech	September 26, 2013	Published	Lipids/NP + mRNA
WO2013/087083	BioNTech	December 15, 2011	Published	Lipids/NP + mRNA

[4] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against

[5] Pharmaceutical companies are not the only claimants of key technology. The U.S. government claims a patent on a key technology which may be relevant for BioNTech and Pfizer to stabilize the spike protein. *See* Public Citizen, Leading COVID-19 Vaccine Candidates Depend on NIH Technology (Nov. 10, 2020), https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/.

[6] "Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets", BioNTech SE, SEC Filing (July 21 2020), https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm.

Which patents cover the COVID-19 vaccine candidates for Moderna, AstraZeneca, J&J and Novovax?

Zachary Silbersher

JULY 21, 2020

A number of companies have announced candidates for a COVID-19 vaccine, including Moderna Therapeutics ($MRNA), AstraZeneca ($AZN), Johnson & Johnson ($JNJ) and Novovax ($NVAX). We looked into the existing landscape of patents that cover many of the existing candidates.

One difficulty uncovering the patent landscape for the existing COVID-19 vaccine candidates is that patent applications are typically not publicly-available when filed. Most of the companies developing the current candidates did not likely commence their work targeting COVID-19 until earlier this year. While there are exceptions, patent applications filed with the USPTO are not typically made public for 18 months. Thus, the companies may have already filed numerous patent applications earlier this year that specifically cover their vaccines, but those applications may not yet be public.

Nevertheless, several companies already appear to hold key patents covering some of the candidates. As detailed below, in some cases (Moderna), the company has taken an older patent application that covered their vaccine technology for other coronaviruses and filed a follow-on application. In other cases (Novovax), the company's vaccine uses proprietary technology that was already patented years ago. In another case (AstraZeneca), the company appears to have done both—recently filed a follow-on patent application from an older patent covering the technology used to develop its current COVID-19 candidate. In yet another case (J&J), the company may end up relying upon patents covering the manufacturing of the vaccine, or in particular, large batches of the vaccine.

Any company with a successful vaccine is likely to use both older patents and newer patents to protect their drug. Patents can cover the vaccine itself or methods of treating patients with the vaccine, but they may also cover methods of manufacturing the vaccine, manufacturing large-scale batches of the vaccine, or other proprietary features required to make or use the vaccine. That is why older patents that issued long before the emergence of COVID-19 may nevertheless provide IP protection for a newly-developed vaccine. That said, in all of these cases, it is still likely that the companies have pending patent applications specifically targeting their existing candidates, but these applications have not yet become publicly-available.

Moderna

In 2015, Moderna filed a number of preliminary (provisional) patent applications directed to mRNA vaccines for respiratory illnesses (e.g., U.S. Provisional Patent Application 62/245,031). The applications covered different mRNA vaccines for numerous respiratory diseases, including the betacoronavirus (BetaCoVs), one of four coronaviruses, including MERS-CoV and SARS.

On February 28, 2020, Moderna filed a follow-on application from this patent family. In a matter of months, Moderna was granted a patent directed to mRNA comprising an "open reading frame encoding a betacoronaviru (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle." The patent is U.S. Patent No. 10,702,600, which is titled Betacoronavirus mRNA vaccine. The patent covers mRNA vaccines where the betacoronavirus structural protein is spike protein (S). Thus, this patent appears to cover Moderna's mRNA vaccine encoding for a prefusion stabilized form of the Spike (S) protein.

In addition, Moderna has two more pending patent applications that claim priority to this patent family, the first filed on May 21, 2020 (Serial No. 16/880,829) and the second filed on June 10, 2020 (Serial No. 16/897,734). These patent applications are not yet public. Based upon a restriction requirement issued by the Patent Office during prosecution of the '600 patent, one of these pending applications is likely directed to a method of administering the mRNA vaccine to a patient to induce "an immune response specific to BetCoV." (The Patent Office will issue a restriction requirement in response to a patent application when the applicant is attempting to patent two separate inventions. The common response is to pick one invention, patent it, and then file a follow-on application and patent the other invention.)

It will not be surprising if Moderna files more follow-on applications that continue to mine its patent disclosure from 2015 for more features of its vaccine. It would also not be surprising if Moderna has filed new patent applications in recent months that cover its mRNA vaccines specifically for COVID-19, but these applications are not yet public.

AstraZeneca

AstraZeneca's COVID-19 vaccine is ChAdOx1 nCoV-19, also known as AZD1222. The vaccine was developed in connection with Oxford University. Oxford filed a British patent application in May 2011 that was directed to novel adenoviral vectors derived from a chimpanzee adenovirus. This application was GB Patent Application No. 1108879.6, and it described the ChAdY25/ChAdOx1 vector and appears to relate to Oxford's use of "a replication-deficient chimpanzee viral vector based on a weakened version of a common cold (adenovirus) virus that causes infections in chimpanzees."

In July 2017, Oxford received a follow-on U.S. patent from British application: U.S. Patent No. 9,714,435. Interestingly, on April 15, 2020, Oxford filed an application for another follow on patent from this family. The application is not yet public, but given the timing of the filing (well after the emergence of COVID-19), and the fact that the disclosure includes ChAdOx1, Oxford is may be using this patent family to target a patent on its ChAdOx1 vaccine for COVID-19.

Johnson & Johnson

J&J has developed a candidate—AD26.COV2-S—along with Beth Israel Deaconess Medical Center, which is part of Harvard Medical School. The candidate is developed from the AD26 adenoviral vector. Janssen, which is J&J's pharmaceutical division, has numerous patents covering different aspects of AD26. For instance, Janssen has a patent (U.S. Patent No. 9,701,718) covering an AD26 vaccine for Ebola, and Janssen has a pending patent application covering large-scale production of recombinant adenovirus 26 (U.S. Patent Publication No. 2018/0080010.) It would therefore not be surprising if J&J has pending patent applications, which have not yet been made public, that are specifically directed to its AD26 adenoviral vector for a COVID-19 vaccine.

This highlights an interesting facet of patenting a vaccine. Patents can cover many different features of a particular drug such as the composition-of-matter of the vaccine formulation itself. In this case, J&J appears to have a patent that covers manufacturing large batches of a particular vaccine. That technology may be particularly relevant to a drug that may have to be mass-produced on a global scale.

Novavax

Novavax has developed a coronavirus vaccine candidate, NVX-CoV2373. The candidate is described as a "stable, prefusion protein made using its proprietary nanoparticle technology," and it was developed using Novovax's proprietary Matrix-M™ adjuvant technology. Novovax has patented features of its Matrix-M™, such as U.S. Patent Nos. 7,838,019; 9,205,147; 9,901,634 and 8,821,881, as well as at least one pending U.S. patent application that has been filed, but it not yet public (Serial No. 16/701,948). To the extent Novovax's NVX-CoV2373 candidate cannot be made without use of its Matrix-M™ adjuvant technology, these patents may technically be sufficient IP protection for its vaccine.

Novovax filed a patent application in 2013 including a disclosure for a vaccine for the MERS coronavirus including an "immunogenic composition comprising a MERS-CoV nanoparticle." The patent application (U.S. Patent Application Publication No. 2016/0206729) has been allowed, but not yet issued. While this patent appears limited to a vaccine for MERS, it nevertheless suggests that Novovax may have filed a similar patent application earlier this year, which are not yet public, that may be more specifically directed to using its Matrix-M™ adjuvant technology for its vaccine for COVID-19.

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Overall, any vaccine for COVID-19 will be meeting a market demand that is unfamiliar for any normal pharmaceutical drug. While the pharmaceutical business is one that is generally not shy about suing competitors for patent infringement, any COVID-19 vaccine will undoubtedly raise different distribution, ethical and policy concerns. Just because drug companies with existing vaccine candidates may be aggressively pursuing IP protection for their drugs does not necessarily mean that they intend to aggressively charge monopoly prices for that vaccine. Rather, the costs of pursuing patents is generally negligible compared to the potentially significant downside of not doing so. Without locking up IP protection, any vaccine candidate may lose control over its ability to recoup its investment, even if that means otherwise agreeing to sharing part of the market.

STAT

Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive

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By Damian Garde , Helen Branswell , *and* Matthew Herper May 6, 2021

A tray of syringes filled with the Pfizer-BioNTech Covid-19 vaccine. *Esteban Felix/AP*

The U.S.'s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it's likely to be more of a symbolic milestone than a turning point in the pandemic.

For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don't magically produce vaccines.

Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it's approved at the World Trade Organization — would be in 2022.

Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said.

"My take is: By itself, it will not get us much benefit in increased manufacturing capacity," Yadav said. "But as part of a larger package, it can."

That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents.

Lawrence Gostin, director of the O'Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines.

"We're not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus," Gostin said. "While they're going to be negotiating the text, the virus will be mutating."

Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies' patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production.

"In our experience, when the legal barriers disappear and there's a market, capacity increases faster than you would think," he said.

In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it's unclear whether anyone has, despite the vaccine's demonstrated efficacy and the worldwide demand for doses.

That underscores the drug industry's case that patents are just one facet of the complex process of producing vaccines.

"There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple," said Norman Baylor, who formerly headed the Food and Drug Administration's Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger

RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.

"In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely," Yadav said.

There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing.

Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well.

"This is an industry-wide … looming crisis that will not at all be solved by more tech transfers," Venkayya said.

He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing.

"I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the 'experts' that are discussing it," said Venkayya, who stressed that while he believes they have good intentions, "nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing."

As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, "handing needy countries a recipe book without the ingredients,

safeguards, and sizable workforce needed will not help people waiting for the vaccine."

Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea "flies in the face of President Biden's stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery."

Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It's highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company.

But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave.

Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: "What do we need to do?" Said Love: "If you really think this is a big emergency, 'what do we need to do' should be the question, not just saying we can't do anything."

That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

An earlier version of this story stated that no company has tried to develop Moderna's Covid-19 vaccine since the Massachusetts-based company vowed

not to enforce its related patents for the duration of the pandemic. It's not publicly known whether that's the case.

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EDITORIAL 30 MARCH 2021

It’s time to consider a patent reprieve for COVID vaccines

The pandemic is not a competition between companies and will not end without more-equal distribution of coronavirus vaccines.

Agreeing temporary relief from COVID-related intellectual property would send a powerful message that richer countries and pharma companies are willing to forgo some profit for the greater good. Credit: Brian Snyder/Reuters/Alamy

The world needs around 11 billion doses of coronavirus vaccine to immunize 70% of the world’s population, assuming two doses per person. As of last month, orders had been confirmed for 8.6 billion doses, a remarkable achievement. But some 6 billion of these will go to high- and upper-middle-income countries. Poorer nations — which account for 80% of

the world's population — so far have access to less than one-third of the available vaccines.

One reason for this imbalance is that wealthier countries have been able to place substantial advance orders with the relatively small group of companies that are making vaccines, most of which are based in richer countries. Unless manufacturing and supply can be distributed more evenly, researchers forecast that it will be at least another two years before a significant proportion of people in the lowest-income countries are vaccinated.

This is why around 100 countries, led by India and South Africa, are asking fellow World Trade Organization members to agree a time-limited lifting of COVID-19-related intellectual-property (IP) rights. The main vaccine suppliers, they argue, should share their knowledge so that more countries can start producing vaccines for their own populations and for the lowest-income nations.

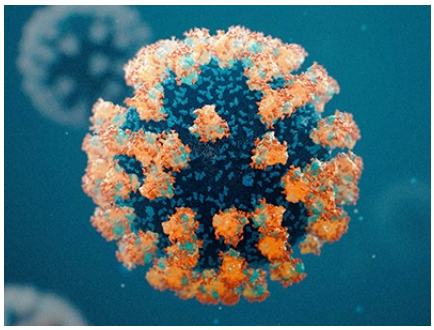
What it will take to vaccinate the world against COVID-19

This idea needs to be considered seriously because a temporary IP waiver could have a role in accelerating the end of the pandemic. It would also send a powerful message from richer countries and pharmaceutical companies that they are willing to forgo some profit for the greater good. The campaign for a temporary IP waiver is called the People's Vaccine and is backed by non-governmental organizations, as well as the United Nations' HIV/AIDS agency, UNAIDS. Its proponents point out that many companies have already benefited from billions of dollars in public funding, through both research and development and advance purchase agreements. And that once the pandemic is over, IP protections would be restored.

But the pharmaceutical industry, richer nations and some researchers argue that temporary relief from patents won't necessarily speed up manufacturing or supply. They say it

isn't clear whether the world has any spare manufacturing capacity. Even if patents did not apply, securing all the vaccine components, setting up factories, training people and passing relevant laws — all essential to vaccine delivery — could take more than a year.

An alternative to the lifting of IP, they say, is for companies to increase the licensing of their product designs in exchange for payment. This would allow vaccines to be made by many more companies. In addition, the World Health Organization is setting up a facility for companies to share their vaccine technology, skills and other know-how.



The sprint to solve coronavirus protein structures — and disarm them with drugs

Companies and richer countries also note that they are already backing a vaccine scheme called COVAX, which has secured more than 1 billion doses towards a 2 billion target for 2021 to vaccinate 20% of the most vulnerable groups in countries in need of help. However, it's not clear whether COVAX will be able to reach its full potential before some of the richer countries that are donating supplies have fully vaccinated their own people.

Richer nations were united in their opposition to the IP waiver until last week, when it emerged that the administration of US President Joe Biden is discussing its merits. One factor that could influence a change in policy is that the US government is named on a patent application for a technology used in vaccines being made by several companies, including Moderna in Cambridge, Massachusetts.

In 2016, researchers at the US National Institute of Allergy and Infectious Diseases in Bethesda, Maryland, working with colleagues at Dartmouth College in Hanover, New Hampshire, and the Scripps Research Institute in La Jolla, California, filed a patent for a technology that manipulates the spike protein found in coronaviruses, and which can be used

to develop a vaccine antigen. The United States could license this technology — or choose not to enforce the patent — once the patent is granted.

Five reasons why COVID herd immunity is probably impossible

Arguably the strongest argument for a temporary waiver is that patents were never designed for use during global emergencies such as wars or pandemics. A patent rewards inventors by protecting their inventions from unfair competition for a limited time. The key word here is 'competition'. A pandemic is not a competition between companies, but a race between humanity and a virus. Instead of competing, countries and companies need to do all they can to cooperate to bring the pandemic to an end.

There is a precedent for this, says Graham Dutfield, who studies IP in the life sciences at the University of Leeds, UK. During the Second World War, the US government asked companies and universities to collaborate to scale up penicillin production, which was needed to protect soldiers from infectious diseases. Companies could have argued that this would affect profits, but they understood the necessity of subordinating their interests to the larger goal of saving lives and bringing the war to an end. "For a time the US produced virtually all the penicillin there was," Dutfield says. "But companies did not sue each other for patent infringement and no one had any desire to hold the world to ransom by charging exorbitant prices."

The fact that the current US administration is now considering the merits of an IP waiver is important, and other countries should do the same. It might not be the best or the only way to rapidly expand vaccine supply, but it does represent an important principle. There are times when competition helps research and innovation; there are also times when it needs to be set aside for the greater good.

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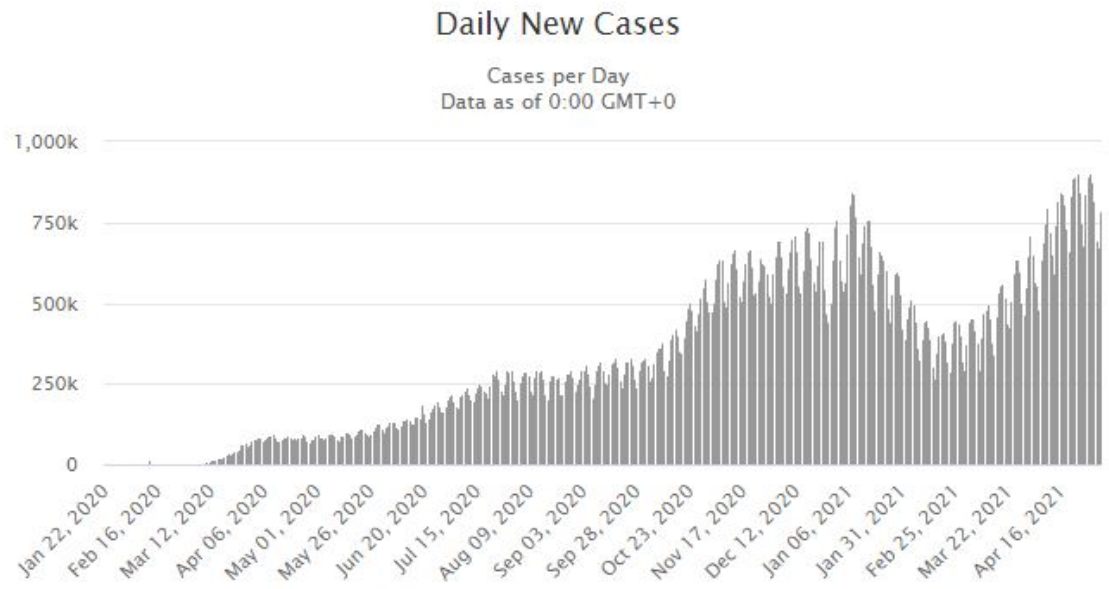
Big Move: US Supports IP Waiver for COVID Vaccine

May 5, 2021 Dennis Crouch
by Dennis Crouch

In the USA, COVID vaccines have been widely distributed and are now available at no cost almost on-demand for anyone seeking vaccination. Vaccines are *not* widely available in most other countries and global COVID cases are again at an all-time high.

And, people around the world don't really trust that Pfizer, Moderna, and J&J are going to be serving them anytime soon. That is where the TRIPS waiver comes into play.



TRIPS: Countries around the world are asking for a waiver of some aspects of the international intellectual property (IP) agreement known as TRIPS as part of their response to the global COVID pandemic. This IP Waiver would be a first step toward countries and companies around the world manufacturing, distributing, and importing already developed vaccines, such as those now being distributed in the USA by J&J, Pfizer, and Moderna. *Without* the IP waiver, a country could suffer trade penalties if they permitted production or importation in violation of rights. The penalties are setup in a *country-versus-country* bases and do not allow for any private action by the individual rights holders. Thus, the TRIPS dispute resolution process does not provide Pfizer standing to sue India for violating IP rights guaranteed under TRIPS; Rather Pfizer could only lobby to the U.S. Government to bring a case, which traditionally might have done.

The U.S. Government is reportedly going to support the waiver proposal, although there are current ongoing negotiations over its actual text and content. Even without a WTO waiver, the US can also act unilaterally to announce that it would not bring any TRIPS cases associated with violations. **This is a major change of policy under President Biden and his new U.S. Trade Representative Katherine Tai.** In the past, the US has always been on the side of stronger IP rights and more enforcement.

Trade Secrets + Patents: In the short-run, the big difference is more about trade-secrets than patents. In the longer run, patents may become equally important.

If we take India as an example, right now there are no patents that have been granted in India tied directly to the COVID response. So, allowing India to waive its promise to enforce patents does not generate any short-term gains. Here, by short-term, I'm really talking about the next two years or so. Hopefully by that time the pandemic will be gone.

Trade secrets are different, most of the "intellectual property" wrapped up in COVID vaccine manufacture is currently being held as trade secrets. Obviously the companies manufacturing the product have the information. Many countries also have information that they received in the process of (1) funding the research and (2) determining whether to allow the vaccines to be distributed. International espionage is also a major element here that will put the information in the hands of various governmental agencies.

TRIPS require that countries protect trade secrets, and also keep secret the information provided as part of regulatory approval.

> *Article 39*
>
> *1. In the course of ensuring effective protection against unfair competition … Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.*
>
> *2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (10) so long as such information: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.*
>
> *3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

[TRIPS Text]

The original proposed WTO waiver would have waived this trade secret protection requirement — a really big deal.

Waiver of the requirement does not force the companies to actually conduct any technology transfer — to provide the information to others who want to manufacture. BUT, it does open the door to governments sharing the information and also to a major WIKILEAKS style sharing of data and information. I believe that a whistle-blowing is actually quite likely because so many scientists and business insiders are wanting to do everything they can to spread the vaccine, but don't believe that it will be permitted by the CEOs and Shareholders.

The other thing that this does is substantially shift the negotiation positions. This waiver signals to the current vaccine-makers to speed-up global access.

We'll be looking for President Biden's action on this as we move forward. As I mentioned above, negotiations are ongoing and I expect a focus on timelines (when does the waiver end) and scope (exactly what is being waived).

About Dennis Crouch

Law Professor at the University of Missouri School of Law. View all posts by Dennis Crouch →

May 10, 2021

If the Devil of the WTO IP Waiver Is in the Details, What Are the Details?

Kevin Noonan

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Patent Docs
Biotech & Pharma Patent Law & News Blog

While the details of the WTO patent waiver have not been determined (or more properly negotiated), it is important to consider the structure of the international trade regime in which the waiver will operate and the consequences of any agreement defining exactly what will be waived.

The GATT/TRIPS agreement is a treaty, which (of course) is an agreement between countries, and disputes and accommodations are between their governments. The extent to which a private company's patent or other IP rights are protected under the terms of these agreements depends on actions of these governments in enforcing them on the company's behalf. Thus, for protections like patents, a government can agree to "turn a blind eye" to infringement by companies in other countries (or other governments) by refusing to press the rightsholder's case before the WTO, to pressure the governments unilaterally (as in the Watch List and Special Watch List of the U.S. Trade Representative's Special 301 Report), or otherwise support a private company's private actions using an infringing country's legal system. Such "passive" actions (*i.e.*, refusing to enforce rights in violating or "scofflaw" countries) requires very little affirmative action by a government. These are the types of *de facto* waivers that can be effe t can be produced by conventional drug production tech pharmaceutical ingredient molecule.

The details of COVID vaccine production have been set ; *et al.*, "Exploring the Supply Chain of the Pfizer/BioNT Weiss *et al.*, "A COVID-19 Vaccine Life Cycle: From DN King, "Why Manufacturing Covid Vaccine to at Scale Is ; Cott *et al.*, "How Pfizer Makes Its Covid-19 Vaccine," *N* e are certainly not disclosed in the detail necessary for cc complexities of production are illustrated in graphics from the *Times* article, wherein the DNA is

prepared in Chesterfield, MO and shipped to Andover, MA for mRNA production; then the mRNA shipped back to Chesterfield or Kalamazoo, MI for packaging into the vaccine nanoparticles; and then sent back to Andover for testing before release. While some of this complexity may be company-specific, it also represents the different technological requirements for preparing an effective vaccine. It is unlikely that most of the countries in favor of the waiver (except India and South Africa) have the technological infrastructure for producing the vaccine. And the company in India, the Serum Institute ("the largest vaccine maker in the world"), having the greatest likelihood of being able to reproduce the vaccine if the waiver is put in place recently was forced to "hand over its vaccines to the [Indian] government," according to an article in the *New York Times* (Schmall *et al.*, "India and Its Vaccine Maker Stumble over Their Pandemic Promises," May 9, 2021).

It is evident that, in the almost total absence of patents involved in COVID vaccine preparation, the disclosure needed to reproduce these vaccines (no matter how difficult that may be in practice) are protected by trade secrets. If the WTO imposes this waiver, the question will be whether the U.S. will compel disclosure of trade secret owned by U.S. companies, or have disclosed them to the extent such secrets are part of regulatory filings. Either action would constitute a "taking" under the Fifth Amendment ("Nor shall private property be taken for public use, without just compensation"); *see* Epstein *et al.*, "The Fifth Amendment Takings Clause," *Interactive Constitution: Common Interpretation*. Seemingly simple and straightforward, almost every word in the clause is open to interpretation, none perhaps as much as determining what "just compensation" entails. It is likely that, should the government act peremptorily with regard to takings of trade secrets justified by any WTO waiver clause, the effect on trade secrets will carry the greatest consequences and be the cause of most controversy. Indeed, the prospects arising therefrom are likely some of the biggest impediments towards effectuating any waiver in a manner that could have any chance of achieving the stated goal of facilitating COVID vaccine production.

This prospect also raises the issue of how any such waiver will be implemented in the U.S. Treaties are not necessarily "self-executing" and need t
Congress. The distinguishing feature of such treaties ar
agreements that would require the United States to exe
assigns to Congress exclusively must be deemed non-se
is required to give such provisions domestic legal effect
Agreements: Their Effect upon U.S. Law," *Congression*
The necessity for Congress to act, although not having
treaties (*i.e.*, a two-thirds majority vote in the Senate) r
significant opposition should it be interpreted to permi
"eminent domain" over pharmaceutical companies' trade secrets. In this regard such an act could

readily be characterized as "forced technology transfer" and even IP theft, should, for example, such trade secrets be capable of use to weaponize rather than immunize against viral infections.

The administration's public position raises the likelihood of an infringement on private property unprecedented in the U.S. It also has implications for other aspects of foreign policy; for example, at least some of the trade secrets belong to BioNTech, a German company. Germany has not agreed to the waiver, and should the U.S disclose BioNTech's trade secrets, no doubt Germany would have cause to seek redress against America. This is but one of the possible legal consequences that the recent capitulation to the purported global "kumbaya" of the WTO waiver is likely to create.

More complications will likely arise as the negotiations proceed. Provided the Administration is properly advised and the waiver properly limited (*e.g.*, to patents) these and other deleterious consequences may be avoided. In view of the possibility of serious liability arising by improvident acquiescence to generally uninformed calls for a broad waiver, it might not be a bad idea for all those involved in innovation (universities, technology transfer offices, pharmaceutical companies, patent lawyers, and economists) counter these opinions with the facts and make their viewpoints known and voices heard.

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