Selected Developments in Biotechnology Law and the Biotechnology Industry

By STEVEN J. ZWEIG

SECOND RNA-BASED COVID-19 VACCINE APPROVED BY U.S. REGULATORS

Only a week after emergency use authorization was granted for the Pfizer/BioNTech RNA-based COVID-19 vaccine,¹ the U.S. Food and Drug Administration (FDA) approved a second such vaccine on December 17, 2020: Moderna's vaccine, which was created in collaboration with the U.S. National Institute of Allergy and Infectious Diseases (NIAID).² Having two vaccines available for use so quickly is an unprecedented accomplishment and shows the power and value of biotechnology. As immunologist James Hildreth, the president of Nashville, Tennessee's Meharry Medical College, put it, "[t]o go from having a [gene] sequence of a virus in January to having two vaccines available in December is a remarkable achievement."

Equally as impressive in its own way as the rapid development of the vaccines is the rapid approval, at least on an emergency use basis: for anyone used to working with government regulators, approval of new vaccines in less than a year fully lives up to the promise of the name "Operation Warp Speed" since it—in comparison with the usual review and approval process—took place at faster-than-light velocity. And also impressive is that not only are the vaccines approved, but they are available and have already begun being deployed: as of

writing, several hundred thousand Americans have already been inoculated and millions of doses are expected to become available each week going forward in a *tour de force* of manufacturing and logistics. The COVID-19 vaccine development and deployment represent collaboration between industry and government on a scale not seen in this nation since World War II. After we get through the current pandemic, perhaps this effort can serve as a template for expeditiously harnessing biotech to address other or future issues and threats.

The U.S. is not the only nation that has approved vaccines for emergency usage: the United Kingdom has also begun inoculations.

Both Pfizer's and Moderna's vaccines consist of RNA encased in a lipid nanoparticle delivery system. The RNA induces recipients' cells to produce a SARS-CoV-2 protein known as the "spike," which then triggers an immune defense. The two vaccines differ primarily in their lipids, which makes for an important practical difference: the Pfizer vaccine needs to be stored at -70 degrees Celsius, which is far colder than most freezers can go, limiting the facilities which can handle it. The Moderna vaccine, on the other hand, requires only -20 degrees Celsius, which while still very cold, is within the reach of many more medical freezers—and it can even be stored in a commonly available refrigerator at -4 degrees Celsius for up to 30 days.

Steven J. Zweig is the Managing Editor of *Biotechnology Law Report*.

¹Not surprisingly, most biotechnology-related news at this time remains COVID-related.

²Dr. Anthony Fauci is the Medical Director of NIAID.

**THE ABILITY TO GET AN EXTRA DOSE
OUT OF VIALS OF PFIZER'S VACCINE
HIGHLIGHTS THE NEED
FOR SCIENTIFIC/MEDICAL PERSONNEL
AND REGULATORY COOPERATION**

A vial of Pfizer's vaccine is supposed to have five doses of vaccine. But hospital pharmacists discovered that it in fact has six (sometimes even seven) doses. However, pharmacists are not allowed to change dosing or use instructions on their own: they are limited to giving the number of doses indicated on the label and had been discarding the additional doses.

Had been, that is. The U.S. FDA, again acting with a dispatch only rarely seen previously, quickly approved the use of the extra dose(s). An e-mail from the FDA stated that "[a]t this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial pending resolution of the issue." That will potentially allow the population to be vaccinated 20% faster. As important as it was for hospital pharmacists to see that they had extra vaccine in a clinically useful quantity in each vial, it was as important for the FDA to approve its use.

**U.S. ATTORNEY'S OFFICE
AND IMMIGRATION & CUSTOMS
ENFORCEMENT (ICE) HOMELAND
SECURITY INVESTIGATIONS (HSI) UNIT
SEIZE FRAUDULENT BIOTECHNOLOGY
COMPANY WEBSITES**

Like carrion draws flies, need draws fraudsters—and the novel coronavirus has created a great deal of desperate need on the part of people looking for hope: a vaccine, a cure, therapeutics, whatever. Scam artists have been creating fake biotechnology company websites as part of "phishing" and similar cyberfraud schemes—to get people to divulge information that will allow the criminals to defraud them.

While certainly many of these fraudulent sites have gone undetected—law enforcement's resources are limited, after all—the good guys have scored some wins. Most recently: working together, the U.S. Immigration and Customs Enforcement's (ICE) Homeland Security Investigations (HSI) unit and the U.S. Attorney's Office for the District of Maryland seized two domain names, "mordernatx.com" and "regeneronmedicals.com," which claimed

to be the websites of legitimate and high-profile biotechnology companies working on COVID-19 treatments ... but which were actually sites used to trick people into disclosing personal information to use in fraud, phishing attacks, and/or for seeding malware.

The spoofed sites were sophisticated: they used the victim companies' names and trademarked logos, and recreated the look and feel of the legitimate websites. The "tells" that these sites were not legitimate may be subtle—e.g., a slightly variant misspelling of a company's name—and so may not have been readily detectable by potential victims (or even by law enforcement not closely familiar with the companies operating in this space).

Stopping people and criminal enterprises trying to take advantage of the pandemic is a priority of law enforcement. As HSI Baltimore Special Agent in Charge John Eisert said, "[f]rom the cyber realm to counterfeit medication to financial crime, we are committed to detecting, investigating and disrupting all types of fraud related to the COVID-19 pandemic." Maryland U.S. Attorney Robert K. Hur warned that "citizens [should] remain vigilant [and should not] provide personal information or click on websites or links contained in unsolicited e-mails." As he went on to say: "Don't become a victim."³

But it's not just individuals who should be vigilant: biotechnology companies need to be vigilant, too, about anyone spoofing their websites. While the regeneronmedicals.com site was found by law enforcement during an ongoing investigation into suspicious publicly reachable websites, the mordernatx.com site was found not by law enforcement but by the head of corporate security for the actual Cambridge, Massachusetts-based biotechnology company being spoofed, who then contacted HSI to report the fraudulent website. In this second case, it was the biotechnology company itself which found the fraudulent website. Attorneys with biotech company clients should tell their clients to redouble their vigilance against websites spoofing their own, since by doing so, they can help protect their own reputations as well as innocent people who may be defrauded in their name.

³Editor's Note: The editor is a former Securities Exchange Commission (SEC) enforcement attorney and will confirm that in his experience, a little healthy paranoia and skepticism goes a long way in keeping someone from being the victim of fraud. Don't trust and always verify before providing either money or personal information.

These two cases are not the only victories scored by law enforcement against those trying to take advantage of people's COVID-19 fears. HSI has (as of November 25, 2020) seized \$26 million in illicit proceeds from COVID-related scams; made 1,709 arrests; and seized over 1,600 shipments of mislabeled or otherwise fraudulent COVID-19 test kits, personal protective equipment (PPE), or therapeutics.

GEMANY INVESTING IN COVID-19 THERAPEUTICS AS WELL AS VACCINES

In addition to investing in vaccines, Germany is investing in therapeutics (some of which will or may be biologicals) which are intended to mitigate or ameliorate, not prevent (as a vaccine would) COVID-19. Tobias Reiss, who is co-initiator of the COVID-19 Therapeutics Strategy and also Parliamentary Secretary of the Bavarian CSU,⁴ stated that “[b]esides protection by masks, social distancing, *etc.*, rapid diagnostic testing, and COVID-19 vaccines, we are now establishing a fourth pillar of emergency measures to mitigate the impact of the corona pandemic: therapeutics!” A member of the CDU, Albert Rupprecht (who is that political party's research policy spokesperson), indicated that German's Federal Ministry of Education and

Research has approved an additional €50 million to support the development of therapeutics, with the option to increase that amount still further. The idea is that reducing the severity of the disease by between 10- and 100-fold through the use of therapeutics would be as effective as a vaccine (and so, added to effective vaccines, would exponentially decrease the pandemic's severity), with the added benefit of helping those already infected as well as those not yet infected. Germany appears to be a pioneer among the nations of the European Union in putting this kind of effort into therapeutics.

NASDAQ BIOTECHNOLOGY INDEX ANNUAL CHANGES

The NASDAQ Biotechnology Index tracks the performance of securities of companies classified under the Industry Classification Benchmark as either biotechnology or pharmaceutical companies. The index is “rebalanced” every year to make sure the companies on it are an accurate representation of this market sector. The NASDAQ just announced its latest annual reconstitution of the list: 100 securities are being added to the index while 16 companies are being removed.⁵

• • •

⁴The CSU is a sister party of the CDU, the party of German Chancellor Angela Merkel.

⁵The additions and deletions can be found in this news release: NASDAQ, Inc., *Annual Changes to the NASDAQ Biotechnology Index*, GlobeNewswire (Dec. 11, 2020), <https://www.globenewswire.com/news-release/2020/12/12/2144097/0/en/Annual-Changes-to-the-Nasdaq-Biotechnology-Index.html>