

Health Law & Business

Vaccine IP Enforcement Takes Stage in Global Immunization Fight

By Ian Lopez

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- Intellectual property rights aren't obstacles, drug companies say
 - Critics say drugmakers should share know-how
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The post-pandemic need for coronavirus vaccine booster shots may trigger intellectual property lawsuits as early vaccine makers aim to keep competitors out of that lucrative market, health experts say.

The situation is complicating a debate over sharing manufacturing know-how to speed up global immunization.

Pfizer Inc. in April reiterated its position that a third dose of its Covid-19 vaccine may be needed to fend off future infection. Moderna meanwhile said a booster for its two-dose vaccine regimen will be available by this fall.

The announcements come as world leaders, drug companies, and advocates argue over loosening IP rights around vaccine production. U.S. officials are seeking waivers of intellectual property protections to help countries like India and South Africa combat their surge in Covid-19 cases.

"The potential need for boosters may lead to a nightmare public health scenario where some people get their third doses before others around the world even get their first," said Zain Rizvi, a law and policy researcher at Public Citizen. "It adds urgency to the call for unshackling vaccine production from the constraints of intellectual property."

Proponents say lowering restrictions would allow manufacturers to produce vaccines on a global scale, making it easier to fend off virus variants and help developing countries while achieving broader immunity. Opponents argue IP built the foundations companies needed to kick out vaccines in less than a year and that sharing their know-how could actually slow down production efforts in the global pandemic push.

Widespread U.S. vaccination could tempt innovators behind Covid-19 vaccines and treatments to declare to a return to IP business as usual, citing the end of the pandemic, some experts say, launching lawsuits to protect their breakthroughs.

Drugmakers “foresee a game of whack-a-mole for the next few years—new variants pop, they develop new vaccines,” said Chris Morten, deputy director of New York University School of Law’s Technology Law and Policy Clinic.

The Covid-19 vaccine space is “incredibly lucrative,” Morten said, which suggests new patents and higher costs for vaccines, as well as litigation, to protect brand products from generics. “This could be a really busy area,” he said.

IP Hurdles

The World Health Organization, global leaders, and others have made much of the IP hurdles in fighting the pandemic.

Pharma companies and attorneys say vaccine producers are taking steps to meet increasing demand and generally haven’t enforced IP. And drugmakers are teaming up with would-be rivals at an unprecedented rate to produce more vaccines. For example, Johnson & Johnson inked a deal with Merck & Co. to ramp up supply, while Moderna Inc. signed deals with Baxter International Inc. and Catalent Inc. to fill vaccine vials. Sanofi will help make up to 200 million doses of Moderna’s vaccine.

These aren’t “rogue manufacturers—you have the Sanofis and Mercks acting as the contract manufacturers essentially,” said Matthew Howell, an IP attorney at Alston & Bird.

Yet booster shots “definitely could” open the doors to IP litigation a few years down the road, Howell said, as companies continue filing patents around vaccines and related treatments.

Over 1 billion doses have been administered to more than 170 countries, with more than 230 million in the U.S., according to [Bloomberg data](#). Vaccinations are increasing via additional manufacturers entering the market, but at its current rate of around 19 million doses a day, global immunity remains years away.

Vaccine manufacturers have come out strong against the notion that IP is slowing vaccine access. IP attorneys from both J&J and Pfizer said in April that their companies were able to build off existing IP portfolios to produce and distribute vaccines on a global scale.

Yet many see things differently. In the U.S., Sen. Bernie Sanders (I-Vt.) and Democratic lawmakers sent a letter urging the Biden administration to support India and South Africa’s push for the World Trade Organization to temporarily waive some rules around Trade-Related Aspects of Intellectual Property Rights, or TRIPS, during the pandemic.

Doing so, the lawmakers urge, would “allow countries to locally manufacture COVID-19 diagnostics, treatments, and vaccines,” and therefore “expedite access to vaccines and treatment, prevent unnecessary deaths, expedite global vaccination efforts, and facilitate a stronger, faster economic recovery.”

Additionally, over 170 world leaders and Nobel laureates likewise called on the Biden administration to waive IP rules around Covid-19 vaccines.

'Know-How'

Still, many think the power of IP in blocking global vaccine distribution is overblown. Rothwell Figg patent attorney Aydin Harston said the debate may have a "sinister aspect."

Countries that compete with the U.S. in every industry want "the companies that have successfully developed these products for decades" to "give all of their know-how and trade secrets and essentially teach them how to make the products for free immediately," he said.

Sharing IP expertise would require vaccine producers to further strain their own efforts by sending key people to teach other companies how to make the vaccines, Harston said.

"I assume that, for example, Pfizer is out there expending every employee and every resource, and everyone has all hands on deck, working overtime stressed out trying to do everything, just to be able to produce the drug that actually works and give it to people," Harston said. The idea that vaccinations will be sped up by taking these experts away from their critical responsibilities and sending them overseas to "teach you and build facilities" is "ridiculous."

IP is a multifaceted arena for pharma, where things like trade secrets and patents protect various elements of a drug, its creation and use.

Much of the conversation on loosening restrictions has revolved around patent protections. But patents "may be the least significant hurdle" to global vaccine distribution," said Arti Rai, a Duke University law professor.

"A lot depends on whether one is talking about patents, trade secrets of the sort that can be made explicit—and can therefore, for example, be submitted to regulatory authorities—or tacit know-how that even skilled scientists may find difficult to articulate explicitly," Rai said.

Keeping the Secret

Trade secrets, pharma watchers say, are the main obstacle to broader distribution.

"They're what protect these recipes" for vaccines, NYU's Morten said. "As long as the original companies are holding on tightly to their trade secrets, we won't have competition, and we won't have global access. We will have as much supply as the brand companies decide they want us to produce."

Meanwhile, the know-how covered in trade secrets aren't easily replicated.

"The main issue right now is there's just not enough companies out there who can manufacture vaccines. And that's largely driven by trade secrets" and the resources held by more developed countries, Howell said.

Drug companies, too, note that IP isn't the obstacle to spreading vaccines it's made out to be.

J&J's chief patent counsel said at a webinar that an IP waiver wouldn't lead to mass vaccine duplication. "If you were to give everything to everybody, you may see a flood of vaccines, but you would have no idea if they were safe and effective."

Still, many think IP is an obstacle.

"IP creates scarcity. That is indisputable. Drug corporations somehow claim that IP is not important to vaccine production, yet at the same time mobilize armies of lobbyists to fight against efforts at waiving IP," said Rizvi. "We need a coordinated, government-led response to sharing technology that prioritizes public health over concerns about intellectual property."

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