

IP Waiver Talks Hinge On Use Of Big Pharma's Trade Secrets

By **Britain Eakin**

Law360 (May 25, 2021, 6:28 PM EDT) -- As advocates for a World Trade Organization proposal to temporarily waive intellectual property protections for COVID-19 vaccines try to win more support from developed countries, one obstacle to reaching consensus is whether compulsory licenses will require pharmaceutical companies to divulge trade secrets, experts say.

The waiver, proposed in October and updated Tuesday, seeks to lift restrictions on copyrights, industrial designs, patents and trade secrets related to the vaccines and their development, and would allow member countries to make or export their own generic vaccines without fear of facing challenges at the WTO.

Though the U.S. initially opposed it, the Biden administration changed course earlier this month, saying it supports waiving IP protections for the vaccines. Meanwhile, leaders of G-20 countries last week only agreed to voluntary measures to share IP.

As talks to reach an agreement on the waiver proceed, supporters say it will be critical for pharmaceutical companies to disclose the know-how to reproduce the vaccines since those conditions can't be easily replicated, particularly for the mRNA vaccines produced by Pfizer and Moderna. That disclosure could include having pharmaceutical companies providing training, technical assistance, materials and company documents.

However, pharmaceutical companies are unlikely to hand over valuable trade secrets willingly, and it's unclear if they could be forced to under a compulsory license, experts say.

Negotiations over the waiver will very likely hit a snag when it comes to trade secrets, according to Lisa Ferri, global co-chair of Mayer Brown's intellectual property practice.

"I think most of us in the IP field would say it would be unworkable, and I can't imagine member countries being able to agree that companies would be forced to transfer proprietary technology or hand over trade secrets," Ferri said. "And certainly, I can't imagine any mechanism that allows for it. It's something companies would never do, as once a trade secret is shared, it is lost," Ferri said.

The waiver, proposed by South Africa and India and supported by more than 100 other WTO member countries, would specifically suspend four provisions of the 1995 Trade-Related Aspects of Intellectual Property Rights, or TRIPS, agreement requiring WTO members to enact laws protecting IP.

The revised version released Tuesday said the waiver should be in force for three years. While the original version said the waiver should apply to preventing, treating and containing COVID-19, the revised version specified it was targeted at "health products and technologies."

Proponents say it will open up avenues to accelerate production to address the disparity in the global distribution of COVID-19 vaccines. Critics, meanwhile, say the waiver will actually impede speedy and equitable vaccine distribution and will weaken IP rights, and it has been blocked so far by the EU, U.K., Switzerland, Japan and a few others.

Compulsory licenses for patents are already authorized under TRIPS and have been used before during public health emergencies, such as to boost production of AIDS and HIV drugs. But they've never required disclosure of trade secrets.

Pharmaceutical companies are likely worried about the long-term impact of proprietary or trade secret information getting out because that could undermine plans to develop other therapies and vaccines down the line, Ferri told Law360.

Should a waiver go into effect in the U.S., it would likely spur a flurry of lobbying to get it reversed or narrowed, Ferri said. It could also prompt lawsuits under the takings clause of the Fifth Amendment, which requires the government to pay just compensation for seizing private property.

"I think you would see our representatives in Congress being lobbied by the pharmaceutical industry to forcefully reject this," Ferri said. "But in addition, pharma companies will likely file lawsuits, and that could potentially tie this up in courts for a while as well."

Foreign Government Powers

One open question is whether foreign governments could have jurisdiction to force U.S. companies to disclose trade secrets under a compulsory license, according to Jorge L. Contreras, a law professor at the University of Utah and a former WilmerHale partner.

That could be especially tricky if a U.S.-based company doesn't have a presence in a country that wants to issue a compulsory license, since compulsory trade secret disclosure would require a company to take a certain action, such as sending employees to the country for training, Contreras told Law360.

"If a country doesn't have jurisdiction over a pharmaceutical company, it's really hard to make that happen. And there's no way the U.S. will agree to force its own national companies to comply with orders like that," Contreras said.

In countries like China where the vaccine-producing companies have a presence, such as Pfizer, compulsory licenses on trade secrets might be easier to enforce, he said. For example, those governments could impose fines on companies that refuse to comply and seize assets if they refuse to pay up.

But enforcement will be murkier when the companies don't have any assets in the countries issuing compulsory trade secret licenses. "The U.S. government could allow a foreign government to bring a claim in a U.S. court, but that's unlikely," he said.

At the end of the day, Contreras said he thinks for most practical purposes, it "will be impossible" to enforce compulsory licenses on trade secrets.

At the moment, it's unclear what kind of mechanism would allow foreign governments to force an unwilling participant to disclose their trade secrets, according to Snell & Wilmer LLP partner Charles F. Hauff Jr.

Whether U.S. companies would have any recourse if ordered to disclose trade secrets as part of the waiver is another outstanding question. Under U.S. law, Hauff echoed Ferri of Mayer Brown that U.S. companies would be entitled to compensation for an unlawful taking if the U.S. government required them to share trade secrets.

However, it's unlikely pharmaceutical companies could challenge a compulsory license on trade secrets issued by a foreign government, since presumably the TRIPS waiver would remove any legal avenues for such challenges, he said.

"That's one of the troubling things about the discussion and where it's going because it's not entirely clear how it would work," Hauff said.

Brazil Takes the First Step

Brazil could be the first country to lay out a blueprint. Legislation recently passed by the Brazilian Senate would require pharmaceutical companies to disclose all information necessary to make COVID-19 vaccines or risk losing their patent rights or having a patent application denied. The Brazilian House of Representatives still needs to approve the bill, and it remains to be seen whether President Jair Bolsonaro will sign it.

Contreras, the University of Utah law professor, said the move is not entirely out of left field since many governments already have mechanisms to collect trade secrets as part of the regulatory approval process — they've just never been used to force public disclosure of this nature before.

"What would be different about this is that the government, for example of Brazil, would be requiring a company to disclose their trade secrets — not to get its own drug approved, but to help somebody else to go into business," Contreras said.

Some see the Brazilian bill as a mechanism that could ultimately get the job done and could be emulated or potentially incorporated into the TRIPS waiver. Yuan Qiong Hu, policy co-coordinator of the access campaign at Doctors Without Borders, a vocal supporter of the TRIPS waiver, told Law360 that the bill is "brilliant."

Governments and others who funded COVID-19 vaccine research and development missed an opportunity to require companies taking that money to disseminate their know-how, Hu said. The next best thing, she said, is for governments to use regulatory leverage to get compliance from pharmaceutical companies unwilling to divulge the know-how to accelerate COVID-19 vaccine production.

"The Brazilian bill makes a very clear link to the obligation of sharing know-how. I think it's a great design," she said. "In normal times, we don't compel companies to do things unless they misbehave. But for the moment, we need some legal ground."

Meanwhile, Contreras said he'll be keeping a close eye on the Brazilian bill, paying particular attention to what companies will comply with and whether it will ultimately work. If the waiver passes, he said it could encourage other countries to take similar steps. But he suggested the waiver might not be as significant as its critics make it out to be.

"People, particularly in the pharmaceutical industry, try to characterize any weakening of IP rights around the world as a major catastrophe. I don't think that's justified in this case," he said. "The proposed WTO waiver just won't have such a big effect."

--Additional reporting by Ryan Davis, Andrew Karpan and Adam Lidgett. Editing by Philip Shea.