

How COVID-19 Could Shake Up Patent Strategies

By **Ryan Davis**

Law360 (April 6, 2020, 9:26 PM EDT) -- The coronavirus pandemic may spur new thinking about patent issues, as owners of relevant patents face the risk of backlash for asserting them, and companies developing equipment or treatments consider ways to limit potential liability. Here's how attorneys are counseling clients navigating this unprecedented situation.

There has already been public outcry over patents related to COVID-19, and such responses will likely grow in intensity if an effective treatment is seen as being hindered by patents. So companies may have to think about using their patents differently than they normally would, attorneys say.

Even if a company believes its patents are being infringed by someone's potentially lifesaving activities, it will need to consider whether alleging infringement is worth the miserable optics, Charan Brahma of Troutman Sanders LLP said.

"Who wants to be the company known as stopping the cure for the coronavirus pandemic?" he said. "So I think there would be a fair amount of pressure on a patentee, just from public opinion, to not use the full extent of its patent rights and try to negotiate some sort of royalty."

Meanwhile, some companies are trying to confront the pandemic by producing things like masks or ventilators that are outside of their usual area of expertise, and may not be considering infringement risks. However, the unique nature of the pandemic may offer defenses that aren't typically available, Matthew Howell of Alston & Bird LLP said.

"You don't want to be so blind to infringement that you're infringing without having put any thought into it," he said. "But at the same time, what we've counseled clients is that there's a safety net at the end of the day if you do inadvertently infringe someone's IP in your rush to get important medical equipment out the door."

Risks for Patent Holders

In March, two companies came under public scrutiny for their coronavirus-related actions. First, a company that acquired patents from disgraced medical testing company Theranos sparked an outcry after it sued a company developing COVID-19 tests, leading it to pledge to offer **royalty-free licenses** for pandemic-related uses.

Later, Gilead Sciences **abandoned its bid** for "orphan drug" status for an experimental COVID-19 treatment, which could have provided it with seven years of exclusivity on sales and tax credits, after critics accused it of trying to profit off the pandemic.

While those situations involved some unique factors, the backlash did "raise concern for companies with IP in this space about what the public perception would be if they enforce it," Rachel Elsby of Akin Gump Strauss Hauer & Feld LLP said.

"Most companies are thinking differently right now than they were six months ago," Patrick Gallagher of Duane Morris LLP said. "I would think there would definitely be hesitancy around pursuing [an infringement case] right now."

Those concerns might extend beyond testing and pharmaceutical companies to those with patents

tied to the pandemic response, like masks or ventilators. Attorneys said companies will have to consider the public relations impact of their patents in ways they might not have two months ago.

"No one wants to be seen as the big bad wolf who's trying to keep their ventilator prices up while other people are trying to help," Howell said. "So that's certainly a huge issue."

The furious nationwide push to stem the tide of the pandemic might force patent holders to think about their priorities differently, he said.

"With the COVID-19 response, we want products to come out as quickly as possible, so in this case, it's probably better that IP rights take a backseat to helping out society," Howell said.

Some companies, such as nonpracticing entities without a public reputation to risk, might still go ahead with infringement suits related to the pandemic. However, any action that could be seen as hindering the crisis response is likely to face heightened scrutiny by judges, who might not be inclined to find infringement or impose injunctions.

"Judges, of course, are all human and they're going to look at the situation and understand that, obviously, this is unprecedented within our lifetimes," Mark Scott of Dickinson Wright PLLC said. "So will the judge treat this situation differently? I would have to think that the answer to that is, yes, even if unconsciously."

One way to handle patent rights during the pandemic is for companies to think about partnering with companies they might otherwise have targeted with infringement allegations, or consider offering royalty rates lower than what they would seek in ordinary times.

At this point, most companies with patents that could be useful in the pandemic aren't really thinking about "building up the walls to exclude other people," Elsbey said, and they may be more willing to license their technology to others, rather than pursuing enforcement.

"Companies will be coming together in ways that are very different from what you see in a nonemergency scenario, where a company might be happy to go it alone or work with one partner," she said. "I think now you're seeing doors open up, where people are willing to work together and try to find a solution."

Risks for Potential Defendants

While patent holders might be reluctant to pursue infringement suits during the pandemic, that doesn't mean companies can just ignore patents.

Howell said he's talked to clients who want to help with the pandemic response by making products outside of their field, and has found that some are surprised when he's mentioned that their work could potentially infringe patents.

"They just wanted to do their civic duty and try to help out any way they can, and for many of them, IP isn't even on the forefront of their minds," he said.

Even though companies may be in a rush to produce masks, ventilators, testing kits or other equipment related to the pandemic, they should still make some effort to ensure they're not infringing.

"Certainly, there is IP involved and it's relevant," Elsbey said. "So looking at licensing and doing your diligence is really what is most important right now, and there's kind of a new urgency and deliberateness to the diligence that's involved."

Even companies can't do the more involved freedom-to-operate patent searches they would normally do, some review of the patents in the space "does give you some comfort that you're not walking directly into infringement on an easy-to-spot issue," Howell said.

He added that if the search does turn something up, it may be worth approaching the patent holder to explain the situation and "see if they might agree to some sort of limited license that would just

cover this emergency period."

Companies involved in the pandemic response can also look at their potential defenses to infringement, not all of which may be available during normal times.

For instance, companies working on treatments or vaccines for COVID-19 are likely shielded by the safe harbor provision of the Hatch-Waxman Act, which holds that testing, clinical trials and other activities required to obtain U.S. Food and Drug Administration approval do not create patent infringement liability.

"To the extent that there is talk right now about companies enforcing patents against people trying to develop treatments, that's really kind of premature," Brahma said. "It's really only after that application has been filed with the FDA that a patentee would have a claim for infringement."

In addition, the U.S. government has issued an emergency declaration under the Public Readiness and Emergency Preparedness Act, providing immunity from liability for claims of loss related to medical treatment for COVID-19.

"Traditionally, that's thought of in the context of product liability, but that immunity may apply to IP liability," Gallagher said.

Finally, the federal government has some rarely used powers to **override patents**, and if all else fails, a company facing infringement allegations due to its pandemic response might consider asking federal officials to invoke them. That would likely be a long shot, but there's a chance the government would be responsive if patents are seen as an obstacle to curbing the pandemic, Howell said.

"There is some comfort if you really are making masks or ventilators or something that really is a critical health need, then there's at least a mechanism there," he said.

While there's no guarantee that companies involved in combating the crisis will prevail if they end up in a patent dispute, they're likely to be viewed more sympathetically than the average patent defendant, Scott said.

In a close case, it's likely that "things are going to fall in your favor as someone or some entity that was doing everything they could to provide some kind of services to help with the pandemic," he said.

--Editing by Breda Lund and Alanna Weissman.