

Skilled in the Art: Q&A: Do Patents Have a Place With COVID-19?

By Scott Graham

Welcome to **Skilled in the Art**. I'm Law.com IP reporter **Scott Graham**. As the world searches for vaccines, treatments and diagnostics for COVID-19, I'm hearing a lot of questions about the role of patents. Are they getting in the way of solutions? Inspiring them? Can the government commandeered patented technology if it's in the national interest? **Drs. Jonas Salk and Albert Sabin** famously passed on the opportunity to patent their polio vaccines (though there's some debate today as to the patentability of the Salk vaccine). Is it conceivable that a COVID-19 breakthrough would likewise be gifted to the public? I'm convening a roundtable of IP experts to address these questions. In keeping with the times, we're doing it virtually.

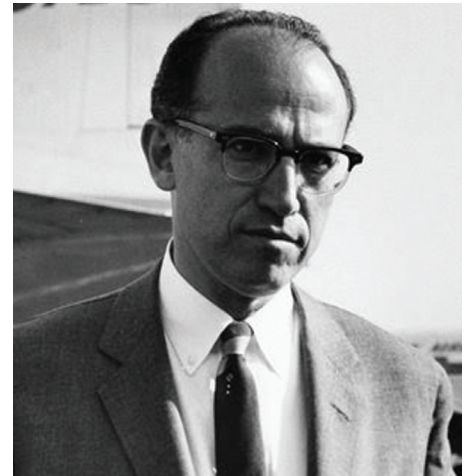
Q. Is it reasonable to expect companies, universities or research organizations that develop an effective test, vaccine or treatment for COVID-19 to try to patent it?

Todd Dickinson, senior partner at Polsinelli and former USPTO director: The short answer is "yes" if what you're asking is "Can they be patented?" There are many patents on all of these technology categories.

If what you're asking is should they, i.e. is it reasonable to seek patents on these, the answer is still mostly yes. The primary purpose of the patent system for the public is the public disclosure function, allowing others to build on the patented technology. That's what would happen here, avoid the company from keeping the manufacturing technology in particular as a trade secret.

Also, to invent/discover, develop, test and get regulatory approvals for many if not most of these technologies, especially under the time criticality that's being discussed, is going to be a very expensive, resource intensive proposition. Generally speaking, the owners or shareholders of the technologies likely have a reasonable expectation that they might get some return on their investment here.

Kassie Helm, partner at Dechert: Is it reasonable? Heck yeah. Patent laws exist to spur innovation. Companies are rising to meet the challenge of developing tests, vaccines and treatments because of the patent system, not in spite of it. The patent system is just as relevant in a crisis to encourage companies to innovate. Companies are currently seeking patent protection



Dr. Jonas Salk (Photo: SAS)

on COVID-19 therapeutics, vaccines, diagnostics, but also kits and assays to identify infection in the immediate term and other tools to address the virus downstream and in the longer term, both for this pandemic and the next.

The patent system provides incentives to keep developing and making the economic investments necessary to create and develop these tools. We have the most advanced, most robust and most innovative medical and healthcare system in the world. That is due to the incentives our patent system has created to reward invention and encourage translation of scientific breakthroughs into clinically significant

products. This global pandemic should remind policymakers that we need to correctly incentivize innovation in all areas of disease identification, treatment and management.

Q. If patents are obtained, would it be reasonable to use them to exclude others from making available infringing tests, vaccines or treatments?

Todd Dickinson: That's as much a corporate ethics and public relations/reputational question as much as a legal one. There would be very likely a lot of public and governmental pressure to either license or dedicate to the public, and the owners might either bow to the pressure or get out in front of it by preemptively announcing what they would do.

A recent example of how this plays out in reality is the dispute between **Gilead Sciences** and the government over the patents both in their name and the government's on their PreP patents for the prophylactic use of preventing the transmission of HIV/AIDS. After protests and jawboning, Gilead fairly quickly dramatically reduced the cost, including donating millions of dosages for free.

Kassie Helm: That would be reasonable, too. But it assumes a fact not in evidence—that the companies, research institutions, etc. would actually exclude instead of licensing and partnering with others to also market tests and treatments. We are seeing more partnerships and collaborations than ever, to assist early stage research and hospitals with access to patients with big pharma that has the rapid development, manufacturing and distribution capabilities.

Pharma companies have already partnered with biotechs and the U.S. government to gain access to recovered

COVID patients, and have screened immune cells, found panels of functional antibodies and are now trying to narrow them down to effective numbers of neutralizing antibodies, to find a cocktail antibody therapeutic. This is happening in real time.

For testing specifically, we have to give credit to our clients who are doing the “right” thing and making available otherwise infringing tests for public use in this time of need. I have to offer a shout out to **Eli Lilly** for its leadership here. Lilly is offering the use of their vast resources and research labs for free to analyze samples from hospitals and ERs.

Mark Lemley, Stanford law professor and Durie Tangri partner: I think there are two sets of things to think about:

1) Existing patents and other IP rights. Here I would expect there to be assertions, like the one we saw this week by Fortress, but there may be enough pushback that they end up granting royalty-free licenses as Fortress ultimately did. I am working with an ad hoc non-profit group right now to draft an open commitment not to assert existing IP against those who do testing or research. But once there is a cure or vaccine, if it implicates existing IP (say, if it uses a current drug) I would expect the patent owner to capitalize on that. Notably Israel announced [Wednesday] that they were breaking a patent on an HIV drug to allow it to be imported for COVID-19 treatment. The U.S. threatened to do something similar with Cipro after the 2001 anthrax attacks, and Bayer promptly agreed to more reasonable licensing terms.

2) New patents on things developed

in response to the pandemic. There I expect companies to be patenting like mad, but none of those patents will affect treatment in the current pandemic. They will be relevant five years from now as suits for damages and perhaps as ongoing treatment or control of the virus if it continues to spread or mutate.

A big-firm IP litigator who prefers to remain anonymous: I think the prevailing view is that it will be perfectly appropriate to patent a new COVID-19 test, vaccine, or treatment, and that companies will aggressively do so. That will allow them to demand a reasonable ROI, and to get license fees from companies that release generic versions of the drug.

But I do NOT think companies are going to use their patents to exclude others from releasing COVID-19 drugs. Not only would they get terrible press and badwill, but they would have no realistic chance of securing an injunction, since an injunction cannot issue under *eBay [v. MercExchange]* if the public interest is against it. Unless the patentee had plenty of capacity to supply the entire population, at an accessible price, I think just about any court would deny an injunction. And I don't think the innovator will try to demand super-high licensing fees—they will ask for modest fees and try to make money on volume.

Q. Could Jonas Salk or Albert Sabin have gifted their polio vaccines to the public if they'd been doing their research in the year 2020?

Alan Fisch, partner at Fisch Sigler: Reports about both teach that their motivation was helping humanity and scientific acclaim, not economic achievement. In keeping with that, announcing the vaccine and then affir-

matively rejecting patent protection allowed others to immediately and continuously manufacture and distribute the vaccine without economic fear—accelerating what was already an enormous demand, and solidifying their position as ground-breaking scientists.

If there's a COVID-19 researcher who shares Drs. Salk's or Sabin's motivations, they too may be able to gift to the public as they did. But Salk and Sabin also had the advantage of having a large voice in their commercialization process. Times have shifted and individual researchers seldom have that decision-making power, and the institutions that fund the research will assuredly have an interest in at least recapturing the costs associated with finding the one solution from the hundreds or thousands developed and tested. And shareholders will have a legitimate economic interest in capturing the full economic value of the discovery.

Todd Dickinson: Regarding Jonas Salk, even though he did his work at my alma mater, University of Pittsburgh, he may or may not have been as charitable as he made it out to be. I believe the rumor has been that his patent lawyers never filed on the basic inventions, because they may not have patentable in the first place.

As for his personal view, you may want to look at some of these patents, listing him as an inventor.

Not to belabor the point [about pandemic-fighting drugs], look what you get when, for example, you search the

USPTO website for "H1N1" and "vaccine."

Q. Given the extremely fast track that tests, vaccines and treatment are on today, will the patent system be able to move quickly enough to provide patent protection in time for marketing?

Kassie Helm: Vaccines are probably 18 months or so from approval. Track 1 applications at the USPTO could be granted in that time frame. Test kits would probably be on the market before patents issue. But improved and second generation kits could likely be patent protected before launch.

Therapeutics, if new chemical entities, are probably slightly faster than vaccines in terms of the time to get to market but not by much. Repurposed drugs might have somewhat faster approval, although initial results are not great.

There has been talk of instituting an even faster track for COVID applications at the PTO, which seems highly unlikely. Not only could it be subject to abuse, but the PTO does not have enough resources to expedite the flood of applications in this area, particularly as companies screen and file on off-the-shelf molecules.

Todd Dickinson: There are a number of ways to accelerate the prosecution of the patent, most easily by paying a fee. It's likely they would seriously consider doing this, although having the patent actually issue is only important if they are going to license or sell. They might try to actually delay prosecution so competitors don't see their work early. How-

ever, they will be published at 18 months for all to see in any event.

Q. If an effective test, vaccine or drug is developed, how likely is the scenario where the government takes the relevant patents and then provides just compensation?

Kassie Helm: This seems highly unlikely. Public pressure alone would likely result in patentees permitting market access to patents claiming kits, vaccines or therapeutics. But supply and demand will play a part. If the owner of the patent can supply the market at a reasonable price, there would be less pressure to license broadly.

Q. How else might bio/pharma companies strike a balance?

Alan Fisch: Pressures will come from all sides, but breakthrough pharma history shows that economics will be where the brightest lines exist. One substantial example of that is found in the economies of developed and developing nations. Already pharma pricing differs between such countries, a by-product of how those two groups differently treat patent protection for pharmaceuticals. That won't change here.

So we should expect that inventors of a COVID-19 vaccine would have little prospect of selling their product for a profit in the developing world. Now some may ask: "Why not give away the vaccine in those areas?" And one company working on a vaccine has already made such a commitment. **Greffex** has said that if its vaccine obtains United States government approval, it'll give it away to certain developing countries.