

Looking Back on Vaccine Deal-making in a Global Pandemic

Intellectual Property



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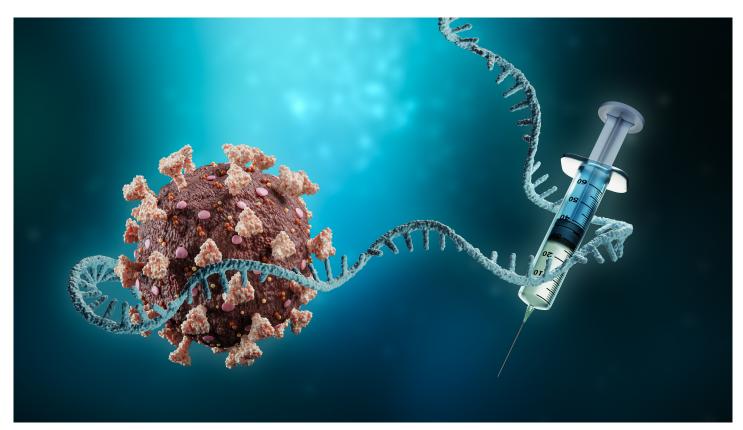
It has been three years since the COVID pandemic changed the way we work. The Docket is conducting interviews with in-house counsel whose jobs changed dramatically because of the pandemic. If you or your legal team has a story to share, email docket@acc.com or submit a draft or proposal through the submission portal.

This interview, which took place in September 2021, describes the challenges faced by corporate counsel in the days leading up to Moderna's successful COVID vaccine rollout.

Prof. Dahl: What kinds of deals need to be done between developing a vaccine and distribution?

Kahlil Mitchell: First, getting the enzymes to make the vaccine — all those chemicals and lipids and things that go into the vaccine. So that's the first thing — the supply agreements to get the raw materials in.

And then also different parts of the vaccine — some of the plasmids, the mRNA constructs as they're called — they had to be scaled up, and we work with different partners throughout the world to help us with that process. And then from there also, once we had all the stuff in the vaccines made, then another company would help us do what's called fill finish — getting it into sterile vials, capped and ready to go.



A collective effort was made from various companies to develop the moderna vaccine, including supplying mRNA. MattLphotography / Shutterstock.com

So really those were the main agreements I saw; I'm sure there were dozens of others; as our legal team grew there were other things happening, for sure. But that was the part of the process that I was working on.

Prof. Dahl: In the beginning, you were thinking about these deals prospectively since the vaccine wasn't finished. Did that affect your approach?

Kahlil Mitchell: That was the scary part of it — that we couldn't be sure we'd have a vaccine. I have to be honest; my gut was always positive. I always had a feeling that things were going to work out.

And then as the phase one and phase two data were released, it was just so incredibly encouraging. I heard the phrase that we were sort of building the plane as we were flying it.

And then as the phase one and phase two data were released, it was just so incredibly encouraging. I heard the phrase that we were sort of building the plane as we were flying it.

Team members constantly needed to alter the direction of their tracks while administering the COVID-19 moderna vaccine. Volodimir Zozulinskyi / Shutterstock.com

It was like we were all on this train speeding very fast down a hill and we constantly had to pivot and do other things and change the direction of the tracks, and while we were always moving ahead down the hill, we were definitely laying out the tracks just as things kind of happened.

Prof. Dahl: You were competing for limited resources against other companies that were just as confident that they were going to come up with the solution as you were. How did you convince your partners at the table that they should sign *your* deal?

Kahlil Mitchell: That wasn't the easiest thing. Because at this point, we were much smaller. People definitely hadn't heard of us the way they have today. And the sense of urgency.

And the supply chain throughout the United States and probably throughout the world was just a mess. There were shortages of supply, not just because we have a bunch of companies now buying up vials and trying to get stuff to make medicine.

People were out of work because plants were shut down, everything was shut down. All of that stuff that goes into our general supply chain was hard to get.

So how did we convince our partners? I mean, it was certainly helpful that we were able to pay. We did get government funding, which, together with private investment put us in the position to have the resources for people to take us seriously. But as the data came out, it was much clearer that, OK, they should be pretty secure with Moderna — at least I hope that's what happened.

Prof. Dahl: What was it like to build a team and do these deals when no one could meet in person?

Kahlil Mitchell: I think, believe it or not, I think it was actually somewhat easier in some respects because people were just sort of always available.

Everyone was home. Everyone was always working. I think the work-life balance wasn't as difficult as it would have been going into the office every day.

I could stop and have lunch with my son, which was fantastic. There was a lot of benefit to that. Yeah, it was scary. We were shut down. We couldn't see people. But the fact that I got to eat lunch with my son helped, whereas if we were in-person, I think it would have been a lot of time away from my family. And then, also the technology's better these days.

I think the fact that people were all in the same boat; it just worked.

Prof. Dahl: Were you able to close deals better just because of the circumstances?

Kahlil Mitchell: Yeah, that's such a great question, because I witnessed sort of an evolution of negotiating. In regular times, you can go back and forth over an "and" or an "or" or something that's pretty meaningless.

And at the beginning of everything, it was still difficult. The folks on the other side of the table were trying to get us to commit to several years out. So that's just a tremendous amount of risk. The vaccine wasn't on the shelf yet. Who knows what's going to happen?

But we were in a spot where we needed them, and they knew that. And I think they were trying to get a little something extra there. And we started negotiating that, and I was sort of just listening in the

background.

And then I just got angry. I just thought about the fact that we're trapped inside, and we can't see family. I stopped the call. I said, "This is it. We're not going down this road. Do you guys realize we're in the middle of a pandemic? Why are we talking about years down the road right now? Let's negotiate what's in front of us."



Through negotiating, a consensus was made to start distributing vaccines to the public. rudall30/ Shutterstock.com

That snapped people out of it. Then data came out. Things were looking good, and more and more, as we would negotiate, it got easier. I remember getting off of a call once and the other team said, "Look, we're rooting for you. We want this to go well." And that was probably one of the happiest moments where I really realized that we were doing something pretty important.

Prof. Dahl: Let me pivot and talk about working in a scientific company. How does the legal department keep on top of the science so that you know what the company needs in order to produce an innovation like this vaccine?

Kahlil Mitchell: It's really been helpful to lean on my colleagues. I'm fortunate to work with some of the best scientific minds out there and I can pick up the phone and say, "Hey, can you explain this a little bit like, how are we going to use this material that we're getting?"

In that way, it can put things into the appropriate light where they can explain how it's used, in what

part of the process it's in, so I can really assess the risk better. If it weren't for that, you almost don't know what you're negotiating unless you can picture where it is in the process and how that the stuff is used, or how we're intending to use it.

So that's been a great help, just having colleagues who can deal with my annoying questions and explain things.

But the neat trick about a patent is that to get the monopoly protection you've got to enable someone to make and use the invention and you've got to disclose the best mode, for the most part.



Patents allow room for others to be creative

and promotes revolution. Teguh Jati Prasetyo / Shutterstock.com

Prof. Dahl: Let me ask you because I'm a patent geek; did patents play a role in developing your innovation at Moderna?

Kahlil Mitchell: When I first went to law school, I didn't think, "Oh, I'm going to do deals." I always thought, "I'm going to protect science."

Science was important to me. I used to work in a lab myself for a little while after my undergrad. And I thought of it from the mindset of like, OK, how are we going to get people to talk about their inventions? How are you going to get people to disclose them and share? And how are we going to get seed money for a great idea?

That's incredibly important in science, in getting science out on the market. I think when people think about companies that patent, they might think that they are greedy because they want everything for themselves. But the neat trick about a patent is that to get the monopoly protection you've got to enable someone to make and use the invention and you've got to disclose the best mode, for the most part.

We stand on the shoulders of giants, like all this stuff that came before us is laid out there for us to build off of or engineer around, maybe make something better. I really think as much as people say it's not fair to grant a monopoly through patent, it's actually really helpful because I think patenting really spurs additional innovation and keeps things from staying behind closed doors all the time.

Prof. Dahl: Relatedly, what do you think is the government's role in incentivizing innovation like the vaccine?

Kahlil Mitchell: It's nothing new — the Bayh-Dole Act allowed universities to be able to incentivize their scientists and get products out to the market and continue to own the technology. That's been around since the early '80s, and it has been very instrumental in terms of getting products into the market. It's not by any means new that the government's been involved.



The government played a significant role in boosting the COVID-19 vaccine. Blue Planet Studio / Shutterstock.com

Prof. Dahl: Let's consider some takeaways. Has it slowed down at Moderna now?

Kahlil Mitchell: I thought if you would have asked me this question in early 2021 and said to me, "Hey, in 2022, what are things going to be like? Are they going to be completely different and slowed down?" I would have been like, "Oh God, I hope so. Yeah."

And it's funny. We're kind of moving as fast as ever, really. I'm not speaking on behalf of the company right now, but I think this was a testing ground for what we're able to do. I don't think we're done. I think there's a lot left to do for science, generally. And I think Moderna is uniquely positioned to do that.

But the neat trick about a patent is that to get the monopoly protection you've got to enable someone to make and use the invention and you've got to disclose the best mode, for the most part.

And that's the thing that I love about where I work. It's just the fact that I know there's going to be so much more. It's going to be helping out, conquering a different disease or a different problem. I know the leadership is very focused on moving forward and continuing to expand the program and to really deliver benefit to patients.

Prof. Dahl: You went to Moderna in August of 2019 and lived through this incredible passage. Would you do it again? And if you would, what would you whisper to yourself in July of 2019?

Kahlil Mitchell: I would definitely do it again. I'll look back on this when I'm kind of in my twilight and fading out in the world, and this will be one of the things that I always remember.

Yeah, I would do this again in a heartbeat. When I started, when I joined Moderna, I remember having a conversation with my sister and just saying, "I really think this company can change medicine. I'm super excited about it."

When I started, when I joined Moderna, I remember having a conversation with my sister and just saying, "I really think this company can change medicine. I'm super excited about it."

What would I tell myself? I'd probably say trust your gut, your gut's right. Just stay confident; stay in the process. It'll work out; you're going to have the vaccine in your arm that you're working to get out right now. That would have been a cool thing to hear myself say.

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Khalil Mitchell is an experienced legal counsel with a demonstrated history of working in the resear industry. Skilled in life sciences, contractual agreements, patent law, intellectual property, and licensing and privacy. Mitchell is a strong legal professional with a law degree from Northeastern University School of Law.	ch