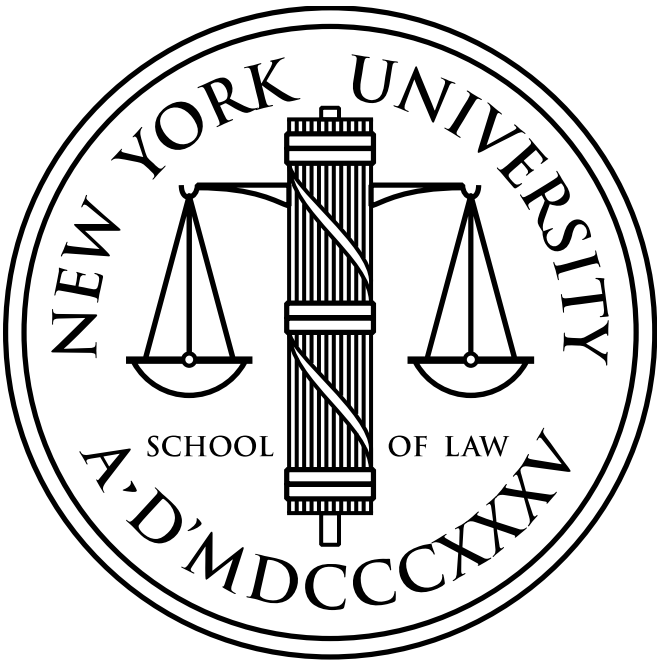


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SHOULD THE U.S. GOVERNMENT ACTIVELY ASSERT ITS OWN PATENTS?

MODERATOR: CHRISTOPHER MORTEN

PANELISTS: BARRY DATLOF, AMY KAPCZYNSKI, DONNA MEUTH, AND ZAIN RIZVI

On March 10, 2021, our journal partnered with the Engelberg Center on Innovation Law and Policy to host a symposium addressing the role and impact of U.S. innovation policy on access to medicine. Our 2021 Symposium Issue—Volume 11, Issue 1—captures that event.[*]

The following article represents the second of four panels. This panel asked, "Should the U.S. government actively assert its own patents?" The panel was moderated by Christopher Morten, Deputy Director of NYU Law's Technology Law & Policy Clinic. The panelists included Barry Datlof, Chief of Business Development and Commercialization in the Office of Medical Technology Transfer at the U.S. Army Medical Research and Development Command, Professor Amy Kapczynski of Yale Law School, Donna Meuth, Associate General Counsel and Lead Attorney of the U.S. Intellectual Property Department of Eisai, and Zain Rizvi, a policy researcher at Public Citizen who focuses on pharmaceutical innovation and access to medicines.

CHRIS MORTEN: The focus of this second panel is on a single question, which is: "Should the U.S. government actively assert its own patents?" The question is timely and important. As Lisa mentioned at the outset of the last panel,

[*] This transcript was modified for editorial purposes. A recording of the panel is available at NYU Journal of Intell. Property & Entertainment Law, *2021 JIPEL Symposium - Access to Medicine: The Role and Impact of U.S. Innovation Policy (Panel 2)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=nDzqa-CXtK4.

it's a minority of drugs on which the U.S. government holds relevant patents. Nonetheless, the U.S. government does hold a large and important patent portfolio.

The U.S. government has long voluntarily licensed its patent portfolio to transfer technology out of government labs and into the private sector. But there are some recent signs that the government may become more assertive with its patents. For example, in November 2019, HHS and the Department of Justice brought a patent infringement lawsuit against the drug company Gilead alleging infringement of government-owned patents on HIV prevention (HIV PrEP) and seeking potentially billions of dollars in damages.[1] Amy Kapczynski and I advocated that suit alongside the HIV/AIDS advocacy group PrEP4All earlier in 2019. More recently, news outlets have reported that the National Institutes of Health (NIH) owns patents on COVID-19 vaccines, which the NIH could conceivably assert against vaccine manufacturers like Moderna to recoup public investment in vaccine R&D or perhaps to coax vaccine manufacturers to share their know-how with the U.S. government or with competitor manufacturers.[2]

We are very lucky to have four eminent panelists with us today to discuss these issues. I've asked each panelist to begin with brief opening remarks. I'll ask Barry to kick us off. Barry, the floor is yours.

BARRY DATLOF: Great. Thank you. As noted in the previous discussion, the model of healthcare in the U.S. seems to have a division between HHS and DoD. We do work on many of the same problems, but what I'd like to talk about today is a little bit of what the DoD bent is, which is to protect the warfighter and bio-defense. We have a phrase for what we do: "Assistive Technology Transfer." The goal really is to get the technology into a product. It's not about patents; it's not about royalties; it's "how do we field a solution for the warfighter?"

I'll provide a little bit of background because we frequently don't think of DoD as a source of health solutions. But if you look at some of the history of just about every vaccine ever developed, it had some component of DoD in it, in part because infectious diseases are a worldwide problem which tends to unfortunately cross borders even easier today in airplanes. But our primary goal is bio-defense and keeping the warfighter safe. We're located worldwide; we do clinical trials worldwide; we have a lot of expertise in tropical disease medicine. So, things that

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[1] *See* United States v. Gilead Scis., Inc., 515 F. Supp. 3d 241 (D. Del. 2021).

[2] *See, e.g.*, Bob Herman, *The NIH Claims Joint Ownership of Moderna's Coronavirus Vaccine*, AXIOS (June 25, 2020), https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html.

affect other parts of the world also affect the warfighter, who is stationed there and is a primary focus of some of our research.

In addition to vaccines and therapeutics, which will be talked about extensively throughout today, just having a good diagnostic (that works), medical devices, and increasingly the medical IT to be able to identify when, where, and how we can intervene have become increasingly important. Historically, the tech transfer office at NIH, at NYU, everywhere focused on patents and licensing. We'd like to believe that there's a better way to phrase it. If our emphasis is on a product fielding a product, then everything that happens before and after licensing is important, contributory, and something that we both can and should be involved in. That's not always possible in all institutions. Some just do basic research; some just do applied research; some just do fielding.

One of the benefits of the model of healthcare that the DoD leverages is this full-lifecycle capability. We actually benefit from that because we see a need, we fill a need, but we also know exactly what we need in order to accomplish that. Some of the speakers before talked about, in essence, "the Valley of Death." Phase One clinical trials and healthcare are really expenses that angel investors and venture capitalists don't want to pay for. And so we have a great emphasis on trying to bridge that, in collaboration with many of our economic development partners, such as Maryland TEDCO. This is critical if we're going to ask the government to step outside of basic research and actually push further towards the product side of life.

We have a lot of tech transfer mechanisms; I won't belabor them today. We also have a lot of funding sources that are not traditional. People don't know about them or think about them. These are all available to us through our website.

Lastly, I'm a marketer, so I always brand because I think that it is important for everybody to be able to recognize whether that vaccine is Moderna or Pfizer, whether the source is the U.S. government or another government. We're always looking to solidify "who do you go to when you have something new, and you say, 'Hm. Is that NIAID or NCI?'" Building a brand is a critical element in our world. And I'll stop there, Chris.

CHRIS MORTEN: Great. I'll turn next to Amy for her opening remarks.

AMY KAPCZYNSKI: Great. Thanks so much and really a pleasure to be here. Thanks to the student team who worked so hard to make this happen.

I wanted to talk a little bit more abstractly to start. The question that is the headline of this panel is "Should the U.S. government actively assert its own

patents?" So, the first question is, I think, what should be our goal? What should be the goal of the U.S. government as it's thinking about managing its patent portfolio? One piece of that is product development. That's what Barry was just talking about. But there's another piece of this, which is about the government's role as the entity that exists in part to ensure that medicines are available to all those who need them. Particularly with something like infectious disease, we need access to technologies as quickly as possible. We see that with COVID; we've seen it with hepatitis C; and we've seen it with PrEP. Particularly with infectious diseases, access makes a huge difference because it affects the course of the disease and communication dynamics.

I think our goal in answering this question—What should the government do?—is to speak to how the government can use its own patents to meet this broader goal: affordable access to medicines, diagnostics, and vaccines for all who need them (especially with infectious disease) as fast as possible. So, what role can U.S. patents play in this? Well, one really interesting thing about U.S. patents, where they exist, is that they can provide leverage for the U.S. government to work toward that goal. If the U.S. government holds a patent that is necessary to a technology that's in use in the world, there's a licensing negotiation that has to happen for that technology to be exploited. And that licensing negotiation can be an avenue for setting out a set of public-facing priorities.

If we were to talk about the COVID vaccines, we have some really superb results, focusing on the mRNA vaccines from Moderna and Pfizer for the moment. It's pretty clear, though, that we need much more scaling up of production in the U.S. and around the world. One could, in theory, use patents that are held by a government entity, the U.S., and also abroad as part of a broader negotiation to achieve those goals. Within that negotiation could be things about know-how transfer, things about cross licensing, things about production targets, things about price—all of that could be folded into licensing negotiations.

The advantage, in fact, of a licensing negotiation strategy is that it's ex post. For different diseases and different technologies, there are going to be different issues. For example, with PrEP (the pre-exposure prophylaxis for HIV), the issue was less about supply constraints than about the price. The price meant that we couldn't scale up to meet the needs, particularly of vulnerable communities at risk of HIV. So there, your licensing strategy would target something other than supply.

There may be issues. Think about foundational research technologies—something like CRISPR—where, in fact, the issue is research barriers. The government would want to navigate licensing its technology in a way that ensures that research was happening in the right way.

Why use patents this way? Why not instead use something like fair pricing legislation? Why this technique? I think we do need things like fair pricing legislation more broadly. (This technique, of course, will only implicate where the government holds patents.) But we're not there yet. In the meantime, government patents can play a positive role and solve real problems in the short run. Another thing is that the problem isn't always price. So, to have these ex post, tailorable solutions to problems can be useful.

Also, I think we should talk a little bit about other strategies beyond patent negotiations, which will be coming up throughout the day, like Section 1498.[3] I think in our discussion, government patent use provides another avenue where the government can address multiple kinds of problems. The Defense Production Act can also be used.[4] Some of those techniques, particularly the Defense Production Act, are not going to be in play in the ordinary course of activities. Those are in play right now. But, in the ordinary course of activities, if the government holds a patent, they can still leverage that patent to say, "We'd like know-how exchange," for example. Some of the other tools that we have, like the Defense Production Act, are going to be limited to emergencies of a kind that we're now in. I think of it as a very flexible tool. It's sometimes additive to other tools that are out there, but in general, additive tools can be beneficial because they can allow different players to play a role, and they can be used conjunctively to try to achieve these same goals.

CHRIS MORTEN: Thanks, Amy. I'll turn next to Donna.

DONNA MEUTH: Thanks, Chris. First, thanks to NYU and to all the organizers of this conference. It looks to be an exciting and very interesting afternoon. Thank you all for including me in the program as well. Secondly, I just want to give my disclaimer that the views that I'll discuss are my own personal views and are not the views of Eisai.[5]

In looking at the topic—Should the U.S. government actively assert its own patents?—and looking at the two cases that we've identified with Gilead and the Moderna vaccine, I think it's a difficult question. From the public record, it looks like the government had some prior partnerships with industry. So, in cases such as this, for the government to assert IP relating to prior partnerships, I think that's a difficult question. The answer to that may be tied to the facts. What was that

[3] *See* 28 U.S.C. § 1498.
[4] *See* Defense Production Act of 1950, 50 U.S.C. §§ 4501-68.
[5] Eisai Co., Ltd.

relationship? What was the research that was done under that agreement under that relationship? What do the terms of the agreement that govern that research state?

Drug development is a long and expensive process. On average, pharmaceutical companies spend $2.6 billion to bring a drug to market, and it takes more than a decade of work. For that investment, drug companies need to have some certainty that they can bring the product to market after putting that investment in, if the product is approved. In looking at partners to work with during this long process, companies have a choice. Do we do the work ourselves? Do we hire a contract research organization (CRO) to do the work? Or do we enter into a partnership with another company, with an academic institution, or with a government entity for collaboration? These options are viewed through many lenses, both legal and scientific.

On the legal side, we look at what the terms of the agreement will be. If IP is likely, who will own it and, depending upon who owns it, are there licenses in place that will protect the investment that's put into the partnership? And will those licenses be exclusive or non-exclusive? There's a lot of legal questions that come into play as you look at how you want to do the work that will lead to a pharmaceutical product.

There's also the scientific questions. Scientifically, we look at whether the investigator to partner with is a leader in the field. Can they offer some sort of expertise that we don't have in-house? What will the economics of the partnership be? Does a potential partner have something that we don't have internally—for example, a particular assay, or access to a certain patient population, or biomarkers? Do they have something that we can't get otherwise? And, will the partner help expedite the timeline to determine whether or not a candidate can become a drug product? So, there are a lot of factors that are built into the question of whether we do partnerships and with whom do we do those partnerships.

If, as a result of the government enforcing their IP, that impacts how the partnerships with the government are looked at, does that become a risk? Is it too risky to work with the government because there's the potential that, at the end of the road, there will be IP asserted against us? I think you have to look at it with that lens. Actions by the government will have consequences. Companies may not look at particular indications because they can't get access to the assays or to the patient population that they need. It may take a lot longer to get to a vaccine product in the next pandemic if there's uncertainty, and that uncertainty creates a willingness not to work with the government. I think those consequences need to be considered as we look at this question. Thank you.

CHRIS MORTEN: Great. Thanks, Donna. These opening remarks are sparking lots of questions for me, but I want to give Zain a chance to give his opening remarks, and then we'll pose a question to the panel.

ZAIN RIZVI: Thanks, Chris.

I thought I'd just do a descriptive overview of where we're at. I'll share some of the process as well, because I think it's illustrative and instructive on how difficult it can be to figure out what is going on with U.S. government patents and U.S. government rights.

So, this is SARS-CoV-2: the coronavirus.

[Image of the coronavirus appears on screen.]

One reason it's called the coronavirus is because when you look at it under an electron microscope, you see that there's little crowns. The crowns come from the spikes. With coronaviruses in general—the latest coronavirus and previous coronaviruses, like MERS and SARS—the spike protein is considered a good antigen. It's considered a good target for producing antibody responses. But the problem is that the spike protein is also inherently unstable. So, if you just introduced a wild-type spike protein into a cell, it quickly changes shape. It goes into its post-fusion spike. The pre-fusion spike is actually much superior for producing antibody responses. This is something that the NIH found out many years ago. They invented a way to stabilize the spike protein so that you can retain the pre-fusion spike shape, even as you're introducing the protein without the rest of the virus.

I was reading a scientific article by some NIH investigators on the NIH-Moderna vaccine, and at the bottom, there was a conflict of interest; the disclosure mentioned that there were a couple of patents involved.[6] To be clear, they're still just patent applications—there might be a long and complicated procedure before they're actually granted—but there are two patent applications. We have more details on one of them because it's been published; others are still provisional, so it's not clear what's going on. But the NIH—working with investigators at the University of Texas, Austin—has essentially come up with a way of stabilizing the spike protein. The approach basically requires substituting two amino acids at a critical junction in the spike protein that helps it keep that nice shape, which we know from prior experiences (with prior coronaviruses) produces a superior immune response.

[6] Kizzmekia S. Corbett et al., *SARS-CoV-2 mRNA Vaccine Design Enabled by Prototype Pathogen Preparedness*, 586 NATURE 567 (2020).

We did an analysis looking at the NIH-Moderna vaccine, but it turns out that it's actually quite a common technology that has been used. If you look at the Pfizer vaccine, J&J, Novavax, Coravax, Moderna, all of them actually use the 2P mutation, which involves the two proline amino acids that I mentioned. What's interesting here is that NIH has done years and years of work. We calculated, since the SARS epidemic in 2002, that NIH alone has spent $700 million on coronavirus research and development. So, NIH has done all this work that has helped us understand coronaviruses and what appropriate antigens might be. What makes this especially interesting is that Pfizer and J&J actually tested other antigens; they tested other proteins, and they found that the 2P proteins—the ones that contain that mutation—were superior. In the Pfizer phase II trial, for example, the 2P proteins had less side effects.

What makes this particularly noteworthy is also putting this in context. We have these amazing new vaccines that rely on government-invented technology, and at the same time, there are billions of dollars of public funding going on. So, I want to contextualize the patent situation because it is one part of a larger story in how the public and private sectors are working together to develop COVID-19 vaccines.

CHRIS MORTEN: Great. Thanks, Zain. Thanks to all the panelists for their opening remarks. I have a few prepared questions for the panel and some that are sparked by those opening remarks.

I want to spend most of our time engaging with the really deep policy considerations that Donna, Amy, Barry, and Zain highlighted about how we should think about the place of assertion of U.S. government-owned patents in the government's broader innovation policy toolbox alongside procurement contracts and grants and so on. But I want to start with what I hope is a relatively straightforward, factual question that's important for us to get our arms around: how many commercially significant U.S. government-owned patents on pharmaceuticals, vaccines, and other medical technologies are out there? Zain just presented some analysis that he and Public Citizen have done about patents that the NIH appears to own on COVID-19 vaccines.

This is a question I'll direct to Barry as someone who works in the U.S. government tech transfer: are patents—like the patents that NIH owns and patents like CDC owns on HIV PrEP—outliers, or are there more such patents out there?

BARRY DATLOF: There are many more out there. It's hard to get this IP into the private sector without a pandemic. Just a little epidemic can even make it hard.

So, there are always vaccine and drug patents and patent applications that are pending—unlicensed at any given time. For all of the U.S. government, there are hundreds to thousands of patents. When things spike—like Ebola, Zika, Corona—we do get a lot more interest, but that interest sometimes comes and goes. You've obviously seen what happened with Ebola. So, the reason for technology not always being licensed right away can be that it's just too early. It's too risky. It hasn't even been peer-reviewed.

When we switched to first-to-file, even government inventors had to rush to get their patent applications on file without all the data that industry would require, normally, for a license to be viable. The government will continue to work on it, but now we have a pending patent application unlicensed. Also sometimes, in the government, we have very small market sizes. Nobody cared about Ebola when it was only in Africa. As soon as it got on an airplane, people started to care about it. Zika in South America—things like that.

Lastly, sometimes the IP coverage is very narrow. It's really critical to differentiate between a composition-of-matter patent and a patent on just an improved way of making something. It could be something that makes a better product in the marketplace—maybe because it's cheaper to produce—but it's not that we created the entire cure ourselves. That happens continually because industry works with the federal government to use our labs or biosafety level (BSL) facilities and to bring their technology into the government in order to get our technology connected to it and back out.

So, if we don't have foreign rights because of first-to-file, industry is looking at our portfolio and saying, "U.S. rights only? Federal government rights only?" That really isn't as attractive. We actually have a problem—and a proposed solution, which I won't talk about today—that we really need to enhance the value of the portfolio of the government; but ironically, on this panel, the DoJ is not sitting. The DoJ is the only group within the federal system that has the right to sue for infringement. DoD doesn't; NIH doesn't. I'll stop there.

CHRIS MORTEN: I'll jump in quickly to say that we did make an effort to get a representative of DoJ on the panel, and they very graciously declined.

BARRY DATLOF: For the audience, it's probably worth noting—because I was able to get DoJ on one of my panels—I asked them, "Number of fingers or hairs left on my head: how many cases have you filed on behalf of federal laboratory patents?" And it was fingers, not hairs. It's clear that our government is not set up to litigate against industry. I'll talk about that later. Go ahead.

CHRIS MORTEN: Yeah, very interesting. Fascinating to hear that there could be many more commercially significant patents out there that the U.S. government holds. I'm eager to let Zain, Donna, and Amy react to what Barry said, but I also want to open up the discussion to bring in some of the bigger policy considerations that you all raised in your opening remarks.

I'll pose the question that is a longer form of the title question of this panel, which is, "When—or when not—and how should the U.S. government actively assert its own patents? By bringing or supporting or perhaps threatening patent infringement lawsuits against drug companies? Are there occasions on which that's appropriate? Could we start to sketch a framework to guide federal policymakers as to when assertion may be appropriate or inappropriate? I'll encourage and invite the panelists to use the example that Zain raised in his opening remarks of the patents that NIH may hold on COVID-19 vaccines, including Moderna's. Is that an appropriate case for assertion? Amy, go ahead.

AMY KAPCZYNSKI: I think that the cases where assertion should be considered are where there's a clear public benefit and where there's some kind of issue: lack of supply, barriers to important research, or price barriers. We can set out a set of criteria. We say, "There's public interest in this technology being exploited in a way that it isn't currently being." Then we identify a licensing technique. Now, notice what I'm doing here: I'm not imagining that the government is acting like Pfizer and managing its patent portfolio. They're not asking, "Is there money on the table? Let's get some money." They're trying to identify where there's a public interest because that's the position of the government. The public interest could be met by managing this portfolio, and that's really important to appreciate.

What I would say about the very exciting work that Zain put out about the NIH contribution to the COVID vaccine is that it presents an opportunity where the patent appears to be foundational to manufacturing many of the COVID vaccines that now have Emergency Use Authorizations (EUAs). One of the really interesting questions is when licensing happens. Sometimes it happens very upstream. But increasingly what we've seen is that industry does not always have a license to government technology, even once the technology is out in the marketplace. That puts them in quite a vulnerable position because they can be sued for infringement. So, I think this is an interesting example of precisely the kind of approach that we're talking about: the government could say—and should, in my view, as part of its strategies—that we need to scale up coronavirus vaccine production. We need a coherent plan about how to do that. How many doses do we need to meet the challenges of both American supply—and boosters and all the rest—as well as global supply—given the variants and the concerns that we have about needing to

control the pandemic at a global scale—so that we're not doing the same thing a year from now that we're doing today. In that case, those patents could be used as part of a coherent strategy about the scale up of manufacturing. Part of what that would have to entail would be barriers to scale up. Some of those are not patent barriers. There may be patent barriers, however, so part of the story might be "let's cross-license to see if Pfizer could produce more effectively if it had the ability to use some of Moderna's technology." Something like that. There could be some cross-licensing of patents in the background. But more importantly, there would be the sharing of know-how. You would be able to turn to the companies manufacturing and build a cohort that can really manufacture through these licensing negotiations. You would get Moderna and Pfizer, for example, or Johnson & Johnson, to share know-how so that you could scale up manufacturing.

CHRIS MORTEN: Great. I'll respond to you really quickly, Amy. It's interesting to hear how you sketched a scenario where the U.S. government could assert its U.S. patents in the United States as a lever to reshape vaccine access globally—sort of like acting domestically/acting locally but thinking more broadly—because the leverage that these patents provide could be used to renegotiate terms.

AMY KAPCZYNSKI: Right, and that really mirrors something that has been a feature of the research and policy thinking on access to medicines. The vast majority of the money and medicines markets are in the rich countries. So, if you have control over some of the rich country's market (as in the U.S. with a patent on COVID vaccines that are being sold in the U.S.), you can leverage that control to enable, at cost, manufacture and sale in low- and middle-income countries (or technology transfer to low- and middle-income countries) by segmenting the markets. That has huge public health benefits. We don't need low- and middle-income markets to ensure that we get boosters for COVID vaccines; we do not need that. There's plenty of money in the rich country markets to get the dynamic R&D that we'll continue to need in this vaccine space. So, we have a real opportunity here to do exactly that: to segment the markets, use the U.S. rights over rich country markets, and leverage that to supply vaccines for the world.

CHRIS MORTEN: Very interesting. I want to invite the other panelists to respond. I was going to ask Donna to think about some of the considerations that you raised: its chilling effects and scaring off future public-private partnerships.

DONNA MEUTH: To feed off of what Amy said, I think the licensing part of it is important. Drug companies generally are risk averse. We assume a lot of risk in the research—there are many more failures than successes in our programs, which

is industry-wide because of the unpredictability—but when it comes to taking a product to market, companies do not want to launch at risk, knowing that there's IP out there that we can be sued upon or have an injunction brought against us. So, I think licensing early on is very important because the industry will want to reach a deal to have some certainty. It's important because you do need certainty—you don't want to launch a product thinking that, a year in, you're going to have an infringement suit against you from the U.S. government. Nobody wants that publicity. Nobody wants that threat against you. You want to be able to develop your products and get them out into the market.

Early on, when we have new projects, one of the first things we do is look at Freedom to Operate (FTO). I have, in my group, two searchers that work with me and will do a prior art search. We'll do an FTO search and look at what is out there; what may be impediments. Is there an invalidity position against this? How strong is this IP? Do we have a non-infringement argument against it? Will the patent expire by the time we get to market? Could the IP potentially be expired? We'll look at ways around that. If, early on in a project, there's a huge risk with an entity that we don't think we can license, then we'll change the program. We don't want to take the risk of investing billions of dollars to get to the point of marketing and then have to come off the market because of IP concerns. Knowing that the government is going to be a partner that we can discuss licensing with is an important part of it. I think that would go a long way to both encouraging the partnerships between us and also allowing the negotiations to happen that will result in not stopping a program, but allowing programs to go forward, and having the end result be a win-win for everyone.

CHRIS MORTEN: I want to react quickly and bring in a question from the Q&A, which is: what remedy do advocates for government patent assertion seek? Or what remedies has the government sought in the very rare examples where it has actually asserted patents? Is the government seeking an injunction against the company who is allegedly infringing? Or is the government merely seeking some kind of royalty or other monetary compensation? My sense from the United States v. Gilead suit is that DoJ is seeking only monetary compensation; there's no injunction. I'm curious, Donna and others, whether that squeezes some of the downside risk out from the industry's perspective if their exposure is only payment of some amount to the U.S. government but no risk of injunction.

DONNA MEUTH: I guess I'd rather have that payment—that discussion on what the reasonable royalty is—upfront without the litigation. Not knowing the dynamics between Gilead and the government, I think—for industry and for my

company—it would be nice to see more of these resolutions occur pre-litigation rather than post.

CHRIS MORTEN: Yeah, that makes sense. I want to go back to Barry. What do you think the general effects of more frequent assertion would be and, in particular, have you seen any impact that the U.S. v. Gilead suit may have had on licensing within your group?

BARRY DATLOF: Assertion has been so rare that it hasn't had an impact. I wish that it did because what it would do, per Donna's comment, is really make sure that companies line up their ducks before the fact instead of running off and saying, "We can do anything because the U.S. government's never going to come after us." We do like the certainty because it identifies for the government who the partner will be, or partners, because it could be non-exclusive or semi-exclusive licensing. It's not like we only do it one way. For instance, during the pandemic, we've been doing licenses where it's really quick and easy to get a license. Why not have licensing activities that mirror the market's needs, the societal needs, not just one size fits all? We acknowledge that our corporate partners would be hesitant to take a license if they knew that there was another company out there already infringing who is unanswerable and won't step up and take a license. We've had that situation occur—call it willful or just betting that the federal government will never get involved. And here, we're only talking about U.S. patents; DoJ isn't going to file overseas on behalf of a U.S. government lab. What are we going to do about that?

CHRIS MORTEN: Very interesting. I want to invite Zain to jump in and return to this hypothetical around NIH, Moderna, and the patents that NIH might own. Zain, I don't mean to put you on the spot, but I know that you and Public Citizen have investigated some of the contracts between the U.S. government and Moderna and other vaccine developers. I'm curious if, in those contracts, you've seen anything about patent assertion or patent ownership? Is there anything that would restrict the U.S. government's ability to assert these patents against Moderna? Also, is there any kind of indication of how close the decision was on the part of Moderna to take the public-private partnership offered by the U.S. government?

ZAIN RIZVI: I started by making a less sexy theoretical point, but I think a very vital one in practical terms, which is that it's immensely difficult to figure out what is actually going on between the government and these corporations. That's been a regular feature of licensing arrangements and technology transfer, but, frankly, it is a harmful feature and it needs much more attention than it gets. What's remarkable is that the U.S. government is the world's largest biomedical research funder, and yet it is so difficult to get details about what patents might the U.S. hold;

what licenses have the U.S. entered into and on what terms; and, in general, it's been a laborious and difficult process.

Just consider a small biotech. A small biotech is required to share lots of information with its investors. The small biotech often posts licensing arrangements with the U.S. government. So, you're more likely to get details from the small biotech than you are, as an American taxpayer, from the U.S. government. There's a fundamental asymmetry, which is problematic.

The second point is in terms of the deals themselves. What's interesting is that Axios actually obtained some licensing arrangement between NIH and Moderna.[7] To clarify, what makes the Moderna vaccine especially compelling is the extent of the U.S. government's involvement from its infancy. It actually started in 2013 when DARPA, part of the DoD, invested in Moderna. The head of DARPA has said, "We invested in Moderna when it was three people." So, you can imagine the kind of support that Moderna has gotten over the years.

We reviewed the NIH-Moderna agreements. Some of them are publicly available—not the ones that are particular to SARS-CoV-2—and there was what's called a research collaboration agreement. There was work to be done on "Pandemic Preparedness Concepts." So, NIH and Moderna have worked on many multiple diseases (including MERS). Under the terms, which were not redacted, there was *not* a provision saying that a license is automatically granted. That's one interesting point. The second point is that the latest patent application (the 2020 one) may have involved Moderna in some way, but the 2016 patent application—which was just done by the NIH itself—actually does not have Moderna involvement. So, I think there's less of a chance that Moderna somehow has rights in that patent unless they get some sort of license from the U.S. government.

As an update: what we know publicly is what gets reported in the media. Public Citizen has filed Freedom of Information Act (FOIA) requests about these arrangements, if there are any. The latest public update is that, in August, NIH was still negotiating terms with the companies.

BARRY DATLOF: Zain, I appreciate hearing how difficult it actually is to get the information that you're looking for. Being in a tech transfer office in the biomedical space, I will say there are ways that we could do it better. But some of the questions that are being asked do need to be appreciated by folks.

[7] *See* Herman, *supra* note 2.

Now, I have a question for Donna. There's only an obligation to put in the Federal Register notice if we're going to grant an exclusive license (or any exclusivity, such as semi-exclusive). But, if I were you, I'd be a proponent for legislation that says all federal licensing should be listed in a public place so you don't have to go through FOIAs. My question for Donna is: would your company or other pharmaceutical companies be comfortable with other people knowing how much you paid the government up front and the royalty that you're going to pay for a licensed technology from the federal government? Would you wish that to be maintained as business proprietary and not FOIA-able, or would you be willing to have that publicly disclosed?

DONNA MEUTH: My first reaction is not to disclose. Generally, we don't want to disclose terms of any agreements because that can influence other agreements. The payment is about the value of whether it's an exclusive license, how broad the IP is—there are different factors that go into that. I think my preference for my companies would be not to disclose it, although on the flip side, it's always helpful to see what others pay because that can help with your negotiations.

BARRY DATLOF: So, Zain, part of the solution for you is what Mark Edwards did at Recombinant Capital many years ago, which was to compile all of the royalty rates confidentially and then make some of them available in aggregate so that people actually know what society would have to pay for a given new technology and a given space, be it antibodies or therapeutics.[8] The one-offs are very business sensitive because it influences the next negotiation that NIH does or the company does; you can't really expect somebody to open up completely. But what I hear you saying is that you need more visibility on at least who *does* have a license.

DONNA MEUTH: Yeah, you'd want to know who has the license. Some technology is easier: you don't really need the exclusive license; non-exclusive is fine if it's broad enough technology that would cover not only your product but a number of products. For those types of IP, I'm fine with a non-exclusive license.

AMY KAPCZYNSKI: This reminds me of conversations we've had with universities for a long time about how public their licensing policies are. While it's clear why there might be private interest in keeping that information secret, it's less clear to me why there's public interest in keeping that information secret. I mean, one of the things that makes markets work well is when you actually know what

[8] *See* Mark Edwards, *Effective Royalty Rates in Biopharma Alliances: What They Are and Why Use Them in Negotiations*, BIOSCIENCE ADVISORS INC. (Mar. 25, 2017), https://bioscibd.com/effective-royalty-rates/#1.

prices people are paying for things. The canonical competitive market, like the grain market, works well because everybody knows the price point. Information is really critical to efficient market transactions. There are ways in which we might want to set out an agenda about what's known, both for accountability purposes as well as to enable markets to actually work like we imagine they might when people have good information about price. But I agree entirely that, given the dynamics we're talking about, it's likely not going to happen voluntarily; somebody would have to establish that it's a priority for us to make this information public for accountability reasons and to enable licensing that works better.

BARRY DATLOF: Amy, it sounds like you're at the University of Chicago: go free market! I concur. I actually do appreciate having that data available as a negotiator on the government side, but I will say that there are plenty of compelling reasons on both sides. The DoD, because our emphasis is on fielding a product, very frequently will either co-fund or, in essence, cut a significant break on the license terms because we don't care about the money; we care about the product for the warfighter. So, if a company goes to NIH and says, "The vaccine we got from DoD was a half a percent royalty. We want the same from you," they may actually get a challenge, so to speak. How efficient is that market? Does it matter if it's value-based pricing? Or is it impact-based pricing? Or cost-based pricing? Those, as you know, have been the subject of many discussions.

CHRIS MORTEN: I'll jump in and say that I'm fascinated by these questions of transparency along with Donna and Barry's colloquy about whether industry would accept licenses that mandated disclosure of the terms. It seems to me that there's a tension between the rational interest of the pharmaceutical companies entering into these partnerships and us—the public—because we broadly benefit from seeing the details of these agreements. Looking back to the first panel, as we think about various different ways to incentivize the development of new vaccines and drugs, one of the really vital pieces of information we need is what it costs to run a clinical trial, and what it costs to fund a pre-clinical R&D program. These contracts are the best evidence we have for that. So, policymakers, legislators, all of us need access to information, critically in moments of national crisis like COVID-19.

I want to pose another question that I see in the Q&A, and I hope it will tie up some of these issues. It asks, "Pharmaceutical companies regularly sue one another over patent infringement. If we accept that sort of litigation as appropriate, why exceptionalize the U.S. government? Why say that the U.S. government should not assert its IP, especially in cases when doing so promotes a public good, like medicine access in the case of Moderna?" The question can be boiled down to: Should the

government, as a patent holder, be viewed differently from a private company as a patent holder? I'll try to give you each a minute or two on that question, then we'll wrap up. Barry, feel free to jump in.

BARRY DATLOF: Yes, and no! We are different from business-to-business patent infringement. We actually run the Patent Office—too bad they can't do us any favors for our own portfolio. But the impact of having the federal government in a lawsuit with a company is really different for investors than if another competitor was fighting because investors don't know the extent to which the federal government will go. By contrast, they *do* know how much a company is capitalized and how deep their pockets are for litigation. I think that it would benefit all for IP rights to be respected, and sadly, the only way to do that sometimes is litigation. There may be other mechanisms that can be employed—and should be employed—before litigation, which the federal government can use and leverage, such as what Zain was talking about in terms of Cooperative Research and Development Agreements (CRADAs) that give you the opportunity to negotiate thereafter for the IP rights based on law.

CHRIS MORTEN: Great. Thanks. Does someone else want to jump in?

AMY KAPCZYNSKI: I'll jump in. I think that there is a real reason to ask the government to behave differently than the private sector because what benefits the private interests of somebody who (presumptively) is profit-motivated and what benefits the public sector are different. My own view is that the government should not step in when the market is working. So, say we've got a product and everybody's got access to it. Let's say there doesn't seem to be any price concerns. All the government is doing is adding a royalty on top of it. I don't see the argument for that, even though it would return some money to the government. Yet, that's the kind of thing that a firm would do all the time.

We also see firms engaged in patent warfare that really screws research up, where we don't have the ability to proceed on important technologies. This is not something I would like to see the government doing. I think there are things that the private sector does that hurt the public interest, and I don't want the government to do this. I think that's a critical piece of the story.

Now, that said, there's something else we haven't talked about in the background: is it great for the government to run around and seek all these kinds of patents on inventions, given that we know we have issues with patent thickets, with over-patenting being a real concern with respect to giving freedom to operate for research and for the manufacturing and dissemination of technologies? I think it's really critical that there be a public policy of the kind we're talking about and some

transparency so that we could monitor whether the government is acting like a pharma company. Because, if the government were to act like a pharma company, I think that would just increase our problems, given the patent system that already has some real drawbacks.

DONNA MEUTH: I think it partly is: what behavior do you want to encourage? Do you want to encourage partnership between the government, industry, and researchers? And, if you do want to do that, then you don't want the government suing people all the time because that's not what you're going to look for in a partner. Over the past five years, one thing I've seen is that there's a lot of pre-competitive consortiums and collaborations where the companies joined together; there'll be research that benefits all the companies. As part of those consortiums, none of the companies involved file for IP. So, knowing that at the start, you're open to sharing information; you're open to exploring the mechanism of action, or what would be a potential target, or what biomarkers are important—things that each company in this area can use but without the fear that one company's going to get this broad IP that will block everyone else, or make it so that we have to license or stop our program. So, I think it's partly seeing the government as being the ultimate partner that wants to encourage the advance of research. It's encouraging companies to solve the problems of the diseases that are threatening society, such as COVID and Alzheimer's—things that need more than just one company and a lot of resources. The best way to encourage those collaborations, I think, is not to see the government as an antagonistic entity that we have to be fearful of, but as a partner that we can work with to try to solve these problems.

ZAIN RIZVI: What's really needed is more policy coherence in the United States government because the U.S. government clearly has goals that go far beyond just getting the products onto the market. Using COVID vaccines for context, there are huge concerns about variants and what that might mean for domestic vaccination, global vaccination, public health, national security—you name it. Yet, there is a reticence on the part of many policymakers to exercise and deploy all the tools that they have to pursue those interests. So, I see patent infringement and the leverage that patents offer as just one more tool in the toolkit that the U.S. government could deploy if it wanted to address some of these incoherencies. Right now, we're talking about the COVID-19 vaccine context, but taking a step back, the central paradox in the American drug pricing landscape is that the U.S. government is the world's largest biomedical research funder, and Americans are compensated for this world-leading investment with some of the highest drug prices in the world. The bang for the buck is not necessarily there. When individual tech transfer offices are narrowly construing just development as the primary goal, rather than access, I think it gets us

into many difficult situations that could be avoided if there were some higher-level organizing structure to advance these goals.

CHRIS MORTEN: Great. Thanks, Zain. Thank you Donna, Barry, and Amy. I think it's clear that this question—Should the U.S. government actively assert some of its patents?—is a very rich one for discussion.