JIPEL
NYU Journal of Intellectual Property & Entertainment Law

PANELS

What Role Should Governments Play in Setting Rewards for Medical Innovation?

Moderator: Lisa Ouellette
Panelists: Michael Abramowicz, Daniel Hemel, and Bhaven Sampat

Should the U.S. Government Actively Assert Its Own Patents?

Moderator: Christopher Morten
Panelists: Barry Datlof, Amy Kapczynski, Donna Meuth, and Zain Rizvi

Whether and How the U.S. Government Should Exercise Its Compulsory Licensing Authority Under 28 U.S.C. § 1498 and the Bayh-Dole Act

Moderator: Arti Rai
Panelists: Rebecca S. Eisenberg, Tahir Amin, Henry Hadad, and Rachel Sachs

Assessing Strategies to Delay Generic Drug Entry

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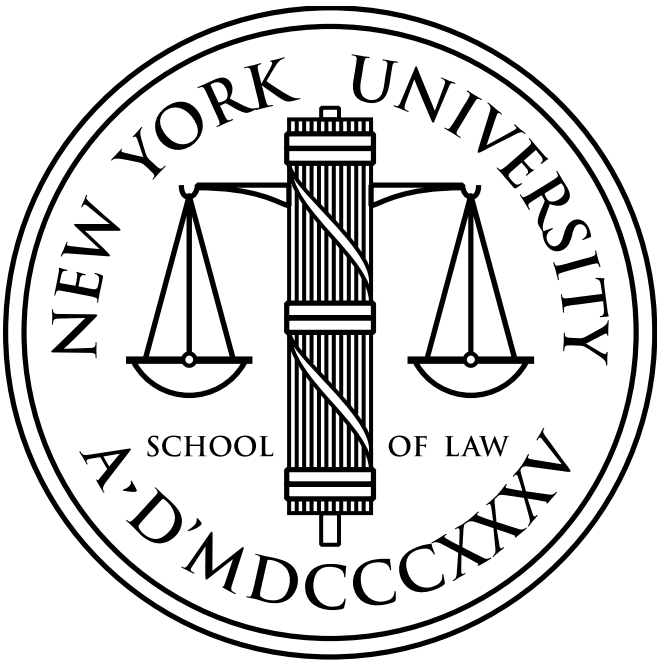

Statement of Purpose

Consistent with its unique development, the New York University Journal of Intellectual Property & Entertainment Law (JIPEL) is a nonpartisan periodical specializing in the analysis of timely and cutting-edge topics in the world of intellectual property and entertainment law. As NYU's first online-only journal, JIPEL also provides an opportunity for discourse through comments from all of its readers. There are no subscriptions or subscription fees; in keeping with the open-access and free discourse goals of the students responsible for JIPEL's existence, the content is available for free to anyone interested in intellectual property and entertainment law.

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The Journal invites authors to submit pieces for publication consideration. Footnotes and citations should follow the rules set forth in the latest edition of *The Bluebook: A Uniform System of Citation*. All pieces submitted become the property of the Journal. We review submissions through ExpressO Bepress (http://law.bepress.com/expresso/) and through electronic mail (submissions.jipel@gmail.com).

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The Journal is also available on WESTLAW, LEXIS-NEXIS and HeinOnline.

PREFACE

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.

Access to medicine is by no means a new issue, but the COVID-19 pandemic demanded full attention to it. The United States responded with Operation Warp Speed and billions of dollars in government spending. Multiple vaccines emerged. As of October 2021, the vast majority of U.S. adults have received at least one dose of a COVID-19 vaccine.[1] Still, we must ask: Is this the new norm? Will the federal government continue to play a more active role in access to medicine going forward? Our 2021 symposium addressed these questions through four panels, which we have transcribed into four articles.

Our first panel considered what role governments should play in setting rewards for medical innovation. The panel was moderated by Professor Lisa Ouellette of Stanford Law School. The panelists included Professor Michael Abramowicz of George Washington University Law School, Professor Daniel Hemel of the University of Chicago Law School, and Professor Bhaven Sampat of the Columbia Mailman School of Public Health.

Our second 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.

Our third panel discussed whether and how the U.S. government should exercise its compulsory licensing authority under

[1] *See Household Pulse Survey COVID-19 Vaccination Tracker*, U.S. CENSUS BUREAU (last updated Oct. 20, 2021), https://www.census.gov/library/visualizations/interactive/household-pulse-survey-covid-19-vaccination-tracker.html.

28 U.S.C. § 1498 and the Bayh-Dole Act. The panel was moderated by Professor Arti Rai of Duke University School of Law. The panelists included Professor Rebecca S. Eisenberg of the University of Michigan Law School, Tahir Amin, Co-Founder and Co-Executive of I-MAK, Henry Hadad, Senior Vice President and Deputy General Counsel at Bristol-Myers Squibb, and Professor Rachel Sachs of Washington University in St. Louis School of Law.

Our final panel assessed strategies to delay generic drug entry. The panel was moderated by Professor Scott Hemphill of NYU School of Law. The panelists included Professor Robin Feldman of UC Hastings Law School, Jay Lefkowitz of Kirkland & Ellis, Professor Sean Nicholson of Cornell University, and Judge William G. Young of the District of Massachusetts.

Although our panelists did not always agree, they shared a common belief that access to medicine must be a national priority. How best to achieve that goal is the focus of this issue.

Thank you for reading.

Sincerely,

Taylor Peterson
Editor-in-Chief
NYU Journal of Intellectual Property & Entertainment Law

NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

VOLUME 11 FALL 2021 NUMBER 1

WHAT ROLE SHOULD GOVERNMENTS PLAY IN SETTING REWARDS FOR MEDICAL INNOVATION?

MODERATOR: LISA OUELLETTE

PANELISTS: MICHAEL ABRAMOWICZ, DANIEL HEMEL, AND BHAVEN SAMPAT

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 first of four panels. This panel considered what role governments should play in setting rewards for medical innovation. It was moderated by Professor Lisa Ouellette of Stanford Law School. The panelists included Professor Michael Abramowicz of George Washington University Law School, Professor Daniel Hemel of the University of Chicago Law School, and Professor Bhaven Sampat of the Columbia Mailman School of Public Health.

LISA OUELLETTE: As the first panel of the symposium, I think it is important to reiterate that everyone participating in this panel and in the symposium more broadly today cares deeply about access to medicines. So, even though there will be disagreements throughout about the best policies for achieving these goals, those disagreements come from a place of wanting to save lives and improve health outcomes.

[*] 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 1)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=g_KdHn3QkKw.

The original framing of this symposium was focused on the role of government patent rights in increasing access to medicine. As a preliminary note, it's important to recognize the value of pivoting away from government patent rights as the key policy lever here because the government has direct patent rights over only a very small percentage of drugs and whether the government has patent rights has little relevance for the system of allocating access to drugs. But the government does have a lot of control in setting both access and rewards without doing anything related to patents through programs like Medicare and Medicaid and the kind of bulk purchasing it's been doing throughout the pandemic and direct government provision. And in designing these institutions, policymakers should recognize that they have independent control over two elements of innovation policy: how access to those new technologies is allocated in terms of the out-of-pocket costs for patients and how those technologies are incentivized. Our panel is focused on improving the incentive side of innovation policy while facilitating access. The panels later in the day are focused more directly on access. I think it's important to remember throughout that, in many real healthcare systems, the choice of patents as part of the incentive side of innovation policy doesn't create a tradeoff with access—we really can think about these questions separately.

On the incentive side, there are a number of reasons that, for medical innovation, market signals are an imperfect signal of social value. Scholars have proposed a number of prize system alternatives—Michael's written a wonderful research handbook chapter on this.[1] Many of the specific prize schemes seem politically unlikely to happen anytime soon, but as scholars—such as Rachel Sachs and Ben Roin[2]—have noted, the current U.S. system actually is already somewhat like a prize system and could be even more so. Other countries are even more directly involved in shaping rewards through health technology assessment. So, the real question facing today's policymakers on the incentive side is how rewards for medical innovation should be set—both how much money should be spent on a given problem and what institutional mechanisms should be used for distributing those rewards. The plan for this panel is to focus on those two issues: first focusing on how the size of the rewards should be set and then turning to the institutional structures.

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[1] Michael B. Abramowicz, *Prize and Reward Alternatives to Intellectual Property*, *in* RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW 350 (Ben Depoorter & Peter S. Menell eds., 2019).

[2] *See, e.g.*, Rachel Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 154 (2016); Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999 (2014).

On this first question of the size for innovation rewards—whether that money is spent through direct government funding or ex post rewards or something else—I thought I'd start by turning things over to Daniel.

DANIEL HEMEL: Thanks, Lisa, and thanks to the organizers of the panel—really happy to be here.

My number one thought on the size of rewards is that they should be bigger. We don't spend all that much on pharma. About 12% of total health spending in the United States is on prescription drugs, so prescription drugs are not why healthcare is so expensive. We devote about 1.6% of GDP to prescription drugs. That seems surprisingly low to me—though it's high by international standards—given that these are the things that, in a lot of our cases, are going to save our lives. I would like to live in a world in which the top STEM students who want to make a lot of money go to biotech rather than to hedge funds. And I think we can do that. The tradeoff between innovation incentives and access to medicine is a policy choice, i.e., we are choosing to pit those into conflict, and we don't need to. A decade ago, that was a major theme of the literature in innovation policy and IP, and it still is to some extent, but I think it's largely a vestige of 1990s austerity politics that, as we are seeing now, the government can spend a lot more money than it does on really important things. And I think saving people's lives is a really important thing. Right now, we're seeing big rewards to Pfizer, Moderna, and Johnson & Johnson, combined with free access to vaccines. The government could just buy a lot more life-saving drugs and give them out to people for free.

We can look at the values that we use in the innovation context. The Institute for Clinical and Economic Review uses in its Remdesivir evaluation a quality-adjusted life year of $50,000. The Department of Transportation—in deciding how much car manufacturers should have to spend to make your roof more crush-resistant or to add a tire pressure monitoring system so that your car doesn't skid out of control—uses a value of a statistical life of $11 million. And those two numbers are only consistent if the average person has 220 more healthy years of life to live. We're using much lower values in the pharma context than we are in other contexts. I think size matters more than exactly how you do it, but ultimately I think rewards should be based on social value, rather than cost. I don't really see an alternative to social value—we want to incentivize researchers to focus on the most promising solutions to the most serious problems.

And the way to do that, it seems to me, is to give the largest rewards to the people who come up with the most life-saving solutions, and to try to (ex ante) funnel government investment into the most promising projects.

LISA OUELLETTE: Great. Thanks, Daniel. Michael, I know you've written about having the costs that we're spending on R&D play some role in rewarding innovators. What role do you think that should play compared to thinking about social value?

MICHAEL ABRAMOWICZ: Good question. Let me talk about that, and then I'll also talk a little bit about what Daniel said in terms of the total amount.

Daniel said, and I agree, that ultimately what we care about is social value. Whether it's patents, whether it's direct government spending, whether it's altering Medicaid or Medicare policy and so forth, we want to give bigger rewards for bigger contributions. I think the trickier question is whether we want to be entirely measuring welfare directly or whether we want to also look at inputs, like the cost that researchers spend on particular research projects. There are arguments on both sides. There's a danger to focusing too much on cost, which might encourage some wasteful spending. At the same time, we need to worry a little bit about the need to adjust for risk. We can't just say, "Well, we're going to reimburse your costs if you're successful and not reimburse you if you're not successful." I think there's wide agreement in the literature among people with a variety of views that, to the extent the government is reimbursing costs, we need to take into account risk. The problem is that this is not so easy to do. There's a danger of hindsight bias, and I think the more subtle difficulty is that a lot of the cost that we want to reimburse is not for the most immediate project that, let's say, a pharmaceutical company undertakes. It's for building the company and building the capacity to undertake that project. I certainly think we see that with COVID. We're really compensating Pfizer, Moderna, and so forth for building their companies in the first place—bringing people together with expertise who know how to work together. We're not compensating them so much for the direct outlays on the particular project—that, too, of course—but not just that.

So, those are some dangers of considering costs, but I also think there is a huge benefit in that cost can be a lot easier to measure than social value. I think that's why we see cost so much in government contracts—why we have cost-plus contracts, for example. We just think it tends to be easier to measure cost than social welfare. In the end, you might want to have some kind of hybrid system: costs less than 100% so we don't have wasteful spending, as well as some kind of assessment of social welfare.

I want to echo a little bit of what Daniel said about the total amount of spending but with a different view. My view is that we've spent way too little during COVID on vaccines and that we probably could have been a lot further along if we

had spent more. I worry that if we switch too much to incentivizing pharmaceuticals based on the anticipation that the government is going to spend money, the government is going to spend too little. I mean, we spent billions on COVID, but not a huge number of billions. If that's the case, are we really going to trust the government to spend enough on other research projects with potential benefits years down the line?

I think overall we do see the government spend a lot of money on healthcare, but maybe less on research because the benefits are further down the line. That's a major problem with our kind of political economy—we don't have systems that will quite give incentives for political actors to value long-term benefits enough.

LISA OUELLETTE: Bhaven, do you want to weigh in here?

BHAVEN SAMPAT: Thanks, Lisa. To be frank, I've thought less about some of these issues, especially the ex post reward issues, than some of my comrades on this panel. So, hopefully my reflections here aren't naive. Let me just pick up on a couple of things that both Michael and Daniel said.

My sense—and maybe I'm wrong—is that when we're talking about both R&D costs and social value, we're talking about two constructs that are notoriously difficult to operationalize and measure. On the R&D cost side, from my reading of the accounting literature years ago, there's no great standards on how to think about capitalization, failures, spillovers across projects, and the kinds of infrastructural investments that Michael talked about. I think social value is even harder. If we took seriously proposals to reward drugs—individual drugs—based on social value, we would have to think through these things.

We would have to think through things like quality versus days—how much quality is worth, and how much do we value lives today versus 10 years from now? How much do we weigh the U.S. versus the global disease burden? And how do we measure the quality gains from a drug? You run into questions like: What kinds of studies count? What is the right comparator? Do you rely on clinical trial evidence? Clinical trials with surrogate endpoints? Real-world evidence? None of this is necessarily insurmountable, but it's hard.

The general point is that the system is broken, and we should do more, and we should spend more, but beyond the kind of theoretical prize discussion or ex post rewards discussion, it would be useful to think through the cost of administering whatever system we come up with in a principled way and the kind of political economy of different systems and how they might be subject to or immune from different kinds of disease group politics.

And one last thing. The perfect shouldn't be the enemy of the good. I think we can comfortably ballpark social value for certain things like a COVID vaccine, an effective Alzheimer's treatment, etc., and come up with some lower bounds for social value. I think it's worth agencies thinking about specific problems in that sort of way. Another useful thing to do might be to create broad proxies for social value and then meter our existing policy instruments—everything from FDA exclusivities to patents to insurance—to those in a more blunt sense that moves with our proxies for social value.

I think a really nice effect of this discussion is forcing us to step back and think about the outcomes we want—working backwards from those, rather than the science push or technology aspects that have characterized a lot of biomedical research policy for the last 75 years or so.

I'll leave it at that and look forward to the discussion.

LISA OUELLETTE: Great. Thanks, Bhaven. Daniel, do you want to weigh in on any of the thoughts Michael and Bhaven have shared?

DANIEL HEMEL: We probably agree on the panel that if, instead of spending 1.6% of GDP on prescription drugs, we spent 3.2% of GDP, we would likely have more life-saving treatments. And we do make some of these hard decisions about quality-adjusted life years versus disability-adjusted life years versus expected value of life years gained in other contexts in deciding how clean our air should be or how safe our cars should be. It is politically challenging but not politically impossible.

I think the Institute for Clinical and Economic Review is a good model of how to do this. We can imagine a world in which Medicare and Medicaid cover a larger portion of the population and more drug pricing is just set by the government based on a measure of social value. That won't be perfect, but I think Bhaven is entirely right that the perfect shouldn't be the enemy of the good. My one criticism of the way that NHS does it in the U.K. or that the Institute for Clinical and Economic Review does it here is that the numbers should be 5 times or 10 times larger than where they are now.

MICHAEL ABRAMOWICZ: I'll jump in, if I may. Daniel may have more confidence in our political system's ability to measure quality and so forth in a reasonable way. Maybe you could create some kind of very independent administrative agency and do it. But I think another thing we've seen during COVID is the need to ration vaccines—that is, we've needed some mechanism for scarce allocation.

I don't feel like any of the state governments have done a particularly commendable job of creating a coherent methodology. People may say, "Well, if you're 64, and you have a serious condition, then you should get your medicine before somebody who's 68 and doesn't have a condition." However you think the big picture looks in terms of which groups should get it first, it's certainly a very crude system that we have. I'm not convinced that you can eliminate that crudeness just through the magic of creating an administrative agency.

We certainly haven't done that well on equity in our allocation decisions either. There was a debate early in the pandemic about the fact that African Americans and Native Americans had a greater burden from COVID, so there was a hope that maybe we could get vaccines to those communities first. And there was a debate as to whether we should consider race directly or zip codes. And, of course, the answer is that we've done more or less neither. There's been some attempt to get the vaccine into underprivileged communities, but there's a lot of fear of creating an allocation system that seems to privilege anyone above anybody else; the result is that any attempt to create more equity will not work.

I think the broader problem is that considering lots of potentially relevant variables doesn't seem to be possible during COVID. I worry that it won't really be possible to have a serious model-based allocation in anything.

LISA OUELLETTE: I think you're right on the inequities in the allocation that we've seen during COVID, but I think these questions of how we are allocating are, as I said at the beginning, separate from the questions of how we are incentivizing. Still, the questions of how we are incentivizing raise similar challenges.

I think that is part of the reason that the U.S. government has largely punted many of these questions to the private sector: it enables the government to avoid making those hard choices of which disease is more important than another, that kind of explicitly valuing lives in this context. It's not obvious to me why, in other contexts like Daniel mentioned, across many other portions of the administrative state, there seems to be more political feasibility in making these kinds of calculations.

DANIEL HEMEL: I want to pipe in and defend the allegations that are going on right now.

We basically have a healthcare rationing system that popped up all of a sudden, and some of us had frustrating evenings trying to get vaccine appointments for older relatives. But most of the people I know who are over 65 have had their

first shot. And most of the people I know who are in their 30s have not had their first shot. I'm in a privileged position—most of the people I know are top few percenters and predominantly white. But still I think if I compare the allocation of vaccines based on risk done by this kind of pop-up-federalist-disjointed-government effort versus allocations that happen in a market process—and when I'm comparing outcomes over the last few weeks to whether the market really allocates medications to the people who need them the most—I'm more confident in socialized medicine as an access allocation scheme than I would've been before. I think we're doing a better job than just the free market. Michael, those were fighting words.

[Laughter.]

LISA OUELLETTE: We have a question from Brook Baker[3] about directing funding toward wasteful and inefficient R&D. All three of you have said that we spend too little on many healthcare innovations and that we would have, if we spent greater rewards, more life-saving innovations. Brook Baker's question refers to evergreening exclusivities and "me too" drugs. Are there cases where there is wasteful spending in that direction? Do you think there are places where the current system provides too much, such that using social value as the lodestar would lower the rewards? Go ahead, Bhaven, you're nodding.

BHAVEN SAMPAT: Oh yeah, absolutely. I think that with a number of things that might come up this afternoon—including evergreening and product hopping—a good technology assessment enterprise could help obviate some of those problems.

As Daniel brought it up, we could also spend more on more valuable stuff. Now, of course, if the consumer faces that cost, then we run into the Sovaldi problem where you have a very valuable, but very costly drug. You'd want to couple that cost with some sort of insurance coverage to decouple the innovation incentives and the price. I agree that we could actually reduce expenditures considerably as well through a reasonable HTA apparatus, imperfect as it may be.

MICHAEL ABRAMOWICZ: I think it's pretty clear that the evergreening probably distorts research in one direction rather than another. I think it's a lot harder to say that the marginal research that's been spent on evergreening is actually not cost justified. I think that would be a very hard thing to measure. Some of the benefits—from some of the improvements to drugs—might be cost justified.

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[3] *See* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303 (2008).

BHAVEN SAMPAT: Why would it be hard to measure, Michael?

MICHAEL ABRAMOWICZ: Well, there's a lot of different drugs, a lot of different kinds of innovations. And I think a lot of the concern on evergreening comes from the access side rather than the incentive side—that is, we're evergreening so that we can keep the prices high. I haven't heard so much the idea that the research expenditures on the improvements are themselves not worthwhile. I've certainly heard the argument that those research expenditures on improvements might be better allocated to other kinds of problems if you could magically move those to other kinds of problems.

I wanted to very quickly respond to Daniel's "fighting words." You know, I don't disagree with him altogether, but I think the danger is that we end up with the worst of both worlds—both incentives and access. On the free market side, if we anticipated a free market in which companies are fully able to exploit their patents and have an option for the first however many thousand people who get the vaccines, we probably would have gotten results a lot earlier. And I think that would have been a plus. The downside is that there was a sense among pharmaceutical companies that they weren't going to be able to do that—certainly if they wanted emergency use authorizations—so I think that depressed incentives to produce quickly.

We obviously still did better than we've done in the past, but this was one of the worst public health crises we've had in quite a while, and I think we could have done considerably better. Even after all that, we didn't do so great in terms of actual allocation, which makes me worry that our institutions—not only for allocation, but also for incentives—just aren't very well calibrated. At the very least, we need to have some better institutions if we're going to be relying on government decision making on these issues.

LISA OUELLETTE: That's a great chance to pivot to our second dimension of innovation policy: the institutions. However much we are spending on innovation problems, there are a lot of different institutional mechanisms that we could use to distribute funding. So, if we decide that more money should be spent on a problem—like a vaccine for a disease with pandemic potential—that money could be spent through direct ex ante funding on grants and national labs, or it could be spent on ex post rewards through subsidies or purchases, etc. To kick off this discussion, I'll start with Bhaven, who has suggested that the public sector should be more directly involved in late-stage pharmaceutical development.

BHAVEN SAMPAT: The idea here is that, under the current system, we have a sort of division of labor going back to World War II where the government focuses on so-called basic research—since there are market failures there—and the private

sector—incentivized by patents and high prices—does the applied work, including clinical trials. There are some exceptions, but this is a high-level overview.

It's my observation, which is not unique to me, that this division of labor is not really God-given; it's actually given by Vannevar Bush, who is the architect of postwar innovation policy.[4] He had fairly strong and conservative views about the appropriate roles of government in the economy, including research. It was his idea that applied research should be left to industry, and we built an infrastructure around that.

But there were critics at the time, including New Dealer Harley Kilgore and the economist Paul Samuelson, who argued that there are pretty high social returns from government funding of applied research.[5] Indeed, they were writing in the wake of World War II, which showed that, as does the pandemic. Kilgore was explicit that government funding should be aimed at fixing market failures on the applied side as well, looking at areas where the market itself doesn't provide the desired outcomes.

How does that work in pharma and how does that relate? One of the counterarguments to the use of government rights to promote lower prices and broader access in pharma is that, even where the government owns a key patent, it's still typically the drug industry financing the costly clinical trials and additional development, consistent with this broad division of labor. But it's not clear that this needs to be the case. The government could go soup-to-nuts or end-to-end, at least in some cases, and support some of the applied work or contract with industry to do so, and then essentially price it at cost.

The idea is similar to those that Lisa and Dan have put forth that maybe the government should be funding trials.[6] But the argument is to start off by doing so in cases where the government already owns a key upstream patent and fully develops it as an experiment for thinking about how that might work going forward. It could give us some data on things like R&D costs and risks that would help us with policy design. Right now, we're flying without a parachute. That's the general proposal in terms of institutional mechanisms. I think some place like HHS would administer something like that.

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[4] VANNEVAR BUSH, SCIENCE—THE ENDLESS FRONTIER (Nat'l Sci. Found. 2020) (1945), https://www.nsf.gov/about/history/EndlessFrontier_w.pdf.

[5] *See generally*, Daniel J. Kevles, *The National Science Foundation and the Debate Over Postware Research Policy, 1942-1945: A Political Interpretation of* Science—The Endless Frontier, 68 ISIS 4 (1977).

[6] *E.g.*, Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, 7 J. L. & BIOSCIENCES 1 (2020).

LISA OUELLETTE: Michael, do you want to weigh in here? I know you've written and focused more on ex post rewards and prizes. What do you think of shifting the institutional mechanisms towards government funding?

MICHAEL ABRAMOWICZ: I think there's a very strong case for that. It brings up this question about ex ante versus ex post. I agree that—to the extent that we can have the government funding more clinical trials, for example—that would be very beneficial. I don't see it necessarily as an alternative to the patent system, but potentially as a compliment.

We know Ben Roin, for example, has written about how the patent system can distort the decisions of which kinds of innovations to work on early on.[7] For example, if you think that a drug has a large danger of being found obvious, then the pharmaceutical company is less likely to actually take it through all the clinical trials, which really shows a distortion in what we're rewarding. What we're really rewarding is not the initial idea; it's the work going through clinical trials. Maybe we can fix that in the patent system, but if we can't, maybe something along the lines of what Bhaven was talking about would be very useful.

If we have a government role, then the question is ex ante versus ex post. I've tended to be an advocate of an ex-post-type reward for a couple of reasons.[8] First, with ex ante, there are a lot of familiar worries about the kind of grants—people may be less likely to find moon shots, for example. You might argue that that's just an institutional detail, but I think that ex ante grants are more likely to be susceptible to political pressures. There may be political pressure to work on A or B and to stay away from ideas out of the mainstream. The benefit of ex post is that it's easier to measure past social welfare than it is to project future social welfare. Also, especially if we can push the decision off in time such that we don't know who the decision-makers will be, then even if we think maybe they won't get the models right and they'll make mistakes, to the extent that that cancels out in expectation, we may get better allocations.

Especially if you think there are some potential investments that might make a huge difference in the future, those are not likely to be fully funded ex ante. Consider the things that we should still be worried about, like antibiotic resistance. It's quite possible that, ex post, people will understand that developing a new antibiotic was really great once all the other ones turned out to have problems of

[7] Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672 (2014).

[8] *E.g.*, Abramowicz, *supra* note 1.

resistance. I think we're more likely to get funding on that from ex post rewards than from ex ante rewards.

LISA OUELLETTE: Daniel, do you want to share your thoughts?

DANIEL HEMEL: I definitely agree with Bhaven that we should be spending more on pharmaceutical development within the Federal Government.

In our first article together, Lisa and I said it's kind of weird that the process of getting a drug through FDA review is something that we have allocated to the private sector, that dealing with a federal agency is something that the Federal Government can't do; only pharma can.[9] The amount that we spend on the NIH is really low. We spend $30 billion a year on the NIH, and we spend something like $705 billion a year on the Defense department. I think I'm much more likely to be killed by cancer than by a Russian invasion, so I think we should have more ex ante government spending.

In order for that to be maximally effective, we'll have to get comfortable with paying government employees more. At the NIH, the salary tops off at about $418,000 a year, which is what Anthony Fauci makes. If you are really good at drug development and you want to make money, you'll leave the NIH and go to the private sector. But there's no reason why that needs to be the case. We could pay people who work for the NIH more or create a new agency within HHS that focuses on end-stage development. I think it's also important to remember with the ex ante versus ex post distinction that, to the Pfizer employees, the rewards are really ex ante; a Pfizer employee's career advancement might depend upon whether a particular drug development effort works, but she or he is a W2 employee who probably has some incentive compensation feature to her contract, but she doesn't own the rewards. We could have incentive compensation within the government, too; we just have to get comfortable with the idea that there will be people on the government payroll who will be making more than a half million dollars a year.

As a final point, one reason why we spend so much on Defense is because we've created a military industrial complex. We have companies like Lockheed Martin and Boeing who are essentially created by the Federal Government to then lobby more for Defense spending. Maybe we need, and we kind of already have, a pharmaceutical industrial complex where we give some rents to pharmaceutical companies so that they lobby for more government spending on pharmaceutical research. That's in no way an optimal structure, but sloughing off some rewards to

[9] *See* Hemel & Ouellette, *supra* note 6.

the private sector is maybe a necessary ingredient for getting the public sector to spend more.

LISA OUELLETTE: I'd like to get out of this institutional question and go back to a question brought up in the chat about funding for things like vaccine development versus state or local public health departments. Primarily we have been focused on new drugs, vaccines, and specific, concrete products. But we probably would all agree that there is an even bigger problem with funding for things that are less tied to a tangible product like public health measures. Are there ways to improve the institutional mechanisms for those kinds of innovations?

BHAVEN SAMPAT: It's a hard question, both on the public and private sector side, because there are no lobbies for prevention. So, in terms of thinking about that kind of stuff, it's hard on the public-sector-research-funding side to generate much momentum, which is probably why prevention and things like that have been relatively underfunded.

Another thing to point out is that there's a market failure on the diffusion side as well. So, going back to this idea that we have a kind of science-and-technology-push strategy, we assume that diffusion will just happen. One unique thing that we've learned from this pandemic is that that part of the process is not automatic. Some investments in government responses or government responsibility for those kinds of activities might yield high social returns.

MICHAEL ABRAMOWICZ: One thing that is challenging is that it's very hard for the government to figure out what the returns are going to be from different investments and whether there will be returns at all. One nice thing about an ex post system that's reliant on the private sector to produce innovations and diffusion is that the private sector then has the incentive to think, "Well, how fast can we do things?"

In the comments, Amy says that she doesn't think we necessarily could have had the vaccines much faster, and there's some empirical uncertainty there. I think we probably could have. There is evidence that some factories were new factories, and new buildings were opened, and yet I wonder, "Why weren't more open?" If we were producing more vaccines per day, we'd be able to get through this a lot faster.

The deeper point is that it's going to be hard for the government to make those projections. The private sector will make a lot of errors, too, but when you move the rewards ex post and make those rewards proportional to the contributions—if you make it such that the government gives you billions of dollars for getting us out of the pandemic months earlier—we can find out how fast we can go. That's the more

general lesson. I think people are not going to like the idea of people making more than half a million dollars on the government payroll. That's more than the President of the United States. I just don't think people will get comfortable. And the broader point is that those decisions are political rather than economic. I think if you can push more towards ex post rewards, we can target social welfare while still giving incentives for production.

DANIEL HEMEL: I'll add two points. One, I think Amy is right in the chat that we would not have had an emergency use authorization approval a day earlier if we had put more money into vaccines. I think there is a question whether we would have more vaccines on the market today if there were 20 BioNTechs and Modernas rather than two. But the rate limiting factor was the clinical trial process—not that it took Moderna and BioNTech so long to develop their vaccine. Moderna had an effective mRNA vaccine for COVID-19 probably before most of us knew what COVID-19 was.

Michael is right that the government can give huge rewards ex post. We currently are in a political environment in which we feel comfortable having the government give large ex post rewards to pharma and less comfortable with publicly-funded efforts in the health space that don't pan out. But I don't think that is necessarily a political constant. In the Defense context, we tolerate a lot of spending on threats that don't materialize, and we're okay with that. If we could shift to a world in which we thought of public health threats the way we think of national security threats, then we could do a lot more of this in-house. My understanding is that we pay some weapon-scientists a lot of money, either within the federal government or nominally working for contractors, but reward them essentially ex ante. If we could do that for pharma too, then I think we could have more on the ex ante side.

MICHAEL ABRAMOWICZ: One quick response on the issue of "could we have done better?" I thought it was striking that we didn't see the pharma companies pushing for challenge trials. There were plenty of papers written by our bioethicists saying, "Maybe this is the time that it's actually ethical to do challenge trials."[10] It's not like the government convened all the ethicists, and they said, "Oh, we can't do it." There wasn't really a decision; it was just sort of a default.

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[10] *E.g.*, Athmeya Jayaram, Jacob Sparks & Daniel Callies, *Justifying the Risks of COVID-19 Challenge Trials: The Analogy with Organ Donation*, BIOETHICS (June 27, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8444865; *see also*, Seema K. Shah et al., *Ethics of Controlled Human Infection to Address COVID-19*, 368 SCI. 832 (2020), https://doi.org/10.1126/science.abc1076.

I think that's because the pharma companies had little interest in getting everything done faster. It didn't matter from their perspective whether they used challenge trials, which could be a lot faster, or the long trials, because either way they'd get paid eventually. It's just six months to a year difference. If anything, they might be better off having the pandemic go a little longer as long as their competitors don't beat them to the punch. But the problem with something like this is that if one company gets it, then everybody's going to do it, and so nobody pushes for it.

Now, maybe that's the right decision on ethical grounds, or maybe not, but I certainly don't think you see incentives for outside-of-the-box thinking that will really move things forward. I think that's more broadly a danger. Maybe we want to have the pharmaceutical industrial complex, but we need to think about the incentives that the complex actually has, and it's not always to advance public health.

BHAVEN SAMPAT: I just want to push back a little bit against the idea that it's difficult for the public sector to take risks. We spend, I think, $40 billion on the NIH, which primarily funds basic biomedical research under the guise of producing health outcomes. I'd say 90-95% of it doesn't actually result in anything that links to any health outcomes. Still, the NIH has perennially been a fairly popular agency with bipartisan support.

But you might argue that, within that bureaucracy, you want to change incentives to take on more risk-taking behavior. There are serious proposals—from adopting parts of the HHMI model to Pioneer Awards. There might be ways that you can tweak the incentives facing not internal NIH scientists, which are a small part of the game, but external researchers funded by the NIH on the basic research side. I think the applied research side is probably a different set of issues; we don't really know much about that, partly because there haven't been that many experiments in terms of government funding of applied research and medicine.

LISA OUELLETTE: I think this discussion is highlighting some of the error costs in relying on all of the different institutional mechanisms. One broader challenge in these discussions about innovation policy is that they often are focused on pointing out the flaws in a particular mechanism while assuming an idealized version of the other one. For the same reasons that we have underinvestment in preventatives by the private sector, it's very similar flaws that lead to underinvestment preventatives by the public sector.

I don't know what the right way is to move beyond that. I like Daniel's point that we spend lots on the military preventing things that never happen. If we could somehow shift the public debate to thinking about threats in the health system in the same way, then that would be useful, but I don't know how.

BHAVEN SAMPAT: Well, this might be a good moment to do that, right?

[Laughter.]

MICHAEL ABRAMOWICZ: There's one other dimension to defense versus medical, which is that medical spending helps everybody in the world. It is, of course, even better. But, on the other hand, it suggests that the optimal locus of organization is global rather than national. To the extent that, over time, the U.S. GDP becomes smaller relative to the world GDP, that's going to be more of an issue. There may be more political pressures. People say our direct benefit from that spending gets to be a relatively low percentage. There have been discussions about international institutions that might fund medical research, and maybe that's a little bit beyond our scope, but it's certainly an important thing for people to be thinking about.

DANIEL HEMPEL: Well, I was just going to say, I think the defense analogy is a great one in that we did decide that we would be the world's policemen; we would defend Western Europe and not really make them pay for it. Now, it may be that, in retrospect, American hegemony benefited the rest of the world less than we thought it did at the time, but in that context, we allowed the rest of the world to free ride off of our efforts. So, why not do the same in pharma?

MICHAEL ABRAMOWICZ: That might not be as politically popular now. I mean, just my sense, and I suspect that may be true in pharma, too. I'm making a political prediction. I'm certainly in favor of increasing spending to the NIH; I just don't know if it's as politically viable as it might be.

BHAVEN SAMPAT: I think a more prosaic difference between DoD and NIH is that DoD explicitly acts like a mission-oriented agency: it has some specific goals, and it funds research to achieve those goals. The different parts of HHS don't really talk to one another. I mean, this is like Burt Weisbrod's old healthcare quadrilemma article in some sense.[11] Medicare is not going back to NIH and saying, "These are the specific priorities." It just doesn't function in that sort of way. Those are two different arms, and it seems like some sort of integration might be useful.

LISA OUELLETTE: One question in the Q&A that we haven't gotten to is asking about who should be rewarded: the scientist at the firm who is doing the research versus the shareholders of that firm. We've been thinking about these

[11] Burton A. Weisbrod, *The Health Care Quadrilemma: An Essay on Technological Change, Insurance, Quality of Care, and Cost Containment*, J. OF ECON. LITERATURE 29, no. 2, 523-52 (1991).

institutional mechanisms at a bigger picture level. Do any of you have thoughts on that issue of the rewards for the actual scientists and what policymakers should be doing in that regard?

MICHAEL ABRAMOWICZ: A lot of times, individual scientists can benefit from *awards* rather than *rewards*. I think it's probably the kind of prizes you put on your wall that might be a better way to recognize individuals. There are certainly lots of institutions, like open source software, that work more on the basis of recognition of individual contributions. Still, I'm skeptical at how well that can be scaled into the pharmaceutical space.

DANIEL HEMEL: It might be helpful to distinguish between the Pfizers of the world and the BioNTechs of the world or the Modernas of the world. There are some companies where the vast majority of equity is held by shareholders; the scientists who are doing the work are not the ones who are getting the rewards. But there are a lot of companies that are involved in COVID-19-related R&D, particularly on the vaccine front, where it is particular scientists who are becoming multimillionaires or billionaires because of this.

There's still a superstar economy, but it's the people with MDs and PhDs who are getting rich. I think that exacerbates the problem of how we get the best R&D minds to stay within NIH or within a new kind of applied pharma agency within HHS. They're the people like Anthony Fauci, who are willing to live a top-1% but not top-0.001% lifestyle because they're public servants. Unless we increase rewards for government scientists, we're going to be relying a lot on the good graces of the future Anthony Faucis for that.

LISA OUELLETTE: We have three minutes left in the panel. I thought we could conclude by giving each of you a minute to wrap up with any concluding thoughts, including if you had to give a Twitter-sized version of—for people who haven't been thinking about rewards for medical innovation—what you hope they take away from this panel. Michael, do you want to go first?

MICHAEL ABRAMOWICZ: Sure. I don't have a Tweet prepared and ready with 140 characters, but one thing I would say, just as a closing, is that it's important to find ways of funding all stages of research, including developing the idea for drugs, clinical trials, and manufacturing. That's where I think they've fallen the shortest during COVID. If the government is going to be focusing on Medicaid or other kinds of programs, they should probably be thinking about where we fall the shortest and try to add incentives on that.

DANIEL HEMEL: I guess my concluding thought would be something like, "More spending on innovation need not come at the expense of access, but will require political will." That's about 280 characters, so I'll stop there.

BHAVEN SAMPAT: It's quite an exercise. "Start from the outcomes we want and work backwards." I think the pandemic taught us that that's a useful way to approach biomedical innovation policy. Start from the outcomes and work backwards to the types of investments and institutions you need.

LISA OUELLETTE: Great! Thank you so much to all of you for having this discussion. There's a lot more we could say, but we are out of time. I will turn things back over to Zach.

ZACH BASS: Thank you, Lisa. Unfortunately, I have to be the villain throughout this event and tell people to stop talking when I could keep listening to all of you talk for the rest of the evening.

I think your panel did an excellent job at really hitting the core of the issue, which is governmental spending as an expression of priorities. It's an expression of our national values. After this pandemic, is there going to be a rethinking of national priorities? I thought Daniel's point of "am I more likely to be killed by cancer or invading Russians" stood out. That's a pretty compelling question after this pandemic. Thank you all. I thought that was masterfully done.

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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.

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WHETHER AND HOW THE U.S. GOVERNMENT SHOULD EXERCISE ITS COMPULSORY LICENSING AUTHORITY UNDER 28 U.S.C. § 1498 AND THE BAYH-DOLE ACT

MODERATOR: ARTI RAI

PANELISTS: REBECCA S. EISENBERG, TAHIR AMIN, HENRY HADAD, AND RACHEL SACHS

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 third of four panels. This panel discussed whether and how the U.S. government should exercise its compulsory licensing authority under 28 U.S.C. § 1498 and the Bayh-Dole Act. The panel was moderated by Professor Arti Rai of Duke University School of Law. The panelists included Professor Rebecca S. Eisenberg of the University of Michigan Law School, Tahir Amin, Co-Founder and Co-Executive of I-MAK, Henry Hadad, Senior Vice President and Deputy General Counsel at Bristol-Myers Squibb, and Professor Rachel Sachs of Washington University in St. Louis School of Law.

[*] 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 3)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=kbGWMDmsBgI.

ARTI RAI: Compulsory licensing can be exercised in at least two different ways under the U.S. government's power: Section 1498[1] applies to all patents; the Bayh-Dole Act[2] applies to patents that emerge from government funding.

There have been long standing concerns about the use of compulsory licensing. Most recently, these concerns have popped up in the context of proposed regulations put out by the National Institute of Standards and Technology for public comment.[3] I believe our panelists will be talking about that to some extent. It is a very topical subject.

More generally, the issue of compulsory licensing raises important questions regarding whether and how it should be used. For example, if the answer to whether is yes, there is the whole question that came up in the first panel with respect to how to calculate and the institutional framework that should calculate.

There's also a set of issues that's slightly independent of patents, but we will discuss as well. Since patents often don't disclose everything that's necessary to make and use the product, contrary to the statutory requirement, there is also going to be know-how—trade-secret-protected know-how—and, in the context of biomedical products, data exclusivities that have to be dealt with if the government actually wants to get the product produced.

We have a terrific panel to address these issues. They have all extensively written about and discussed the issues of biomedical innovation and access. They're going to speak for a short intro period, and then we will have them all react to one another. So, with that, Professor Eisenberg, could you take it away?

REBECCA S. EISENBERG: Yes. Thank you so much. I'm delighted to be included in this very interesting discussion. I am going to focus my remarks on the Bayh-Dole Act, which is something that I know more about. I find the topic endlessly fascinating, and I've been thinking about it off and on for the past 30 years or so. I'm going to be focusing on "march-in" rights under the Bayh-Dole Act.[4]

The Bayh-Dole Act is about using patents—resulting from government-sponsored research—to facilitate technology transfer and further investment in commercial product development. In 1980, this was a big change for some agencies that had previously thought that the best way to achieve widespread access to

[1] 28 U.S.C. § 1498.
[2] 35 U.S.C. §§ 200-12.
[3] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35 (proposed Jan. 4, 2021) (to be codified at 37 C.F.R. pt. 401, 407).
[4] 35 U.S.C. § 202.

research results was to leave everything in the public domain. So, although the goal was to promote more widespread access to practical benefits of government-sponsored research, members of Congress worried that Bayh-Dole patents could easily have the opposite effect: they might restrict access to new technologies that had been created with taxpayer funding.

Congress therefore put some safety levers in place in the statute. One of those safety levers was march-in rights. The statute gives federal agencies that funded the research behind Bayh-Dole patents the right to "march in" and require patent holders, or licensees, to grant further licenses to responsible applicants on reasonable terms—or to grant such licenses themselves—under certain circumstances that were specified quite clearly in the statute. The specified circumstances include failure of the rights holder, or licensee, to take effective steps to achieve practical application of the invention, as well as necessity to alleviate health or safety needs, which the rights holder is not reasonably satisfying. "Practical application" was further defined in the statute to mean that the invention is being "utilized" and that its benefits are "available to the public on reasonable terms."[5] That's not me talking; that's the language of the statute. The statute authorizes federal agencies to use march-in rights to extend further licenses in order to ensure that the benefits of the invention are available to the public on reasonable terms and as necessary to alleviate health or safety needs.

No agency has yet exercised march-in rights, although NIH has considered and rejected a half dozen or so petitions for march-in rights over the 40 years in which the system has been in place. I think that's partly because current regulations make it difficult and cumbersome, but partly I think it's also because it's very unpopular with the important constituencies of NIH.

Nonetheless, the National Institute of Standards and Technology (NIST) has a currently pending Notice of Proposed Rulemaking that was published in the Federal Register in the final weeks of the previous administration proposing to "clarify" that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.[6]

This is not a clarification; this is an interpretation that is contrary to the plain language of the statute. Moreover, it uses rulemaking by NIST to take away discretion as to determinations that the statute directs funding agencies to make and

[5] 35 U.S.C. § 201(f).

[6] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35 (proposed Jan. 4, 2021) (to be codified at 37 C.F.R. pt. 401, 407).

that can only be made on a case-by-case basis. NIST has statutory authority to promulgate procedural regulations, but not to determine when the exercise of march-in rights is appropriate. The statute clearly allocates that judgment to the funding agency.

This proposal is open for public comments until April 5th, which is coming up soon. Put it on your calendars. Meanwhile, I expect we will have a lively conversation about this issue today.

ARTI RAI: Indeed, I'm sure we will. Very topical. Mr. Amin, could you discuss your affirmative statement of the case?

TAHIR AMIN: My affirmative statement. So, the question is whether and how Section 1498 should be used. Whether: yes. How is a much more difficult question given the way the provision is worded. There's been a lot of discussion by people who are far more educated on this particular provision, but the two words that come out to me are the words "reasonable" and "entire" compensation, referring to how one is compensated when a government actually enacts Section 1498.[7]

When we look at the pharmaceutical sector and drug pricing, we've seen in the last four or five years how drug pricing has really been on the agenda in terms of the rising prices. My organization has a number of works looking at this patent situation around drug prices.[8] If you look at the top 10 selling drugs in the United States, the average price increases 71% between 2014 and 2019. And if you look at the number of patents that accumulate on many of these products, we're looking at an average of 131 patent applications, of which, on average, 62 are granted. We take all this into account.

There have been particular cases, like sofosbuvir (the hepatitis C drug), for which various states were looking at ways to use Section 1498. They never got used; but with the threat of it, they've made other types of arrangements. I think similarly with PrEP, we've had that discussion going. Christopher Bolton, who's been involved in setting up this symposium, has written a lot about it. So, that's the Section 1498 problem.

Ultimately, I think that the "how" is problematic because, as lawyers, we will sit around and happily finesse words and talk about what it could be, but I think

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[7] 28 U.S.C. § 1498(a) ("Whenever an invention [. . .] is used [. . .] by or for the United States without license of the owner [. . .], the owner's remedy shall be by action against the United States [. . .] for the recovery of his reasonable and entire compensation for such use [. . . .]").

[8] *E.g.*, I-MAK, Overpatented, Overpriced: How Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices (2018).

there's a deeper problem. The deeper problem is actually a cultural private property issue that the United States has. I think trying to actually litigate these kinds of words in court is hugely problematic.

I also come from an international perspective because, when I look at some of the language used in compulsory license provisions around the world, the words "reasonable" and "adequate remuneration" appear in a lot of provisions. But the word "entire" throws things off here in the Section 1498 provision. Of course, people have different readings of it, and there is case law that suggests that it does not extend to profits. But if you've tried to do it for drug pricing, for example, are we going to reward "entire" amounts to the pharmaceutical companies. That's one argument that's kind of concerning.

I think, ultimately, Section 1498 needs a revision. We need new language. I think it's actually too confusing. From my experience in the United States, everything gets litigated when it comes to property, including patents, so we need language that's actually going to eliminate some of that and make it very clear.

When we come to the Bayh-Dole march-in provision, there are people far more informed than I am, but when I look at it, it's in terms of the drugs that have come out of public funding. Take Lyrica, for example, which is a drug by Pfizer. It was developed by Northwestern University. You have a company that's making $5 billion a year on a product which originated from public funding. And yet, the government has no backbone to come in and try to alleviate some of the price pressure, despite the public funding.

We've seen this with COVID in terms of people asking, "Should the government come in and act?" I feel it's all great litigating this stuff, but, at the end of the day, we need political will. We've seen that, around the world, anytime any country tries to issue a compulsory license, the United States is first in line to use its power and influence to try to stampede over anybody's sovereignty. So, the question of "how" is actually deeper. I think it's a cultural psyche, and it's actually more than just the legal words that we panelists can play around with.

ARTI RAI: That's a terrific statement of the case. Mr. Hadad, would you like to give your statement of the case?

HENRY HADAD: Sure, thank you. As already mentioned at the outset, I'm chief IP counsel at Bristol Myers Squibb. I'm not talking in any official capacity today, but rather as an individual that has focused my practice on IP.

Let me start by saying that I am probably the least credentialed in terms of legal scholarship of anyone on this panel. I'm really privileged to be with this group. Hopefully I bring some real-world experience from my 30 years of practice and my 20 years working in-house in biopharma. Based on this experience, not surprisingly, I do have considerable concerns on the question of whether the U.S. government should utilize compulsory license or Bayh-Dole to appropriate technology. The reasons aren't born of having concerns about the balance of access. I certainly share everyone's concerns about that. It's largely born from what it does to the innovation engine; I'll get into that in a moment.

Biopharma is the most research-intensive industry, as measured by our spending against revenue. As Donna mentioned in the prior panel, developing a biopharma product is long, expensive, and risky, taking 10 to 15 years. The process has a huge failure rate of almost 90% and an average of $2.6 billion development cost per drug. That $2.6 billion covers a lot of ground. It covers a lot of failures and the few successes. The only legal right that justifies that risk and that expense is an IP system that makes a simple promise to innovators: if you invent something, and you work hard and invest to make it a reality, the law will provide a limited period of protection from appropriation, after which that technology is freely available to be used and improved upon. That's such a fundamental promise that it was part of our Constitution.[9]

Congress further considered the issue of IP protection in this space in the context of Hatch-Waxman in 1984, which created the generic industry as we know it and was really a means to balance innovation and access.[10] That act has been famously successful; over 90% of prescribed medicines are generic, and the Hatch-Waxman process is actually a great engine that drives further innovation by branded companies in anticipation of older products going off patent. In 2010, of course, the BPCIA introduced a biosimilar pathway to create an analogous set up for biologics.[11]

As we've probably talked about in other panels before, the U.S. patent system is in a bit of an inflection point. There's a lot of uncertainty in the patent system, which is born from a number of different areas. One is a combination of Supreme Court cases that have created so-called "flexible standards" and maybe eroded some

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[9] *See* U.S. CONST. art. I, § 8, cl. 8.

[10] *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), Pub. L No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301, 355, 360cc).

[11] *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-28 (2010) (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.). The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 804 (2010).

IP doctrines in a way that gives less confidence in the promise of that limited period of exclusivity. At the same time, you have the introduction of the PTAB, which provides multiple administrative challenges against intellectual property. So, while other countries, including China, continue to develop their IP system to encourage domestic industry, we seem to be doing a bit of the opposite.

Now let's add the question of compulsory license into the mix. First off, it's not simply that I don't believe it's permitted by the existing law. I believe Section 1498 was passed to create government liability with respect to patent infringement on the basis of potentially appropriating patent rights but not being able to use sovereign immunity to bar liability. So, it was not contemplated as a basis for compulsory license as we think about it today. Turning to Bayh-Dole, while it technically permits march-in rights on patents covering government funded innovations, there are a lot of good reasons why it hasn't been advanced thus far. I think—and this is just reality—when you consider the investment and the risk that companies have to make if they have a choice between investing in a technology which doesn't have this potential march-in versus technology which does, they're going to lean toward investing in the technology where there is no march-in right. They don't want to make that investment and then 10 years down the road be told that the investment wasn't warranted because it effectively is going to be taken away from you. It may be, or may not be, in terms of "reasonable compensation." That's an open question; I think that's worth discussing.

So, let me just be clear: I know there are situations where the government may have to move forward with respect to patented technology. If a patent holder is not working the patent and an important biopharmaceutical is not available in the event of a global health crisis—I think we certainly have some real-life examples there—the U.S. and other countries can and do move forward. There are existing TRIPS flexibilities just for that reason.[12] But, absent that situation, I'm hard pressed to see how compulsory licenses advance the public good overall as it would undermine future biopharma innovation.

The risk and uncertainty of drug discovery and development require a stable and predictable period of exclusivity. Every new drug and its success fund the next generation of potential therapies, 90% of which fail. So, we have got to make sure that innovation engine is there to improve or save lives around the world. We've seen this firsthand over the last decade. There have been incredible things that have

[12] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 30, 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

occurred. Hepatitis C is effectively cured. While we have a long way to go on a permanent cure, HIV is no longer the death sentence it once was. Heart disease has decreased dramatically. Many, if not all, of these products have gone generic. More recently, new cancer treatments like immunotherapy and cell therapy have the potential to extend patient lives and improve them. And every day, new data comes out on these existing products which further extends these to new patient populations, new types of cancers, and provides hope to them. It's very inspiring to be part of. Of course, the incredible innovations around the mRNA vaccines that led to Moderna's and BioNTech's vaccines are just a testament to what a robust biopharma industry can do when pressed with a significant issue.

Three things have jumped out at me just going through that experience. First, companies have partnered with each other and other public stakeholders to find a solution, investing huge sums with uncertain economic outcomes, largely because it was the right thing to do. I believe only through the general health of the industry are we able to react in situations like that.

Secondly, these companies develop these vaccines with their eyes wide open as to the potential of what they could and could not do economically with them. I think that says something. Going into a situation knowing that the government will have a right from the outset may change a bit of the dialogue versus finding out 10 years after you've made those investments.

Lastly, I have not seen a meaningful instance where the patent system has been an impediment to getting therapies for COVID around the world. I think it's really a testament to some great work by the industry and, frankly, by the public sector as well.

Let me conclude by acknowledging: we have an imperfect system. Discussions like this today and more academic scholarship are an important part of identifying areas to improve and acting on them. Constructive and thoughtful discussions balancing the need of innovation and access really allow our legal system to adapt to the needs of today. I feel extremely privileged to work in this industry. I really want to thank you all for your time today and look forward to the panel discussion.

ARTI RAI: All right. Professor Sachs, you're going to take us home for this first part.

RACHEL SACHS: Great. Thank you. I want to join the other panelists in thanking the organizers. This has been a wonderful discussion thus far, and I'm glad to be here.

I'll focus my comments on the point that our existing compulsory licensing authorities are not well suited for our current incentive structures and access problems; we should think about modernizing these compulsory licensing authorities to do so. I'll say a little bit about both Bayh-Dole and Section 1498—what they allow you to do, and, more importantly, what they don't allow you to do, and why that matters to us.

I'll start with Bayh-Dole. Bayh-Dole allows you to use your march-in rights on patents that result from government-funded research. But if the aim is to use these rights for prescription drugs, there are some predictable problems that arise.

First, there's not a one-to-one correspondence between a drug and patents because most drugs are protected by several patents. If we're talking about small molecule drugs, we're thinking in the high single digits. But, as Tahir's group has done fantastic work to show, especially around some of these biologics, they may be protected by dozens or even hundreds of patents. So, it may be that some but not all of the drug's patents were developed under a funding agreement with the federal government; in those situations, Bayh-Dole limits your ability to use it as a compulsory license for these drugs. That problem is solved in Section 1498 which speaks, not in terms of patents, but in terms of inventions described in, and covered by, patents. So, Section 1498 can much more easily be used in the drug context. But it also has gaps that limit its effectiveness. These apply to Bayh-Dole as well. In particular, it doesn't clearly allow you to circumvent either the FDA exclusivity period or trade secrets, which may be of greater importance for particular classes of products. This is not a surprise given the times in which these statutes were passed and the existing incentives then.

Many people in this conference will be familiar with Amy Kapczynski's article with several of her former students which has this detailed history of Section 1498.[13] The statute has existed in its current form since 1942. But we didn't get the concept of an FDA-administered exclusivity period until the early 1980s with the Orphan Drug Act,[14] the Hatch-Waxman Act,[15] and then more recently, the BPCIA.[16]

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[13] Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 15 HEALTH AFFS. 791, 793-95 (2016).

[14] Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified at 21 U.S.C. §§ 360aa-360ee).

[15] Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), Pub. L No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc).

[16] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-28 (2010) (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.).

So, it's not a surprise that Section 1498 doesn't allow you to circumvent those periods, but it is a limitation. It's likely to be particularly problematic for complex biologics, which just weren't part of the discussion in the 1910s when the first version of Section 1498 was passed, nor in the early 1940s with the trade secrecy issue.

When you take these limitations, in its current form, Section 1498 might be most useful when dealing with drugs of more moderate ages: drugs whose exclusivity periods have expired but whose patents are still in force, where their manufacturing techniques are either known or can be reverse engineered. This is more likely to be true for small-molecule drugs or simpler biologics. One set of products which is starting to fit this category is the Hepatitis C drugs, which were approved mostly in 2013-2014. Some of them have follow-on approvals that may make this more complicated, but their initial FDA exclusivity periods have likely lapsed.

I think these limitations are important ones to remember for people who are on both sides of the issue. One argument that you may hear from the pharmaceutical industry is that using these laws would destroy the incentive to innovate for prescription drugs. And while I do have concerns about this, I come out somewhere in between Henry and Tahir on this issue. I think the answer is "sometimes" for when you should use these. But in this context, because you can't use Section 1498 before the FDA exclusivity periods have lapsed, the argument can't just be that "it will destroy innovation." The argument has to be that "five or seven or twelve years of exclusivity isn't enough," which is a harder argument to make.

Then, on the other side, we're talking about how and when we'd like to use these compulsory licensing authorities. We should think more about whether there are existing ways to circumvent FDA exclusivity periods or trade secrecy protections. I've thought more about the FDA side of this, but I would bet Arti has thought more about the trade secrecy side. If not, can we create ways through either legislation or regulation? Thank you.

ARTI RAI: Terrific. Those are all great statements of the case. We've got a range of positions on all of these issues. Before I get to all of my questions, though, I would like to see if any of the panelists have an interest in responding to one another in some way because you've all been provocative (in good ways).

REBECCA S. EISENBERG: I agree with much of what everyone has said; but one thing that I disagree with is this: I don't think it's true that everything gets litigated in the United States. I think much gets negotiated in the United States, and you just don't see those things. We may be litigating more things than get litigated

elsewhere, but we are also working a lot of things out through voluntary or consensual agreement. And I think a lot of these rights set the stage for who has a seat at the table, and who is participating, and what are the relative positions of all the parties.

Maybe one reason why you don't see more compulsory licensing happening in the United States is that everybody's bringing something else to the table; you can't simply go it alone and litigate the issue and expect to accomplish anything, partly for the reasons that Professor Sachs has been explaining. There are too many different sticks in the bundle of rights that are held by different parties. By the time a new pharmaceutical product comes to market, there are a host of patents, and lots of know-how, and supply chains, and production facilities, and lots of reasons why you're not seeing compulsory licensing here, even though all sorts of countries in the early days of the pandemic were making noises about it. You're not seeing that happen here because they can't simply go it alone. They need to work with the suppliers of these vaccines in order to get access to them, and so they work out a deal. Israel worked out a deal with Pfizer, even though they have very favorable compulsory licensing laws; they worked out a deal that involves paying money and also providing data to Pfizer, and it's quite valuable all around. Everybody has something to bargain with, and the potential for compulsory licensing doesn't necessarily mean that that's the way it's going to go.

ARTI RAI: All right. Does anyone want to respond?

TAHIR AMIN: Henry talked about this sort of "social contract" with a limited period of protection. I think we're living in a world now where that is not quite what it was intended to be, or as it was written in the Constitution. We've seen the growing number of years, on average, the top 10 selling drugs have; whether they will actually use them all, it's at least 38 years on average.

Then, on the TRIPS flexibilities and Rebecca's point, I think we have a history where any time anybody's tried to use them—let's just put COVID aside and all the peculiarities of who needs to work with who—there's an immense amount of pressure to actually not use compulsory license provisions, even if countries have reasonable provisions and are very clear on when they can use them. So, I think that it's not as straightforward because the "how" is the problem. It comes from not just nice legal language, but it comes from an implementation and how governments are allowed to act in this current political economy.

I think the United States is a driver of the IP system as it is today. I mean, obviously China's got its own version now, but I think China's just following what the United States is doing. And then eventually, in 20 years, if China has a hold of

all the biotechnology power, what will the United States be doing when it comes to actually demanding some kind of compulsory license because the United States doesn't have certain technologies?

We need to see past the end of our noses here and look at where we're going with a lot of this proliferation of IP.

ARTI RAI: Henry—we've gone to first names now since we're all familiar.

HENRY HADAD: Absolutely. I really enjoyed the comments of everybody. I'm just responding to what Tahir said.

I realize he's had a lot of good academic scholarship on patents and the number of patents per product. But when you look at the reality, first off, the average exclusivity for biopharmaceuticals is 12 to 13 years I think; that's been done and been reviewed by certain independent groups. Then, if you look at the Orange Book,[17] which lists small molecule patents, and what's actually litigated, the end result is that the net number of patents is single digits (low single digits) max.

We don't seem to question whether an iPhone may have multiple innovations, but we do seem to question whether a biopharmaceutical does. It's particularly true in the biologics space. There is so much complexity to first identifying the active ingredient, then making it, then using it, and then new potential indications for it: extending it from people who have melanoma to people that have lung cancer. I realize that this creates a little complexity, but I think these are the kind of innovations we want to incentivize as a society. We want to encourage more opportunities for patients to improve their situation.

From my perspective, I think the IP system does what it's supposed to do. We have to remember that even where there are multiple patents on a product, overwhelmingly, the original product proposition goes off patent. There may be other indications or a new version of it that may stay on patent, but the old version does go off patent. Again, that's something we want to encourage going forward as a society.

As a citizen of the United States, I do not want to cede biopharma innovation to other countries. I realize that the United States and Western Europe, to some degree, have shouldered the burden of innovation and the expense of innovation. In an earlier panel, someone mentioned whether it's a bit like defense. I don't know

[17] The common name "Orange Book" refers to the publication by the Secretary of Health and Human Services of "the patent number and the expiration date of any patent which claims the drug" in connection with an application for approval of a new drug. 21 U.S.C. 355(b)(1).

whether it is or not. But I do think it's something we, as a society, should have an open discussion about: how much of that burden of innovation should we shoulder versus the rest of the world?

One additional point to Rachel's points on data protection. The small molecule data protection, which was part of the original Hatch-Waxman Act, is five years. It's actually four years to a patent challenge. I can tell you from personal experience, that is not a sufficient runway to develop a small molecule product in and of itself, and the patent system is particularly important for those situations. I would love to see a situation where there was more data protection for small molecules that would run concurrently to patents, so it wouldn't extend the time, but it would provide predictability and the opportunity to take some older drugs, which maybe never were developed but are off patent, and bring them to patients. I think that would be a great thing as well. I'll stop there. Thank you.

ARTI RAI: Rachel?

RACHEL SACHS: I want to make a small point, which I think is floating around and related to some of the points that several of us have made.

The title of this panel is "Whether and How the U.S. Government Should Exercise its Compulsory Licensing Authority," but we haven't really talked about what "exercise" means.

We've been thinking about it in the sense of "what if the government were to formally invoke, and carry to its full conclusion, the Section 1498 process?" What would that look like, and what would it require? It has all of the pros and cons that we've been talking about. But to exercise the authority may mean to credibly threaten to use that authority in the hopes of attaining a much better deal from the company involved, recognizing that all parties know that it's far easier to do that and more profitable for the originator company than to force everyone to go through this process.

You could make a convincing argument that the Louisiana and Washington uses of the subscription model for the Hepatitis C treatments were exercises of compulsory licensing authority given the extensive public discussion of the use of Section 1498 that preceded those licenses. Now, do I believe that Secretary Azar was on the verge of issuing a Section 1498 notice to the companies about their drugs? No, I do not. However, I do think that building pressure, and statements, and interest in this issue *were* relevant to that process. So, I think that's something worth bringing in.

ARTI RAI: I'm so glad you brought that up because I do think that's precisely part of the puzzle and may be part of the reason why NIST has felt compelled to clarify that pricing isn't part of the equation, even under Bayh-Dole, because the prior administration seems to have not been averse to threatening, in the context of Sovaldi and some other situations. Threatening may be all that's necessary in a lot of cases. So, this is an open question to all: these threats are out there, and they play a role; so, aren't we already here in some respect?

HENRY HADAD: Yeah. Already I think it's really a question of: "Is it reasonable to expect private industry to bear the burden of healthcare where countries are not willing to necessarily pick up the bill?"

I think there's a fair amount of that that already goes on. Look at how Hatch-Waxman and the BPCIA basically permit the use of data so that there's no need to spend a billion dollars to make a generic or a biosimilar. You can go in and, with limited data, get approval because you're utilizing data in a way that's leveraging and that's co-opting the investment of a company that's done the work.

It makes sense, right? It makes sense from a policy perspective. It would be crazy to reinvent the wheel, so to speak. But just because it gets done doesn't mean it's necessarily right. I think the broader question should be: "Is there some way to look at how we provide healthcare across the board?" It's not just biopharma: it's hospitals; it's the middlemen; it's the pharmacy benefit managers (PBMs); it's the whole enchilada. We have to seek to provide reasonable and ethical coverage for people across the board rather than say, "This drug's too expensive. I'm going to threaten this unless you do what I say."

ARTI RAI: That's a really important point. As the first panel noted, pharmaceutical spending is a small part of the overall healthcare dollar. Maybe we should be spending more.

That leads to a question that's in the chat, which is: at the end of the day—let's say we went past "whether" and consider "how"—would we want to go to some sort of system where "reasonable and entire compensation" was all of the social welfare value provided by the drug?[18] That was one possibility raised by the first panel. Or would it be some sort of cost-plus arrangement? It's not necessarily the

[18] *See* 28 U.S.C. § 1498(a) ("Whenever an invention [. . .] is used [. . .] by or for the United States without license of the owner [. . .], the owner's remedy shall be by action against the United States [. . .] for the recovery of his reasonable and entire compensation for such use [. . . .]").

case that—as Professor Ouellette put it—a liability rule has to treat industry less well than a property rule.

So, to translate: we could pay a ton of money in "reasonable and entire compensation." We could pay the entire social welfare benefit provided by Sovaldi, for example, which would probably be in the billions. Would that be okay?

RACHEL SACHS: Lisa Ouellette and I write together. We've been writing a series of posts with our colleagues Nicholson Price and Jake Sherkow about innovation and COVID-19 on Lisa's blog, writtendescription.blogspot.com.[19] So, Lisa knows (or I hope knows) that this is something that I've now internalized by writing with her for so long.

I will say that I agree. One reason that I was particularly nervous about the use of Section 1498 for Sovaldi when it was first created was that I thought this is precisely the type of drug that we should be paying pharmaceutical companies a lot of money for. This is a drug that cures a disease which is predominant among disadvantaged populations, and there are huge social welfare advantages to being able to eradicate a communicable disease. That's so rare.

However, it was such a budget buster for states, so some people at the time proposed that the government should buy Gilead and make the drug available at cost. It's not at all a crazy proposition—this idea that Gilead should be paid a lot of money for doing what it did, but also that we can and should think about using compulsory licensing. You can hold both of those views at the same time.

I really worry about this idea that we would disproportionately disadvantage innovation into neglected diseases by only using Section 1498 in those contexts. But my bias is that we should pay more for drugs that work better.

I should disclose that I'm on one of ICER's public advisory committees. I'm not an employee; I'm an independent. I sit on one of their public panels, and you should all come to the meetings. So, my biases are in line with the work that was talked about in panel one.

ARTI RAI: Henry?

HENRY HADAD: Just further building on what Rachel said: one of the challenges at quantifying what reasonable compensation looks like is that rarely will

[19] *E.g.*, Jacob S. Sherkow et al., *Are Patents the Cause of–or Solution to–COVID-19 Vaccine Innovation Problems? (No!)*, WRITTEN DESCRIPTION (Mar. 4, 2021, 1:50 PM), https://writtendescription.blogspot.com/2021/03/are-patents-cause-ofor-solution-tocovid.html.

you say, "Well, you spent $2 billion on this particular drug, and I guess you get some type of kicker because you're providing some social benefit." The way the system is built is that today's revenue funds tomorrow's therapies. You can't just look at that one drug in a vacuum because you've got to look at the other 90% of the drugs that were in your pipeline that didn't make it, that you spent a ton of money on over the years. If you don't have that sort of return, the next generation of therapies just doesn't happen.

I think there are a lot of valid points being raised, and access is a serious thing. I know companies take it seriously. Governments take it seriously. People take it very seriously, of course. I'm a patient; my mom is a patient; my family is. But at the same time, I worry about chilling the innovations that are coming down the line.

ARTI RAI: Henry, let me do a quick follow up. Let's say that we agree with Henry Grabowski (my colleague here at Duke) that, including the cost of failures, including everything a drug costs, and including the cost of capital at a significant percentage (13 to 14%), a drug costs $2.5 billion just to develop.[20] Add a profit kicker to that, and are we done?

HENRY HADAD: I don't think so necessarily. I think there's a model there. I'm a firm believer in the IP system. I think it's been the engine that has driven us to the greatest innovations the world has ever seen. I think that's great. But we've talked about people who say, "Why don't we just give money out?"

There's no reason that they're mutually exclusive. If the government has something they want developed, and they say to a company up front, "We'll give you this amount of money—a flat fee up front. Knock yourselves out." If this is an appropriate incentive, then great. Let's see if it works.

What I fear is not going into these things with eyes wide open. What happens if 10 years later somebody says, "We're taking this from you." That's where it breaks down. Suddenly, investors flee. They go to safe investments, which are commodities, and they don't go to the high-risk, R&D-intensive ones because of that fear.

ARTI RAI: Now you've got lots of hands. I think Becky was first, and then Tahir.

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[20] *E.g.*, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH. ECON. 20 (2016).

REBECCA S. EISENBERG: IP is very high-risk, high-reward, always has been. There's a lot of invalidation of patents, always has been. But there are advantages to taking a risky strategy on the reward side.

Sometimes you're lamenting, "We need security. We need to be sure that, at the end of the day, we're not going to have these profits pulled away from us." And sometimes you're saying that you want the possibility of extraordinary returns. I can see benefits to both of those systems, but you really can't have it both ways.

The closest thing to a sure bet is regulatory exclusivity. I think the pharmaceutical industry initially was not pushing as hard on that as patent protection, believing that that was the side their bread was buttered on. But you can't have it both ways.

HENRY HADAD: I have a quick response to Becky, and then I know Tahir has a comment, too.

I would just say, on regulatory exclusivity, clearly that was the focus in the BPCIA because there was a recognition that biologic patents aren't quite as robust as small molecules. But there have been various things talked about—like MODDERN Cures, for example[21]—where, at the outset, you have a choice when it comes to biosimilars or small molecule generics. When you get approved, you can choose to get 15 years of protection or choose to rely on the patent system.

That degree of predictability has some advantages. The one downside of it is depending on the waxing and waning of society and people's concerns about pricing today: they could knock that down significantly in a way that there's no recovering from. So, I think there's a bit of a balancing act, but I like the idea of data protection. It does provide predictability, Becky.

ARTI RAI: Tahir?

TAHIR AMIN: I seem like the outlier here.

I'm going to talk about compensation value. What's interesting to me is that, if we look at the rising prices of drugs, these prices are set by the industry. We don't have any kind of independent authority like a lot of the European authorities that at least put some value-pricing qualities on the price of drugs. If we're going to be doing compulsory licenses—the "how"—then we need an independent authority. Courts can do one thing, but we need some kind of medical evaluation of these drugs,

[21] MODDERN Cures Act of 2013, H.R.3116, 113th Cong. (2013).

and what they really do in terms of value, if you're going to do these kinds of assessments.

I think it's okay for the industry to talk about innovation and what the value should be. They're the ones who are driving up the value, according to what their shareholders and investors want. But I think that's not what a health system should be entirely built upon.

I also want to go back to something that Henry mentioned. The work that's being done in terms of the average life of exclusivity is only for small molecules. We're living in an age of biologics now and, if you look at the biologics on average, according to our data, we're looking at 17 to 20 years of exclusivity on the market before any competitor can even get a sniff.[22]

This is the way it's headed. The Grabowski analysis gets wielded out every time, and I've never yet seen anyone come up with a biologic statistic. So, I'm telling you, based on the data that's out there. Biopharma always goes to the Grabowski statistic. But it's apples and oranges. We're living in a different world now, and all statistics are relevant.

HENRY HADAD: A quick response with respect to that, Tahir. I agree that the dust hasn't settled on the BPCIA yet. It's relatively recent. There were a number of products that were pre-BPCIA that ended up becoming part of the BPCIA. I think, over time, you're going to see a little bit more predictability around the time of exclusivity. I think it varies greatly at this point.

ARTI RAI: Rachel?

RACHEL SACHS: This is why, in my introductory remarks, I took pains to note that exclusivity periods are just not part of what Section 1498 allows you to get at—I find it really challenging to continue to confront the innovation arguments when they can't be used until five, seven, or twelve years after a drug is brought to market. Henry, I really appreciate you saying that five years is just not enough for exclusivity periods. I find that to be helpful in terms of thinking about what's going on.

But you mentioned that *twelve years* is roughly an average period—although we've just talked about how that's for small molecule drugs rather than for biologics. You mentioned MODDERN Cures, but one thing you didn't mention is that MODDERN Cures would have given (for most drugs) a *fifteen-year* exclusivity

[22] *See generally* I-MAK, *supra* note 8.

period. That would have dramatically elevated from five, seven, or even twelve years, to much *longer* exclusivity periods.

So, a question is: what period of exclusivity would companies accept in exchange for price regulation thereafter, in whatever form that we decide we would like that to be? There is no answer that I've ever been given. I imagine it's very different for different types of products as well.

I think it's helpful to clarify some of these distinctions and points of debate because, if it is your position that twelve years is enough, then compulsory licensing a biologic shouldn't be troublesome to you because you should be able to *get* that twelve years, and only *then* have Section 1498 be used.

HENRY HADAD: To respond to that: I was citing certain studies in which they range from 12 to 14 years depending, of course, on patents or restorations. It's capped at 14 years in the United States; it's 15 years in Europe. There are a variety of views. I think you're right: I think it's very product-specific.

But businesses thrive on predictability. It can't be a predictable one-year period, of course. I mentioned to you that five years isn't enough. But I think having a predictable period somewhere in the range that some of these parameters have set out is needed. Whether it's thirteen, fourteen, fifteen years, I think that provides predictability and a runway which justifies investment.

I don't believe that compulsory licensing is a wise decision north of that. First off, if you chose MODDERN Cures, you're ceding asserting your patents against biosimilars and small molecules, so that effectively ends that. And remember, for every biologic, there are many, many branded competitors. That's one of the more interesting dynamics of the biologic space: for every target, there are several competitors. They may end up having patents which cover each other, but they more often than not end up licensing each other because they believe it's in the best interest of patients (and themselves) to be on the market and competing in the marketplace.

ARTI RAI: Let's say, for the purposes of argument, that we've figured small molecules out; Hatch-Waxman did an okay job; we've got 12 to 13 years effectively. For biologics, we've seen that prices really only go down, to the extent they do, when biosimilars enter—that's largely been the case for small molecules anyway. One question is: what can we do, if anything, to deal with the trade secret and manufacturing problems such that biologic and biosimilar manufacturers, not just branded biologics, can enter? Rachel, I'm going to turn to you on that one.

RACHEL SACHS: There are "stick" options, and there are "carrot" options. But there are also other options that bypass the question entirely and regulate the prices of the products. You can do that using compulsory licensing, but that has limitations for the reasons we've been talking about. So, instead, most governments choose to set the price which they will reimburse the products. At that point, it may matter less whether the product will retain exclusivity or not because most of these companies are willing to provide significant discounts off of the United States price for their products. I think you are seeing increasingly in the United States a willingness to say, "Why is it that we pay so much more for the very same products?" Price regulation is a big part of that.

ARTI RAI: All right. I'd like to give each of you an opportunity to make a one-minute closing statement. Let's have Tahir go first.

TAHIR AMIN: In a nutshell, we live in a system where any time you mention a compulsory license or any other kind of removal of an exclusivity, the pharmaceutical industry says they're not going to develop new drugs, or there's going to be no innovation. They throw their toys out of the pram. Basically, there's a threat. I think that is a fundamental problem to the kind of system we live in. We're living under threats, where power-holders can broker the rights they want and get. Compulsory licensing is the only counterbalance to that, and yet we're not willing to use it.

I think we really have to look at ourselves as a society. Are we living under a society where those that have the power can just threaten to get their way? We have to really look at the tools at our disposal and start to use them to create a little bit more of an equitable healthcare or an equitable drug pricing system.

ARTI RAI: Becky, I'd like you to go second.

REBECCA S. EISENBERG: I think the political economy in this area is in flux, and we may see some profound changes in the years ahead. There's been a lot of shifts.

At this particular moment, the pharmaceutical industry is looking really good because of their extraordinary success with these COVID vaccines. I think they're looking better than they've looked in a long time, although they've been less successful with therapeutics. The government is also looking pretty good right now. I was interested to hear Daniel Hemel observe earlier that "socialized medicine looks great." We're getting all these vaccines right now under a single-payer system, after all. I think that there is a lot of anxiety about access to healthcare in the United States.

More than there has been—certainly more than there was at the time of the Bayh-Dole Act.

It may be that there will be more forces to make profound changes in the healthcare system than there would be to change the Bayh-Dole Act (paradoxically, something more modest). Universities have changed their tune on the Bayh-Dole Act. They've become much more unabashed about asserting their own rights and their own interests in their own patents as a revenue source. At the time of the Bayh-Dole Act, they were much more coy about that. They're so over that now.

The politics of this is really hard to sort out and figure out where we're going to land. I'm sure that things are going to change going forward. For now, there are worse things to be had than ambiguous legal rules that give everybody something to come to the table with and try to achieve good results, as we're achieving with the COVID vaccines. It could be better, for sure, but it couldn't be much better. And this is much better than I think we had any reason to hope for at this stage.

ARTI RAI: Well, I wish you went last, Becky, so we could end on that high note. But I think Henry and Rachel are in the order we will follow.

HENRY HADAD: Tough act to follow. Further to what Becky said, I think COVID does provide a nice example of what can be done when the private sector and the public sector work together. But they're coming in with their eyes wide open at the outset. Again, not something that's going to be appropriated 10 to 15 years after you've made a huge investment, but at the outset, people realize what the opportunities are and what the investments need to be.

That's the framework we need to really think about. If the government sponsors research, and they do a deal with a small company, they should say, "We reserve the right to come in and take this one day." Then a bigger company who wants to do a deal would know outright if this is a company that it should do a deal with or shouldn't. That probably wouldn't work for the reasons I mentioned at the outset: you're going to be very concerned about that risk if you're going to invest a couple billion dollars in a drug. But I like the COVID example, to Becky's point, because of that early appreciation of the circumstances around the relationship.

In terms of the "threats" that Tahir mentioned, I think the threat isn't that innovation will go away; that's a foregone conclusion. I don't think that it will go away completely, but every time you undermine the incentives for innovation, it's going to be reduced. That's just a natural human inclination. How much? I don't know. It really depends on the situation. The threat of compulsory licenses raises

that concern, and it's something we have to watch as we think about this going forward.

ARTI RAI: Thank you. Rachel?

RACHEL SACHS: Thank you. The topic of today's panel—compulsory licensing—seems narrow. But I think we've also been provided some lessons in seeing how the different parts of our innovation ecosystem work together or don't work together. It's not just about patents; it's not just about exclusivity periods, government reimbursement in the form of royalties, trade secrets in the manufacturing space, etc. We see all of the arguments.

From these arguments about innovation, I'm particularly concerned about the one-way ratchet—that we can never reduce prices or we will be harming innovation. There's never any sort of agreement about what would be permitted, and we've been seeing that once again in this space.

To close, I'll just say: many drugs have high prices, but they have high prices for very different reasons (especially, as we talked about, small molecules and biologics). Compulsory licensing might be *a* solution to *some* of these high prices, but it can't structurally or practically be a solution to them *all*. So, this conversation should be understood as part of a broader access to medicines, but also an innovation-protecting reform effort, which I think is important.

ARTI RAI: Thank you to all of you. I totally agree with what was just said: this might have seemed to be a narrow topic, but we have expanded it to encompass so much about our healthcare ecosystem and all of the complexity and problems that it has. I wish we could say we fixed it all, but that's why we have day jobs. Thank you.

ZACH BASS: Thank you, Professor Rai. This is such a contested topic. I just want to commend every single person on this panel for how professionally they handled it.

At the end of the day, I think we're seeing a common theme amongst all these panels: these are value judgments. This strikes at the heart of morality. Although we may have differences in how to get to the ultimate result, I think we all can agree that we want better access. Thank you all so much.

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ASSESSING STRATEGIES TO DELAY GENERIC DRUG ENTRY

MODERATOR: SCOTT HEMPHILL

PANELISTS: ROBIN FELDMAN, JAY LEFKOWITZ, SEAN NICHOLSON, AND JUDGE WILLIAM G. YOUNG

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 fourth of four panels. This panel assessed strategies to delay generic drug entry. The panel was moderated by Professor Scott Hemphill of NYU School of Law. The panelists included Professor Robin Feldman of UC Hastings Law School, Jay Lefkowitz of Kirkland & Ellis, Professor Sean Nicholson of Cornell University, and Judge William G. Young of the District of Massachusetts.

SCOTT HEMPHILL: Hi everyone. It's a pleasure to get to convene this distinguished group and talk about these important issues.

Our topic is "Assessing Strategies to Delay Generic Drug Entry." We have in mind our generic—typically, bioequivalent, for those steeped in the jargon—versions of branded drugs. This is the cheap and cheerful alternative that you get at

[*] 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 4)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=XrD16RKx204.

the pharmacy, which is automatically substituted under state law or the practices of insurers. When the generic comes in, the average price tends to fall. Now, as one can imagine, that has an important effect on the innovator's profits and on branded profits. In response, a variety of strategies have been advanced over the years—both individually and in combination—to forestall the entry of generics, generating a robust debate about which of these practices are legal, appropriate, beneficial, or their opposite.

We'll be talking about a few of these different strategies, including what is sometimes called a pay-for-delay settlement, or a reverse-payment settlement, where the brand is forestalling generic entry by paying the generic to abandon patent litigation that, had it been successful, might have brought earlier generic entry. We'll be talking about thickets of patents—something we typically associate with other industries but have arisen in biopharmaceuticals—where dozens or hundreds of patents may be brought to bear in ways that some observers find troubling. Sometimes the strategy is as simple as denying access to the samples that a generic needs to perform the FDA-required tests to get on the market, thereby making life quite difficult for some generics.

So, first we've got a set of strategies that we'll be thinking about and evaluating over the next hour. Second, we have a new development that has arisen over the last few years, whereby not just federal antitrust law, but also state law is being brought to bear as an additional tool for thinking about these questions, raising a number of interesting questions in both law and policy. Fortunately, we have an all-star panel to help untangle this. I'm sure at the end, we'll all have clarity and be on the same page about these important questions.

First, Robin, let me turn to you. When we think about this terrain—this broad set of strategies to delay generic entry—can you give us a lay of the land? How big of an issue is this? What are the major components as you see them? And importantly, since we sometimes see multiple strategies being deployed on the same drug, how do you think about their intersection and combination to the extent they might generate synergistic effects?

ROBIN FELDMAN: I'm thrilled to hear that we're going to have full clarity and solve all problems by the end of the hour.

[Laughter.]

In terms of what you were asking, there are two things we know for certain about the pharmaceutical industry. The first is that generics bring prices down. The FDA tells us that a single generic brings the average price of a drug down about

40%, and when you get four generics in, prices come down about 80%.[1] So, we know if you have generics in the market, that's reducing a drug's price. Second, delay tactics *do* pay off. Drug companies don't need to keep a generic competitor off the market forever; just the delay itself can be worth its weight in gold.

Consider the narcolepsy drug Provigil. The company paid $300 million to generics to stay off the market.[2] Then it paid $1.2 billion in fines because of the pay-for-delay settlement.[3] And then it paid another $69 million settlement to the state of California in a case that's just finishing up now.[4] All in all, the pay-for-delay strategy cost the company about $1.6 billion. That sounds really painful—but not so fast. The company executives estimated that delaying the generics brought them an additional $4 billion in sales. So, even after paying more than a billion dollars in fines and case settlements, the company still netted a tidy sum of more than $2 billion. These tactics pay.

You also don't need a single tactic that is a knock-out blow to your competitors. Stringing these life-cycle management strategies together is highly effective, and it really is business as usual in the pharmaceutical industry. To give you one snapshot: 78% of the drugs associated with new patents are not new drugs coming on the market; they are existing ones.[5] In other words, the patent system in pharma is largely recycling and repurposing existing drugs. Recycling old drugs can have value, particularly for some patients at some times. But when a company makes a secondary change to a drug, the R&D investment is generally far less than what's required for the drug's initial development. A company should be able to earn its reward in the market for that.

More importantly—this really is critical—some of the claims in these piles of patents are of questionable validity. But the more you have, particularly with a biologic drug, the more expensive it can be to challenge them. In other words, the piles of patents and the piles of delay tactics can have synergistic effects in which

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[1] Generic Competition and Drug Prices, U.S. FOOD & DRUG ADMIN. (last updated Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

[2] Rebecca R. Ruiz & Katie Thomas, *Teva Settles Cephalon Generics Case With F.T.C. for $1.2 Billion*, N.Y. TIMES (May 28, 2015), https://www.nytimes.com/2015/05/29/business/teva-cephalon-provigil-ftc-settlement.html.

[3] *Id.*

[4] Mark Terry, *Teva to Pay California $69 Million in Pay-To-Delay Deal Settlement*, BIOSPACE (July 30, 2019), https://www.biospace.com/article/teva-endo-and-teikoku-settle-with-state-of-california-over-generic-drugs.

[5] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & BIOSCIENCES 590 (Dec. 7, 2018).

the whole effect is even greater than the sum of the parts. Antitrust law has a very hard time handling synergistic effects and tends to look at each individual behavior. I have a piece coming out with Mark Lemley at Stanford that's titled *Atomistic Antitrust*.[6] We look at how modern antitrust law struggles to handle the broader picture even though companies themselves consider all their activities in these broad life-cycle management strategies.

My favorite example of the way current law struggles with seeing the full picture comes from last year's *Humira* decision, where the court noted that the company filed a total of 247 patent applications.[7] I will just pause here to say: that is *a lot* of patent applications. Out of those 247 applications, that yielded 132 patents. Again, *a lot* of patents on a single drug. Ninety percent of those patents were granted more than 12 years after the drug got to market. Now, the court described this as a "batting average" of 0.534—New York baseball fans will appreciate that—or about 50%, which the court said was too high to allege bad behavior.

Regardless of whether you think a 50% success rate is the right number for finding good behavior—I have my doubts—there's a more fundamental problem with this type of logic. If you just count up the number of petitions that were granted versus the number of petitions that failed, it entirely misses the point of the possible synergistic effects of all the company's behavior. I like to say that one cannot understand the magnificence and the power of a symphony by counting the individual notes, nor can one understand the full effects of multiple delay strategies without looking at them as a whole and understanding how they work together.

SCOTT HEMPHIL: Great. Thank you. Sean, let me turn to you. There's a balance between ensuring affordable access to drugs, on the one hand, and maintaining adequate, robust innovation. I think that was implicit in Rachel's comments at the end of the previous panel. How should we think about this balance as it might bear on some of these debates about barriers to generic entry? How much of the value of these new drugs do consumers hold on to? Any thoughts that you might have about how that balancing question bears on the antitrust analysis of evaluating strategies to delay generic entry would also be most welcomed.

And one more thing on the table since it was in Robin's comments: thinking about small molecules versus biologics, is the story different? A lot of our battles have been in small molecules. Of course, we are moving into a world of biologics.

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[6] Mark A. Lemby & Robin Feldman, *Atomistic Antitrust*, SSRN (Feb. 26, 2021), https://papers.ssrn.com/abstract_id=3793809.

[7] *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (claim of sham litigation under *Noerr-Pennington* doctrine dismissed without prejudice).

Do the same intuitions and battle lines carry over to the new context, or are there important differences that change the state of play in some important way?

SEAN NICHOLSON: Thanks for inviting me, and thanks for the great question.

I will start with a little theory, and then I'll quickly get to the empirics that you mentioned on who is capturing the value. From a policy perspective, what policymakers are trying to do is allow pharmaceutical firms and biotech firms to have an effective market exclusivity length. I'm using that term as the amount of time from when the FDA approves the drug to when the generics actually enter, not when the patent expires. They want that period of time to be sufficiently long so that pharmaceutical firms and biotech firms will invest the hundreds of millions of dollars that it often requires to bring a drug to the market. But they don't want that amount of time to be so long that the pharmaceutical firms are making "excessive profits." That's the theory.

The government is trying to balance that. Make it sufficiently profitable. Let those profits accrue for sufficiently long that it merits investing the money to get the drug to the market but not give away the ranch, essentially. I mean, that's hard. The government is doing it by allowing patents and issuing laws like Hatch-Waxman that regulate the way the generic firms enter.[8] How long is that market exclusivity period? Remarkably, it's been pretty stable at an average of about 12 years. That's an average—of course, you'll have drugs that have market exclusivity longer than 12 years, and some less, but the average has been pretty stable.

Most people think it's really two offsetting forces. One is to Robin's point: you have the evergreening behavior from pharmaceutical firms of patenting like crazy. They would argue that it's justified. Then, you have very aggressive litigation on the part of generic firms because the incentives of being the first and getting the market exclusivity on the generic side is really strong. Those two forces have tended to offset one another and keep that market exclusivity at about 12 years. That doesn't mean that 12 is optimal. That just means that it's been pretty stable.

To look at the optimal, I can think of four fairly well-done studies that look at how much value a drug brings to society in terms of health gain: how much is captured by the consumer patient, and how much is captured by the pharma firms. They're kind of on opposite ends of the spectrum. For HIV/AIDS and statins, the studies show that a majority of the value is captured by the consumer. It's not even

[8] *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), Pub. L No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301, 355, 360cc).

close in those two examples. According to studies, about 90 or 80% of the value accrued to the consumer. Then you've got a couple other examples—one of which I was involved in: multiple myeloma and colon cancer[9]—where the pharma firms, at least when the patents were in place, were capturing almost all of the value. The story would be that when those patents expire, consumers might then capture the value. But, at least for that first 15 years, the pharma firms were pricing the products to extract most of that value.

I'll finish with your biosimilar. In 2009, Congress tried to think carefully about the right balance for biosimilars.[10] They decided to make the minimum market exclusivity 12 years. Obviously, the average will be larger than that, in part because the patents are probably easier to work around if you're a biologic company. In practice, it's not until the last couple of years that we've seen substantial biosimilar entry in the U.S. and prices coming down. It's taken about ten years from the 2009 law for everybody to understand how the biosimilar patent litigation is going to work. I would say that, even though there haven't been a lot of studies, most of that value is being captured by the industry on the biosimilar side.

SCOTT HEMPHILL: Great. Thanks. Just picking up on one of the things you said at the end: I wonder whether ease of avoidance has turned out to be higher in the biosimilar context than it was in the small molecule.

Let me turn to Jay. There has been a lot of activity in this space—not just in reverse payments, but other areas, too. I'm wondering, from your perspective, what are the main issues that are being litigated today? Are there trends or outcomes that have surprised you, or that seem to be headed in the right or wrong direction?

JAY LEFKOWITZ: I think *Actavis* has basically set forth a few very clear guidelines and left an awful lot unclear.[11] Judges, like Judge Young, have to figure it out on the fly. Right now, we don't have that many cases being litigated; in fact, very few patent settlements (according to the FTC's last report[12]) actually on paper

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[9] Darius Lakdawalla et al., *Quality-Adjusted Cost Of Care: A Meaningful Way to Measure Growth in Innovation Cost Versus the Value of Health Gains*, 34 HEALTH AFF. 555 (Apr. 2015).

[10] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-28 (2010) (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.). The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 804 (2010).

[11] *See* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013).

[12] Fed. Trade Comm'n Bureau of Competition, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2017* (2020),

violate *Actavis*. The FTC only identified three settlements out of 226 in their last report that raised any type of trouble at all, and they weren't the kinds of lump-sum payments that we used to deal with. But we are now seeing a lot of litigation on other related issues: settlements that have exclusive licenses, accelerator clauses, most favored nation clauses, situations where the brand will give three, four, or five different generics part of its authorized generic supply. I think the wave that we're in right now includes all of those types of cases, and yet they still present the same sets of issues, in theory, that *Actavis* has.

The real issue is that a dollar doesn't necessarily mean the same to a generic or to a brand. If you and I are having a dispute over $100, and we decide to settle for $80, we both know what that $80 is worth. We might settle for $80 because I think I can't collect the $100, and you think you might not keep the $100. So, maybe we'll settle for $80.

But when you're settling a patent case, and the patent has 10 or 15 years to go, and you're litigating today, you have to pick some entry date. Any particular entry date is just as easy to be seen as a delayed entry as it is to be seen as an early entry because it's in the eye of the beholder. The time value of that period of exclusivity is obviously worth much more to the brand than it is to the generic that simply is going to get 180 days of exclusivity—or really, co-exclusivity with the brand—before the market opens up. So, sometimes other things have to be taken into account in order for them to reach a settlement. We all want settlements because if there is no settlement, then the brand monopoly persists until the end of the patent term.

What judges have to do is look at the ultimate questions, which are often questions of causation. What we're seeing right now in these litigations is, on the one hand, that we don't want to re-litigate the patent case in the antitrust case. On the other hand, patent issues are obviously important. If you have a generic and a brand suing each other, and the generic knows that three other generics have lost that same invalidity case to the brand, you can understand why the generic is going to take almost anything it can get in a settlement. Or if the generic has some problems with the FDA and knows it can't get a drug approval, that's another causation issue.

We're seeing a lot of the wrinkles coming out of the *Actavis* decision, and of course, we're now also starting to see some more aggressive FTC enforcement. They just filed a lawsuit a few weeks ago against one of my clients in a case that wasn't even a typical reverse payment situation. I think we're going to see a lot of regulatory

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https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.

activity and a lot of private litigation in the coming years on the margins of the *Actavis* decision.

SCOTT HEMPHILL: Great. Thanks.

Judge Young, let me turn to you. Reactions to what you've heard so far? One question that I want to ask you, either now or as a follow-up, is what do you make of trying to deal with these complex issues in a courtroom, staffed by a generalist judge with lay jurors if it's a private damages case?

JUDGE WILLIAM G. YOUNG: That, of course, is the basic challenge. It's a very worthwhile challenge for the justice system. Let me speak directly to it. What do I make of it? You sort out the issues as best you can. You depend upon competent counsel and an adversary presentation so that they may be presented to a jury, and you accurately instruct that jury to reach out for justice.

These are extraordinarily complex economic and policy issues. One of the desirable things about the *Actavis* decision is that the law that you are applying is *an opinion* of the Supreme Court.[13] You don't have various—even Federal Circuit—nuances; in the antitrust area, you don't have different degrees of persuasion. You've got the Supreme Court. And, of course, you ask yourself, "Mother of God, what do they want us to do here? What were they thinking of?"

I started out saying I didn't try this case very well, but I did try it fairly. Part of that was I didn't even understand the case until we got going. I had made rulings on summary judgement.[14] Those rulings were wrong. They were just how the jury came out, but they were wrong. So, I listen to those who are skilled—far more skilled than I—and I'm making notes here as we go. I'm thinking to myself, "Well, these really are the issues." The reverse payment, if we can talk about it—Jay has already very skillfully laid out—doesn't need to be monetary. You're rarely going to see that. It's going to be far more complex than that.

I looked at the verdict slip I gave the jury. Imagine the jury being asked this question: "Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive? That is, did the anticompetitive effects of that settlement outweigh any procompetitive justifications? Answer no/yes." Well, that really boils it down, doesn't it? People could go on for a long time about that.

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[13] *See* Actavis, 570 U.S. at 136.

[14] *In re* Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231 (D. Mass 2014) (order denying summary judgement), *aff'd as harmless if error*, 824 F.3d 34 (2016).

Here's a take-away, though, as a sitting judicial officer, and this I would state very strongly: delay. There is too much delay in the litigation of these cases. The delay that's been talked about is delay pre-litigation. But once the complaint has been filed, there is too much delay. That's on us. I take the position that these cases should go to trial no later than 13 months after the complaint is filed. Frequently, you will find in these types of cases that the parties want a preliminary injunction. I always find that interesting because under Rule 65(a) of the Rules of Civil Procedure, you can collapse a preliminary injunction with trial on the merits.[15] I try to do that routinely. That causes everyone to tear their hair and focus on the real issues.

Now, I'm biased as a sitting judge. I'm biased in favor of our dispute resolution system, and I stand to be challenged on it. But I'm here to take the position that we *can* handle these complex issues, and we can handle them in a *timely* fashion. "Timely" for me is about a year or a year and a half.

SCOTT HEMPHILL: All right, Judge, let me follow up on that.

First, as to the verdict questions that you were just reading from, I put that on a PowerPoint in my Antitrust class and show it every year. For people who don't know, what Judge Young just did was greatly simplify the series of questions that was offered. And, to plug into Jay's comment about causation, one of the many aspects that makes this case so interesting is that the jury basically said the conduct was unreasonable. The payment to induce a delay was unreasonable. So, the jury found that the defendant was bad across the first three or four questions. Then the trial court asked, "Okay, *but for* this conduct, would the plaintiff have gotten an entry date before the entry date that occurred?" The answer to that, the jury said, was *no.*[16] So, you're left trying to figure out, what were they thinking? Some of the post-verdict briefing and opinion writing got at that.[17]

Now, in the last paragraph of *Actavis*, Justice Breyer said, "As in other areas of law, trial courts can structure antitrust litigation so as to avoid" all kinds of problems, including litigating a patent case inside of an antitrust case.[18] Basically, "District courts can figure this out on their own. Just work out your own procedure. You can engage in shortcuts. You have a lot of flexibility. Go for it." How do you

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[15] Fed. R. Civ. P. 65(a).

[16] Jury Verdict, *In re* Nexium (Esomeprazole) Antitrust Litig., No. 1:12-MD-02409 (D. Mass. Dec. 5, 2014), ECF No. 1383.

[17] *See, e.g.*, *In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107 (D. Mass. 2015) (order denying new trial).

[18] *See* Actavis, 570 U.S. at 159-60.

feel about receiving a kind of general instruction like that? This is not uncommon in antitrust cases, by the way. After *Leegin*,[19] the Supreme Court basically said, "We're going from *per se* liability to the rule of reason. District courts, go put some meat on these bones that we've offered you. Just do your best to structure and come to the truth in whatever order you think makes sense." Do you find that liberating? Do you find that frustrating? What do you make of a pronouncement like this when you're then faced with this sprawling, complicated case that you have to boil down in a way that jurors will be able to make sense of?

JUDGE WILLIAM G. YOUNG: The short answer is: I find it liberating. The discharge of that duty is daunting because it presumes a very high degree of economic knowledge. I realize that I do not have the sophisticated economics background that many others do. I am an advocate of the adversary system. One fortunate aspect of these types of cases, because the stakes are very high, is that they attract outstanding advocates—outstanding advocates across the board, and that is delightful. So, you learn a great deal.

SCOTT HEMPHILL: Jay, let me turn to you. As I've mentioned, you've litigated a lot of these reverse payment cases, including *Nexium*. You were essential in the *Nexium* case that Judge Young was talking about. Where do you see the causation discussion ending up?

JAY LEFKOWITZ: The Supreme Court, at least Justice Breyer, was trying to strike a middle ground.[20] If you remember, the companies went into that case saying, "Scope of the patent. As long as we have a patent, we can do absolutely anything to exploit our patent. It doesn't matter." That was one extreme. The other extreme was the government position, which was essentially *per se* liability. And the court was very clear. It's hard to always understand. I probably read that decision a thousand times, and I gleaned different things every time I read it. But I think the author was trying to strike some kind of middle ground and then give it to trial judges to do this.

What happens, largely because of the billions of dollars in liability, is that the issue tends to collapse on the question of "is it a large and unexplained payment?" That's the threshold question. You can have a large and unexplained payment—although unexplained and unjustified don't necessarily mean the same thing in the context of that opinion—but then the question is, "if you have a large, unexplained payment, that doesn't actually mean you have liability, at least according to the Supreme Court rule?"

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[19] Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 887 (2007).

[20] *See* Actavis, 570 U.S. at 136.

There are a lot of folks out there (like the FTC) that would like to take the position that it is *de facto* liability. We have one case right now in the appellate court that's going to tee up that specific issue. But if you look at the rule of reason, then it just shifts the burden. At that point, you have to look at procompetitive benefits and justifications. Then, you still have to look at least restrictive alternatives: was there some other way to achieve these benefits?

The problem is the companies have a hard time staying in the game as long as AstraZeneca and Ranbaxy stayed in *Nexium* because of the overwhelming potential exposure. So, not many of these cases get litigated. I've had one other case that's been litigated, but it settled prior to the jury making a decision. Other than the *Nexium* case, every other case has settled. As we get some more ground rules from some of the appellate courts about how you conduct the rule of reason analysis, it will breathe more life into the fundamental question, which is causation: what would've happened in a but-for world? Then you'll start to see the law percolate a little more.

SCOTT HEMPHILL: Robin, let me turn to you and move toward the underlying empirics here.

We've already heard mention of FTC studies about frequency and how frequency has fallen over time. There's also an FTC study estimating the costs from settlement, which they may have put at $3.5 billion a year.[21] I might be off by a bit, and it may be lower than what some of us would've expected. We've talked about individual drugs, like Nexium, where on a $3 billion drug, a year of delay might be associated with a consumer harm that's also north of $1 billion. So, we could have a number that gets up pretty fast depending on how we cut the data. How should we think about the size of the potential issue?

ROBIN FELDMAN: You're right about the Federal Trade Commission study. It was more than a decade ago, they published a report on pay-for-delay, and they estimated that pay-for-delay settlements cost American consumers $3.5 billion a year.[22] That number has been cited by everyone since. There's a lot of information that's still hidden, but there's much more public information about pharma pricing and lawsuit settlements available today than there was a decade ago. Like Scott, I

[21] Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[22] *Id.*

thought that the $3.5 billion figure was not just *old* but *off*, so I set out to calculate an updated cost.[23]

There are different ways one can measure these things. I wanted to be as fair as possible, so I used six different sets of calculations, using different kinds of approaches that you can find in the literature. All six methodologies yielded results that were much higher than the old FTC figure. Rather than the $3.5 billion a year that was estimated in 2010, the lowest result from the six methods that I used yielded an updated cost of roughly $26 billion a year. The others were much higher; it tops out at about $169 billion. So, to put this in perspective, even the lower-end figure is *seven times* the old FTC figure.

As the basis for all those calculations, I used 16 pay-for-delay deals in which there's sufficient public information available. I looked at the list price. I looked at the out-of-pocket cost. I looked at the overall Medicare cost. I sliced and diced this thing six ways from Sunday. But the point is simply that the cost of these deals for society is much greater than anyone has thought, and it's worth thinking about those impacts.

SCOTT HEMPHILL: Great. Thanks.

JUDGE WILLIAM G. YOUNG: Could I ask a question?

SCOTT HEMPHILL: Yeah, Judge.

JUDGE WILLIAM G. YOUNG: Professor Feldman, I'm going back to your first presentation, which I found so helpful. I understand your concern about what you call "thickets of patents."[24] But of course, it is our policy to give these limited patent monopolies, and we have a procedure for granting them. If we were in a case where that argument was made in an antitrust context, I would say, "So what? The Patent Office has given them these patents." Where does the liability lie?

ROBIN FELDMAN: If we had confidence that everything issued out of the Patent Office is of good value, that might be a different story.

Now, legally, there is a presumption of validity. But empirically, if you look at how often patents fall (particularly the secondary patents), you'll find that the value of the patents coming out of the Patent Office is not so great. That should give

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[23] Robin Feldman, *The Price Tag of 'Pay-for-Delay,'* SSRN (2021), https://ssrn.com/abstract=3846484.

[24] *E.g.*, Robin C. Feldman et al., *Viral Licensing: Ensuring the Public Interest when Taxpayers Fund Pharmaceutical Research*, 59 SANTA CLARA L. REV. 641, 659 (2020).

you pause when you see a huge number of patents being thrown at a particular drug in a way that raises the cost for any individual generic to come on the market. If you break down what is in these patents, it's not an inspiring vision.

JUDGE WILLIAM G. YOUNG: Have you got any judge who has expressed that view? I'd be interested since that judge is saying, "Well, we've got a Patent Office, but they make a lot of mistakes. Look at what they're doing with their patents." I'm interested in your argument; where's the authority?

SCOTT HEMPHILL: Judge, I'm going to let Professor Feldman respond, but I just want to add another element here: even if that were granted, there's a second front that's opened, which is that a duly-issued patent might not be infringed by a generic product, or an alleged infringer. So, even if you thought that they were all valid patents, you might still be worried that a plaintiff would misuse them and engage in vexatious or knowingly frivolous litigation in order to throw sand in the gears.

So, the fact that you have a duly-issued property right doesn't tell you whether it's pertinent or not in itself to a generic product. On these secondary patents, it's often a question of infringement. Maybe the granted patent is valid, but they'd use some other strategy to come to market that doesn't implicate it by the patent. Especially as to these patents that issue long after the therapy has entered the market, a suspicion arises that because that therapy is prior art, maybe the patent that's filed isn't essential to practicing the therapy.

JUDGE WILLIAM G. YOUNG: I'm familiar with patent misuse. I know it's pompous when I just say that, but I am.

SCOTT HEMPHILL: But I don't mean to make a misuse argument here.

JUDGE WILLIAM G. YOUNG: This argument's a little different. This argument is the "thickets of patent" argument that I'm asking about.

SCOTT HEMPHILL: I mean to be addressing "thickets of patents." A piece of the puzzle is: you can have 100 patents, 60 of which have to do with your drug but aren't actually practiced by the drug. If someone is trying to offer a very close version of the drug, they too might not be using the technology as to these patents that are valid and yet not infringed. That can be troubling for reasons that don't need to implicate misuse. Robin, you were actually addressed.

ROBIN FELDMAN: You have a wonderful response there.

In terms of an interesting piece of authority, the state law that just passed in California specifically says that the court should not presume that the patents are valid as a reason to say that the behavior is appropriate.[25] I'll have to look at exactly what the language is, but they are addressing exactly the question that you're thinking about. I'm not sure whether Oregon has some similar language, but that's part of what states are beginning to look at because they're hitting their head against that issue.

Practically speaking, if I've got a big bag of weapons, I can just keep throwing those until one of them sticks. Frankly, I don't even need 50% of them to stick. I only need, as a patent holder, *one*: you only have to have one claim standing at the end to be able to block that generic. So, it's in my interest to have a huge bag and just keep throwing and hoping something's going to last. That's not really a good way to run a patent system or a competition system.

SCOTT HEMPHILL: Let me bring Sean in with comments, and then I want to turn to Jay since the California law was raised—among other things, something that would reverse a statutory presumption of validity seems like something Jay might want to weigh in on.

SEAN NICHOLSON: I'll be brief. I just want to add my sympathies to the judges and juries in these reverse settlement cases because I think it's a difficult issue. To attempt to explain why, there are some situations where, without a reverse payment, the generic firm and the branded firm are not going to be able to come to an agreement on an entry date. Imagine that the branded firm thinks there's a 95% probability that if the patent or patents are fully litigated, they're going to prevail: it's going to be proven valid. But just that 5% probability of seeing their potentially multi-billion dollars of profits disappear is going to get them willing to pay substantially. "Pay" can mean allowing an earlier entry date than they otherwise would *and* adding some sort of compensation. But how do you figure that out? You can't just measure risk aversion. That's not something judges and juries are used to doing.

I think there are situations where reverse payments can be merited, but I sympathize with trying to figure out when that's appropriate and when it isn't.

JAY LEFKOWITZ: I think Robin is correct in terms of characterizing what the California statute does. It does a variety of things that are very interesting. Just to be candid about this, I've challenged the constitutionality of the statute, and I'm waiting for a decision from the judge. It raises serious questions of federal

[25] *See* Cal. Health & Safety Code § 134002 (West 2020).

preemption because it takes a presumption of patent enforcement that comes from Congress, and it flips that burden. It also says that an exclusive license is presumptively unlawful even though Congress has said in Section 361 of the Patent Act that you have an unqualified right to have an exclusive license.[26]

As interesting as the preemption tension is in the California statute, the bigger problem with the California statute is that it purports to hold conduct that takes place entirely outside the state of California unlawful. We're all familiar with California having environmental laws that impact the auto industry—they can say, "You can't sell a car in California that doesn't have certain emissions," for example—but they couldn't well say that a Michigan manufacturer couldn't sell an automobile to a New Yorker without those emissions. And yet, what California's law would do is tell two companies who are not California citizens, who are entering into a settlement in a case that's pending before Judge Young in Boston that their settlement violates California law.

If this case is litigated in much the same way that a recent case that we litigated in challenging the Maryland law gets litigated, it's likely to be found invalid. It's not that California doesn't have enormous antitrust tools. We know that when state antitrust law is substantively the same as federal law, then the extraterritorial doctrine may well give way based on an implicit understanding that the Sherman Act was intended to allow states to regulate intrastate commerce. But the problem is when a state tries to project its power and regulate an economic transaction entirely outside of its boundaries. That runs up against the Commerce Clause.[27]

I think the laws in California and Oregon are in jeopardy both because of preemption considerations and Commerce Clause considerations.

SCOTT HEMPHILL: Thank you. Robin, you've testified in favor of arming states with new tools. Why do they need them? Why isn't the current set-up enough?

ROBIN FELDMAN: Sure.

Before I answer that directly, I pulled up the California law. Just to clarify, it says that as the parties are trying to defend their behavior, the factfinder shall not presume "that any patent is enforceable and infringed by the non-reference drug filer in the absence of a final adjudication binding on the filer of those issues."[28] In other words, when you're trying to think about the different parties' behavior and what

[26] *See* 35 U.S.C § 351.
[27] *See* U.S. CONST. art. I, § 8, cl. 3.
[28] Cal. Health & Safety Code § 134002(b)(2) (West 2020).

you're doing, don't presume—unless you have a finding on that—that this is enforceable and is infringed in the circumstance. Judge, those are the types of concerns that I was talking about.

In terms of "what do the states need? What does the law need? Do we need any more?" I would say the following: the *Actavis* case opened the door to antitrust liability in cases of pay-for-delay, but the legal system just keeps banging its head on the door jamb.[29] In particular, there seem to be difficulties in fighting each of the terms: "pay" and "for" and "delay."

We also know from the Federal Trade Commission reports that there have been roughly 1,100 settlements between brands and generics in seven years. The vast majority of those involve an agreement by the generic to stay out of the market for some period of time. We also know that the number of settlements between brands and generics each year has more than doubled across that time.

There are, as Jay mentioned, some troubling signs about anticompetitive aspects of these agreements. In the most recent year, for example, 76% of the settlements between brands and generics contained some form of acceleration clause. Acceleration clauses can discourage other generic companies from entering because other potential generics know if they enter they're going to face immediate entry from the generic who settles. It's one way a brand company can get additional bang for their buck: you settle with a generic manufacturer, and you discourage others from entering.

There are hints of other anticompetitive aspects of the deals: if you look at the most recent FTC report, 90% of the settlements involve the generic receiving rights to patents not subject to any litigation between the parties. Rights like those could easily be the vehicle for transferring value or sharing markets. The bottom line is that there's good reason to believe that *Actavis* did not solve the pay-for-delay problems, and that additional clarification is needed.

Regardless of whether you think the California law is right—some people think California gave up too much with the exceptions it allowed, and others think the legislation is too strong—there's a lot of additional work that remains to be done in pay-for-delay. We really haven't solved it.

SCOTT HEMPHILL: Thank you. I have a question for Sean, and then I'll give Judge Young the last word.

[29] *See* Actavis 570 U.S. at 136.

Sean, one of the questions that comes up—you could imagine it coming up in reverse payments or in other contexts where we're concerned about delayed generic entry—is: where are the purchasers in all of this? I don't mean individual cash purchasers who have no insurance and find themselves paying some extremely high price at the pharmacy, but rather pharmacy benefit managers (PBMs) who presumably have some power to insist on particular prices or particular terms of dealing as a condition for being put on a formulary. Couldn't the PBMs engage in some kind of self-help to protect themselves against entry-delaying conduct? Is this a feasible alternative? Is this pie in the sky? How do we think about it?

SEAN NICHOLSON: I think what PBMs *are* doing and can *continue* to do is be amazingly effective at shifting market share from the branded drug to the generic drugs as soon as entry has occurred. More than 95% of market share is going to shift very quickly. But I really don't think PBMs can do much more than that.

Imagine that a PBM becomes convinced that a branded firm is engaging in inappropriate activities to delay generic entry. The PBM has the power to say, "We're going to move that drug to the fourth tier, and it's going to become expensive in the eyes of the patient. We're going to stick it to the pharmaceutical firm," but that's harming the health of the enrollees. I would see that as not being an effective strategy for the customers they're supposed to be looking out for.

SCOTT HEMPHILL: Judge Young, final reactions to what you've heard here?

JUDGE WILLIAM G. YOUNG: Well, I'll be very brief. I hope this has been recorded because, aside from me, what a marvelous grouping of people who truly care and are raising profound issues, both economic and policy issues, in our healthcare field. These are matters in which the Federal Trade Commission, Congress, and the courts, as well as the Patent Office, share responsibilities for reaching out for justice. I have no answers beyond seeking to discharge my duty with respect to a particular case in controversy, but it is fascinating.