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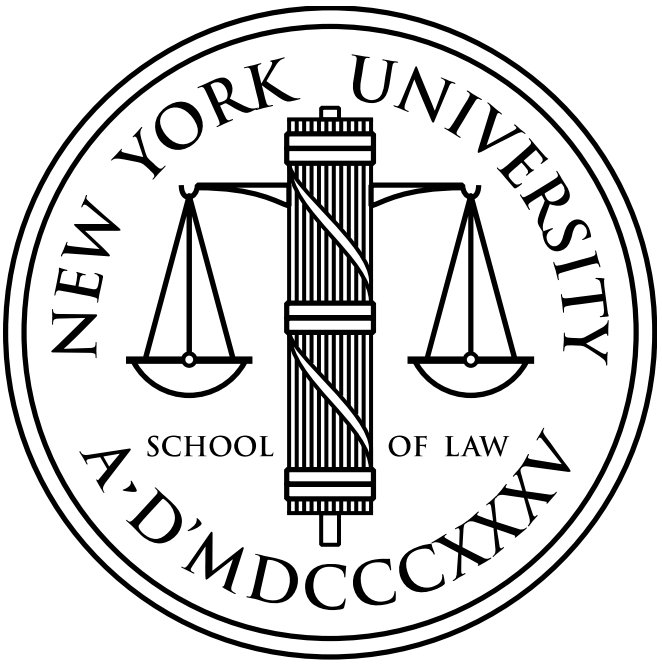

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WHETHER AND HOW THE U.S. GOVERNMENT SHOULD EXERCISE ITS COMPULSORY LICENSING AUTHORITY UNDER 28 U.S.C. § 1498 AND THE BAYH-DOLE ACT

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.