INTELLECTUAL PROPERTY

INTELLECTUAL PROPERTY RIGHTS: ADVANCING OR HINDERING MEDICAL BREAKTHROUGHS?

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MR. TROY: Good afternoon. I'm Dan Troy, Chief Counsel for the Food and Drug Administration.

The question today is whether intellectual property rights advance or hinder medical breakthroughs. The answer to this question is yes. The answer is also no. Of course, it depends.

Everyone can agree that if commercial entities, such as drug companies, lack the incentives that attend intellectual property rights to fund research, then medical breakthroughs will be hindered. At the other end of the spectrum, pretty much everyone can agree that intellectual property rights that are too expansive can prevent other entities from access to elements that they need to engender medical breakthroughs.

To be more concrete, if companies aren't given any incentives to isolate a particular gene and identify what it does, they are less likely to fund research, and then all such research would have to be funded by the government. Of course, much research is funded by the government, but the question is would anyone want a regime where basically all such research was funded by the government.

If, however, companies are able, as they are now in certain circumstances, to patent a particular gene or a stem cell line, then presumably the ability of others to develop therapies based on that gene or stem cell line becomes limited. Any therapy developed by the non-patent holder would then have to be licensed by the patent holder, and that, of course, is going to reduce the amount of research on that particular therapy. So, as is often though not always the case, the question is where to draw the line and why. A related question that I hope we'll be able to touch on is whether intellectual property rights advance or hinder the availability of medical breakthroughs. These are very closely related but slightly different questions. After all, the medical breakthrough serves a rather limited purpose if it's not widely and easily available to those who need it. This is an issue that my agency, the FDA, wrestles with everyday. We have a statute known as Hatch-Waxman, which allows generics to rely on the research of innovators to secure FDA approval. In exchange for surrendering the intellectual property rights to the data that the innovators, after all, developed, innovators were given additional periods of exclusivity. As long as they hold such exclusivity, they have an incentive to do additional research to find new uses for their drugs. Once the drug becomes generic, though, that incentive largely evaporates.

At the same time, the price drops markedly and this breakthrough becomes much more widely available. As you might expect, the political pressure to authorize generics is intense, but of course no one wants to cut off the research of the innovator companies to fund and find medical breakthroughs — hence, the dilemma.

Interestingly, as our panel reflects, these are issues that really cut across ideological and political lines. There are libertarians who believe in strong intellectual property protection and those who believe in extremely limited intellectual property protection, or not very much at all. The same is true of conservatives as well as liberals. Frankly, to me this area seems to be one in which utilitarian arguments may ultimately be the most persuasive.

Today, we have a panel the utility of which cannot be denied. One of the things that's really daunting and intimidating about getting into the food and drug and scientific world is we lawyers think we're reasonably well credentialed. Listen to the resumes of the people who are on this panel. Everybody's in the scientific community. They have gone to school much longer than we lawyers have and they're much, much better educated. And they remind me of that all the time.

I'm going to introduce them one at a time immediately before they speak so that they can be properly recognized, and we've asked everyone to limit their remarks to eight or ten minutes so we can have time for discussion and questions.

Our first speaker is going to be Professor Arti Rai, who is a professor at University of Pennsylvania Law School. She graduated Harvard; attended Harvard Medical School; and received her law degree from Harvard Law School. (See what I mean.)

After law school, she clerked for Judge Marilyn Patel of the Northern District of California and was a litigation associate at Jenner & Block and an attorney at Federal Programs Branch at the U.S. Department of Justice, which is not the part of Justice that represents FDA.

Immediately before entering law teaching, she was a faculty fellow at Harvard's Program on Ethics and the Professions. Her teaching and scholarly interests include law and biotechnology, patent law and healthcare regulation, so she's eminently qualified to address these issues today.

She's authored many articles in these areas and is a co-author of *Law and the Mental Health System — Civil and Criminal Aspects*. She's on the Board of Editors of the *American Journal of Law and Medicine* and has also taught at the University of San Diego and at the University of Chicago.

Please join me in welcoming Professor Rai.

PROFESSOR RAI: Well, my role as the first speaker on this panel was to provide some background on the issues and then weigh in with my own thoughts. Dan Troy has done such an excellent job of providing some of the background that fortunately, because I have way too much to say, I can perhaps abbreviate at least some of the background. In any event, as Dan has very acutely pointed out, there is no yes or no answer to whether IPRs advance or hinder medical breakthroughs. The question really is, when do we need them and where in the continuum between upstream and downstream research should they attach?

I think it's pretty clear, at least to me, that we need patents on end-product drugs. There is really no dispute about that. The question with respect to end-product drugs is how large the scope of IP rights should be. That is why, to some extent, we have this very complicated scheme, which Dan has already alluded to, known as Hatch-Waxman for end-product drugs. And then, of course, there are the very important access questions, which I think — unfortunately, we don't have as much time as we'd like to go into it today — but access questions get raised when you have monopoly rights on end-product drugs because of the supra-competitive pricing that necessarily is entailed. However, access questions can, of course, be dealt with on the insurance end of things. So, I'm not going to really focus on that issue today.

What I'm going to be talking about is rights on what might be characterized as upstream research — *i.e.*, more basic biological research — and how these rights affect the biomedical enterprise.

Once upon a time, this was not an issue because basic biological research was not the sort of thing that had much cash value. It was very much an ivory tower enterprise. So the idea of seeking patent rights or other IPRs in basic biological research would have been somewhat odd. Now, of course, everything has changed. Basic biological research is the foundation of the pharmaceutical industry, which, as we all know, is dominated by patents, and rightly so.

So some of the reasons why basic biological research has become the subject of this big debate are purely exogenous to the legal system. It's just a question of this research becoming much more important for commercial purposes. But there have also been some ways in which the legal system has done a great deal to encourage patenting of more upstream research.

The Federal Circuit, which, as many of you know, is the specialized appellate court that deals with patents, has lowered the so-called utility standard so that even inventions that are primarily useful, for further research only can be patentable. The court has also opened up the whole area of information technology to patents, and that could be the subject of a whole other panel, which unfortunately we do not have time to get into.

Basically, in this new world of patents, private firms have been seeking a lot of patents on upstream research. Over the course of the past decade, they've filed patent applications on everything from gene fragments of unknown function and sequences and proteins embodied not in their biological form but as data structures on a chip.

For reasons I'll talk about more in a minute, though, the legal change we should perhaps be most concerned about is the change that has influenced the behavior of institutions that receive public funding to do basic research. In this area, the most important influence has been two technology transfer laws known as the Bayh-Dole and Stevenson-Wydler Acts. These laws, which were passed in the early 1980s, explicitly encourage the patenting of research by publicly-funded entities, particularly universities and government agencies. Since these laws were passed, university patenting activity has increased precipitously. While universities secured only about 250 patents annually in 1979, immediately before the passage of Bayh-Dole, by 1997, that number had increased about ten-fold to about 2,500. This ten-fold to increase far outstrips the two-fold increase in overall patenting that we witness during this approximately 20-year period.

So, what sorts of patents are universities seeking? Well, they haven't gone quite as far as the private sector. They seem to have been constrained by academic norms, from going as far as the private sector. For example, they have not tried to patent gene sequences of unknown function, as has the private sector. But they have certainly patented some very fundamental research.

I want to cite in this regard one recent and prominent example of which many of you may be aware, which is the very broad patent that the Wisconsin Alumni Research Foundation, the technology transfer arm of the University of Wisconsin, has on what are known as primate embryonic stem cells. Because human beings are, of course, primates, this patent covers all human embryonic stem cells as well.

A little-known fact in the stem cell debate is that the research that was necessary to get this primate patent was, in fact, publicly funded. Nonetheless, WARF has not only patented stem cell lines but it has exclusively licensed most important therapeutic and diagnostic uses of these stem cell lines to a single company, a small biotech company known as

Geron, which is located in California.

Proprietary activity in academic biomedical science now extends not just to patented research but also unpatented research tools, such as databases, cell lines and the like. Private firms often impose not only access or subscription fees for the research tools they give to universities but also what are known as reach-through royalty rights, which essentially claim a percentage of any invention that might come out of work on the research tool.

Universities return the favor by imposing the same restrictions on private firms. It's a tit-for-tat sort of situation. And now this arms race to seek rights has even spilled over to transfers of tools between universities. Transfers of tools between universities can often contain some of these same restrictions.

So, why worry? Why worry about any of this? Perhaps there's no reason to be concerned. I would offer three reasons, though, why I think we should be concerned. The first is the problem of supracompetitive pricing that attends the creation of all monopoly rights, even when those rights are freely licensed to all comers. Concerns about supracompetitive pricing are particularly acute for publicly-funded research. In the case of such research, the conventional argument that one tolerates supracompetitive pricing in order to provide an incentive for invention simply does not apply.

In addition, the argument that motivated Bayh-Dole, which was basically that we need universities to patent inventions and then license those inventions, probably exclusively in order to attract risk capital for commercialization, doesn't really make sense for discoveries like stem cell lines that can be disseminated widely without patents. We see lots of people who are very eager to get their hands on stem cell lines. Stem cell lines can also serve as the basis for patents further downstream.

Second, there are reasons to be concerned about monopoly control of basic research platforms — again, like stem cell lines. A monopolist is unlikely to see the myriad applications of basic research platforms. The standard response to this argument is the monopolist will have an incentive to license widely to lots of different researchers who will see these different applications. Unfortunately, these types of licensing negotiations often break down due to either inadequate information on the part of the parties involved or, even more frequently, strategic behavior. Breakdowns in negotiations are particularly problematic in the biological area because it's difficult to "invent around" research platforms like cell lines or receptors that will be targets for a drug, for example. We have to take biology, more or less, for better or worse, as a given.

Now, these problems of inadequate information and strategic behavior only compound when the basic research platform is owned not by just one entity but by many different entities. The follow-on researcher who wants to work with the platform has to negotiate with all these different entities. In this situation, we get what my colleague Rebecca Eisenberg has called the anti-commons problem. A good recent example of the anti-commons problem is posed by single nucleotide polymorphisms, or SNPs. Now, that's quite a mouthful, but basically, a SNP is a single based locus at which the DNA sequence of individuals varies. SNPs — particularly SNPs found in coding regions of DNA — have promise as tools for tracking down disease genes, and also as tools for predicting individual patient responses to drug.

Not surprisingly, biotech companies have in recent years identified and sought patents on lots of these SNPs. This has prompted the concern that rights in this important research platform will be balkanized and difficult to aggregate usefully by follow-on researchers.

So, what should we do as a response to these concerns? The most obvious response would be some sort of change in the patent statute, or at least in its interpretation. In fact, some small changes have occurred and I would argue that, in large part, they have been quite salutary, particularly in addressing the potential for an anti-commons problem.

For example, in response to pressure from the National Institutes of Health and from the academic science community, the Patent and Trademark Office has issued some new utility guidelines that raise, to some extent, the bar with respect to patenting inventions that only have speculative research uses. The PTO has also issued related guidelines that indicate the scope of patents on gene sequences will be relatively narrow.

We should be concerned, however, about making large changes to the patent law. Patents clearly matter, as many of you probably know, to the biopharmaceutical industry. And if you talk to biotechnology entrepreneurs, they will insist that they need patents on their research platforms in order to develop those platforms in the first instance, and then also to attract risk capital for further development. And there are reasons not to dismiss these claims out of hand.

It is pretty clear that although biopharmacology is increasingly becoming an information industry that's based on data, it needs to have property rights claims, at least in downstream research, in order to get the research done. There's no reason to believe that biopharmacology will become like the software industry, for example, where we have seen so-call open source models of development, models of development that actually forbid property rights in any aspect of the software that is developed. It is unlikely that we are going to see that in the biopharmaceutical industry. So large changes in patent law are probably not a good idea.

Some might think that we could try to draw a line within the patent statute between what is upstream and downstream. Those who would think this might be encouraged by the fact that even pharmaceutical industry players have decided that, at least in certain circumstances, upstream research should not be patentable.

For example, pharmaceutical companies have spent their own money to put SNP research in the public

domain to basically preempt the possibility of patents in SNPs, and hence the possibility of an anti-commons problem. So, one could perhaps think that maybe there is a way we could cordon off certain types of research and say that it is not patentable because it is too upstream, and then what's downstream should be patentable. Unfortunately, what is downstream is very much in the eye of the beholder.

If Congress were to try to draw some sort of line that was more specific than the current, rather vague utility standard, every industry stakeholder around would be trying to convince Congress that their particular inventions would be or should be sufficiently downstream to be considered patentable. So we would have this massive rent-seeking going on, and the prospect of Congress trying to draw a line in that environment is not particularly attractive.

I would argue that when research is publicly funded, though, the situation is quite different. Obviously, no one can claim that the patents are necessary to develop the initial invention. The argument that motivated Bayh-Dole, which was basically that we need patents in order to commercialize invention, isn't always persuasive. For example, stem cell lines can be rapidly disseminated, and they will doubtless be developed because of the potential for downstream patents.

In fairness, though, even with publicly funded research tools, there might be circumstances in which patenting in exclusive licensing are useful. For example, patents were useful in developing machines for DNA sequencing into commercially reliable equipment. The policy challenge is to distinguish publicly funded invention that is best developed through patents or other proprietary claims from inventions best developed by being left in the public domain. Needless to say, in an area as complicated and rapidly evolving as biomedical research, this is a really formidable task.

Briefly, I would argue that the institution that should have authority to determine what lines should be drawn in terms of what publicly funded research is patentable and what is not is the National Institutes of Health. In the question and answer session, I would be happy to go into the reasons why. But the problem, as matters currently stand, is that under the Bayh-Dole, NIH has very limited discretion to issue a policy of no patenting or no proprietary rights with respect to publicly funded research. I would argue that NIH should be given more discretion in that regard.

I've clearly run out of time and I'm happy to take questions.

MR. TROY: There is this tendency to think, that if a drug has been publicly developed and so, therefore, it shouldn't be able to be patented. There is a drug called Taxol. Some of you know about it. It is the standard treatment for ovarian cancer. It comes from the bark of the yew tree. NIH developed it decades ago, but they need to aggressively find a partner to bring this drug to market.

It's one of those situations where the company can be characterized as seeming absurd because they are trying to patent this thing that comes from the bark of the yew tree and was developed decades and decades ago. But if they didn't have any patent rights, their incentives to develop it would be limited. Again, NIH really was looking for a partner because NIH can't bring the drug to market itself; they can't manufacture it; they can't produce it.

So again, the initial reaction of, "It's publicly funded, therefore nobody should be able to patent it," is probably too facile.

I am not suggesting that is what was said, but it's a reaction that I initially had, and the more I learned about it, I realized that was not the right approach.

Our next speaker is Dr. Oldham. He is an internationally recognized cancer specialist. He is regarded as a leading pioneer in the development and use of biotherapy, which it says here is the fourth modality in cancer treatment. I don't know what the other three are; I'd be interested in hearing.

He is the CEO of Cancer Therapeutics, Inc., so he is from the private sector. It would be interesting, Dr. Oldham, if you have any reaction to the sort of accusation of private companies patenting things like gene sequences of unknown purpose and the implicit suggestion that there is, on occasion, an abuse or overuse of the patent system by the private sector.

Dr. Oldham attended the University of Missouri at Columbia. He completed his M.D. in 1968. During his medical schooling, he was awarded a PHS Student Research Fellowship and two PHS Cancer Clinical Research Fellowships.

He did his residency in internal medicine at Vanderbilt, continued his education with Medical Oncology Fellowship and graduate studies in immunology at the National Cancer Institute.

From 1975 to 1980, he served as the Associate Professor of Medicine and Associate Director of the Vanderbilt Cancer Center. He was the founder and Director of the Division of Oncology. He went back to the National Cancer Institute from 1980 to 1984, and then in 1984 he established the Biological Therapy Institute and the Biological Research Center of the University of British Columbia and Biotherapeutics, Inc., which he took public in 1986.

In addition to his current role as CEO, he is the Associate Director of the Singletary Oncology Center in Georgia. He holds a Clinical Professorship of Medicine in Hematology Oncology at the University of Missouri at Columbia and a Clinical Assistant Professorship in Internal Medicine Oncology at the University of Kentucky.

He is also the Medical Director and Vice President for Business Development for CBA Research in Lexington, Kentucky, which I assume, among its other things, researches how one can do all these things without ever sleeping.

MR. TROY: He is the founder and has served as the editor-in-chief of three medical journals. He has contributed over 400 papers to the medical scientific literature and has presented thousands of abstracts, posters and lectures at various meetings on cancer research and treatments.

I hope you're suitably intimidated, because I certainly am. Dr. Oldham.

DR. OLDHAM: And as you know, my time is now up.

I'm going to take a completely different tack and try to be very brief about it.

In 1902, the Food, Drug and Insecticide Agency was created by legislation. In 1938, it was changed to the Food and Drug Administration and the charge was to make sure that drugs were safe. In 1962, the intent of Congress changed such that Act was altered to prove that drugs were not only safe but efficacious. As a result of these legislative changes, an agency has grown and expanded to regulate the drug development that we know today.

Most of the drugs and the intellectual property that were spoken of earlier had to do with drugs being applied to broad markets — hundreds of thousands of patients. The cost of those drugs run from $300- to $500 million each to develop, taking 15 to 18 years to get through the regulatory maze. That is the current situation.

The reason intellectual property and patent and proprietary rights are important is you have to somehow raise the money to create the hundreds of millions of dollars that you need to develop a new drug under current Food and Drug Administration regulations.

I want to suggest that our technology has bypassed this whole system in a dramatic way. We need to change the Food and Drug Administration or we need to develop a new track within it. Here is the reason. Today, my company, as with other companies, can take your white blood cells from your blood, your tumor, and we can grow them in the billions. We know that these T-lymphocytes can be curative in certain forms of cancer, when used with a drug called Interleukin 2.

Today, I can take a tumor, grow the white blood cells out, give them back to the patients as a form of therapy, and that treatment can only be used on that patient. Of course, the DNA, cells and tissues involved all came from that patient and are used in that patient. Therefore, all the ideas of managing risks for large populations don't apply to that circumstance. And indeed, I would suggest, when you talk about property rights, that those cells really belong to that individual.

The Food and Drug Administration and government has great limits on it, in terms of impinging on our property rights — something that this society spends a lot of time talking about. This morning's session was a good example of that. I wonder if we ought not to begin to think about our own DNA, our own cells, our own tissues, our own organs and our own bodies as the property of the individual to which those elements have been granted.

Maybe initially, it belonged to our parents, so some would say today the creation of the first cell in the embryo created a new individual, and that individual is imbued with all of the rights of ownership of the things that develop from that single strand of DNA. I would suggest that there is good reasoning behind that.

There has only been one case that has gotten any play in the courts that I know of, though I am not a lawyer. The John Moore case that went to the California Supreme Court was about that issue. Cells grown from Mr. Moore were used to develop drugs. Mr. Moore said, "Gee, you used my cells to develop drugs; maybe you should recognize my ownership of those cells." Indeed, there was recognition of that in the Supreme Court of California — not as complete as Mr. Moore's lawyers would have liked, but excellent recognition nonetheless.

So I would wonder today if it's not reasonable to test this issue, and I would ask all of you who are mostly lawyers whether or not this is something we should talk about and think through. Do you own your own cells? Is this my hand, or is the Food and Drug Administration's hand?

This is my arm, so I believe it belongs to me. I would like to ask whether, as you get ill, your parents get ill, your children get ill, if the elements of their bodies can be used to develop treatments that can be curative, should this be an area that the Food and Drug Administration regulates or not? I would suggest that they should not and we need to test this position in the federal courts.

Thank you.

MR. TROY: Well, the FDA would answer yes.

It is actually a really interesting thing called a transgenic fish, where you change the gene of the fish. To make the fish grow much faster, we have developed these transgenic salmon that grow twice as quickly, and grow to five, six, seven, eight times the size of a normal fish.

But it is not the fish whose gene you change but the children, the spawn, of that fish. So the question is, is the gene an article that is intended to affect the structure and function of the body of man or animal? And it is, clearly, when you put it into the first fish. But what about the fish's child?

That is a real issue we are wrestling with right now — does the FDA have jurisdiction over the transgenic fish.

MR. TROY: You think I'm making this up. But what it illustrates — I think this is Dr. Oldham's point — is that we're taking these very old tools from 1938 and trying to adapt them to technologies that nobody ever conceived of.

MR. WERNER: Thank you.

Yes, I did, and over several beers, I'd be happy to tell you my war stories. I will say, professionally, it was remarkable because there were really interesting issues and a lot of smart people, policy-wise. Obviously, there were some people who made some severe political miscalculations, but that's another story. But yes, I do admit that.

I tell you, there are some audiences that I speak in front of, where they say that they can't believe I admit that I work for the biotechnology industry. So, I get it coming and going.

I also will be brief, and I wanted to lay out some of the things that my members, who are biotechnology companies, think about. Dr. Oldham is somebody who is active in our organization, and I want to elaborate on some of the things he mentioned.

The important thing to remember, by way of background, is that the biotechnology industry is an industry comprised of small- to midsize companies. We have about a thousand members. We're a big trade association. We've got about a thousand members, over 90 percent of whom have no products on the market, and therefore no revenues from the products. About 40 percent of them have fewer than 50 employees. So the vast majority of them are small businesses. They are small companies.

As I said, they have no products; they have no revenues. You've heard that it takes how many years, how many hundreds of millions of dollars, to get through the FDA regulatory process? Of course, they all hope that they will have some product eventually, or some technology platform eventually.

So how are they going to get that $300 million and how are they going to fund all the research that they do, which ultimately will lead to the kind of medical breakthroughs that all of us as a society want? That's how we get all the drugs and all the biological products and all the vaccines and all the other things. The way they do that is by going to Wall Street and attracting investors. The primary asset that they have is their intellectual property because, as I said, they do not have a product. Sure, if you're Merck or your Pfizer, you might be able to fund your next research project with all of the money you made on Viagra. But if you're a biotech company, you can't do that. So what do you have? You have intellectual property. That's your asset. That is what is valuable. That's what keeps it going. That's what finances the research, and ultimately it's that research that gets turned into the product that we all use and we all want when we are sick.

Now, you also heard the relationship of the Bayh-Dole Act and some of the other federal statutes. It has been, I would argue, the explicit federal policy in this country for two decades that we create this relationship between the federal government through the National Institutes of Health, academic institutions and the biotechnology industry.

The rules are such, with technology transfer and the like, that public funding, which as we all know is a huge investment of public money in biomedical research in this country — the combination of all those things is why we have in this country a biomedical research enterprise and a biotechnology industry that is literally the envy of the world. It's why the best scientists in the world come here to work. It is why patients come here to get access to the kind of products we develop. It has been an enormously successful policy. It's something our government and our leaders should be proud of and we all should be proud of. And intellectual property is a fundamental foundation of all that.

Let me just talk about how these issues go from the macro level and get down into the micro. You've heard a little bit about this, but I was going to use stem cells as an example.

What is interesting is that there are numerous ethical issues that are implicated by this kind of research. What we have seen, though, after the President's announcement in August, is that Congress, in particular, but also, the advocates of the research, the scientific community or patient groups, have focused less on that. They have now started to focus on what they call the viability of the cell lines, which is to say, are these cell lines from which we can do more research? Are they scientifically viable? And related to that, is the availability of these cell lines. That's where intellectual property has suddenly come barging through the door, and why suddenly people who didn't think much about intellectual property issues, and they argue didn't know about them or didn't care about them, suddenly now care about them a great deal.

There has been at least one, if not more, congressional hearing since August, where the focus has been not on what is the scientific potential of stem cells and whether it's a good idea to use cells from embryos — that was the debate pre-August — but who is going to have access to these cell lines and commercialize all of this.

Who is going to do all this research? And are the intellectual property laws an impediment to that because, as was discussed, the University of Wisconsin has licensing arrangements with a particular biotech company? In NIH's recently published registry, there are a few biotech companies that say they've got any number of cell lines.

From our perspective, of course, this is the system that has worked very well in this country for many, many years, as I talked about. It has led to the availability of lots and lots of medical breakthroughs for all of us.

You know, a company like Geron or companies that develop stem cell lines didn't just get into it. They've been working on this stuff for a long time. They took business risks and they attracted investors because of it, and they've made a commitment to commercializing this research. They did that because they had intellectual property rights. It would

seem unfair, at best, now to suddenly say, "Well, we, Congress, can strip all that away. "

When we talk about solutions, it's an important discussion, and obviously one that is worth having. But it's going to be important to remember what kind of precedent you are setting. If you have a whole industry whose foundation is the intellectual property system, you have to be very careful about changing those rules. For what it's worth, the companies that are involved in the stem cell matter have said they will make the cells available for researchers, or at least Brezogen (phonetic) came out publicly and said, if academic researchers want this, we'll make it available. The University of Wisconsin said it will make these available.

When we get down to commercialization of that research, then that's a whole different question and obviously that is something that companies with the intellectual property rights now say, as you would expect them to, "Well, we'll talk and we'll see what kind of licensing arrangements can be reached." It remains to be seen whether anybody can work anything out.

What is interesting to me is that we have gone from this issue about stem cells, all the lightning-rod issues about embryos and when life begins and all of those really important issues. Now we are going to get into the nuts-and-bolts questions about things like intellectual property.

At a certain point, hopefully, we will start talking about other issues, and it will be intellectual property issues that dominate the stem cell matter. I expect lots of congressional activity next year. Whether or not there's legislation, who knows? But lots of pressure, I would expect my members to start getting a lot of pressure, maybe from the public or maybe Congress, to start relinquishing their intellectual property rights. It remains to be seen how we will proceed.

Thank you very much.

MR. TROY: Thank you. One of the things that is interesting about being at the FDA is that you see the intersection of bio-terrorism and national security and biomedical research. One of our most important responses in the national security context is going to be developing rapidly things like vaccines and treatments. I should hope we wouldn't need them, but you have to be prepared, unfortunately, in this day in age.

Stem cells are almost the easy case in intellectual property rights, but maybe Professor Mahoney, who is coming up next, can address it.

One of the hard questions is, what if you have a gene that you haven't discovered or developed but you were the one to discover its uses, you were the first one to map that out? Is that the kind of thing that intellectual property rights should address?

Our next speaker is Professor Julia Mahoney, an Associate Professor of Law at the University of Virginia. She also has taught with the University of Southern California and Chicago. Before law teaching, she was associated with Wachtell Lipton Rosen & Katz, where she worked in a corporate department on acquisitions, mergers, divestitures and restructuring.

She received her J.D. from Yale Law School in 1987 and her Bachelors from Columbia in 1984. She teaches the interesting mix of corporations, mergers and acquisitions, reproduction and the law, feminist jurisprudence and property.

PROFESSOR MAHONEY: Thank you. I'm here because of my interests in property, business organizations and the regulation of medical technologies.

As we have heard already, the problem is easy to state but difficult to solve. We want two things. We want to encourage innovation, but we also want to ensure that the innovations that we encourage are widely disseminated so that human suffering can be alleviated, and so that these initial innovations can form the foundation for later innovations.

The tension is obvious. Legal regimes that promote innovation at initial stages — what Professor Rai referred to as "upstream" innovations — will not necessarily promote wide dissemination. Of course, legal regimes that promote wide dissemination may frustrate initial innovation. Realistically, we ought to recognize that it is hard for law to get it exactly right all the time. We should expect to run into problems because what we are trying to do is difficult, and we will need to ask ourselves constantly on what side we are erring.

In short, the fact that things may be out of kilter – as evidenced by the strong criticisms triggered by some of the property rights accorded to biotechnology companies or the Wisconsin Alumni Research Foundation — ought not to cause us surprise. Moreover, we ought to expect to be constantly modifying the contours of property rights.

It is important to understand that the history of property law is replete with instances where existing property rights have been adjusted. This is not to say, however, that the history of property law is filled with major overhauls. Rather, changes in property rights tend to be incremental.

What matters in terms of designing property rights regimes to strike the appropriate balance between initial innovation and dissemination of knowledge is that we create effective institutions; that we have the sorts of societal organizations that we need in order to encourage the kind of behavior that we want. And this is the point where things can get tricky.

I want to talk about something that I think is terribly important to this debate but which has not, so far, been showcased in discussions, and that is the following. When we examine issues revolving around property rights in medical innovations, we note that three types of institutions interact. We have for-profit firms, we have non-profit firms and we have governments. So let me talk about each of these three institutions, and detail how thinking carefully about the social roles of these institutions are and how they interact with one another can illuminate our consideration of the problems that this panel addresses.

The first institutional category is that of profit-making firms. Or maybe, since a lot of biotechnology companies don't throw off a lot of profits yet, I should refer to them as profit-seeking firms. Profit-seeking institutions raise capital. And the reason that people give them capital is that they expect to get money back some day; ideally, a lot of money. These institutions are, in theory at least, operated to promote the financial interests of their shareholders. Do we think this is a bad thing? Of course not. If I asked you what institutions have fueled the explosive economic growth of the past 200 years, one of your first responses would be: "Corporations." Now, if I followed that with the question, do you think that corporations have no duty to the public whatsoever, you would probably say no. But there is widespread agreement that the principal goal of business firms is to enrich their owners.

Everyone understands that when corporations engage in charitable behavior, they do so with an eye toward benefiting their shareholders.

This is not wrong. We have set up legal regimes of corporate governance so that investors in profit seeking firms can realize returns on their capital. It should not offend us that managers of corporations are not, every hour of their waking days, seeking to further the public interest. The fact that they strive to maximize the returns of their shareholders does not make profit seeking firms evil, or even bad corporate citizens. But we ought to recognize what their incentives and objectives are because that helps us to understand how they will interact with my next category, which is the government.

The government has a crucial and important role to play, both directly in conducting research at NIH and other governmental entities, and also indirectly in funding research conducted by others. If I asked you what the government ought to be doing, you will all reply — this is the Federalist Society, after all — in one big voice, serving the public interest. No, I realize you probably won't reply that—I was only joking.

Nevertheless, if you went and asked a group out on the street what it is the government is supposed to be doing, one thing people would say is, "promote the public interest." They invent things that will cure sick people; they fund important research and make it available to everyone. That is what government should do.

Of course, we want the government to do that. But there is the problem of what happens when the government interacts with a profit-seeking firm. When governments interact with profit-seeking firms, the profit-seeking firms often attempt to get as much of the valuable government property as they possibly can and then exclude others from it. That is the nature of the profit-seeking firm. So we ought to be alert to the possibility that the government will, in effect, either give away valuable property, or transfer valuable property rights for less than their full financial worth.

There has been a great deal of upset about the fact that various stem cell patents have been gotten on various developments that were funded on public money. The solution to this problem is to understand that this is an endemic problem, this is going to occur all the time, and to figure out ways to avoid its happening.

The third category is non-profit institutions. Now, Professor Rai talked about the Wisconsin Alumni Research Foundation, which holds many valuable patents and which defends its property rights as vigorously, I think it is fair to say, as any profit-seeking firm in existence.

The University of California also holds a number of extremely valuable patents and, again, they don't seem eager to give them away and join hands and sing Kumbaya with the rest of the world. Not surprisingly, they would like to be compensated for these patents.

We have to ask ourselves the extent to which we are comfortable with non-profit institutions behaving so aggressively. I think that the specter of non-profit institutions developing valuable property, often with the use of government money, and then pursuing their financial self-interest as aggressively as profit-seeking firms gives a great number of people pause. In discussions I have had with non-lawyers about biomedical issues, concerns about "greedy" nonprofit firms have come up on many occasions.

When we look at non-profit institutions, we do not expect them to behave as profit-seeking firms do. We know that they don't have residual shareholders. We know that they do not, in theory at least, have owners. And so, the question arises about whose interest they are supposed to be promoting.

Now, I suppose in the case of WARF, the interest they're supposed to be promoting is the Wisconsin alumni. But at the same time, a lot of people believe that non-profit institutions do have some duties to the public. It is fair to say, however, that so far there has been little sustained discussion of the precise duties that non-profit organizations that hold these sorts of property rights have to the general public.

I don't think we've even begun to develop a theory about what kinds of behavior we expect from non-profit institutions. But I think that the enormous role that non-profit institutions play in this area means that we need to start

thinking much more carefully about what it is that we expect from non-profit institutions.

I want to emphasize how important non-profit institutions are in this area. Not only are there the universities, but there are a lot of non-profit organizations that are set up by people or families of people who suffer from terrible diseases. One question that constantly arises is, if they had gotten patent rights or if they had simply collected a database of the blood samples that would shed light on genetic predispositions to such diseases, then what obligation should they have to share with others?

For example, when families have donated blood samples to non-profit institutions, they often are surprised or horrified to learn that the non-profit institution is not sharing the blood samples with all interested researchers. This, again, is a glitch in our understanding of non-profits and betrays the fact that we have not yet thought a great deal about how the rights and responsibilities of non-profit institutions.

I think Mike Horner was correct when he said that we have a great deal to be proud of, in the institutions that we've developed in this country. But I think that there is always room for improvement, and that in shaping the society that we want in order to encourage both initial innovations and wide dissemination, we have to think carefully about what we expect from all three types of these institutions, and in particular, what we expect from the way these institutions should interact with one another to maximize social welfare.

MR. TROY: Our final speaker before our discussion is Professor Scott Kieff.

Remember how I talked about how absurdly well-credentialed people are in this area. Mr. Kieff is an Associate Professor of Technology, Law and Business at the Washington University School of Law and also a faculty fellow, The John M. Olin Senior Research Fellow in Business and Economics, at Harvard Law School.

He was a trial lawyer and intellectual property lawyer, and was visiting as an assistant professor at the University of Chicago Law School and Northwestern University School of Law. He graduated with a degree in — get this double focus — molecular biology and applied microeconomics — from MIT in 1991 and, as an undergraduate, was awarded a two-year fellowship sponsored by the National Science Foundation for research in molecular genetics. As an undergraduate. That makes me feel pretty inadequate.

He served as a law clerk to the Honorable Giles Rich at the United States Court of Appeals for the Federal Circuit. He's delivered many articles and speeches about obtaining and enforcing intellectual property rights. He's the co-author of the treatise and casebook, *Principles of Patent Law*, which is now in its second edition.

His research interests involve the interface among law, economics, ethics and creative endeavors such as science, engineering, medicine and art, with a focus on technology law and business, intellectual property, contracts, unfair competition, antitrust, complex litigation and the allocation of decision-making ability and authority in disputes involving technological facts.

He was an associate at the firm of Pennie & Edmonds in New York and an associate and counsel at the firm of Jenner & Block in Chicago.

In addition to teaching at the Washington University and Harvard Law, he maintains his connection to the law firm and business communities through an ongoing consulting practice. So he is at least another member of this panel who never sleeps. Thank you very much, Professor.

PROFESSOR KIEFF: Thank you very much. I really wish my folks were here because they would have liked that.

When we think about the role of government and we think about legal systems, we can imagine some having a difficult time. We can imagine having a difficult time, if the legal system is trying to decide what to do with stuff that we have at a certain time, but that changes. We might have to change that system. Or the stuff we had yesterday changes, and tomorrow we have different stuff. We might have to change that system.

But imagine a system designed to help us figure out what to do with all the stuff we might get. Then, as we get it and as it wants us to get more, why should we necessarily redesign the system? You see, patent law asks us to get new technology. I'm not sure that it makes sense to say that, therefore, patent law doesn't know what to do with new technology.

It seems to me that patent law was designed from the very beginning to get all the stuff that we couldn't conceive. In fact, if we really could conceive it, it wouldn't be patentable. It would be not new or it would be obvious. Patentability is all about the stuff that's not obvious. It's all about the stuff that's not foreseeable.

So, the notion that patent law is broken because new technology that we didn't expect has come to be — I don't know – but it does not make sense to me. I think we expected it because we didn't expect it. That's the stuff that patent law was supposed to get us, exactly that stuff we didn't expect.

Now, how could patent law be working out for us? Imagine the notion that patents on upstream stuff could frustrate the ability of us to make downstream stuff. That seems to be a big problem with patents on express sequence tags or SNPs or other basic biological research tools like stem cells. We also can imagine, in fact, entire industries breaking down because of patents on all the upstream stuff. That's why we don't drive cars — because patents on screws prevented us from getting cars.

PROFESSOR KIEFF: Oh, except I've got one. And most of us have them, too. We've seen patents on upstream stuff before. So the upstream nature of the problem can't necessarily be the problem.

I'll now make a little regression here to patent law. Imagine I have a patent on a composition. I think it is going to be great as axle grease, but it turns out that it really tastes great. It's great as a sweetener. Well, for those of you who know patent law, it turns out that intent is not part of the patent case. If I claim the product and you use the product, whether you use it to shine your shoes, or sweeten your tea, it does not matter. You still infringe.

We have never required a patentee to stake out the turf of all the possible uses for her invention. The fact that the patentee doesn't know all the uses is arguably nifty because then other folks can come along, figure out those uses and they can get some patents, too. That's not so bad, and we have seen that work in lots of industries, again, like automobiles, radios, TV, telephones.

What we've heard, in fact, is talk about the utility requirement. I've always thought it was kind of a funny problem because it seems to me, the argument goes, "Well, you've got a patent on this thing and I really want it, so it's not useful."

PROFESSOR KIEFF: Well, then you don't want it, right? If it's not useful, then what are you in court for, or why are you up on the Hill asking for that patent not to be issued? You're up there because you want it. And the fact that you want it means it's useful. It seems to me, you want it badly and that makes it very useful.

We've asked a lot of important questions up here, like, when is it best to have so-called strong property rights or weak ones? When is it best to have strong enforcement or weak enforcement? I don't know. But I do know someone who knows.

I wish Steve Forbes had been up here this afternoon to give his talk because I would have just inserted that right here. How does the story go? Well, if there are folks lining up to use the stuff and they really want it, we have a name for that. Those are called customers. And for those of us who like markets, we love customers. They're the best thing since sliced bread because we sell to them. So the notion that the patent is going to restrict output is a funny thing.

In fact, patentees want to push output. Why? Not because they care about the public in the "gee-I-really-care-about-everybody" kind of way. No. They care about it the way Steve Forbes told us; they care about it because they have to. That's what they're in the business of doing. That's how they make their money. That's how markets work.

I only make money if I have customers. That means I need to pay attention to my customers. I need to sell them what they want, and I need to do it at a price they'll pay because charging them a price they won't pay doesn't do me any good. It really hurts me.

So, why do drug dealers give away free cocaine? To get more customers, and to tell the other customers who will pay a lot of money, you see how well it works? These folks are lining up to do it.

If you're a drug company and you have a patent on a drug and want to charge a lot of money, might you choose to give it away for free to a lot of other people? Sure, so you can tell the FDA, look at how well it works. It works really well. Now give us approval so I can charge these other guys a lot of money.

You would rationally choose to engage in aggressive price discrimination. We know that even a dyed-in-the-wool ultra-aggressive, cold-hearted monopolist will push output to the full competitive levels, if she can price-discriminate. In fact, we see an immense number of mechanisms designed into the patent law, designed long ago, before we even thought about price discrimination theory using those words, but purposely designed into the system to allow patentees to elect to price discriminate. We did that, I think, because we wanted them to price discriminate. We wanted them to aggressively push output.

Remember, to the extent we don't like monopolies — that's an interesting question, especially for this audience, but let's assume for a second that we happen not to like them— the reason we wouldn't like them is because they restrict output, not because they raised price.

If they push output to the competitive level, all the rest of this becomes a distributional problem. We could have income taxes or we could do other things to re-distribute wealth, but it's a wealth problem. It's not a problem inherent with a market — at least, a market that has some wealth.

There are some other kinds of problems that we have explored, and I'll probably stop early because I want you to have lots of time to ask questions. But let's just think a little bit about one of them. How are we going to get the information about what patents should be gotten, what patents should be enforced? How are we going to get that information to the decision makers, and what decision making process will be the least expensive? It seems that if that information exists and is knowable by private parties, then wouldn't it be great if we could just get those private parties to come together and negotiate.

If that information is knowable by the government, then let's ask the government. But the interesting thing about each of the markets we have heard about is that most of the participants are pretty well expert. They know their stuff. They know what each other has. They can value what each one has. There will always be bargaining breakdowns, strategic behavior. There will be lots of problems. It will not be a perfect market because no market is perfect.

But all the standard tests we have learned in law school about when decision making is best left to private parties and when it's best left to government agencies tell us that when the information is in the hands of the individuals who would be talking to each other, if we force them to, then we ought to let them talk to each other and force them to. That's exactly what property rule treatment does for patents. It requires that the patentee talk to the licensee and vice versa. If the licensee doesn't need to talk to the patentee, then we have to make a decision about what value to put on that license.

Everybody's familiar with basic liability rules. You are allowed to infringe, and then you go to court and fight over the price. But the neat thing about property rules is that you don't just go to court to set the fee because the property holder has the right to enjoin you. And you enforce this property rule strictly with the injunction. That forces parties to bargain. So the nifty thing about patents is, people are forced to negotiate with each other.

Now, let's ask this question. Have they done that in the biotech industry with patents on basic research tools? For those of you who do biotechnology, you'll be familiar with just two quick examples — Restriction Enzymes and the Polymerase Chain Reaction. One is a product and one is a process. In both cases, we had patents, and in both cases, patentees aggressively went around to all the possible users in the world and said to them, would you please use — those six o'clock phone calls at dinner time.

That's what patentees do. They go to every lab and they say: "would you use my process; would you use my product?" "And by the way, how much money are you making because we'll adjust our price accordingly." We've seen that market work in the biotech area before with upstream technologies — technologies for which downstream applications were not known. And I'm not sure that it won't work again, time and time again.

Thank you.

MR. TROY: Thank you. Before we throw it open, I just want to ask whether any of the panelists have anything they want to say.

Arti, you were furiously writing. Do you have some responses?

PROFESSOR RAI: I'll just be very brief because I know that you guys have much more interesting things to say than we could ever say.

As with all questions, the question of whether markets work better or government works better, is an empirical question and I would basically disagree with Professor Kieff's characterization that markets have, empirically, necessarily always worked to disseminate broad-based patents widely.

Unfortunately, I think the auto industry and the aircraft industry are two prime examples of situations where broad-based patents early on actually delayed innovation. In the aircraft industry, for example, there was lots of litigation between the Wright Brothers and follow-on licensers, and they didn't manage to get to "yes," as it were.

I think these questions are really empirical ones, and that's why I would urge us to look at the history, for example, of the auto industry and the aircraft industry and determine whether in particular cases broad-based patents were really the way to go on upstream information are really the way to go.

MR. TROY: Questions.

AUDIENCE PARTICIPANT: The WTO meeting just finished, and there were some changes in TRIPs. Can I get some reaction, first of all, to the fusion of technology and also international property rights and the regimes to regulate them.

PROFESSOR KIEFF: Yes. It's funny. All the folks who happen to live on sand in Saudi Arabia have a lot of money, whereas all the folks who happen to live on sand in Central Africa have no money. It's because underneath the sand in Saudi Arabia, there's oil, whereas underneath the sand in Central Africa, there's no oil.

I think all the evidence shows that the one natural resource that seems to be located wherever humans are located is brainpower. Therefore, it seems to me that strong intellectual property protection is, if anything, the great equalizer for national economies.

In fact, if I were designing a national economy for a developing country, I would want a very strong IP system because I think it would develop a strong commercial center in my country. It would capitalize on a natural resource that I have. It would be a capital-intensive industry and would be an industry that is inherently one to engage in trade.

And you could do it all very inexpensively, by the way, by simply saying whatever the U.S. court or British court or the French court — you could pick a country — whatever that court decides, will just apply as precedent. You wouldn't even need your own courts. You'd just need your own police system.

I actually think that strong IP rights ought to be what every country should strive for, especially the poor developing countries. In the short term, there would be some wealth transfer away because while they have brain power they don't have education, and you need to get education to make the best use of brainpower. But that can be fixed in the medium term. In the long term, that's always going to be a winning strategy.

PROFESSOR RAI: I actually agree with Professor Kieff in one respect. This goes back to something he mentioned in his talk, that price discrimination, which is what has very much ended up happening in terms of the international patent regime for drugs, is the way to go. Basically, third-world countries that can not afford to pay for these drugs and would not be a market for these drugs anyway, should get them pretty cost-free, and the first world should essentially subsidize the third world in this respect. So, that is on the access side with respect to end product rights.

With respect to whether we should have an intellectual property rights system that's strong across the board, I think that a basic, minimal level of intellectual property rights is probably necessary for industrial development. But, because I am an empiricist at heart, I look at the empirical data that economists such as Josh Lerner at Harvard Business School have gathered about how patent systems have affected countries in different stages of development. The answer is, well, we don't really know and the empirical work really doesn't yield any definitive conclusions. So, I guess I'm not as sanguine that the strongest possible intellectual property rights system is great for all countries.

MR. TROY: Yes.

AUDIENCE PARTICIPANT: First of all, this is a wonderful panel. It's very interesting.

Why isn't contracting essentially establishing the right with respect to forcing the right, and then giving parties the right to contract and pursue whatever objectives they want to? Really, the answer to some of the questions that Professor Mahoney was proposing.

PROFESSOR MAHONEY: I think it is important to note that if investors fear that property rights will be compromised, there will be less investment. That is why I said that it is important to keep in mind that in the grand course of things, if you look at the history of property rights, it is unusual to have huge dislocations, to have huge changes in property rights.

I am not saying that we should never have huge changes in property rights. I am simply saying that when people think about doing something like saying to Bayer, oh, by the way, the deal's off, you ought to bear in mind that goes against the whole force of history, and there is a good reason why the history of property rights has emphasized minute incremental changes in property rights, and not big dislocations. So you and I are in solid agreement on that.

With the question of the non-profits, I think it gets quite hard because we in this country tend to worship non-profits — I guess probably not at the Federalist Society, but outside the Federalist Society. I think here in this room at this conference, there's probably a healthier skepticism about the claim that non-profit organization equals social good.

But out in the general world, people do equate non-profits with social welfare enhancing, and of course that's not the case at all. Of course, non-profits pursue their own agendas. But non-profit behavior can be more quirky because they do not have the disciplining effect of the residual shareholders. One thing that you can say about a profit-seeking corporation is that the shareholders by and large — not always perfectly — pay attention to what's going on and it's a little bit easier to predict their behavior, that they're going to be profit maximizing.

With non-profits, things can often break down. Many of you have probably been on non-profit boards of directors and you probably have your own tales of waste, indolence and so on that leads the non-profit organization not necessarily to behave in the way that a profit-seeking firm would. Think about what Professor Kieff raised: we expect that if a good deal could be struck, it will be struck unless there is a really good reason, like massive transaction costs or some kind of big information failure, or you just can't find the rights holder. We assume that deal will be struck. When we look at non-profit institutions, I think we have to not abandon, but relax that key assumption. So, my talk was meant to be a plea to everyone who knows something about this and is involved about this, to start thinking about how non-profit firms behave differently from profit-seeking firms and what that means for trying to solve this set of difficult problems.

MR. TROY: Professor Kieff.

PROFESSOR KIEFF: Just one minor comment to tie into what I think will be a difficult issue for all of us, especially in this group.

Your question in the federal context is, if the federal government wants to take, can it take? The answer is yes. But interestingly enough, the federal government — federal, keep that in mind because it'll change in a second — the federal government has actually given a limited waiver of sovereign immunity in 28 U.S.C. 1498 for patent and copyright cases. And you can sue them for royalty in the court of claims.

The real difficult problem for those of us who worry about states' rights is that the modern 11th Amendment jurisprudence means that any state today could start infringing, and they do not have to pay. That is actually a much more difficult issue, by the way, and it's not one that I've gotten my mind around but one that I think we all ought to think about, for those of us who think about states' rights.

The big picture here is that if a state wants to waive its own sovereign immunity, it can. So, if state X has

a statute or a constitutional provision that says, if we take, you can sue us in our own court, that's fine. But you can't sue a state for patent infringement anymore. That's the College Savings case in the U.S. Supreme Court.

For those of us who were interested in states' rights for a long time, and there are lots of good reasons to be, keep in mind that this presents a very difficult problem for intellectual property rights.

If I were the king of state X, I would make my automobiles myself because they would be non-infringing and I wouldn't have to pay any royalties. But I wouldn't ever open a factory; I'd just call Ford or Chrysler and say, you're now the state X automobile manufacturer. All my software, every copy of Windows that I have, would be non-infringing. Every patent, every copyright, would be non-infringed by any state.

Now, the Supreme Court decided that the Congressional Record wasn't good enough on that. That's why they struck down the waiver of immunity in the Patent Act. Keep that in the back of your minds for a different discussion on state's rights.

AUDIENCE PARTICIPANT: I agree with what I think everybody's been saying, that price discrimination in the pharmaceutical industry has worked out well and that we pay much higher prices here, and that's probably as it should be. However, that only seems to work because a lot of people don't seem to know that is going on. And as more and more states and more and more consumers groups know that it is going on, there have been a lot of laws trying to change this.

Do you think, politically, this kind of price discrimination can last? If not, what is the alternative?

PROFESSOR RAI: That's an excellent question, and that worries me. Believe me, I wake up at night thinking that this is a real problem because, unfortunately, there are, as you've suggested, populist pressures against this sort of price discrimination, economically rational as it is. I think, unfortunately, this is a problem we face with our healthcare system more generally, that people have this conflicted feeling about it.

On the one hand, they don't really want it to be something that the government takes care of for us. On the other hand, they don't really think they should have to pay a lot for it. Well, those two instincts are completely contradictory because healthcare is expensive. This is one reason I got out of doing healthcare regulation, because the political problems are just so extreme in this area. People have this sort of cognitive dissonance. They believe that they should have access to all the healthcare that they can possibly desire, yet not pay for it.

MR. TROY: Sir, go ahead.

PROFESSOR KIEFF: I agree with that. A political analysis would be that you won't see anything on the federal level. There might be some noise, but I don't think anything happens in terms of pricing at a fair level.

What you will see is that in, let's say, 20 states, you will see lots and lots of activity. Whether or not at the end of the day anything gets enacted is another question. If I understood you, you asked if it's sustainable. I don't know if you meant sustainable for the big picture that we're talking about. The political pressure will be sustained, I suspect. You will have, presumably, Democrats in an election year talking a lot about the price of pharmaceutical products. At the federal level, I don't think it would happen, but it will create this sort of climate that will spill into the states. So, I think you'll see a lot. And the reason is, as my colleague just said, first of all, Americans really do think they can have everything.

Second of all, in politics, which spills into life, there is also this feeling that in healthcare if my neighbor got it but somehow I didn't get it, and I don't know why that is, then I'm sort of upset.

We've seen the insurance industry be the fall person, if you will. And I think the pharmaceutical industry's next up.

PANELIST: In the Federalist Society, you can say "fall guy".

PROFESSOR KIEFF: And "the villain".

MR. TROY: Susan Braden.

AUDIENCE PARTICIPANT: Interestingly, as this one panel is going on this afternoon, across the street, down the hall, they are announcing that the Federal Trade Commission is going to begin a series of hearing in January throughout the spring, what they may do about problems with intellectual property.

PROFESSOR KIEFF: You know, patent breadth is something that people write about and talk about quite a bit. It's not something I really understand, in the following sense.

I worked for this guy, Giles Rich. Giles Rich was a patent lawyer for 28 years in New York, and then wrote what became Title 35, the Patent Act, then got appointed by Eisenhower to the federal appellate bench to interpret the statute

he wrote, which he did for another 43 years until he died. So, he knew a lot about patent law.

PROFESSOR KIEFF: I remember when I started clerking for him, I used to ask him these questions about patent breadth, and one day he sat me down and said, you know, Scott, you're really not thinking about this the right way because the stronger a patent is, the weaker it is; the weaker a patent is, the stronger is.

And I said, what the hell are you talking about?

PROFESSOR KIEFF: And he pointed out to me that this is a very ingenious device built in, in the patent system, which is that patents are self-limiting.

PROFESSOR KIEFF: Consider a patent that is strongest on offense because it is likely to cover all commercially significant stuff. It is also weakest on defense because it's also likely to cover something that existed in the world before. If so, that going to be found out as a fact. The prior art not going to be litigation-induced. That fact is just going to be out there. Or, the patent is too vague and the Federal Circuit, the court that deals a lot with these cases, has a lot of case law on vagueness or in the court's terms "the written description requirement."

But in fact, the flip side is also true. So a patent that is strong on defense because it's crystal clear, clear as a bell, and also very narrow and doesn't cover anything in the prior art, is also likely to be of no commercial significance.

Now, if that's true in the absolute sense about patent validity — strong on offense, weak on defense — then the question becomes, how do we decide validity? Interestingly enough, the people who have the information on validity, these are folks with facts. Those folks come to court in patent infringement suits.

Actually, a lot of people look at the Patent Office as falling down when it issues patents that are later adjudicated invalid. It issues a patent that's presumed valid but later found invalid; isn't that a bad thing? I think the answer is, normatively, actually no. To get that information to the decision maker requires the patent infringement suit because it's the defendant who has that information and that's the only way to get it to the attention of a decision maker.

AUDIENCE PARTICIPANT: It seems like the assumption here has been that this particular genetic material is property and the question whether it's even property. Certainly, property is not just a utilitarian kind of scheme. There's something deeper. I'm more philosophical about property

We all have the same genetic material. Is it really property? Can it really be fit under the same structure?

DR. OLDHAM: This is what troubles me about all of this. To me, intellectual property is when you use something called your brain to improve on something that you've recognized in the your work or studies. That's not what I was talking about today. I was talking about property rights that are inherent to ownership — your house, your car, your DNA, your cells.

I think those property rights have not been properly adjudicated in a court of law in terms of who owns them. I do not believe that a company can use DNA from an individual without a contractual relationship with that individual and have ownership of that property before they make a drug from it. Yet, none of the companies are requiring those kinds of ownership rights *a priori*. And informed consent does not convey those rights.

PANELIST: Let's take the issue that was in the *Wall Street Journal* article that you shared among us. That is, you have a gene that presumably is a gene that is not specific to an individual. Is that the kind of thing that can and should be able to be patented? It existed in the world before. It's not the kind of thing that someone has created. So, it's different than what we normally think of as covered by intellectual property rights.

And I think it's somewhat different than my own hand because my own hand is specific to me, at least until someone chops it off. So, what is your thought on the issue of the gene, the sort of ubiquitous gene?

DR. OLDHAM: Well, you have to come down in steps from the body to the organs to the tissue to the cells to the DNA. I think we'll all agree as you come down through there, at least at the cell level, you know, nobody else has those. Nobody has my cells or your cells. Not a single person in the world, unless you have twin.

Now, get down to the DNA level, and no one has that DNA either, precisely. If you take a particular gene sequence out of the DNA, is that shared? Sure. The gene pool's got lots of them. That's what the gene pool is. But, we each differ in specific sequences.

PANELIST: So, can somebody patent that?

DR. OLDHAM: — but at some point in time, there is ownership of property, just like at some point in time, there's a human being when you combine two DNAs. Yet, somebody's got to say when that is. I happen to believe that once the whole DNA is operative, that is a form of property as strong as your house. A gene from it, probably not.

SPEAKER: Yes, you can't get a patent on the letter in the alphabet. But obviously, when people string letters together and they form words or sentences, we create intellectual property rights, too. I think, to some extent, it's analogous with a single gene versus utility of what the gene does and the sequence of gene —

PANELIST: But isn't the difference — if I write a word, presumably I could copyright that word because I've created the word or a bunch of words together. But the genes is; it is there. Your company may be the first to discover what it's used for, how it works, etc., but it pre-existed nature.

PROFESSOR RAI: I think that part of the misunderstanding most people have — and I get this question all the time, of how can you patent a gene? — is one has to understand that within our patent system, we have allowed, historically now for years, the patenting of things that exist in nature in some impure form. And what the patent system allows you to do is claim rights to some "purified version" of something that existed in nature.

We have this famous case back in 1912, where somebody got a patent on a purified form of adrenaline. Well, adrenaline existed in nature, obviously, but once you purify it, the legal move that's made is that you've created something that has human input in it, and that's all you need to patent.

PROFESSOR KIEFF: Well, I might approach this slightly differently, I mean, just because a lot of people think of that as a so-called natural products exception it's important that it not be conceived of as anything other than the application of the ordinary rules, not some exception.

The rule is this — this is another cute little one from Judge Rich — the name of the game is the claim. The claim is everything in a patent. And the claim is never 'I claim adrenaline' or 'I claim interleukin'. Interleukin exists in nature. Adrenaline exists in nature. The gene for adrenaline exists in nature. The claim — that's the name of the game – is often directed to something like "a highly purified version."

I have to tell you exactly what I mean by "highly purified". I've got to have data. I've got to have details. I've got to have charts. And if I don't have them, my entire claim is invalid for the disclosure reasons discussed earlier. There has to be a clear test. You need to know, are you on my turf or not? And if you can't know that, then my entire claim is invalid. But the claim is never just "adrenaline."

We talk about a claim on a piece of DNA colloquially as a gene patent. That's not what it is. It's a patent on a bunch of other words and then a gene. And the really important thing is, always pay attention to all those other words because you've got to look at the claim in its entirety. That's true for a patent on something you've made up or a patent on something you found existed before and what you've made up is a pure version of it or a different version of it.

MR. TROY: Last question. Yes.

AUDIENCE PARTICIPANT: One of the kinds of property we didn't talk about that probably is not patented consists of scientific data. The FDA as well as Congress is looking at these issues and bio is looking at these issues. Does anybody see a different principle being applied to the government's use of data to bring more generic products to market?

PANELIST: Why don't you just write us a letter on that.

PANELIST: Well, it's an important question. You always have to remember that that other data's out there as this other form of IP, and it's typically associated with contract law and private ordering. One of the things you see is that when you don't go for patents in these areas, you end up seeing much more trade secrecy or lots more toll booths and people actually collecting at the toll booths. The neat thing about patents is because the right is absolute-enforced by the government, you can discriminate very aggressively in your licensing.

For example, if you walk down midtown Manhattan, a lot of times you're walking on private property. You don't know it; it feels like public property. But if you look down, there's a little anti-adverse possession plaque, a plaque that says you're welcomed to walk here but it's private and when we go to sell this property, this plaque will serve as the marker for our outer boundary being much larger.

The point here is that in a regime where you have a strong property right, the property owner can elect to let a lot of folks use for free because she'll be comfortable knowing that when she needs to enforce, she can enforce.

If you force her to go the contract alternative, she'll be very, very secretive. First of all, she won't let output go to any place where she can't be very careful, and second, she'll be extremely careful at work. So the life of the employee will be very different. There will be video cameras, there'll be pat-downs. If you think security's tough at the airport today, in a trade secret world, security's tough every time you leave work.

PANELIST: I really have to take issue with that. One of the background considerations in your question might be the pending database legislation in Congress. I think it's pretty clear that with privately created databases, we have, through the contract regime, very good price discrimination going on, and I don't think we really need an additional statutory layer of protection on top of the contractual regime, which allows a very useful system of price discrimination.

MR. TROY: Well, this has been a terrific panel, and thank you all for your participation.