

**THE NATIONAL ACADEMIES
BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY
COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN
THE KNOWLEDGE-BASED ECONOMY**

Workshop on:

**Academic IP: Effects of University
Patenting and Licensing on
Commercialization and Research**

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CASET Associates, Ltd.
10201 Lee Highway, 160
Fairfax, VA 22030
(703) 352-0091

CONTENTS

	<u>PAGE</u>
Welcome and Introduction	
Steve Merrill, Executive Director, Board on Science, Technology and Economic Policy	1
Richard Levin, President, Yale University	2
 Session I: Issues in University Patenting and Licensing: View from Academia and industry	
Moderator: Richard Nelson, George Blumenthal Professor of International and Public Affairs, Columbia University	6
 IP and Technology, Transfer from the Academic Perspective	
Robert L. Barchi, Provost, University of Pennsylvania	9
 Bringing Innovation to Market	
Jim Finnegan, Director of Marketing, Lucent Technologies	27
 Trends in Patenting, Licensing and the Role of Equity at Selected U.S. Universities	
David Mowery, Professor, Haas School of Business, University of California, Berkeley	45
Maryann Feldman, Research Scientist, Institute for Policy Studies, Johns Hopkins University	63
 Session II: Effects of Patenting and Technology Transfer on Commercialization	
Moderator: Bronwyn Hall, Prof. of Economics, UC, Berkeley	76
Panelists: Donald Siegel, Prof. of Industrial Economics, University of Nottingham	81
Katharine Ku, Director, Office of Technology Licensing, Stanford University	90
Don Felch, Manager, Growth and External Collaborations, UOP, Inc.	101
Jack L. Tribble, Patent Counsel, Merck & Co., Inc.	112
 Discussion	122
 Session III: Effects of Patenting and Licensing on Research	
Introduction: George Elliott, Fellow, Board on Science, Technology and Economic Policy	147
Moderator: Wes Cohen, Prof. of Economics and Social Sciences, Dept. of Social and Decision Sciences, Carnegie Mellon University	148

Marie Thursby, Burton D. Morgan Professor, Krannert School of Management, Purdue University	155
Eugene Bauer, MD, VP for the Medical Center and Dean of the medical School, Stanford University	162
joan Leonard, VP and General Counsel, Howard Hughes Medical Institute	168
Discussion	179
Session IV: The Implications of State Immunity	
Moderator: John Barton, George E. Osborne, Prof. of Law, Stanford University	198
Panelists Julie Katzman, Democratic Counsel, Senate Judiciary Committee	203
Justin Hughes, Office of Legislative and International Affairs, USPTO	216
James F. Shekleton, General Counsel, South Dakota Board of Regents	227
Discussion	239
Wrap-up Discussion	249
Scott Giles, Deputy Chief of staff, House Science Committee	250
Mark Myers, CTO Xerox (ret.) (project co-chair)	255
Richard Levin, President, Yale University (project co-chair)	257

Verbatim Transcript

8:42 AM

DR. MERRILL; Good morning, ladies and gentlemen. My name is Steve Merrill. I am the Director of the Science, Technology and Economic Policy Program at the Academy and Project Director for a project called Intellectual Property in the Knowledge-Based Economy which you will hear about shortly.

I want to call your attention first of all to the screen which shows the home page of the Web site on the Academy Web site. There is a flyer at the table. We are launching a first subject matter Academy Web site which is designed to make it easy to access the wide variety of work that the Academy has done recently and is doing and will do on intellectual property issues, and, also, to stimulate discussion among a wider audience of people including many of you from academia, from business, from law, from the judiciary and from the courts and to inform our Committee and inform our process and to bring to your attention the work we are doing.

Secondly I wanted to announce that the proceedings today are being Web cast. It would be helpful if all the speakers were introduced or introduced themselves by name as they begin so that people in the Web cast audience will know who is speaking, and finally, I want to introduce the Chairman of the project, Co-Chairman of our project on

intellectual property, the President of Yale and a pioneer in empirical research on intellectual property, Rick Levin.

DR. LEVIN: Welcome to this conference on academic intellectual property. Before we begin I just want to take a minute to set the context for you so that you understand how this particular topic fits into the overall work that the Academy is doing on intellectual property.

Most of you may know that there is a Board established in 1991 by the Academies on Science, Technology and Economic Policy. That group which consists of representatives from industry and the Academy and academic life, principally economists has spent the past decade producing some I think very valuable studies, hosting conferences and ultimately coming out with reports and making recommendations on a variety of ways in which the advance of science and technology is critical for economic growth and national prosperity and one of the big projects that was run through the latter half of the nineties by the Board on Science, Technology and Economic Policy was a major study of US industrial competitiveness looking at about 10 or 12 sectors of the economy in great detail in case studies essentially and by and large producing an overall assessment, published under the title of something US Industry in 2000 of which I think there are some copies out on the table outside.

There were a few generalizations reached as a result of the study, and one of them is what really led directly to this current project of the STEP board. The conclusion was that there has been obviously rapid technology change in the last 20 years or so in this country, and there is certainly at least a correlation in time between that productivity burst and a gradual strengthening of intellectual property rights of inventors and creators, and the question that that study posed as one of their conclusions was are we sure we have got the right balance; have we possibly gone too far in the strengthening of intellectual property rights over the past 20 years.

So, that was the starting point for the formation of a new committee of the STEP Board which Mark Myers of Xerox and I Co-Chair, and our task is really the broad question, is society striking the right balance between protecting the rights of inventors on the one hand and the free flow and dissemination of ideas for general use on the other, and there is succession; there has been since about 1976, a succession of legislative acts, judicial restructurings, court cases that have all moved more or less in one direction, and so, to that end we held a general conference about a year ago here in Washington in this very room which attracted wide attention, developed a working list of issues to focus in on and among those are is the

administration of the Patent and Trademark Office itself something that could be improved so that higher quality patents are issued. There was concern about patent quality in other words. That is one of the tasks we are looking at and whether the costs of processing a patent and particularly litigating patents were excessive, the second question we are looking at.

We are focusing on two sectors of the economy for special relevance. One of them is essentially biotechnology and the question of genetic patents and whether there are certain aspects of patent law and practice in those areas that need to be rethought and finally we are focusing on this question of business method patents for the Internet whether, in fact, our conceptions of what constitutes an inventive step have been somewhat compromised by some of the patents that have been granted in that area.

A final issue, and this is setting the context, that the Committee has looked at and wondered about, and it is one that attracts particularly attention from university-based researchers is the question of whether performance of universities under the Bayh-Dole Act of 1980 has been a positive development overall and whether there are areas that are problematic under that regime.

So, that is what today's conference is focusing on. We are looking at essentially an evaluation of the Bayh-

Dole regime, and I will leave it to the chairs of the various, at least the first three panels who will focus expressly on aspects of that question which I think is an illuminating and useful one. I have to confess, I guess with full disclosure, I am representing a university that benefits from the Bayh-Dole Act very substantially but, also, is cognizant of some of the dilemmas and conflicts that commercialization of university-based research can present within the Academy.

I think it is a fascinating subject. I think we have got a wonderful mix of participants today from the university world, both faculty and administrators and from the corporate sector and indeed from government.

So, I hope you will enjoy this. We are looking forward to hearing the results. To give you a sense of how it gets processed the results of this conference will be part of the input that the Committee will consider over the course of the next roughly a year until we expect to be issuing our final policy recommendations.

So, thanks for coming, and I look forward, as I know you do to today's events.

Now, I would like to turn this over to the moderator of the first session, more full disclosure, a person who happened to be my dissertation adviser at Yale, but that is just a coincidence, a person who really is a

pioneer in thinking about and conceptualizing the role of technological advance in economic growth and development, Richard Nelson.

DR. NELSON: Thank you, very much, Rick. I am very much looking forward to the presentations and discussions today in this workshop on the Effects of University Patenting and Licensing Activity on Commercialization and Research and as Rick Levin indicated I think the time is ripe for such a deliberation.

It has been about 20 or 20-plus a little bit years since the Bayh-Dole Act was passed. Those of you who followed the deliberations then or those of you who have read of the hearings that led to the Bayh-Dole Act will recognize very well that Bayh-Dole was based on a theory, a set of propositions to the effect that if universities had the rights to patents resulting from at that time government-funded research that they undertook this would be a structure that would greatly facilitate and enhance technology transfer from the universities.

I think it is pretty clear and we will get reports on the numbers here very shortly that since the late seventies or early 1980s there has been a dramatic increase in the amount of university patenting and license revenues.

I think it is, also, clear that over this period of time universities have made very impressive and important

contributions to the technical change and economic development that has driven the American economy, particularly in the 1990s, but I guess a question that Rick implicitly posed is whether these two particular facts necessarily are tied together.

The same period of time of course saw the rise of biotechnology as a mature and yet rapidly advancing field. It saw the development of a national patent regime regarding intellectual property rights and biotechnology starting from Diamond versus Chakrabarty, and there is a real identification problem, if you want to put it that way as to whether the university contributions, so many of which have been in biotechnology and a number of other, small number of areas to economic development in the United States would have occurred even if we had not had a regime like Bayh-Dole.

I think it is useful as we get into this discussion to recognize that American universities have been contributing to economic development in the United States for a long, long time, for much more than a century.

Consider, for example, the tremendous contributions that were made by the land grant colleges to agricultural research and the enhancement of agricultural productivity, the contributions of the American medical school and research complexes toward technical advance in

medicine aren't something that occurred only after Bayh-Dole but have been occurring long before Bayh-Dole and what is apparent if you go back into the history of these activities is that for the most part the contributions of university research to economic development prior to Bayh-Dole were proceeding without the universities establishing intellectual property rights on what came out. So, there were certain exceptions to that particular structure.

So, I guess the question that we are addressing is what does the policy really as a relatively new one with Bayh-Dole, where there is a presumption that universities will take out patents and will essentially license materials that are patentable coming from the research that they do, does it add; does it subtract; does it do a little bit of both to the role of universities as significant engines of economic progress.

I think it is useful, and I think we are going to look at this question from a number of different angles. One of them certainly is looking at the role of patenting and licensing by universities as a facilitator or in some cases possibly a hinderer of technical progress.

There is a different but related issue that the title of the workshop signals, and that is what does the patenting and licensing activity as it reaches farther and farther into what used to be the domain of science do to the

conducting of the scientific enterprise and then there is third of all the question of what does the post-1980 regime in which patenting and licensing and gaining revenues from that as the norm now among universities do to essentially life in universities, collegiality and the way that universities operate.

The panel this morning comes from several different places and as I understand it will start off with a couple of presentations, first from Robert Barchi who is Provost of the University of Pennsylvania, talking about intellectual property and technology transfer from an academic perspective, then Daniel McCurdy of Lucent Industries where he is President of the Intellectual Property Business will take a business eye view on that and then we are going to have several people, David Mowery and Maryann Feldman talking about trends in patenting and licensing as a result of research that they and their colleagues have been doing on the subject.

So, why don't we start out with Robert Barchi?

DR. BARCHI: Thank you, David. Let me make a quick technology change here. I have no license for this. I am certainly not getting any royalties, but we will try it anyway.

Thank you very much. It is a pleasure to be here today. I have to make a confession before I start though.

Unlike our esteemed convener and the Chairman of our congress here and his frequent co-author, Dr. Mowery I am not an economist. I am not an expert in IP, and unlike Jim Finnegan I am not an expert in the translation of new products to the market, although, Jim, given the stock market recently I have to put a caveat on that one, too with Lucent.

I bring a much more pragmatic view to the table I think. It is a pragmatic view of having been a sponsored investigator running a fairly large research lab for 25 years and for the past 15 years heading various institutes, departments and now in my role as Provost of the University of Pennsylvania, and I was asked to talk a little bit about intellectual property and technology transfer from the academic point of view, and I am going to try to stay on the pragmatic side.

I will start very simply because I am a very simple person, and I have simple ideas, and I think of these things as going back to some of the early theories of Vannevar Bush in the time after the Second World War with the Roosevelt Administration really making a fundamental case for pouring government dollars into academic institutions as a way of building a reservoir of knowledge and that reservoir of knowledge then flowing out in new industry, new companies, new efficiencies, increasing the

tax base flowing back to the government and making one very pleasant cycle, and the United States made a conscious move to invest large amounts of money in its academic enterprise as a way of driving its economy, and one could ask whether in fact that was successful at all and in this paper by Naren et al that came out several years ago looking at patents filed by industry; these are industrial patents and looking at the source citations for those industrial evidence showed that more than 70 percent of the source citations for the industrial patents did, in fact, come from the academic sector either from academia itself or from government labs or other non-profits, and then of course the second big step that we are hearing about today is the Bayh-Dole Act the watershed act in 1980 that allowed small businesses and non-profit organizations to retain title to their innovations even when made with federally funded research dollars and ostensibly the purpose being to promote the investment by the private sector in commercialization of these federally funded discoveries for the quote, common good, and under Bayh-Dole we are as institutions encouraged to collaborate with industry, to file patents on our inventions, and the government retains non-exclusive license and march-in rights.

Now, I know that some of our colleagues on the panel will disagree with this but from a simplistic point of

view looking at the 10 years before Bayh-Dole, the increase in patents, approximately 40 percent in the 10 years afterwards, about 360 percent I certainly agree that the advent of new technology and bioscience had as much to do with this as anything else, but the numbers certainly are up, and again looking at what has happened over the 10 years of the 1990s we see in sponsored research about a doubling of the sponsored research dollars from about 12-1/2 to 26 billion dollars in the academic sector, about a doubling in invention disclosures, about a tripling in university license activity and most important to me about a quadrupling in licensing income.

According to an AUTM survey that was taken last year this academic to industry technology transfer accounted for about \$40 billion in the economy, supported about 270,000 jobs and produced about 5 billion in new tax revenues.

Now, why am I concerned about this sort of thing?

Penn and other R1 research universities transfer technology for a number of reasons. Now, if we stick with the Bayh-Dole Act then our first and foremost reason should be to facilitate the commercialization of research for the public good.

We certainly are very interested in promoting economic growth in our environment, in our neighborhood, in

the city or town in which we are located. We need closer ties to industry because more and more of what we do reflects interactions between the technology industry and the biotech industry, the commercial areas and the academia, but we, also, needed to reward routine and recruit faculty.

Faculty expect to be able to interact at the interface with commerce. They don't have to do it with us. They are free agents. They can pick up their marbles and move, and finally, we do it to generate income. Now, I suspect that if we look at the panelists today and we arrange ourselves from top to bottom I wind up on the bottom of this list from a pragmatic point of view, and we might hear a discussion of the upper reaches of that from Dr. Mowery and his colleagues.

So, why would we be interested in research ties to generate income in an environment like an R1 university? Let me take just 1 or 2 minutes to show you the basics of the finance. In my institution, the University of Pennsylvania we have an academic budget of about \$1.4 billion a year and of that academic budget large segments of it in gray are essentially non-discretionary revenue.

Sponsored research programs account for about 25 percent in direct costs and another 8 percent in indirect costs. Tuition brings in about one-third. Most of those boxes are not expandable. As a matter of fact they have very

little plasticity. The top-to-bottom range in Ivy League tuition is only about \$1000. You cannot move very far and help your budget. So, sponsored research programs and the indirect cost recovery seem to be one of the areas in which universities of our type can keep afloat, and in fact if you look at the growth of research activity at the University of Pennsylvania in the last 10 years the numbers look fairly dramatic from something in the neighborhood of \$225 million in 1990 to in excess of \$500 million of sponsored research in 2000.

Much of this has been in the biomedical sector, as you can see from the School of Medicine growth.

Unfortunately, the bad news is here. The money that is provided with the research grants to cover the cost of research at our institution, the indirect cost recovery rate has been steadily going down, and the federal ICR which is the highest ICR paid in the country has dropped over that same time period from something in the neighborhood of 65 percent to a projected level close to 56 percent at our institution next year, and these trends are national trends.

The bottom line is that we are losing about 10 to 20 cents on every dollar of research that we bring in, and as you have heard the saying, you are just not going to make this up by volume at the margin.

So, when I go back to my revenue streams and I

look at the pie chart, the only one that really has a lot of potential for me is that 2 percent other school revenue at the side. That is the one I have flexibility on. That is the one I can move. That is the entrepreneurial activity, and that is where the revenue transfers from tech transfer come into play.

So, as a provost I have a very pragmatic interest in the outcome of this activity. So, how do we do it at the University of Pennsylvania? We put together an operation, an organization that is led by Lew Burnham and who is here in the audience, and Lew's office is responsible for integrating the transfer of knowledge from the research laboratory through this enterprise function process to the far end of licensing and eventually the creation of new ventures.

It involves disclosures that either become intellectually protected through copyright or patent. It involves commercialization strategies. It involves the granting of licenses for a return, and again drawing on information from the AUTM licensing survey covering the 9 years from 1991 to 1999, looking in rough dollars about \$175 billion worth of research leading nationally in the top 150 research universities, leading to about 84,000 disclosures and those disclosures are then triaged to either patents or other protection mechanisms, eventually leading to about

23,000 licenses and about 2300 start-ups.

So, you can see there is a tremendous winnowing out that takes place during this process. The volume that is needed at the top end for success at the bottom end is very large, and of those 23,000 licenses just to give you an idea only about 10 percent will make it to the point of break even where they are generating net income in excess of expense, and those of you who have experience with start-ups realize that the probability of success there is certainly no higher.

Again, looking at the Penn experience with CTT, our Center for Tech Transfer in the past fiscal year about 1300 transactions, 221 new patent applications, 42 new patent options and licenses, 22 copyright licenses. The bottom line is about \$30 million in income, a particularly good year. We average more like 10 to 15 million dollars worth of income and a number of SRIs that come out of the same kind of activity.

The other thing that we learn pretty quickly in this business is that it takes time. It takes time from before Bayh-Dole. It takes time down the pipeline, and if you look at the licensing income that universities have received from tech transfer as a function of the time when they started to process patents and licenses, it is pretty obvious that the older players are the more successful

players, and MIT and Stanford, Harvard, Columbia who have been in this for 20, 30 years or more generate substantial annual revenue to their university. Chicago and Penn as you can see, we are relative newcomers, and we are down in the lower 10 to 15 million dollar range, but let me put this in perspective. If you were at MIT bringing in \$60 million worth of revenue from tech transfer, that is the equivalent of an additional billion dollars in your endowment, and a billion dollars in the endowment is not something that is raised overnight. So, these are substantial amounts of money. They are at the margin. They are very, very important for new initiatives and for the creation of new program at universities like ours.

Now, the Bayh-Dole Act requires income sharing and Penn's patent policy splits the money up about 30 percent to the inventor's personal share, about 30 percent split between the department and inventor's laboratory and the remainder divided between the school and research foundation within the school that supports new research.

The other aspect of this patenting and licensing that is not widely appreciated is the non-exclusive licensing of research tools. Now, I have read articles suggesting that this approach to licensing restricts the availability of research tools to the research community.

I can tell you a an investigator who has over the

years produced more than a few monoclonal antibodies that were widely sought after, I simply could not keep up with the demand. I didn't have the personnel or the time or the money in my laboratory to make monoclonal antibody to send out to all the people around the world that wanted to use it. Simply licensing this to a company who was willing to do it for a modest cost gave me a little bit of income to the lab but more importantly relieved me of the burden of having to provide those research tools with my own time and really provided complete access to the research community to the tools.

So, I think there is something to be said here where there really isn't much of a profit motive in mind either.

Now, it all sounds good, but where are the problems? Some of the problems come right here at the interface between the university and the industrial sector. In the university we would like to think we are looking at issues like knowledge for knowledge's sake, academic freedom. Our lives are committed to teaching and research, but we certainly are interested in the commercialization of our ideas.

If you are Jim you would certainly be much more interested in the management of knowledge for profit and in the confidentiality and limited public disclosure of some of

this information until you could ensure yourself that you were far enough down the line to profit from the investment that you had made.

That is the dynamic tension, and it is a tension that certainly does have the propensity to get us into problems. Conflicts of culture, one area, probably more prevalent in engineering and technology than in biotech. Some of the things that I hear typically in these discussions are and I quote, industry paid for it. Industry should own it. I hope I can show you or have shown you already in the numbers on the research dollars that the cost of research that is on the direct side is only a small part of the cost to the university.

It is not covered by those dollars, No. 1. No. 2, the use of our faculty and the use of our resources represents standing on the shoulders of generations. There is a huge investment that has already been made to get to the point of asking one investigator to do one experiment and the university really needs to retain IP rights in these areas.

The second is the issue of academic freedom and publication. Our faculty members live and die by the code of academic freedom. It is the basis for tenure. It is the basis for promotion. We must and will retain the right to publish, respecting reasonable delays for IP protection

which might be 1 to 3 months in some cases but that is a right that we do not feel we can give away.

On the other hand we as institutions have to be very sensitive to the short life cycle of new ideas, especially in areas of technology like computer science and electronics. If one waits for the patent to be issued by that time someone else would have done it differently and better.

So, we have to have ways of timely contracting, and we have to think of ways of efficiently practicing the interface between academia and industry.

The other big area that is just blowing totally out of sight these days as was mentioned in the introduction by Dr. Nelson is biotechnology. I mean it is no secret that biotech is the place to be these days, and if you look just at R&D spending by the pharmaceutical companies and you look at the tremendous rate of rise in that pharmaceutical spending just I would like to point out between 1993 and 1997, the increase in the amount spent on external alliances, that means interactions between these companies and academia or other small organizations has gone from 1.4 billion in 1993 to 4.5 billion in 1997, at a time when the total spending only went from about 13 billion to 19 billion.

So, you see there is a tremendous shift in the

focus of research from these companies towards using the resources of academia. Why? because it is more efficient. If you talk to a pharmaceutical director or president many of whom were formerly in academia, they recognize that the hard work of generating ideas is being done in the academic environment and then they can quickly make the transfer to a high probability hit in the commercial sector realizing that it may take anywhere from 5 to 10 years to bring that product to market, and it may take anywhere from 2 to 3 hundred million dollars before they break even.

So, they cannot afford to be as all inclusive as academia is, and of course if you look at the number of biotech drugs that are coming on the market now that use high technology to produce them you see the complementary wave in that activity as well.

The problem is that there are all kinds of financial ties between academia and industry, grants, consulting, faculty members with equity, faculty members serving on boards of directors and scientific advisory boards, even things like speaking engagements, promotional activities gifts and contracts, and this is where we get in trouble in biotechnology and it is conflict of interest, and here we are talking about conflict of interest both at the institutional level, what investment does the institution have in the product being developed and at the level of the

individual investigator, and we are talking really about laboratory research on the biological side and most importantly about human research and more and more of the developmental side of these drugs requires clinical trials.

Institutions like the University of Pennsylvania do a huge volume of clinical trials. We have about 1500 clinical trials under way at the University of Pennsylvania right now, about 500 or so new clinical trials up and running every year.

When Donna Shalala visited Penn last May she made a statement that I thought really hit the nail on the head, and I am just going to quote that. She said that Americans' confidence in our academic research enterprise will unravel if researchers are not extremely cautious in their private interests and absolutely truthful in their research results especially when adverse events in situations where their research activities and personal interests converge.

So, we have to be extraordinarily careful about not only conflict of interest but the appearance of conflict of interest in the kind of work that we do, and we are talking about conflicts between primary and secondary interests in an individual situation and not necessarily ones that lead to scientific misconduct. So, we are not even talking about eliminating conflicts of interest here. We are talking about managing conflicts of interest.

I think it has been said that if you don't have a conflict of interest, you don't have an interest. So, really what you need to be doing is managing conflicts of interest in these settings and from an academic point of view, from a university point of view I am most concerned as provost about commitments of time. How much time are you spending on an activity that is related to your university role and how much are you spending related to something that is independent of it?

What is your financial interest? Do you have equity in the company that you are working for? Do you have a financial interest in the outcome? Do you have a financial interest in the results of your trial? Is it in any way impacting the research integrity from the point of view of how you are doing the study, how you are managing the number, how you are documenting your results, and is it consistent with the educational mission of the university?

At Penn we have very clear regulations about how we manage conflict of interest that have been in place for a decade or more. We have a conflict of interest standing committee which is responsible for adjudicating all issues of conflict of interest, composed of faculty members and administrators. Our Center for Technology transfer and members of the CISC sit down regularly and present cases to each other to decide the outcome. We do permit industry-

sponsored research, and we do permit limited equity with prior approval and ongoing oversight, limited equity meaning limited in terms of the amount and limited in terms of the potential outcome down the line.

We do prohibit faculty from serving in a managerial or fiduciary role with our licensees, however.

Okay, I would like to stop there and wrap up by presenting you with what I think are some of the issues from my point of view, and maybe during the course of the morning and the rest of the day some of these issues can be a topic for conversation.

They are not easy ones. I don't have any answers for these, but since I got to talk first and I don't know anything about IP. First, should universities promote, create, manage and/or invest in start-ups? Should we be doing this at all. Is there just an unavoidable conflict of interest that is inherent in this kind of activity that makes it difficult for us to do without being accused of that?

Should institutions conduct industry sponsored research in which the university has a financial interest in the outcome? Say we hold stock in Merck, and we are doing clinical trials for Merck, is that a conflict that is unavoidable or is that a conflict that is acceptable?

Should faculty be permitted to be involved in

start-ups as managers or directors? We have a pretty strong feeling about that, but not everyone does.

A more difficult issue, should students be permitted to be employees of faculty start-ups and what do we have to do to protect the rights of students in an academic research institution where participation in the research of our faculty is a key part of what we think we have to offer as value added at the undergraduate level?

Should faculty be permitted to take sponsored research from a start-up in which he or she has a financial interest, again, the difficult question of the degree of conflict that we will be willing to accept, and should students be allowed to participate in academic research projects supervised by a faculty who have a financial interest in the outcome?

Now, you are getting two steps removed, but you can see that it is very difficult to get students away from laboratories in which there is absolutely no connection to IP transfer at some point now or in the future.

So, I hope that we can bring some of these questions up during the course of the morning. It is my opinion as an investigator and an academic administrator that the reservoir has indeed been filled and our job really is to make the water flow, to make it flow quickly in the right directions and don't get soaked when we are doing it.

Okay, thank you very much.

(Applause.)

DR. NELSON: Thank you, Robert Barchi for what I thought, and I am sure everyone else thought, too, was a very broad and thoughtful discussion of a lot of the issues that are at stake here at university.

I want before giving the floor over to Jim Finnegan to make one observation drawing on what you said and that is that it is apparent that this was not anticipated that clearly at the time of Bayh-Dole that universities have developed a very significant financial interest in the current regime of patenting and licensing, and that is important to recognize and look at hard in terms of what are the consequences of that.

It, also, is clear that measures like license revenues are a very inadequate indicator of the technology transfer that is affected through the vehicle of holding and licensing a patent and which would not have occurred had that patent not been taken out and been licensed. A striking example, of course, is the Cohen-Boyer(?) patent which until recently at least and probably even now was the largest revenue earner of all of the university intellectual properties, but it is very clear that Cohen-Boyer was being picked up by industry before a patent had been issued on it.

The patent in no way was an important part of the

technology transfer process, but rather what the patent did was to the great good of Stanford University and the University of California to enable the universities to reap a financial return on the work that they had done, most of which was government financed.

So, the flow of license revenues is not really adequate evidence that the new regime of patenting and licensing is an important contributor to technology transfer. It is an indicator of the fact that universities now are drawing significant funds from that and are becoming dependent on it.

Next, let us hear from Jim Finnegan who has insisted to me, and I already knew it that he is not Daniel McCurdy, and I am sorry, Jim. Jim is with the intellectual property business of Lucent Industries and we will now get another point of view.

DR. FINNEGAN: Thank you, good morning. Thank you for the invitation to speak this morning. Daniel McCurdy, my boss, the President of the Intellectual Property Business at Lucent was the original speaker. Unfortunately he had an engagement that he had to attend to this morning. So, he asked me to substitute for him.

First, I would like to start maybe by performing a non-scientific, if you would engage me, non-funded research study. I am not receiving a grant for this, but I am going

to ask everyone in the audience if they consider themselves to be a technology licensing professional in a university please raise your hand?

(There was a show of hands.)

DR. FINNEGAN; So, there are not that many out there. I am just curious. Okay, great, thank you.

I have been in this business for about 10 years. Prior to that I was a manufacturing engineer in Lucent Technologies microelectronics business.

Before that I had no idea what a patent was, what intellectual property was. My job was to look at wafers in a microscope in a bunny suit and try to improve yields.

About 10 years ago I jointed the IPB group and I think this is really a fascinating field to be in, and what I am going to try to do today is give you the corporate perspective of how we manage our IP business and then maybe at the end we can talk about some of the issues where we see universities and corporations coming into some potential conflicts.

Okay, so as I said, and I will move quickly through the slides to give you a sense of our business. Essentially Lucent receives in the magnitude of hundreds of millions of dollars a year and that is net royalties, mostly from patent licensing. There is a little bit of technology licensing, and I will talk about our move into that and then

I will talk a little bit about our group and how we are organized, but essentially the key to recognize here is that Lucent made a conscious effort to treat this as a business.

Our job is to maximize the value of the portfolio, and royalties is one way we do that. We, also, get involved with some of the things that Bob was talking about, equity, start-ups, technology transfer. We handle issues of incoming patents or technology licensing and support the business units in their endeavors.

The interesting thing that has happened for us is that we really came into this as a patent licensing business and now we are seeing the issues of technology licensing and internal conflicts with our business units to be almost as difficult a negotiation as external conflicts.

There is some laughter. Good. That means that there is some agreement out there. Okay, so what does Lucent Technologies do besides go from 80 to 7 dollars in one year?

(Laughter.)

DR. FINNEGAN: I thought it was a good buy at 40. So, don't ask me for any investment advice. Revenues in the year 2000, \$33 billion, 110 worldwide employees. It is the home of Bell Laboratories. When Lucent split from AT&T in 1984, Bell Laboratories came with Lucent.

This was Western Electric essentially. This is the manufacturing arm of the telecom system. Bell

Laboratories has been home to 11 Nobel Prize laureates including Shockley, including Arno Penzias, including most recently Horst Stormer who has a relationship with Columbia and there is a huge focus on invention at Lucent.

Now, what is my business unit's mission? No. 1, to protect the innovations. We have a team of intellectual property attorneys. I am going to guess wrong, but I am going to say that that group is about 90 people big that spends their time filing patent applications and protecting IP. At this point if you are looking for some kind of data I think we use outside counsel now for about 60 to 70 percent of our patent filing when at one time almost 100 percent of that was done internally.

As I mentioned we create value from the portfolio through licensing, through divestitures which we seem to be doing a lot more lately and through the formation of alliances, partnerships and ventures, and then finally this one issue which I think I am going to spend a little bit of time at the end is we, also, have to deal with incoming patent licensing, I was going to say conflicts, potential relationships from others, and we are seeing a little bit more of this from the universities.

What does Lucent spend on R&D a year? In the year 2000 about \$4 billion and that did not include Avaya which was the PBX business that we divested in the year 2000. What

does this mean for patent creation? We were issued, I think 1512 patents in the year 2000, 26,000 worldwide patents, 10,000 active US patents. The maintenance cost for this portfolio is about \$10 million a year.

I have a person whose full-time job is to manage this asset. What has Lucent done with respect to patenting? We actually had a conscious effort about 5 years ago to try to get Lucent back in the top five of US issued patents. You probably know that IBM is up there at the top and just blows away the competition, and they do a lot of interesting things to encourage patenting.

About 4 years ago for the first time Lucent started an IP awareness program, intellectual property awareness program that included a cash payment or case bonus to each inventor that disclosed a new invention that would be patentable. There was a lot of conflict with Bell Laboratories. They felt that that was not a good incentive to have, that the nature of Bell Laboratories that was the job of the researchers there to invent and that this incentive wasn't necessary. Maybe you can hear some of the things that universities think about or agonize over, but if you think about Bell Laboratories and if you ever get a chance to go to Murray Hill it really looks like a college campus.

So, there was a concern about actually rewarding

people for inventing, but essentially what it did was patent disclosures went up incredibly and in fact this year we were No. 4 in the US. There you go, 1415. I think I said that I said 1412. We were fifth this year, and we think that number is going to continue to increase based on the number of disclosures that we have had and submissions we have had.

Through the first quarter of this year we were No. 4, and you can see just barely edging out Samsung but we expect that trend to continue, and there you can see IBM and their numbers.

What does Lucent have patents in? You name it. If it is in telecom we probably have some patents in it, and that specific area includes everything from data networking, speech recognition, MPEG(?) technology, digital audio, speech compression, modems manufacturing. There are lots of creative ideas that came in the semiconductor business including plasma etching. If you ever view the history of Silicon Valley you can see where the Bell Laboratories names are sprinkled all over Silicon Valley, and there are new inventions all the time in optical electronics and Internet technology.

As far as business method patents go, we don't necessarily aggressively go after that segment. We think we have been doing that for a while. A lot of our research dollars are in software and a lot of our inventions are in

that area. So, we think we are already in that space.

This is the business. Dan McCurdy, our president and the numbers underneath these things, I don't know why undotted, but the numbers underneath these things are the --

(Laughter.)

DR. FINNEGAN: Maybe that is the next divestiture. These were Dan's slides. Now, I am nervous.

(Laughter.)

DR. FINNEGAN: Six months, it is time for a reorg, right? So, essentially what we do differently than a lot of other groups do is our legal team is part of the IP business. So, Don Pedila you see there in the bottom right hand corner with his 95 attorneys and support.

Roger Stricker, VP of Licensing, that is essentially our sales force for patent and technology licensing and my team of about 30 professionals thinks about mining the portfolio and relationships with the business units and encouraging them for new technology and patent licensing.

Operations, Al Leonard, that includes both financial operations and patent creation support. So, that is not included in the legal counsel numbers on the bottom.

I think we are about 200 people big. I hate to show this in front of this group. There is our hockey stick. That is our actual growth in IP, mainly from patent

licensing. The separators are, in the past we have been pretty quiet about sharing these numbers, but essentially that is one-half billion dollars is what the top line is there for the year 2000, about 400 million in patent licensing, and of course, the most important part of this is, I will use the laser pointer. That is where I joined the group, about right there.

(Laughter.)

DR. FINNEGAN: They didn't know what they were doing before that. Now, what challenges do we face? We have decided to get into the divestiture business. That is Lucent, I mean. We have spun off our PBX business, Avaya. We sold our power supply business, Totiko(?). You may have heard of Agere. That is our semiconductor business and that was a big part of our portfolio. That IPO was completed in March and there will be a final distribution of shares to shareholders in September and if you have read the press you may heard us talk about possibly the optical fiber business being spun off.

So, we are becoming a very focused data networking optical networking company, wireless networking company. What are the challenges that I have to face or we have to face from the IP business perspective? It is that our portfolio goes from about 11,000 patents to about 6000.

To give you a sense of the bench marks I use about

2 percent of this portfolio is where we see the money coming from. Now, one of the interesting things that Lucent is trying to do is get from being an aggressive patent holder into the technology licensing business, and I will show you some slides why we think that is important for us, but what are patents? Essentially when we do a patent license we give someone legal permission to use our ideas, and that is essentially it. There is really no know-how that is transferred.

That sometimes is contentious both inside and outside of Lucent. Obviously it is contentious outside, but often business units are concerned about licensing their patents or technologies to others. That cycle can be as long as 3 years to do a patent licensing agreement with a new body and it essentially is a win/lose. There is a transfer of money or value probably from one corporation to another with very little exchange other than the rights to use something they may perceive to have the right to use anyway.

Now, what is technology licensing? Technology licensing is teaching others how to use or how to do, requires support from both sides, technical support from both sides, and this is where we run into the real contention inside. Why do you want to give my optical switch to my competitors? Why do you want to give my MEMS(?)

technology to my competitors? Why do you want to teach them how to make wireless base station antennas better than anyone else? How does this help me?

So, I will show you a few of the slides that we are using inside to try to convince our business units that this is a good idea but this, if it is longer than 3 to 9 months the technology probably has passed you by, and we perceive this to be a win/win for both sides.

Okay, so why are we pushing technology licensing? From our perspective we think that time, not competitors is the enemy anymore. If you spend any time with the licensing executive society you will hear the same kind of talk that the challenges to this business about intellectual property are keeping up with the life cycles of technology. Here is Western Electric. Here is AT&T in 1950. Your phone bill is going to go up from one-half penny to a penny a minute, and it really doesn't matter how quickly you move you know you are going to get that money.

So, you are not really concerned about someone else beating you to the market. This was a monopolistic endeavor. You had forever to extract your value. So, you maximized it through the life cycle. There is no need to introduce new technology. You are making your profits from your current technology.

Now, what do we see today? I believe that

innovation, that there is no company that holds a monopoly on innovation. So, there are lots of players that now come to the game with ideas, with patents, with technology that are all creating these new things that we see out there like wireless Internet.

Now, because of that you need to share and by sharing your technology you can create a new de facto standard and drive the industry a certain way. You can enable component suppliers. As we have divested some of our suppliers now we find ourselves going back and setting up relationships with these optical component suppliers to support our optical network.

Now, you can, also, extend the life cycle of some of these technologies through widespread acceptance as well, but the concern is that the best thing you can possibly do for your team is cannibalize it yourself.

If you sit on your laurels and expect a 5 ESS switch, the circuit-based switch to forever rule the world you may not have seen the Internet coming. You may not have noticed that packet-based switching is the way to go. So, by pushing your technology out there you can challenge your R&D team to not sit on its laurels, and I think you have heard some other companies if you pay attention to this that they really have measurements that say that 50 percent of our products are based on inventions made within the last 3

years or 5 years.

I don't have that metric for Lucent today, but it is one that we are driving to. Okay, now, the question that we are facing with universities is we are seeing universities be a little bit more aggressive with their patent assertion business. Now, that is different than the technology transfer business. I believe that Lucent is different than the universities. The universities probably are coming from the starting point of setting up technology endeavors with others, maybe prior to patents being issued and it is really about driving new technology out there, but what we are seeing now is that there is some play between universities in this traditional business that the IBMs and Lucent and TIs of the world are strong in which is patent licensing.

Now, what is happening is once you step into that game you start to play in a whole different realm, and one of the questions that Lucent is raising is when you go into the negotiation of a patent license unless you are familiar with it there is really a couple of steps that happen.

The first is that you may approach a company and say, "Hello, I believe you are using my inventions in the area of data networking." Now, that company probably has a portfolio of its own and what starts is a discussion then about what is the real value being exchanged. I will take a

license to your stuff. You take a license to mine. So, we do assertion. I assert my patents against you. You assert your patents against me. We negotiate. We end up with some kind of resolution or we go down that ugly trail called litigation.

Now, if you look at the, I think it is Genentech dollars, there we go, I read this morning that at one point, and this is University of California against Genentech that the desired damages that were talked about out there were in the range of \$30 billion, \$28.8 billion. That was what was talked about. Maybe that was what was in the case.

The settlement was for \$200 million. So, think of this as coming downstream. There at the assertion the number is \$28 billion. Okay, there is some discussion and some negotiation. What happens is the settlement is for \$200 million and of course, the legal expenses which is something that just goes astronomically out of control if you jump down into this box down here for that case was \$20 million.

For Lucent we kind of bench mark it that the litigation is going to cost you about \$3 million a year if you want to go down that path.

Our most recent case that we won is going to be at best a break even, but it was one that we felt we needed to pursue. So, when you think about universities as they step into this game, the perspective that we see right now is

there is an assertion by a university against a corporation, and then there is this belief that then it jumps right into negotiation and resolution and what Lucent is considering and I think has thrown on the table; Dan McCurdy threw on the table with the panel that is talking about this is saying, "Why are universities immune from this counter assertion step?" What we have done is we have done a little bit of homework, a little bit of research, and our research to date shows that so far universities are immune from this counter assertion, and I think we had one of our paralegals look at case law for about the last 15 years, and what we saw was about 47 patents and 46 cases. There are 46 cases where a university aggressively asserted its patents against an industry, a company. Now, 36 of those cases were by universities, and 10 cases were brought by their exclusive licensees.

Now, in those cases there were counter claims. This is what we were trying to understand. Is there any case law that suggests that universities are subject to counter claims, and in 22 cases in which there was a counter claim the case did not involve patent infringement nor a declaratory judgment claim. Rather they were disputes over ownership or licensing terms.

So, to date we don't believe that there are any cases out there where corporations are in order to defend

ourselves, in order to do what we think we have done in the past, what are our options relative to counter assertions against a university?

Now what considerations would a corporation need to face or to drive them down to this infringement counter claim? Of course, I am not a lawyer. So, excuse me if I get some of this wrong, but I believe for an assertion claim it has to be for commercial use. Universities in the past have been allowed to play in what they perceive philosophical curiosity or where Lucent believes is that it probably would not make a step unless it was about a commercial use issue.

Now, commercial use when you see universities stepping into creating start-ups or licensing their technology to corporations for dollars now maybe the equation starts to change.

What other considerations would a corporation have to consider? Public opinion. What would be the perception about a university being sued by a corporation? That would be a tough one to sell, maybe, except that you say that I am just defending myself. This isn't me aggressively approaching a university. This is me defending myself against an assertion by a university.

So, is that one tough to swallow? Maybe, but probably doable. I don't think Lucent is too concerned about

all the good press we are getting lately.

(Laughter.)

DR. FINNEGAN; I don't know if we worry about that, and I am not speaking from -- I am kind of just throwing some questions out there for us to discuss. I am not saying that there are any real cases where Lucent is considering this now. I am just saying this is kind of the thinking that goes in up front.

Finally, where would the damages be? If a case is going to cost you \$3 million a year you hope to at least recover your costs. Where are the damages? What would the injunction be? Would you attempt to stop a university from researching in a specific area? Would you attempt to stop a university in researching in MEMS? There are some interesting questions, and also what is the perceived liability? So, some of these questions as universities step down the path from pure technology licensing to enable a market into an aggressive stance on patent licensing it kind of brings them into this model, and I think there are some interesting questions that will eventually have to be pursued and we will probably wait for that first time when we see a company out there somewhere that files a counter claim against the university because a patent lawsuit is filed against them.

So, I may have spoken to most of this. So, again,

maybe this is a little bit of PR right there by looking at how some of the questions are framed, but is industry entitled to defend itself with traditional means against commercial activities of academia, and as commercially directed IP activities should a separate set of rules apply and if so why, and lacking parity in behavior and process, will academic IP activities enhance or harm industry-academic cooperation?

So, I think as Bob mentioned we wanted to throw some other questions out there on the table for this group to consider as universities become more aggressive out there in the patent licensing world.

Any questions?

No questions, okay, thank you very much.

(Applause.)

DR. FINNEGAN: Oh, yes sure, go ahead.

DR. BOUDREAU: I am Daryl Boudreaux. I direct the technology transfer function at Rice University. I wanted to comment that in general there is a difference between the patents that universities consider in a large sense and the kind of patents that you probably consider at Lucent. Ours are at a much earlier stage in most cases and so there is a qualitative difference between the portfolios that we are talking about, and I think some of the issues that you are concerned with here would reflect on those qualitative

differences in a sense that we haven't really explored in this talk.

DR. FINNEGAN: I would disagree. From the research engine that I know of of Bell Laboratories I would disagree that university inventions are by their nature more fundamental. If you look at some of the things like MPEG(?) Roone Netravali essentially invented digital video compression. The laser was invented at Lucent. The transistor was invented at Lucent. So, I think it is hard to make that statement unless you -- that is a hard one, but a patent that is infringed is still a patent that is infringed.

Okay, that is not a question. That is a bathroom break. Thank you.

(Applause.)

DR. NELSON: Thank you very much, Jim for a fascinating discussion and for getting out on the table an issue that I think is going to be of very significant importance in coming years.

I think there has been a tendency of the people who don't know what is going on in any detail to think that universities can take out patents and enforce those patents without getting themselves into major legal disputes and litigation sort of goes with that territory, and universities are going to increasingly have to face the

problem how far into that territory they actually want to go.

Over the last 5 or 6 years or so there has been a group of academic scholars who have begun to explore in some depth the details of what is going on behind the scenes in this significant increase in patenting and licensing that has been occurring at universities and also going back in history a bit to understand better its genesis, and David Mowery of the University of California at Berkeley and Maryann Feldman have been prominent within that group, and we turn now to some reports from David and Maryann regarding what they have been finding out along with their colleagues regarding what has been happening.

David?

DR. MOWERY; Thank you, Dick. It is a pleasure to be here. I should emphasize that what I am going to talk about today draws on work by myself as well as Richard Nelson and Arbut Sudanus and Bob Ansampat, all with the generous and much appreciated support of the Mellon Foundation.

What I thought I would do is try to provide a little bit of historical context for today's discussion of university patenting and licensing and then briefly discuss Bayh-Dole and some evidence that we, part of this research team have developed drawing on the licensing and disclosure

and patenting data from the University of California system, Stanford University and Columbia University on looking before and after Bayh-Dole, at the trends within these leading institutions in the licensing of technology during the 1990s in their activities in patenting and licensing, and then I will fairly briefly present some of the data from AUTM on the trends during the 1990s since that was covered I think quite well by Dr. Barchi and then present my list of issues and unanswered questions and concerns.

I am going back a way here because many of the issues that we are talking about today really have been debated for much of the previous century and indeed there has been a fair amount of patenting activity undertaken by US universities through much of that century. A well-known Berkeley faculty member, member of the Chemistry Department and patent holder of a series of patents in electrostatic precipitation technology to remove particulate pollution from emissions, Frederick Cotrell was quite active in the early 20th century as a patentor and inventor and in fact founded an organization to serve as a third party manager and licensing manager of university patents, the Research Corporation.

The university patenting activity through much of this pre-1940 period drew on a long established tradition of collaboration between researchers in academia and

researchers within industry spanning sectors such as chemical engineering, chemistry generally, pharmaceuticals and the like.

Nevertheless during much of this period and really after 1945, as I will talk about there was considerable ambivalence within a number of US universities about assuming a direct role in the management of the patenting and licensing activity, and I put up a couple of modestly lengthy statements from Catrell for a couple of reasons. First, these give you a sense of the longevity of these issues and secondly, they give you a sense of Catrell's own ambivalence about some of these issues.

The first statement, a certain minimum amount of protection is usually felt necessary by any manufacturing concern before it will invest in machinery or other equipment to say nothing of the advertising, etc.

A number of meritorious patents given to the public absolutely freely by their inventors have never come upon the market chiefly because what is everybody's business is nobody's business and in summary fashion a pretty good statement of one of the premises of the Bayh-Dole Act and 1912 is the year of articulation of this position by Catrell, a fairly prescient observer.

The second statement really goes to this ambivalence about universities asserting or assuming a

direct role in managing their patenting and licensing activities, again summarizing university trustees are continually seeking for funds and in direct proportion to the success of our experiment its repetition might be expected elsewhere.

The danger this suggested was the possibility of growing commercialism and competition between institutions and an accompanying tendency for secrecy in scientific work.

So, I think that these issues we talk about today have a long history. There are extensive debates over all of these issues, really beginning in the 1910s, 1920s, 1930s, and to a surprising degree these issues remain unresolved partly because of the rather limited nature of the data to which we have access and the complexity of really trying to understand what would happen under a different set of conditions.

The post-war era is one of continued growth in university research performance obviously, much of it sponsored by federal funds and the growth in federal funding during and after World War II really leads a number of universities at the behest of federal agencies to develop formal patent policies.

By the late 1950s most of these universities had adopted formal policies, but again, these policies are somewhat schizophrenic or ambivalent with respect to

patenting. Many of them, especially in medical schools explicitly discourage or in some cases prohibit patenting.

In other cases universities outsource their patent and licensing activities to entities such as the Research Corporation which had by the late 1950s hundreds of agreements with individual universities to manage their licensing activity and the land grants by comparison with their private research university counterparts are somewhat more active in the direct management of patenting and licensing.

I am going to just throw up some trends here and then show you the figures that underpin these statements in a minute. What we see during the post-war period is that universities' share of overall patenting is pretty flat through the early post-war period down here at somewhere around .2 percent of overall patenting. Then beginning really around 1970, we get a bit more of a bump up and then almost a steady increase in the rate of growth of university patenting as a share of overall US patenting.

So, we get a 12-fold increase in the share of overall US patents. These are domestically assigned patents accounted for by research universities between 1970 and 1999, and I think what is also interesting about that increase is that it so greatly exceeds the increase in the share accounted for by universities of overall R&D

performance. It really bumps up only about 1/6th from about 12 to 14 percent. So, this lower curve here is the university share of overall patenting and the upper one is the share of overall R&D performance.

There is very little parallel movement between these curves. You can see that the patenting is not really responsive to the share of overall R&D performance and as I said earlier the patenting share increases overall by a much more dramatic factor than does the share of R&D performance.

The other interesting development that occurs during the 1970s and again I am talking here before Bayh-Dole is that private universities significantly increased their involvement in the direct management of their patenting and licensing activities.

So, their share of university patenting triples during the period from 1960 to 1980 from about 14 percent in 1960 to 45 percent by 1980.

So, we see patenting beginning to grow during the 1970s and we see private universities significantly expanding their presence in the direct management of their patenting and licensing activities.

The other important development again predating the Bayh-Dole Act that is going on in this patenting activity is the biomedical technology's share of university patenting is increasing quite significantly, 11 percent of

university patents in 1971, a more than four-fold increase to 48 percent in 1997 again, more significant by far as an increase in share than the increase in the share of federally funded university R&D accounted for by the National Institutes of Health.

So, you see here the red segment here is the biomedical technologies within research university patenting, and that is steadily growing as a fraction of overall university patenting through really the 1960 through 1999 period and again, this is this figure doesn't come out too clearly, but this is the share of biomedical patents within research university patents, and you can see it simply replicates the figure shown on the slide, but it is a much sharper increase than the share of overall university federal funding accounted for the by National Institutes of Health.

So, we see in this expansion in patenting a shift in its composition toward biomedical patenting and in both cases this growth in patenting which predates the Bayh-Dole Act really is not well explained by changes, it is not solely explained I should say by changes in the characteristics of federal funding of the university research enterprise nor is it explained well by changes in the university share of overall R&D.

As a result of the growth of universities'

activities in managing their patent portfolios and the licensing thereof directly we see a fairly significant decline and really by the end of the 1970s the crisis in the operations of the research corporation and its eventual decline into a role of much less significance, so, the significant shift before Bayh-Dole in the willingness of universities to become much more directly involved in the management of their patenting and licensing activities.

Now, we come to the Bayh-Dole Act which I think was fairly well summarized by Dr. Barchi, again passed to encourage commercial development and transfer of federally-funded inventions enabling non-profits to obtain patents and to license these patents to private parties including the use of exclusive patents.

Bayh-Dole did not legalize patenting of federally funded research results but it did greatly simplify and rationalize what had been a very complex web of individual institutional patent agreements and it effectively represented a congressional endorsement really of the validity of university patenting as a means of facilitating technology transfer and as all of the data suggest the university patenting which had been growing prior to 1980 accelerated after 1980, and again, these figures, the share of overall US patent growing from about .7 to 3.6 percent by 1999, but it is important to keep in mind as Dick Nelson

suggested other things were happening during the seventies and eighties that also played a very important role, the *Diamond v. Chakrabarty* decision which essentially recognized the patentability of life forms, the creation of the Court of Appeals for the Federal Circuit which emerged as an important champion really of patent holder rights and other federal actions, a number of congressional statutes that strengthened intellectual property protection both domestically and internationally during the 1980s.

Finally, a long-standing trend of increased federal support for biomedical research and particularly as a result perhaps of the war on cancer announced in the early 1970s the explosion of scientific advances in the area of molecular biology also, are very important underlying factors particularly when we look before and after Bayh-Dole at a couple of leading patentors and licensors, and this is what I want to turn to now looking really at Stanford and the University of California system before and after 1980, trying to get a sense of what was going on before and after in both the level and the composition of their patenting and licensing activity and then compare the characteristics of the patent and licensing portfolio of these two universities with that of Columbia which really enters after Bayh-Dole and emerges as a very important academic licensor during the post-1980 period.

Finally another important effect of Bayh-Dole again as Dr. Barchi alluded to is the fact that a number of universities enter, universities with relatively little historical experience, particularly in the management of patenting and licensing, enter this activity after 1980.

What do we see before and after Bayh-Dole at the UC system and Stanford? I think what we see before consistent with the other data presented on overall trends is both a growth in invention disclosures and in patenting that really picks up during the 1970s and importantly a shift in the composition of these disclosures in patents to favor biomedical inventions, all before the passage of the Bayh-Dole Act.

So, we see that at both of these institutions you have a jump up in the share of biomedical inventions within the flow of faculty invention disclosures and an increase in the share of patenting that predates Bayh-Dole, and I think this reflects a combination of factors including the developments, advances in the underlying science of molecular biology producing advances that emerge as enormously interesting and attractive, as potentially licensable intellectual property from the point of view of industry and, also, from the point of view of the universities these advances turn out to be highly profitable as a source of licensing income.

So, you have developments going on both sides as well as the overall strengthening of intellectual property. Bayh-Dole contributes to this, but it is really one of a set of factors, and that is one of the reasons I think that one sees this overall increase in licensing activity, the entry of a number of private universities before Bayh-Dole and entry activity that really accelerates afterwards.

If we look at the characteristics of the patent licensing income of the UC and Stanford before, as well as after Bayh-Dole and compare that with Columbia during the post-Bayh-Dole period I will put up a table. This all draws on this table, but I am pretty sure for this audience it may not be highly visible. So, I am going to summarize the trends here.

The first thing is the table shows constant dollars gross licensing income, and the first point I think that is interesting is just the magnitude of the growth in these income flows, 50-fold at the University of California over a 25-year period, 200-fold at Stanford, UC and Stanford, obviously dividing with an additional share to Stanford for its management of the royalties from the Cohen-Boyer patent but also at Columbia a very dramatic growth during a shorter period of time, fiscal 1985 to 1995 in gross licensing income.

The other two points I think that are important

here are again something that characterizes almost all licensing portfolios, university or otherwise which is a relatively small number of inventions generate a very large fraction of the gross income at all of these universities. That is this line here.

At UC we have something on the order of two-thirds of total licensing income flowing from the top five inventions by fiscal 1995, at Stanford 85 percent, Columbia 94 percent. The other point about these five inventions is their dominance again by biomedical technologies, 100 percent at UC, 97 percent of the licensing flows associated with biomedical inventions, 91 percent at Columbia.

So, you have a very skewed distribution of inventions in terms of their licensing income, and the winners, the home runs tend overwhelmingly to be derived from the biomedical technology.

The last point that is interesting I think about these three universities' licensing income is simply how much the portfolios, at least the distribution, the concentration on a small number of inventions and its dominance by the biomedical technologies resemble one another by the middle of the second decade after the Bayh-Dole Act.

So, the entrance in the form of Columbia now bears a close resemblance to the licensing and patent portfolios

of the two rather well-established incumbents by the middle of the second decade following Bayh-Dole.

The other point that I mentioned earlier is the effects of Bayh-Dole on entry by universities with relatively limited experience in patenting into this activity after 1980, and the most experienced academic patentors whose share of overall academic patents account for about 87 percent of these patents in 1975, by 1992, their share has dropped to about 64 percent and the less experienced universities, the so-called "medium intensity academic patentors" with less than or equal to 10 patents during the decade of the 1970s, their share increases from 15 percent to 30 percent and universities with no experience, with essentially no patents during the seventies increased their share to 6 percent by 1992. So, by 1992, you have more than one-third of the patents being filed by universities coming from institutions with relatively limited experience in this activity, and this matters because the evidence suggests and I think Dr. Barchi referred to this, it takes time to develop both the staff, the known-how and some of the context within the industrial community to manage these patenting and licensing activities effectively and this is reflected to some extent in the data and the patents particularly received by some of the less experienced university entrants during the 1980s in the

sense that these patents tend not to generate a comparable stream of subsequent citations by other patents.

So, in some sense the new entrants are receiving patents early on that in some respects are less important.

Over time we observe some learning behavior, and these entrance patents tend to essentially approximate or come close to those of the more experience universities in terms of their ability to generate follow on citations.

These trends in the 1990s are taken from the autumn survey which report results separately for recurrent respondents and all respondents which again allows you some control for entry into and out of the survey respondent population and here we have disclosures, patent applications; issued patents is the yellow line. This is the annual number of licenses executed, and the annual number of new patent applications and this is taken from the recurrent respondents in the AUTM survey. So, this is people who respond throughout the 1990s to the AUTM survey and I think the bottom line here is that everything is going up, that we see fairly significant growth from about slightly less than 5000 annual disclosures to almost 8000 across the 1990s. We have issued patents growing from somewhere on the order of about 1000, slightly more than 1000, almost 3000 by the end of the 1990s.

This is a per institution plot of the same data

for all respondents and here you see a slight well essentially very similar trends, a slightly more modest rate of growth per institution in disclosure, but nevertheless everything is going up.

Patents for R&D expenditures, how intensely are universities patenting relative to their reported R&D spending where R&D spending is reported in constant dollars?

Again, quite a significant increase here, more than a doubling in the rate of patent for R&D dollars spent during the 1990s. Gross licensing income nearly triples across this period of time.

This again is looking only at the universities who respond consistently to the AUTM survey. We move in constant dollars from about 200 million in 1991 to almost 600 million by 1999, and this actually just reports gross licensing per institution which again is growing, more than doubles across this period of time for all response to the AUTM survey and the last which I think is an important factor that is alluded to in Mr. Finnegan's remarks, gross spending, gross legal fees increasing quite significantly across this period of time reflecting the growth of litigation activity in constant dollar terms from about \$40 million to almost \$80 million by the end of the 1990s.

So, what we are seeing here is significant growth in gross income and significant growth, it seems to me in at

least one very important element of the costs of licensing activities.

Let me just put up my list of issues here which bears a certain resemblance to those we have seen so far. The first is what are or what should be the institutional objectives of university patenting and licensing. We have certainly heard an allusion to generation of income from licensing fees and royalties. There is obviously a technology transfer mission and a regional economic development mission that bears more or less upon public and private universities.

Many universities use these and for many years have used their licensing activities to leverage or encourage the sponsorship of research by industrial enterprises. These objectives are not always consistent with one another on individual transactions or licenses nor are they always given comparable priority or weight by different levels of the university administrative hierarchy and one of the key issues here I think is how US universities are managing conflicts among and trade-offs among these different objectives.

A second broad issue is simply how effective is the patenting activity really in supporting the transfer and commercial application of university technologies.

Dick Nelson mentioned Cohen-Boyer as one case in

which perhaps the patent itself was not indispensable to the transfer and commercial application but did serve as an effective means of capturing a portion of the revenues, but this is a difficult experiment to run, and this is an experiment for which our evidence really at present doesn't provide us very conclusive data or evidence at all it seems to me.

Another issue is how the growth of university patenting may be affecting the research culture, the norms of research in leading US universities. Again, this patenting activity and particularly the licensing activity and the licensing revenues tend to be very concentrated among disciplines, tend to be dominated by the biomedical disciplines in particular and therefore the pervasive effect or the pervasiveness of any effect on the research culture is likely to be limited and highly concentrated among fields.

Nevertheless, this is something on which certainly the overall and patent-based evidence don't provide us much insight.

An issue raised by both of the previous speakers is when does patenting help and when may it hinder the kind of research collaboration that has been a hallmark of US universities and industry literally for decades. Again, this varies by field I think.

You can think of at least a couple of dimensions in which the emphasis on intellectual property rights can hinder university-industry research collaboration. First, the negotiations can in many cases be extremely complex and can delay the development of collaborative relationships particularly in fast-moving fields, again in areas such as information technology area rather than in the biomedical area and secondly as Mr. Finnegan's remarks suggested there is a sense in some fields in which the relationship between universities and industry in some dimensions is becoming a more competitive one rather than one of collaboration, particularly in the assertion of intellectual property rights in some of these areas.

Another issue is how if at all should patenting policies, the policies governing both the outcomes of research and the treatment of background intellectual property be tailored to the different circumstances the different value of intellectual property rights in different technology fields, issues of any limitations on dissemination of research results formerly published that may be resulting from emphasis on patenting or relatively more restrictive policies on licensing in particular and finally most of the data we have give us gross income flows. We have very little data on the institution-specific distribution of debt income from technology transfer and

licensing operations. It is our guess that this income tends to be highly concentrated among a small number of universities that are fortunate enough to generate biomedical-based home runs. Nevertheless, it is likely that these returns are highly skewed, and we don't have any information really to speak of on the distribution of the net income from these activities among different institutions.

So, I will stop there and I appreciate your attention.

Thank you.

(Applause.)

DR. NELSON: Next is Maryann Feldman of Johns Hopkins University.

DR. FELDMAN: Very good. Well, it seems my challenge as clean-up speaker is to try to say something that hasn't been said already, and really I represent a new perspective from what Dave has talked about. I am reporting on some collaborative work with Irwin Feller from Tennessee and Janet Berkavitz and Rich Burton at Duke University, and the perspective of our three universities is really the new entrants, universities that were not very active or even indifferent to technology transfer and commercialization pre-Bayh-Dole.

So, the perspective that I am talking about is

really one of the adaptation, experimentation with technology transfer mechanisms as a sort of learning that has occurred at our universities, and I am really going to be talking about sort of three sort of separate sources of data. We have done extensive interviews with people at the technology transfer offices, with faculty and with individuals at companies trying to gain their perspective.

We have, also, used the AUTM data. Everyone who works in this area uses the AUTM data and we have, also, done an original survey of research universities, both the Carnegie 1 and Carnegie 2 institutions trying to understand their perspective.

So, the things I am going to talk about are first university motivations, and Dr. Barchi has talked about sort of what these motivations might be. We have actually asked people and I want to present that data.

I want to talk about sort of the key mechanisms that are available to universities when they transfer technology, notably licenses, sponsored research agreements, university spinoffs and then also equity-based licenses and really these are the sort of menus that are available to universities who are engaged in technology transfer, and it is a matter of sort of looking at the advantages and the disadvantages associated with them and then really adopting these mechanisms and tailoring them to their own

experiences.

I want to talk a little bit about the evolution of these mechanisms over time and then finally close with some unanswered questions. So, really we went out about a year ago and talked to Carnegie 1 and 2 research universities and asked them of these sort of things that might be motivating your technology transfer what is the most important, and sometimes people mentioned two, but the highest ranking on criteria was service to the faculty so that most technology transfer managers felt that service to their university faculty was the most important mission. Knowledge dissemination followed a close second. Revenue generation was third and service to industry and economic growth are sort of a close fourth.

So, really to look at these sort of different mechanisms that are available to universities licenses, again, the license of an intellectual property here what the university gains is immediate up-front fees and, also, milestone payments so there is some revenue, also, revenue in terms of ongoing royalties, and licenses do affect knowledge dissemination, but we are not quite sure.

One of the things we are sure of in talking to universities is that there is a prestige factor. If you are licensing your technologies you are seen as being a player. You are active in knowledge dissemination, and that affects

sort of the perception of the university standing vis-a-vis its cohort.

What does the company gain? Really in taking out a university license the company gains the right to use intellectual property but really that is a reactive right because this is kind of a technology push mechanism where the technology is on the shelf and a company can come to use it and it matters to companies whether it is exclusive or non-exclusive, but here there are some trade-offs because with certain kinds of technologies you want to have a non-exclusive license because that means that other people will be working on that same technology platform.

Sponsored research agreements, and again, this is something that universities are very familiar with, what the university gains is research funding and faculty support and this is then important to providing a service to the faculty.

Also, what the university gains is access to industry resources, both the knowledge that resides at places like Lucent Technologies and also gains to use of sort of defining problems better and so there is a great synergy there.

Also, industry just has good instrumentation and that is a benefit to sponsored research. What the company gains in sponsoring a research project at a university is

really a place at this table in technology transfer. They can then go in.

The define the problem that they are going to fund and really gain access to tacit knowledge. They can sort of develop and craft this project as it proceeds. They, also, have the right to first refusal to any intellectual property that is developed in a sponsored research project and also they get contacts and contacts with faculty but also with students, and we see a large number of students who have worked on industry-sponsored research projects subsequently going to work for those companies.

University based spinoffs, again for a university when we think about a spinoff the sort of most rigorous definition, the definition that is used by AUTM is a company that is built around a university license, and a spinoff company allows the university to put a license into play. It could be something that an existing company might not be interested in but by forming a company you are putting this license into play and also to the extent that faculty members are frequently involved in promoting these companies it does provide a service to the faculty, and increasingly as David mentioned universities are seen as engines of local economic development and the way that they can point to their impact on a local economy is through the generation of spinoff firms, and what we witness is that companies really

become a vehicle for furthering technology development, that companies and faculty involved with companies have access to new sources of funding, new government programs that are not available to universities and also venture capital, and what the new company can do is it can move a technology closer to having some commercial value, and we have some anecdotes of licensing agreements that fell through with large companies between the university and the large company that were subsequently enacted with the university spinoff and the large company so that for some reasons companies find it easier to deal with other companies rather than universities.

Finally, I want to talk about a new mechanism, and it is something that again these are all drawn from papers we have worked on, but we have been looking at university equity licenses, and what I mean by this is when the university accepts an equity share ownership in a company in exchange for the right for the company to use the intellectual property. So, this is in lieu of the traditional licensing fees and royalties and really again what the university gains is it puts a license into play. Also, there is some upside revenue potential in that the university can gain revenue from the total value of the company, not from the value of one individual license. It does provide service to the faculty and again this sort of

mechanism of taking equity is something that is associated with universities that are at the cutting edge that are more entrepreneurial. Companies gain the right to use intellectual property without having to put out money. It is a conservation of cash. Also, for these individuals when the university takes an equity interest in them it provides a legitimacy. They can then go out and say to potential funders, "Look, the university has an equity interest in us," and it also seems to align the interests of these various parties.

Now, this is how you can tell you are an economist. If you look at this curve and your heart beats a little bit faster, well, you know, this is the traditional sort of S-shaped diffusion curve that is well known in economic phenomenon and this is really giving us the diversity of the establishment of these technology transfer offices, and as Dr. Barchi mentioned we see WARF being formed, the Wisconsin Alumni Research Foundation formed in 1929 and then Iowa in 1930. So, there is sort of very slow adaptation of this phenomenon, but then post-Bayh-Dole it really takes off and so in fact there are three new technology transfer offices that are initiated at universities in the year 1999, and sort of simply what is associated with this, we find two factors are highly correlated with the speed by which individual universities

adopted technology transfer offices and no surprise as Dave mentioned a lot of this action is biomedical so that universities that had a medical school were more likely to be early initiators of a technology transfer office.

Also, those universities that have large sponsored research budgets were more likely to -- that increased the speed at which a university adopted a technology transfer office.

Licensing revenues, and again, this is some data from the AUTM survey. This is that constant sample of AUTM respondents, and this is just going through 1995, and I want to point out that even though licensing income has gone up in aggregate when we look at this little red line average income per license per income generating license, it is actually sort of flattening out, and so we have simply greater aggregate license revenue because we have more licenses in play, not because the average license is doing better.

Licensing again when universities sort of evaluate this and they are experienced with it, there have been a few big hits, but really only a subset of invention disclosures generate any licensing interest and of those that do very few generate returns.

There is, also, a very significant time lag between the license and any revenue generation. Industry-

sponsored research, and again, this beautiful S-shaped curve, and so what you can see is sort of this really takes off, and so this is actually millions of constant 1992 dollars, and so you can see that there has been a lot more sponsorship of research by industry at universities.

Now, sponsored research does offer when we compare it to licenses some advantages. First of all for universities it is going to be immediate and certain income. It is, also, a mechanism to move early technology forward and this is important for the university and for industry because it increases the potential intellectual property value, and also, sponsored research is valued by faculty, but again the down side for the university for sponsored research, it has a limited direct up side revenue potential.

You simply get a certain amount of money for a finite period of time and no annuity as you might get with a license or with an equity start-up, and also, what we find is that sponsored research is increasingly being used by universities as a way to leverage a relationship with the company so that you start out with sponsored research and that relationship will develop, but again there are some institutional barriers to this kind of moving from these mechanisms to a relationship.

Now, spinoffs, I wanted to present this is again companies that are formed around a university license, and

this is for all universities and in fact, pre-1993 is kind of just a sort of from AUTM what is our best guess, and we think sort of during the period of the 1980s universities were on average and again average over these 13 years generating about 100 spinoffs, and that has increased. There were 270 spinoffs in 1999, and roughly two spinoffs per university that participated in the AUTM survey.

Now, this is looking at that constant set, and so if you will this is kind of the A team of technology transfer. These are the people who consistently respond to AUTM and really in 1998, they generated 2.75 spinoffs per university, and so really if these are the sort of people who are more serious about it, a little bit different from the incumbent entrant, these are the people who really are the Carnegie 1 institutions predominantly, you can see that spinoffs have become much more important and in fact much more important since 1996.

We then sort of looking at equity, and really the experience that universities have had with start-up firms sort of introduced this mechanism of taking equity in lieu of a licensing fee. What we have found in our interviews and in looking at data from our universities is that equity is no longer limited to start-up firms and that universities are taking equity in new issues for existing companies and it offers some advantages and specifically affects potential

litigation down the line over the use of an intellectual property.

So this is the here, again, first equity deal, and it follows again this kind of a diffusion curve. First equity deal was initiated in 1978, and again the number of universities taking equity has increased. This is based on a sample of 67 Carnegie 1 and 2 research universities that we conducted last spring, and this is the only data that I am going to show you that has actually the number of sort of individual transactions per university.

You can see it is highly skewed. There are a large number of universities that have never taken any equity, in fact, 16. There is one university out here that has had 90 individual equity deals, and so there is a sort of you know, a very interesting distribution but what you should realize we haven't shown you these data but for most of these technology transfer mechanisms we have the same skew.

A lot of things clump close to zero and a few outliers. The equity deals, what has happened with these, actually an equal number have gone bankrupt or have been cashed out. Johns Hopkins University last year doubled its technology licensing income and it did that by cashing out on two of its equity investments. There are a large number of these that are still in existence. Equity is a mechanism that really existed post Bayh-Dole and it has diffused

rapidly through the technology transfer community and it is an example of this kind of adaptation. Equity is no longer being used for start-ups, and it is being used in a variety of different situations, and it is really perceived as offering something that is in between licensing and sponsored research in terms of the revenue potential, the alignment of interests between the university and the company because after all if the university owns part of the company their interests are aligned and, also, equity seems to offer this certification effect affecting both the ability of the company to raise money but, also, making the university look better in terms of its colleagues and what we found in our survey was that the majority, two-thirds of respondents expect that their involvement in equity deals is going to increase in the next 5 years and really this is not to say that equity is without its problems. There are problems with equity, but what we can see, sort of what I would like you to take away from this is that in this university intellectual property technology transfer game the cat is out of the bag.

More universities are participating in technology transfer and this runs the spectrum of all institutions. More mechanisms are being used, and they are being used more creatively, and also, increasingly greater emphasis is being placed on the universities' role in economic development.

Technology transfer bench marking has become important and so the AUTM report which comes out every fall is heralded with a lot of let us see what universities are doing and let us see how your university ranks. We have found that the adoption of equity by universities is strongly influenced by their position vis-a-vis their cohort institutions, and so a university is more likely to use equity in its technology transfer practices if it lags its cohort of similar institutions.

Again, as we sort of survey the landscape we know very little about material transfer agreements. Most of what we have been studying as a community has revolved around licenses, start-up companies, but really these material transfer agreements are very important and they affect the flow of knowledge between universities and, also, between universities and their corporate partners, and also I want to mention, and I think it is critical that the numbers are only part of the story.

They mask a great diversity between universities in terms of the organizational motive, the strategies that universities are deploying to diffuse knowledge and, also, the incentives that are offered at the various institutions and so I want to close with a quote from the President of Johns Hopkins University and he has great titles for his speeches. This one was called From Minds to Mind Fields;

Negotiating the Demilitarized Zone between Industry and Academia, and he says, "Patent protection takes a lot of work and time and money. The dirty secret is that for many universities, perhaps most they are not yet breaking even much less making money on the proposition and in some instances and in some industries patent protection may in fact be an oxymoron."

He goes on to say, "Universities are designed to operate not for profit, and usually they do quite well at it."

(Laughter.)

DR. FELDMAN: On the other hand it is expected that they should benefit the public. What is that thin line between their benefit and our benefit, and how do we keep sight of it?

Thank you.

(Applause.)

DR. NELSON; Thank you very much.

Coffee break now.

(Brief recess.)

DR. HALL: I am going to open the session even though there are still people trying to find their seats. We have according to my watch around an hour and one-half until lunch as opposed to 2 hours on your program, but we will probably manage to get it in because I have a feeling that

hunger will take over at some point around 1 p.m.

This session, *The Effects of Patenting and Technology Transfer on the Commercialization of University Research Output*, is a parallel to the session that is just after lunch which is going to essentially focus not on industry of the effects of academic IP on industry but its effects on the university research input. So, we are starting with the output and then moving to the input which is presumably a perfectly good way to go, getting away from the linear model.

The format of this session is different from the preceding session. I am going to introduce the topics of the session as the moderator and then I am going to ask each of the panelists to speak for about 10 minutes on the general questions raised in this session. I am not asking them to answer specific questions. I am asking them to essentially give their own thoughts on the topic and then we hope to have some lively discussion and questions from the floor. So, be ready.

The questions for this session focus on the following four topics which I will just briefly review for those of you who like me find it a little hard to read the handout due to the aging of eyes.

The questions are the effects of academic IP and technology transfer, first on the flow of research output

and information about research from academe to industry, on the behavior of research personnel and then on the institutional behavior of the university and finally on probably the most important topic, the commercialization.

Now, what we mean by the flow of information is the question is does academic IP increase, decrease or simply change the way information flows from the university to industry which is to say that once you move to a situation where there -- I liked the previous, I cannot quote it but I liked the President of Johns Hopkins analogy the mine field on the border. I refer to it as the two worlds of intellectual discourse, the academic world where the competition is via early publication and the industrial world where trade secrecy is often a factor.

There is a lot of tension when you get to the border between those two and this affects directly the information flow.

So, that is something we want to talk about. Variation over technology in industry and finally direct question is the issue that I think affects a lot of us empirical researchers which is this issue of whether open access and open publication of database type information, and here I refer to biotech, but it could be things like geophysical maps, does that increase or decrease innovation? That is an area of current tension.

On personnel issues are whether it is good or bad in a sense for retention at the university. Is there any effect on corporate recruiting at the university level, and finally, I have been influenced a little by reading in the report of a conference report of a conference held at the University of California at Berkeley in February in the agricultural biotech area where some technology transfer officers and others expressed concern that there was in a sense a goal conflict between academics producing individual research outputs and the administrators of the university which has to do with the problem, well understood by economists of how to allocate the returns to an innovation which has as inputs many different ideas and inventions, and in particular there seemed to be an experience in agricultural biotech that it was sometimes difficult to get professors to agree to license technology that was essential for an innovation because of the fact that it was hard to identify which portion of the returns they should be entitled to. Okay, so, I raise that as an issue.

I think a number of the questions that we are talking about in this session were actually addressed very nicely by the two presentations at the end of the last session, Maryann Feldman's and David Mowery's. We already learned a lot about these things and presumably will learn more and in particular this issue of goals, you know, what

is the goal of the university? It has always been very unclear to me particularly because I am at a large state university which has very many conflicting agendas, but in particular are they trying to maximize diffusion or are they trying to increase licensing income?

Again, as an economist one of the things you know is that if you have some form of monopoly, in this case the monopoly on an invention you don't necessarily get maximal output if you are engaged in maximizing profits, and it is possible that that is a tension here, and then there is the sheer performance question, are the technology transfer offices actually doing what the university administrators are wanting them to do, and finally, on the commercialization side the questions that we are interested in are essentially the facts, a number of which we already learned, how does success vary across different forms of technology transfer; who are the firms licensing the technology? How does it vary across these technologies, and finally, again this cumulative innovation issue which comes up very often which is the effect of academic intellectual property protection, the intellectual property protection for the outputs of academic research and for say, upstream commercialization such as things like research tools or gene sequence identification, is the effect on downstream innovation positive or negative, and I think this

is still something of an open question.

Now, the speakers on this session are arranged in order in which they are going to speak at the table there, and they are going to give us their perspective from universities and from technology transfer, people experienced with technology transfer and then from industry specifically in the pharmaceutical area and I am going to start by asking Don Siegel to talk for about 10 minutes and we seem to have both computers working here which is good and then we will move on.

DR. SIEGEL: I will be talking about lessons learned from recent quantitative and qualitative research on the effectiveness of university-industry technology transfer. This is joint work with Al Link and what I am going to try to do in the interests of promoting technological diffusion is not just report on my own research which was funded by the Sloan Foundation with Al, but I will, also, try to draw in some evidence from papers that appeared in recent special issues of the Journal of Technology Transfer on organizational issues in university-industry technology transfer.

I had the privilege of co-editing several special issues of this journal with Marie Thursby and Jerry Thursby and Arvid Sedonis on various issues in the university management of intellectual property and indeed several of

our contributors are delivering presentations today. So, I would like to draw in some of that evidence as well, and Al really liked the fact that I could get the slide of the journal on there so you can do some promotion.

With respect to our research we had three goals. The first was to improve our understanding of how the process works. This is a relatively new phenomenon at universities, formal university management of intellectual property portfolio, and we wanted to try to improve our understanding of that.

Second, we wanted to develop a framework for assessing and explaining the relative performance of universities. Why do some universities transfer technologies more effectively than others, and then finally we wanted potentially to try to identify a set of organizational practices that might potentially enhance university-industry technology transfer.

We rely on a mix of both quantitative and qualitative methods to answer these questions. We conducted a fairly conventional type of econometric analysis of the relative productivity of 113 US research 1 universities and combined that with qualitative analysis teaming up with management professors who had much greater expertise and skill in conducting qualitative work.

We did some initial field research and came up

with the following production function for universities in terms of licensing activity, and we are just looking at that dimension.

We hypothesized that licensing activity is a function of the invention disclosures at the university, the staff in the technology transfer office and expenditures on lawyers who are involved in negotiations.

Now, we came up with the specification based on two key stylized facts that we learned when we went out in the field. The first was that firms were licensing technologies that were not patented and that patents indeed were not that important for certain technologies and in certain industries, also that some faculty members were not disclosing inventions as they are required to do. So this implies that technology transfer officers can play an important role simply by eliciting additional invention disclosures.

In estimating this kind of a model we, also, needed to account for environmental and perhaps even institutional factors that might explain why some universities transfer more technologies than others such as whether they have a medical school, how much R&D is conducted in the local region, whether they are public or private and some measure of the economic performance of firms in the local area.

Suffice it to say that we estimated this model, the econometric model and our key quantitative results are as follows: First, we found that the production function model provides an excellent fit to the data. Second, we find that while licensing agreements appear to be characterized by constant returns to scale licensing revenues on the other hand appear to be characterized by increasing returns to scale which implies that larger universities may have some advantages in the commercialization process.

We, also found that staffing the technology transfer office adds significant value to the commercialization process based on the econometric estimates of their marginal products, but really the key empirical result is that environmental factors do not explain a very large percentage of the variation of productivity across universities. There is something else going on, and our interpretation of this result is that it may have to do with managerial practices or organizational practices at those particular universities, and in order to explore this we went out in the field and we did extensive field research, 55 structured in-person field interviews with 100 of the stakeholders in this process which means we interviewed academic and industry scientists, university administrators and directors of technology transfer offices, managers and entrepreneurs at five research universities.

We think that these universities are somewhat more representative of the average research one experienced with technology transfer and some of the work that has been conducted in this area.

I think it is important to note that much of the analysis in this arena has been on the extreme right tail of the distribution, that is the universities that have been most successful at transferring technologies like Stanford and Columbia and MIT and some of the UC campuses, and we think that in terms of evaluating the desirability of the policy you also want to look at what is going on in the middle of the distribution as Maryann pointed out earlier.

We were, also concerned about the representativeness of our sample of interviewees because it is very easy to get a biased sample of respondents. So, we tried to use state-of-the-art qualitative research methods in an attempt to as much as possible get a random sample of qualitative respondents.

We have loads of anecdotes and stories and qualitative results. I am just going to present the ones that are most relevant to the questions that Bronwyn posed earlier and those that appear to be somewhat relevant to Bayh-Dole.

There are three key impediments according to the respondents in our survey, in our field research I should

say, three key impediments. The first, and this doesn't surprise anyone is the existence of very strong informational and cultural barriers between universities and firms.

In some of our recent research we find that this is especially problematic for small companies which could have implications for Bayh-Dole since Bayh-Dole was supposedly a program that was supposed to favor smaller companies.

Second, there were complaints about the fact that faculty members didn't want to get involved in this process because they weren't being rewarded for it at promotion and tenure. In fact, in some cases it was held against them, and so that is another issue and then finally the big complaint from the business community was essentially about skill deficiencies and the need to reform HRM practices in the technology transfer office. So, they pointed to the very rates of turnover in technology transfer offices and specifically insufficient business and marketing skill and also the possible need to switch towards incentive compensation as some universities have done in recent years.

We reached two conclusions based on these qualitative results and some other results that I don't have time to present. The first is that if universities fail to address the barriers that we have identified it will

encourage more and more faculty members to circumvent the process and engage in informal types of technology transfer such as consulting.

The second conclusion is in some sense almost sort of a normative one in a way is that universities should really consider this activity from a strategic perspective and I would like to follow up on that by noting that if indeed they decide to really think about this from a strategic perspective then there are really two sets of issues. There are formulation issues, and then there are implementation issues, and I would like to talk about those in turn.

First, they have to decide how important this is as an institutional priority. Second, they have to make, not surprisingly they have to make resource allocation decisions, and this may even affect the choices that they make regarding which technological fields to emphasize or which initiatives to support and then finally they need to make strategic choices regarding the modes of university-industry technology transfer, the outputs and as was pointed out earlier there are various types of outputs here. The universities that we studied were focused primarily on licensing, revenue and licensing agreements but some universities focused more on start-ups. Some have traditionally focused on sponsored research and others are

more focused on forms of technology transfer that stimulate economic and regional growth and development such as science parks and incubators. Again, these are all strategic choices that need to be made by the leaders of the institution in consultation with stakeholders.

Next, implementation issues. Improving information flows, to extricate some of the informational and cultural barriers that we mentioned earlier. In Arizona we had the case where we had town hall meetings where we brought together the three parties to the intellectual property disputes and this helped to resolve some of the issues.

Maryann Feldman and Janet Berkowitz and Irwin Feller and Rich Burton had a very interesting paper in our recent special issue in which they argued that issues of organizational design and structure may be important in this context as well in terms of implementation, reporting relationships; how does the technology transfer office relate to the overall research function, and how close to the customer is the technology transfer office?

We, also think that personnel practices are important here, HRM practices relating to technology transfer officers and individuals in that function but also perhaps even to faculty and indeed if in institutions that truly decide that they want to value this activity it should be matrixed into the reward system and indeed maybe even

into promotion and tenure.

We, also, think that there are implementation issues regarding the modes of technology transfer. So for example, if a university decides to focus on entrepreneurial start-ups they have a choice between relying on academic entrepreneurs or external or surrogate entrepreneurs.

In our recent special issue Mike Wright presented some evidence from UK universities where he discovered that universities that wanted to foster entrepreneurship were more successful when they relied on surrogate entrepreneurs as opposed to academic entrepreneurs.

Policy questions that need to be resolved I think with better data and we heard some evidence, some discussion of this earlier, but first and foremost we need to know which organizational practices specifically and institutional policies actually enhance various dimensions of performance. This would be very useful to those who manage this process as well as to policy makers.

The second question, we still know very little about the actual trade-offs between involvement in this activity and education and basic research. Paula Stefan has a piece coming out in our next issue which looks at the educational implications of this and argues very strenuously that this is disrupting the information, free flow of information among students and faculty members and we still

don't know how this affects the quantity and quality of basic research, and I would like to play the role of prognosticator on the last one and say that I predict that somewhere down the line universities will be experiencing tremendous pressure from activists and other groups regarding their relationships with companies that have emerged from this process and also the fact that they have ownership stakes in some of the technologies in very, very controversial issues, in genomics, in biotechnology and they are going to be increasingly vulnerable to attacks on their ethnics and corporate social responsibility.

(Applause.)

DR. HALL: Thanks a lot, Don.

I will ask our next speaker, Katharine Ku who is the Director of the Office of Technology Transfer, one of the oldest, at Stanford University.

DR. KU: Thank you. I am very honored to be here. As you might notice from the program I am one of the, I am the only university technology transfer practitioner on the program, and so one reporter asked me if I was getting into the den of lions. I don't think so.

What I want to do is share with you our experience from my perspective. There were many interesting questions that were brought up for this session, and I just kind of presented some random thoughts about some of the questions.

The bottom line message that I would like you to take home is that from our perspective technology transfer is very complex. Basically we don't all even agree what technology transfer means. From the Stanford perspective I would say that we always say that it is students and publications that are the greatest form of technology transfer, licensing patents, licensing in general is a very small part of the whole overall technology transfer picture.

We, also, come to this discussion I think with very different views on what we mean by technology transfer even in the patent technology licensing perspective. There are exclusive licenses, non-exclusive licenses. It depends on the industry that you are coming from. It depends on the stage of the technology and many of us come to the discussion thinking about exclusive licenses only.

On the other hand the non-exclusive strategy for certain technologies is excellent but non-exclusive licensing in essence is a tax. Exclusivity is what motivates incentives to have companies invest resources and people into technology developments.

A non-exclusive license which means access to more players nevertheless is a tax. So, in the discussion probably later on on genomics, inventions and databases, etc., even if you talk about a non-exclusive license strategy you need to think about it in terms of what do you

mean by making it available to all because if it is a non-exclusive licensing strategy there is usually a payment involved.

From our perspective the technology champion is the most important factor and so if we have someone in the company who is interested in the technology that is the most likely way that technology will be transferred.

When you are talking about an exclusive license we need a champion inside the university an inventor or entrepreneur who really believes in the technology.

You need that same champion in the company but when you are talking about a non-exclusive license the champion probably doesn't matter that much.

Stanley Cohen of our university was not at all involved in the licensing process although of course he checked on the patent prosecution.

We believe that patents are really actually only a small part of technology transfer. At Stanford we are well known for our entrepreneurial climate and there are many, many technologies that were transferred to industry, many companies that were started that were totally independent of our office.

It starts with Hewlett-Packard. We go to Cisco(?). We go to Sun. We go to Rambus(?). There are companies that started Yahoo for example. I mention often

the two stories about Yahoo and Google(?). Yahoo kids started out at Stanford, didn't use our resources. They came to our office and asked if we owned the technology, and we said, "No, we don't," and they went off and started a company. We said, "God bless." The Google kids came and they had worked on the invention for about 4 years using university resources, a sponsored project. We said, "It is Stanford's," and we licensed the entrepreneurs, so, the same types of technologies, a very different story behind the scenes.

We think that commercialization of university research is very, very high risk, high risk for the university, high risk for the companies, and the success very much depends on the type of company and our technologies are 10 to 15 years away. So, the companies have to be willing to consider the long development time before they take on our project.

In general this is how we see the world, and I know that all universities look at things differently and different kinds of technologies come out of their research, but I just want to just make a generalization of the industry and how we see it.

In general life sciences has the lead in patents. They understand the long-term benefit of R&D. In general we find if it was a comparison between life sciences and

physical sciences life sciences would license more readily.

In the physical sciences, and we are talking about computer technology, telecommunications, wireless, etc., the physical sciences companies generally don't like to license university technologies, and understandably so. Their product life cycle is very short, 18 months. The patent doesn't even issue in that time frame. They have products that involve thousands of patents.

My friend at Intel says that there are hundreds and thousands of patents in one PC and they are not in the mode of taking onesies(?) licenses. What the physical science companies want is access and freedom of actions. Again, life sciences they would probably like proprietary protection. We, also, see the world divided into small companies and large companies. We in technology licensing probably work more closely with small companies who want proprietary protection but then I am talking about exclusive licenses.

We do work with large companies. Large companies generally want freedom of access. Again, with the physical science companies they typically want non-exclusive licenses, but we are finding that the pharmaceutical industry, also, wants non-exclusive licenses to tools.

We have generically an easier time working in the life sciences with small companies and that was pretty much

through the 1980s.

We are now seeing a lot more activity in the physical sciences and small companies where we are seeing a lot of the dot coms and the Googles and the wireless telecommunications companies interested in starting and taking an exclusive license so they can raise capital.

We are seeing a tiny bit more activity in physical sciences in large companies and we are seeing kind of a general flow of pharmaceutical licenses but typically they still tend to be non-exclusive licenses.

This is another random thought. One of the questions was does technology transfer affect institutional behavior, and I can only talk from my perspective at Stanford.

Basically I would say that we suffer and benefit from benign neglect. Basically the administration doesn't know about the deals beforehand. They don't know the financial terms. They don't know what deals we are doing or what companies we are working with, and so it is a little bit hard to say that the institutional behavior would be changed by something they don't even know about.

The royalty revenue, the next point for us doesn't even rise to the level of Stanford's annual report and actually in the University of Pennsylvania Provost's talk technology licensing fell into miscellaneous if you recall,

this unspecified group. So, in reality ours probably falls into that category, but it includes many, many other sources of revenue, and so basically although we are a very old office and we do bring in good royalty income it doesn't rise to the level of much notice within the university's central structure.

Conflict of interest review for us is independent of the deal. We don't tell the reviewers what the financial deal looks like, and so the conflict of interest review is really quite independent of the potential for royalty revenue. They will know that it is an exclusive or non-exclusive license and basically we tell them it is more or less a standard deal or not, but they are not looking at this as a million dollar deal or a \$10,000 deal when they are looking at a conflict of interest review process.

Lastly I know that the word "equity" makes everyone jump and that we are going to change our behavior because of equity. Again, every university handles their equity differently. At Stanford we sell our equity when it is liquidatable and so we don't really make a judgment. We are not trying to maximize equity. We are not trying to optimize it even. In this downturn of the stock market we are going to be just selling when we can, regardless.

Part of the complexity of our work is that we have so many constituents. Again, we all have inventors. There

are faculty inventors, student inventors and staff inventors, and they don't all think alike, and they don't come from the same page. Many faculty may be co-inventors and don't even agree on how we should license the technology.

Faculty and students have their issues. Sometimes we have students who want to start a company where the faculty thinks that starting a company isn't the right mechanism for transferring that particular technology.

So, we have a lot of differing points of view, even among inventors. You cannot look at them as one homogenous group. The university administration also, for us is not a homogeneous group. In our particular royalty-sharing scheme inventors get one-third. The departments get one-third, and the school gets one-third, and so they will look at various deals in different ways.

It turns out that our equity policy says that departments and schools do not get a share of equity for conflict of interest reasons, and so there is a little bit of a feeling that our office should not take equity because this department and school will not see equity.

We are in the position of trying to make the best technology transfer decision for the university but I wanted to point out that the various constituents even in the university administration look differently upon the

particular deal.

The government. In my opinion the government is slightly schizophrenic. They want us to do technology transfer. Under Bayh-Dole we have very clear guidelines on what we should do, but if we do it a little bit too well maybe make a little bit too much money maybe they will want some of it. The government wants us to do the best for the particular technology. They obviously want us to do what we think is right for research tools. I think the debate is very interesting and I think that the government doesn't quite know sometimes. It is very fine line between doing what is right for the particular technology or not.

So, the government itself is a mixed bag. Second and lastly the companies. The companies in some ways are our clients or they are recipients of technology transfer. The large companies as I mentioned earlier would like freedom of access generally. They would like tools to be made available.

Some of them want exclusive licenses but some don't at all. The small companies primarily would like exclusive licenses but in order for the technology to diffuse as broadly as possible the small company will generally want to aspire to become a large company, and their view on technology will change as the company evolves and then certainly start-ups usually want an exclusive

license. Anything that says, "Exclusivity" helps them raise money, but the reality is on a start-up company many times they will not end up developing the particular technology that they started the company around and so their view of the technology transfer process will change as they evolve their own goals.

Is there evidence of success? Certainly there is the financial picture and that is the easiest to measure and I actually am a proponent of looking at it although I think it is only one part of the picture.

I wanted to talk to you about Stanford. Stanford is 31 years old. We have generated accumulative royalty receipt of \$455 million. The DNA case was our biggest case. That generated \$255 million and it was shared with University of California. Look at the equity picture. We had equity in about 95 companies, probably now around 70, but we have only cashed out about 20 million. So, in the big picture at Stanford in a very entrepreneurial environment and certainly it is not the same everywhere we have seen that equity is not a big player in the royalty scheme.

In our 31 years we have seen around 4500 disclosures. I really want you to take home the message that if Cohen-Boyer is our biggest hit which it has been to date, our next biggest one is only around \$27 million then one out of 4500 technologies that we have seen is a big winner. It

is a high-risk game, and it is not an easy job.

The reality is almost 50 percent of our licenses produce less than \$10,000 a year. So, yes there is some financial success but you have to look below the surface to see the real picture.

So, I said, "Yes, there is some evidence, but it is complicated." One of the advocates of Bayh-Dole would say or the advocates of Bayh-Dole would say, "Products on the market; start-up activities are good evidence of success, enhanced university-industry relations as we have more sponsored research for example, and economic development."

So, you have seen these statistics, innovation, too. You have seen these statistics, again very quickly, products are coming on the marketplace through Bayh-Dole; new companies are being formed; license revenue is being created; lots of disclosures and lots of sponsored research, but by and large I say, "Is there evidence of success?" I think it really depends on where you are coming from and what the expectations are. so, I think it is not a simple answer. I would encourage you to look at everything with not a grain of salt but look beyond the surface, and I would say that the bottom line, too, is that the universities want to do the right thing. We feel that we want to promote technology transfer for the public good, and when you look at individual controversial cases you do have to look at the

actual story to find out whether in fact it was a success or not.

Thank you.

(Applause.)

DR. HALL; Thanks to Katharine Ku for her presentation and now we will move on to the view from industry.

Don Felch who is the manager of growth and external collaborations at UOP, Inc., and what about your slide situation?

DR. FELCH: They are right here. I am not high tech with regard to slides, but I am high tech for mobileness.

UOP is not University Pacifica. It used to be Universal Oil Products. I represent the industrial point of view, but today I am really going to represent an organization called ERDN which is the External Research Directors' Network, and that is a group of about 40 or 50 organizations, and we meet twice a year, and we discuss issues on technology transfer. So, it is a very small version of AUTM, you know? So, we are the other guys, and we just finished working on a paper which is called Industry-University Intellectual Property, and I have brought about 30 copies not thinking I would be in this huge auditorium here and if you are interested I will put them

out in the back at the end of the talk, and also if you aren't lucky enough to get one I would be more than happy to arrange to see that you get one.

So, the presentation really is based on some of the discussions we have had at the ERDN and will give you I think a good perspective of how a group of people involved in this business from industry feel about this topic.

A very quick agenda, the first 10 slides, and I only have 13 are going to go pretty fast, but then we will move on. I want to talk about the benefits of working together, intellectual property scenarios, some commercialization steps, other issues and conclusions, and the reason I am presenting this is because these are issues I think that cause difficulty in our relationships and I hope at the end of this meeting that you will have our perspective and perhaps by having this open discussion and dialogue and you can get me up at the stage after the meeting or during the discussion with some pointed questions, but the benefits I think industrial and the strongest one you are going to hear and you heard it several times is competitive advantage. Why would we want to work with you? Because we think there might be some benefit. We view that there are sources of employees, long term and short term. We like your research results. We think it is an extension of our technical competencies because we think we

have good scientists, too, and we can maybe participate in some cutting edge research.

From a university point of view, this is our view of your view, we have an opportunity to give you relevant sponsored research projects so you can then get some industrial input of what might be valuable. There is, also, funding. That is probably the least interesting to you people. Equipment donations student professorial employment; we employ students during the summer; we employ them while we are doing research, consulting and basically sharing knowledge.

So, you see we have a lot of really good strong common things and there are lots of reasons why we should work together. This is our view of major roles. We are in business to provide goods and services, capitalize on new ideas, provide employment opportunities and make a profit. Now, there is a dirty word, but we actually enjoy that and right now that has been a struggle for a lot of industrial organizations.

Our view of your view is educate our society, train new scientists and engineers, continue beyond leading edge. I think it is very important that you are on the leading edge. We offer modern equipment and facilities, and we want you to offer graduates that we want. So, we are not completely altruistic.

We think you have a tremendous value to bring to us. We like the research and general dissemination of knowledge. We will talk about publications in a couple of minutes because that is just a tiny issue, really. I don't think industry really objects to publication. So, here is the word "competitive" advantage again.

To be a successful relationship there needs to be an increase in value from the relationship for both parties. From the viewpoint of industry that translates into competitive advantage as a major driving force.

You probably wonder who made that quote up. I did. So, now we are getting to the nitty gritty, the importance of intellectual property, and from our perspective competitive advantage shows up. It is a building block for additional IP and now we are going to get into the next couple of slides that talk about ownership because we like to have starting IP, but we want to build because in my business we license technology to the refining petrochemical industries. We like to be able to take some intellectual property and build and build and build because we have our own scientists, and we have our own licensing people and our own patent lawyers.

It is a part of the oil company's strategy from concept to sales and it is a part of the portfolio. So, intellectual property is not just all the research. It is

embedded in the whole organization the salespeople, the marketing people, the engineering department and all these people.

From a university perspective we have potential future compensation. That is royalties. Prestige. That came up in an earlier presentation and potential spinoff companies. So, I am not saying anything new there.

So, here is probably the stinger of all the slides. I am going to go through five intellectual property arrangements, and they are listed according to the number of collaborative opportunities, and one of the things I want to stress before I go down this slide, so don't be looking at; close your eyes and I will talk to you, is that one of the things I want to stress is does IP inhibit the number of opportunities by having strong demands on industry of what you want? Are you getting as many collaborative opportunities as possible? Are you maximizing the number of hits, and I think it is a very important point because I can tell you from an industrial point of view there are things we just walk from because of the intellectual property issues. Now, not everyone has that, but I can assure that that has happened.

So, the other thing I think we want to consider as we go down this list is we have seen tremendous money being made on some very few projects, and you will notice that the

money being made is made by some of the very great universities in this country.

There are lots of other universities in this country, and there are lots of other universities in the world, too, who should participate somewhat in this process, particularly the US universities going for university money. So, the smaller organizations should participate in opportunities for their students and their professors to grow and contribute to society.

So, that being said, thinking I am that altruistic, No. 1, is I want to own the IP. Now, that sounds kind of counter intuitive, but the reason I want to own it is that gives me flexibility to build off it a little bit easier, and we will talk about some of the awkwardness if I don't own it in a couple of minutes.

So, that can be a barrier, but the most important part is I want rights to it. In the organization I am in I like exclusive rights, but there are other opportunities. So, industry owns IP that allows the university to continue to develop for research purposes only. That means the graduate students, professors can continue on and it also helps build a stronger relationship because we are kind of locked together arm in arm.

The third one is the university owns the IP, but industry has exclusive rights. The fourth one university

owns the IP but the business has exclusive rights in a narrow field of use. Now, these are all appropriate. Every organization has probably done all of these five actually. So, I am not saying that each one is exclusive of the other, but on the relative value to industry that is kind of an order of the value which I would place on it, and the last one is the university owns the IP but offers technology non-exclusive royalty free, and that is only valuable for very basic research where we know we can build off that to come to some commercialization product. Consortiums, for example, are an opportunity for that. Some companies don't view it as quite as valuable as to have exclusive rights, but it has to be very, very basic research to have a value to industry.

Here is just a simple little model. You see I cannot use a PowerPoint very well because I cannot get the boxes lined up but this is kind of how we view an industrial model. We have intellectual property. We want a proprietary position. Some kind of competitive advantage comes out of that proprietary position. We get a unique product innovation and acceptance in the marketplace and each one of those has some time and risk involved.

Now, this is one of the unique things. Everybody wants to be involved in this, and everybody wants a piece of it, but the word "risk" is kind of a scary thing because

industry basically takes the risk.

So, I have got eight things, the idea generation, develop design testing, market and sales, start-up, initial use, process acceptance and repeat sales and those are kind of time lines and that time line for our industry can be 7 to 10 years long, and you heard good examples here that that is not incompatible with some of the industry observations.

University costs are usually in the idea generation phase and then we pay some of that even though it was pointed out that I don't pay the full load but I pay a lot more after that I can assure you, up to the first sale, and so one of the issues that comes up is where do we set the royalty rate. Well, the university did the work. I want a royalty. Here is the royalty rate, and I have got all this future to look at which is very uncertain and fraught with some difficulty as Katharine pointed out, one out of 4500 for that.

So, what we want to do is have some reasonable basis on which to negotiate with you, and so each university has a different negotiating strategy. Some say, "Here it is. Here is the deal." Some are willing to negotiate with you, but I think you need to take some of these ideas into consideration. Which party initiated the idea? If we come to the university with an idea and want some contract research that has a value. Just the idea itself has a value.

Who is contributing financially has a value. Technically we contribute technically too, in a lot of cases.

Cost of overall development program, cost to bring it to market, and the risk; who pays for the failures? We look at the big moneymakers up there, \$255 billion, a million or jillion(?) dollars but what about the ones that didn't work? Who paid for that? You know the answer to that. So, that is a rhetorical question as I learned when I was younger.

Who should file the patents and this is where I think the issue of ownership has a value. Industry we have full-time experienced staff unless it is a very small company. We are focused on certain market segments. We can select the proper filing and universities usually ask us to do that anyway and to pay for it.

We work with the people who are developing the use and the market. Now, that might not seem important on simple things like some patent. There are lots of patents written in a way to capture the value to the market, and we know where the technology can be applied for similar opportunities and that is another reason we like ownership because if in my company we make catalysts, if I can apply this technology to catalyst A and it looks like I can apply it to catalyst B and then catalyst C and we can get an additional intellectual property it is a lot easier.

Our observation of the university and again it is our perspective; so don't be offended because I could be wrong you know, they have experienced staff that is spread thinly and the communication between scientists and IP personnel is more distant.

In our organization the communications is real easy. The science is not connected to its market because their market is industry. We are the market, and they do not foreign file due to costs.

So, these are just barriers that come up when we have discussions and I think that they need to be addressed so that these issues can be more easily handled.

Other issues, patents, balanced publication time with IP. A lot of them say, "Gee, we will give you 30 days to look at it." You cannot do anything in 30 days nowadays. So, that is a very tough requirement. Who pays? Who owns? Who maintains? How do we keep informed of the status? You own a patent. How do I know 5 years from now if you are maintaining that patent? How do I know who is paying for it? What is the status of that and foreign prominence. Background rights is an issue that comes up because you may have a great patent but you don't own anything that is behind it, and if we want to buy it we need to know that and somebody has to do the work to find that out.

Here is my last slide. So, I hope I didn't take up

too much of your time. Here are some conclusions. Benefits to universities. I think we have a lot of benefits working together and I think we should do more of it.

We have a driving force. It is a word that has not come out a lot. Competitive advantage is what we are looking for. We should have strong ownership rights when we pay for the research. I know that was contradicted there but the road to commercialization is long, twisted and risky and who bears the risk and who pays for failures, and maintenance and patent strategy should be done by industry because I think we actually do have a distinct advantage and that is another reason why we ought to work together and timing of publication should consider the overall IP requirements and that communication is really difficult.

So, those are some thoughts and some ideas and I presented it in this form other than some of the questions because these issues here prevent even getting to those questions there, and that is why I presented it that way

So, thank you very much for this opportunity. I hope you have a great day and hope we can answer some more questions for you.

Thanks.

(Applause.)

DR. HALL: So, we are going to move on to Jack Tribble who is the Patent Counsel from Merck & Co., for

another view from industry.

DR. TRIBBLE: I will bring a little different perspective to this. Looking at technology transfer associated with a major pharmaceutical company I think takes a little different light than we just heard for the chemical companies and from a number of universities or other academic institutions.

As background let me state that Merck is a leading research-driven pharmaceutical and vaccine company, over 40 million in revenue in 2000, more than half from the sales of medicines and vaccines.

Merck has introduced 16 new products worldwide in the last 5 years. The research and development budget for 2000 was over \$2.3 billion, almost 11.2 percent of sales of Merck pharmaceuticals and vaccines, a relatively large company with a diverse group of products.

Now, the budget essentially has to take care of research and development and for those of you who may have been keeping up with the current literature even though the FDA is supposed to be speeding up the process for drug approval part of that seems to be larger clinical trials and with the increase in size of clinical trials we have increased costs so that essentially the budget covers the high cost of preclinical and clinical R&D and really there is not what I would say ample amount of research budget to

do all of the basic research that a large pharmaceutical company might need to do.

Now, by basic research I will refer to that as the research basic or exploratory that is conducted by academic research laboratories and possibly small or medium-size biotech companies, and keeping in mind it takes 200 to 500 million dollars and about 10 to 12 years to bring a pharmaceutical or a vaccine to market.

So, then how does the pharmaceutical industry access basic research? I think most of you in the room understand that, and I hope you will bear with me. I will go through or take notice of a 1999 Business Week article by Tom McCullough, CEO of AstraZenica(?) in his discussion of why AstraZenica had 600 collaborations in 1999 between his firm, the biotech industry and the academic I guess industry if you would worldwide.

The one thing to note I think, and this is something I think academic institutions need to look at, also, is that 99 percent of everything exciting that happens will happen outside of your own research labs, a very interesting piece of information.

Merck does a lot of research, but 99 percent of research worldwide is outside of our laboratories. I think you could say that for any academic institution, any other pharmaceutical company, and in 1998 more than half of the

compounds in clinical trials originated outside of the labs for the top 20 pharmaceutical companies, a lot of licensing if you will or technology transfer associated with that.

Pharmaceutical companies and biotechnology companies generally strengthen their internal R&D capabilities by alliances with other pharmaceutical companies, biotech and information companies and academic institutions. These may include new product candidates and programs, new technology platforms for research and/or discovery, improvements or enhancements in existing programs and enhanced recruitment of academic scientists into the industry.

Indeed in 2000 one-third of Merck's products came from external research and licensing collaborations. So, it is an extremely important part of our business and the entire pharmaceutical industry.

Now, when at least I look at technology transfer it is the ability of information to flow from the generator of the information to the users of the information and keeping in mind any one piece of scientific discovery can stimulate many other laboratories, many other individuals to come up and build on that and push the science forward.

We need that in the pharmaceutical industry. We need it in academia. It is something that the flow has to go both ways. Now, we have heard a couple of comments on

publications. Publications are extremely important for the free flow of information between academic institutions. They are important for the flow of information to private companies and I will, also, comment that Merck has taken a position and has for many, many years that major and some minor information that is generated within the corporation and possibly most of the scientific information that is generated within the corporation flows out of the corporation by publication.

Merck publishes probably more than any other pharmaceutical company that I am aware of so that we have information flowing back and forth. There may be a period of time in which Don talked about where you cannot publish until you have taken care of your intellectual property. We have taken that into account on how we do business.

We prioritize inventions within Merck. If it is an invention that has a high likelihood to become a product we actually will file that in 15 working days or less. Many of these inventions are filed within 2 or 3 days. So, it can be done if it has to be.

When I look at the relationship between a corporation like Merck and the academic community there are many types of information transfers. Now, we heard a comment just I think two speakers ago relating to material transfer agreements. These are not high on the list of tech transfer

offices. These are extremely high on the list of individual investigators. The information has to flow.

Now, the information flows both ways between pharmaceutical companies and at least Merck and academics. We process probably around 4000 material transfer agreements per year, probably equal numbers coming in as going out and one of the problems we have is that, and it is going to depend upon the efficiency and savvy of tech transfer offices, the time it takes to get materials out to an academic researcher or get materials in to a Merck scientist. Those tech transfer offices that understand that these should be done quickly because science is waiting for it; it is important; you can do these in a matter of weeks, many of them in a matter of days.

We have had other situations where it may take 3 months or more for a material transfer agreement to be completed. It has to be, depending upon the institution it may have to be negotiated multiple times and it can at both ends of the transfer hold up basic research for some period of time.

Merck does other agreements, some of which have been discussed today. One that was not is we may do fee-for-service agreements with certain academic laboratories where we need something done specifically on a one-time or few-times basis. These will be simply a fee for the research;

since they are individual or short segments of research generally not publishable either party can use the information. It may be a situation where the material is sent to the university, coded so that they run the assays; they get us the information back; we can move forward.

We do a number of collaborations. Some of these are major collaborations. Some of these are small. The collaboration agreements are generally those between Merck and an individual laboratory or an individual researcher. We do and have funded larger entities at academic institutions in which large sums of money will be given to a specific lab or group of labs for a set period of time, both for the generation of information in which the results of that are owned by the university and with the development of students and scientists that could potentially be employees of Merck.

We have done consulting agreements. We have done basic license agreements for patent licenses where there is no know-how transferred simply Merck needs access to a certain piece of technology for research purposes. We have agreements for clinical trials, and there are probably some others. That is enough, I think.

So, we run through the whole gamut of types of agreements that we do, and the interactions that we have with academic institutions.

Now, I think I may have a slightly different view

on flow of information, transfer of information and it may be coming from my many years ago as a scientist, but I think the information flows relatively freely. Scientists publish whether they are in academia, whether they are in industry. Those publications are available to anyone who wants to read them.

The flow is constricted when as an example a pharmaceutical company or a scientist sees some new methodology. That methodology is something that would enhance what they are doing in the laboratories. They read the publication. They sit down and they do it. Okay? They start building on that and as they build on that they are adding value to it, but the initial observation, lo and behold a patent application was filed on it. Okay, we are now probably 18 months down the road with the research program. We notice in our continuing review of publications of patent applications that have been filed; to date those are generally outside of the US; soon it will be inside the US, but this information that started a small part of a program a patent application has been filed. So now we have to make a decision. Can we get a license to it? Is it basic information, a research tool and will licenses be available for a reasonable price? Maybe it is a research tool and the academic institution has over valued this and they say, "Okay, we will let you have it for a very

reasonable up front sum, but we want a 4 percent royalty because but for this you would have never had the program."

We have actually stopped programs because we couldn't get access to research tools. I will, also, say that in many situations one can design around research tools. I think there are a number of instances where someone has found a better way of doing something. We are quite innovative, and we are able to expand the technology so that they could have another way of doing that.

Now, one of the questions I think that we were supposed to consider for this group was the effect on transfer of information, flow of information if there were no patent applications or patents that would impede the flow.

Let me just give you an anecdotal instance on this, and I will refer to the Merck gene index project which was actually a collaboration put together by Merck, funded by Merck and the goal was to identify expressed sequence tags, those segments of human DNA that are expressed as proteins and to get this done rapidly and have it distributed within the scientific community as quickly as possible.

This was in response to first NIH and then some private companies that were founded on the concept that they would identify all of the ESTs. They would file patent

applications on them, and they wouldn't be available for the scientific community.

So, in the project itself I think Lawrence Livermore Laboratory was involved in clone arraying. University of Washington was involved in sequencing, University of Pennsylvania in clone tracking and informatics and over a relatively short period of time a very large number of ESTs were actually placed in the public domain free to any scientist who wished to use it. So, here is a situation where the information was not made available to Merck prior to entering into the database. It was put out in the databases and was available for everyone.

I believe, and I think there are a number of others that believe that because of that and getting that information out there, there was a mushroom effect in the number of full length genes, cDNAs that were identified and most of which have had patent applications filed on them, but I think it was a large stimulus for the biotech industry.

A couple of other things. We have heard about the sums of money that Stanford and University of California made on the Cohen-Boyer patents. Merck happened to be I think the institution that developed a biotech product first and brought it to the market. This was our recombovax(?). Consequently we made a great investment in the two academic

institutions. The other part of the recombo-vax, the hepatitis B vaccine is also illustrative of our relationship with academics.

In the late 1970s Merck did not have the technology in house to actually go out and identify that part of the hepatitis B virus that could be used as a vaccine. So, we collaborated with the University of California, Bill Rutter's lab and the university was able to isolate, purify and express the hepatitis B surface antigen gene which made a particular protein that could then be used as a vaccine entity.

The agreement was royalty bearing agreement, milestones in royalties. The patents are still in effect, and I would say at least from my point of view that was probably a blockbuster. Many of the things we do do not rise to that level of sales.

Another quick point, and I have talked a number of times on this issue, and that is the effect of IP on upstream materials used in the pharmaceutical and biotech industry. The patenting of genes, the patenting of processes, assays, other processes I think probably does have an effect. We won't know that probably for 10 years, but I think there is going to be an effect on the downstream products.

A brief example, if you identify a gene product

that can be used as a target for a disease state in which you can start looking for small molecules that will interact with that target and ameliorate the disease, in order to do that you will have to have a vast array of other molecules that you can screen against, other targets other than the one you want to hit specifically because you want to have a product that is highly specific to a single target so that in order to put together an array of counter screening materials you may have to go out and get a large number of licenses to do this. I think that has had some impediment on drug discovery. It could have an economic impact on drug discovery so that I will end with the comment that I think Bayh-Dole actually states that academic institutions can commercialize those materials that are products. I, also believe that Bayh-Dole can be interpreted to say that the commercialization may be simply the transfer of research tools for reasonable prices to the entire scientific community so that research can go on at the speed it needs to go, and with that I will close, and thank you very much.

(Applause.)

DR. HALL: Thank you, Dr. Tribble.

Now, I am going to open it up to discussion from the floor, but before I do I want to emphasize the fact that this session is being Web cast and encourage people who want to ask questions or make statements to identify themselves

before they do so so that the Web cast audience has some idea, and we have some idea who they are.

I can see Pam. So, we will let Pam Samuelson start. Do you want to kick off?

DR. SAMUELSON: Okay. I have one I think very quick question for Katharine Ku and then a second question which may be of broader interest. The first question is you talked about 47 percent of the patent licenses as producing less than \$10,000 a year in revenues. My question as to that is what effect does that have on decisions about renewals of patents given that you don't get the sort of patent for 20 years; you actually have to renew it and so are there patents that you let lapse because of the lack of income and then the broader question is that I have the impression from listening to the presentations particularly by the Lucent Technologies person that the goal of industry is often to get as many patents as possible and they are not making decisions about which ones to file patent applications for based on will this in fact be effectively commercializable. My sort of intuition is that universities may try to make more of a decision based on is this innovation going to be commercializable and if I am wrong about that I would like to know, but I mean it may be that you say only one out of 4400 is a big hit, but I assume that when you were looking at those 4400 that you were hoping

that there were going to be more hits than one, and so, my sense is you are not trying to compile a huge portfolio to use in the way that Lucent Technologies is doing which is the bigger the portfolio the more revenues that they can get just for the portfolio.

So, could you and others address those questions?

DR. KU: I will go first. We are very selective about what we patent. We want to patent those things that we think will be commercialized in the 20-year period. The reality is many of our technologies come to the marketplace in that last 5 to 3 years before the patent expires.

So, we do keep our eye on the financial picture which means that there is a bit of emphasis on dropping patents that aren't going to produce revenues.

DR. FELCH: I guess we should go back to the screening. We set our in our business MOIs and the ratio of MOIs to patents is about seven to one. So, we have seven or eight hundred good ideas for every hundred patents, and so there is the first preliminary screening and then upon renewal we go back and see are we going to make any money, not so much for what has happened. Perhaps we have not made any money, but we would move forward and say, "Is there still a future potential there and then make a decision on whether to renew.

DR. HALL: Anybody else want to say anything on

this subject?

DR. FINNEGAN: Do you want me to speak to this?

DR. HALL: That might be good because I had a comment on that last question if you don't.

DR. FINNEGAN: As far as Lucent is concerned at one time when we first started about 6 years ago to start the engine up to get into the top five we did not carefully filter the incoming disclosures, but we do today. So, we categorize our patents into commercial potential and then from that we drop out the disclosures that we don't feel like putting into the pipe. So, we do manage it for expenses and also the maintenance as well aggressively.

DR. HALL: That was Jim Finnegan from Lucent Technologies. My comment on this is just a general one that I suspect that what you are hearing is partly the difference between the physical science based industries and the life science based industries, and I won't go into details because you already know quite well that patents are used because of what was alluded to earlier, the many, many patents in individual products. They are used in a cross-licensing way much more heavily in the physical, particularly in the electronics and semiconductor sectors. So, the idea of having lots of patents I think arises from that type of activity, and I am sure there are other people here who might even want to make comments on that subject.

I can see Wes Cohen already thinking, but let us go on.

DR. KU: I wanted to add a couple of kind of statistics. We see, however many disclosures we see. We file patents on about 40 percent, and we license about half of those, and there is not a one-to-one correlation between patents and licensing because we do license a lot of things that are not patented.

The other statistic i wanted to throw out is we do try to categorize our inventions by A, B and C, A, being the best, and we would say that 10 percent of them are about A's and then almost 40 percent are B's and the rest are C's. So, we do have the pyramid effect, too.

DR. HALL: Why don't we go to the other microphone? I am going to go forward and then back, I think. That is going to be the simplest.

Could you identify yourself?

DR. HUGHES : Owen Hughes from Pfizer. I had a question regarding the research tool versus immediately commercializable invention distinction. I realize it is a little fuzzy and perhaps for many it is very fuzzy, but in the case of research tools where presumably you are not waiting years and years for people to make use of your invention and possibly reap a royalty from it, does that suggest a business model for licensing that would favor

parameters such as quick, cheap and easy versus few, expensive and controversial?

DR. KU: I think you are aimed at me, again. Research tools. Yes, we actually are perfectly fine about licensing them non-exclusively. We have one really hot research tool which is a software program and the pricing is \$10,000 sign-up, \$10,000 a year, click, wrap and then print out the license agreement on the Web. So, the transaction costs are very, very minimal.

We are trying to do that with other research tools. I think the problem for us is often the definition. I know that the pharmaceutical industry feels that targets are research tools, and I think early on we didn't necessarily see targets as a research tool, and then assays we usually make available just on a yearly basis, a user fee kind of thing.

DR. HALL: Anybody else want to comment? No.

So, why don't I move to the back there?

DR. ELLIOT: I am Russell Elliot. I am with Sandia National Laboratories, and I noticed in Don Felch's presentation, Don, you mentioned several different licensing arrangements ranging from broad exclusive to narrow exclusive and then you said, "Non-exclusive royalty-free." Does that suggest that there isn't any room for non-exclusive royalty bearing?

(Laughter.)

DR. FELCH: No, it doesn't, but there are about 20 more you could list there and just for brevity I said that we would go all the way to the bottom I guess is the way I look at it. No, non-exclusive royalty bearing is a possibility and frequently they sometimes come out of consortiums also or other types of joint development work.

DR. HALL: Okay, we will switch over here.

MR. WALLACH: My name is Steven Wallach with the law firm of Pennie and Edmonds. My question is for Ms. Ku, at least initially. Mr. Felch identified some industry recommendations such as industry should own the rights and prosecute the patent and have exclusive licenses. When would you disagree with those recommendations?

DR. KU: We generally never give title to the company, and much of the thinking is you know the use of university assets and the worry about commingling funds. In general the government requires us to take title, and so we feel that if there is some commingling of government funds and industry funds in a particular project which can easily happen then the university should take title. We do give royalty-free licenses, actually for sponsors who sponsor research but generally the policy is not to give exclusive licenses without a royalty attached to it.

DR. TRIBBLE: Let me comment, if I may? There are

times when we will have collaborations where you will have scientists both within the corporation and with the academic institution working together. In that situation you most times will have joint inventions so that you will have a joint application so that there are really no conflicts of interest. Merck will generally pay for the filing of the application. Many times, if not all the time it will be done with an outside firm to reduce any problems that may exist and at some point in time then we will get back together and determine does Merck want an exclusive right in this? Does the university want to maintain it when they transfer it back to them? If Merck has no interest in it, and the university has no interest it will lapse.

DR. HALL: Could I ask both of you, I mean this brings up a question that I have that maybe you can clarify now that you are talking about joint assignment of rights, if I am hearing you correctly? I actually recently had occasion to take a look at the patent data, the US PTO assignment data on this subject and discovered that my own university has effectively, I think, no joint assignments in that data, and my own university is the University of California, and Stanford has, I think two or three in 5 years or a very small, really a very small number, and CalTech might have had one. I was looking at the California universities to see what there was there, if there would be

anything interesting in the data, and the answer is very little, and is the reason for that that the records are rather poor because assignments are happening later than they are getting into the US PTO data or is it in fact the case that companies and universities almost never take joint assignment of patents?

DR. TRIBBLE: In many of the situations where you go into some type of arrangement with an academic institution they may already have a patent application filed. You are getting access to that. If it is not a quote, true collaboration then essentially by law you cannot have both parties on there if both parties were not involved with the invention itself.

DR KU: In principle we are fine about joint title, and I think that it might be just a little bit of the data, but I, also, think that they are not always joint inventions that arise out of collaborations even though we intend that there could be.

DR. TRIBBLE: That is another possibility, that certain things may be parceled out during the collaboration that end up being done in one of the partners labs versus the other.

DR. HALL: So, in fact, joint ownership of the IT is rather uncommon in that form of IT.

DR. TRIBBLE: I think it probably is. I can

probably count on one hand the number that we have done.

DR. HALL: That was the impression I receive, but I just wanted to confirm that that was true.

Okay, so, let us move on to the popular microphone over here.

DR. AHMAD: I am Osmad Ahmad. I am with Tiebridge, a local consulting company. I have got two questions, one for Ms. Ku. You mentioned that there is some schizophrenic relationship with the government. You want to sort of know a little bit of elaboration on that, and the second question is for Don Siegel. You talked about inadequate compensation for the Technology Transfer Offices. Are you talking about the structure of the compensation or just the level of the compensation? Are you suggesting that the technology offices should be incentive-wise with the performance of the portfolio or do you have any other further thoughts on that?

DR. KU: The schizophrenia. It is probably part of the business. Again, as I talked about early on, non-exclusive licensing and exclusive licensing have very different outcomes. The government originally encouraged exclusive licensing if it meant technology transfer. Actually exclusive licensing goes hand in hand with the incentives to develop new products, but now they are saying that perhaps we should go more non-exclusive licensing because of the research tools and access issue. So, I think

again the reality is the quote, right decision if there is one is very case specific, and many times, for example, we have technologies which we think are important but no one recognizes it until an exclusive licensee comes forward and then it is years later that the industry says, "Oh, it should have been a non-exclusive license."

My case in point would be the micro array technology that came out of Stanford, very simplistic, simple blotting technology. We sent marketing letters to the whole industry asking them to take a license, exclusive or non-exclusive and no one was interested except an exclusive licensee start-up in which case years later there was some view that maybe this technology should have been licensed non-exclusively and now lots of people are using the technology.

DR. SIEGEL: I was referring not to the level of compensation but to the structure of compensation and specifically the movement towards incentive compensation as some universities are doing.

DR. HALL: Our next questioner?

DR. GOLDSTEIN: My name is Mitchell Goldstein. I am the Director of the Virginia General Assembly's Joint Commission on Technology and Science. Two of the issues that I have heard raised here and two of the issues I have heard in our own state have to do with the money and with

licenses. So, I have got one question directed toward the industry and one directed toward the universities.

For the industry, specifically Mr. Felch, you mentioned that if industry pays, industry should own the intellectual property, but from what I have heard from many of the universities they always pay in some form or another, either through the infrastructure or through the professors, through the graduate students or what have you. So, the question to you is how do you determine whether or not you have paid, and on the flip side to the universities I have heard from industry that their biggest problem is with every license they have got different terms, different definitions for those terms. So, are there any attempts either nationally or in your specific states to standardize terms and do you talk to one another in industry when you determine how to structure a license?

DR. FELCH: On your first question we know we pay because we have an invoice.

(Laughter.)

DR. FELCH: So, that is how we know we paid. Now, it is almost impossible for us to determine whether we are paying full load, half load, three-quarters load based on -- I mean the university sets the rates and sometimes they are somewhat negotiated. So, if they are losing 20 percent or 10 percent or whatever the number was quoted earlier on every

research project, then that is probably an accounting issue that needs to be brought up.

Some of the things that always come up between industry and the universities is overhead. Some industries object to overhead. We have overhead. So, I don't have a problem with overhead as long as it is rational and reasonable. So, we should pay overhead, and the issue that I think a lot of -- you know it is interesting who owns the money which I guess is the big issue.

Universities are getting a lot of money outside from government and then they say that that is their money. Well, it is because it was given to them by the government, but if you do an overall economic balance we had to pay for that out of profits and that is another issue. We don't want to go there, do we?

DR. KU: You asked whether there is an effort to go with standard terms. I think it would be very difficult. I think that by definition licensing new technology is new technology and so each time you look at a new technology you value it differently.

We are always working with different companies and where that particular technology fits within the product, also, changes with the particular product. That said, we would like to see some sort of range of license fees for our own office. We certainly wouldn't expect other offices to

follow that. Transgenic mice probably fall in certain categories. Assays fall in another category, therapeutics versus diagnostics, etc., might have some ranges that are traditionally more acceptable.

DR. FELCH: I would like to make just a brief comment, kind of an industrial viewpoint, but industry to industry is everything is negotiable, and so the issue is with regard to universities, too, everything should be somewhat negotiable, and I think that is a really open way to make sure that both people understand the value of the technology that they want transferred and what they are willing to pay for. So, it is kind of an open -- I think having an open situation is better which will lead to different types of agreements. Then I think one of the things we don't put in agreements in some of the negotiations or discussions with the universities is that element of risk. So, some of these things are unknown and some of the things have value, intrinsic value that doesn't show up on any of that, for example, prestige or marketing or using our name with the university, the university using our name to say, "We are really doing some really neat stuff," or your company's name or some other company, and all that should be incorporated, I think, in the overall deal, and that is how we would do business with industry to industry, and I think that is not a bad way to look at it

from industry to university. That is kind of our mentality. I don't know if anybody else agrees.

DR. HALL: Let me make a suggestion here? Part of the problem I am seeing, it is interesting that this panel has settled on the area in its discussion where whenever you talk to academic-industry collaborations this is the area on which they have the difficulty, this IP. It is absolutely this ownership issue.

Now, you showed a slide which I found actually quite helpful even though not for possibly the reason that you showed it which was the slide which has the royalty decision being made after the university has done the research and before a large piece of the development had gone on in industry, okay, which is simplification but still it is a reasonable simplification, and one of the other problems with that from the point of view of writing a contract at that point is that the university, you already know which of the risky projects the university did is the one that is going to pay off. So, at that point it is easy for industry to say, "I don't need to pay for those other projects, the other ones that failed." There are not 4000 but you know, the 1000, the 500 or whatever that didn't work.

On the other hand, you know it is a question of where the uncertainty gets resolved. The uncertainty on

development is yet to be resolved. So, you want to set the royalty to cover the fact that there is actually considerable uncertainty going forward, but if you are going to do that in a sense you have this problem that it is easy not to compensate the university for the uncertainty it faced because that has been resolved already, and I think this is part of where the tension is coming from if you look at cost base. So, this is a problem I throw out for some financial types here, how to work this one out.

Okay, let us go forward to Professor Cohen.

PROF. COHEN: Wes Cohen, Carnegie Mellon

University and this question is directed to Katharine Ku, and there may be other folks in the audience who can address it. As Bronwyn suggested before and as considered by the presentations by Lucent and as well as Katharine patents are used differently in different industries and particularly they tend to be used more typically for bargaining leverage in cross-licensing settings, in say electronics industries which is not the way they tend to be used predominantly in say the drug industry, and those differences in the way they are used and presumably the derivation of value from patents really is a derivation from a portfolio of patents in say electronics whereas that is less the case not altogether not but less the case really in drugs and even in chemicals.

What are opportunities for universities? Why

would they want to patent in these industries where portfolios, bargaining leverage across firms are key and maybe that is why you find a lot less licensing and patenting activity in those domains as distinct from biomed but then I was particularly interested a few years ago when Stanford pooled, it was reported I think in the Chronicle, 400 patents and patent applications with the Yamaha Corporation if I recall in the area of sound synthesis which seemed well, okay. Stanford was going to join with Yamaha and become a part of this game of leveraging and amassing portfolios and trying to benefit from that.

So, my question is what has been the experience with that pooling with Yamaha; is Yamaha using it to their advantage in cross licensing negotiations? Indeed, are there other universities who are pursuing similar distinctive strategies in electronics and related industries and technologies?

DR. KU: My favorite field is actually the physical sciences. I do want to say that we do have some exclusive licenses with physical science companies. We have a huge portfolio of inventions licensed exclusively to Litton because they have been sponsoring research for 15 years. These are in fiberoptic areas, and we are going to see these patents being sublicensed to companies

We, also, have an arrangement with Texas

Instruments, but they acquired our licensee, our exclusive licensee and so, this is in the DSL, digital subscriber line area. So, exclusive licenses in physical sciences do exist and they will pay us royalties. We have an arrangement with Yamaha that was unusual and probably one of a kind. We had about 20 basic patents in a new area of music sound synthesis and they had about 400 patents which we considered to be more improvement patents. So, they might have had the numbers but not the quality, we would say. We pooled them and we have been trying to license them to various companies.

Now, the industry in the music arena is very, very competitive and it turns out that many of the Yamaha patents have to do with their particular format, and their competitors don't want to acquire that particular format. So, we have tried to license it extensively, but I would say that by and large it has been neutral. It is not a great effort of pooling patents and getting everybody to sign up.

I, also, wanted to mention that we had a program. We offered a portfolio program to the physical science industry in the hopes of getting them engaged with us. So, we offered, it was called engineering portfolio on inventions for commercialization. We offered a subscription-like program for essentially \$100,000 a year for 5 years. They could get whatever they wanted in our portfolio that

was available, and that is key. It has to have been available or be available for licensing, and they had a set price, and it was a sweetheart deal, \$200,000 fully paid for any of the technologies that were patented in our portfolio. We wanted to give them incentive to take licenses early. So, we said that if you took a license while the patent was pending it would be only \$100,000. That is a sweetheart deal. We had to do a lot of work internally to be able to make that happen. These are inventions that come out of engineering.

I will tell you we offered it to the community industry at large and two signed up, Intel and HP. So, we have tried to reach out to the physical sciences, but I would say that the response has still been very neutral, if negative. It is hard to license into that arena.

DR. HALL: Could I ask on this one since I did have this example in mind of ag biotech where apparently there were problems or there are problems associated with individual academics having only a piece of what is being licensed and holding up some of the license negotiations because of that because it is the same old problem, very hard to allocate the value across a set of inventors? Do you have this problem? Did you experience this problem with the physical sciences portfolio?

DR. KU: Sure. In the portfolio there might have

been the gem, the one in 4500 winner, but we were willing to take that risk because we thought that in the broader picture it was better to try to engage the industry.

DR. HALL: But I meant in your getting the inventors themselves to sign on.

DR. KU: Our view is that the inventor has input into the licensing strategy but not the final say, and we need to keep in mind the broader picture when we are coming up with a licensing strategy. So, if there was one inventory who didn't want -- they could not decide not to have their patent in the portfolio.

DR. HALL: Okay, that is how you do it.

Let us switch to this microphone for something completely different.

MR. SCANLON: Maybe. I am Bill Scanlon. I am an intellectual property lawyer from Madison, Wisconsin. I will just take this off since it is a little bit short for me. My comment or question is directed to Professor Siegel. One of the points he made was that the staff of technology transfer offices are a critical component to the way the offices work, and whether they work well. That was one of his findings I think. One of the roles that staff necessarily play is making decisions on which invention disclosures should go forward into patent applications, and of course, staff are caught in a sense between a rock and a

hard place because these offices are concerned about how much it costs to operate them. So, they feel they cannot go forward with everything and they cannot and the staff have to make some decisions.

Have you looked at all at the qualifications of staff for resolving which invention disclosure should go forward and which shouldn't, and the premise of my question is that we are dealing here by and large with early stage research, with early stage research with basic research where it is extremely difficult to tell which inventions will turn out to be licensed revenue or other valuable type of thing producing during the 20-year life after a patent application is filed and which will not be.

So, how do these staff deal with that decision-making function, and a related question would be to Katharine Ku, and that is how many in Category C if you look back do you wish you had pursued for patent applications? I mean somebody made a decision that it is going to be in C and you are not going to go forward with the patent application. How many mistakes have you made?

DR. HALL: I am going to take the last question here because I have now noticed that we are having so much fun that we are going to miss lunch. Then let the panelists respond. So, why don't you go ahead here? You seem to be the last person in line.

DR. BERNEMAN: I am standing between us and lunch.

DR. HALL: No, the panelists are standing between us and lunch.

DR. BERNEMAN: First, I am Louis Berneman. I am with Technology Transfer at the University of Pennsylvania. My compliments to the National Academies and STEP. Just for those of us who are doing this on the ground every day to explore these issues at this kind of forum is wonderful.

I was struck just speaking for myself by the tremendous disparities between the successes of the life sciences industries in utilizing collaborations with industry and the reservoir of knowledge created by universities, and the chemical industries and the electronics industries and again speaking just for the University of Pennsylvania we clearly have to learn to do a better job in working with the engineering and electronics people and we need to do that for the chemicals industries and certainly probably with life sciences, but I am wondering if you all would comment on perhaps something you may have learned in terms of how you might use the tremendous successes of the collaboration in life sciences to promote technology development, commercialization, economic benefit for all of us in the chemicals industries and the electronics industries?

DR. HALL: What I would like to ask the panelists

to do is just go in order and answer whatever question they feel inclined to answer briefly.

DR. SIEGEL; I can briefly answer the first question. Unfortunately we didn't look specifically at how they evaluate invention disclosures for patents. We were more interested in how the licensing officers interacted with managers and entrepreneurs. So, we focused more on that. We didn't ask questions about that. I wish we had.

DR. KU: I will follow that. I think staff qualification is the most important and problematic part.

As a manager of a fairly big office I always worry that if we gave the same invention to two different people the outcome would be very different, and I don't know. We haven't done that experiment.

(Laughter.)

DR. KU: But the last thing was are there mistakes there? Sure, there are mistakes, and there are many big winners I am sure we have let go. We basically don't worry about it, but I will "fess" up. One of the technologies that I handled when I was a licensing associate I definitely wanted to drop. It was a tool, a research tool, the use of DHFRA amplification technology to increase yield, and it was a tool. I said, "We are not going to be able to enforce this." We managed to keep that going, and it is one of our higher revenue producers now and so, again, no one is

perfect.

DR. SIEGEL: I can just follow up on that by saying that none of the firms and none of the faculty members that we interviewed ever expressed any reservations about the technical skills of the individuals in the technology transfer office. However, they did express reservations about their business slash marketing skills.

DR. FELCH: With regard to the chemical industry I think that the issue really is what can the market bear a little bit from the point of view that high royalties with a great deal of uncertainty are more difficult for us than on for example, pharmaceuticals or electronics, particularly pharmaceuticals where the margins if they do get a winner can match the one out of 4400.

So, I think what you need to consider is going back to industry-university collaboration and the help in the sponsorship of the government is how can you open up opportunities for more different types of industries; how can you open up the opportunity for more universities, some that aren't the top tier universities but lower tier? They have good researchers. They put out very good graduate students. They have very good professors. They have very good training. We hire people from those smaller universities. It is an opportunity I think that you need to think about so when you make these technology transfers

sound very glowing and very great for them, and they all rush out and set up the technology transfer office. It is maybe not as lucrative for them as perhaps a Stanford or some university of that size and so I am kind of looking. There are lots of ways to do it. Industry has different needs. Every industry has different needs. I went through one through five. Some people like five. Our industry doesn't like five but some people like it for the very basic research. Some people like four because they have a very narrow field. So, they are happy to have agreements in a narrow field because the costs are less and then if you want a broad base it is -- so, different strokes, different folks, and I think that there are good opportunities, and we just need to be flexible on both sides.

DR. HALL: Thank you all.

(Thereupon, 1:20 p.m., a recess was taken until 2:13 p.m., the same day.)

DR. ELLIOTT: Welcome back, everybody. I think I am going to go ahead and get this afternoon's session started because we are running a little bit late.

First, I want to thank our panelists and speakers from this morning because I think we had a very excellent discussion this morning, and I was very pleased to sit and hear what these people had to say.

I, also, want to thank you for your questions at the end of the last session, generating a lot of good discussion.

This afternoon we are going to do two more sessions. The next session will be taking a look at the Effects of Technology Transfer Activities in Patenting and Licensing on Research in the universities and to a certain extent on essentially the academic life or academic atmosphere in the universities.

The last session dealt with getting technology out of the universities and the interaction between industry and universities. Now, we want to take a little closer look at the effect on the universities.

The last session will be looking at the implications of a couple of Supreme Court decisions from a year and one-half or two years ago regarding state sovereign immunity. It is going to be an interesting session.

You may not immediately wonder how that is going to affect academic technology transfer, but I think we will see some issues coming out of it that could.

Without taking any more of your time let me introduce Wes Cohen. Wes is Professor of Economics and Social Sciences in the Department of Social Sciences and Decision Sciences at Carnegie Mellon University and he is going to moderate the next session.

DR. COHEN: Thank you, George. This is really a pleasure to be here, and I would like to thank the Academy and the STEP Board for holding such a wonderfully informative and provocative and useful session today.

Okay, in Session III we will be talking about the effects of patenting and licensing on research in the university looking at several issues, financial implications for university research, looking at the effects of patents and licensing on the resources available to academic researchers including say, information and research tools, the effects on personnel, particularly if one considers the effect of the lure of commercial returns on faculty retention for example.

We will be talking about the communication of research findings from universities to the public and across the researchers themselves, and we will finally be examining the impact of patents and licensing on the character of

research within universities trying to address whether the prospects of the returns to patenting and licensing might diminish university efforts in basic research. Before we move into the panel itself, I would like to provide some broad contextual information emerging from a little bit of work that I have done myself with colleagues Richard Nelson and John Walsh and back at CMU with Richard Florida as well.

First, I would like to consider whether patenting and licensing affects the incentives and behavior, well, the question is to consider whether patenting and licensing affects the incentives and behavior of academics and firms. It is surely useful to understand whether they indeed offer effective protection. In some sense I want to put patents in context and this is partly out of a paper of that title, but let us move to this. What this does is provide responses from industry R&D managers, their responses on a question of the percentage of product innovations for which each of these different means of protecting inventions were considered effective in protecting the competitive advantage due to those inventions.

As you can see the major mechanisms or means employed and thought to be most effective in industry include secrecy, lead time as well as the exploitation of complementary sales and service and complementary manufacturing. Patents, while surely important compared to

these other means of protection might be considered less central to what we might call the appropriability strategies of firms broadly.

Yet, these are aggregate data and they hide an enormous amount of heterogeneity across firms and across industries in particular, and it is important to say particularly in light of this morning and what is ahead that drugs and even medical equipment are very unusual relative to the sample as a whole.

These industries are different. In fact, patents in the drug industry instead of 35 percent being considered as a score for effectiveness it is more like 50 percent on a par in fact with secrecy, lead time and the other mechanisms, medical equipment roughly comparable.

In other words drugs and medical equipment are unusual industries in that regard and more broadly the point is that when we consider the effects of patenting and licensing we should recognize that those effects will not be uniform across fields of science and engineering broadly and surely not across associated industries.

I would like to provide, also, a little bit of context on the question of the possible effects of patenting and licensing on both the nature and character of research and on particularly the communication of research. On the former I think it is useful to realize that basic research

as a percentage of university research has been hanging in there roughly at about two-thirds since around 1980.

That is the aggregate numbers per NSF though while there is no evidence of a shift away at least if one accepts those aggregate numbers, while no evidence of a shift away from basic, there is a shift across fields in those numbers, particularly a sharp movement in recent years toward the biological sciences.

Okay, I think it is useful to, also think about as the session is concerned with the information flows from universities back to industry and one question is what are the key channels through which that information flows back to industry and particularly what role does licensing play in those communication channels and patents particularly in the form of patent disclosures. There as well we did recently collect some original data and I think this puts it in some context and it is very consistent, these results with what we heard from Katharine Ku and Jack Tribble this morning that if you look, well, let me tell you what the scoring scale is.

These are the percent of respondents across the manufacturing sector scoring each of these channels of information flow, scoring them moderately important or higher to their R&D activities.

You see publications, informal information

exchange, public meetings and conferences are the dominant, particularly publications. The traditional channels of open public sciences surely dominate.

Okay, patents and particularly licenses as you can see are pretty well near the bottom of the list. Again, drugs are unusual here. The score for drugs on patents rather than 18 percent for the drug industry it is on the order of 50 percent. Again, drugs is an unusual industry. I think we can say that the biomedical area is rather different broadly in this regard from most of the rest of the industries in the manufacturing sector.

One thing these data do not address. They address how useful are these channels with regard to the content of information that is conveyed say in patents, licenses, etc.

What we are not addressing here is the incentive effects associated with patents and licenses. We are agnostic. It could well be the case that while licenses and patents don't convey key content that perhaps they provide important incentives for the research to be undertaken. That is clearly a question that others today, earlier and later today are trying to address.

Now, is there any evidence that patents and licensing are related to restrictions on the disclosure of research, of university research in particular? Some evidence that I have gathered with Richard Florida sometime

ago now is not evidence on the restrictions associated with patents and licensing but rather is evidence related to the deepening of ties between universities and industry reflected in the formation of university-industry cooperative research centers and efforts.

The experience of these UIRCs, University-Industry Research Centers suggests that in fact universities have been willing to accept restrictions on the flow of information. We find, for example, that these centers allow policies essentially restricting the flow of information between the centers and staff at the centers and faculty and staff at other universities. Roughly almost one-third of them will permit such restrictions, and for that fraction of those centers that embrace the mission of improving industries, products and processes that fraction is even larger. That is roughly, and we are talking about numbers of 500 centers and here we are now talking about one-quarter of those. Forty-six percent of that quarter will permit such restrictions.

Similarly with regard to restrictions in the form of a deletion of information from either scientific reports or manuscripts again we find 35 percent of the centers permit such deletion, and that was of concern to us when we discovered that some years ago, and that number rises to the extent that again the centers embrace more strongly the

mission of improving industry's products and processes.

Now, why is that important other than on the surface? It is important because recall that the most important channels for the flow of information from universities to industry are just those most public channels, publications, conferences and meetings and what such policies do is raise the possibility certainly of what you might think of as a tragedy of the commons that each firm which has an association with a center in its own interests may try to push for policies restricting the information flow but in the process will in turn affect the information available to industry broadly through those most important channels.

There is though and again these data were collected in the early nineties, things may have changed, and I have a question, and I would be curious to see if the panelists or other here today could address this. Perhaps this was in the era when universities weren't patenting that aggressively and perhaps patents may, in fact, if secrecy and disclosure restriction is the alternative, it is conceivable that patents actually can enable such flows by assuring the firms that protection is there in some form. So are patents really enabling to any degree with regard to those flows?

With that, I would like to introduce our speakers.

We will be hearing today from Marie Thursby who is a professor at the Krannert School of Management at Purdue. We will then hear from Eugene Bauer who is the Vice President for the Medical Center and Dean of Stanford's Medical School and we will hear then from Joan Leonard who is the Vice President and General Counsel at the Howard Hughes Medical Institute and with that I would first like to introduce Professor Thursby, from Purdue.

DR. THURSBY: I don't now if this came out dark enough. Einstein is supposed to be in the background.

Thank you, Wes. It is a pleasure to be here. I am going to focus on three of the questions that were put to us.

The first is has licensing increased sponsored research to universities. A second is how has it affected knowledge sharing and the use of research, and then finally, the question of have the incentives created by the Bayh-Dole Act diverted faculty in terms of their research agenda, and my focus in all three is going to be looking at what we know and what we don't know.

My view given my own state of knowledge is that we know a little about the first question. We know a little more about the second, and we actually know despite a number of us looking at it very little about the last question.

Looking at the first, license revenue and does it

generate sponsored research, let me give you two pieces of evidence? In 1994, the AUTM survey document started asking respondents the amount of sponsored research funds associated with a license executed that year. What you see in the figure is that revenue as a percent of all license funds coming into the university, taking out patent reimbursement.

If you look at it for the first 3 years you are looking at a little over 30 percent and then there is a drop to 20 percent roughly in the next 3 years.

Interesting questions are what fields are affected by that sponsored research; is the change that we see there spurious or is that a significant change? On my graph the scale doesn't make it look very large, but that is a drop by one-third in the last 3 years of sponsored research coming in.

Another piece of evidence comes from a survey that Jerry Thursby, Rich Jinson and I did of 62 US universities and one of the things we asked was the split of royalty income coming into the university. What we get on average in that sample is 41 percent of the revenue goes to the central administration and to the inventor's department. We, also, know from that survey that about one-quarter of the departments allow the inventor to use the funds coming to the department for their research labs. So, again, we know a

little but, but a question is, and I think this is a question that has been discussed in the survey statistics committee of AUTM is should they ask their membership questions about how the funds are used coming into the university.

Okay, turning to the nature of sponsored research, what are its benefits and costs, one of the benefits that is documented that hasn't been mentioned today and it is not associated with licensing per se is that in many cases the applied research that gets done with industry is complementary to the basic research agenda of the scientist.

Ed Mansfield has a wonderful study that goes across a number of fields including physical sciences showing that many times researchers get research ideas from their consulting, and Len Zucker and a number of partners have shown similar complementarities in the biotech area.

Other benefits which others have mentioned today, Maryann among them are access to equipment and data. There are a number of surveys funded by the National Science Foundation done by Bob Morgan and a number of partners that show the benefits to researchers both across the sciences and engineering from industry-sponsored research.

What are the costs? A number of people have mentioned restrictions associated with IP issues. One of those is delay of publication or deletion of materials. West

has mentioned this. David Blumenthal and a number of co-authors have done work in this area, and in my own work Jerry Thursby and I have done a survey of businesses who license from universities, and we have looked at their licensing behavior and their sponsored research behavior.

Of those who sponsor research, 64 percent required a delay of publication. Of those who gave us the number of months that they asked for the average is 4.7 months.

There is another issue, and that is sharing of materials in research among scientists themselves, and there has been an implication, and Blumenthal's work is interesting in this regard because he has looked at this aspect as well of refusal of scientists to share research among themselves because of commercialization.

What I found interesting looking back at the papers is that they tend to find that delay of publication is more associated with commercialization activity, that the refusal to share research results, they attribute most to the academic reward system of scientific priority.

Oh, and it was worst among the geneticists.

(Laughter.)

DR. THURSBY: Okay, what are the other costs associated with this? Maryann had said that you knew you were an economist if you recognized an S-shaped curve. How do you identify an economist? If they say, "Opportunity

cost."

There is a cost in terms of faculty. Faculty who accept research funding from industry or licensing, get involved with it, there is an opportunity cost in terms of what they would be doing if they didn't do that.

So let me look first at what I am going to talk about now which is associated with licensing per se and not sponsored research. From our university survey we found that in order for licensed technologies from the universities we sampled to be commercially successful 70-some percent were viewed to need faculty involvement and further development of the technology for commercial success.

A. J. Agerwall has found similar results looking at mechanical engineering technologies with MIT. So, there is a cost in terms of licensing, in terms of faculty needing to be involved in further development. Why is it there? For most of what is licensed from universities, a number of you have mentioned they are pretty early stage. In our data we find that 75 percent of what is licensed is no more than either a proof of concept or a Lamb(?) scale prototype, and again this figure comes from our survey of businesses that license from universities, and it is interesting. Businesses gave similar answers to this as did the university personnel.

They said that when something was licensed in

either of those two stages more than half of the time faculty were involved with them once the license was executed. That doesn't tell you anything about their research agenda. It just tells you about time they are spending in development as opposed to research.

What do we know about the research agenda? A number of people, most of them here have looked at this issue. You have heard earlier from Mowery and Nelson, and Sompat(?) and Ziedonis that this type of activity has been going on for a long time. So, this may not represent a big change in terms of research agendas.

Jerry Thursby and I have another study that combines AUTM survey data with some data from the NRC on resources and universities and the conclusion we get in that study is we don't really see a switch in the research agenda. We see a switch in the way faculty look at their research. They are more willing to disclose inventions than they were in the past, and then there are some people who find evidence of changes in academic research. Wes has referred to this own work with a number of co-authors.

Again, the surveys that Bob Morgan and a number of people have done have shown a shift. In the past I think it was maybe 15 years in research agendas in a more applied direction. The problem with all of this is that you really cannot identify even if you agree with any of our results

here why the result is there. You don't know what it is coming from. So, dealing with what I think we don't know, what I think we need in order to examine this issue is individual data. I think you need to figure out have research agendas changed.

If you look at the individual have you changed the research agenda of people who were doing basic research? Are you changing the agenda of people away from their area of comparative advantage, and you really need individual data to do that. Is the change from individual characteristics or policy effects? Individual characteristics might be the age distribution of faculties changing, and you typically change the types of research you do with age for a variety of reasons.

People may have changed their research agenda in response to funding availability or they may have done it in response to university policies. There is one thing I don't have up here, and I suspect it is very important is that this is going to vary by field and the state of science in the different fields.

There is some work going on in this vein. The National Science Foundation has just funded us. Jerry Thursby and I are amassing a database of roughly 7000 faculty at 11 universities from 1983 to 1999, and we have their disclosure activity. We have faculty in this sample

who have never disclosed. We have their vitae and we have or are getting their funding as to whether it is government or private. We have their age. We have department characteristics so that we can look at some of these issues, and I think the jury is out.

(Applause.)

DR. COHEN: Marie, thank you very much. We will now hear from Eugene Bauer, Vice President of the Medical Center and Dean, Stanford's Medical School.

Eugene?

DR. BAUER: I have no slides. What I want to do is sort of take us one, two, third step down. We have heard from a university president. We have heard from a university provost, and I want to come down if you will on the impact of university or school industry relationships at an academic health center and at a school of medicine within a research intensive university.

To do so I am going to approach two of the five questions that were raised as part of this issue but rather than doing it at a macro level I want to do it if you will from a worm's eye view. What is the impact on the faculty? What is the impact of the financial resources on the school of medicine as a way of approaching some of the questions that have been brought forward for this session?

I will do so mostly if not wholly from a purely

academic and experiential viewpoint. First let me talk about how financial resources have been effective in generating revenues that can be allocated to support, if you will the research infrastructure.

In the last 5 years cumulatively at the School of Medicine at Stanford intellectual property has generated in the aggregate \$90 million for the school and for its investigators. Less a certain amount that goes administratively to the Office of Technology Licensing one-third comes to the school. One-third goes to the inventor's department, and one-third goes to the inventors themselves.

Those dollars in the aggregate are used as general revenues at the school level and the department level to offset faculty salaries, to deal with graduate student stipends and to renew infrastructure in terms of bricks and mortar, instrumentation and many other things.

In effect those funds help bear the cost for the renewal of a research infrastructure and thus could be used more broadly in the sense that they are being applied to research and graduate education.

The issue of licensing revenues versus equity is really the issue of a dependable resource, an annuity if you will versus the multiplier. Traditionally at Stanford as you heard from Katharine Ku this morning we have tended not to take large pieces of equity although some of those policies

have changed, and in the case of Cohen-Boyer essentially all of the monies that have flowed to the School of Medicine have been in the form of licensing royalties.

More recently, however we have created an essentially wholly owned Stanford School of Medicine spinoff originally known as SHINE, standing for Stanford Health Information Network for Education, now converted to the name E-Scholar which is a Web-based education product and we decided to form this because it was wholly in keeping with our mission. In other words, we aligned what we viewed ourselves to be as an academic institution, an educational institution with our goals in spinning off this company. In some cases it meets essentially our educational needs for undergraduate education tools, for graduate education tools. It is a Web-based resource for both of those education goals. It deals with our goals for continuing medical education and has recently been validated by the American Medical Association for Continuing Medical Education credit in real time.

It meets our goals for local and distance learning both at the physician level, and we have developed a co-branding with Yale University School of Medicine for continuing education in nursing.

It provides timely information, and it seeks to keep accurate, up-to-date information that ultimately will

improve the practice of medicine. So, in moving in this direction which is different from the one that we have traditionally moved in, we have done so because there was an alignment of our investing goals if you will in this corporation and our educational goals as an institution.

Next, I would like briefly to look at if you will the impact of academic-industry relationships on faculty, and the questions that were raised in the outline were do increased interactions with industry help or hinder faculty recruitment and retention; is there faculty time that is lost of because of their involvement with various start-ups, and is entrepreneurial activity a criterion or among the criteria for promotion or hiring or advancement?

Unambiguously industry interactions do affect the lives of faculty who are about many things. They are about basic discovery. They are about early translation which may involve patients and often is not sponsored. They are about late translation, patient-oriented research which is often industry sponsored but irrespective of their level of involvement, whether they do or do not become involved with industry relations are not used as criteria for appointment, promotion or tenure.

What I cannot assert, however, is that there may not be subtle institutional and I mean not only at the school of medicine level but at the university level, kudos

that flow to faculty members and prestige factors that are associated with faculty members who found companies or who exist on boards of directors or scientific advisory boards.

The question raised this morning by Bob Barchi about should universities be involved in promoting, creating or managing start-ups, I will stipulate that at least in terms of the management side the answer should be no.

On the other hand, the faculty's access to information to create companies is really a reflection of each institution's own culture and how it has been played out over a number of years, and it clearly at Stanford is multilevel.

Probably the best metaphor I can use for this one is curriculum. There is a formal curriculum for the School of Medicine or for any institution, and there is an informal curriculum. The formal curriculum is what does the institution do to promote interactions, if you will with industry. The informal curriculum is what is the fellow down the hall doing and how many VCs does he or she know.

In our case the formal curriculum involves the office of technology licensing. It involves an organization known as Spectrum which we created to have a university academic-industry affiliates program, and it involves a second organization which is called Access which mimics Columbia University's single point of interaction between

clinical departments and industry usually big pharma supported clinical trials.

The informal side of it is as I said, the proximity of venture capitalists, the experience that other faculty members have had and easy access in both directions from the faculty to funding and vice versa from the venture capitalists to the faculty.

Sponsorship of the faculty by industry in fact creates issues of conflict of interest. Our single most important goal should be as academic institutions engendering and retaining the public trust.

I believe as Donald Siegel indicated earlier this morning that we are perhaps emerging into an environment of distrust, one in which academic institutions because of their tight relationships with industry and of their faculty members' relationships and financial interests in a variety of start-ups or other in fact are looked askance at by society.

It would be too strong to say that it is an emerging McCarthyism where there is in fact the presumption of guilt as opposed to innocence, but the truth of the matter is that academic institutions must now move expeditiously and definitively to create adequate safeguards with regard to disclosure, monitoring where necessary, disclosure of time commitments and of financial linkages

between what they do as part of their university activities and what they do as part of their commercial activities.

This is in my view one of the most important issues that we as academic-industry cooperative individuals must address. How are we going to maintain the public's trust in what we do?

(Applause.)

DR. COHEN: Thank you very much, and we will now hear from Joan Leonard, Vice President and General Counsel, Howard Hughes Medical Institute.

MS. LEONARD: It is my pleasure to be here. I appreciate the opportunity to participate in this panel. I have chosen two topics to talk about as well, the issue of access to research tools and the question of the effect on basic research.

Before I get started though I want to talk a little bit about the Howard Hughes Medical Institute because not everybody knows how that works.

First of all it is important to know that we are committed to science-driven cutting edge research. That is our mission. We are, also, committed to the translation of its discoveries. Those two things aren't always easy to reconcile.

The first point I want to talk about when we get to the issues is the reliance on patenting and exclusive

licensing can really affect the research autonomy in the lab of investigators who are trying to get materials, particularly research tools, particularly broad-based research tools that are necessary for a lot of different kinds of research, and when I say, "Industry's reliance," what I mean is that these tools may have originated in fact in academia and been licensed out under terms which make it very difficult for other scientists to get them either from the place where they originated or from the company that has licensed them.

Another impact occurs when the institution where the invention occurs licenses it out or decides to commercialize it in a way that may make claims or try to make claims on the investigator's ongoing lab activities.

My last point is that if you try to maintain a thoughtful balance between nurturing science driven research and translating that you are going to spend a lot of time and resources doing it, and that is what we have had to do.

I want to say a bit about HHMI. We are the largest private research, I should say scientific biomedical research philanthropy in the United States with an endowment of about \$12 billion. We carry on our research through collaborative relationships with research institutions across, academic research institutions across the United States. We hire faculty members. They stay in place. They

stay on the faculty of the campus. They maintain their labs there, but we hire them, fund them, equip them and provide personnel.

We are committed to having their interests be fundamental basic cutting-edge research, and they are employed for renewable term appointments, 5 years usually and they are renewable, but there is no tenure with the institute.

They are renewed near the end of their terms and a determination is made as to whether they will continue for another term. We have now just under 350 investigators at 70 different institutions.

Our method is to identify what we believe are exceptionally creative scientists through competitive searches and then to provide them with stable long-term funding, and the idea here is to fund people not projects. So, we don't ask for a research plan, and we don't ask what they are going to be doing for the next year or so, and we don't have annual check ins on how they are progressing. Instead what we want them to do is to follow their scientific noses, exercise their creativity, identify important problems, generate interesting and unique ways to pursue them and then we hope be productive in solving them or at least making progress on them.

When you fund people with the idea of turning them

loose to follow their scientific noses you want to make as sure as you can that the influences that are going to be driving them are in fact scientific and not commercial or otherwise.

So, we try to minimize as far as we can those influences in the lab. We don't permit corporate sponsorship, and we do make sure that we are aware of and look at agreements with industry. So, that is research collaborations and PAs, consulting and the like.

The investigators do have a dual affiliation though. They have two roles. They remain on the faculty. They teach and continue to do faculty duties, and they are subject to our IP policies as well as the conflict of interest policies of their host institution.

So, the most stringent policy always applies. They don't like that very well, but that is the way it works out.

As I said before, all the agreements with industry are subject to our prior review and approval, and we coordinate all of this with the host institution. In general our institution takes the lead on things that have impact on the ongoing research. So, research collaborations, MTAs and consulting agreements we take the lead on, but once there is an invention in the lab it is disclosed to the host institution. It is assigned to us by the inventor because of the employment relationship, but we have a pre-existing

obligation to assign that intellectual property to the host institution, and the host institution is then responsible for undertaking efforts to commercialize, to decide whether and where to patent, to decide whether and how to license, to identify licensees and basically to strike the entire financial deal. We do retain some rights to review the licenses, and we have some things that we require to be in licenses, but the deal making is entirely out of our hands. We do share in the costs though, and the resulting revenues, if any.

So, how does patenting and licensing of research tools really affect academic research? Whenever we want to get materials we are reminded that companies, and it is very true have fiduciary responsibilities to their shareholders.

They have to protect their positions and their proprietary information. They have to retain control of the development of their own research programs, and so the result of that is that virtually every MTA inbound from industry will have some sort of claim of exclusive control over the recipient's downstream research.

We have some policies to respond to that, and they are very similar to those of our host institutions. There is really not much difference here. We don't want to grant actual ownership in the downstream research nor do we want to grant exclusive licenses in the agreements themselves,

but we do recognize the need for industry to protect its positions, and we will grant a time-limited option to take an exclusive license on the downstream research and of course preserving the freedom to publish with the appropriate delays as necessary to protect intellectual property.

This has the attachment of strings to the future research in the laboratory, can affect the way in which that research goes and of course this is something given our commitment to freedom of research is problematic. It can inhibit the scope of the research or the direction of the research because of difficulties in getting future tools or future materials. If this is an ongoing long multistage project you may well have the need for other things which will want to make the same claim of a first right and you can only sell that once. So, that can create a problem. You may have difficulties in distributing the results of your research if you have made a prior commitment of it to a company and for the same reason you may have trouble undertaking research collaborations with colleagues that may have conflicting obligations to industry.

There are other costs, too, the dead weight costs of delays and administrative costs just in reviewing all of these. So, it is not an optimal situation but in the end the investigator usually gets the reagent he needs but at some

cost. That is a cost that just has to be borne because of the conflicting needs of the entities involved.

How does academic patenting and licensing affect research in Hughes Labs, let us just say? Start-up companies present the most acute form where we run into issues with managing the autonomy of the research lab at the same time that we want to facilitate the translation of the discoveries that arise in products and services.

There are lots of pressures to form start-up companies. We deal with 70 different institutions, and we see a very, very wide range of approaches to this kind of commercialization. Some institutions are deeply committed to start-ups as the principal way they want to develop intellectual property.

Stanford is somewhat at the other end, but we have a lot of pressure for start-up companies as I say from academic administrators who want the up side, from governments who see it as a way to develop a tax base and greater employment, economic development and from investigators themselves who are looking both for the psychic and economic benefits of having their company. So, we are under siege sometimes.

The issues for us are the following: We worry that the independence of the research in our labs which is critical to our doing the kind of research we are committed

to doing could be compromised if the company makes excessive claims on the investigator. This means a whole range of things, on acting as their scientific department, as a chief scientific officer managing and directing their research, doing their investor relations, doing their public relations, doing their hiring, tending to 101 corporate details that are involved in setting up and trying to get a company going. All of this can be a tremendous drain on an investigator's time, let alone his or her, always implied "or her" intentions, and then the investigator's attention can become divided. The notion of what is institute research, what is the company business; how do we keep them segregated; how do I know who I am working for when I am working and avoiding a conflict of interest where something that may be funded by the institute and claimed by the institute is diverted somehow, probably unintentionally and inadvertently and subconsciously to the company and then there is the problem of the lab being or being perceived to be the extramural research arm of the company, that it is simply a pass through of our resources to the company that the claim on much that goes on in the lab is really just a way to boost the value and the growth of the company.

Lab issues are funny because it also can create second-class citizens within the lab. You have some graduate students or postdocs who are with the company doing work

related to the company, maybe even have equity in the company and others who don't, and so there can be splits and rifts within the lab and the suggestion that perhaps mentoring qualities change depending on who is doing what. All of these are problems for us.

We have developed some policies that we hope mitigate some of these issues. There are policies on consulting actually that apply to all consulting relationships not just start-ups but we give start-ups special attention because of the acute nature of the issues, but for virtually all consulting agreements the investigator may not hold more than 5 percent of the company stock although we do provide for any dilution recognizing that 5 percent of a company on the date of its birth is probably going to be a good deal less than that after the first round.

No investigator may consult for more than 36 days every year, serve on the company's board of directors or act as an officer, perform or direct the company's research on a day-to-day basis. We expect that the role would be advisory, that they would help with the direction and steering the way in which the research goes, but we really look for an independent, a self-standing scientific group within the company that can in fact manage the scientific aspects of it.

The investigator may not collaborate with or receive any funding from the company or give the company any preferential access to HHMI research and on the licensing side our policy is that we expect that our host institutions when they grant rights to companies will not grant any rights in future research in the lab beyond that necessary to give the benefit of the bargain for the technology that is already in being. So this is the formulation that we use CIPs to the extent that the claims are directed to the subject matter specifically described in the existing patent application.

Now, we don't have any illusion that somehow the existence of these policies stops an investigator from thinking about the company the first thing when she gets up in the morning or the last thing when she goes to bed at night or while she is taking a shower or any of that. We know that this is an extremely stimulating and exciting event, that probably the distraction is going to be substantial, but we do believe that the benefits of having these policies in place from the beginning and having the agreements entered into before the transactions get started have some real benefits and that is that all the parties to this transaction and that means the company, the host institution the investigator and us all must focus on the policy requirements, understand the issues underlying it and

the values underlying it and why we have those policies through the discussions that have to accompany the negotiation.

We, also, think that reviewing and approving agreements before the transaction begins really helps because it means that ground rules are established. You are not having to unwind something after it has happened where people feel that the rules have changed in the middle of the game. That is a very difficult situation, and the investigator we think benefits by being reminded that he or she has dual roles, that there is the kind of research that he or she is doing for the institute and there are very real roles and valuable roles and helpful roles that can be played and should be played with the company.

So, it isn't a matter of saying, "That is bad, and we are good." It is a matter of saying that these are two different things, and they really should be kept separate and understood to be separate.

So, the result, what we hope is another compromise that the translational work does get done and the start-up company does have the benefit of the investigator's ongoing assistance and help but that relationship is defined and constrained.

So, our conclusion is we do think the patenting and licensing are essential to translate discoveries and

that at the same time they are creating incentives that can affect the autonomy of the research going on in our labs. We work hard to maintain a balance between the two which requires a lot of time and resources, but we think it is well worth it.

Thank you.

(Applause.)

DR. COHEN: Thank you very much, Joan.

We will now begin the discussion period and remind all participants from the floor, please identify yourselves and provide your affiliation as well.

Yes?

DR. TAO: My name is John Tao. I am with Air Products and Chemicals. The sessions this morning as well as this one were focused very much just on US only. I realize Bayh-Dole is a US issue. However, IP transfer and technology transfer between university and industry is not a US issue.

I cannot speak for the life sciences or the numbers in Europe but I am familiar with the number of institutes in Russia in the former Soviet Union alone. That is 4000 institutes, almost 2 million scientists, most of them PhDs and increasingly we find ourselves, at least in the chemical industry going overseas for our work because of the IP barriers here in the US.

I would like to ask the question not only of this

panel but anyone in the audience from the academic arena, has anyone addressed the amount of research, revenues lost for sponsored research because we are going overseas for the work?

DR.COHEN: Is there anyone on the panel who can address that? I certainly cannot. Is there anyone in the audience who is able to address the question?

Okay, I don't see any other participants at the mikes. Oh, okay?

DR. HERSEY: I am Karen Hersey from MIT and I guess since MIT probably has the largest range of university-industry research of any of us, the question is have we lost or are we aware of lost opportunities because we have US companies going abroad to foreign universities to do research because they get a better deal I guess with respect to IP or there is less of a barrier from our perspective? No, we have noticed no reduction at all in the number of US universities doing or funding research at MIT nor have we noticed any reduction in foreign universities coming to MIT to do research. So, that is the best I can tell you from the trenches of day-to-day negotiating research agreements with industry. We have not noticed a change in flow either way.

DR. COHEN: Thank you.

Yes?

DR. WEBB: I would mention on that point, Robert Webb from the Embassy of Canada in terms of Canada and what I know from my colleagues in the diplomatic club, the science club in Washington, certainly in Canada the IP issues are as much of a problem as they are in the US. I don't see companies gaining from going to Canada from the US. I have worked at the National Center for Manufacturing Sciences in Ann Arbor, and I know some of the companies there don't find there is any difference in working with Canada or the US and in terms of countries outside of Canada my experience is that there are similar problems. Maybe it depends on region, but certainly you may not have an IP issue in Russia, but you may have other issues.

(Laughter.)

DR. COHEN: Thank you, very helpful.

DR. GARDENIER: I am here as an individual private citizen, but I informally follow IP issues for the American Statistical Association, and particularly I follow database protection legislation initiatives. I noticed that an underlying theme which has not been explicit today but has been subsurface in all of the panels is the reliance on all of the science and commercial development on database technologies of various types, and this leads me to wonder about an issue that has not been raised, and that is the efforts in the European Database Directive, in the World

Intellectual Property Organization and for the past 4 years in the US Congress to pass what is called strong database intellectual property protection and by that I mean protection that would grant for either long terms or indefinitely ownership of the factual content of intellectual materials rather than their expression or a particular commercial product.

I wonder how panelists and others in the audience feel about this. Would a lot of people like to jump at trying to lock up as many databases as they could and charge on a pay-per-view basis for them or are you as outraged at that concept as I am?

DR. COHEN: Again, that sounds like a general question. If there is anyone from the audience who can and wishes to address that, certainly take the mike.

DR. GOLDSTEIN: First I guess I should say that the views I express aren't those of my employer.

DR. COHEN: I am sorry, name and affiliation?

DR. GOLDSTEIN: I am Mitchell Goldstein. I am the Director of the Joint Commission on Technology and Science of Virginia, but as I said the views that I express aren't necessarily those of my employer.

I happen to be an attorney in Virginia and one of the best things I think we have is that the facts are not locked up. Otherwise we would have companies like Reed-

Elsevier(?) which owns the LEXUS database and Thompson which owns the West database. We wouldn't have access to it at all, and it is because those facts are free flowing in the United States that we have so many free services. It is because those facts are so free flowing that the information is available on the Internet and in other sources.

I think that is what leads to further innovation. That is what leads to better policy, and if we turn around and lock them up in the United States we are going to lock up those policies as well.

DR. COHEN: Thank you.

Yes?

DR. FISCHER: I am Eric Fischer of the Library of Congress. I am going to pass on the database question.

(Laughter.)

DR. FISCHER: But I want to ask about something that hasn't really been broached, and it is sort of about whether there might be some structural effects on universities from the emphasis on commercialization or the increasing importance of commercialization and that is to say do any of you know or anybody else in the audience of any evidence with respect to whether the success of those scientific disciplines that lead to commercial applications might actually be having some dampening effect or some effect of any type on other scientific disciplines that

aren't so readily amenable to commercialization but that might as even some people like Harold Varmus in the biomedical area have noted may be very important in developing some of the knowledge that is important for those other areas?

DR. BAUER; I actually can give at least one example where I think the reverse, that is to say not a dampening effect but an enhancing effect of the interactions occurred so that for example with the explosion in genomics and then in proteomics there has been a significant increase in attention in part picked up at the NIH level, in part picked up by HHMI as well for stimulating interactions between the life science and the hard sciences, physics and chemistry and indeed in order to do any kind of analysis that is going to be required as a result of genomics proteomics and then ultimately translating that to human health is going to require massive computation.

So, I think it is quite the reverse. In fact, we have stimulated interactions that 5 or 6 years ago we hadn't really been contemplating at nearly the level that is already being implemented.

DR. MERRILL: Steve Merrill with the Academy staff. Overwhelmingly this morning we have been talking about research performed on campus under whoever's sponsorship, philanthropy, government or industry, and in

this session we have heard a lot about managing the individuals who have feet in both camps, both in industry and in universities and the length to which funders and institutions are now going to manage those relationships.

I wanted to actually ask Maryann Feldman a question since we were shut out from that pleasure this morning about equity arrangements and then have Joe Leonard and Gene Bauer comment on whether in equity situations not only individual investigators but institutions interests in where the research is performed, whether on campus or in a corporate laboratory isn't diluted by equity relationships and whether there are any cases and how institutions have managed those questions.

DR. FELDMAN: Actually the question of the conflict of interest over the university having an equity holding seems to be somewhat mitigated when there is this joint ownership because the boundaries become maybe a little bit more fungible because we know that these conflicts exist, that people are working on similar types of projects. If the university has an equity interest in sort of taking this forward they seem to be a little bit more tolerant was our belief about this.

MS. LEONARD: I am not sure I understand when you say that they were more tolerant. I am not sure that I understand. The fact that the institution holds equity as

well as the investigator?

DR. FELDMAN: Actually in this case it is the university itself can worry a lot about these problems of sort of intellectual property escaping out the back door when a faculty member has a company.

If the university has an equity interest it somewhat aligns their interests so that they are working towards this common goal.

DR. COHEN: John?

DR. BARTON: John Barton, Stanford Law School. I am wondering if you have had any indication of universities avoiding lines of research because of fears of infringing patents or other forms of intellectual property rights?

DR. BAUER: I actually have no indication of that one at all, but I mean again it is how do you know what you don't know.

DR. THURSBY: I would like to follow up on the equity question. In our survey of universities we asked about types of contracts used, and the cases we examined when the university took equity the inventor had the normal share in that equity, and so if you think about the incentive that is created in part it solves a moral hazard problem on the part of getting the inventors to work to further develop the technology because they have an interest in it.

DR. BAUER: Could I just follow up? One of the positions that Stanford has taken at least in the past on the equity question is that as you heard from Katharine Ku this morning the licensing arrangements, the intellectual development of the intellectual property, the licensing arrangement is done largely absent the involvement of the faculty member.

The charge to the office of technology licensing is to get the best deal available and to build the value and the argument that has arisen in the past is that when equity is part of this, that is to say a substantial amount of equity, and I don't know what substantial means in this but let us say for the sake of this argument it is more than 10 percent that when a substantial amount of equity is involved there is a hazard that the fundamental curiosity driven research paradigm which is extraordinarily highly valued at Stanford as it is institutionally by Hughes investigators will be compromised because there is always that hope that there will be the multiplier effect as opposed to developing the license in some sort of revenue stream in an ongoing way.

MS. LEONARD: I was just going to say that in fact Hughes historically did not take equity did not want its investigators involved in any licenses that had equity. That has had to be reluctantly altered about the mid-

nineties when it became clear that a lot of licensees did not have cash. We started out we would get the cash and the company and the university would get the equity. That ended up being very difficult to value and was much more trouble than it was worth.

We now have a policy where the host institution holds all of the equity. We retain an income interest in our share of it when it is monetized, whenever that is and that I am sure is an evolving policy as well.

DR. COHEN: Thank you.

Yes?

DR. HUGHES: Owen Hughes from Pfizer. This is just a question of my own. I suppose this is pushing the outer limit. We won't get there, but at what point do revenues to a university from this type of activity become so significant that the compromise its 501(c)(3) status?

DR. BAUER: I can tell you it hasn't happened at Stanford yet.

MS. LEONARD: I think it would take a long time to get to the point where it was your major activity or where it so displaced education that you would have to worry.

DR. COHEN: In the back?

DR. STINE: I am Debbie Stine of the National Academies staff. One of the things mentioned about how to maintain the public trust and what universities do and then

we just saw an article a couple of days ago in the Wall Street Journal talking about student protest about university-company involvement in some of these companies regarding AIDS research. Do you see that as a problem? Is this a widespread phenomenon that there is concern about loss of public trust because of universities' interactions in these areas?

DR. BAUER: I think it exists at two levels. I think there is the issue of the type of investments that not-for-profit institutions, universities make and often that gets played out with regard to child labor and access to certain kinds of therapeutics in Third World countries or whatever.

The second issue is the one that I was addressing in my introductory comments which really has to do with the issue of public trust in the research that is done and in the results that are produced and very quickly at Stanford, Stanford policy allows its faculty members to participate in consulting 1 day per week or 13 days per quarter.

Conversely Stanford policy requires the following: If you use Stanford resources, the intellectual property is Stanford's. Annual disclosures must occur in terms of consulting times, financial relationships. It is reviewed at the department, decanal, provostal and if necessary the presidential level.

Industry sponsored research there is an automatic conflict of interest disclosure form. There is decanal review if there is a conflict. A monitoring body is established on gift funds that may come from industry to faculty members. There is a conflict of interest disclosure form. There is decanal review before authorization if the dollar amount is greater and it is some very small number, I don't remember offhand what it is, but if there is a potential conflict an independent monitoring group is established.

So, I think as Joan said in her talk what we are really, I am trying to argue for here is that it is not that this is all bad or all good in a moralistic sense. It requires a kind of process that we can look to with consistency and say that it is transparent to those who question.

DR. NELSON: Dick Nelson, Columbia University. Actually Gene I think responded to my question before I asked it, but to continue the discussion that Maryann began a short time ago regarding issues of university and university researchers holding equity interests in companies who on the one hand fund their research and a problem that seems to me to be particularly difficult in the context of health-related activities associated with medical schools.

Columbia University, and I suspect Stanford is

quite similar has a broad policy of not allowing university researchers to hold equity in companies that fund their research. We are particularly vigilant on that regarding research that goes on in medical school or health-related issues and especially in contexts where an implicit university endorsement or university undertaking of tests of various kinds of products are involved.

So, I think this is an area that you are trying to get at where I think you have among the greatest potential hazards of real conflict of interest.

DR. BAUER: Could I respond to that? Actually I think that this is an area which both deserves and requires in my view a significant amount of ongoing debate. The distinction I would like to make in the comment that you made is that of very early research where the investigator himself or herself has created the discovery and then is perhaps in a non-hypothetical situation that I can describe later. The faculty member is one of half a dozen people in the world who gathers together this subset of patients and he or she necessarily needs to be involved at the if you will Phase I half or Phase I level.

Once you get beyond that I think unambiguously I totally agree with you. There just needs to be export and if at all possible non-involvement.

DR. SAMUELSON: I am Pam Samuelson from the

University of California, Berkeley. There is a couple of issues about effects of these patents and licensing on universities on research that haven't come up, and I will just quickly name them and then see whether some of you have a reaction.

One of the reasons why I think there has not been more conflict within the university about patenting and licensing is my view is that there are in many faculties people who make their own individual decisions about whether or not to, faculty members who are doing things that could be patented and decide that they want to disseminate them anyway and that universities are not generally speaking in a good position to tell the faculty member that they absolutely must propertize this knowledge and it seems to me that is a place where there is a potential for conflict, and the more the universities feel that this is theirs and that the faculty member is depriving the university of income I think there is more of a conflict potential there and I am glad that in some sense that hasn't surfaced so much as an issue because I don't want to see more stresses within the universities on that issue, but I do think that is in some sense a safety valve that is part of the informal context.

A second issue goes back to something which was talked about this morning which is should there be more incentives for faculty members to cooperate with offices of

technology transfer and licensing, and that might include giving people credit toward tenure, promotion and the like for contributions in patents and licensing revenues and the like.

I will tell you within many university contexts that would be a very, very sensitive subject. Part of the reason why I think there has not been more difficulty within the university context so far about patenting and licensing is because everybody who goes up for tenure is expected to meet the same quality of publication standard not oh, well, I generated this much revenue for my university through a patent even though I couldn't get my articles placed in such and such or I no longer thought I had to do kind of real academic publishing. So, again while I think it was good to raise the issue, I think that part of the reason why the system works as well as it does right now is because all the academics who are doing, might be doing patented research or might not still have to meet more or less the same criteria and a third thing is that there is another place where there is a lot of stress and that is a worry on the part of people who are in for example, the humanities or social sciences where they cannot really generate patents or at least they haven't yet and they are worried about whether or not their funding in fact is going to go down because they are not part of kind of the new profit centers within the university

context.

So, those are just a few issues to kind of throw out as part of this kind of larger thing, but it does seem to me right now this hasn't become as much of a problem as I think some people predicted but I think it is partly because of these kind of informal understandings so far that people have some rights to decide whether or not to reveal it or not and also that the academic standards really are the same across the board in terms of publications.

DR. COHEN: Okay, I have a couple of points kind of randomly choosing across the broad menu offered by Pam. A follow-on question regarding as Pam said the degree to which faculty themselves choose to propertize their discoveries. I know at Carnegie Mellon there have been occasions when faculty and directors of research centers have actually chosen although they had patents not to assert them, and they chose not to assert them because they recognized that the research activity in that center depended heavily on the reverse flow of information from industry back to the university.

Okay, and I guess to me that poses a question broadly that I would like to pose to the technology transfer officers and other related personnel who might be present. To what extent when you choose to patent and then assert a patent, to what extent do you really become concerned about

what that is going to do to the flows of information between industry and the academy, the reciprocal character of those flows and the importance in many, many fields, particularly of engineering where those flows are essential to academic progress? So, I follow up Pam's point and question with yet another question, and I guess I am not as optimistic as Pam about the norms of academia.

I know not just at Carnegie Mellon but at other universities certainly a standard for promotion at the margin at least if not a central one is the raising of grant money and grant support comes up in meetings of this sort. Is it central? No. Is it there? Sure, but certainly not licensing income. That is true, but clearly revenue generation for support of the broader mission and endeavor is certainly there, and the question is how far distance is it moving from being concerned about grant money to in fact generating revenue for the department and the institution via shall we say privatized channels.

Does anyone else on the panel have --

DR. BAUER: My only comment is that I agree with Pam. The faculty's empowerment if you will for a yes or no decision about seeking intellectual property I think that that is a potential, I think it is a great safety valve. it is one that we honor. I think going the other direction and demanding or attempting to demand the creation of

intellectual property will create a firestorm that none of us would like to deal with.

DR. COHEN: I see we are starting to get close to our end.

One more question?

DR. BOUDREAUX: I am Daryl Boudreaux. I may be the only tech transfer director left in the audience. I know several of us had to leave early to catch trains back. I direct the tech transfer function at Rice University.

I just wanted to comment on your last question. It is my experience that when we have a patent available for licensing or something that we are prepared to assert that quite the opposite happens. It becomes an opportunity to build relationships, relationships between the university and the potential licensees. We generally involve our inventors in that process. They generally get to know new people and build relationships that can be productive even if the license is taken by someone else. The potential licensees who do not take a license have found certain skills that exist in the university that they may use for other purposes. So, it is just quite the opposite. It is an opportunity for relationship building that I have found to be productive. I don't know whether anybody is still here who might have any comments on it, but that is my own personal experience in that.

DR. CHAMPNESS: My name is Mike Champness. I am with a group called the Business-Higher Education Forum and we just concluded a study on university-industry research collaborations, talking more about the collaboration piece than the licensing piece, and I just wanted to point out something that we observed, and I do think there is an important relationship building aspect to working together and trying to find common interests and common ways to approach the problems, but that I think that it is important to remember that patents and publishing have I believe at their essence the same goal and that is getting the information out and available in a way so that you maintain ownership to use that phrase of the idea.

The alternative is trade secrets from the corporate perspective and hiding your academic information from the academic perspective because you are concerned about your Nobel prize. So, we want to remember patents are good and publishing is good and they have similar goals. It is when you get to the licensing that you then have these problems and not to downplay them and there are certainly lots of challenges there, but that we, also, have to maintain that distinction, too, I think.

DR. COHEN: Thank you very much, and if there are no more questions I think we can proceed to coffee and thank you very much to all members of the panel.

(Applause.)

(Brief recess.)

DR. BARTON: Let me welcome you back to this final session which starts out at least with a set of real lawyers' problems but ends up having significantly more importance than one might expect at the beginning.

Let me describe the problem first in one sentence?

Patents are no longer enforceable against state governments or therefore against state universities.

Now, let me talk just a moment about how we got there and then a little bit more about the implications? We got there ultimately because of the majorities of the Supreme Court the key decisions are five to four and with the conservative majority over the liberal minority, the Supreme Court majority interpreting the relationship between 11th and the 14th Amendments.

Now, for those of you that are not constitutional historians the 11th Amendment was passed in 1794 in response to a case hearing an argument brought by an individual against a state and the state said, "No, no, no, this is a government of limited powers. We don't think we should have to be sued in federal court," and so the 1794 11th Amendment gives state governments a very strong sovereign immunity right against federal courts and therefore federal law.

This is necessarily balanced by the 14th Amendment

which came after the Civil War and which in essence said, "By the way, the Union won the Civil War, and we intend to make states live up to certain minimum principles."

So, the issues then are to what extent does the 14th Amendment which gives rights to sue the states in contexts such as obviously equal protection, avoidance of state discrimination and so forth, gives the people the right to sue the state government in federal court, to what extent does that right override this 11th Amendment from 65 years earlier?

In an effort to build that balance, and reinterpret that balance the current Supreme Court majority has issued a good number of recent decisions. The relevant ones for us are two decisions involving would you believe I think what can only be described as a business method patent, a process of marketing and selling certificates of deposit designed to finance the costs of college education.

A company got a patent on the methodology of administering this kind of finance arrangement. The government of Florida or Florida university system decided to do it itself and got sued in two parallel cases, one for patent infringement and one for essentially misrepresenting the sort of copyright style aspects although it was not technically a copyright case and in resolving that case the Supreme Court decided in favor of the state on

constitutional grounds and against the company in both cases and Scalia wrote one opinion and Rehnquist wrote the other and to take the patent one which I think is the much more important one to us today it ended up saying basically there are two ways that the states can be held liable for patent infringement. One is the states waive it.

The second is the Federal Government acts actually to remedy a genuine problem which has been found and which amounts to a depriving of property of individuals or rights of individuals without due process of law.

Let me quote two of the key sentences. One is we thus hold that for Congress to invoke the 14th Amendment it must identify conduct transgressing the 14th Amendment and must tailor its legislative scheme to remedy or preventing such conduct, in other words to act under that basis you would have to show that states and obviously state universities have been ignoring patent laws.

The other provision is a state's infringement of a patent though interfering with the patent owner's right to exclude others does not by itself violate the Constitution. Instead only where the state provides no remedy or only inadequate remedies is the Constitution violated.

So, to get jurisdiction under that other aspect of the 14th Amendment you have to show that the state doesn't provide adequate remedies.

The dispute, therefore turns to elaborate questions of what actual violations there are and what kind of remedies there are. Now, what are the implications of this dispute? Let me mention four because I think at least some of these will be discussed by our panel.

The first one I want to mention which I haven't seen flagged before is this decision is only one of a sequence of decisions. We have certainly seen the other versions of the sequence in the newspapers in things like saying whether or not states can be held viable for not complying with federal age discrimination legislation and so forth, and there is a variety of these cases which have been coming out over the last decade.

Let me just suggest we haven't even begun to think about what the implications are for the federal regulation of research at state universities for things like the Shelby Amendment. Need I go on? I think in many of these you could probably find a waiver through the state universities accepting Federal Government money but nevertheless I think this principle may go a lot further than we have begun to think.

Second, do we want to try to remedy this and make the state universities liable and make state governments, of course, liable? I mean certainly at least as things stand there is at least a technical infringement of the TRIPs

Treaty. I think there is no question about that.

Now, the states can take care of it themselves by adopting their own legislation which provides appropriate remedies and of course then makes federal legislation impossible. Alternatively what kinds of findings, what kinds of studies would be necessary to make federal legislation permissible under these new constitutional standards?

Third, and this is one again I think I haven't seen discussed, and this is what does this do to relationships between a state university and a private institution? If I am a corporation and I enter into a contract with, we will pick on the University of California, I enter into a contract with UC, and I cannot sue them for breach of patent law, am I going to consider entering into that contract or not? Am I going to solve the problem simply by automatically putting a waiver of sovereign immunity clause into the contract such that whenever I enter this agreement with UC, UC on behalf of California State Government waives its sovereign immunity? In general but more broadly how is this immunity going to affect negotiations between a state university and the private sector and then finally of course the fourth question of to what extent is there now an unlevel playing field; to what extent does this disadvantage Stanford to the benefit of Berkeley, and clearly all four of those issues are involved.

We are going to take our panel slightly out of order. We talked about this quickly. Justin Hughes is first going to talk. No, we are going to stick with the order. Okay, Julie Katzman is going to talk about the congressional response to this line of legislation.

Justin Hughes is going to talk about what happens if we don't get a response and Mr. Shekleton is going to discuss the issues of the level playing field and parity or not between state and private universities.

Julie?

MS. KATZMAN: Thank you. As John said, my name is Julie Katzman. I work for Senator Leahy on the Judiciary Committee and I am going to discuss three topics briefly. First, although this is very arcane and it has already been covered to a certain extent, a little more particulars with regard the intellectual property area of the law in how it has developed over the last 10 or 15, 20 years because it really speaks to why Congress might be concerned in this area; second, why Congress should be concerned about this; and third, a bill that Senator Leahy introduced in the last Congress, and I expect will introduce again in this Congress that seeks to restore a level playing field in the IP area, and that is a bill called the intellectual property protection restoration act.

So, let me start with a little bit more of the

legal background, and the case really as far as Congress is concerned and Congress' real interest in this area really starts in 1985, with a case called Atascadero(?) and it was not an intellectual property case, actually. It was a case that had more to do with sovereign immunity under the 11th Amendment.

Now, again, as John already explained the 11th Amendment bars certain suits against states in federal court and there are two exceptions that states can waive their immunity and consent to being sued in federal court for whatever reason and second, that Congress in certain specific and rapidly narrowing areas can abrogate the state's immunity without the state's consent.

Now, what Atascadero did and that became an issue for Congress in the early nineties was that it added a new wrinkle to abrogation known as the clear statement rule. What a court said in Atascadero is that if Congress wants to abrogate the state's immunity it has to make its intention very clear. It has to give a clear statement of its intentions to abrogate in the text of the statute. This was sort of the 1980 version of what the court is doing today, very much along the same lines, trying to accomplish the same goals.

The court said, "Okay, you can abrogate, but you have to really be clear about it," and I think possibly

thinking that Congress would not go back and rewrite its statutes, but in fact what happened is that is exactly what Congress did. Following Atascadero there were a number of federal statutes that Congress had passed thinking that they were abrogating the states' immunity and the court started finding that there wasn't a sufficiently clear statement, and some of those statutes were, in fact, the intellectual property statutes. Courts started finding that the patent statute which everybody always thought applied to the states didn't apply and that the states were immune. It did not abrogate the states' immunity, the same with the copyright statute, and that is why prior to Atascadero intellectual property owners could sue the states for damages. There was nothing preventing them in cases involving intellectual property rights.

After Atascadero, you know, as I say these courts held that there wasn't a sufficiently clear statement and Congress actually reacted relatively swiftly for Congress in the early 1990s passing no less than three statutes saying, "Hey, we really meant it. We really want the states to be subject to the same laws as everybody else."

There was the Copyright Remedy Clarification Act in 1990. There was the Patent and Plant Variety Protection Remedy Clarification Act of 1992, and then the Trademark Remedy Clarification Act in 1992.

Now, notice they are all called clarification acts, and the reason that they were clarification acts was because Congress was saying, "Hey, we are just clarifying this so that there is no doubt about it. This is an abrogation. The states are not immune from damages suits under the intellectual property laws."

All three bills did nothing new. They just clarified. None of them were controversial. They all passed unanimously in both houses in the early 1990s.

So, everything seemed like it was pretty much back to where it had been until the court changed the rules again in 1999 in the Florida pre-paid and college savings bank cases. Those cases effectively invalidated all three of the clarification acts. That is what they did, and they created new rules for how Congress can go about abrogating, and this time just a clear statement was just not going to cut it. You had to do much, much more for Congress to abrogate the state's immunity. So, the bar has been raised.

The court basically held in the Florida pre-paid and college savings bank cases, the conceded that the states are bound by the intellectual property laws and in fact you can get an injunction against the states to stop them from violating the intellectual property laws but because of this concept of sovereign immunity which is basically the 21st century equivalent of the divine right of

kinds you cannot get money damages against the states unless they consent to be sued, and that is where we are today.

So, let me just again put it in concrete terms. If you are professor at a private university and a state university starts marketing your fabulous new invention that you have spent your life creating, it takes you some time to figure out what is going on, to hire a lawyer, to run to court and during that whole time the state university is profiting from this invention; you are not and eventually you should be able to get an injunction today. Under today's law you should be able to get an injunction to stop them, but you cannot get anything for all the prior infringements that have been going on because unless the state waives its immunity it can invoke this notion of sovereign immunity and not have to pay up.

So, the question then becomes, and I think it is kind of a foregone conclusion where I am heading, why should Congress be concerned? Congress has always been concerned. This is not anything new. Congress should be concerned because it has had the same policy all of this time. It has been trying to effectuate that policy and it keeps getting thwarted by the Supreme Court. So, Congress should be concerned because the policy as always has been to have a level playing field and to not allow people's artistic creations and inventions to be used without compensation and

not to have anybody above the law in this area.

There are additional policy reasons as well. Firstly, I would say uniformity. There is a need for uniformity in this area. Uniformity has always been an important policy consideration for Congress in the area of intellectual property. In fact, Congress took the unprecedented step of creating a special court to hear all appeals in patent cases because it recognized a special need, a special degree of complexity in these cases.

Now, instead of one proven system you are going to have possibly potentially 50 different systems. That means a lot of time and money to get judges in 50 states up to speed, potentially conflicting results as to what a patent means and how it should be enforced.

So, uniformity would be another reason why Congress should be concerned about sort of proliferation of intellectual property suits all over the 50 states in state courts.

Third, there are the international implications that John mentioned. The fact that the states may claim immunity in intellectual property cases puts the United States in violation of certain treaty obligations, plus the fact that many countries that have intellectual property laws that allow for non-voluntary licensing and governmental use provisions really what you are talking about is devices

for legal expropriation which the United States has always really aggressively tried to stop, and I think that the United States might have a hard time persuading other countries to adopt strong and comprehensive intellectual property laws if we have a loophole in our own law which allows the states to infringe freely.

So, Congress should, also, be concerned about the international implications of these cases. Fourth, I think that the idea that the states have immunity from IT suits really undermines the whole essential purpose of the intellectual property laws and the constitutional provision that supports these laws.

The whole system as put into place over 200 years ago by the framers of the Constitution is based on the premise that giving inventors and artists a limited monopoly for a limited of time on their inventions, on their artistic creations will encourage technological innovation and artistic creation, and one can imagine that the threat of state infringement without compensation could at the margins at least discourage people from investing the time and money that is necessary for developing new technologies and new inventions and products and stuff, and finally, another thing that John touched on as to why Congress would be concerned is because this is not the only case.

The Supreme Court has really shown that it has got

a very activist agenda in this area of state's rights and federalism and I think that Congress really does not to act to re-open a dialogue with the Court, a respectful dialogue. It is going to be quite a serious dialogue.

Over the last 5 or 6 years or really the last decade the Court has been striking down federal statutes at a rate that really is totally unprecedented in the country's history. These have all been five/four decisions. They second guess congressional policy judgments. They strike down federal statutes, and they generally treat Congress as sort of a least favored administrative agency requiring Congress to build the sort of administrative record that we don't even require of our federal agencies.

In addition to the clarification acts which I mentioned in recent years the victims of the Court's federalist agenda have included portions of the Violence against Women Act, the Age Discrimination in Employment Act which bans discrimination in employment against the elderly, the Americans with Disability Act. That was this year banning discrimination against the disabled. State employers are no longer subject to that. Before that it was the gun control laws, work place standard laws and of course the intellectual property laws.

Congress needs to push back a little and test whether there are ways that it can pursue its policy agenda

given the new legal framework.

One last thing on the policy issue which is the states make hundreds of millions a year just on patents. They own hundreds of patents. Congress has encouraged the states to do this through research grants, through legislation like the Bayh-Dole Act. Universities not only, it is not only patents and copyrights. They have their team mascots, their jerseys, their emblems. They make a lot of money selling the accoutrement of their football teams. They have become serious commercial players, and they are routinely in competition with the private sector. This is not states acting as states, as sovereigns. The concept of sovereign immunity is when the state acts as a sovereign doing the sorts of things that we expect the government to do. These are states acting as commercial players, and there really doesn't make much sense to give them an economic advantage over their private competitors.

Now, I expect that you will hear that it is not that the states want to infringe and it is not that the states should be entitled to infringe but rather well the states really have no intention of infringing. So, Congress doesn't have to do anything.

Now, I have to say and I will just anticipate, and maybe I am wrong, but I don't think that the states are going to be massive infringers. I don't see them going out

and beefing up their endowment by marketing, you know, rip-off nuivicombags(?).

(Laughter.)

MS. KATZMAN: That just doesn't seem to me what states are about, but on the other hand there have been infringements in the past. There will be infringements in the future. There will be less obvious inequities in the context, for instance of licensing negotiations where states might be able to strike much harder bargains given the fact that they really don't have to pay anything at all if they don't want to license inventions or whatnot because they could just infringe with impunity. So, I think that even if we don't see the sort of really in your face sort of infringements that the court might be interested in seeing in order for Congress to show that there is a problem here I think you don't need to have murder all over the United States before you have a statute prohibiting it, and I think it is enough to just say, "Look, this is wrong. You shouldn't infringe," and if there are any infringements going on there should be a remedy for those infringements.

Let me just say a few words about what Senator Leahy has proposed and will be proposing I expect again this Congress? Congress does have very limited possibilities. As I said, the court in the last 10 years has really continuously shrunk the area in which Congress is able to

do anything about anything, and we have been studying the various possibilities and consulting with the experts, and so, have come up with what we believe is the most promising way to try to restore a level playing field in this area. It has two essential components.

The first is that it would allow intellectual property owners to sue states for intellectual property infringements that rise to the level of a constitutional violation, whatever that is and that is unclear what that is, but if you do it, if it rises to that level Congress absolutely has the power to provide a remedy for that. So, this is pretty much a relative non-controversial provision I think. All it says is that the court finds that an intellectual property holder's constitutional rights have been violated because for instance there has been a taking, something that arises to a 5th Amendment violation of something. Then he should be compensated.

Now, that provision given how hard it may be to prove a constitutional violation may not get Congress where it wants to go, and so there is a second component of the bill which is really the heart of the bill which is a quid pro quo waiver scheme and the concept is this. If a state institution applies for an obtains a patent or a copyright or some other form of intellectual property then for a limited period of time that state institution waives its

immunity from any intellectual property infringement action in federal court

The bill wouldn't have any retroactive effects. So, any existing intellectual property rights would not be affected, but in the future if the University of California just to take an example out of the air applies for a patent and is in fact issued a patent then for a period of perhaps 5 years though that remains in flux the university if it were sued for an infringement of any sort of intellectual property would be deemed to waive its immunity from suit.

The theory behind this concept is that Congress doesn't have to let states have intellectual property at all. The states can do all the things that states have to do without getting rich from intellectual property. The Federal Government has denied itself, for instance, the right to hold copyrights or the right at least to copyright its own works, and it gets along fine. It doesn't need to do this, and by the same token the states could, also, not have any but we don't want to deny states the right to hold intellectual property. What we want them to do is waive their immunity and agree to play by the same rules as everybody else.

So, the concept is that given that the Federal Government could deny the states any intellectual property rights, it can impose conditions on states that apply for

and are granted intellectual property rights.

One of the nice things about this proposal is that every state university, every state hospital, every state agency has a free choice. It can play the intellectual property game in which case it has to play by the same rules as everybody else or it can abstain from seeking any intellectual property rights in which case it will not be held liable for damages if it infringes on somebody else's, unless its infringement rises to the level of a constitutional violation, whatever that is in which case the other provision of the Leahy bill would cover it.

The other theory behind this proposal is an analogy to the spending clause cases. As I think you probably all know, Congress routinely conditions federal grant money. The concept is that we don't have to give the states any money. If we give them money, then we can tell them what we want to do with the money or what we want them to do with the money or what we don't want them to do with the money. This is the same concept. It relies on the same case law and one could clearly condition federal research grant money for instance, states waiving their immunity but nobody really wants to deny the states the research money.

Some of the best research in the country is done by state universities and we don't want to in any way throw a wrench into that. So, the Federal Government has always

done what it could do to support research of state universities. So, again, conditioning money is certainly something that is open to Congress but is perhaps less palatable than just saying, "If and when you apply for intellectual property rights then you waive your immunity," which would allow the states to pretty much carry on the way that they have been. They could accept their federal funding, do their research, patent their inventions and the only difference would be that when they patent their inventions they are in fact waiving their immunity if in the future they commit any IP violations.

That is pretty much the bill. I would be happy to answer any questions about it afterwards.

DR. BARTON: Thank you.

(Applause.)

DR. BARTON: Let me turn to Justin?

MR. HUGHES: My name is Justin Hughes. I am at the Patent and Trademark Office at the Department of Commerce, and I have been the Administration or now the Administrations', plural, person on this issue.

Julie is quite right that this is a place of great arcane constitutional law, and we have a mutual friend who just published an article where he in print gloats over the fact that this is the first time people who pore over 19th century constitutional cases have been able to lord it over

those of us who do not intellectual property issues.

Now, I am responsible for the confusion about the order of the panel. That is because all tribes as you know have their customs, and the customs among lawyers and law professors is that we ignore the questions that are put in front of the panel.

When I listened to the last panel here I found they actually tried to answer the questions. So, when I saw Julie I said, "Julie, we are in trouble. The questions are actually here, and we are not planning to answer them in the way that they have been presented to us."

So, I will try to race through the questions and give you the best answers or give you an outline of the answers to these questions.

The first question is are state universities claiming immunity, and that and the second question, is there evidence of infringement, and the final question, what data, if any, are needed to determine if a remedy is needed, all point to the issue of empirical data, empirical information we have. I am not going to surprise you to tell you that we don't have a lot.

In the particular field of intellectual property as many of you will know and Pam Samuelson would testify Congress, and I am not ragging on Congress with Julie here, Congress has a tendency to tell us to conduct studies but to

not really give us much in the way of resources to do it.

So, we put out a public notice for comment. We get in a bunch of letters, and then we write what we call a study.

I am not going to try to fool any of you here at the National Academies that that counts as good empirical work. We don't have a lot of good empirical work on this issue.

Senator Hatch with the agreement of Senator Leahy has asked the General Accounting Office to actually look at some of these issues, particularly the first two questions, are state universities claiming immunity and is there evidence of infringement by state universities and state entities. The General Accounting Office has actually set some staff people to work on this, and they are working on that process now.

Let me just adumbrate some answers to these questions? Are state universities claiming immunity? The answer is yes. The anecdotal evidence we have is yes. In fact, the reason we are relatively sure that states have immunity now from copyright violations is not a determination by the Supreme Court but in fact a determination by the Fifth Circuit concerning the University of Texas's assertion that it was immune from copyright violations in a case called Chavez.

Now, not to pull an institution from the air, but the University of California has been notorious in its assertion of sovereign immunity and in fact it asserted sovereign immunity in the Genentech v. Regents(?) case in 1998, in the New Star Laser litigation in 1999 and back in 1988, it was early on one of the forerunners in the vanguard of asserting sovereign immunity in the BV Engineering v. UCLA case.

Now, I am not out to blame universities. I want everyone here to understand what is happening. Universities are not homogenous entities. They are entities with disparate interests and lots of different people with different goals.

If you are in the general counsel's office of the university and you are faced with a patent infringement action or a copyright infringement action or a trademark infringement action you file an answer to the complaint that has been lodged against you.

Any good litigator, those of you who are lawyers or those of you who have had the pleasure of reading an answer to a litigation know that a lawyer raises all the possible defenses. You throw everything at the wall hoping something will stick, and the general counsel's offices invariably raise the sovereign immunity defense.

Now, if you as a general counsel can go in and

defend on this constitutional defense and quickly get out of court you have done a good job as a general counsel. In the long run it may not be the right policy answer, but you in the short term have done what you should do fulfilling your obligations to the university.

I want to say that because I don't think this assertion of sovereign immunity by these general counsels is maliciously motivated. It is simply what you would reasonably do, indeed, what your obligations are to do as a lawyer for an institution, raise all the possible defenses and get your client out of court as quickly as possible.

You would want your lawyer to do it, and so a university will want its lawyer to do it. So, it is not surprising that state universities are claiming immunity, and we should expect state universities to continue claiming immunity in these circumstances.

This assertion of sovereign immunity by state universities is not limited to intellectual property. In fact, one of the important cases last year which strengthens the argument that Julie presented that there may be a viable approach to eliciting waiver by participation in a federal program or in the federal intellectual property program is a case of *Littonon(?) v. George Mason University* where George Mason raised the state sovereign immunity defense to a claim brought under Title IX funding.

So, this happens in all kinds of areas, not just intellectual property. Is there evidence of infringement is the second question. Again, there is just an absence of good statistical empirical evidence. We can assemble a couple dozen reported cases. I can say to you and any of you who are lawyers would know that reported cases will generally be the tip of an iceberg because reported cases are cases that have made it into the books, cases which often have been appealed. There are many trial decisions that are never appealed. There are many cases which never reach a trial decision. There are many disputes which never become a case.

So, we don't know, but we have good reason to think that there are many occasions of state institutions infringing federally protected intellectual property. If you ask the intellectual property community they will certainly say, I believe with some justification that the changing environment and particularly the potential of the Internet increases some of the probability of state institutions, particularly state universities getting more involved into the intellectual property business and any of you who are familiar with the issues about distance learning and the ongoing interchange between faculty and administration at universities about the ownership of intellectual property rights for distance learning can just

see that as one area, just one example of an area where the increasing potential to commercialize and to distribute intellectual property works may bring state universities into an environment, into an ambiance where they are more likely to infringe someone else's intellectual property.

There are some big differences, I will say. I would say that you have to recognize that the Internet raises the potential that state universities will infringe copyrights. It augments the probability of copyright infringements far more than patent infringements.

I actually have to tell you all an anecdote which I told someone outside about evidence of infringement. Last year I discovered one of my Law Review articles was reprinted in a book called The Politics and Morality of Intellectual Property. To make this ironic they did not get permission.

(Laughter.)

MR. HUGHES: So, I sat there thinking, okay, I am going to call the editor and suggest that he send several dozen free copies to placate me and it dawned on me last month that it was the Ohio State University Press.

(Laughter.)

MR. HUGHES: So, I guess I need to talk to people about being conflicted out of this problem now. Now, the third question is does legal immunity affect industry

activities or industry attitudes. Again, we have no evidence. We are even more speculative here, but I think as Rob Mergis made this point on this stage actually a year ago it would be hard to imagine that rational actors in the private sector will not take this into account when you consider all the litigation for example, between Genentech and the University of California over that distribution of know-how and patent rights and when you think about the point Wes Cohen made in the previous panel that a university researcher is interested in the feedback, the informational feedback from the private sector. There is a real symbiotic relationship going on there and if in that symbiotic informational relationship one side is known to be immune or partially immune from the legal protections the other one hopes he or she has, that definitely if you are a rational actor can impact how you approach the relationship and as John said, maybe the answer is simply that you write in waivers into all your contracts, but everything being equal, and things are rarely that everything is equal but everything being equal you might simply choose no, I will go to the private entity where I don't have to worry about whether the terms I write into the contract are going to be held to be a waiver where I won't actually have to spend the extra \$10,000 to litigate the sovereign immunity issue.

Is there a need to restore a level playing field?

This, unfortunately, is the one truly open-ended question which lets me do more of what is my wont to do and both John and Julie have talked about the TRIPs Treaty. Let me explain to everyone what the issue is in the TripPs Treaty just so you know. The TRIPs Treaty, the trade related aspects of intellectual property is the intellectual property treaty that is part of the World Trade Organization which is the follower on to the GATT system.

Under the TRIPs agreement for copyrights and patents and trademarks each of those principal areas has a treaty obligation which says, and I will read you the one relevant to copyrights, but it is practically verbatim language for patents. Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with the normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the rights holder. So, for example, our fair use system under US copyright law must be fit within this limitation and exception language, that it does not conflict with the normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the copyright holder.

Now, Julie said that this Florida pre-paid problem puts the US in violation of international treaty obligations. Being from the Administration I would not say

that.

(Laughter.)

MR. HUGHES: I would say that some of our trading partners may argue that this puts us in violation of our international treaty obligations, and that is just as bad.

(Laughter.)

MR. HUGHES: That is just as bad because you know Julie told the story quite rightly, and I live it because I actually spend a lot of time working on these international issues. When you go out and the government of Ruritania says, "Why can't we use all these medical devices in our hospitals without paying any patent royalty? They are state hospitals and the State of California, UC system can do it, too. Why can't we?" So, the issue is really there that they can take this problem that we have, this apparent hole in our enforcement system and whether or not it is TRIPS compliant they can say that this large hole in our system which your industries are complaining about is really no worse than what you have with your Florida pre-paid situation.

That being said, the Administration has tried to be and is intent on being engaged and cooperative on this issue. We aren't committed to any particular solution. We think Senator Leahy's staff has done a fantastic job on exploring these issues and when you look at the recent

tendency of the Supreme Court it is fair to say that the waiver approach looks if not better and better absolutely, it looks better and better relatively.

So, I think that when the Administration does take a final view on this that it will look towards something like what Senator Leahy is working on, something that focuses on a waiver system.

Now, let me, I don't know, I am sorry, I am going to rail once more on the University of California system. I want to read you something from a case which I think really tells what this is all about.

In the 1999 New Star Laser v. Regents of California litigation it involves a patent that is held by the UC system and in that case UC has settled a litigation in Massachusetts over the patent and they had threatened in writing New Star Lasers. New Star Lasers did what people do when they are threatened in writing with patent infringement sometimes. They filed for a declaratory action invalidating UC's patent.

Now, the UC counsel being aggressive lawyers had the audacity to come into court and say, "Oh, I have sovereign immunity. You cannot sue me to test my patent," and the judge said, quote, the regents wish to take the good without the bad. The court can conceive of no other context in which a litigant may lawfully enjoy all the benefits of a

federal property or right while rejecting its limitations.

I think that that is really what this is all about. Universities which wish to play in the commercial world of federally protected intellectual property should be prepared to play on both sides, offense and defense, and I think that the solution if we can find a constitutionally viable solution is one that pretty much everyone should support.

Thanks.

(Applause.)

DR. BARTON: Mr. Shekleton, to give the public universities their voice.

DR. SHEKLETON: Good afternoon. My name is James F. Shekleton. I am General Counsel for the South Dakota Board of Regents. I hadn't intended to talk about the divine right of kings.

(Laughter.)

DR. SHEKLETON: But I think that we ought to at least make some stab at apologetics. First of all let us remember the context here. I suspect that America being the kind of country it is and we having the kind of common background that we have you are probably all familiar with the story of King Solomon and the two women who came to him.

One woman's child had died and the other woman's hadn't, and the woman whose child died said, "That one is mine."

They were unable to resolve their difference privately. So, they had to go to the king to get a solution. It is a wonderful little story about law and it has something to tell us about sovereign immunity, about sovereign power. Where private decision making fails people within a community turn to their government to try to find a solution.

Now, the question that the Supreme Court is worried about and these lines of cases involve the way in which sovereignty is practiced in these United States. Under our system of government people have granted sovereign powers to organs of government. There are limited powers that have been conferred upon the national government, and they are articulated in the Constitution. The patent clause is one of these. The powers that have not been granted to the Federal Government under the Constitution have been reserved to the state government except to the extent that they have been prohibited to government altogether, for instance, the right to control what we think.

Now, the critical issue in these sovereign immunity cases involves how do we go about making decisions, that is we the American people. Do we turn to King Solomon? Do we turn to some other king? Do we go down to the temple?

In our case if we want to know what is a patent; how long is a patent we turn to the Federal Government

because they have the power under the Constitution to decide those issues.

If we want to know whether I can inherit Uncle John's patent after Uncle John has passed away we turn to the state government because under our Constitution the state government makes decisions about the descent of property.

National government and the state governments as our court has said, are joint participants in the governance of the nation. It is a coordinate sovereignty that exists under the American system of government.

Now, the framers designed government that way in order to prevent what they perceived to be the greatest evil in the 18th century, that is the consolidation, the concentration of governmental power.

So, this is a deliberate feature of our unique American system. Neither the states nor the national government may interfere with the operation of the other coordinate sovereign so long as the other coordinate sovereign is acting within its sphere, and that means that absent the express constitutional authorization the national government has no power to dictate to state governments their policy decisions. That is the critical background that the court brings to this 11th Amendment line of authority because what the court has said in *Alden(?) v.*

Maine is that the 11th Amendment preserves the state's ability to govern in accordance with the will of their citizens. The court is looking at these decisions as trying to preserve the integrity of our way of distributing sovereign powers and making sure that you when you are in conflict know whether you have to turn to the national government for a solution or to the state government for a solution.

The problem that the court has with the patent system as it had previously been set up with the attempt of Congress to say that we, the national government may open the door to the state's treasuries is and again I quote the private suits against non-consenting states, especially suits for money damages may threaten the financial integrity of the states.

Now what the court has come to understand is that there is in fact a link if you will between the ability of states to make decisions as sovereigns and the practical consequences of litigation. Justice Kennedy summarized the point thusly. Today as at the time of the founding the allocation of scarce resources among competing needs and interests lies at the heart of the political process. While the judgment creditor of the state may have a legitimate claim for compensation other important needs and worthwhile ends compete for access to the public fist. Since all cannot

be satisfied in full it is inevitable that difficult decisions involving the most sensitive and political judgments must be made.

If the principal of representative government is to be preserved to the states, the balance between competing interests must be reached after deliberation by the political process established by the citizens of the state not by judicial decree mandated by the Federal government and invoked by the private citizen.

The 11th Amendment holdings reflect the understanding that a \$300 million judgment may impair the ability of states to discharge quintessential state duties, duties involving education, providing welfare, duties to protect the public safety.

The purpose of sovereign immunity in the 20th century is to reserve to the people acting through the appropriate organs of government the decision of whether or not they are going to open up the public treasury to private litigants.

Now, that is the primary concern that the court has before it. In my remaining comments I want to address three quick issues. First, I want to talk about the level playing field canard. Second, I want to talk about the dubious project of trying to circumvent the Supreme Court's decisions. I promised I wasn't going to be confrontational

and three, I want to suggest how the national and state governments can coordinate their efforts to respond constructively to the predicament in which federal and intellectual property owners find themselves.

First, going to the unfair charge that the Supreme Court has denied federal intellectual property owners the level playing field. This is really an engaging sophistry. It is an old lobbyist's trick. When a public policy issue has been set up in a fashion that your client is going to lose, then the clever lobbyist always tries to find a way to change the topic to something that is a little more likely to be favorable, and if you can change the topic in a way that will take the moral high ground and invoke the language of morality so much the better.

The level playing field arguments arrogates to federally protected property owners the language of fairness and justice, always a very high ground. What better way to preserve a system of privileges that are not available to any other property owners?

Now, this is really a rhetorical game and if you want to find confirmation of that it becomes clear once you look more carefully at what the actual argument is that the rhetorical gambit may not be made to fit the facts.

In truth the immediate problem that confronts federally protected owners is a function of a congressional

decision that preempts state jurisdiction over infringement claims which has the practical effect of permitting states to provide remedies to federally protected property owners that they provide to the owners of state-protected properties including state-protected intellectual properties such as state marks and trade secrets.

The obvious response to this conundrum would be to go ahead and to allow states to exercise jurisdiction over infringement plans that have been brought against states, but this is not something that anyone appears much interested in doing. They want to have special rights. They want recourse against states that are not subject to state adjudication. They want to have enhanced damages, the sorts of damages that are usually only reserved for private parties, subordinate governmental entities and rogue nations.

They want to be able to treat Massachusetts and Delaware in the same fashion that they would treat Libya and Iraq. Some people might find that reasonable.

(Laughter.)

DR. SHEKLETON: What is being sought by the proponents of certain ventures is not a level playing field but it is a different playing field, different from the one that is occupied by every other property owner.

Why do federal intellectual property owners

require a different playing field? Why do they need to have something that is different from the owners of trade secrets? There is no clamor from those who are dependent upon state-protected intellectual properties. There is no evidence of state predation on trade secrets or under former law on products of the mind. The state remedies have not impaired the business relationships between state entities and the owners of trade secrets. It is not apparent in the least that the state remedies would be inadequate if only Congress would allow the states to provide them.

Let us take one other look at this level playing field because the whole field was never level, at least not when sovereigns entered onto the playing field.

Remember there are good and compelling reasons why a sovereign people want to decide the terms under which private litigants will be able to attack their monies. That is a critical policy decision. The Federal Government when making that decision on behalf of us as federal citizens decided that intellectual property owners were not going to be able to have recourse against the Federal Government and get enhanced damages, and hence damages are off the table for the national government. Moreover they are off the table for foreign governments except of course for those rogue nations, Massachusetts, Delaware, Libya and Iraq.

So the playing field was never really level in

that respect. Much has been made of the fact that state governments go into the marketplace, but even when a state government is in the marketplace it is not the same as a private entity. The state government losses have to be borne by all of the citizens either in the form of reduced services or in the form of reduced diversion of private incomes through tax raises.

Government action always implicates public welfare, and it is for this reason that Justice Scalia summarily dismissed the notion that the fairness argument was appropriate in the marketplace.

Let me read from his statement? In the sovereign immunity context even handedness between individual states, individuals and states is not to be expected. The constitutional role of the states sets them apart from other employers and defendants.

The playing field only included a narrow band of property owners. It never provided enhanced damages against all sovereigns. It countenanced intrusion by private individuals on the determination of public policies in a manner that is inconsistent with the American system of public accountability.

Restoration of those special privileges should have no claim on our moral sentiments.

Now, on to the circumvention argument, and I will

not take you down the path of trying to go through each of the problems that have been presented or approaches. Let us simply say that the committee has done its work very well. The Senate Judiciary Committee has done its work very well. These are all very lawyerly arguments. They are not free from substantial controversy, but nevertheless they are very well made.

The problem I think lies in the fact as has been mentioned that the great work of the Rehnquist court throughout the nineties has been to shift the nation towards a form of reinvigorated federalism. This is the signal work of the court. It is not going to abandon this work when presented with a highly technical lawyerly argument.

I think that while this may be an effective approach in other areas, the fact is that this is the central station on the road that the Rehnquist court has taken. As I have tried to suggest to you in my description of its version of sovereign immunity it goes straight to the heart of the ability of the population to control state government and to make sure that they have a government that will have the funds ready to put teachers in the classrooms and policemen on the streets, just as Congress has made sure that our national government has monies ready to put aircraft at sea and to put congressmen with staff.

Okay, the last thing, a practical approach. I do

think there are some things that can be said and obviously the TRIPs issue does require congressional response. My suggestion would be that the appropriate response is to implement the Constitution as the Supreme Court has told us it was meant to be implemented. That would involve allowing states to take jurisdiction over infringement claims that have been brought against states. It is a very narrow opening in the door, but it does allow states to have the possibility of accepting these claims, determining the infringement claim and providing a state remedy.

The state remedies for federal intellectual properties would doubtless be the same as those that are provided for every other state property, and as has already been mentioned the due process considerations are going to provide some guidance as to what is an appropriate remedy.

Uniformity of interpretation of federal copyright and patent law clearly is a consideration. Uniform interpretation of the 4th Amendment protections for people charged with crimes is clearly a federal concern of the first magnitude.

We protect the 4th Amendment interpretation by providing for appeals mechanisms. We can do the same for property interests as we do for liberty interests. It works in the 4th Amendment sphere. There is no reason why it won't work here.

If uniform remedies are desired so that your remedies are not going to be different in South Dakota from what they might be in New York, there is a mechanism that is already well established in the states to try to address that, and that is to turn to the Uniform Laws Commission which was established and exists specifically for the purpose of trying to help states determine a balanced way to achieve uniformity in matters of commercial law and other forms of law that are relegated to states under our constitutional system.

The Uniform Trade Secrets Act is a good illustration of how this process can work, and we could certainly expect that states would be responsive to this.

Ever since Hammurabi carved his code in stone and raised it to the public in the Temple of Mardue(?) government has been responsive to the needs of property owners and government has been responsive to the needs of business people. There is no reason to expect that states wouldn't be just as responsive if there is a clear need for a uniform set of federal property remedies.

Likewise states recognize that there are substantial advantages to the states to be obtained from having uniformity across borders. Every state wants to attract business. I have never heard of a state that doesn't, and they will take every action they reasonably can

to try to facilitate that.

Conclusion, thank goodness. The American system of divided government has been effective and it has proven its resiliency for over 200 years. If federal intellectual property owners take their case for damages to the American people and approach those people through their state legislatures there is every reason to expect that they will get as favorable a response as they would if they went through the halls of Congress. There is every reason to believe that this temporary bump in the road can be resolved in an equitable fashion that will not compromise our nation and the family of nations worldwide or that it will work to the disadvantage of either state entities or private parties.

I appreciate your patience and I would be happy to respond to any questions and see if I could obfuscate things further.

(Applause.)

DR. BARTON: Thank you. I think we have time for just a couple of questions, and I know the panel will want to make some closing remarks. Go ahead.

DR. GARDENIER: I am John Gardenier, a private citizen with a doctorate in business. So, I have some interest, but I have no lawyerly experience. So, I am going to ask for a couple of clarifications, one from Julie and

one from James.

Julie, if the 11th Amendment trumps the 14th, why does not the 1st Amendment trump the 11th, and then would James please explain to me if the GAO report is to furnish empirical evidence that the states are in fact infringing patents and copyrights without compensation and the state courts are not providing relief then does it not appear to the states that the publication of such information could be injurious to them and motivate them to find a remedy?

MS. KATZMAN; The question is why doesn't the 1st Amendment, Article 1, actually it would be, trump the 11th Amendment. It is actually oddly enough counter intuitively just the reverse in the sense that the 14th Amendment can trump the 11th because it comes later than the 11th, but Article 1 which was part of the original Constitution no longer can trump the 11th. That is another thing that happened about 6 years ago in a case called Seminole Tribe where the court decided for the first time that Congress could not abrogate the state's immunity using its Article 1 powers which includes the commerce clause, most importantly and, also, the patent and copyright clause so that Congress can only abrogate when it is exercising its 14th Amendment authority under Section 5 of the 14th Amendment which is usually thought of as being used to remedy discrimination but can also be used to remedy other forms of constitutional

violations.

DR. SHEKLETON: And as for the GAO survey I know that many attorneys who are looking at that are answering it very gingerly. In point of fact, the difficulty with that approach is that there are a number of structural impediments that states encounter. So, long as a state cannot adjudicate the infringement issue how is it going to provide a remedy for something that it has no power to adjudicate? So, in a sense the question calls for an answer that states are prevented from giving. Every state is going to have a set of statutes that allow for remedies against the state for claims brought by property owners, and those are going to be open. Our statute I think it typical. It does not limit it to property of any particular distinction. The rub is that federal IP owners cannot take recourse to that because the court would have to determine infringement and exclusive jurisdiction rests with the United States District Court.

So, states are impaired there. There are a number of other theories that intellectual property owners can and have brought against states that are not contingent upon the infringement but are alleging related torts or contract claims, and those generally are subject to review by state courts in resolution.

So, I think the GAO survey while well intended is

not going to elicit the kinds of responses that would really prove the point that they are trying to prove.

MS.KATZMAN: I should, also, add the reason that Congress is unlikely to be able to accomplish much under the 14th Amendment in this area is the most recent case which was in the age discrimination basically said that Congress didn't do a good enough job of assembling record of discrimination by state universities or state entities of age discrimination where Congress had had multiple hearings over a number of years, compiled a record that was thousands of pages long with hundreds of incidents of discrimination and the court said, "Sorry, that is just not enough."

So, given the experience in that context it would appear very unlikely that Congress could assemble the sort of record to accomplish and abrogation in this area under the 14th.

DR. NEWBERG: I am Josh Newberg. I teach at the University of Maryland at College Park. This doesn't implicate the relationship between federal and state law, but I think it is related. In the context of industry-university research collaborations companies often will ask university researchers to execute non-disclosure agreements where there is a contractual obligation, state contract law and trade secret law on the part of the researcher not to disclose proprietary, confidential trade secret-type

information, and I am interested to know are you aware of cases in which private firms have ever successfully sought to enforce such agreements? Would there be anything that would preclude a state from asserting a sovereign immunity defense to the enforcement of such non-disclosure agreement?

MR. HUGHES: Literally speaking, and I will use your question to respond to something Jim said, but I will be honest about it, the problem is that you cannot have or cannot know ahead of time uniformity, and uniformity in this area would take a vast amount of time to work out because this is a state-by-state issue.

Let me read you, Jim said, "Gee, you can sue in state court." Let me read you a few constitutional provisions from different states? The Wisconsin Constitution says that the legislature shall direct by law in what manner and in what courts suits may be brought against the state.

The South Dakota Constitution says that the legislature shall direct in law in what manner and in what court suits may be brought against the state.

I could read you on and on and on, but it really then becomes a question for state law, and whether or not the state is amenable to that type of suit.

DR. NEWBERG: Thank you. Would somebody like to answer the question though?

DR. SHEKLETON: I would say that what you have described is a contract claim. If you are bringing it in federal court, yes, you could have the 11th Amendment pled by the state entity in federal court. If it is brought in state court it would be resolved.

MR. HUGHES: But in state court the state can plead immunity, also. The state may raise immunity.

DR. SHEKLETON: I think that gets to something that as a state actor seems to me is at the core of some of this. I noticed that the piece that was handed out as part of the brochure that discusses this, the Supreme Court's war on intellectual property, that is pregnant language, isn't it?

In the states we have to figure out ways to provide employment for our citizens. Trying to raise impediments to businesses to bring claims against states is not a good way to convince business that we in this state provide a good business climate. As a practical matter I don't think that you will find states willy nilly, especially if the ball is thrown back in the state court, you will not find states trying to limit their exposure to these claims. You may find they limit the amount of coverage or the manner in which you have to go about securing a remedy, but states are practical places that operate in just as responsibly to government as does the national government

DR. BARTON: We are now running over time and the last session cannot be shrunk very much. So, let me ask each of you to raise your questions and then each of our panelists to give the answers and any final points in response fairly quickly.

Steve?

DR. BARROW(?): Okay, Steve Barrow, with the Academy. I actually have a Web caster listener question which actually has been answered, but I want to parley it into another question. The Associate General Counsel of NC State asks, "Is it not true that states are still subject to injunctive relief in the federal courts under the Supreme Court decisions?" which Julie has answered affirmatively, but the question is why isn't that an adequate or effective remedy. In a recent famous case, Amazon v. Barnes & Noble it appeared that injunctive relief was swift and sure but that may often not be the case.

DR. AMSTUTZ: My name is Pete Amstutz. I am a private citizen. I have worked just recently for a very large American company located in Michigan, and there is a real battle out there among the states to attract corporate investment and corporate research dollars.

So, I am wondering do all 50 of the states claim this immunity or have some of them stepped out and said, "We waive it because we want to be a more attractive partner. We

want to attract companies to do their business in our state and with our universities," and if any of them have maybe you could mention their names with some prominence today.

DR. BARTON: A final question from the floor?

DR. WALLACH: My name is Steven Wallach. I am with Pennie & Edmonds. I am wondering if the Leahy bill might be a half measure because it seems to me that if say the California Highway Patrol has an infringing motorcycle since the California Highway Patrol is not likely to have patents of its own you could never sue that government entity.

MS. KATZMAN: I should take the last one. It is not a complete solution. It is the 80 percent or 90 percent solution, and the reason for that is because the barriers and obstacles that have been put up by the court that we are trying to circumvent on some people's views and on other people's views where we are just trying to restore what has always been until this round of really radical Supreme Court decisions, has revived this totally moribund doctrine.

It is not a complete solution, and that is why the second part of it would be to allow suits for constitutional violations if it rose to that level, but I guess there will always be some escape and can infringe without consequence.

MR. HUGHES: I will try to answer the first question, injunctive relief. Injunctive relief remains a powerful tool to be used by intellectual property owners,

but many in the intellectual property community feel it is insufficient, and as I am constrained to say many of our trading partners might argue that it is insufficient for terms of our treaty obligations.

Let me as a closing point address something Jim said? The whole question of whether the waiver approach is a dubious way around the Supreme Court majority's clear position on the abrogation doctrine, I don't really think it is and in fact if we are going to talk about the characteristics of the Rehnquist court one characteristic that is extremely important is the Chief Justice's heartfelt belief that the Congress may impose conditions on things which it distributes as a gift or gratuity, and he is strongly of the belief that a greater power includes a lesser power and in this case the greater power would be Congress's ability to simply say that there will be no patents or Congress's power to say that there will be no patents owned by states which seems constitutional and therefore attaching it to say that if you want a patent you have to play in the intellectual property system probably does fit within Justice Rehnquist's vision of the greater power contains lesser powers.

Do all 50 states claim immunity? Actually there are three states which in their Constitution absolutely assert immunity, that is there won't be suits against them

and I believe the State of Colorado only permits suits against it for traffic accidents.

So, this question of having all states willfully come up to the table because they want to attract business, someone needs to tell Arkansas and West Virginia and I cannot remember the third state, Alabama that they aren't going to get any business because their Constitutions say that they assert sovereign immunity and Colorado, but that is my take on this.

DR. SHEKLETON: I do think that market forces will operate on state legislators and on state voters. They have throughout history. So given the proper circumstances I am not despairing of that. I remain skeptical of the waiver rationale because it is clear from the college savings banks in Scalia's opinion that trying to condition participation in a legitimate activity on a waiver is a sanction and is not an inducement and surpasses the point of a potential limitation and as Justin knows I take the position that the examples of waivers that have been upheld by the court or *indicta*(?) suggested as being appropriate all involve very unique stack patterns in which the required waiver and some of these are the compact clause where you are creating a quasi-governmental entity that is outside the usual political process of control and under that setting it makes sense especially since that was viewed by the founders as

being one of the chief threats to the integrity of the union. It makes sense to require waiver of sovereign immunity so that citizens of other states who have no political control but come into dealings with that state may have some recourse and also in the Title 6 analogy, Title 6 seems to me to be very broad, but it is, also, a statute that seeks to preserve the integrity of the political process within each state and a broad requirement of accepting conditions on federal money that is designed to enhance the integrity of the governmental processes sounds very attractive to the court. Thus, I am not sure that the waiver examples that we have been provided auger well for a broad waiver whereas here the court has said that 11th Amendment immunity goes to the very heart of state decision making.

DR. BARTON: Let me thank you all for making this highly abstruse issue both intelligible and interesting.

Thank you.

(Applause.)

DR. LEVIN: Okay, let us move right into the wrap-up session before everyone is gone. We are going to have some closing observations, first from Scott Giles who is the Deputy Chief of Staff at the House Science Committee, then by Mark Myers, the Co-Chair with me of the STEP Committee on Intellectual Property Rights and then I will make some final

observations.

So, Scott, if you would?

MR. GILES: Thank you very much for having me here, and I am going to try to make my remarks very brief in the hope that we can have a little bit of conversation, but first of all by way of introduction I work for Sherry Bowler(?) who is the new Chairman of the House Science Committee and although he is the new Chairman he is not new to these issues. He has been on the Committee and actively involved in university research and IP policy for nearly 20 years, and I want to thank the Academy and all of you for participating in this.

When Sherry made his maiden speech before the University Research Associates as Chairman of the Science Committee, he called for new examination of the changing nature of the research university and of questions raised by the growth in the partnerships and I mean at the outset I want to say that this renewed examination doesn't reflect a nostalgic desire for a return to a pure institution and an earlier state of grace as some people commented afterwards. It reflects a belief that research institutions are facing new challenges and that many of these challenges are products of the growth of these partnerships.

Many of these changes may be good, but it would reflect poor leadership on your part and on our part if

these changes went unexamined. So, I want to thank you for taking that challenge that he made seriously.

After sitting through the presentations today two things seemed particularly clear from all the presentations. One, Bayh-Dole has been pretty successful in spurring commercialization and new university-industry partnerships, and when I say that I want to put things in context.

When we were debating Bayh-Dole nearly 20 years ago only 5 percent of federally owned patents were being used commercially, and I think that the presentations that we saw throughout the day showed how much new activity has been spurred in large part as a result of that law.

The second thing that is I think quite clear is that the impetus for commercialization is coinciding and may be causing real changes in the university as an institution and I am just going to run down through some of the things that I kind of found most notable or some of these challenges.

Conflicts of interest were raised repeatedly, and I guess the one thing I want to say about that is that is that the public in general as we all know has a distrust of institutions, but universities have been held in fairly high public esteem, and university and research in particular has been endowed with a high degree of public confidence which I will add in turn makes politicians more likely to support

federal research and development funding.

Challenges to this perception of neutrality have both micro and macro implications and I think that Dr. Bauer in particular was correct to challenge us to make every step possible to try to safeguard that public trust.

The second thing that was striking to me about some of the discussion today was the emergence of the university as an entrepreneur. Fifteen years ago I remember being at a conference of sponsored programs directors when one of them proudly stood up and noted that 5 years earlier there had only been 5 of us and now there are 500 and similarly we are seeing a rapid expansion in the number of patent and tech transfer offices which is probably a good thing, but one of the things it does reflect is a shift in institutional resources and something that I think needs to be noted and considered.

The third thing that we have heard described is the emergence of the faculty as an entrepreneur. It was noted that increased pressure is being placed on faculty to commercialize their discoveries and to participate in the creation of start-up companies, and we all know that time is one of the most valuable and constrained resources that a faculty member has. Time spent on commercialization is time not spent on other traditional faculty roles, in some cases maybe basic research.

Again this may or may not be a good thing, but the change is clearly undeniable. Before we heard that these partnerships seem to be having some impact on the research questions that are being asked.

One of the earlier panels noted that we don't see any evidence of a shift from basic to applied research which is one of the kind of anecdotal claims that has been made out there, but there does appear to be evidence of a sharp shift towards biological sciences, and I think that one of the things coming out of this conversation at least in my mind is that we need to gain a better understanding of the reasons for this shift and the opportunity costs associated with them, and in fact there may be factors like federal investment in R&D that may be having more of an effect on this simply than the industry partnerships.

Five, I think issues were raised about the free flow of information, and I think here that one of the concerns that I have goes back to the importance of the university maintaining the public trust. There is evidence that commercialization has had an impact on the publication time frame for research papers and that has been an issue that has been discussed frequently but recently there have been several highly publicized legal cases drawing public attention to the ability of industry partners to utilize or impact the disclosure policies of university research

centers and to affect through contract the publication of so-called "adverse" results.

I think this is a question that needs to be considered more fully because to the degree that these kinds of challenges pose a challenge both to the whole notion that we have traditionally had of a university but also to public trust and then finally one of the things that we talked about to some degree but I think merits additional attention as well is the whole notion of ownership of research tools.

Without getting into all the legal and economic considerations the increased effort primarily in biomedical science to assert proprietary rights over research tools and genetic materials represents another change in the way researchers are engaging each other and I think it is one that we need to consider.

The previous panel I think very thoroughly highlighted some of the issues regarding state immunity. One of the implications that we didn't discuss as much was what this may bode for the relationship between private and public institutions and the partnerships they are able to form.

In closing I just want to say the challenge I think that lies before us is to kind of sail between the shoals of Scylla and Charybdis to nurture the entrepreneurial spirit that generated this kind of

commercial activity and success while making sure that we preserve the integrity and public trust that has made the research university such an important public institution, and with that I think I will stop and look forward to hearing your comments.

DR. MYERS: Thank you. My observation is that the landscape has fundamentally changed, and it is continuing to change. The role of the research university is growing ever important as an economic force in our economy, and it is not just a shift of economies from manufacturing or earlier economies to a knowledge-based economy but that it is also a shift in the nature of the industrial sector itself.

When I started my career in fact the really seminal research that was important in an industrial sense went on in what I would call quasi-public private institutions such as Bell Laboratories, Yorktown, later on Xerox Park but even before that the Dupont Research Station.

These were all created as various forms of public monopoly. They in fact had an openness because of that. Now, all of these institutions still exist, but they are in some sense in a competitive environment that is no longer characteristic of that monopoly and the kind of outflow of information that their roles are so important to their different companies, you are not going to purposely see the openness and spill overs that in fact have been

characterized in those kinds of institutions in the past, and I see that the public research and private research universities in fact have increasingly fulfilled that. Intellectual property will be an important part of that.

Now, we heard, in fact, intellectual property is growing. It is growing from a fraction of percentage of patents to 2 or 3 percent.

I would say though that margin is a very important margin because where that intellectual property is created as time goes on we will probably be able to develop the kind of research to find a great amount of seminal ideas will in fact be patent in those three and probably growing up to sometimes maybe 10 percent in the future. It will remain small as a percentage of the whole, but I think it will become increasingly important in terms of the originality and the seminal nature of that intellectual property much like was created in the Bell Laboratories or Yorktown in the past, and so, I think that that role is fundamentally in place and growing.

The margin although as we heard the University of Pennsylvania 30 million, 24 million clear, on the margin though going to the profit line, 24 million is a substantial influence and that will continue to grow.

So that brings me to the issue of distortions. To what extent will this become a force of distortion with

respect to the fundamental purpose of education and research informed education processes of the university which requires openness? I was impressed by the processes I heard both from Penn and Stanford today as well as the Hughes research activities in terms of building safeguards with respect to vigilance.

I would only simply say that it is going to get tougher. It is going to get a lot more complex and a lot more difficult, and that will become part of the challenge of people like my colleague next to me to in fact build check systems that in fact provide that kind of vigilance for the institution.

DR. LEVIN: Thanks, Mark.

Let me try to summarize a bit about what I take away from this conference generally because it will feed in as intended to the work of the National Academy Committee on Intellectual Property Rights.

I am heartened to see my economist colleagues investigating the question of what have been changes in the landscape occasioned by the Bayh-Dole Act and essentially a significant regime change of which we have now had about 20 years of data which as Bronwyn Hall will tell us is almost enough to have a time series to analyze.

I would say that the work that I see my colleagues doing on the subject is still not a completely full picture

and part of that may be the difficulty to get access to data, but I suspect, also, part of that may be, and I would suggest this for future research, part of that may be spending more time looking at numbers and not talking to the people involved in the creation of those numbers.

I think we need more conversation with some of these technology transfer officers. It would be very helpful because these people do have a very grained knowledge of what is going on inside the institutions underlying the general data.

I would agree with Scott Giles identifying what some of the questions are within the university in terms of internal governance and self-regulation, and I would, also, agree with Mark that I think we have actually done a pretty good job at in most of the larger institutions at least, and i am less familiar with the smaller ones and how they conduct themselves in terms of establishing clear policies on conflicts of interest, internal review mechanisms, setting guidelines on conflict of time commitment on the part of faculty. At Yale, for example, we have had a longstanding policy actually written within a year of the Bayh-Dole Act passing that said that if you are a faculty entrepreneur and you have doubts about whether you can comply with the 1-day-a-week on outside activity rule you can take a year's leave and go out and found a company.

We will grant that and at the end of that time decide whether you want to come back and work on our terms as a full-time faculty member with only a day a week on outside activity or in fact go off and work in the company and maybe you have an adjunct faculty arrangement with the university and a much reduced role.

So, I actually think that institutions have been wrestling with these problems now literally for 20 years. I agree with Mark. They are going to get tougher. The numbers get bigger.

The number of faculty involved get bigger, but I think that is certainly an area where we could all benefit from wider dissemination of the practices we have and some external scrutiny.

I would much rather be scrutinized frankly by the social scientists than by the government on this question. As a private institution I don't really think how a faculty member allocates his or her time as long as it is not on government-funded time is really any business of the Federal Government. I just have to assert that from the point of view of the private research universities.

One issue that did not come up except in passing a couple of times is the question of the university's role in making decisions, to whom to license and on what terms because we are not purely commercial enterprises. Sure, we

want to keep -- we are not profit maximizers.

We want to keep good relations with the companies we are interested in having partnerships with, and we want to get inventions into practice for sure.

Those are legitimate social objectives and frankly they are university objectives, but from time to time there will be questions about ethical issues about the dissemination of the products based on university technology that warrant exceptions or deviations or special consideration so that this has come up just recently and when in South Africa it became possible to contemplate importing generic substitutes at a much lower price for AIDS drugs there were requests coming to Yale among other institutions and our licensee, Bristol Myers among other drug companies to take action to reduce the price of drugs in this area where the AIDS epidemic is so rampant in all of Sub-Saharan Africa and in fact we did contrary to New York Times reports move immediately to work with Bristol Myers together. You know, we strongly encouraged them to take some action.

They did, in fact, say that they would not assert their patent against the generic substitute in South Africa, and they lowered the price of the drug from \$10 a day to 15 cents a day, and this is where we felt it was time.

It was appropriate to address the AIDS issue in

South Africa, and both Bristol Myers and Yale have already reaped substantial returns from this particular drug, and I think from time to time universities are going to act that way rather than in what would otherwise be an unconstrained commercial profit-maximizing way, and we are going to have pressures in our own communities to act that way, and that will serve as another interest we have to balance.

So, there is more to learn about the landscape. I think wider discussion of the ways universities regulate themselves internally is a very positive development.

Now, all that said, it seems to me that the main question that at least we posed in the outline for this conference is one on which we get a pretty clear answer and that is all this considered is the Bayh-Dole Act a good thing; has it improved the welfare of Americans; has it improved economic welfare; has it created problems greater than the benefits?

I don't hear very many strong arguments that something about the Bayh-Dole Act per se is problematic. I mean the putative benefits of the Bayh-Dole Act obviously quite clear. It is to get government-funded research results out into practice for the benefit of humanity, and the record I think is strikingly clear. The statistic you cited you cited that so few government-funded innovations were patented in the old days, the clear movement in the time

series data that David Mowery showed us, and I want to come back to that because I think there is a couple of interpretations that need to be made, but clearly we have seen some of the benefits. The costs do seem to be present but minimal. Are we in fact privatizing some things that should be public? Maybe research tools, but that is not the fault of the Bayh-Dole Act. That is the fault of the construction of the patent law by the courts and could be addressed there, not by some modification of the Bayh-Dole Act.

Another way of talking about privatizing what should be public would be to say, keeping publications from the public for a period of time. At least that is privatizing it for a while and you know I think that is clearly a modest cost, but you know the advent of electronic journals has probably speeded up the time to print in many scientific fields much more than the Bayh-Dole Act has delayed it.

So, on balance I think it is a pretty emphatic positive answer that the Bayh-Dole Act has created public benefits.

Let me say a word about the measurement of those benefits though, just to touch for a minute on the time series data that Dave Mowery showed us? He was trying to say that at least at Berkeley and Stanford there has been

rapid growth in the number of inventions and in the revenues and in the number of patents since the 1960s.

Now, it isn't steady. If you look at the numbers the implicit growth rate, I didn't try to calculate it, but clearly at least three or four times faster since 1980, than it was before 1980, and second what is missing in that gross picture even in those universities and of course widely is that the composition of what is being done in the universities has changed, and this is the other point that Scott was just raising. There has been a major shift toward biomedical technologies and that has a number of implications. First it has a cause which isn't private funding. It is public funding, but growth rate of NIH funding over this same 20-year period is about 6 percentage points faster than the rate of inflation. The growth rate of NSF, DOE and DOD funding over the same period is about 1 percentage point ahead of inflation. That is a huge change over 20 years in the sectoral composition of government-funded R&D. So, it is no surprise that there has been a shift in the direction, and remember government-funded R&D is still triple the scale of private for-profit funded R&D.

Thanks to the Hughes Institution if you say, non-government it is actually pretty big. There has been a pretty healthy growth in non-government R&D, but a lot of that is foundations as opposed to for-profit firms.

So, we have moved to biology and what are some of the implications? One implication is that in biological sciences as Wes Cohen pointed out as the old work that Dick Nelson and I and others did pointed out the patents matter a lot more than they do in some of the electronic technologies that so dominated the period before 1980.

A second point is in fact that even within biological sciences the nature of research has changed, that is some gross split between basic and applied research may show that percentages haven't changed, but the truth is that advances that are pretty fundamental and regarded as important for scientific reasons alone in biology today are very close to having important implications for applied work. The time lags are from the discovery of the prospective drug to the actual implementation of that drug but not from let us say inventing the laser to finding some commercial use for it which was many, many years happening.

So, all of these factors suggest that just the time series of the data understate the importance of the Bayh-Dole Act because now ask yourself the counterfactual. Suppose that we did not have the Bayh-Dole regime now. Suppose universities could not take property rights on government-funded research and now recognize these are mostly biological innovations. Almost all not all but almost all the big winners are drugs, and ask yourself what

pharmaceutical company would be spending 200 to 500 million dollars to develop an unpatented drug. I will give you the answer, but you know it.

So, I think we have AIDS drugs today because of the Bayh-Dole Act and a number of other very important therapies.

I guess I mentioned the point about access to tools. I do think that is a problem, research tools, and I don't think Bayh-Dole is the way to get at it, and our committee has taken that as one of its central topics.

Finally I just have one cute idea I thought I would throw out which is I think that Congress has unwittingly created an incentive contract with universities without knowing it in the combination of things. It gave the universities a potential windfall by allowing universities to patent and assert private property rights over government-funded research, but at the same time it took away, you know, it reneged on the Vannevar Bush contract in its original form by shortchanging the full recovery of overhead expenses, and if you ask yourself the question, you know on balance, are those two canceled more or less? I was doing a rough calculation as I looked at some of the data. Actually not quite. The government has taken away more than it has given because I can only think of two universities whose revenues from licensing exceed their unrecovered

indirect costs. I think most of the others the licensing revenues fall short of the sum total of their unrecovered indirect costs.

Yet, all that considered it is not such a bad scheme you know. You get most of the full cost of research and then at the margin you have an incentive to commercialize. So, I am sure the Congress never put it together that way but altogether it is not such a terribly perditious regime.

So, I want to thank everyone in conclusion for their contributions to the conference just so that can be said everyone goes away. All the presenters I think served us very well, and I guess we have time for a few more questions.

Are there any more questions?

DR. COHEN(?): I thought all three of those discussions were articulate and persuasive and basically in accord with how I think I see the matter. One of the things that has happened over the last 10 years or so as a result of research is a lot of things that used to be in the fog are now a bit clearer than they used to be. Some of those things that we now see confirm what we thought we saw and some of the things that we now see sort of clearly we hadn't really seen before and here I want to suggest, Rick that the case that in fact Bayh-Dole itself in the arena of say

pharmaceuticals or biologically related university developments has been absolutely key in most of the technology transfer efforts. I think it has to right now be regarded as less well proved than you proposed. It is not that I am arguing against it, but I don't think that that is a clear case yet.

I would observe first of all as I did earlier that if you look at a number of the really big biotechnology money winners in university you have Cohen-Boyer. You have the actual patents and basically these are ones that are picked up by industry even before the patent emerges and as somebody was observing, what happened there was that the universities picked up a nice revenue --

DR. LEVINE: But those are the tools rather than the drugs.

DR. COHEN(?): Those are the tools issues. I think the issue with respect to embryonic pharmaceuticals is more complex than you have proposed. One of the sets of studies that really needs to be done and a number of us have tried to do it, and we have been unable to achieve it because we haven't got the people to do the studies involves detailed case studies of individual university inventions and how they got out into the world, and we have not been able to progress that far on those.

However, I am struck by the number of instances in

which you had an embryonic pharmaceutical where in a couple of cases I know about companies were not insisting at all on exclusive licenses early in the game but proceeded with their own development efforts without an exclusive licensing, obviously on the presumption that if they came up with something good they would be able to patent that down the road.

I am, also, struck on a number of instances in which an exclusive license was given to a particular company and that company essentially was not able to push the development through and essentially abandoned it and you had to go to another company and another company and another company down the road.

Now, this is, for heaven's sakes, you say not an argument against Bayh-Dole, but it is an argument that we should be a little bit cautious in ascribing so much of the success that has been happening with respect to technology transfer from universities in the area of pharmaceuticals to the university's ability to grant exclusive licenses.

Sometimes that has mattered but in a number of cases it is not clear.

DR. LEVIN: We will await the case studies

Over here?

DR. GARDENIER: John Gardenier. I would just like to bring up a couple of the complications that Mark Myers

may have been alluding to when he said that things are going to get more difficult. One is with the great increase in biomedical research funding there has not been a commensurate increase in the staffing of the NIH mechanisms for reviewing the applications and checking on the productivity and the ethical conduct of the grants.

Now, for many people this would not make a difference, and perhaps at the leading universities and research institutes that we have been hearing from today this is not a great problem, but I would suggest that as we put more and more money together with fewer and fewer controls there is an almost inevitable opportunity for scam artists to get in and grab some of the money.

Eventually some of that is going to be public, and the institutions who are effectively controlling this have to be a little bit concerned about the people who will not control it or who will take insidious advantage of the situation.

The other thing that I would like to point out as a caution for the future here is that the ethical rules and expectations on the part of the public keep changing, and we saw this most recently with the University of Pennsylvania gene transplant case where the university's defenders pointed out that the institutional review board had considered every rule that was in place, every practice that

was there, and that everything that was done was fully legitimate by all the rules that were in place. The problem was that the public's expectations of what those rules should be had shifted, and I would say that it is a net loss for the University of Pennsylvania, and I think all of the research institutions are going to have to be alert to the shifting ground more and more in the future.

DR. LEVIN: Fair enough. My colleague Gerhardt Caspar wrote a very persuasive paper in which he showed as fast as the NIH budget may be rising the fastest growing segment of the budget in universities is regulatory compliance.

DR. GARRIS: Charles Garris, George Washington University. I have enjoyed the workshop today very much, and I have learned quite a bit. I think I come from a different side of the house than most of the presenters here today. I am a faculty inventor, and one thing that struck me from participating today is that one segment of the community has been glaringly absent from this whole proceeding and that is certainly a major stakeholder in the whole process, and that is the faculty inventors that are involved, and I think there are lots of dimensions that could have been brought out had there been faculty, active faculty inventors here that were not brought out today.

For example, on the one side I think people

glaringly brought out our obligation to society which I have no quarrel with and how the university must be an honest and must be a strong contributor to society and in order to assure that we have to worry about conflict of interest, but Adam Smith pointed out when he wrote *The Wealth of Nations* that in a capitalist society there are all kinds of horrors and terrible things that go on, but there is an invisible hand that in the aggregate makes the capitalist society work, and in a way academia is the same way. One thing that I have seen from 30 years in academia is that very often something terrible will happen. There will be a horrible conflict of interest. There will be a faculty who does an abomination, and all of a sudden the administrators feel that they must make a solution to this, and they have to change the system, and the problem of that is that it kind of takes away the whole idea of the patent system.

In this particular case President Lincoln put it very well. The patent system is designed to provide the fuel of interest to the fire of genius, but you don't want to kill the fire of genius, and I think that is something that really has to be brought out, and the other issue that I don't think anyone mentioned today, and I am an inventor and I really understand the passion that one has for his inventions. This is something that really when an inventor is hot on something it is so exciting. I mean it is a thrill

to be trying to develop something and get something going. I mean it is so thrilling.

Now, this is something that has an educational value. I mean after all I am an engineer, and this is the National Academy of Engineering, and in engineering education students learn by participating with excellent faculty who are engaged in this sort of thing. So, you don't want to be so concerned about conflict of interest that you take the passion and you take the fire away from this faculty member, and I am not saying that there was anything said today to go against that, but I do think that this is a dimension that would be good if you considered bringing it up in future meetings and future conferences.

PARTICIPANT: It is with great trepidation I step to the microphone here this late, knowing that folks would like to leave. So, I will be extremely brief, but I wanted to make one observation about the rationale for Bayh-Dole that I have not heard mentioned here today that from my investigations of the research collaboration areas I think is in many ways the most compelling, and that is the fact that the Bayh-Dole law removes the Federal Government as a party to the licensing negotiations, and if you think it is hard to establish licensing terms with two entities try with three, and I think ultimately that is one of the biggest reasons in favor of Bayh-Dole is that is what it does, and I

think as you look to the states and some of their regional economic development opportunities that they are trying to pursue some of them will probably not, at least at first blush be quite as open minded to that kind of thing. I just wanted to put that on the record.

DR. LEVIN: That is a great point, actually, and it does speak directly to at least a little bit of rumors we picked up around this city that people are worried about the big money that some universities are making from this and that maybe the government could get a little cut of it and that if they get a cut surely they want to be at the table and negotiate the deal, and we would be right back where we started.

DR. BREMER: I am Howard Bremer. I was Patent Counsel and still work with the Wisconsin Alumni Research Foundation which is a separate organization from the university, and I wanted to emphasize the point that Mike Champness made. The premise of Bayh-Dole was that it transferred certainty of title from the government to the universities and that is the fundamental premise. Without that you would have no private sector cooperation.

The fact that the private sector would not license from the government because it was so susceptible to political influence was one that changed that premise, and it raised the issues, we raised those issues early on in

moving Bayh-Dole through the legislative process but that certainty of title is the key to the functionality and to the success of Bayh=Dole.

DR. LEVIN: I think perhaps we should call it a day. It has been a very successful and productive conference. I hope you have all enjoyed it, and we certainly on behalf of the National Academy and the STEP Board thank you all for your participation.

(Applause.)

(Thereupon, at 6:08 p.m., the meeting was adjourned.)