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P R O C E E D I N G S

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MR. KOVACIC: Good morning everyone. My name is Bill Kovacic, and I'm the general counsel of the Federal Trade Commission, and I want to begin this morning by once again expressing our thanks to the University of California at Berkeley for being such wonderful hosts for these hearings.

It's a tremendous pleasure for us to have this event at this magnificent jewel of an intellectual center for work in the fields that we're going to be speaking about today and to have participation from so many individuals in the academic community and business community in the Bay Area that have made this field a rich and exciting area for policy analysis.

I also want to express my thanks on behalf of the Federal Trade Commission and it's Office of Policy Studies, headed by Susan DeSanti, the Department of Justice and it's Policy Unit represented today by Frances Marshall, and the Patent and Trademark Office with Ray Chen sitting in throughout the week to participate in this process. I can't say enough about the wonderful work that this team has done to assemble the hearings that you're seeing this week.

Let me simply spend a couple of minutes talking

about, again about our motivation for having this set of intellectual explorations.

I think that many observers who have studied the antitrust system have concluded that the concepts that are key to the operation of the antitrust system are quite adaptable and well suited to adjust to circumstances posed by challenges in what's called the knowledge-based economy or the new economy. And this is a result of a far-sighted institutional design of the U.S. system. The key operative provisions of the U.S. antitrust laws have a deliberately open texture that contemplate an evolution of concepts and doctrines over time.

The crucial operational terms are defined very generally and Congress in 1890 anticipated that the specific analytical content that makes those terms operate would be informed by continuing developments in the fields of legal and economic theory. In short, Congress assumed that there would be a process of adjustment, a process informed by exactly the type of intellectual inquiry we're pursuing this week.

I think that the real challenge in the antitrust system is not so much the adaptability of the concepts, but the adaptability of the institutions that implement them. I think in many respects what we found

is that rapidly changing, highly dynamic industrial sectors put tremendous pressure at the weakest of the joints of the antitrust systems that -- antitrust institutions that don't always adapt or move as quickly as changes in the market.

And I think what we've learned is that it is absolutely imperative for the institutions to be capable to expand the knowledge base on which they operate. A continuing theme of yesterday's sessions, for example, was the crucial value of detailed, sophisticated industry-specific study in formulating and applying rules of competition policy in technologically dynamic markets and to the intersection of intellectual property and antitrust.

And these hearings help demonstrate the utility of continuing efforts by our institutions to establish and expand that knowledge base. In short, the only way we can ensure that the institutions are truly competent with these questions is to make sure that we are at the state of the art in the marketplace of ideas.

I want to turn the program to Bill Cohen, who is a member of my office, and with Susan DeSanti in our office, and Hillary Green and Mike Barnett, Michael Wroblewski, Robin Moore and Gail Levine have been instrumental on our side in preparing the hearings.

And I'd say as a final note that from our perspective, and with our colleagues at the Department of Justice, what we see ourselves doing is building on a relatively recent tradition. One, that Susan DeSanti, whom you saw yesterday at this podium, developed one that placed an absolute premium on increasing our knowledge base, a tradition established also at the Department of Justice in their formative hearings on the international enforcement of antitrust laws.

So, I want to turn the program to Bill's very capable hands to moderate the discussion today. Bill.

MR. COHEN: Thank you, Bill.

Bill has already introduced to you Fran Marshall from Department of Justice and Ray Chen from the Patent and Trademark Office. Also joining us from the Federal Trade Commission today is Hillary Green, to my left.

Today's session is going to take off where yesterday's left off. We're going to delve again into the area of economic perspectives on intellectual property competition and innovation, whereas yesterday's session tended to give some emphasis to competition. Today's session is going to shift the focus a little bit more strongly on intellectual property.

We have a wonderful collection of speakers

joining us. What we think we will probably do is start off with four of our speakers who will address, among other things, some discussion to the area of initial and follow-on innovation. We'll leave some time for some discussion, take a break, return with our two final speakers and then some concluding discussion.

What I'd like to do is to alert our speakers, as we move in the discussion just turn your little name tents up, I'll be able to see who has something to contribute and then can recognize you as we go.

We're going to begin this morning with Robert Stoner, who has prepared the results of his literature search in the area. Bob Stoner is a vice president of Economists, Inc., and a former deputy assistant director for antitrust in the Bureau of Economics at the FTC. He has testified on a number of antitrust cases and before a variety of governmental agencies, and in particular has recently submitted testimony in an ITC Section 337 proceeding involving patent licensing. He has his own Berkeley roots, having received his Ph.D. here.

Bob, why don't you start us off.

MR. STONER: Thanks very much, Bill.

When the FTC first asked me to review the literature on patents and innovation I thought they were asking me to teach a course, and then they told me I had

10 minutes. So I hope you'll bear with me as I rush through this, and just blow the whistle whenever you want me to stop, because I'm off.

As the first speaker today I'd like to try to bring some perspective to the issue of the relationship between intellectual property, in this case patent protection, and innovation. This is a very complex subject, and I believe it helps initially to present the dichotomy of the various rationales that have been put forth for patent protection. These rationales are sometimes conflicting, or at least they create conflicting issues. More importantly, the context of the innovation process presumed in the different rationales can be very different and, thus, it's not surprising that the theoretical and empirical work on optimal patents that I will briefly review often has conflicting conclusions, depending on the particular patent rationale and underlying innovation context that lie beneath each model.

Turning to slide one, there are four principal benefits or rationales of patent protection that are discussed in the literature. I will adopt the rubric of Mazzolini and Nelson's 1998 JEI article, but these concepts are widely recognized. The four rationales are, briefly, invention motivation, invention dissemination,

invention commercialization and orderly cumulative development of invention. We'll discuss each of these in turn.

The most widely recognized theory is that patent protection provides the incentive for innovation. This is because without patent protection innovators cannot appropriate the full benefits of their innovation. Some of the benefits go to free riders without payment.

Patent protection is said to restore appropriability and internalize externalities. Note that the assumption here is that inventors cannot gain the full benefit of innovation by using a new product or process while keeping the relevant information secret to prevent rapid imitation. Further, the invention motivation theory of patenting is generally couched in terms of invention as a one-time stationary phenomenon, not a cumulative process whereby inventions build on each other.

Thus, increases in appropriability unambiguously increase innovation since there's no offsetting retardation of innovation that could come from the increased risk of infringement by followers in the cumulative chain.

The cost side of this appropriability rationale for patents is that patents restrict access to completed

innovations and may allow the exercise of market power. Also more invention may not be desirable if it results in a wasteful patent race to be the first successful inventor. And because of these offsetting potential costs to patent protection there is an implied optimal patent duration and breadth that attempts to balance these factors. Much of the theoretical literature on optimal patent protection attempts to explore this balancing.

The second rationale for patent protection concentrates not on the enhanced incentives of the innovator but on the role of patents in encouraging wider use of inventions. Under theory two, patents encourage dissemination of innovation because patents induce inventors to disclose their inventions when otherwise they would rely on secrecy to obtain their innovation rewards, and also because patents induce licensing of inventions.

Note that relative to theory one, where patenting is seen more as restricting the use of innovation, theory two stresses that patents bring about wider dissemination. Of course the two theories are really more consistent than that, to the extent that patenting encourages licensing, since licensing of a patented invention can both increase the returns to the

innovator and promote dissemination.

Theory two is likely to have the most applicability when (a) the inventor by himself cannot exploit all the uses of the invention, and (b) secrecy would otherwise be effective in enabling the inventor to reap at least some returns. Some studies, such as the Yale survey of Levin et al., in 1987, suggests that this is the case for many process innovations. In these cases, to the extent that patents facilitate licensing, they increase the reward for disclosure relative to secrecy and facilitate wider use.

By contrast, for product innovations where secrecy may be less effective in the first instance as a means of appropriating returns, patents may do less to encourage disclosure.

The third rationale for patent protection is that patents induce development and commercialization of initial inventions which have little or no value in their initial form, but need further development to be commercially valuable. In this theory patents either facilitate exclusive licensing to entities who would invest in necessary development work, or they induce initial inventors to be entrepreneurs.

This theory is particularly important in assessing the issues surrounding patent rights on

inventions that emanate from government-funded research projects. The Bayh-Dole Act of 1980 gave universities and government labs such patent rights, but there has been a good deal of discussion in the literature about the efficacy of that policy change.

The reason that such patenting rights have been at issue is that they are arguably unnecessary to induce inventing since the original invention is, by definition, underwritten with government funds. If patenting is thus unnecessary to induce the original invention, the question then becomes whether patents on the original invention and subsequent licensing are necessary to assure commercialization.

Opponents of Bayh-Dole have argued that there is no reason that patents cannot be taken out on subsequent development work, or that the results of such development work cannot be made proprietary in other ways. For examples, studies by Levin, 1987, Mansfield, 1986, and Cohen et al., in 1996, indicate that a simple head start on commercialization can yield large profits on a new product, and secrecy can protect effectively new process technology used by the commercial developer. If this is the case, the follow-on developer would not need to license the seed invention to profitably develop it.

By contrast, if the follow-on developer is a

small firm that must marshal outside funds and may be swamped by quick imitation from a large firm, the case for the Bayh-Dole Act may appear stronger.

Theory four posits that strong patents assure appropriability and orderly development in the case of inventions with strong follow-on or cumulative potential. These types of inventions are sometimes called broad prospects.

Theory four differs from theory three in that instead of positing that the initial invention has only one commercial product at the end of the invention process, the initial discovery or invention is seen as opening up a whole range of follow-on developments or inventions. Such a cumulative framework tends to set up a much richer set of theoretical modeling possibilities that is missing from the non-cumulative framework underlying, in particular, theory one.

Under theory four the holding of a broad patent by the original inventor on such a prospect-opening invention is argued to permit the development of the full range of follow-on possibilities in an orderly fashion. The goal is to grant the prospect-opening invention sufficiently broad patent protection that the inventor has an incentive to create what has been termed broad shoulders for following inventions to stand on.

It is argued that this is only possible by preventing, through broad patent protection, duplicative R&D that closely mimics the patent holder's patent. Balanced against this, however, is the potentially offsetting effect that broad patent protection, while needed to maximize the incentive to create broad shoulders at the initial stage, might also hinder inventive activity at later stages if efficient licensing opportunities prove to be hard to transact and follow-on innovation is hindered because of the resulting overreaching threat of infringement.

Having set up this four-part dichotomy, it's instructive now to review some of the patent literature through this lens. I would like to briefly summarize several strands of the theoretical and empirical literature on optimum patenting in this fashion.

First I'd like to briefly look at the optimal patent length and breadth literature considered in a static or noncumulative mode. This literature essentially comes out of a theory one framework of appropriability, i.e. it is primarily concerned with providing the best incentive mechanism to develop a primary invention that has no follow-ons.

In this literature there's a tradeoff between providing adequate incentive for the inventor to innovate

and the static efficiency loss associated with the monopoly power conferred by the patent. The literature on optimal patent life is generally connected to Nordhaus, 1969, and Scherer, 1972. This literature has been extended by Gilbert and Shapiro, 1990, and Klemperer, 1990, and others to consider both optimal patent life and breadth simultaneously. This latter literature chooses a combination of breadth and patent length that minimizes the welfare loss associated with a specific degree of innovation incentive.

Klemperer considers two kinds of welfare loss in a differentiated product model. First, reductions in the consumption of the preferred product to less preferred products, and, two, simply not consuming the product at all. If reductions in consumption of the preferred product is the larger expected effect of extending patent breadth, then an optimal patent policy would be wider patents of shorter lengths to eliminate inefficient shifts among closely substitutable products. If simply not consuming the product at all is the larger expected effect of extending patent breadth, then an optimal patent policy would be more narrow patents of greater length to eliminate the efficiency from not consuming.

Gilbert and Shapiro's model, since it is a

homogenous product model, only recognizes the inefficiency connected with not consuming the product in question and, accordingly, their model generally advocates long-lived patents of narrow breadth.

A second strand of literature that analyzes the relationship between patents and innovation is the literature on patent races and so-called over-fishing. When investment opportunities are public knowledge multiple firms will have the opportunity to invest in innovation. In this environment an optimal patent policy must take into account the strategic interaction between firms competing in the innovation market. More competition is not necessarily efficient. Firms might duplicate investments by entering races or engage in over-investment.

I'd like to skip discussion of the earlier patent race and over-fishing model in the interest of time. But I will mention that DeNicolo, in 1996, has specifically attempted to extend the analysis of the optimal patent breadth/length mix to the case of a patent race where there is R&D competition. DeNicolo observes that the optimal patent breadth literature of Gilbert and Shapiro and Klemperer takes the socially-desired R&D investment as pre-specified and studies the efficient way to incentivize firms to invest in R&D of exactly that

amount.

By contrast, DeNicolo attempts to take into account the effect of R&D competition itself on the incentive to innovate and, therefore, on optimal patent breadth. DeNicolo concludes that the more inefficient is R&D competition in the sense that it spurs patent races the broader and shorter patents should be. The reason is that inefficient R&D is less likely to be promoted by broad patents that limit competition.

Another important strand of literature is that connected to the determination of optimal patent breadth in a world such as posited in theory four, where there is cumulative innovation, i.e. a multistage process of inventions, changes in these initial inventions and improvement. In this framework an optimal policy is concerned both with providing the best incentive mechanism to develop a primary invention, as well as to assure incentives for secondary follow-on inventions.

Initial inventions usually require larger investments and the incentives of the initial inventor will depend on the potential to share the benefits from follow-on innovation.

To the extent that the patent protection for the primary invention controls the development of the follow-on invention, the patent becomes an instrument for

orderly development of more innovation.

Kitch, 1977, views this as a problem of optimal coordination among different researchers working on related technologies. In the absence of coordination there will be wasteful duplication of effort and possibly over-investment as firms seek to beat each other to important results. Kitch argues that granting broad patent rights to a pioneering inventor early in the development of a line of technology will allow that inventor to ensure optimal orderly development of the technology.

To the extent that other inventors have ideas or capabilities that contribute in the development of the technology, the pioneering inventor would have an incentive to include them in the development process via licensing or other contractual arrangements.

Later work has brought the incentive of the potential follow-on inventors explicitly into the models. The question of patent scope or breadth can be characterized in terms of the magnitude of the improvement over the original patented idea that a follow-on invention must represent before it is granted a patent of its own or before it will be held to infringe the patent of the previous inventor. This line of research is associated with Scotchmer, 1991 and 1996,

Green and Scotchmer, 1995, Chang, 1995, and O'Donohue, 1998.

For example, Green and Scotchmer show that in the case of sequential innovation where the follow-on innovations compete with the primary innovation there could be inadequate incentive to invest in basic research. According to Green and Scotchmer, an optimal patent policy will reduce this inefficiency by transferring profit to the first generation innovators. Other literature in this line also confirms Kitch's view that broad patent protection should be afforded to the initial invention in a cumulative development line.

The intuition behind this result is that the incentive to create broad shoulders for others to stand on is socially inadequate because setting the table for future inventors represents a positive externality. Scotchmer has even argued in some context that second generation products should not be patentable at all. Scotchmer, 1996.

This result, however, seemingly depends on the assumption that the trajectory of innovation is known, such that the first inventor will have an ex ante incentive to license his technology to the second whenever it is optimal to do so under terms that do not prevent the development of second-generation innovation.

Others have pointed out that this assumption may not be tenable in some situations, given the uncertainty of future innovation paths.

If the ex ante licensing assumption is not tenable then there may be situations, particularly when we are dealing with inventions that are likely to spawn many fertile lines of subsequent cumulative innovation, that infringing second-generation products will not be developed.

Hopenhayn and Mitchell, in 1999, explored the implications of the fact that inventions differ in the extent to which they are likely to generate cumulative innovations, and the speed with which they are likely to do so. An optimal patent policy should take into account this heterogeneity. For example, if an innovation leads to multiple and rapid improvements an initial innovation effort will likely require greater initial rewards, that is broader patents, in order to recover the value of the investment before the invention becomes rapidly obsolete.

On the other hand, this broad patent protection might not be necessary when secondary improvements take place at a slower rate. Hopenhayn and Mitchell show that overall innovation incentives can be improved by offering patentees a menu of combinations of patent duration and patent scope or breadth. Optimal construction of this

menu induces patentees to reveal their private knowledge regarding the fertility of their inventions and the likely speed of follow-on, and thereby achieves a better balance between the incentives of the initial and subsequent inventors than can be achieved with uniform patent scope.

Finally, we briefly review some of the empirical work that has been done in this area. Virtually all the systematic empirical work that has been done on the effects of patents has been guided by theory one, i.e. looking at whether patents appear to provide an incentive to invent through increasing the effectiveness of appropriability.

There have been several interview or survey studies that have explored the perceived importance of patents as a means of enabling firms to profit from their inventions, all of which have explored inter-industry differences. These include a study by Mansfield, 1986, the Yale survey of Levin, 1987, and the Carnegie-Mellon study of Cohen, 1996. All of these studies come basically to the same conclusion, that patents are an important inducement to invention in only a few industries.

In pharmaceuticals, for example, patents seem to be an important part of the inducement for R&D.

However, in industries like semiconductors and computers, the advantages that come with a head start, including setting up production, sales and service structure and moving down the learning curve were judged much more effective than patents as an inducement to R&D. In some of these industries the respondents said that imitation was innately time-consuming and costly even if there were no patent protection. In others it was said that technology was moving so fast that patents were pointless. In any event, the empirical literature on appropriability certainly points up that there appear to be some industries where patents play a much smaller role than other forces in shaping the pattern of innovation.

When we are looking at patent policy we have to do so within the context of understanding how means other than patents induce invention and related activities. These other means include government grants and contracts and strong first-mover advantages.

There have also been several studies of the effects of different degrees of patent scope on innovation. First, there are two studies across countries. Kortum and Lerner, 1998, studied the significant increase in patenting in the United States since the 1980s. They look at four possible explanations: changes in the legal system which increase

patent scope, changes in the regulatory system, the development of new areas such as biotech and information technology, and increases in research productivity. They conclude that stronger patent protection and increased scope did not explain the surge in patenting; rather, the main factor was judged to be an increase in the productivity of the research process.

Brandsetter and Sakakibara, in 1999, estimate the impact of an apparent increase in the scope of Japanese patent protection starting in 1988, when Japan converted to a system much like the U.S., in which a single patent can have multiple claims. They find no evidence of an increase in patent -- in inventive activity, either in terms of overall R&D spending by Japanese firms or the number of innovations produced by Japanese firms in the U.S.

Nor is there compelling industry evidence on the effectiveness of changes in patent scope. Hall and Zionidis, in 2001, analyzed the semiconductor industry, which is characterized by rapid technological change and cumulative innovation. They do not find that stronger patent protection since the 1980s is driving the innovation effort or output of firms in the semiconductor industry; they find that patenting in this industry is driven by patent portfolio races aimed either to ensure

access to technology and not be held up by rival patenting of the same technology or to strengthen bargaining power when negotiating the access to other technology.

Finally, Merges and Nelson, in 1990, present evidence on how patent scope effects innovation in the U.S., based on case studies of several important historical technologies, Merges and Nelson question the theoretical literature advocating broad patent protection for pioneering innovators in the context of cumulative innovation.

The analytical basis for the disagreements is that Merges and Nelson believe that ex ante uncertainty and disagreement among competitors about which lines of development will be most fruitful makes licensing agreements or other such coordination mechanisms unlikely and/or ineffective.

Examining the historical development of electrical lighting, automobiles, airplanes and radio, they argue that the assertion of strong patent positions and disagreements about patent rights inhibited the broad development of the technologies rather than aiding subsequent development.

I'm confident that some of the other panel members will have further comments on some of these

empirical studies and what they might or might not have added to the debate.

So, with that brief synopsis I'll turn the program over to the next speaker, or the moderator.

MR. COHEN: Okay. Thank you, Bob. That survey is wonderful in that it shows -- will help to show how all these different elements that are going to be talked about fit together, and fortunately we are able to have many of the people who you referred to here to speak for themselves.

One of those is Suzanne Scotchmer, who will be our next speaker. She is a professor of economics and public policy at the University of California, Berkeley, and has held visiting appointments at universities ranging from Stanford and Yale, all the way to the Sorbonne and the New School of Economics in Moscow. She has published extensively on the economics of intellectual property and other topics, and she has appeared before several committees of the National Research Council, mostly regarding intellectual property.

It's my pleasure to introduce our next speaker, Suzanne Scotchmer.

PROFESSOR SCOTCHMER: Well, thank you. And let me also congratulate my colleague across the room, a really well thought out survey; not just a survey, a well

thought out kind of framework for thinking about these issues.

I want to come back to the subject about which I have thought the most, in conjunction with other colleagues, and that is the context of cumulative innovation and how that context for intellectual property intersects antitrust policy.

In part I am going to follow from some of the conversation of the panelists yesterday. Yesterday our colleagues gave testimony on what drives competition in the economy, what we know about what drives competition in the economy, which raises for me the question of: What's the proper domain of intellectual property policy, and what's the proper domain of competition policy, and how do they fit together?

So, for example, our colleague Howard Shelanski gave testimony on what we know about whether or not size of firms matters for their innovativeness, their inclination to innovate and their success at innovating. And if you ask yourself the question, "To what policy issue that's within the purview of the agencies, is that inquiry directed?" you kind of scratch your head and say, "Well, is that inquiry directed, for example, to the question of whether the agencies should be more lenient with mergers if, for example, there were evidence that

the merging firms were medium-sized and medium-sized were more innovative and, therefore, you should favor" -- I mean, to what question is that directed? What exactly is the mandate of the agencies as concerns innovation policy as opposed to competition policy, how does that fit together?

In preparation for these remarks I actually went back and read the 1995 guidelines which are a very clear statement, I think, of how the agencies view their role in innovation policy. And maybe the intent of these hearings is to revise those, so I thought I would get it clear what I think the agencies -- how the agencies view themselves now.

My reading of the guidelines is that there's a clear division of powers. That the agencies see a clear division of powers between the Congress and the competition policy authorities.

There is no mandate that I could find in the guidelines for competition policy to take incentives into account in a proactive way. That is, the guidelines enforce some perhaps elusive notion of market power embodied in intellectual property that Congress reasonably could be interpreted to have intended, but not to create market power or permit market power that goes beyond the rights that Congress reasonably intended.

And that raises the question, one that, you know, raises its head in various guises, and certainly raised its head implicitly in the conversation of the panel yesterday, it raises the question: Should competition policy be viewed as a proactive tool, rather than competition policy being viewed as a way of implementing or enforcing an innovation policy that the Congress intended?

Now something that lawyers often remark upon, and sometimes economists also but I've heard it more from lawyers, is that competition policy is more flexible in this regard than intellectual property policy. And that's because competition policy typically is made on a case-by-case basis. The agencies decide whether to challenge a merger, they decide whether to bring a case against a licensing practice, and they do that on a case-by-case basis, as opposed to intellectual property, which has this broad -- at least as concerns copyrights and patents -- has a broad stroke, you know, comprehensive, one-size-fits-all character, and that gives -- that flexibility could conceivably be used as a way to buttress innovation policy in a way that intellectual property itself is possibly not equipped to do.

And the question is should -- one question that one could raise is: Should competition policy view

itself that way? Should the agencies view themselves that way? Another way to put that is: To what question are these hearings addressed, and is that one of the questions to which these hearings are addressed?

Now, I want to come to these issues as they relate to the area where -- about which I've thought the most, and that's the cumulative innovation context. Okay. So let's come to this question of cumulative research.

I want to start by pointing out that there are two views which aren't inconsistent but have different emphases of patent and antitrust objectives.

The more recent literature, in which I've been involved and which only recently rediscovered the Kitch literature, the more recent literature is focused on the question of: In a context where later innovators build on earlier innovations, how is the profit divided so that all generations of innovators have an incentive to do their part?

And in particular, the problem that arises there is that earlier innovators are laying a foundation for later innovators. And they're, in a sense they're creating an option on later innovations. That option has value. How do you reward the earlier innovators for the option they create for later innovations?

So the focus on this later literature of economists, which was nicely discussed by Dr. Stoner, is focused on that question of how do you divide the profit so as to give the right incentives at each stage.

In contrast Kitch, who also discusses this cumulative context, had a different focus, although these, these models implicitly share many elements. His focus was not on the question of rewarding the first innovator, he was pretty much taking a pioneer patent holder as already having innovated, but rather, his focus was on the question of how do you use that patent to ensure efficient coordination of follow-on research.

And there are important implications of that focus for a competition policy, which I think, in the many discussions of Kitch's contribution, are not discussed enough. And I want to come back to the implications of the Kitch perspective for competition policy.

Notice that both of these perspectives, the perspective that focuses on how it's profit-divided, and the perspective that focuses on the ability of a broad patent holder to coordinate follow-on research, both of them come to the conclusion that licensing and the ability of prior innovators to consolidate market power, if you want to put it that way, through licensing -- both

of them come to the conclusion that that's a good thing.

Well, if that's a good thing, somehow the goodness of that thing, licensing, ought to intersect with the concerns the competition policy has about licensing, and that's what I wanted to come to.

Let me begin by pointing out the danger to competition policy and intellectual property policy of, say, narrow patents, and then I'm going to point out the danger of broad patents, and then I will come to Kitch.

The danger of narrow patents is that there won't be any incentive for follow-ons due to competition with the prior innovator. So if a -- if in fact you have a narrow patent and a follow-on comes along he has the right, you know, he has the right to innovate with a small improvement, say, but he's going to do that in a way that's harmful to both of them. Well, if he does that in a way that's harmful to both of them, then not only may there be no incentive for the second innovator, there may also be no incentive for the first innovator because, after all, a large part of the value created by the first innovator is the option on later innovations which aren't going to occur because of the narrow patent. So this is one way to view a possible harm of, say, a narrow patent.

Now, can competition policy mitigate this

danger? Well, yeah, it could allow merger or licensing between these potential innovators if the agencies and the courts, or the agencies wanted to permit it, even though there's no infringement, that's what the narrow patent gives you. But notice that that's not consistent with the guidelines and it's not consistent with current practice.

I mean, the guidelines typically would not allow either merger or licensing consolidation between these two innovators if, in fact, their intellectual property would be non-infringing. And that's because the guidelines support a competition policy isn't proactive vis-a-vis innovation, that is it simply implements the intellectual property, as I understand it, that the Congress gave -- and if this is what the Congress gave and these patents would be infringing they wouldn't be blocking -- then there's no mandate for the antitrust authorities to allow a consolidation of those property rights.

So that may not be the appropriate competition policy stance, I only point this out because it could be otherwise.

Okay. What's another danger of narrow patents?

Another danger of narrow patents is the effective patent life in the cumulative context is not

the statutory life, and that's largely due to narrow patents. So what happens?

We talked about this in yesterday's panel, in particular, Ken Arrow talked about it, various people talked about it in yesterday's panel, the idea that in the modern economy the way firms compete is by sequential monopoly, by leap-frogging, one technology overtakes another technology, dominates the market for a period of time and then another technology dominates the market.

Well, one way to think about that, each of those technologies is protected by intellectual property, but is protected for some period of time that's shorter than the statutory 20 years. Why? Not because the 20 years expires in four years, but because a competitor drives out that product. So in that sense the effective life could be four years and not 20 years.

So, various of our colleagues have studied this question and the data, and particularly our colleague Mark Schankerman at the London School of Economics, and they've used the patent renewal data to try to understand how long patents actually last in fact.

And it turns out -- it's hard to study this in the U.S. system because we've only had a renewal or maintenance system since the early '80s, so most of the data comes from Europe -- and at least in many places in

Europe the bar to patents is higher in the U.S. so the results aren't entirely comparable -- but notice, even in places with a very high bar to patents, Germany in particular, only 11 percent survive to 20 years. That says that this phenomenon is extremely important. The statutory patent life is probably not very important as regards how patents actually operate out there in the economy.

One of the other really important things that Schankerman discovers is that half -- no matter how you cut the technology -- and he cuts it into electronics and chemical patents and pharmaceuticals, some other categories as well -- but no matter how you cut the technology, almost half, around half of patents die by year 10. Die in the sense that they're no longer renewed. Once you don't renew the patent you lose the option on it. So that means that most patents don't come anywhere close to their statutory life.

And the other interesting thing, not relevant particularly to this conversation, my talk here, but worth pointing out, is that only about 15 percent of the costs of R&D are covered by the additional revenue that comes from the right to patent, from the revenue that comes from patenting as opposed to other ways of protecting intellectual property.

Now, you'll have to read the paper to see how he massages the data to get that conclusion. But, it's not inconsistent with other evidence, especially other evidence we heard yesterday from the survey, from the surveys that have been conducted, and probably the reason for it is that patents -- because of this phenomenon that they don't last their statutory life -- probably that's an important reason that they're not as profitable as in theory we would like to believe they are.

Now, can competition policy do something about that? Well, that's a matter of policy for the agencies I think.

Okay. So those are dangers of narrow patents, that patents don't last long enough, they don't generate enough profit.

Can the agencies step in proactively to do something about it? They could if they wanted to. But to my understanding of the guidelines, they don't view it as their mandate to do that.

So there are also dangers to broad patents, and that's what I want to come to now. And in fact this goes back and connects to Kitch's argument about prospecting.

Okay. So what are the dangers to broad patents, dangers to competition policy and intellectual property policy, of having to fine-tune broad patents?

Well, broad patents can stifle follow-ons, and that will be true -- unless you get contracting -- unless the pioneer patent holder actually finds a way to contract for those follow-ons before the follow-on investments are made -- if he can't do that -- and this is the point I think that's really made by Merges and Nelson -- if he can -- in their 1990 paper -- if he can't do that then a follow-on innovator who will infringe the prior patent puts himself in jeopardy of holdup, they now have blocking patents, there's nothing the follow-on innovator can do without negotiating a license ex post. Well, then he's in a -- he's already sunk his costs, he's in a position of holdup, that possibility can stifle follow-on innovation. That's probably the most important danger of broad patents.

And of course if the follow-ons are stifled so are the original innovations. Because again, remember, the mantra here for cumulative innovation is that one of the primary values of the early innovation -- created by the earlier innovator is the option on later innovations. The things that that innovation facilitates that we hope will occur, but if they don't then the value is much undermined and the profitability is much undermined, so if you stifle the follow-ons you also stifle the prior innovation and the whole research line dies.

Can competition policy mitigate this danger? Well, yes, it can allow ex ante merger and licensing to avoid the ex post holdup problem, and that's kind of the thrust of much of the literature that I have been involved in on the economic side here, and that's completely consistent with current practice. Because these patents would be blocking, then certainly as a mandate embodied in the antitrust guidelines of 1995, certainly the agencies would view it as within their powers to allow the licensing and merger that allows consolidation ex ante between these potential patent holders.

Okay. And now I want to come to Kitch. As you all know, what Kitch argued was broad patents are valuable because pioneer patent holders with broad patents can coordinate research efficiently. The thing that Kitch does not emphasize is that what he means by efficiently is privately efficiently; efficiently for the firms, efficiently for the broad pioneer patent holder and for the follow-on innovators.

Now the thing that -- a fundamental to the economics literature in this regard is that private efficiency is not the same as social efficiency, and where that appears most evidently is in the arguments behind competition policy in this regard as embodied in

the 1995 guidelines.

So here's an example. Suppose we have a gene sequence that codes for a disease -- okay? -- and there's some pioneer patent holder that has a broad patent on this gene sequence that codes for a disease, what are the powers enabled by the holding of that patent?

Well, one thing that it enables is, it enables the patent holder to coordinate the pharmaceutical firms that would race for the therapy. And by coordinating them -- usually patent races have -- are -- in fact the premise of the guidelines is -- or a premise of the guidelines is that patent races are a good thing. They dissipate profit for the firms, that is the firms could increase their profit by making a deal, avoiding a patent race, but it's good for consumers because typically the patent race will get us the product sooner, and may get us the product with higher probability, but typically we say it'll get to us sooner. So there's a conflict between the private incentives to cut back on R&D and the social incentives.

Now, if you allow the pioneer patent holder to coordinate the research that's like allowing him to coordinate the research in a way that cuts back on this patent race, this profit-dissipating patent race. He can simply form a joint venture; he has the right to do that

because he holds a patent that blocks them, prospectively, from marketing their innovation. So you're -- that's the intersection with competition policy.

In the same way competition policy would think it would -- would certainly respect the view that restraining the race would be contrary to social interests, then surely you would have to conclude that if you give a broad pioneer patent which also gives the right to restrain the race, that's also in some way contrary to social interest.

Okay. And then there's another way that coordinating the follow-on research can be contrary to the social interests, and that is in bullet point one I was assuming that these pharmaceuticals were racing for a patent and only one of them would get it.

In bullet point two let's suppose that's not true. Suppose that this gene code's for, say, a therapy or a vaccine or different therapies that would be non-infringing ex post. In ordinary competition policy, as embodied in the guidelines, you would certainly not allow those firms racing for non-infringing substitute patents, you would typically not -- and according to the guidelines -- allow them to form a joint venture and merge their efforts and avoid the competition among the

later patents, you wouldn't allow them to do that. If Congress intended those patents to be non-infringing, then Congress intended them to be non-infringing and we wouldn't let them overcome that by forming a joint venture.

In this context, however, if all of them are going to infringe a prior patent, and the prior patent holder is allowed to coordinate their efforts, for example, by giving an exclusive license to one of those potential therapies and not to all of them, then he -- then the pioneer patent holder can do precisely what would not be allowed under the ordinary interpretation of the 1995 guidelines.

So it seems to me that these considerations should -- this is where primarily I think competition policy meets this question of broad versus narrow patents in the cumulative context and deserves some attention.

Okay. I think I'm overstaying my welcome here.

Notice that the -- the conclusion of my prior remarks is, if the agencies were going to interpret their mandate as taking a proactive stance, vis-a-vis innovation policy, that is using antitrust policy to step in where perhaps intellectual property rights are inadequate, which, as I understand it, is not their stance, but if they were going to, notice that they can

remedy one of the dangers and not the other. They can remedy the problem of narrow patents by being lenient as regards antitrust policy, but they don't have to do so as regards the dangers of broad patents. And so there's a slight asymmetry there that might be worthy of consideration.

So, my conclusion. Competition policy has more flexibility than intellectual property policy to fine-tune incentives to innovate.

As now written, I think, the 1995 guidelines do not assert the right to exercise this flexibility as regard to proactive stance.

As I understand it, antitrust policy as regards innovation policy respects intellectual property but does not augment it.

And it is easier to exercise the flexibility to mitigate problems of over-broad patents than to mitigate problems of too-narrow patents.

MR. COHEN: Thank you.

PROFESSOR SCOTCHMER: That's backwards. Sorry.

MR. COHEN: Thank you.

Our third speaker will be John Barton. He's a George E. Osborn Professor of Law at Stanford University. He chairs the U.K. Department for International Development Commission on Intellectual Property Rights,

and he is a member of the National Academy's Committee on Intellectual Property Rights and the Knowledge-based Economy. He's written extensively in the patent antitrust area.

PROFESSOR BARTON: Thank you.

I have the nice privilege on being able to build on what has just been said.

What I want to do is apply what has just been said in the sense of what I see as the three paradigms that are emerging patent antitrust issues, not so much as to give answers to the paradigms, as to try to describe the paradigms as fairly specific questions that we need to face.

The first one of these, the scope of the IPR and their exclusion, is really precisely the issue of which Suzanne was just talking about, it's the question of the follow-on innovation versus owner innovation. The second one is the use of patents as the basis for an intellectual property generally, as a basis for leverage. And the third pattern is the issue of cross-infringing oligopolies, which we -- I think we're beginning to see in a fair number of industries, indeed, as one of the results of Bronwyn Hall's research.

Let me look at each of these in turn. Here we go.

Starting with what I've identified as the scope of IPR, but in a sense that may be exactly right, because when you begin looking at the patents it becomes not so much broad and narrow as a question of what claims you're talking about.

The issue of course, at least as I would put it, is what is the optimum strength or form of IPR at a first-stage innovation in order to encourage that innovation and not create too many barriers to the subsequent innovators.

Let me take as a good working example this third one, the utility patent on a plant restricting use of seed for breeding. The kind of patent which the Supreme Court just upheld a few months ago for plants has two important claims that I want to talk about.

I claim I produce a new variety of plant and I have two important claims, one of which says "I claim the use of this plant for growing a crop," and the other is "I claim the use of this plant for breeding purposes." And let me distinguish the two of those because it makes the distinctions very clear and very sharp.

Pretty obviously, claiming the monopoly for use of breeding purposes is a very traditional pattern of what patents are all about. You have invested significant sums in the breeding, you need a monopoly for

a period of time in order to be able to reap the returns from that investment in breeding.

The monopoly against use of it for breeding, however, means that you or I cannot go to the company in the midwest, buy a bag of the seed and start crossing it with our own material to see if we can find a new variety that is better than the variety that we bought in the market. In other words, I have, by the second claim, significantly weakened the ability and subsequent innovators to build on the invention that was initially made.

Indeed, I will not only -- when I buy that seed I will not only be faced with this patent provision, I will also be faced with a contractual provision in which I agree that I will not use the seed for any purpose but growing a crop, and now to broaden the logic, I will deliberately not be entitled to reverse-engineer the product. The same thing as the quick wrap license on the software that
says I may not reverse-engineer this, I may not de-compile it.

In short, we have the question: To what extent an initial innovator who needs the innovation to create the breeding should be entitled to slow and complicate subsequent innovation, and subsequent innovation by

competitors of course.

And I might note this undercuts a very traditional principle that anything that has entered the chain of commerce may be reverse-engineered freely, a standard principle trade secret law. Currently we should have some questions whether I should be entitled to get that second kind of claim.

Now, I think you can raise the same kinds of questions in almost all the others of these dimensions, which -- well, let me skip that one for the sake of time.

Patents on an EST or research tool.

We all know that it's relatively easy to find sequences of partial genes. It is very appropriate, no question about that, that I should be entitled to obtain a patent on that gene as I -- that partial sequence as I use it as a research tool to try to identify the complete chain.

Question: Should I be entitled to claim the complete gene even if it was discovered and sequenced in some other way? And that of course depends on the details of the claims that are granted in the patent office.

Similarly, with diagnostic sequences, you have the question: Of course you want to encourage people to discover new diagnostic sequences, but do you want them

to be able to keep people in a hospital from screening large numbers of patients for different sequences in order to make new discoveries about what's going on in the disease?

I think this is one of the contemporary versions of this first problem of subsequent and follow-on innovation, and I think these examples should give us a sense of the way that problem plays out in the patent system, and also the way it may play out in some contractual provisions in which we attempt to do with contracts exactly what we might do with patents.

The second paradigm I'd like to suggest is the contemporary extension of the traditional leverage paradigm. Of course we all said, following Bill Baxter's work and following the real -- you know, a little bit of microeconomic realization, that there's nothing wrong with tying. And yet in some contexts there may be something wrong with tying.

Now, it is not a patent case, but it's a software case, but it raises exactly the same case situation of Microsoft moving into the browser market. We're concerned not so much that in the traditional leverage analysis, the question would be: Does the tying enable the patent holder or intellectual property rights holder, does the tying enable that person to charge a

different price for people who use the product to a different intensity.

And so we all said it's -- though, you know, the courts reached it in a bizarre ray -- it is quite right for IBM to be entitled to say "I will sell my computers for a little less, and sell my IBM cards for more, and if you use my computer you have to use my IBM cards," so that the heavier user of the computers use more IBM cards and pay more than the light user of the computers.

But what's happening with Microsoft? That's not what's happening with Microsoft at all. What's happened with Microsoft is, it already has a very powerful position in the operating system market, it would like, by tying the browser to that operating position, to be able to gain a strong position in the browser market. And, after all, there are network externalities in the browser market. If you have the browser that two-thirds of the world has, especially if you manage to get some features in it that are used in some of the websites that are going to be contacted, then you have locked in a monopoly. So you are using the leverage process now, in the presence of network externalities, in order to move from one monopoly position, or strong power position I should say, to

another one.

Now I've given you two more examples, since I admit that one's copyright rather than patent, I've given you two more examples to show that the same thing can happen with patents and then with trade secrets.

In the case of the video game the classic question is: Can I require that when you buy my video game you buy your cartridge from me, and in one way or another, by patent device, trade secret device, contractual provision -- in one way or another try to prohibit other people from making video games for my cartridge?

All right. Same kind of leverage question -- I'll come back in a moment to whether it's a good idea to apply restrictions.

And then one which I ran into a couple of years ago. Now when we make automobiles they are driven by carefully-controlled computer chips which carefully design everything so you reduce the emissions. California of course was the leader in this.

All right. The computer program and the chip are arguably protected by trade secrecy. If you would like to build a repair part for the car, or if you would like to repair it, you may need to know what's going on in that computer program. If the company won't tell you

what's going on in that computer program then the company has an effective monopoly not only over the automobiles but over the after-market, including both repair and replacement parts.

And I might just note for thinking purposes, automobiles today have computer chips in them, tomorrow everything will have computer chips in it.

Now, I recognize fully I have questions in both these last two cases whether my models of network externalities really apply. We all know that there's an antitrust law debate over whether the market for the product is a separate market from the market for repair and replacement part services, or whether or not those are really one market. I recognize fully there's a controversy there, but simply flag the issue is going to be posed very often.

And then in the middle one, the video game device, you know, are there network externalities? Maybe not as it is. But on the other hand, suppose we're talking about an internet game and a few games catch on very strongly and become something which is used by every game player -- you know, 60 percent of the game players in the country and therefore, of course, would effectively be used by a hundred percent of the game players in the country due to some form of network

externality and tipping behavior.

So we have now a second paradigm, this leverage paradigm, which in a high tech sector looks quite different from what it does in things like the old International Salt case and the old IBM case and all these, all these old patterns.

I think I want to say one more thing about it, that -- and it's really exemplified best by the Microsoft case -- note what my policy balance here is. My policy balance is I know I'm going, especially if there's network externalities, I know I'm going to have dominant companies. I know also that any company that is currently competing in a business should be a reasonable contender for the dominant position in the next generation of the business, and that in any high tech business there isn't one market, there's a market today, different markets tomorrow, still different markets the next couple of years, and the question is sort of what is the optimum probability that an existing incumbent is going to be knocked out in the transition from one generation of market to the next generation of market. I would certainly say that's kind of the ultimate underlying issue which we have to face there.

Now my third problem, I don't have such a sharp and crystal clear antitrust question, but I sure have a

hard set of questions. As Bronwyn put it, on her work on the semiconductor industry, the semiconductor industry is fundamentally an industry in which everybody has enormous portfolio patents that nobody ever looks at, and everybody infringes everybody else's patents. And if my portfolio is a lot bigger than yours, maybe you're going to have to pay royalties to me, but otherwise we won't really worry about royalties, we'll just kind of keep these portfolios of patents in case somebody is silly enough to sue somebody else, in which case you say, "Well, you're infringing my patents, wouldn't you rather negotiate."

So, you know, we have a situation in which whatever the patent system is doing, it's doing something very different from the traditional models.

I think clearly the semiconductor industries in this world -- I have a strong suspicion that the financial services industry will be in this world as we evolve through, you know, a generation of business method patents. I wouldn't be surprised if the biotech industry ends up in this world, and, you know, there may be others. But certainly this is not going to be an uncommon situation.

Now in that situation -- no, let me give you sort of two serious antitrust problems that might well be

viewed as popping up in this situation.

One is, suppose sitting there is one of the oligopolists, the three or four others were oligopolists too, we happily don't sue each other because we know we'll be sued back and therefore we give each other at least a tacit license, and we maybe give each other a formally explicit license with some kind of formal cross-license. A competitor comes in, a new start-up, one of us sues him to keep him out. Should that be an antitrust problem?

And note kind of the pro argument is, it's the oligopoly rent for maintaining an oligopolistic situation that becomes the reward for the research we have built.

On the negative side, pretty obviously, those patents aren't serving the same kind of incentive purpose that we were thinking of when we created the patent system. And, indeed, it seems abundantly clear to me that in the semiconductor industry, as an example, the key incentives are built around the character of the product cycle, the character of consumer demand for ever more sophisticated chips and all this kind of thing, and the fact that, you know, you don't issue a -- you don't get a patent issued until your three, you know, three generations of product down the development cycle. So, you know, strong questions whether or not how I want this

one to come out.

Second example that I want to give you, because it's already been a significant antitrust question, is the question of what about the cross-licenses that we have for a particular purpose, like these cross-licenses between a variety of semiconductor companies, media companies, television companies, and so forth that we have for the DVD and MPEG standards and so forth, that have been approved by the Department of Justice.

I think it seems abundantly clear, and absolutely correct under the traditional antitrust analysis, that a license arrangement like that is appropriate because we have zillions of mutually-blocking patents.

But what would happen if indeed the royalty fee that was involved for charging for that were not simply enough to cover a reasonable share of the research costs and so forth, but the royalty fee was so big as to knock everybody else out of the industry? I think we would then have some questions.

Now these are obviously tricky ones, and I'll own up that I have an article coming out on this set of issues in the issue which comes out March 10th, of the Antitrust Law Journal, in which I attempt to explore the way the oligopoly rents and the incentives to innovate

compare with a number of firms in the industry, and then try to draw some of the -- you know, tentative I think would be the best way to put it -- tentative antitrust conclusions that come out of this.

But I do think that these three patterns, this follow-on innovation question, the new-style uses of leverage, and the cross-infringing among oligopolies and what you do about it. I think those are three of the most important and common patterns that we're going to see in the next generation of patent antitrust issues. Each one is obviously a rule-of-reason kind of question because the balances are pretty high.

MR. COHEN: Thank you very much, Professor.

Our final speaker before we head into discussion is Professor Robert Merges. He teaches intellectual property and contracts right here in Berkeley at the Boalt Hall School of Law. His primary scholarly interest is in the economic aspects of intellectual property rights, especially patents. He's an author or co-author of several leading student casebooks on intellectual property and he has written numerous articles in both the legal and economics literature. Professor Merges.

PROFESSOR MERGES: Okay. Thank you very much. Well, it's an honor to be here, not only as the token

lawyer, but also just to be here. I learn so much at these things that I'm madly scribbling notes as I go along.

What I wanted to talk today about was what I call second-order patent scope. A lot of the economic literature on patent scope implicitly centers on only a couple of doctrines in patent law, and, you know, we've made really good progress in exploring the economic effects of those doctrines, especially with respect to setting up this bargaining problem between pioneers and improvers, which, you know, now runs under the header of the cumulative R&D problem.

But I wanted to bring into view a couple of other doctrines, and a couple of other issues that I think affect patent scope in the hopes that by enticing my extremely talented economist colleagues to be interested in them, I'll actually learn what they're about and how they work. So that's my hidden agenda here.

Traditionally, let's say in the last 10 years or so, the patent doctrines that we've dealt with, implicitly anyway in the economic literature, are doctrines of enablement and infringement.

Enablement is the doctrine that says, to use Suzanne's very helpful terminology, how many future

options should an inventor be granted, how many next-generation products should a given patent cover.

John Barton was talking about the problem of deciding whether an expressed sequence tag patent, the patent on a little gene fragment, ought to dominate or cover the full gene patent which comes along later. And that's an example of how deciding the enablement question assigns the number of options that you're going to grant to the patentee.

In the area of infringement the doctrine of equivalence -- this is one of the areas that has been talked about a lot -- especially the problem of whether or not the doctrine is going to be applied so as to cover improvements that came along after a particular invention was created. That's what the lawyers call after-developed improvements, and that's very much consonant with the economic literature in this area.

So these are doctrines which we now know something about from sort of an economic point of view. But there are a lot of other doctrines that affect patent scope.

First is the so-called written description requirement, which is an important determinant of what the economics literature now calls leading breadth, which is to say the number of embodiments of a particular

invention that are developed after an inventor actually files for a patent.

A second, which is really a kind of a subtle mix of rules and doctrines, covers team research. And I'm going to argue here that there's a kind of subtle favoritism for pioneering corporate teams, which I think is really interesting in light of a couple of the presentations that have been made so far, and of unpacking what those effects are and thinking about what economists might be able to teach us about them. That's an interesting issue.

Likewise double patenting. Also kind of a complex doctrine that confers a subtle advantage on pioneers in the race for improvements. I'm going to talk briefly about how that works and how, again, sort of economic perspectives can help us understand it a little better.

The written description requirement often applies when a patentee amends claims after a patent application has been filed but before the patent issues. And what happens is the patentee files a patent application but keeps an eye out on the market and sees what competitors are doing, and there's a certain amount of wiggle room that you have in amending your claims during prosecution. And during that pendency period you

can actually amend your claims to cover, to explicitly cover competitors' products.

There's a kind of -- this is a good example of what the economists call leading breadth, in the sense that you don't understand when you file all of the particular embodiments that you might want to claim or cover, but during pendency some of the competitors' products may come into view, and there's an opportunity to amend your claims during prosecution to actually cover competitors' products. And I just spell this out here in kind of a longhand form. The idea is that you can amend your claims specifically to cover competitor products, and I give an example of a case where this happened.

And these issues, the question of whether the inventor, I in this little example, will be permitted to extend his or her claims to cover the competitor products that runs under the doctrinal heading of the written description requirement. If you look at it sort of symbolically the way the issue plays out is whether or not, even though you enable a broad range of embodiments; that is to say, you generally teach people in your field how to build lots of embodiments, that's the lighter circle here.

But the question is, did you really contemplate all those embodiments when you filed your application.

And the subset of the big circle, which is labeled here "described," and I'm sorry it's a little hard to read, is the subset that the Federal Circuit now is saying, that you are limited to in terms of claim amendments. And what this means is, in effect, that at least during pendency and at least when the other requirements for the written description requirement are met, the Federal Circuit has cut down on what the economists would call leading breadth. The embodiments that your competitor introduces while your patent application is pending can no longer be included in your set of claims, or at least under some circumstances.

Just like the original discussion of some of the issues on patent scope, I believe there's a lot of policy issues floating around in this legal doctrine. And I believe it's the kind of doctrine that we'll have to start looking at as we broaden our understanding, our conception of what goes into patent scope.

The notion of leading breadth has been championed by Suzanne Scotchmer and, a former Berkeley grad student, Ted O'Donohue, and the notion that they have is of course that the leading breadth is a key determinant in the bargaining or division of profits between the pioneer and the improver.

And I call this a kind of short-term leading

breadth issue, the written description issue, because of course it only applies during the pendency of the patent application. Once the patent is issued there's another set of doctrines that kick in that also affect this general topic, but that runs under the heading of reissuance. There's a two-year limit on broadening reissuance which is another leading breadth issue that I don't have time to talk about today, and those of you who are bored by patent law will be thrilled to hear that.

The second set of issues that I wanted to talk about in the what I call the second-order patent scope topic, are questions of portfolio-level scope issues, and in terms of sort of the conceptual issues, in terms of the intellectual richness I think there's a lot here that many of us can explore.

I'm going to talk about two of them today. There are a series of prior art rules that have to do with team research that in effect encourage a pioneering corporate research team. And the way that that encouragement takes shape is there's a kind of subtle favoritism for the assembly of a fairly broad patent portfolio, or a relatively broad patent portfolio.

And what I'm talking about here is the difference between the rules as they apply to a corporate research team, a big group of inventors who all work

together, as opposed to the way the same rules would apply if all of these inventors were separate, if they were independent entities. And for various reasons -- and a couple ways I'm going to explain -- the big team has an advantage, the big team can wind up with a broader patent portfolio than the individual people could if they invented in isolation and later aggregated their results. Okay?

And this grows out of a whole series of sort of procedural and substantive rules that developed over the years. And if you're a fan of political economy you won't be surprised to learn that big corporate R&D is favored in patent law, because of course the constituents that push for legal rules and legal change in this area tend to be drawn from that world.

Anyway, the second doctrine that I want to talk about works very much the same, and it's the so-called double patenting doctrine, which is really just kind of a variation on that theme of team research.

The way it works in practice is, you see this first bullet item, inventions conceived and applications filed by team members do not count as prior art against other team members. And what that means is that you don't have to worry necessarily about what the other team members are doing, you don't have to worry about the

patents they file and the inventions they work on affecting the patentability of your own invention. Whereas, if you were separate and working in independent entities, if all the inventors were separate, the prior work by each of them would threaten the patentability of each other's work. That's just a kind of feature of the details of patent rules.

What it means in practice is that there's a kind of relaxation when you have a team research project. If you understand that if most of the people who are working on a particular problem are working within your corporate department you don't have to worry quite as much about their work in effect imperilling each other's patents. And that can have a big effect sometimes in a fast-moving field.

What this does is, as I say here, facilitates the building of what I call a pioneer portfolio. And I just want to drop a footnote here and say that one of the things that characterizes what I would call the first generation cumulative R&D literature is a focus on individual inventions or individual patents. But we heard from John Barton, and we know from just looking at the world, that out there in the real world the patent portfolio tends to be the more important unit of analysis. Individual patents are a good kind of, let's

say a conceptual framework to work with, they're simpler, but in reality real business firms tend to deal in patent portfolios.

And so one way to look at what I'm talking about this morning is just to say that I'm trying to open up the idea of exploring patent scope into the broader world of patent portfolios, rather than look patent by patent, a pioneer patent and an improvement. What I'm talking about here is kind of looking across a whole portfolio of patents held by a firm, and then we would then talk about the pioneer portfolio versus the improver portfolio and, of course, it would get more complicated, but also I think more realistic.

Another doctrine that affects patent scope, again at the portfolio level, is this notion of double patenting. And my students who are in attendance will hear a sickening amount of detail on this later in the semester, but I'll give you the quick version now.

In general, if two independent inventors try to patent obvious variance of each other's inventions they're not going to get very far, but the double patenting doctrine permits this to happen, where two inventors work for the same inventive entity, where they work at the same corporate R&D lab basically.

And there's a subtle favoritism here of

pioneers over improvers in the race to develop improvements, because what often happens is that once a pioneering discovery is developed and filed the race for improvements begins, but in many ways -- and I don't think the literature has necessary understood this very well -- in many ways the pioneer has a leg up, they have a head start in the race for improvements. Obviously they have an informational advantage, they developed the pioneering invention. We all know that because patent applications are secret they have a legal advantage, at least for the 18 months now that the patent applications are secret.

But what I'm talking about here is an additional advantage. There's the ability to spin out some obvious variations on the pioneering invention, not only during the pendency of the first patent application, the pioneering patent application, but also for a short time thereafter.

The tradeoff in this doctrine is that you can file patents for obvious variations, but the law requires you to file what's called a terminal disclaimer, which requires you to limit the patent term of the second patent so that it coincides with the patent term of the first patent. From a policy point of view this has an obvious source in the understanding that we shouldn't

allow patents on obvious variations to in effect lengthen the term of the patent, and that makes a certain amount of sense.

But what I want to point out this morning, and relate it to the very excellent summary of the existing literature on patent scope, is that in this literature length versus scope is a tradeoff that's well understood. And the legal rule that focuses only on the patent term I think fundamentally misunderstands how important scope is. To put it in the context again of the Mark Schankerman study that Suzanne Scotchmer was talking about, the full patent term is often not what's really important, scope is often much more important. And if that's true, then the fact that you can file a terminal disclaimer doesn't really hurt the patentee much. So it's been viewed, you know, in the legal system as kind of a tradeoff.

Well, we'll allow a kind of implicit broadening of the portfolio at the expense of this terminal disclaimer. It might not be much of a tradeoff at all. And I simply point out that inherent in this notion of double patenting is this kind of invisible built-in favoritism for the pioneering firm, and it's a favoritism that might not really cost them much because the terminal disclaimer mechanism doesn't really have much bite.

Okay. I'll just take an excerpt from a recent case on double patenting that sort of explains what the doctrine is about, and I just highlighted the key part of it, is where the Federal Circuit says double patenting -- I'm going to paraphrase here -- enables some limited protection of follow-on improvements. Okay? And again, this is just an explicit judicial recognition of the fact that double patenting favors the pioneer in the race for improvements.

To revert to Suzanne Scotchmer's talk, I just want to say that there may be good reason to do that, it may well be that having that broad pioneer portfolio is a very helpful inducement so we'll get more pioneering invention. It may also be the case that in setting up a race for improvements we might want to favor the pioneer for a whole variety of reasons.

My point this morning is simply to say there is a legal rule that does that, and it does impact patent scope and it's something that we might want to think about.

I couldn't come into a setting like this without talking about another topic. And I'm sorry I'm running over, but I'll try to be as brief as I can.

In some ways our focus on legal rules and doctrines as interpreted and applied by the courts misses

probably the biggest source of intellectual property scope, which is Congress. There are all kinds of bills proposed in any given time, and the number grows over the years, has grown rather precipitously, and in all kinds of ways Congress is expanding patent rights -- and also expanding other IP rights, but that's a topic for another day.

And I just, you know, have a quick reference here to Doug North, who says you've got to watch the legislature, there's no guarantee that they're going to get the allocation of property rights correct.

In light of that, I just wanted to point out that the Supreme Court recently granted cert in a case that wouldn't seem to have much to do with what we're talking about this morning because it's a copyright case and it has to do with an extension of term as opposed to scope. However, there is the potential here for a kind of new monitor, there's a potential here for a whole new player in the game of patent scope and IP scope generally, and that's the Supreme Court.

If they choose to, they could announce something that looks like some kind of constitutional restraint on rent seeking. And I would say in terms of the overall system, one of the things that the FTC and the DOJ ought to be doing is watching that process

carefully and encouraging it in a healthy direction, because I think a lot of the action in the intellectual property world happens in Congress these days. Not that the doctrines I'm talking about aren't important, they are, but a lot of the additional strength and scope of IP rights is happening legislatively. And as long as we treat that as a given, something we can't affect, something that's not a policy variable, in some sense we may be missing one of the main events, and so I thought I ought to point that out.

Anyway, sorry to run over. Thank you very much.

MR. COHEN: Thank you very much.

We've certainly heard a variety of approaches to these issues, at least three paradigms have been presented over the last couple days, and in one of our earlier sessions probably even more than that, but three that strike me.

One is the idea of vesting strong rights in the initial innovator, perhaps going so far even as to bar follow-on innovators from patenting and relying on ex ante licensing to develop a good result.

Another approach suggested is to limit the extent of first generation protections, so that follow-on innovators are left free to proceed.

And a third approach is to vest both initial and follow-on innovators with patent rights and let their mutual ability to block each other lead them to some form of ex post cross-licensing.

What I think I'd like to do is just throw these different models and any variants that you want to come up with out on the table for our panelists to discuss the various tradeoffs between them and help us in assessing how each of them leads to maximizing welfare.

Anybody want to start? Well, maybe I'll start us off with Suzanne and the idea of stressing the first innovator. You've, in some of your writings I know, talked about the idea that if you want to maximize innovation you want to give full value to the first innovator because that would give the incentive at least to develop any efficient innovation out of that.

One of our panelists in Washington, Jim Langenfeld, pointed us to the work of Landes and Posner and helped extend that, and told us that the place along the spectrum of property protection, intellectual property protection where you maximize innovation is a little bit different from the place where you might maximize welfare, perhaps slightly less strong protection maximizes welfare because it takes into account the values of competition. How does this fit into your

thinking?

PROFESSOR SCOTCHMER: Well, of course, welfare, in a deep sense there shouldn't be a contradiction between innovation and welfare because innovation is a component of creating welfare for consumers. So of course it's a conflict between two ways of creating welfare for consumers, which is to create welfare by encouraging innovation or to create welfare by keeping prices low, and that of course in the end is the tension between intellectual property and competition policy.

When Robert Stoner brought up my paper that you just reiterated, that if you were really only concerned about the innovator you might want to go so far as to give strong rights to a first innovator so that everything subsequent infringes so that you're protecting the subsequent innovations not by giving them their own intellectual property but by giving -- but by making sure they infringe a prior patent and protecting them thereby with the prior patent rather than... Okay.

So when you brought that up I wrote a note to my neighbor, John Barton, that said, "This is in the category of most regretted paper," too clever by half.

There is something true about that, in the sense that it is true that if you create a situation where one piece of intellectual property infringes

another, you can protect the infringing by an exclusive license on the infringed. That is absolutely true.

Where that line of reasoning is extremely misleading, though, is precisely in the context of not the two-generation cumulative context that's mostly been our focus here, but rather in the broader cumulative context where you have an infinite sequence, if you will, of leapfrogging improvements, sequential innovators in the market that keep going on and on, who all exist more or less, not simultaneously, but with kind of -- in parallel, there's no notion of first and second because every innovator will be both first and second.

And in that context, you know, suddenly that changes the focus. Suddenly the question there is not how do you divide profit between the first generation and he second, because there's no such thing, the question becomes what's the total level of profit, what's the profit flow, if you will, in this market that's being generated for these innovators, because the profit flow, just looking at the profit flow that's going to generate the incentives to want to be the next innovator in the market.

Now, how do you increase or decrease the profitability of being the current incumbent in that kind of market where, you know, you have firms leapfrogging

each other?

Well, what is it that constrains price? Think of it that way. What is it that constrains how much market power the current incumbent has? That which constrains market power is the distance between the incumbent and his closest competitor, which would typically be the previous incumbent.

Now, how much distance will there be? That is a question of patent breadth, so the thing that determines who gets to compete in the market is the distance between them that's required not to infringe each other's patents. Fundamentally that's a question of patent breadth.

Now there are also questions of, you know, the patentability standard, what's required to get a patent. But fundamentally that's a question of patent breadth, because the thing -- if you're within the patent breadth you can consolidate your patents and consolidating the patents will increase the flow of profit by putting more distance between you and the next previous competitor, and increase the flow of profit.

So it's fundamentally a question of intellectual property policy, but going back to my previous remarks, if the agencies viewed it as their business to support innovation in a proactive way, it

could also be a matter of competition policy, allowing consolidation of rights along that quality ladder that perhaps might not be justified by the intellectual property itself. Pretending as though we had blocking patents when in fact we don't, for purposes of competition policy.

I think that's an open question. It's not the current practice of course.

MR. COHEN: Yes.

PROFESSOR BARTON: Let me first add a -- I want to respond to Suzanne, but let me first add a possible fourth version to your list of options, which may be a variant of the third. And this is the research exemption dependency license, some way that, at least during the research phase, a subsequent innovator has a right to use a patented invention, with or without a royalty of some type, with, of course, being subject to clear veto by the initial patent holder if the final product happens to infringe that initial patent. You know, there are some options of that type in there as well.

But I most wanted to respond to Suzanne and your general discussion by pointing out there's also a dimension of the sociology of innovation, which leads me to want to have as many people involved as possible.

And my two examples are the laser. Whatever

you might have thought of when the laser was invented, you probably -- you might well have thought of energy delivery to a particular point. Would you have thought of radial keratotomy? Would you have thought of using a laser for surveying? Would you have thought of using a laser as a read-in/read-out device on something like a CD-ROM? And the fact of the matter is, you know, different people bring different ideas, and it's good to have different innovators attacking.

My other version is when we freed up everybody and said "you didn't have to tell -- you didn't have to get permission from AT&T to bug something into the phone networker," we didn't just get cheaper telephones, we got designer telephones and modems and faxes and et cetera, et cetera, that there's some benefit I think in having a certain multiplicity of innovators able to work with an initial group of ideas.

PROFESSOR MERGES: Yeah, actually I had a point on that too. I think that's a very well-taken point, and I think, you know, looking at how the innovation communities are sort of imbedded in different institutions is really essential if you're going to get a full picture.

And I just wanted to mention in that respect, pick up on something that Suzanne said. You know, she

was talking about some of the social welfare loss that you might have if you had a Kitch sort of coordination paradigm where you were awarded a broad prospect patent, and the notion was that, you know, there might be a lot of private gains from coordinating the development, but there might be some social welfare loss as well. And I think that's true in general.

But I wanted to point out that university licensing offices are often in that same situation. And, you know, those of us who know the university licensing people know that because of their situation within universities they do not take a strictly profit-maximizing view. And what they do when they have something that's a kind of a broad gene patent, like in Suzanne's example, they tend to restrict each licensee to a particular field of use.

And the idea is they don't want to give an exclusive license so that we only get one therapy based on a particular gene sequence, or some basic discovery. They try to encourage that multiplicity of applications which the models tell us will happen if you open up the broad prospect to a lot of competitors.

So, it doesn't mean that AT&T would have benevolently, you know, licensed access to the plugs if only we'd waited long enough. It just means that the

innovator and the person who holds the broad property right may in some cases have some incentives, and sometimes they're not even financial incentives, to do that.

It's just one cautionary note, when we look at these sort of models strictly in the abstract, and university licensing offices are really an interesting example of entities that in a sense hold a lot of options, but for various reasons decide to give them away or not enforce them. I think the non-enforcement of the property rights is a really interesting feature of the IP system that we haven't looked at.

Most of our models kind of assume maximum full-bore enforcement whenever possible. And one of the things that we observe in the real world is that that doesn't happen.

Does that mean we shouldn't grant broad rights in hopes that people will elect to not enforce? The policy implication is complex, but it's a fact people don't always enforce their rights, and sometimes they don't enforce their rights for profit-maximizing reasons. Anyway...

MR. COHEN: David.

PROFESSOR TEECE: Well, I think we can sort of all agree that there's a great benefit to variety and so

forth.

But I'd like to pick up on John Barton's comment about cross-licensing, because, you know, in the semiconductor industries you recognize that is an industry where people pretty much do enforce their intellectual property rights. But I was struck by the fact that you came away thinking that there was sort of nothing beneficial, this sort of happened and this was sort of a perversion of the patent system.

When you look more closely at it what you discover, of course, is that it's not just simply everyone cross-licensing everyone, there's certainly a lot of that, but some folks who don't have intellectual property end up paying, so they're balancing payments.

And it seems to me that, one, you know, the major players do license and they don't actually use intellectual property to keep people out of the industry, they just simply use it as a way to extract a fee. So the latecomers who didn't, you know, incur a lot of those early expenses end up, you know, having to pay something, and you seem to me that you've solved the classic sort of free-rider problem.

So in that context I'm struck by the fact that you don't see anything socially beneficial in this cross-licensing arrangement when it seems to work pretty well,

and I don't think anyone would claim that the semiconductor industry is not advancing at a very rapid pace. You've got rapid innovation, strong intellectual property, cross-licensing that doesn't seem to stand in the way of new entrants, but you do end up some wash payments going back and forth.

So what's the problem? Did I miss something?

MR. COHEN: I see Suzanne's tent up, but I think I should give John a chance to...

PROFESSOR BARTON: I guess what I see is a great deal of legal churning. In other words, I think if you would ask an executive in the semiconductor industry they would say, "We have to build the portfolio because we risk getting sued, but that's not why we're investing, that's not why we're investing in research; therefore, we're expending a significant amount on legal bills to apply for patents and on occasion, of course, to defend ourselves."

It isn't clear that the system is contributing in fact, there are other sets of motivations in a particular industry that are leading to the high level of research, and the patent game is sort of a fallout of that that you engage in because of the risk that you're competitor will engage in it and sue you, as happened when Texas Instruments started the litigation early on.

Indeed, I think I can add, the risk of litigation is strongest if a company is not making it in the marketplace, because then it has smallest market share and, therefore, least risk of counter-claims and counter-royalties, but the greatest chance it has of asserting whatever portfolio it has against its competitors.

There are some fairly perverse aspects here.

MR COHEN: Suzanne and then Bronwyn.

PROFESSOR SCOTCHMER: I liked Rob's optimistic view, especially of university licensing and patenting, but maybe the way to think about that is that, you know, it's possible to hold a patent of any type, in particular a pioneer patent, and use it in a copy-left kind of way as opposed to a -- that is -- and one might want to stylize the difference between using the intellectual property in a copy-left kind of way as opposed to a proprietary kind of way, as precisely the difference of coordinating follow-on research for private gain rather than social gain.

PROFESSOR HALL: I just want to go back to the discussion between David and John, of course, on semiconductors. John said if we asked a semiconductor executive, I think I just want to underline that I -- we did ask semiconductor patent executives, CEOs in some

cases, in the case of small firms, and patent attorneys in the case of large firms, and they said exactly what John said, which is that they were -- the system works but there's a lot of resource waste. They did not view it as important for their innovative activities, they viewed it as essential for preventing them from facing the threat of preliminary injunction and shutting down manufacturing plants because they were infringing in their manufacturing of semiconductors.

Most of them could not think of anything they would miss if the system went away, except that they thought that entry into the industry would actually be harmed. Not assisted, but harmed. Because the positive benefit of the patent system that they pointed to, and these were people in large firms, was the fact that it enabled new entrants to obtain financing to enter the industry.

Now, this is of relatively small effect compared to the amount of money that was being spent on patents, but it's still something, it was something to keep in mind when thinking about the system.

But they were -- even the patent attorneys, the patent counsel themselves were not of the view that this system was creating a lot of value on the whole, which was, you know, a little surprising since those are the

people that are most heavily vested in the system.

MR. COHEN: Okay. I think we can return to all these issues a little bit later, but I think we could all use a short break. Let's figure about 10 minutes, and let's say 11:15, we'll try to start right then.

(Whereupon, a brief recess was taken.)

MR. COHEN: All right. I think we can resume.

Our next speaker is Professor Bronwyn Hall, in the Economics Department here at the University of California at Berkeley, and a research associate of the National Bureau of Economic Research, and the Institute for Fiscal Studies in London. Her current research includes comparative analysis of the U.S. and European patent systems, measuring the returns to R&D and innovation at the firm level, and studying recent changes in patenting behavior in the semiconductor and computer industries. Professor Hall.

PROFESSOR HALL: Thank you. I want to first of all try to remember to speak into the microphone, and secondly to thank the organizers for inviting me to participate in a panel with such distinguished people. I really enjoyed listening to the first part of the session, and I'm looking forward to hearing David's remarks.

I decided that I would talk about something I

know something about rather than talking about antitrust, namely patents and their effects on the innovation system. So I'm going to focus on that.

I have the usual economist's view of the patent system as a somewhat necessary evil, which is to say that -- so I'm stepping aside from the whole property rights approach to the analysis of patents.

But with a patent grant we're trading off this short-term monopoly in return for the two most important things I think out of the two that Stoner listed earlier where, first, the incentive to innovate, the thing that's been analyzed the most by economists; and, secondly, the publication, the early publication of information about the invention, rather than the use of secrecy to protect innovation.

Now, this view, a sort of skeptical economist's view of the patent system, was well stated 50 years ago by Edith Penrose, and I'm grateful to Josh Lerner for informing me that Fritz Machlup, who is also known for having said essentially the same thing, presumably had her quotation in mind when he said what he said about the patent system.

But the problem here is that it's difficult to make a conclusive case in many situations for introducing a patent system, but it's also difficult to make a

conclusive case for removing or limiting it once it's in place because institutions and organizations and firms adapt to whatever rules and regulations you place in their way. And I think that's one of the things that we've learned from our empirical research.

Now my take on this -- on the broad subject, I sat down and I said, "Okay, what do they mean by IP innovation and competition?" And I thought I would -- the blue on the slide is intended to highlight the area where I think -- I'm going to just tell you what I know so far -- which is to say, this is the patent system as viewed by a two-handed economist, of which I am one -- okay? -- and I'm not going to repeat the old saw about the need for a one-handed economist -- which is basically there -- it has benefits for innovation in the sense that it should, and I think probably does create incentives for research and development in some areas, and innovation.

It has a cost, which is that it can impede the combination of new ideas together and new inventions together, and subsequent innovation, depending on exactly how it's structured. The reason for that is fundamentally because in the presence of licensing it will substantially raise the transactions cost of reaching agreement. And I'm sure many of you are

familiar with the extreme version of this argument, which is the Heller and Eisenberg article about the tragedy of the commons -- the anti-commons, sorry.

The second benefit cost tradeoff, and the one that I'm not going to spend as much time on, is the competition side, what do we think the effects of intellectual property would be on competition, and we've discussed that a lot already this morning.

And the things that I can identify as benefits are primarily that it does facilitate the entry of new small firms or new inventions in situations where the producers of the innovation have relatively limited assets, tangible assets to protect and therefore have in a sense only an idea. And being issued ownership of that idea is an advantage both in securing financing and just being able to exploit the innovation. And, of course, absence of that might mean that you would never produce the idea in the first place.

Why do I emphasize this point? I emphasize this point because for me one of the most important safeguards for competition is to make it easy for new entities to enter. That's the thing that drives profits down to zero, that's the thing that in a sense limits market power in the long run, is facilitating entry. And so I am concerned about things that do that. And I

thought, you know, the AT&T example, the regulated industry example was a good example in that setting.

And the cost of course is the short-term monopoly, and I think right now, today, we're worried about the fact that short-term monopolies which enable you to take over dominance in a network industry may put you in a position that lets you extend the length of the monopoly longer than the typical patent term because of cumulative -- really because of switching costs in many cases.

Okay. So the question I addressed myself to was the question that Bob Stoner actually did a really nice job of surveying. So of course, like everybody else, I feel, you know, a little bit like some of my presentation is a waste of time. So what I'm going to do is focus on the things that I know about the answers to the question: Does the patent system increase innovation activity from the empirical side -- okay? -- rather than from the theoretical side?

And why do I emphasize that? Because if you have theories which tell you it could increase it or it could decrease it, then inevitably it does become an empirical question, and in particular it depends on what time period we're talking about, and it depends on what industry we're talking about, and it depends on a lot of

factors in the environment.

Now, what I put up here was two pieces of 19th century evidence, and I'm -- not because I think we're moving back to the 19th century, but because the 19th century was a period when there was more variation in patent systems and more things going -- being introduced and stopped and so forth than there is today, at least in developed countries, in countries that were otherwise rather similar. Okay? We have a lot of variation today, in spite of what you read about the TRIPS agreement, but much of that variation is between economies that are so different in other respects that it's very hard to conduct an experiment of this kind, which is basically to say "change the patent system, what happens to innovation activity." Two things. Okay.

One is, a graduate student of mine has studied this by measuring innovation by measuring inventions at world fairs and expositions across many countries. And she basically finds no effect on overall innovative activity within a country of having a patent system, or having longer or shorter patents.

But she does find that the industries in which innovators innovate are influenced by the presence of a patent system. They tend, when there is no patent system, to go towards industries where trade secrecy is

more important and more salient, where they're able to protect their inventions with trade secrecy. In other words, they do respond somewhat, but only in focus not in levels.

The second finding is a new one which -- by Josh Lerner which -- I don't know, Josh may have talked about this at some point to at least some of the people in this room --

MS. GREENE: He hasn't.

PROFESSOR HALL: He didn't talk about this at all?

MS. GREENE: No.

PROFESSOR HALL: I actually found this very interesting. He has compared patent systems in the 19th century across a great many countries and identified many changes where -- many times when the systems were strengthened, and he has asked, "After that strengthening what happened to patenting," sorry, "What happened to innovation and patenting in the countries where it was strengthened?" And what he finds is that foreigners tend to patent more in a country when the patent system is strengthened.

Domestic firms do not. Nor do they increase their patenting in Great Britain, which at the time is the big economy where they have a big market -- okay? --

because these are mostly European firms. In other words, the interpretation of that is the domestic firms weren't innovating more because they weren't increasing their patenting in Great Britain, but foreign firms, seeing that there was a stronger patent system came in and started patenting in that country. Okay.

Now in the 20th century evidence -- we'll skip over Hall and Ziedonis because that was mentioned, Branstetter and Sakakibara was mentioned -- there is one cross-country comparative piece that looks like Lerner's. And in that piece, by Walter Park and Ginarte, what they found was that there is some evidence that the strength of intellectual property rights, including -- one of the measures they use is the -- is whether your country covers pharmaceuticals because up until TRIPS many countries did not cover pharmaceuticals, they did not allow patenting of pharmaceutical products, and even of some chemical products -- what they found was that that was somewhat positive for research and development, it did -- countries with stronger IPR rights, developed countries with stronger IPR rights did tend to increase their research and development.

I won't go into the details of Baldwin's study, but it's a study on Canada, and basically it does seem -- it doesn't -- it seems to be somewhat pessimistic on

whether patenting is increasing innovation.

Some of you are familiar with Bessen and Maskin who have argued that the software industry was doing fine without strong patent rights. The evidence that they give is not very strong; however, I think that what you can point to is some changes in organization within the software industry since patent rights became -- ease of entry with pure -- as a package software entity, internet, the internet industry. I think, I think much of this reflects the activities in those industries, not the industry itself but the activities in those industries reflect the rise of software and business method patents.

Now, I have to confess at this point that one thing that isn't in my biography is that I'm a dinosaur, and I have a very small niche product software firm which was established in the pre-patent era and has always viewed copyright as the appropriate protection, and operates in an industry without -- that does not, by in large -- a niche of the industry, which does not, by in large, worry about patent rights, so I'm a little bit biased in this respect. Newer entities, newer entrants tend to have different views.

I cite here Lanjouw and Shankerman, and I finally go on to talk -- let me talk a little bit more

about Cohen and Levin, because that's the survey evidence, and that was cited -- that was alluded to by Stoner, and I think what's interesting about that survey evidence, they surveyed R&D managers. That's the first thing to understand. Okay? So the people they were talking to were the research and development executives at firms.

It was two surveys 10 years apart and they both reached the same conclusion with respect to patents, which is that they were not important for securing returns to innovation except in pharmaceuticals and possibly some small mechanical-product industries. However, they were important for defensive purposes for blocking and for a variety or other things.

And Arora has built on this, Arora and his co-authors have built on this basically to, you know, focus on the pharm and biotech question. Okay.

I want to just conclude and spend a little time talking about the four conclusions I've reached from reading this literature, which I obviously didn't do justice to by quickly going over it.

The first thing is, it's unambiguous that if you strengthen or introduce a patent system you will increase patenting activity. That's the strongest result that comes out of the literature, it's no surprise to

anybody.

You will also increase the strategic use of patents if -- in that setting.

It's much less clear that you get an increase in innovation activity, although you may get some redirection towards things that are patentable and/or are not subject to being kept secret within the firm.

Three and four are, if there is an increase in innovation due to patents it's likely to be centered in pharmaceutical and biotechnology, and possibly specialty chemicals, and I include agricultural chemicals there.

The existence and the strength of the patent system -- and this is where -- may be a relatively newer thought -- does affect the organization of industry, and this is -- again, this is going to bear on the antitrust issues -- because what it does is, it allows trade in knowledge. I am hoping here that you've heard from Ashish Arora, or are going to hear from Ashish Arora -- did he speak yesterday?

MS. GREENE: Yesterday.

PROFESSOR HALL: Yeah. Because this is a subject about which he can speak eloquently.

And what trade in knowledge does is, it facilitates vertical disintegration of knowledge-based industries, and we saw that in the semiconductor

industry, where you now have firms that are mostly designed, and being mostly designed, being able to produce the design for a chip but not necessarily manufacturing it, sending your manufacturing over to merchant firms in Taiwan or even, you know, to firms in the valley, it's facilitated if you know that you can protect your design ideas and your inventions via the patent system. Okay? So that's a vertical disintegration taking place, and specialization.

And the second thing is the thing I mentioned before, which is it facilitates the entry of new firms that possess only intangible assets.

So, you can expect the patent system to have consequences for the organization of industry. Once you've had those consequences it's difficult to then change the system drastically because not only will you actually weaken the current way industry operates, but the other thing that happens of course is you've created a whole bunch of people that have vested rights in the system. All right? And that is obviously going to inhibit the -- your ability to change it, to change it very drastically.

Okay. That's all I want to say.

MR. COHEN: Our final speaker will be David Teece. He is an applied industrial organization

economist and an economics professor here at the Haas School of Business. He has testified before Congress and government agencies on regulatory technology and antitrust policy, and he's authored, oh, over 150 books and articles.

David.

PROFESSOR TEECE: Thank you. Since I'm the last speaker I thought I would take advantage of the last slot to sum up a little bit on some of the things I heard yesterday, as well as today, and to congratulate the agencies for I think finally stepping out and endeavoring to address these very hard questions that we have before us around dynamic competition and the relationship between intellectual property and antitrust.

And let me begin by saying that I thought something very important started to happen yesterday on the panel, and that is that people let their hair down, and once you let your hair down a little bit I think you have to -- if you're honest, you have to end up saying, "Gee, a lot of things are different if you start factoring in the innovation story and if you have to take intellectual property into account."

I don't think we can pretend much longer that the old static approaches really work, even though I recognize that from the agencies' point of view they have

to create certainty, so this is the great conundrum. You don't want to let your hair down too much because you have to provide some degree of clarity and guidance to industry with respect to enforcement. And so it's inherently the case that the agencies must be conservative, which puts into context the exercise we're going through here, because this is a chance for the agencies working with academics to really take the lid off and probe further.

I was struck by one of the remarks that Dan Rubinfeld made yesterday, which is that once you dig deeply here two things happen: you recognize that the cost of getting it wrong goes way up, and also potentially the benefits of getting it right go up. So the agencies should like this because in some sense it means the payoff to what they do is greater in the new economy than possibly it was before.

But at the same time, I think it means, because of the lack of understanding on a lot of these issues, that there's no place for hubris and that in fact there's plenty of room to roll up one's sleeves and get down to the hard work, such as is taking place yesterday and today.

Let me just make a comment first of all about Howard ShelanskI's survey yesterday, because we got two

extremely important surveys of the literature, and Shelanski had the job of sort of looking at the relationship between market structure, firm size and innovation, and he summarized for us what we all know. Namely, there really isn't much effect. I suppose there's almost two generations of scholars now that have plowed that turf, and someone maybe out at some point will come up with some better metrics and maybe we'll find some small effects.

But I think we need to stand back from it and say, "Well, why is it that we're not finding a relationship, or much relationship between market structure, firm size and innovation," and I think the answer is, "Well, there isn't much of a relationship."

And in a business school that's not surprising. If you take a course in the management of technology or in innovation, and if at the end of the class you were to ask the students, "Well, what are the main factors driving innovation," I don't think they would have market structure, or a lot of the traditional things that economists look at, near the top of the list. They probably wouldn't be on the list at all.

In fact structure does matter, but the structure that matters the most is the internal structure of the firm. And there are many, many articles in the

strategy literature and the innovation literature that speak to, you know, incentive questions, speak to questions about centralization, speak to questions about bureaucratic decision-making. There's a long litany of things that are important, firm-level determinants of innovation, but firm size is hardly one of them.

And to the extent to which, you know, historically and through Schumpeter or whatever, the financial resources of firms mattered, that link has also substantially been broken by the venture capital industry, so that while it's true that in many -- for many large firms there's a strong -- the best determinant of R&D spending is cash flow, once you get down to smaller firms it's not cash flow, it's venture capital funding. And the basic sort of historic links that existed between access to capital and corporate treasuries has really being broken quite some time ago.

All of this says we shouldn't be surprised by the lack of a strong statistical relationship. It's not to say there aren't some, and no doubt some will be found, but the level of explanatory power that we're going to get from looking at the traditional metrics I don't think is ever going to get high. But, there's lots of other things that help us understand why.

Unfortunately there's not a lot that naturally

the agencies can get their handle on, although over time -- and I think particularly in the context of mergers and acquisitions, one can begin to understand how aspects of the internal organization of the firm affect economic performance.

And indeed, I found it striking that yesterday the languages of competencies and capabilities and so forth, some of the things that I always thought were important, and that in the corporate strategy literature are frequently referred to, are now getting into the lexicon of antitrust. Complimentary assets, competencies, capabilities, these factors -- you know, these are some of the tools that one can use to try and understand the process.

Let me also just dwell for a moment on some of the points that Hal Varian was making when he talked about his half-baked ideas. Those, such as myself, that respect Hal will recognize that one of Hal's half-baked ideas is just as good as most people's fully-baked ideas.

And he stressed -- in fact, drawing on the examples that Gilbert put out -- the importance of competition for monopoly as a primary driver of the innovation process. And I think indeed that's -- you know, that's what you see in many industries, it's the opportunity to compete for a monopoly which is

significantly motivating, and it tends, but does not guarantee, that you'll -- the competition will play itself out in the form of a number of transient monopolies or sequential monopoly, whatever you want to call it.

You see it at the micro level in industries like medical imaging, you know, where one generation of products will wipe out a prior generation, typically in the hands of a different set of innovators.

And this dynamic is in fact the dynamic that characterizes competition in many evolving industries, whether it's a cumulative process or whether it is more of a revolutionary process. And certainly the different -- you know, the difference between regimes in which innovation is cumulative and those which it's more exogenous, I think that they are part of the important metrics that we have to play with as we begin to think about innovation and competition.

All of this is to say that I think a lot of the structuralist apparatus that antitrust has historically relied on should probably be relegated to one side, if it's not already being relegated in that fashion as I think to some extent it has.

But the old structuralist approach which, you know, quite frankly came out of Joe Bain's work here at

Berkeley in the '50s and Mason's work at Harvard in the '30s, if it's not dead it ought to be dead. Joe is dead but his ideas live on perhaps longer than they should.

Now, why does all of this matter? Why do these stories matter? Well, you know, traditional things such as the way you think about predation, I mean, if you take Hal's framework, the notion of predatory pricing, you know, just gets tipped over once again.

Not that we ever got to any resolution in the economics profession of what predation was and what it wasn't, but certainly if you take the framework that Hal was tentatively putting forward where, you know, the way you capture markets of course is to price low, not just because marginal costs are low but also because it's important to build some kind of an installed base. You know, all of that the traditional notions of predation just have to be looked at through a completely different lens.

Also, unfortunately I think it also puts into context the whole sort of snip approach to market definition. I mean I think if you think about the snip approach at a conceptual level it's just fine, but the basic apparatus by which you start thinking about market definition has to be thought of in very different ways in a dynamic context.

So, the conceptual apparatus I think is alive and well and is fundamentally sound. But thinking about how you actually apply that is a different matter.

And then a final comment which relates to some of the points that Bronwyn was making was thinking about entry. First of all, if you look at the innovation literature it says that, you know, most innovation comes from outside the industry. You know, the basic paradigm of antitrust is to focus on inside the industry as being, you know, the main driver of innovation, but the literature and the anecdotes all speak to the importance of the innovation which comes from outside.

Which of course there's a natural road to incorporate that into traditional analysis, and of course through entry analysis. But it's sort of entry not from other players inside the industry but from the small players within, but from the small and the large players from without.

And, whereas historically there's been a focus on patents as a barrier to entry, you have Bronwyn telling us a few moments ago that patents are in fact the tool by which new entrants come into the market. So the old-fashioned ideas that you find in Bain and Mason about, you know, incumbents sitting there with patents and blocking entries turned completely on its head by

some of the observations that the talent around this table here has been able to identify.

With those few broad comments, let me make a few narrower comments that are -- will hopefully build off of these more general points.

You know, at the end of the day, this debate on patents as a determinant of innovation I think is probably going to be inconclusive. But I think that when the dust settles, patents do have some effect. You know, it's not clear it increases the overall rate of innovation, as Bronwyn's just explained, it may simply be that it directs and channels the nature of innovation.

But there is an effect on innovation, it is important for appropriability in some industries. I mean there are very important studies that have been referred to many times by Levin and Nelson and Winter and so forth, you know, the new version of this stuff essentially says that patents have become more important over time as a device to capture value.

And I think this is particularly important, and it doesn't necessarily shine through in these studies, for small firms.

I want to pick up on the point that Bronwyn was just making, and that is that to the extent to which -- you know, in the antitrust arena we favor the role of

small firms. Small firms are the ones that I think benefit the most from patents. And this is hostile to the traditional view; the small firms benefit the most in two regimes.

One, that enables them, if they're good at invention, to specialize in invention. And this is a very old and sort of Adam Smith idea. But I think it's, I think it's correct.

I used to always enjoy in class asking my students, "Give me the name of a company that just specializes in invention." and of course there weren't any.

Now you've got a few, like Rambus. And Rambus, just what are they, what's their product, patents? What are they -- you know, is it -- well, their products is technology, and their technology's protected by patents, but they don't have any complementary -- they're not in the business of making semiconductors, they're simply in the business of licensing intellectual property to others. So, a well-oiled patent system facilitates specialization and division of labor.

So, you know, one of the very sort of oldest ideas in economics I think can possibly be enabled by the patent system and, of course, the big question is: Well, how efficient is that market? And I will, in the next

couple of slides, try and address that through talking a little bit about some of the issues around the strengths of patents.

I think the -- you know, the economics literature tends to deal with patents at a fairly broad level, you know, and length and breadth is something which, you know, is in most of the models.

What's not in most of the models is the validity. I think, you know, we always like to think that a patent is something that's valid and is a clear piece of intellectual property, but as you look closer patents of course are very unclear in terms of the intellectual property that they contain and the exclusionary power that they convey.

Which brings me to I think a very important point that has to be understood with respect to understanding the market for know-how and understanding some of the competition policy issues. And that is that there are a lot of fuzzy boundaries around intellectual property, unlike real property, unlike tangible property which is usually defined fairly well. Certainly if you -- even if you own land in Berkeley it's relatively well defined, but if you're on intellectual property anywhere in the United States it's not well defined.

You know, the various claims that are out there

will pretend to describe the scope of the intellectual property, but it's only when subsequently tested in court that you know that in fact these claims are valid.

One of the implications of this is that -- and this comes from the market for know-how -- if there are unclear boundaries it tends to foul up the workings of the market for know-how.

And this, by the way, is something of great importance to the agencies because to the extent to which you inject antitrust into the market for know-how, and to the extent to which you affect the property rights of intellectual property owners through enforcement action, if that's not clear then, then you create another level of ambiguity around intellectual property rights which, in turn, fouls up the efficient workings of the market.

Most patent disputes arise because people disagree as to the scope of the patent. It's not that, you know, there's a clear view of the patent on both sides and they can't come to a meeting of the minds, it's simply that there's a disagreement as to the scope of the patent.

And, you know, this is a, you know, straight Coase Theorem point in a way, that, you know, if you define the property rights well things will get sorted out to the benefit of the parties, not necessarily the

benefit of the public interest, but certainly to the benefit of the parties. But the greater the ambiguity around intellectual property rights the less likely that the market will be able to work and so transactions move from the marketplace into the court.

And this is a topic for tomorrow when we talk about patent thickets and so forth. But one of the things the agencies have to be cognizant of to the extent to which they change perceptions of intellectual property rights and create ambiguity around that, it can potentially foul up the market for know-how.

That's not to say the agencies shouldn't get involved, but if they do get involved they have to do so in a fashion that leads to clarity of understanding in the outside world with respect to how the agencies are going to act.

One of the other aspects of intellectual property -- and this is purely a conceptual chart -- is that the value changes over time and, and this chart really builds on the comments that I've just made.

You know, there's a presumption when you get a patent that it's valid, but that presumption can be overturned in court. And so, you know, this is very much the manner in which the venture capitalists would think about patents, if someone's got an invention, if they

apply for a patent, yes, well, that's a couple of points in your favor. Is the patent being granted? Yes. Well, that's significant, but it's not particularly significant. Value is really only established once you have proved the validity of a patent in court, and then of course after the patent expires you're left with nothing, potentially some reputational benefit.

But I think it's very infrequent that people sort of have this view of the dynamics of the life of a patent where value changes according essentially to how the property rights change and very few patents, as Mark Lemley has explained in his papers, very few patents ever get into court and ever get tested, and so one is always, one is always implicitly discounting the value of intellectual property.

Another aspect of this is that the values that you observe for intellectual property in a marketplace almost always reflect deep discounts. They reflect deep discounts because no one wants to test the patent. So if you think there's a probability of -- if you think your intellectual property's really worth X and you've only got a 50 percent chance of prevailing in court, well, then, you know, it'll trade at half X or something like that.

And to the extent to which the numbers are much

lower than that, which is probably typical, then the observed prices in the marketplace would be different from the observed prices in court, and perhaps even on the courtroom steps. So you have the very unusual circumstance that the value of intellectual property is a function in part of where you're measuring it.

Now if intellectual property is not the primary appropriability mechanism, what are some of the others? Well, I think they're well known, you know, the positioning of a firm in the market, it's complementary assets and so forth, it's lead time advantages, all of these things are now well recognized as being important determinants of the ability of a firm to appropriate value from technology. And in a way, in saying that the -- you know, intellectual property's not important, it's -- in some sense it's because firms have had to invest in these other things. I mean, there's a little bit of a causation issue here.

I mean if for instance there was a rule which said you can't vertically integrate maybe the value of intellectual property would be high. I mean firms vertically integrate in order to position themselves in a market so they can capture value from intellectual property, and the weakness of the intellectual property system perhaps is one reason why firms are structured the

way they are, to capture value from technology. So there's a recursive system there which I don't think is frequently addressed.

Well, what does all of this mean in terms of licensing and antitrust policy? I'm not really going to get much into policy today, but I did want to lay the foundations, building on some of the remarks that John Barton made and Bronwyn made, and that is that -- well, and Bob Merges -- the world is increasingly one where you have to think about patents in terms of portfolios. The unit of analysis for patents is portfolios, is a strong version of what I'm saying.

Most of the case law, the unit of analysis is the patent. Economic theory, the unit of analysis is a patent. The reality in the real world is that the unit of analysis is the portfolio, and that makes a big difference I think.

Certainly we recognize that all innovators stand on the shoulders of others, the cumulative innovation story is there. I think there's important distinctions to be made between complex and discreet technologies, or systemic and autonomous innovation as I prefer to call it.

But there are significant implications for the changing nature of the unit of analysis around the way we

think about licensing and cross-licensing. And antitrust does get implicated in these issues. I mean the guidelines obviously deals with licensing policies. But there's an enormous tendency amongst economists, and you see it in telecom and everywhere else, to think the world is better if you unbundle. There's an enormous tendency in institutional economics to question that.

And fundamentally, if the unit of analysis is the portfolio, the notion that somehow rather you should piece-part the portfolio and license on a, you know, patent-by-patent basis, which I think is what the instinct of the agencies is probably to do, I'm thinking a little bit about Dell Computer there I suppose in the back of my mind.

But I think one has to recognize that when you have a portfolio you don't necessarily know what the value is of each individual patent, you don't necessarily know which patents read on which products, and that if in fact you force unbundling of a portfolio you in fact -- you require the owner of the intellectual property to incur a tremendous amount of transactions costs.

I mean in the extreme form where companies have patents that -- they may have thousands of patents in their portfolios which in turn read on thousands of other products. Then how are you going to figure it out, which

products -- which patents read on which products? Well, you've got to reverse engineer all those products. So it's not just transactions costs of haggling, it's -- you're forcing people to go into the lab and spend huge amounts of resources doing what everyone thinks of as pretty unproductive research, namely reverse engineering for purposes of establishing whether there's infringement.

I mean, reverse engineering can be very valuable in other contexts for learning about technology. But if all you're doing reverse engineering for is to figure out if someone's infringing your patent and which ones, then it's very different.

All of this is to come back to a basic theme here, which I think is fairly uncontroversial, which is that a lot of licensing does enable one to achieve design freedom or freedom to operate at low transactions costs and a footnote on that, which I'm not sure I got John Barton to agree with, is that -- and by the way, it also enables you to hook the free rider and make them pay some piece, make them pay something for the intellectual property that they're using which others have invented.

So this system does have certain costs associated with it, John, you're absolutely right about that. It's not clear if the agencies get in the middle

of it that those costs will go down. I think, and certainly in terms of unbundling, they'll unquestionably go up. And at the end of the day -- and this may be the property of well-established industries.

I mean, it was interesting to me to notice yesterday once again, in Hal Varian's presentation he pointed out, and you see the same thing today, that in the early days of an industry -- and he mentioned sewing machines but he could have mentioned automobiles -- there frequently are battles around patents. In fact Bob Merges in his paper with Dick Nelson talks about Henry Ford having to battle the Selden patents before he could commercialize the automobile because Selden had a patent on the automobile. But what tends to happen is that these problems get solved.

Now in the case of radio, the United States government jumped in the middle of it, but there may well be a difference here between the early stages of an industry and later stages. You know, the semiconductor industry works just fine because there is sort of norms with respect to licensing practices. In the early phases of an industry such as biotechnology people have got patents, they don't necessarily know what they're going to do with those patents, they don't necessarily know whether they want to license them to other people, and so

that can clog things up.

So finally, since I'm undoubtedly running out of time here, there are important implications I think from this with respect to licensing policies, and there are also important implications with respect to dynamic competition more generally. But my time is up so I won't go further right now.

MR. COHEN: Okay. Thank you, David. That was certainly a provocative presentation, but let's take one piece of it and throw it to the group. I think you said fairly categorically small firms benefit the most from patents.

What do people think about that? Any reactions?

PROFESSOR SCOTCHMER: I'm wondering whether there's solid evidence or whether that's speculative.

PROFESSOR TEECE: Well, there's anecdotal evidence of that. I mean, if you think about -- if the unit of analysis is the portfolio, the small firm, you know, has -- the small firm without any product but only intellectual property is actually in the position to hold up the big firm.

I mean, let me say that the traditional way of thinking about this is I think wrong. There isn't a lot of evidence for what I say, but I do think we should bear

in mind the following: Where does the real power come from? It comes from someone who's got intellectual property and has no product. Someone with intellectual property and product will enter into a cross-license, but if the norm is cross-licensing, who can screw up the cross-licensees and the cross-licensors? The answer is someone with intellectual property and no product.

I think the other element of the argument is if you believe the story about the mechanisms of appropriability, what were they? Lead time, complementary assets and so forth. Where are the small firm's position on complementary assets? By definition, zero.

So reading into the Nelson-Winter-Klevorick studies about appropriability, I think there's a reasonable inference that small firms benefit because they are less well positioned with respect to appropriability mechanisms.

PROFESSOR BARTON: Let me just comment with sort of a pro and a con. I think you're absolutely right that in many contexts the small firms do benefit. I think there's no question venture capitalists look for intellectual property.

But I want to add, and a good example is like the fellow who held up Microsoft with a patent on, you

know, some kind of software device. At the same time there's a counter-argument, very often small firms can't afford to engage in patent litigation.

I mean one more set of the uncertainties that I think you did a masterful job of presenting, is it's enormously expensive to go through litigation, you know, at least in the millions of dollars, which on the whole a venture capitalist doesn't want to fund, and so that simply by creating uncertainty in a legal relationship, sometimes the small firm can be hurt. And indeed, from another side of it, trying to get a decent legal opinion that, no, this product does not infringe that patent, even that is a very expensive task that may sometimes be beyond the ability of a small firm. And of course a lawyer's going to be very, very careful about writing an opinion letter on it.

MR. COHEN: Suzanne.

PROFESSOR SCOTCHMER: This is on a different topic, is that okay?

MR. COHEN: Okay.

PROFESSOR SCOTCHMER: This is on the question of bundling complements and substitutes, which has been a latent issue in this panel and I want to bring it up more explicitly.

Susan DeSanti actually raised an interesting

issue at the break in the cumulative context, pointing out that in the situation where you have an underlying innovation and a follow-on which is an improved -- a follow-on can take many forms, it can be an application, but one of the forms it can take is that it's an improved version of a prior product. And what she pointed out was on the question of whether the intellectual property on those two pieces of knowledge are complements or substitutes is ambiguous.

They're complements in the sense that you need the -- the whole point is you need the prior for the latter, you can't have the latter without the prior. But ex post, if one is an improvement of the other and they compete in the market they're substitutes.

Now, given that the question of when complements are substitutes is an extremely important determinant as to how the agencies will view merger and licensing, enshrined in fact in the 1995 guidelines. That leads to a question of how should the agencies view licensing in that context, whether or not the intellectual property -- should they allow those intellectual properties to be merged. So that's one question.

But another question that relates to this ambiguity about complements and substitutes is in fact

the bundling context, which David Teece has now emphasized, as did also John Barton and Bronwyn. And that is in many patent portfolios when you're -- it used to be, back in the pre-1995 era of the nine no-nos, that bundling was -- I don't know if it was per se illegal, but it certainly called for scrutiny, as did many other licensing practices which have -- the stance toward which has been softened subsequent to 1995.

But one of the issues with bundling is if everything in a bundled package were complements then of course, as described in the guidelines, we should be less suspicious, we should think that that was very pro-competitive to patent -- to license them jointly, at least in the sense that you're likely to get lower prices than if they're licensed separately, and there's nothing that impedes competition.

The problem is that one presumes that many of these bundled packages contain both complements and substitutes. And I'm thinking for example, and this is probably something that John Barton knows more about, I'm thinking for example of ag biotech, where now you've had a lot -- you've had in the last five or eight years a lot of consolidation, much of which has been achieved through merger and other forms of actual corporate joining rather than licensing, a lot of merger of intellectual property

where it's ambiguous whether the constituent parts of the things being merged are in fact complements or substitutes.

So for example, traits that you might want to insert into a germ plasm can be substitutes or complements, methods for doing that can be substitutes or complements, and so the question becomes, you know, when these mergers take place and you end up with these big patent portfolios, these bundled rights, what kind of control or guidelines should the agencies assert over the joining of those rights in bundles as concerns complements and substitutes, and how much of each.

When these packages get large enough, as in semiconductors for example, the inquiry as to whether the constituent parts are complements and substitutes is a huge inquiry, much more complex than even, say, in ag biotech.

And I just want to raise that as an unresolved issue, the principles of which I think are clear in the 1995 guidelines and in the agencies' practice as I understand it.

MR. COHEN: Go ahead.

MR. KOVACIC: Just a question that follows on that. If one were formulating an approach for -- that took careful account of whether one's dealing with

complements and substitutes, I take it from your comments that -- and others today -- that it might be very difficult to tell in some instances. And in fact that someone who seems to be the producer of a complement in fact ends up being most likely to be the producer of a substitute because the producer of the complement knows a great deal about what the producer of the principal product, just to use a label, is doing.

Do you have thoughts about how an analysis of the problem ought to try to classify or evaluate whether one is looking at complements or substitutes? Or is this perhaps -- is this an area as suggested by some of yesterday's panelists, where only an extremely deep knowledge of the sector and the industry permits you to correctly identify what you're looking at?

PROFESSOR SCOTCHMER: Well, I can't imagine that there's any substitute for a deep knowledge of the industry. And in fact that's one of the great virtues of how the agencies proceed, you know, an investigation always involves a deep knowledge of the industry.

MR. KOVACIC: Thank you. That's very reassuring.

MR. COHEN: While we have this group of experts assembled, I think if I could turn us back to one point that was raised in the first session and throw it out for

some discussion. I think John Barton suggested briefly that there's a lot that might be done for restriking the balance between first and second generation by some type of work on experimental use or fair use approach which might enable research to be done even if you don't allow the final commercialized product to go forward without honoring the first innovator's rights.

What does the panel think about this? How does this fit in?

PROFESSOR BARTON: I've had my say on it.

PROFESSOR SCOTCHMER: Nevertheless, I defer to my colleague.

PROFESSOR BARTON: I've had my say on it, let's get some other ideas.

MR. COHEN: Any other ideas?

We had a presentation by Professor O'Rourke, who stressed a fair use idea in patent law and felt that that would be a good addition.

No takers on this one?

PROFESSOR HALL: Well --

MR. COHEN: Okay.

PROFESSOR HALL: -- I'm in great sympathy with John's position, I mean, I have to say. It's only that I have been confronted several times with this -- it's difficult to know where -- it's difficult to know where

to draw the boundary, and I don't find myself really understanding how this would work. In principle I get it -- okay? -- but then I think, well, there's the output of that research, and then what kind of ex post licensing are you going to require if it becomes commercially feasible.

It's kind of -- I'm not quite sure where to draw the line and I'm -- I'm assuming that we're going to hear more about this tomorrow morning, I guess. Is tomorrow morning, we're talking about biotechnology and issues like that? Because I think it comes up really strongly in that industry.

Now maybe I provoked you to say something more, because my attitude is I don't know. You know, I'm very sympathetic to the view because I think we've gone a little bit too far --

PROFESSOR TEECE: Yeah.

PROFESSOR HALL: -- in the patenting direction with respect to research. But I don't quite know how to fix it.

PROFESSOR TEECE: Let me come back to one of the key problems that fouls up the market, and that's uncertainty with respect to rights. The minute you put a fair use thing in there it means, okay, somebody's going to determine fair use, which means you've just thrown the

patent into another tailspin because there's uncertainty as to what that means. The minute you create additional uncertainty the incentive of the parties to come together and strike a deal goes down.

I mean, Ken Arrow was saying, "Well, gee, I was working on this blocking patent thing and, you know what, yeah, it was a blocking patent. But do you know what? It settled when I was in the middle of my work." And of course the reason it did was because, you know, if in fact there's a hard position that it's blocking and you've got rational people they can almost always find a way to cut through it.

So I think that whatever you do in this area, if you do something you have to take into account the effects of the policy on the perception of the property right itself. And clarity, once again, clarity is the answer. It's better to get it clear and wrong than to get it unclear and correct.

PROFESSOR BARTON: I'm obviously provoked to respond to a couple of points.

I think first, if we look, take the EST example right now, we don't yet have a clear judicial decision whether or not an EST patent can block the protein for which it codes a part. We're having to have millions of dollars, if not billions of dollars, in investment in the

industry with that issue already being uncertain.

I agree completely with you, having any kind of fair use analog right makes us still more uncertain, but part of the underlying problem here is in fact the technology and the necessity for investment decisions is moving faster than the ability of the litigation system to give us reasonable answers to some of the uncertainties here, and that's simply a fundamental part of the problem.

In response to Bronwyn's point, in some cases I think I can rely on the patent claims. That is, in other words, I take your invention, I tinker around with it under some fair use right, and I produce something new which might be within the claims of your patent, in which case I owe you a royalty, or it might not be within the claims of your patent, in which case I don't owe you a royalty, except perhaps something for the fair use.

Now there is a real problem in here which is, you know, sort of the final point on this, my final point on the issue. What I do about inventions that are really designed for research. I mean, I design a new analytic balance, I don't want you to have the right to use that invention freely, and clearly we have to have some way to cope with that set of questions as part of any kind of fair use concept.

MR. COHEN: Later on we're going to have a couple sessions that move into some of the details of patentability standards. Professor Merges has had to leave early but he'll be available for that one, and I know Professor Scotchmer will be available for the other one. But John Barton I think has written somewhat in this area, talking about issues such as enablement and utility and not-obviousness.

While we have you here, since you are concerned about the breadth of first-generation claims, where in the system do you think we should look if you were to try to design it more optimally, to try to get an optimal result?

PROFESSOR BARTON: Let me try to expand on that, and also use it to make another point.

In terms of the system, I have some combination of research exemptions, fair-use type of arrangement, interpreting utility doctrine more strongly in order to make it harder to get a patent on something very fundamental or something closer to a discovery than to an invention, in a naive sense. I know of course the patent law says whoever discover or invents.

Or, third, I can do something in the order of my non-obviousness standard, presumably to decrease the number of patents, in essence. Say there should be fewer

patents on minor incremental inventions. Although clearly I think a real research to a problem is with the significant invention in the first instance, followed on by minor inventions.

But I want to use that as a springboard for, you know, a sort of one final point to make, and that is, you know, Dave and I are sort of trading debates.

There's two kinds of industries. There's the semiconductor-type of industry where it really is the portfolio that matters. Nobody ever looks to see whether the patent's valid, you only negotiate a kind of a rough-and-ready license arrangement. There is at the other extreme the pharmaceutical industry, where you are very carefully concerned about the precise scope and detail in specific patents. You instruct your scientists to avoid infringement, you carefully negotiate all the licenses you need.

Now clearly the number of patents, which is related to the non-obviousness standard, affects which one of these patterns an industry takes. And it seems to me that there's an important challenge for the economists to say, "Can you tell us when an industry will be in the portfolio style and when it will be in the detailed patent style, and might we not need different antitrust laws for the two kinds of industry." I simply want to

kind of flag that point.

MR. COHEN: Okay. We just have a couple minutes left before our scheduled closing time. I don't want to constrain the panelists, if any of you have anything that you would like to get out on the record which the questioning hasn't been able to get to, feel free. This is a final opportunity.

I think then the thing to do is to thank you all for, you know, just terrific presentations.

I've been asked to announce, for those of you who aren't familiar with the campus and will be coming back for the afternoon session after lunch, that there are two possibilities. One is, there's a cafe directly across the courtyard, I guess on the bottom floor across, and the other is the faculty club, which I'm told is 50 yards to the west of here, and you do not have to be a member to eat there, so that gives you a couple possibilities for your lunch.

We look forward to seeing you in the afternoon.

(Whereupon, at 12:29 p.m., a luncheon recess was taken.)

AFTERNOON SESSION

(2:02 p.m.)

MR. WROBLEWSKI: Good afternoon, and welcome back. My name is Michael Wroblewski and I am Assistant General Counsel at the Federal Trade Commission in Washington.

This afternoon's panel is the first of three panels to obtain business perspectives on the use in the role of patents. Today's session will focus on the biotech industry; tomorrow's panel will examine patents in software and the internet; and the business panel on Thursday will focus on hardware and semiconductor patents.

Each of these panels, each of these business perspective panels will examine how patents and antitrust systems aid or discourage the innovation process in the specific industry that we're examining.

Before we get started I'd like to introduce my co-moderator and my supervisor, Susan DeSanti, Deputy General Counsel of the FTC, as well as Ray Chen from the U.S. PTO, and Sue Majewski from the Department of Justice, who will be joining us as questioners of the panelists.

I would like to cover six or seven topics this afternoon that build on what we heard this morning, as

well as what we heard yesterday afternoon, and then we'll follow with a panel discussion. The six or seven topics include the importance of patents to the innovation in the biotech industry, competition's role in innovation, the quality of biotech patents that are being issued, the impact of the granted patents on the industry, licensing and the use of alliances in the industry, research tools and how research tools are being handled, and finally, if we have time, the tragedy of the anti-commons that we heard mentioned this morning and that we heard yesterday afternoon.

Before delving into any of these topics, I've asked each of the panelists to provide a brief introduction to their company and the issues that face each one of those companies so that we can have a context in which to view the discussion that we're going to have this afternoon.

I'll start first with David Beier. David Beier is a partner in the Washington, D.C., office of Hogan & Hartson, focusing in fields such as biotechnology and pharmaceuticals. In addition, Mr. Beier counsels biotech, pharmaceutical companies and trade associations on bioterrorism, related legal issues including indemnification, antitrust treatment, and intellectual property issues. Before joining Hogan Mr. Beier served

as chief domestic policy advisor to the Vice President of the United States. Mr. Beier is also serving as senior fellow at the Wharton School of the University of Pennsylvania.

Mr. Beier.

MR. BEIER: Michael, I take it you want an introduction just of each person before we...

MR. WROBLEWSKI: Yeah, if you can --

MR. BEIER: Sure.

MR. WROBLEWSKI: And actually introduction of who you're representing today --

MR. BEIER: Sure. Sure.

MR. WROBLEWSKI: -- as well as the issues facing you.

MR. BEIER: Well, thank you for the opportunity to appear before you here today. I'm here representing the Biotechnology Industry Organization which, as you probably know, is a trade association consisting of more than 1,000 members, mostly biotech companies and mostly small biotech companies, universities and others who are interested in the biotechnology world.

Bio represents an industry that has about 1200 members, 1200 companies in the United States that produces about 450,000 direct and indirect jobs in the

United States that has produced 117 products that have been approved for commercial use, and it's an industry that is probably more capital-intensive and more R&D-intensive than any other industry in the world.

MR. WROBLEWSKI: Okay. Thank you.

Next we'll hear from Lee Bendekgey. He's the general counsel for Incyte Genomics, which we understand has the world's largest intellectual property portfolio of genomic information.

As general counsel he has directed the company's patent and licensing strategy. Before joining Incyte Mr. Bendekgey was the Director of Strategic Relations at Silicon Graphics, and a partner at Graham & James, a San Francisco law firm specializing in intellectual property production and licensing.

Mr. Bendekgey.

MR. BENDEKGEY: Hi. Just to make sure, I too am playing by the rules: so aside from identifying the organization you wanted us to describe a little bit about --

MR. WROBLEWSKI: The company --

MR. BENDEKGEY: -- the company and the issues that --

MR. WROBLEWSKI: Sure. Exactly.

MR. BENDEKGEY: Well, as you may have gathered

from the introduction, Incyte Genomics is a genomics company. Traditionally our focus has been on the discovery and characterization of the function of genes and proteins, and more recently antibodies as well.

Historically Incyte's business model has been to sell that information non-exclusively or license it non-exclusively to multiple customers for their use in the development of therapies and diagnostics.

We are a prolific patent applicant, as the introduction indicated, and that's played a critical role in our traditional business, in that having intellectual property rights and information you're selling makes for a potentially more attractive business model than reselling public domain information, or information that's otherwise publicly available. And those have been the primary values that we've been providing to our customers, our intellectual property and novel content information that's not otherwise available to them.

More recently we've announced that we are also going to begin applying some of what we've learned to the development of drugs and diagnostics ourselves.

And in terms of the kind of the issues as we've seen them, in terms of intellectual property and competition that have been sort of predominant for us, I would say the most obvious is that whenever a new

category of technology or innovation comes along, the legal community in particular I think has a tendency to treat it as if it is unlike anything that's ever come before, and deserving of a whole new set of rules.

And in fact in general, while it takes some time, we think that the patent system in general has shown that it accommodates new waves of innovation and new types of innovation quite well if allowed to evolve on its own, and that, you know, historically when we've attempted to adopt industry-specific intellectual property legislation we have done best when we've come up with something that turns out to be an irrelevancy, like the Semiconductor Chip Protection Act.

That said, we have been both the plaintiff and the defendants in patent litigation. We don't think that the patent system as it's currently operating is necessarily perfect. You know, I think most of the issues that people raise when it comes down to particular categories of invention, really in many cases just come down to the quality of examination, whether you're talking about gene patents or whether you're talking about business method patents there are issues with the quality of examination, and I think that is partly -- can be addressed through additional resource allocation to the patent system.

You know, I've had reason, and I'm sure others around the table have had reason to think hard about the incentives that we use for our patent examiners. I've certainly had comments repeated to me to the effect that incentive -- examiners have an incentive to move cases along and dispose of them, and sometimes they think there's something novel here, they're not sure what, and so they're just going to allow it and let things get sorted out in litigation. And I can tell you, when you're at the receiving end of litigation like that it has a decidedly chilling effect on competition.

But I think that we could also -- I think we ought to think hard about taking a page from a private sector company by the name of Bounty Quest, with which some of you may be familiar. We've been on the receiving end of Bounty Quest bounties. This is a company that will accept -- for a $10,000 fee they will post a patent and give a reward to anyone who finds supposedly invalidating prior art.

And that is actually -- I mean, as I said, we've been on the receiving end of that, and it was actually useful information that we got from it. And so I think that we could profitably borrow from Bounty Quest, and borrow actually from other international systems that have opposition proceedings and public

comment proceedings that allow the public to contribute prior art and reasons why someone shouldn't get a patent, or why a claim is too broad that it may be unrealistic to expect the patent office to have access to on its own.

So, you know, we do have some of those issues, but, anyway, that's an overview.

MR. WROBLEWSKI: Okay. Thank you very much.

Next we'll hear from Robert Blackburn. He is a distinguished scholar here at the Berkeley Center for Law and Technology, and he's also Vice President and Chief Patent Counsel of Chiron Corporation. He has been actively involved in the development of legislative and judicial policy affecting biotechnology IP, and he has served as Chairperson of the Intellectual Property Law Committee of the biotechnology industry organization, and also is a board member of the Biotechnology Institute of Public/Private Initiative that aims to educate U.S. PTO personnel.

Mr. Blackburn.

MR. BLACKBURN: Thank you, and thank you for inviting me here today. I just want to -- do you want just an introduction now or the overview of the testimony? I'm...

MR. WROBLEWSKI: Since it's the third time that this question --

MR. BLACKBURN: Yeah --

MR. WROBLEWSKI: -- obviously I wasn't --

(Several persons speaking simultaneously.)

MR. WROBLEWSKI: I actually wanted a background of the company so that people in the audience understood --

MR. BLACKBURN: Right.

MR. WROBLEWSKI: -- what Chiron did and what Incyte did -- Bio's slightly different because it's a trade association -- and then some of the issues that you believe are facing it.

MR. BLACKBURN: All right. Chiron is an unusual -- I'm going to call it a biotechnology company, really a biopharmaceutical diagnostics company is really what we are. The Chiron today is not the Chiron that was founded by two University of California professors in Emeryville just down the road here; the Chiron today is a -- the product of the merger of a number of organizations. That original corporation plus Cetus Corporation, plus Behring Werke Vaccines' business, plus Sclavo Vaccines.

So actually through Behring Werke we go back a hundred years of corporate existence now, including Emile Behring, the first Nobel Price winner in medicine, and in our Cetus incarnation another Nobel Price to Cary Mullis

for PCR. I think we stand in unique distinction of being the only commercial organization with two Nobel prizes coming out of its work.

So our interest in innovation is long and deep, and our business today is composed of a number of business units. We have a biopharmaceutical group, we have -- which is mainly directed to vaccines -- I'm sorry, to cancer treatments and to antibiotics. I should mention that that came through the acquisition of a company of a company called Pathogenesis; we're also one of the few multinational biotech companies.

We have a vaccines business that is based primarily in Germany and Italy. We have a diagnostics or blood screening business which is in large part J.V.-like work relationships with -- one with Johnson & Johnson, not a small company, another with Genprobe, which is a small company.

The -- about 25 percent of our revenue comes from intellectual property directly, so we are keenly aware of the need to protect this and to capture the value that's been created and disseminated through the industry.

MR. WROBLEWSKI: Okay. Thank you very much.

Next we'll hear from David Earp. He is the Vice President of Intellectual Property at Geron

Corporation. He was formerly with the intellectual property law firm of Klarquist, Sparkman, where his practice focused on biotechnology patent law.

Mr. Earp.

MR. EARP: Thank you.

Geron is probably down at the very small end of the scale of biotechnology companies, certainly compared to the other people sitting around the table today who represent other companies. We are a biotechnology company down in Menlo Park of about 120 people. We are a multinational, in that we do also though have an office in Edinburgh, Scotland.

If you've heard of us at all, you've heard of us because of two of the three technologies that we have: the Dolly-the-sheep cloning technology and we also work on human embryonic stem cells. Our third technology platform is around an enzyme called telomerase. Telomerase is the enzyme that adds little bits of DNA on the ends of chromosomes and it's very relevant to determining the life span of cells.

We have four business units arranged around those technology platforms. The two major business units are our regenerative business unit which focuses on making products, therapeutic cellular products from human embryonic stem cells. We have three primary focuses:

We're looking to create dopinergic neurons from human embryonic stem cells for the treatment of Parkinson's Disease. We're also looking to create cardiomyocytes for congestive heart failure, and pancreatic islet cells for the treatment for diabetes.

Our second business unit is our oncology platform. Telomerase is the enzyme that allows cancer cells to escape the cellular clock of mortality and become immortal. We've cloned the telomerase enzyme and we know now that when we turn it off we can make cancer cells mortal again so they senesce and die after a certain number of cell divisions. So we have a number of products that are either inhibiting telomerase or inducing an immune response as a cancer vaccine against telomerase.

Our other two business units are a nuclear transfer business unit, which is simply an out-licensing opportunity through which we're leveraging the value we obtained when we bought the Dolly cloning technology. We've currently licensed that to seven different companies that are using the technology to clone animals for various purposes including agricultural uses and biologics production.

The fourth business unit is what we call research and development technologies, and that's focused

on the use of cells that we can make from human embryonic stem cells in drug discovery. An example of that would be hepatocytes. The pharmaceutical industry struggles a lot with toxicity prediction of new drugs. When they screen drugs for toxicity problems getting reliable sources of hepatocytes that are going to be predictive of toxicology in humans is very troublesome, it's very problematic. Mostly they use hepatocellular carcinoma cells, which liver cancer cells or actually slices of human cadaveric livers to try to predict the toxicology of these drugs. Having a renewable uniform supply of liver cells in which you could determine the toxicity of new drugs will be very useful.

We do not as a company have significant revenues from cells products. We have some product cells but they're research-use-only kits, so they're very small revenue. So we rely very extensively on the capital markets for funding to continue our activities. And we really have two major assets: the scientists and the science that they produce and the intellectual property with which we protect -- through which we protect that innovation.

We are both a licensee of technology and a licensor of technology, so we see things from both sides of the coin.

Issues that affect us on a daily basis that I think that are very relevant today would be patents that we think are troublesome and might in fact be a hindrance to us entering particular product opportunities. We do quite a lot of work internationally in the patent field, and so our experiences are, for example, European opposition procedures shows us that there are perhaps better ways of dealing with patents that really shouldn't have been issues in a system that falls short of the need for full scale litigation.

Other issues that we deal with relate to patentability, what is patentable subject matter. There are significant differences between the U.S. laws and laws of many other countries with regard to what is regarded as patentable subject matter, and when you're dealing with cloning technology, cloned animals, human embryonic stem cells, that's very relevant for us and it certainly affects the way that we think about the competitive positioning of the company in the global marketplace.

MR. WROBLEWSKI: Thank you.

Next we'll hear from Michael Kirschner. He's Vice President for Intellectual Property at Immunex Corporation. Before joining Immunex Mr. Kirschner handled intellectual property litigation and patent

prosecution matters at the law firm of Finnegan, Henderson in Washington, D.C. Mr. Kirschner is an active member of the Association of Corporate Patent Counsel and is on the Board of Directors of the Intellectual Property Owners Association.

Mr. Kirschner.

MR. KIRSCHNER: Thank you for inviting me.

Immunex Corporation was founded in 1981, shortly after the Chakrabarty Supreme Court decision, which I think many view as the establishment of the biotechnology industry. We are dedicated to bringing therapeutic products to treat human diseases and conditions to the market. It took 10 years, until 1991, before we brought our first product to the market, recombinant modified human GMCSF sold under the trade name of Leukine. It took another six years before we brought our second product to market, a new fusion protein called Enbrel, which is used to treat rheumatoid arthritis and now psoriatic arthritis, and is promising in many other inflammatory conditions.

From the time we were founded in 1981 until 1998, except for one or two fluke years, we lost money every year. The people who originally put their money into Immunex did not see a return on their investment really for 17 years, until 1998.

We for a long time were known as Immunex University, because our scientists were dedicated to the proposition of publishing papers and sharing materials with pretty much anybody who would ask, and I think even today we are viewed in the university community, the academic community as being one of the easiest companies from which to gain reagents and materials.

I have noticed that our industry is extremely different, or has many significant differences from the pharmaceutical industry. I was interested in noticing this morning that it always seemed to be pharma/biotech, pharma/biotech. Well, I would suggest that in many ways biotech is situated differently from pharma. I think as the bio testimony points out, is that we are probably more research intensive than the pharma industry. By the nature of what we do, there are a lot more complexities involved and uncertainties involved in the research than in the pharmaceutical industry.

I think, you know, it's a bit of an exaggeration to say this, but I think by in large it's fair to say that the pharmaceutical industry pretty much has a love affair with patents without any ambiguity, whereas I think in the biotechnology industry, from where I sit, it's best described as a love-hate relationship. Certainly the industry would not exist, and our company

would not exist but for the existence of a strong patent system and a predictable ability to obtain and enforce patents.

On the other hand, given the complexity of our industry, we are highly vulnerable to this theory that I think is expressed in shorthand as the tragedy of the anti-commons, being reliant upon and needing to have access to a wide range of technologies to discover, create, manufacture and market a human therapeutic product.

For example on our product Enbrel at one time every vial of Enbrel resulted in royalties to seven companies. That is now down to six. But -- or, not companies only, but entities. But the one patent expired but the patent owner tried hard to get a bill through Congress that would extend that particular patent, which would mean we were still at seven.

And we still have to deal with other people who approach us suggesting that maybe we might want to take a license, thereby adding to our royalty stacking, royalty problem.

Especially painful for us to deal with are patents that are issued in the United States which are issued to the wrong parties, or on a surprising number of occasions patents on an invention, the same invention

issued to multiple parties without the patent office having discovered that there would be the issuance of multiple patents or having declared interferences to resolve that conflict between various parties, or patents that contain overly-broad claims in view of the prior art or the scope of what was enabled or the scope of what was described.

It is my personal view that the PTO's ability to provide a meaningful examination of biotechnology patents right now is in a crises. We've had an increasing number of examples over the last two or three years that examiners are not taking the time to read what they send to us. And on one occasion an examiner admitted to us that they didn't have time to read a response that we had sent back to them before they printed out a response to the response that was not read and sent back to us.

I've talked with examiners who were in the patent office or have left the patent office who are extremely frustrated because they did not have time to do what it was they really enjoyed doing, which was provide a examination based on the substance of the patent application, rather they felt their job had been reduced to looking for ways of finding shortcuts and engaging in those shortcuts in order to get a patent issued.

Brand-new examiners are given a total of 25 hours from beginning to end in which to examine a biotechnology patent; more experienced examiners are given 20 hours. It often takes one of my practitioners 40 or more hours to write this application. During this time they're supposed to read and understand the patent, do a search, provide a thoughtful office action, review our response, provide a thoughtful response, and so on and so forth. It is clearly inadequate given the complexity and difficulty of biotechnology patents to expect an examiner to conduct a meaningful examination of a patent with those time constraints.

There is some concern that the patent office is focusing more on pendency times for patent applications instead of the quality. Increasingly some of these shortcuts are I think making the situation worse. For example, wherein a situation where something called restriction requirements are used routinely in group 1600 to meet the time goals within which applications are to be responded to, and not -- and the patent office is taking a single application and saying that it contains not two, not three, not four different inventions but I'm now getting a restriction requirement that says this application has 120 different inventions in it, or 180 different inventions in it. Clearly it would not be

economical for us to pursue out of a single application 180 new applications, trying to get each different invention that the patent office is saying is contained within that application.

You know, to give away kind of my punch line, it is my view that what we need to do most to cure innovation problems in the United States is to increase the quality of the patents coming out of the biotech group at the patent office primarily by increasing the amount of time the examiners are given to examine these applications.

My suggestion, my personal suggestion is we need to at least figure out a way to double the amount of time each examiner has to examine a biotechnology patent and to provide these examiners with more training and mentoring.

And lastly, I think we need to supplement the work of the patent office now with a vigorous opposition system in the United States, not directly copied from Europe, but taking the best features of a European opposition system and the United States reexamination system so that we are not wholly dependent upon overburdened examiners in the patent office who are doing I believe an heroic job under the circumstances they are currently facing so that we can supplement their work

with that of interested parties in the United States to improve overall the quality of patents so we don't have to rely upon ultimately the choice that we're often given of avoiding an entire area or running the risk of litigation, which is becoming ever riskier given what the Federal Circuit is doing with damages these days.

MR. WROBLEWSKI: Okay. Thank you.

And finally we'll hear from Ross Oehler. He's Vice President for U.S. Patent Operations at Aventis Pharmaceuticals, a research-based global pharmaceutical company. He manages their U.S., U.K., and Japan patent functions, as well as the patent function at Gencell, the Gene Therapy Division of Aventis. Mr. Oehler is responsible for providing patent and trademark prosecution, counseling and studies and litigation management services, as well as licensing support services.

Mr. Oehler.

MR. OEHLER: Good afternoon. Thank you for inviting me.

In some respects I'm an odd man out, but in many respects the concerns that we as a company have are very much in line with some of the concerns we have already heard this afternoon.

Aventis is in some respects a new company,

being the result of a merger between Hoechst, Marion, Roussel and Rhone-Poulenc Rorer in late 1999. Traveling back in time though, we do head back over a hundred years in the legacy companies. We are, as Michael pointed out, a research-intensive company, spending in excess of $2.5 billion a year in research and development efforts.

We concentrate in the areas of respiratory and rheumatoid arthritis, central nervous system, CNS, oncology, cardiovascular metabolism, to name a few.

We're located in several countries. While we do have offices in -- and scientists in Japan and the U.K., our main research sites are in the United States, back in New Jersey, France, just outside of Paris, and in Germany, just outside of Frankfurt.

We are involved, as I mentioned, focusing in those therapeutic areas and we sell today everything from Maalox to Allegra for respiratory allergic issues. So we're in many areas in the pharmaceutical area, but we're also, as pointed out, in the genomics business, both internally and through many collaborations. And we also are involved with gene therapy in the form of Gencell in particular.

We have many of the same issues that we've heard this morning, rather this afternoon, and many of those from our perspective are, while we do an awful lot

of research and development, we bring in an awful lot from the biotech industry. So many of the people seated here at the table have agreements with Aventis, and we are constantly looking for new technologies, not just from within but also from the outside in biotechnology.

Accordingly, we spend an awful lot of time in the patent group in particular looking at issues such as patent coverage, patent validity, freedom to operate, infringement and litigation. So we have concerns that cross all of those areas. And again, I would agree with many of the issues that were raised, not necessarily all the solutions perhaps, but many of the issues.

MR. WROBLEWSKI: Okay. Thank you very much.

Some ground rules before we start the discussion. I will try to guide the conversation along, and if any of the panelists would like to add something please just turn your name tent on its side and then I will be able to recognize you.

Before we get started really with all of the topics that I laid out in the beginning that we'd like to talk about, I was hoping one of the panelists, just for the clarity of the record, could flesh out what is involved in developing a biotech product, in terms of how long does it take, how much does it cost, just so that we have this on the record and a common understanding going

forward.

And then I'm going to ask Ross to contrast that to how we develop a pharmaceutical product or a small-molecule product.

So starting with the biotech side, David would you like to go?

MR. BEIER: Sure. And I'm sorry, I didn't understand your instructions the first time through.

MR. WROBLEWSKI: That's okay, I wanted you to be the cleanup man anyway.

MR. BEIER: Okay. I'm not sure that there really is fundamental difference, other than that pharmaceutical products historically have been small molecules taken by mouth and absorbed through the digestive system, and biotech products for the most part are large molecules that are either injected or inhaled. Obviously biotech products are more complicated.

But the fundamental point, which is that if the 20th century was the era of physics and astronomy, or the era of the automobile, the 21st century is going to be the era of life sciences. And the cost and risk associated with producing a new product is so different in these two industry sectors that it's beyond any comprehension of any of the panelists this morning, who merged semiconductors and biotechnology as if they were

fungible parts of fruits and vegetables. It's just not true.

The best and most accurate research in terms of developing a new product, the work done at Tufts suggests that the average cost of developing a new pharmaceutical agent is $802 million, using year 2000 numbers. That obviously includes the costs of failed products and the time value of money, or the opportunity costs associated with investing in year one when the product's going to come out in year 10 or 12.

The risk associated with developing a new product is either on the range of -- one estimate is 10,000 chemicals produce a hundred targets, which produce 10 products that go into the clinic, three of which make money. So you've got a filtration system where the risk is phenomenal from the point of discovery or even identifying a target.

So I think one of the things that I'd like to get across, at least on behalf of the biotechnology industry, is that there is a huge difference between electronics and life sciences.

If you go back to the work done by Professor Mansfield and Professor Scherer, going back to 1959, and you up date it with Josh Lerner's work up to and including 1999, if you do a scale of one to 10 on the

importance of patents to an industry for pharmaceuticals, biotechnology and to some extent agricultural biotechnology, it's six or seven, and for electronics it's one. And so you should not assume that you can easily make these analogies that some of my academic friends have suggested from this morning.

MR. WROBLEWSKI: Okay. Thank you.

Mr. Blackburn.

MR. BLACKBURN: Thank you. I just want to add to what David said, and maybe give a slightly different spin on how to look at this.

I'm not -- I don't think it's helpful to really divide biotech and pharmaceuticals that much anymore. There is an end point, there's a product that is a -- it's a drug, and that drug could be a small molecule or it could be a protein or it could be an antibody. All right? So we can divide it into small molecules and biologics. A company like Chiron does both. And the small molecule-type research today, which is the traditional pharmaceutical industry product, is done with biotech tools and recently proteins and genomic sequences are used in developing them in a much more efficient way. So I think you see both ends of what the industry, the two industries look like 10, 15 years ago, they're converging in the middle here.

And also what sort of fits in a little bit with what the panel this morning was talking about, there's actually a division of labor in many instances, where there are research tool companies and companies that take it to the next step, and then partners who have the money to pay for clinical trials, et cetera. So you can find examples of all of those. The two industries really blend together in that sense.

And I can think of an example now where we're going, I know of a pre-IPO company, it's been in existence for three years, has a research tool technology base and they have a small molecule in phase two clinical trials. All are now under one roof in a pre-IPO startup.

So where we are today is quite different than I think the classic way the industry was 10, 15 years ago.

MR. WROBLEWSKI: Okay, thank you.

David Earp.

MR. EARP: Yes, just a quick comment on what Bob was saying.

I entirely agree with the merger of biotech and the pharmaceutical industry, but I think one of the things that we're tending to see now is a trend within the life sciences is it's almost like a food chain, the biotech companies that do a lot of the fundamental research simply cannot afford, because of the costs of

developing a drug all the way to market, to do it by themselves.

So in most instances you will see a biotechnology company doing the fundamental research, and then partnering with a pharmaceutical company, or perhaps being acquired by a pharmaceutical company which will take the product through to commercialization.

There are certainly biotechnology companies that are of much larger size, and perhaps Chiron might be an example of that, and you might think of Genentech or Amgen, that border on the size of pharmaceutical, of traditional pharmaceutical companies that have the sorts of financial assets to be able to develop products and take them all the way through to commercialization. But most, what you think of today as, you know, classic biotechnology companies don't have that ability, and so there is sort of a progression through the industry of many biotech companies doing basic research and then merging, partnering, collaborating with pharmaceutical partners to realize the commercial product.

MR. WROBLEWSKI: Okay. Thank you.

Ross, do you have anything to add? And then I'm going to go on into the importance of --

MR. OEHLER: Well, we have one more point here --

MR. WROBLEWSKI: Okay.

MR. OEHLER: -- perhaps before we...

MR. WROBLEWSKI: Okay.

MR. KIRSCHNER: I wanted to come back, and I agree that nowadays pharmaceutical companies are more likely to have involved in biotech, and biotech companies more likely to be involved in small molecule work.

I think the point I was trying to make, and perhaps unsuccessfully earlier, that a biotechnology product is far more vulnerable to third-party patents than is a small molecule, in addition to the underlying economics which make a traditional small molecule far more profitable than a traditional biotechnology product.

MR. WROBLEWSKI: Okay.

MR. OEHLER: You know, on that last point, I tend to agree with Michael. But having lived through it many times, and I expect to live through it many times more, small molecules tend to be vulnerable to third-party patents as well.

We simply deal with freedom to operate all the time, and one reason for that is because we don't know what our colleagues up the road are doing in their laboratories until their patents come out. We live with a now shortened blackout period because of the publication after 18 months, which we typically I think

at this table all participate in now. But 18 months can seem like an eternity when you're caught in the middle of it trying to answer "am I free to operate." So whether it's a biologic or small molecule, I think we both have that.

But I do fully understand the point, particularly in the biotech industry. I think given the age of the industry relative to the more chemical-based pharmaceutical industry, that can be expected. But I think both are vulnerable.

I think it's true to say that the large pharmaceuticals aspire to be small biotech, and the small biotechs aspire to be large pharmaceuticals. And we look to one another I think for ways to achieve that, either through collaboration, through acquisition, through partnering of some sort. So I agree with those comments completely. But I think it's also fair to say that there really aren't a great number of differences.

I will point out that the cost of coming to market with a biologic or a small molecule is very high. We heard the number 802, I'd like to know where the two came from, but I've very often heard in the range of 800 million. I think it's nearly impossible to calculate it because of some of the factors that were pointed out, it's a very complex calculation. But it's a lot of

money.

And so much so that even the large pharmaceuticals don't act alone all the time. There are many instances of co-promotion, co-marketing between two very large pharmaceutical companies with tens of billions of dollars each in sales. It still requires a huge investment in dollars, in terms of dollars, in terms of manpower and the risks associated with it. So even large pharma turn to one another for that type of partnering.

MR. WROBLEWSKI: Thank you.

We heard this morning a lot about the role or the potential role that patent protection plays in simulating innovation, and I'd like just to kind of explore that a little bit more in terms of how does patent protection play in stimulating innovation in the biotech industry.

One of the things that I found interesting this morning, I don't remember who exactly said it, but said that most of the new entry comes from smaller firms, and that the size of the firm, in terms of innovation, doesn't really matter anymore.

And I was just wondering what people's reaction was to those comments from this morning, in terms of what role does patent protection play, where is the innovation coming from, is it from small firms or larger firms, and

how does that patent protection play into those two areas.

Lee, I see you nodding your head so I'm going to call on you first.

MR. BENDEKGEY: Well, you know, I certainly would not get into trying to isolate the, you know, one sector where innovation is taking place. There's lots of innovation going on in a lot of places.

I think in terms of the role that patents are playing right now in innovation, you know, there's two or three things that occur to me.

One is that, you know, all you need to do is look at what happened to the biotech sector in the two days after the Clinton-Blair announcement, which was interpreted as some general pronouncement on gene patents, and I think the whole sector lost about half of its value in two days.

And it's hardly surprising. I mean, David's description of Geron is not unique in this sector, in that most companies would say that their -- you know, that their principal assets are their science and their intellectual property.

So clearly it plays a very important role in capital formation which, in turn, plays an important role in research as we've heard. And I don't know what the

latest statistics are, but, you know, a couple of years ago the story was that the biotech sector spent between 45 and 50 percent of all of its revenues on research and development. You can't keep that up for long without accessing the capital markets.

The other thing that -- the other things that I would say in terms of the role of a patent system and encouraging innovation are twofold.

One is that the patent system itself, as we've heard, you know, people talking about the 18-month publication and possible oppositions, the patent system inherently promotes disclosure, which encourages innovation. And in fact if you look at Incyte's original database agreements back in the 1994 time frame, at that time the company relied almost exclusively on trade secret protection because the patent landscape was very uncertain, so you had this very lengthy, essentially glorified confidentiality agreement, was what the database agreement was.

And the transaction costs associated with doing something like that versus a transaction involving inventions that are patented where the content is already known are very different.

So, you know, we now do licensing on the internet at Incyte, which we wouldn't have done in the

day when we only had to rely on trade secrets.

So, and I guess the last thing I would say, kind of to -- and I know we've been cautioned about making analogies to other sectors -- but I think some of the -- the last comment I'd make about the role of intellectual property, and you can think about it also in some of David's comments and some of Bob's comments about various of Chiron's businesses, as well as the Aventis description, is in some ways what the biotech industry is, is an outsourcing supplier for pharmaceutical research.

There aren't that many companies that are like Chiron and Amgen and Genentech that are fully integrated. Most of the biotech sector -- and so what you can see, if you look at the pharmaceutical industry over the last several years, is gradually most of the functions have been outsourced to a greater extent to entities that provide comparable services to multiple people, whether it's starting with patient management, manufacturing, distribution, clinical research organizations now through the clinical development process, and then you have the biotechnology industry is kind of the outsource or the supplier both of tools and sometimes, you know, often are product candidates to the pharmaceutical industry.

And I would say that when -- what you were

selling is some piece of the product or something that will be used to develop the product somewhere along the way, having the potential of getting intellectual property that will enhance your returns on the sale of that product becomes more critical. If you're fully integrated, like, you know, as was the old model in pharmaceutical companies, you'd actually just as soon not have any IP on anything other than the final drug that's sold.

And so I think we're seeing an evolution in the structure of the market. Which actually, if you think about it, is not unlike the evolution of the computer industry. You know, 10 years ago you had, you know, one company making the microprocessor, the operating system, building the box, selling the box, servicing the box. That obviously has changed to the vast benefit of consumers.

And I think, getting back to my final comment, is, you know, there's a lot of innovation going on everywhere, but we think that genomics, when it succeeds on its promise of providing a reasonably comprehensive understanding of biology, ought to remove a lot of the risk associated with developing and prescribing therapeutics.

And so in terms of the how fundamental the

innovation is and what it could mean ultimately to what's available to consumers, how safe it is and at what price, we think it's pretty dramatic.

MR. WROBLEWSKI: Okay. Thank you.

Mr. Blackburn.

MR. BLACKBURN: On the issue of innovations and its role in market entry, I think the research tool area is a very important topic to understand.

And you had asked me before if I could say a little bit about what is a research tool --

MS. DESANTI: Yes, thank you.

MR. BLACKBURN: -- so everybody would understand.

I think we could all come up with a slightly different definition of research tool. My operative definition is it's technology that's used to find, refine or otherwise design and identify something else that will be sold in the marketplace, the final drug. It is not a patent that covers the final product that is the subject of ongoing manufacture and sale.

Classic examples of research tools are targets, that is like receptors on a cell where drug -- you hope a drug will act, combinatorial libraries from which drugs will be fished out of, high-throughput screening technologies, array, micro-array-type technologies,

genomic databases, modeling programs, et cetera, they go on.

And I want to also, in the context of this I want to address something that Suzanne Scotchmer discussed this morning on the Kitch work. She pointed out that the conclusion of that paper was that there was efficiency in resolving the -- that licensing dilemma, but it was private efficiency and not social, necessarily social efficiency.

And I think that goes across the board if a patent is involved. A patent is a distortion of one efficiency for the other, and certainly in every instance and what we really have to look at is that over time is there social efficiency for that distortion. And I think the answer clearly is "yes" when you look at something like research tools because they are enabling technology that allow market entry.

I mentioned earlier about the example of a very small pre-IPO firm that has moved into a phase two product in there years based on research tool technology. That was inconceivable to have happened 20 years ago, before the invention of research tools.

If you look at the $802 million that is spent in product development, the vast majority of that time and money is in the clinical trial portion, and at the

far end of that, it's increasing as you go from phase one to phase two to phase three.

In the front end the discovery and the -- in today's world the investment has gone down considerably that's required to do that front-end research because of research costs.

How would you do it classically, when it was only small molecules and you just had to find a small molecule? You hired a thousand chemists to make lots of compounds one at a time and stick them in an animal model or some sort of biological screen to see if they did anything. That was the approach. Now it's much more systematic, much more perfect.

Where you run into problems today is you have so many leads how do you sort them out, where do you prioritize what you take into the clinic.

So there's been a -- this technology has been extremely powerful, and I think is responsible for more products being in the clinic today than we could have conceived of 25 years ago.

Now, and it's research tool technology that has permitted that and, therefore, in my mind it's pretty straightforward, if there's anything you want to protect and incent with patents it's the research tool technology.

Now what if you don't protect that research tool technology? I don't think you'll get the next generation of tools. And this is extremely important because we're still talking -- the expensive part of the process is still out there.

We now have people who are working on -- small startups who are working on research tools that will address the toxicology side of drug development, maybe shorten it by six months and several million dollars. That's a little increment, but that's marching down that development pathway.

We will never see the investment in all of these research tools. To my knowledge, of the significant research tools that have really made a difference, have all come as a result of venture capital investment that was premised on patent protection, and have been acquired by larger corporations. And speaking for Chiron, I think we are a net buyer of these tools. We won't get that next, that second and third and fourth generation company coming in and trying to work on this high cost of drugs.

Now the -- even if you look at the licensing issue again for research tools, there sometimes can be I think a disconnect in -- as we see in the panel this morning, there's the assumption that, well, if you -- the

patentee will do an exclusive deal. In our experience that's not how we have handled it.

A research tool that we've owned of significant importance, we did the analysis and it -- where it's a target, it's a target for an important disease. Why would we exclusively license that?

We cannot pick out the company that has in their combinatorial libraries the best compound or the efficacious compound to do this. Our incentive is that there be a product and a good product on the market, because that's -- with designs like research royalties, that's what incents us to make sure that the license gets into the right hands. And when you cannot predict ahead of time the incentive is there to broadly license.

Now I think there are examples of tool owners who have done exclusive deals, and I think there are probably examples of tools that maybe are appropriately exclusively licensed.

If you look in the area of cancer, we have a cancer genomics program, and we've pretty much slowed it down because we've gotten more cancer targets than anybody can possibly work on. There are -- it is a buyer's market for potential genomic cancer targets. So you may not want to do it, you may not get anybody even to take a license unless you can offer it to them

exclusively.

But, you know, that's a -- it's going to be very difficult I think for you folks to shape a policy that can distinguish between those instances and those where they are broadly -- should be broadly licensed.

As long as the right incentives are there that the patentee can actually profit from the downstream exploitation of the tool, I think that's the best way to drive the broad dissemination of these tools and bring in new market entries.

MR. WROBLEWSKI: Okay, thank you.

David Beier, you wanted to add something to the role of patents and innovation.

MR. BEIER: I want to answer your question.

MR. WROBLEWSKI: Okay.

MR. BEIER: And I'll try to do it succinctly, three facts and one observation.

The biotechnology industry, 70 percent of the industry is less than 15 years old, only 30 percent of the industry is publicly traded. I think you can make a rough approximation, it's many, many small companies, most of whom do not yet show a profit.

Individually patents are hugely important. The testimony, we cite work by Professor Lerner, suggesting that the average biotech patent's worth somewhere between

$9 million and $14 million. He's attempted to quantify that.

The observation, in terms of the importance of intellectual property in the industry, and I think Lee talked about this, the industry in the year 2000 had revenues of about $22-23 million and spent about 10.7 billion in R&D, so it is a hugely research-intensive operation, with the hope that they're going to produce a patent.

While I agree both with Lee and Bob about the potential of genomics and research tools, it would be wrong I think if the government agencies who are here assumed that somehow the cost of drug development or the cost of products as a result is going to go down. In an era of personalized medicine you are more likely to have a targeted product for a smaller patient population and the clinical trial designs at the end may not fundamentally change, the cost of development in constant dollars could remain very high and the price could actually go up if you have a smaller patient population.

But the tradeoff is you're going to have a product that is targeted and really effective, that doesn't produce adverse reactions, that increases its efficacy.

So as you think about trying to calibrate the

perfect patent scope, perfect quality, perfect licensing regime, you have to I think avoid the problem of making the perfect the enemy of the good. And in the view of Bio we have a good patent system now, that doesn't mean it can't be improved, but the sky has not fallen.

MR. WROBLEWSKI: Okay, thank you.

Lee, you had a comment --

MR. BENDEKGEY: Occasionally an anecdote is useful perhaps, and I was reflecting on Bob's comment about exclusive versus nonexclusive licensing.

Following up on my earlier comment, if you think in terms of this question of research tools, you look at Bob's definition and on one end a research tool could be a computer, his definition fully comprehends a computer, but when people start talking about research tools in the context of patents somehow I think they're not thinking about that.

At the other end of the spectrum a research tool could include, as Bob said, a target. And as these technologies and the knowledge advances, it certainly is now the case that if you have a certain category of genes that you know to be secreted on a cell surface and you have a highly-specific disease association for that gene, you don't need to know any more, you can develop a therapeutic antibody, you will develop a therapeutic

antibody to that gene.

So all of the invention really -- or I shouldn't say all, but a huge percentage of the invention is associated with the discovery of the target in that particular case, not going from target to therapy.

So this idea that we put everything in a research tool bucket, and that once it's in that bucket it is somehow deserving of some kind of different status, whether higher or lower, strikes me as misguided. And I think a lot of people agree with that, which is when they in turn that shift and say, "Okay, well the problem is not with the patents, the problem is with how people license them," and people might do exclusive licensing.

Well, in Incyte's case, actually Incyte's success is in large -- I shouldn't say this too publicly, but there are many people who believe that Incyte's success is in large measure a function of the fact that in, I believe it was 1995 or 1996, Human Genome Sciences, which was then an Incyte competitor in selling -- in the database business, did an exclusive deal with SmithKline Beecham, and gave SmithKline Beecham exclusive access to the database with limited rights to sublicense. But basically they gave it a five-year, six-year exclusive deal to SKB.

The consequence, the immediate consequence of

that deal was that every other big pharmaceutical called Incyte and asked if they could get a nonexclusive access to Incyte's database.

And one of the reasons was they were worried they were going to get left behind. And from Incyte's standpoint it's sort of the same analysis of if you're in the business of selling the database having one customer is not a real business. And so if you're trying to build a real business of course what you're going to do in the research tool context is nonexclusive. Because you want to sell the same thing to multiple people, that's the only way that economics are going to make sense.

MR. WROBLEWSKI: Okay. Thank you.

David, you had something you wanted to add.

MR. EARP: Yeah. I'd like to push the area of research tools a little further into reach-through royalties, because that's what Bob was really talking about, leveraging the value of research tools by collecting revenues based on royalties of the product that is actually sold, the product that is discovered using the research tool.

Some of these research tools can be very far removed from the final product. I mean, in Lee's example, the computer that you use to analyze the database versus the actual target that you're screening

against to find the product.

As a licensee and a licensor of technologies I come across many instances of companies that are trying to license research tools with these reach-through royalties, and I think it raises some interesting questions that there is really no clear legal analysis at the moment, or certainly no clear guidance for companies to think through.

The crux of the problem is the licensing company is demanding royalties on the sale of a product that is not covered by their patent. Clearly we have antitrust, potentially patent misuse issues here.

I've looked at license agreements that have been offered to my company on a number of occasions with those sorts of issues in them, and I've scratched my head, and I've gone to the FTC and the DOJ guidelines on licensing and I've tried to find some guidance there and I've been relatively unsuccessful.

I have read the case law on patent misuse, and there's some very clear case law out there, the 1969 Hazeltine case, Zenith Radio, talking about patent misuse and the conditioning of a license on the payment of royalties on a product that is sold that isn't covered by the licensor's patent -- I'm sorry, the -- yeah, the licensor's patent.

So I have struggled with this, it's exorcised me, and when I talked to antitrust counsel and asked for opinions on this they talk about rule-of-reason analysis and market power. But when we're talking about biotech companies where there is as yet no product and we get into them, the incredibly vexing problem of innovation markets and technology markets, it's very difficult problem for biotech companies to try to figure out a clear answer to this.

It's made even more difficult by the fact that when you're getting into licensing arrangements at an early stage of development. You may well be in a situation today as a small biotech company, even if you go with the innovation market, there is no market power involved. There's certainly no product. There may well be no market power involved, and you can enter into a license agreement that even your most conservative outside counsel will say, "You know, looks actually pretty okay."

Ten years down the road though, if you're successful, if your product and your technology become very successful, you do now have marketing power, you do now have market power, that license agreement gets scrutinized at that time, the outcome might be very different.

And I struggle with -- and of course the analysis of whether there is an antitrust issue, and potentially maybe the patent misuse issue, although I think there's a very different jurisprudence behind patent misuse and I don't -- I think it's a mistake to put the two of them together, as you've seen many times.

But the problem with market power changing, the problem with these reach-through royalties I think is an area where I would like to see more guidance on, for more practical guidance for biotech companies.

MS. DESANTI: Let me ask a follow-up question. Do you have an idea of what you think the answer should be?

It's certainly something that the antitrust agencies have wrestled with from time to time, the fact that you can look at an agreement at one point in time, and under a rule-of-reason analysis there's not a competitive problem. Well, competitive circumstances change and, therefore, you can have a 10-year-later situation. As you point out, the competitive circumstances are different, therefore the competitive analysis is different.

That's a very difficult problem for us to deal with at the front end, not knowing any more than you do, how the competitive circumstances are going to change.

And I'm just wondering if you have practical insight from your business perspective into what would make sense, what's feasible.

One idea that's been raised from time to time is the notion that you put into the agreement itself something that says "of course we will re-examine this agreement if competitive circumstances change," and it may be that one party to the agreement or the other has market power, or something more artfully framed than that.

But I'd be interested to know what's your -- from a business perspective what would make sense to you?

MR. EARP: The very simplistic answer as what would make sense is to tell me what I can do. So --

MS. DESANTI: You don't care what the answer is.

MR. EARP: So, well, there are going to be people around this table who care very much one way or another. For a small company like mine, where we're involved on both ends of this, you know, I don't have an opinion as to what the preferable -- I mean, you could say, "Well, you go back and you look at the analysis at -- you know, you do the analysis when the agreement was signed," I don't think that's an appropriate answer.

Clear guidance is what I would like.

I have seen agreements and worked on agreements that do contemplate the future modification of the agreement as might be necessary. Those sorts of agreements are difficult to negotiate because they clearly are open-ended so you're having an agreement between two parties that says "if things change we'll talk about this." Well, you know, that's always the case with any contract, isn't it? I mean, look at the State of California and it's energy contracts today. It's always the case with any deal that companies get into.

The problem is where you have a deal that's locked in place and you have now one of the entities potentially facing antitrust problems as a result of it. If the party that got the better end of the deal on day one isn't interested in renegotiating along those lines, then that's not going to be a solution, and having a meeting of the minds later on is going to be problematic.

I also though would like to just, back to you again, the issue and the conflict between patent misuse and antitrust and licensing, because I think there is a lot of uncertainty there.

And there are very clear circumstances in my mind that constitute clear, I think, black-letter patent misuse which when you look at them from an antitrust perspective, particularly under a rule-of-reason

analysis, might absolutely pass muster.

So I would also like to see not necessarily harmonization of patent misuse in the antitrust and the licensing arena, because I do think there are different bodies of law, but I would like to see a little more consistency in the results of the outcomes.

MR. WROBLEWSKI: Bob, did you have something you wanted to add on the --

MR. BLACKBURN: Yes. Well, I think I can address Susan's question directly, about what we would like to see practically happen with these type of royalties or these licensing arrangements.

I think we'd like to see in the world affirmation that it's okay to do reach-through royalties, and it's okay to do them in a nonexclusive way, and perhaps that there is an option to either have a fully paid-up royalty or a reach-through royalty.

And the reason is if you -- if reach-through royalties are not available that means the cost of licensing tools initially goes up, goes up significantly.

Reach-through royalties are a way to lower the up-front costs for the smaller firms and to have a risk-sharing arrangement basically with the tool owner but whether if the -- anything useful comes out of the tool. It means that firms can license-in many more tools. And

the only way that, you know, sort of mid-size biopharmaceutical companies or small biopharmaceutical companies are going to hope to catch up to the Mercks and the Glaxo SmithKline's of the world is that it's through the access to tool technology, and reach-throughs facilitate that greatly.

MR. WROBLEWSKI: Okay. Thank you.

David, did you have something you wanted to add?

MR. BEIER: Just a quick footnote.

You might ask the folks at the National Institutes of Health about their research tool licensing program. My colleague --

MR. WROBLEWSKI: I see Ted Roumel is back there, yeah.

MR. BEIER: -- is back there. At least they have attempted to articulate what the appropriate role is with a government-funded research tool. But I agree with Bob's observation in general.

And with respect to David's comment about attempting to reconcile misuse with antitrust law, in a previous incarnation I spent 10 years on Capitol Hill and attempted to do that, and failed miserably because no one can agree what current law is, let alone try to codify it.

MR. WROBLEWSKI: Thank you.

Ross, did you have something to add on this point?

MR. OEHLER: Yeah, David, I'm glad you pointed out the NIH guidelines, and I think that makes sense to look at some of that groundwork.

I'm not sure that I agree with what I've heard on some of the likely direction of reach-through royalties, and I think some of that is because I'm kind of troubled with some of the premisses behind that.

We've heard over the last half hour or 45 minutes about the role of research tools in reducing costs and reducing time. But I would suggest that we don't quite have those answers yet, that we're not really there yet.

There has been a reduction in time. If you go back 15 years or so -- in fact I would commend the current issue of Script magazine that kind of looks at this carefully -- if you go back you can see that early, the early phase of the work has sped up, but the latter part of the work has not. Not only has that time not caught up, but the risks associated with the fallout of compounds through trials is still quite high, so the costs aren't necessarily saved the way we would like to see it yet. There's great promise there and the hope is,

and expectation is, that that in fact will reduce time and costs further but we're not there yet.

And I would suggest that until we're there we don't necessarily know what type of royalty schemes are necessary.

Lee pointed out earlier that, you know, you go back into the early '90s and there were different ways of doing business in the biotech as a licensor than there are today. There's more thought about pooling for example, there's a more open structure to many of the license deals.

Reach-through royalties are a very real issue I think for large pharmaceutical in particular when they're on the receiving end of the license. Clearly, from a monetary point of view that shouldn't be a surprise.

I also think it's somewhat flawed to suggest that risk should be shared. I'm not sure that the risk is truly shared when you're talking about a tool versus the product itself. The tool may prove itself quite early; the product may fall out yet at the end of the clinical trial. So the risk is still back-loaded at the most expensive phase of the research and development time line, and I don't know that that's a true sharing of the risk.

So for those reasons I think that to conclude

from those premisses that a reach-through royalty is a good idea, I think it's flawed.

MR. WROBLEWSKI: Thank you.

One last comment, then I want to change gears.

MR. BLACKBURN: Okay. Ross makes some interesting points on the risk sharing in particular, and I think that really reduces to a price negotiation, how much does the tool owner profit from the successful development of a product. So that allocation of risk I think is taken care of in the pricing.

So, you know, and on the other hand I think it's rather unfortunate that we have a system where, a patent system doesn't recognize I think fully that back-loaded investment.

And let me give you an example of where the patent system is a complete failure. And that is if somebody brought you a -- table salt today and said, "You know, I think this can actually," if it's given in the right way, "control hypertension." You can't get a patent on table salt, and nobody's going to do the back-ended investment in that clinical trial to prove it.

You know, in my mind we've had an intellectual property regime developed for it for drugs where the market isn't large enough to provide the incentive for it, it's completely independent of patentability, and

it's fair to say that there could be a -- some sort of an award for that risk of investment as well, separate and apart from the patent system.

MR. WROBLEWSKI: Okay. Thank you.

I'd like to switch gears just a little bit. You know, we started out this conversation with what role did -- do patents play in the innovation process, and I'd like to switch gears. One of the things that we really examined yesterday afternoon in the introductory session was what role does competition play in the innovation process. And I'd like to turn it over really to anybody who would like to start, in terms of, you know, what role does competition play.

We heard a lot, I guess it was yesterday afternoon and then this morning, about that there was the race -- there's a new model in these new kind of high tech industries, in which there's a race to become the monopolist, and so I'm interested to see how that plays out in the biotech industry. If anyone would like to start with that? David Beier.

MR. BEIER: Well, let me try and answer the question by referring to the questions you raised in your notice for the hearings. You raised a question in the notice about mergers and merger conditions and let me try and address that, because it's in our testimony.

At least a couple of times the Federal Trade Commission, both in 1990 and in subsequent mergers, conceived of the idea of an innovation market and imposed conditions. And I think, as the testimony points out, that conclusion is speculative. It's unclear what the market is when you have no marketed product and you're basically dealing with naked intellectual property.

And care should be exercised when the potential economic efficiencies, as a result of a merger, could actually produce a product. The example that I think is cited in the testimony is gene therapy, where you all required a certain level of licensing when there was no market for gene therapy, and I dare say there's no market today for gene therapy for a variety of reasons associated with intellectual property.

So one concrete suggestion that Bio has that could conceivably improve the precision of the antitrust agencies' examination of these merger questions in innovation markets is a retrospective review of the previous licensing obligations you imposed on companies. That's without prejudice as to whether they were good or bad, and it's not commenting on any of the individual mergers, but rather it's an area where you all have staked out a position that there is such a thing as an innovation market and that there should be some testing

of that hypothesis over time.

The other question that is implicit in your inquiry, Michael, is whether the antitrust agencies have materially improved the ability of companies to compete by issuing relatively clear guidelines. I think on behalf of Bio, the 1995 guidelines, were a material improvement over previously rigid and, frankly in some cases, irrational rules. So the existence of those guidelines and this relative certainty that was associated with their evolution and promulgation has actually been a positive thing.

And then the last point on competition. You raised in your inquiry questions about patent term, and I would actually offer the following hypothesis: that the Hatch-Waxman Act and the essentially balance that Congress achieved in 1984 achieved a level of competition that's unheard of in Europe or elsewhere by creating the generic drug industry as an offset to the brand-name industry, and in partial compensation gave partial patent term extension to pharmaceutical and biotech products. But that competition could actually be enhanced if that patent term restoration was made full and complete so that you got day-for-day extension of the terms that you go through in terms of clinical trial development.

MR. WROBLEWSKI: Okay. Thank you.

MR. OEHLER: No. You've raised a lot of good points, particularly the last. I think it's -- you should not lose sight of the fact that in many instances patents aren't enough. They're either not long enough in term or their terms have been essentially shortened due to the regulatory period of review that's involved, and simply the length of time that's involved in our industries. And so we, you know, we often turn to the market exclusivity granted by the FDA. And so, you know, patents aren't always enough.

But I'm a little puzzled by your -- in your questioning you said, you know, there seems -- there's a rush, and without the benefit of this morning's testimony, but there's a rush to become a monopolist. And I wonder if there's a difference. Isn't there a rush to become the first to patent a particular innovation or invention? Isn't that the very point? So I'm wondering where you're going with that question; perhaps --

MR. WROBLEWSKI: Sure. No, the model that they posited yesterday afternoon was, I think it was Professor Arrow talked about how it would be a race to become the monopolist and then technological improvements and developments would then supersede that, so there would be a sequential number of monopolies. And that was actually what was driving the innovation, was the ability to

become that.

And it was especially important, and maybe he may have been talking about more in network industries, but wanted to bring that out, or bring that topic up for discussion here to be able to differentiate those industries, and that was the concept that he was going for --

MR. OEHLER: Well, I, for what it's worth, I would suggest that it's the point of the patent system that innovations are rewarded with that monopoly period in the firm of a letters patent. And of course there's always a rush to that, to be the first to invent in this country, and that it does not necessarily exclude others from coming in.

We live in a multi-layered or multi-patented area that there's -- we're not as in depth perhaps as the computer industry. I recall a seminar within the last year where they described opening up the box that they made, the computer, and they had flags inside representing the number of patents, and they were color-coded for what was theirs and what was not theirs, and there were hundreds of flags inside of this box and most of them were not theirs.

So, you know, it's not as multi-layered as that, but there are very often many layers of patents

that go behind either a product or the means to get to that product.

MR. WROBLEWSKI: Okay, thank you.

Lee.

MR. BENDEKGEY: Just a couple of comments.

As your introduction mentioned, I had spent a few years at Silicon Graphics before coming to the biotech industry. And I think that in fact -- I mean, everyone used to joke, and I guess probably still does in that industry that, you know, everyone, you know, sort of loves to hate Microsoft and Intel and then secretly wishes they were that.

But I think some of the analogies -- I think because of the network effects in that industry, you know, it doesn't really translate, although I would wager that there are a few people, a few companies spent some time trying to figure out how they could become the Microsoft or the Intel of biotech.

I will say that in both circumstances, to answer your question about the role of competition in innovation, actually I witnessed variations on the same phenomenon play out at both Silicon Graphics and at Incyte, in that both companies really were founded, or had their initial success I guess you should say, off of the introduction to market of a product for which there

was not previously a comparable product. In the case of Silicon Graphics it was 3-D graphics workstations; in the case of Incyte it was these databases of biological information.

And managed to, you know, become the 800-pound gorilla in each of them in a, you know, sort of moderate size but promising product category, at which point, in the case of Silicon Graphics -- well, both cases, in the case of both companies, much bigger, much funded competitors emerged and decided that that business was big enough that they needed to participate in it.

In the case of Silicon Graphics, those people included Intel, Microsoft, Hewlett-Packard, Sun Microsystems, IBM, everyone was in 3-D graphics all of a sudden and was going to do it bester and cheaper than Silicon Graphics and, you know, the result to Silicon Graphics is now history.

In the case of Incyte, about three years ago what was then Perkin Elmer announced that they were creating a new company, Celera, whose role was to, among other things, put Incyte out of business.

And I can say that one thing that competition does is, it sure makes you hurry up. In the case of Incyte we successfully, I think, defended our franchise and really didn't lose any customers to Celera, but we

lost money, and to a significant degree, for the next couple of years trying to keep ahead of them.

So in my mind that pattern is something sort of significant in terms of, you know, a new company identifying a new opportunity, then these other entrants sort of with more resources sort of follow on.

MR. WROBLEWSKI: Thank you. Bob Blackburn, you wanted to add to that.

MR. BLACKBURN: Yeah. The sort of sequential monopolist model does not really work in the pharmaceutical field, because of sort of the plethora of diseases, people are going after different indications and it doesn't work.

It may work as, in the sense as Lee is suggesting, in research tools, what's the latest, best array, what's the latest, best whatever, high-throughput screening.

And also certainly where it's a factor is in diagnostics, where you actually do have something similar to an operating system, and that's the test format.

And I mentioned for the PCR patents that came originally from Cetus and their current owners, as a result of a merger, were required by European authorities to make those available non-exclusively for licensing and -- because they really did have a networking effect.

It was the latest, best, perhaps, test format that all the diagnostic labs were employing. And there is competition now to come up with yet another better, you know, sort of an Apple-type analogy, of test formats to come up with -- to compete with PCR. But, you know, the barriers of market entry there are enormous because of installed machinery that runs a certain particular format of test.

So that is one area I think where this might translate well.

MR. WROBLEWSKI: Okay. Thank you.

I'm going to switch gears, if anyone else wants to add anything to that point.

People brought up in their opening statements, I think Michael Kirchner, you brought up in your opening statement in terms of issues dealing with the quality of patents that are issued. And I guess my question is, is I wanted to expand on the themes that you brought up in your opening statement, and has there been uncertainty in the industry with respect to the validity of patents that are coming out of the PTO now in the biotech industry? And if so, what are the reasons for them?

MR. KIRCHNER: Well, I think there is. On an individual basis I think you can say that there are uncertainty in the validity of patents.

When a particular individual patent issues that perhaps touches on certain of your activities you are under a duty, in essence, to analyze that patent, determine whether or not you're infringing it and/or whether or not that patent is valid.

Frequently we find that there is in fact real validity questions coming out of that patent, frequently we find that the best prior art was not cited to the patent office, was not discovered by the patent office, or was cited to the patent office and clearly the examiner did not appreciate it, which again is not a surprise when you understand the conditions under which the examiners are examining the patents in question.

We also find, like I say, that there seems to be an increasing number of patents coming out filed by different parties covering the same invention so that you have, if you want to practice a particular technology, several different parties you need to go to, to discuss either getting a license or several different parties you're going to need to fight in court and when in order to practice a particular technology.

I think that the quality of the people the patent office has is very high, I think they are dedicated, I think they're working under really tough circumstances. So I'll stand by my other comments and

basically say I think the bottom-line problem is they are not given the resources in one form or another that they need in order to examine a patent to the sort of degree that the law assumes it is being examined when it says "it shall be presumed valid, and you can overcome that presumption only by clear and convincing evidence."

MR. WROBLEWSKI: Do you want to add something?

MS. DESANTI: No.

MR. WROBLEWSKI: David.

MR. EARP: I think this is a clear area where the effects on competition and innovation is marked. If you are a small biotechnology company looking to enter into a particular space and to use a particular technology and your analysis of the field shows that there are patents that potentially would block your entry into that area --

MS. DESANTI: I'm sorry, I just want to interrupt to ask everybody to please speak into the microphone --

MR. EARP: I'm sorry.

MS. DESANTI: -- just so we can get everything on the transcript. I apologize for interrupting you.

MR. EARP: So if you're looking to move into a particular area of technology as a small biotechnology company, and you identify potentially blocking patents

which your analysis shows may have some -- may be invalid, may be susceptible to prior art attacks, perhaps were improperly issued by the patent office, you have two choices. You can either walk away from that area and decide not to engage in development in that technology, or you can take the risk and start investing the dollars, usually millions of dollars even early on, to move into that technology area and risk getting sued by the company that holds the patent.

For companies such as small biotechnology companies it's often not a choice. You will avoid that area. It's one thing to have a letter, a letter from -- an opinion letter from outside counsel saying the patent is invalid, go ahead; all that does is it insulates you potentially from the threat of treble damages from willful infringement down the road. It doesn't insulate you from, first of all, the jury deciding that your patent counsel gave you the wrong opinion; and, secondly, what's more problematic for small companies, just the actual process and the cost of engaging in the litigation in the first place. So litigation is truly a fairly horrifying option to smaller companies.

In other jurisdictions, in Europe for example, there are opportunities to challenge a patent immediately after it is granted. Patents are published in the

official gazette in Europe and there's an announcement in which you have a nine-month period to file a notice of opposition and tell the European patent office why that patent shouldn't issue. That is an in-depth process in which both sides file briefs with the European patent office, there is a hearing and there's an assessment as to whether the patent was or was not properly issued.

That system isn't perfect, but it's certainly a lot better than the choice that we're currently faced with in the U.S.

MR. WROBLEWSKI: Okay. Thank you.

Ross, did you want to add something?

MR. OEHLER: Yeah. I think we should be clear that this is not specific to biotechnology. I mean the issues that come up in whether patents coming out of the U.S. patent office are good or not good is really not field-specific.

And in fact, I would suggest that, given the concentration of the patent office on guidelines and resources in the biotech field, which I think have been pointed out in some of the materials that have been distributed today, have really, in the biotech field, has benefitted more than perhaps the other fields in the last, say, 10 years.

Clearly more resources are needed at the patent

office to hire and retain qualified people and, as Michael pointed out, to give them the time necessary to actually do their job and do it well.

And I would also point out that we should be careful shifting the burden to a public sort of thing. I agree certainly we --

MR. WROBLEWSKI: I'm not sure -- what do you mean by shifting the burden to a public...

MR. OEHLER: Well, we as a company participate in the opposition proceedings in Europe all the time, and it certainly is less expensive than all-out litigation.

But I would rather see a concentration on better resourcing at the patent office than, say, institute an opposition-like proceeding in the U.S. where now the public or the companies of interest are -- it's just not true with the public and the individuals, although that opportunity is there.

It then puts the burden on them. The cases are there before the PTO, the PTO is dedicated to the task of reviewing these and granting those that should be granted, and denying those that should not. I'd rather see the resources focus there. And it's -- not only is the PTO dedicated, but you would shift the cost to the public by instituting a system whereby opposition would be the preferred way to go.

We should not lose sight of the fact, as well, that there are opportunities for the public to submit comments to the patent office. Now with an 18-month publication there's an increased opportunity for those that do want to follow what is pending at the patent office to get comments in. It may not be as perfect and as targeted as an opposition proceeding, as in Europe, but there are opportunities there.

MR. WROBLEWSKI: Okay. Thank you.

Bob, did you have something you wanted to add?

MR. BLACKBURN: I think there's going to be a finite limit to quality. The PTO is a human institution and there's no doubt in my mind they need more resources to do their job.

But beyond that, there will necessarily be a percentage of patents which -- it's not an issue of quality, it could be a misinterpretation of the law or a change in legal doctrine, or whatever, that there are patents out there that are subject to challenge.

The unique problem in the biotech and pharmaceutical industry is the ability to challenge these, because under current U.S. law you cannot begin a D.J. action and challenge the validity of a patent unless you've been threatened with litigation by the patent owner. And usually people are not dumb enough to do

that.

And you couple that with Hatch-Waxman, which suggests that there's no infringement in any event during the expensive clinical trial phase, so that there is no infringement to even threaten litigation over, these patents can hang out there.

You have the ultimate result -- to follow up with David's comment -- is you go to your head of R&D and says, "Can I do this," they say, "Well, invest the 800 million and I'll tell you in 10 years whether you can do it or not." And that's unacceptable. And every other developed countries' patent system allows challenges to the patent's validity, not just within nine months, as in the European patent office.

But what people forget is that once that patent finally issues from the European patent office it becomes a national patent and there's a national system of bringing third-party challenges to validity which is available, which does not have the same U.S. requirements of standing.

And the -- you know, for example, I believe the system in the U.K. is you write a letter to the patent owner and say, "Is the license available on it, on what terms," and then it's your sole discretion whether you like the answer and you can begin to sue to have the

patent revoked.

You know, it is a significant drag I think on competition when there are these bad patents that sit out there and you can't touch them.

MR. WROBLEWSKI: Thank you.

David, did you want to add?

MR. BEIER: At the risk of disagreeing with some of my colleagues, my assignment here today is to represent the Trade Association, and the development of the testimony was a consensus process, so I'll attempt to honestly and faithfully develop that consensus.

Essentially the consensus is that if you look at the broad sweep of the last 25 years, the patent system has remarkably been self-correcting. And if you go back to when I first started working on this in 1979 on Capitol Hill, and you think about everything that's happened in the Congress, in the PTO and in the courts, it's gone in the direction of improving the patent quality and the ability to obtain higher quality and appropriate scope.

Starting with the creation of the Court of Appeals for the Federal Circuit in 1982, an entire series of patent law changes enacted by the Congress in the 1980s. And then, frankly, a remarkable set of administrative reforms within the Patent and Trademark

Office under four different commissioners, starting with the creation of a biotech patent group, the issuance of written description guidelines, the issuance of utility guidelines, the creation of special training for patent examiners, special quality review mechanisms. Every time there's been some kind of public controversy within a discreet period of time the Patent and Trademark Office has responded affirmatively.

The most recent examples I was involved in personally in my previous government service, one was gene patents and the second was business method patents.

On the gene patent side there was development of guidelines that essentially represented the reconciliation of views between Harold Varmus, then the director of the NIH, and Todd Dickinson, the PTO commissioner. We spent hours hammering out those distinctions and differences. And I think generally speaking the stakeholders are largely pleased with the outcome and will produce higher quality gene patent guidelines with appropriate levels of utility and specificity.

The same thing happened with respect to business method patents. There's no doubt that there was valid criticism of early-on-issued business method patents. But again the Patent and Trademark Office came

up with a comprehensive approach of improving examination of prior art, training examiners, et cetera.

If you add to that the final question, which is judicial review, and you may not like all of the decisions, and I know my colleague Bob doesn't like some of them, from the Court of Appeals for the Federal Circuit, they have attempted to match the law with evolving technology, and in many cases provide the level of certainty that would improve the ability of the Patent and Trademark Office to examine patents and to come up with an appropriate question of quality.

I think the question isn't whether the patent system is perfect. It's, if there's a problem what the solution is. And if the solution causes more harm or creates more uncertainty or more delay, which I would submit, at least on a personal basis, an opposition system could -- if you look at the Japanese experience, I think that suggests that you'd end up with multiple oppositions and delay in certainty -- you could end up with a worse system.

So the question isn't whether there are problems, the question is whether the solutions can match the problems you've described and whether you can reasonably assert that those solutions are enactable and practical.

MR. WROBLEWSKI: Thanks.

Lee, did you want to add to that, or disagree with that?

MR. BENDEKGEY: Well, I was going to disagree a little bit, but poor Ray has been waiting a long time so why don't we give him a chance.

MR. WROBLEWSKI: Ray, go ahead.

MR. CHEN: Appreciate that, thanks.

Mr. David Beier has already said a lot of the things I was going to say, and obviously the primary goal of the PTO is to have a strong system of valid patents. And to that effect, in the biotech industry, obviously the PTO has done a number of things such as issuing a new set of utility examination guidelines and written description examination guidelines, as well as doing other things in the business methods patents arena.

But also it appears that, based on our quality review statistics, just a percentage of all allowed applications do undergo a second-look quality review, that those statistics have been improving from each year to year but -- and obviously if you give more resources to the PTO there will be a correlation to an improved process.

But also there's still always going to be a public element when it comes to these issued patents, and

therefore, because the PTO oftentimes doesn't have perfect information, it's really the competitors out there who have access to the best prior art references.

And so I understand that industry oftentimes has a dilemma when they feel like there's a bad patent that it either has to suffer through expensive litigation that's risky, you never can be sure what's going to happen with a lay judge or a jury. Then your other option is to just completely stay out of that particular market.

However, there is a third option that exists, which is the re-examination proceedings. But I've also heard here that there's perhaps a strong interest in some type of opposition proceeding.

And I guess what I'm wondering is, is there at this table today a particularized interested or proposal in some form of improved re-examination, or some particular form of opposition proceeding they have in mind?

I know personally, from my experience I've seen several patents die in the PTO under re-examination. And, you know, obviously oftentimes that gets affirmed at the Federal Circuit.

MR. WROBLEWSKI: I think David wanted to respond to that.

MR. EARP: Yeah. I think it's highly appropriate that we raise the re-examination proceeding issue. There are relatively new re-examination procedures in place today, but I think it's probably your experience, perhaps you could confirm that, that very few people are using them because there are some severe disadvantages with the re-exam procedure that's in place.

There's legislation pending now, and perhaps you can update us with -- tell us whether new legislation is pending -- but some of --

MR. BEIER: If I could interrupt there. To answer your question, there are four cases where people --

MR. CHEN: Four is it?

MR. BEIER: Yeah, out of I think 160,000, so people are obviously not using it.

MR. EARP: Right.

MR. BEIER: In the Bio testimony there are references to the specific bills that would eliminate the preclusive effect of participating in the re-examination process, which is something, at least as a trade association, we would support doing to make it easier to participate and not risk as much by participating.

MR. EARP: So just let me summarize for people who aren't familiar with some of the issues.

There is a preclusive effect of going into a re-examination proceeding and failing and not being able to raise those sorts of -- the same prior art defenses in it's party's litigation proceeding. There's no ability currently to appeal a re-examination decision beyond the Board of Patent Appeals and Interferences.

And there's also the Portola Packaging case, in which the Federal Circuit said you can't use as the basis for re-examination prior art that has already been made of record by the examiner or by the applicant during the patent application process.

So there are I think a couple of House bills, 1866 and 1886, and the Senate bill, which I think the re-exam provisions are tacked onto the end of the PTO appropriations bill for this year. I don't know what the current status of them is, maybe you could tell us where they're at today.

MR. CHEN: As far as I know they're all still pending. And like all bills, they're turning into Christmas trees, where things are just getting tacked on, and it seems very speculative whether or not in this session any of them will pass.

MR. EARP: All right. So I think it's appropriate to note that there is a re-examination proceeding, but it's also appropriate to note that

nobody's using it, and it truly isn't an alternative to an opposition proceeding at the moment with the way the law is currently construed, or configured.

MR. WROBLEWSKI: Lee, did you want to add, finish --

MR. BENDEKGEY: I just had --

MR. WROBLEWSKI: You ceded your time.

MR. BENDEKGEY: -- two quick comments.

One is that from our standpoint the big defect with the current interference -- I'm sorry, re-exam regime is the lack of appeal. The fact that, you know, you're stuck with the outcome you get, you know, right then and there really, you know, why would you -- if you really thought that you were potentially going to be in an infringement litigation you absolutely would not take your one shot, you know, at the board there, at the patent office. So that's the big defect from our standpoint. It's not surprising that there's a grand total of four people who've taken advantage of it, and good luck to them, God bless.

But the other thing I would say actually, which is in general, you know, we agree that the patent office is doing its best without enough resources. We also agree that -- I don't think we're talking, Ross, about shifting responsibility from the patent office to the

public, but rather supplementing what the patent office is doing, particularly, as Ray says, in a lot of sectors, you know, the patent office is not going to have access to the best prior art.

One of the places where I really take issue is to claim that the written description guidelines and the utility guidelines are some huge improvement.

You know, in my experience one of the things that has been also damaging to the morale of the examiners in section 1600 is the politization of the guideline process. I mean, with all due respect, how Frances Collins and Harold Varmus are feeling should not go into the formulation of the utility standards, and when you have the patent office, the director of the patent office and many of those who report directly to him marching around, talking about raising the bar and lowering the bar when the law that they are applying was enunciated by the Supreme Court in 1965, there's something wrong with that, and it should not be a question of the patent issue, it should be a question of the patent office with appropriate resources faithfully applying the law that exists, not reacting to the latest P.R. problem created by -- whether it's Jeremy Rifkin or Harold Varmus.

MR. BEIER: I assume then you would have

disagreed when the industry complained in 1989 about the fact that the patent office had increased the utility bar --

MR. BENDEKGEY: I think the question --

MR. BEIER: -- to require virtually clinical trials until the response to that complaint was for the patent office to lower the utility --

MR. BENDEKGEY: I think the answer should be what is the right answer under the patent law, not reacting to the latest tempest. And if the law has been on the books since 1965, the law ought not have changed multiple times.

MR. BEIER: And so I assume that the law shouldn't match current technology then either. You should just have a divine ability to determine what the law is and apply it to technology regardless of what year --

MR. BENDEKGEY: You have to apply the law to technology, but you shouldn't be raising and lowering standards.

MR. WROBLEWSKI: Okay, that's great. Thanks.

I'm going to -- if you're adding something different then we can go forward, if you're going to --

MR. BLACKBURN: I am.

MR. WROBLEWSKI: Okay.

MR. BLACKBURN: Or maybe some context as well.

This really falls under what Professor Teece was talking about this morning on uncertainty. And the reason we have this kind of breakdown is because the patent office actually isn't the final arbiter of what the law is. Usually it's the Federal Circuit, sometimes it's the Supreme Court.

And these policies, establishing a policy and then issuing patents to it is actually I think a creation -- it contributes to uncertainty. Because the patent office decides you can't -- because of this inability to -- for third parties to challenge issued patents in any reasonable time period we don't get any judicial review, and unless they're rejected by the patent office they don't go up to the court on review.

So really what you ought to have is the patent office taking a fairly aggressive view and doing rejections so somebody can go up to the court, or we'd have to have a system of third-party challenges or whatever that can get the issue up to the Federal Circuit. Because whether I agree with them or not, they're generally the final arbiter and that, the fact that they haven't had a chance to address these issues is a huge area of uncertainty, and people don't know whether patents, or classes of patents are valid or not, whether

they should be spending R&D dollars going ahead with the program, or paying for a license or blowing them off, or getting out of the field.

MS. DESANTI: Sue, would you like to ask a question? But I also have a follow-up question, so why don't you go first and then I'll --

MS. MAJEWSKI: I wanted to ask sort of a new direction question.

MS. DESANTI: Let me ask a follow-up question first then.

I'm interested in the extent to which you can tell in the biotech field which patents are important.

One of the issues that's been raised in some of the literature is the question of should we really try to reform anything at the PTO, and obviously that would not be the role of the Federal Trade Commission, but this is an exploratory, we're trying to understand things better, and this is a Mark Lemley article that basically says, look, the vast majority of patents do not become subject to any dispute. Maybe you have one, two percent of patents that are actually subject to dispute, they are commercial important enough that that really matters.

And so the premise of his article, and he goes through trying to develop some ballpark estimates, is that as a general rule it wouldn't make any sense to try

to make anything more certain at the PTO, but rather you might want to question whether there should be a patent -- an assumption of patent validity.

But one of my questions is, do you know -- I mean, in biotech is it different in terms of the number of patents that actually become in dispute, and where it might be helpful to have an opposition system or a re-examination system where you didn't have to pay the price of preclusion from further litigation?

MR. KIRSCHNER: I don't know about other industries, but I can say at least in our company we keep a review of patents that are issued each week out of the patent office. We also review each week what is being published in the European patent office, and now we're reviewing each week what is being published but not yet issued by the U.S. patent office.

As a result of these reviews we are able to identify patents that are potentially problematic for us. And for example in Europe, then to file an opposition within the limited time that you have to oppose an issued patent if it is of significant concern to us.

I would say that you can't -- just because the vast majority of U.S. patents do not end up in litigation does not mean that you can assume that they are not problematic, and that the problem hasn't been dealt with

simply by avoiding an area that otherwise you may have worked on and innovated within, simply because the risk is too great with their not being in the United States an effective way to determine before you've spent your $800 million and 10 years in product development, plus incurred liability, add on to this potential damages of 500 million or more on top of that, whether or not you were right or you were wrong.

MR. BLACKBURN: There certainly are areas of research that Chiron would have done, or would have pursued a little bit longer than it had if there had been an effective, cheap, quick way of testing the validity of a third-party patent.

And the fact that you decide not to go forward with that area means there never will be a challenge probably to that patent, and so we'll never know. And it won't show up in the Lemley statistic, and it's just a -- there's got to be some sort of multiplier there, and I don't know what it is.

MR. WROBLEWSKI: Okay. Sue, do you want to...

MS. MAJEWSKI: Sort of following up on this discussion, this issue -- it makes it sound as if there's a large proliferation of patents that maybe shouldn't be out there.

And much earlier in the panel someone had

brought up the issue of contemplating patent pools as a solution to the royalty stacking program, and this is something that the academics have also contemplated in earlier sessions.

And what I've noticed is no one here at the table has really talked about a tragedy in the anti-commons.

So my question to the panel is, you know, what examples do we have of cases where royalties become too high to make R&D or commercialization of a product really viable? And to what degree is proliferation of overlapping patents a problem in the industry?

MR. WROBLEWSKI: Michael, do you want to go ahead?

MR. KIRSCHNER: I think there is a risk of a problem with the anti-commons in the biotech industry. I think we tend to be tasting it when, like I say, for every vial of our product we sell we have to pay seven or six other entities. And this was in the era before what are now called research tool patents and reach-through royalties became all the rage, not only of other companies but also of universities.

I think in the earlier days you got a cell line, for example, you would be allowed to pay a one-time reasonable up-front fee to use that cell line and forget

about it. Now with everybody wanting reach-through royalties, and with research tools being defined as broadly as they are, any cell line that's used somehow within your research program, any target, any reagent or molecule that you have screened against to see if there is cross-reaction, any particular assay type that you have used, and of course you end up in the course of researching the biological properties of a molecule using a wide variety of assays, you're going to start to attach reach-through royalties to each of those research tools, I think you have a severe risk of a problem of the anti-commons.

How you deal with that I don't know.

MR. WROBLEWSKI: I'm going to go with David --

MR. BEIER: Let me try and respond a little bit about patent pools and a little bit about Professor Barton's observations this morning about whether there should be a research exception or fair use --

MR. WROBLEWSKI: That was my next topic we were going into so --

MR. BEIER: -- which is probably the worst idea that's emerged, at least during the course of the day.

The idea that you should create special rules for biotechnology or pharmaceutical products is both a bad idea and inconsistent with both domestic law and

international law and would produce bad social consequences, for the reasons that Professor Teece explained. It would produce tremendous uncertainty. There's no bright line between commercial and noncommercial.

Moreover, the idea that there's this huge problem out there is contradicted by the best and most available and most recent study, which I think you all heard about from Professor Cohen of Carnegie-Mellon, which was commissioned by the National Academy of Sciences. And that suggests that there is not a patent thicket, that there is less problem in the licensing context than the academic literature suggests.

The message, at least on behalf of the trade association representing hundreds of companies is that the most important thing the government can do is to make sure that it avoids any imposition of a compulsory license. Patents are more than the right to collect royalties, they are the right to exclude others from copying your invention. And in this case there is a tremendous risk that people will associate patent pools with compulsory licenses.

If there's one message that we want to get across, the paper that was published by the Patent Trademark Office in January of 2001, which described the

pros and cons of patent pools for biotechnology, was completely appropriate because it stressed the voluntary nature of patent pools and outlined in great detail the potential competitive benefits and anti-competitive effects, depending on how the patent pools were structured, whether the patents were valid, whether you needed all those patents to complete the research activity.

So I think the question of patent pools needs to be seen in this larger policy context. It would be wrong to go down the road of suggesting that the government should intervene and impose conditions, to require the licensing of intellectual property for some other larger alleged social good, as Professor Barton suggested this morning, either by taking away part of the bundle of rights and giving the public a research exception or a fair use right. It would also be wrong to have the government impose a patent pool requirement in order to achieve some alleged efficiencies when there's no proof that there's a patent thicket or stacking royalties.

If companies in the marketplace decide that they want to engage in patent-pooling behavior, and the antitrust agencies find that it's pro-competitive, that's fine.

MR. WROBLEWSKI: Bob Blackburn, you wanted to add something.

MR. BLACKBURN: The -- first a little bit on a patent thicket which might justify a pool.

A couple weeks ago when I was looking at some of the literature that was cited in the Chairman's speech on this topic, I saw in the first -- from a faculty member at Berkeley -- first page about the patent thicket in semiconductors, biotech, et cetera. I went, "Wow, there's a patent thicket in biotech." I didn't know that.

Went into Lexis, did a patent count for about the top 10, 12 market cap biotech companies in the United States there were three companies that had issued U.S. patents numbering around 600, 700, and there's a -- dropped down to the next one, it was about 300, then 200, and then everybody else was well under a hundred. There's not a patent thicket.

And when you're talking about developing a particular product, there's not many instances I can imagine, actually I can't imagine any instance where pool would be an efficient solution. Michael's example, he can count the number of patents that are at issue there, and they're owned by different parties, and you wouldn't -- there's no reason to form a pool.

You might look at genomics, you've got a lot of targets out there, you might want to look at all of them maybe. I'm not sure that, again, whether that can't be done by going to, you know, a one-source-type license or whether you really need a pool to do it. We certainly haven't found a need to do it.

But in the royalty stacking issue what we found in negotiations, all the parties tend to be fairly sensitive about it. If the licensor in that instance is about to propose a royalty that's going to kill the product they're not going to make any money. And most of the players in this field are sophisticated enough to understand that.

Now, and while there's this theoretical threat with the anti-commons, you tend to see the reach-throughs in more unique tool technology, you don't see it in, say, fungible research tools, and there are a number of those, there's a number of different array technologies for example which are fungible today, and the screening, high-throughput screening machinery and other equipment, so you don't get stacking from all of these different tools that go into the process.

But mostly the players, in our experience, are fairly sophisticated and know that they'll kill the goose if the stack is too high.

MR. WROBLEWSKI: Thank you.

Lee, you wanted to add something to that as well.

MR. BENDEKGEY: Just briefly.

We have in our database agreements actually a provision that could be thought of as an example of a patent pool. This is in the context that Bob alluded to of patents on genes as targets really. And so when we license our gene patents and the database to our customers they can't -- if they discover for example a -- if they find a partial gene that looks interesting to them in the database they can, you know, discover the full-length gene and characterize it and figure out what it does and get a patent on that.

And so we have a provision in all of our agreements that's voluntary, everyone has -- you know, we're happy to delete it if people don't want it -- that says that if people obtain patents based on data derived from our database, there is a nonexclusive grant back to Incyte and to everyone else who's working with our database only in the research field. So only for research purposes, both Incyte -- so the model is very much like what subsequently became the open source model, where there's kind of an improvement grant-back that applies to everyone else who's working with the same

stuff.

And as I said, it's entirely voluntary and so far everyone has signed up to it. But for those people who don't want to, or who may not even be interested in the Incyte patent portfolio because they just have a small number, they're always free to go to the small number of targets that they're interested in working with, they're always free to either develop their own patent position or go to the people who own the rights to, you know, those handful of targets.

But it is a way we found of reducing transaction costs and allowing, you know, kind of everyone who is using our stuff in a broad sort of way to get freedom to operate under each other's portfolios as well.

MR. WROBLEWSKI: Thank you.

Susan, you had a question you wanted to ask.

MS. DESANTI: Yeah. I have a different question, and it follows to some extent from your comments, Michael.

One of the points that Judge Newman made in the very first session of these hearings was the tradeoff value in the patents. On the one hand you're granting an exclusivity, make, use and sell for a certain amount of time, but the upside to society is that there is a

disclosure that's required and associated with that.

And I'm wondering whether in the biotech field the disclosures that go along with patents are a significant source of your ideas for further innovations or not. And I'm wondering in part, Michael, because you were saying that you were reviewing patent disclosures, and clearly one of the purposes is to find out whether you're doing research in an area where there may be a conflict. But the further question is, is that a source of other ideas as well?

MR. KIRSCHNER: Well, I cannot give a categorical answer. But in my experience it has not been a significant source of ideas within the research we've been conducting.

Now, I think it's fair to say on occasion our scientists have read scientific articles which contained information that turned out -- had been filed on in a patent application, and we tried to review our publications to make sure that we have appropriate patent filings made before they are issued. But again, having been Immunex University, that process was not as tight as it might have been.

But, frankly, in our experience, for example on some of the patents on which we are paying royalties, we are wholly unaware of the work that was done that gave

rise to those patents, it was work that we were doing in-house on our own, and yet because the patents issued and because they're presumed to be valid, whether or not they actually gave us knowledge that was useful to us, we've ended up taking licenses.

MS. DESANTI: Bob?

MR. BLACKBURN: I think it's important to realize that in this field an awful lot of the information transfer happens in the scientific literature of the patent literature, but quite a bit of the scientific literature is enabled by the fact that there's been a patent filed on it.

And I have seen over time an increase in the relevance of the patent literature as a source of technical improvements that might be patentable but may not excite a journal editor.

MS. DESANTI: Thank you.

MR. WROBLEWSKI: Ross, did you want to add something?

MR. OEHLER: Yeah. I would add that, in my experience, there are -- most scientists that I have dealt with at some point in their research efforts are looking at patent publications and issued patents, so I think there is value to be found in patents as literature. But you have to recognize of course that

there's at least an 18-month blackout, and for the U.S. that's relatively recent. The blackout could have been years.

And so the scientific literature per se would be more timely for their purposes very often than the patent literature itself. And that may be why you see the turn to the patent -- the scientific literature first and patent literature second.

MR. BLACKBURN: I have just one quick...

It occurred to me actually in the small molecule area I think the primary source of information of what competitors are doing and things like -- is the patent literature, not the scientific literature.

MS. DESANTI: Thank you.

MR. WROBLEWSKI: That wraps up the prepared questions that we had, and I was going to open it up to the floor. And I realize a couple of the panelists were misled or didn't understand my earlier directions. And so if there are closing statements that you would like to make that don't have to do anything with your company but want to deal with the issues, you can certainly go ahead. We can go around the table and then we'll wrap up.

MR. BEIER: Let me address two questions which were in your notice which we didn't talk about. One is the unilateral refusal to license and the second is

international.

As I think Ray knows full well, there's been a dispute going on between the 9th Circuit and the Court of Appeals for the Federal Circuit over the unilateral refusal to license.

Bio's view is not to side with either particular Circuit, but to suggest that there is a principle at play here, which is a patent is the right to exclude, it's also a right to license.

And as the President's own economic report, written by the Counsel of Economic Advisors, suggests there can be tremendous values that can be derived from licensing. And the question is whether there's a legitimate business justification and whether there's a presumption, and what evidence is necessary to overcome that presumption to bring the anti-competitive question forward. And Bio's request of the various agencies, that you attempt to clarify that, because the lack of certainty on that question is a result of the Supreme Court's not taking the Xerox case is going to continue to hamper developments in this context.

On the international side, I know you have a day devoted to this later and you also have a debate about the application of the TRIPS agreement to development of drugs in developing countries.

Let me take a step back and point out where we've come from and where we are today and why it's beneficial.

From the 19th century until the formation of the World Trade Organization and the obligation of the TRIPS agreement there was not an obligation to protect pharmaceutical products. And those countries that had pharmaceutical patents had pharmaceutical industries, those who did not -- I'm thinking of Italy, South Korea, Canada, et cetera, where they had either no protection or very weak protection, those countries did not benefit from having innovation nor research and development.

And one of the remarkable things of this international agreement was an obligation to patent essentially all technologies, and we could get into the details of what the exclusions are. But that obligation being undertaken for trade purposes has been if it's implemented an opportunity for all countries to benefit from patent protection, and to do so in a nondiscriminatory way.

The availability of patents for biotechnology, as several people have talked about, we would all not be here representing the biotech industry if the Supreme Court had not decided the Chakrabarty case in 1980.

We also would not be here 10 years from now

talking about the export market for biotech products, which currently is in the billions of dollars, if other countries did not honor and protect the patents issued to American inventors in the biotech context.

So I think one of the challenges for the executive branch is to make sure that the right to exclude others from practicing your invention is applied in a way that's consistent with the TRIPS agreement, and that it's done so on a nondiscriminatory basis.

One of the things that is troubling about many of the academic comments from yesterday and today is the suggestion that somehow you can pick and choose technologies and create special rules. The TRIPS agreement doesn't admit to that possibility, with some exceptions. And I would suggest that you not go down that road of trying to create special rules for biotechnology or for pharmaceutical products.

MR. WROBLEWSKI: Thank you.

Lee.

MR. BENDEKGEY: I've said quite enough. Thank you.

MR. WROBLEWSKI: Okay. Thank you.

MR. BLACKBURN: Maybe I have too, but I still will say more. Okay? A couple of comments from this morning's panel I wanted to call to your attention.

Professor Merges talked about two areas that maybe required some inquiry, and that was the team research and prior art in that context, and the other was double patenting. In both instances he suggested that some of that was an advantage to the large organization or team, and in fact I take a quite different view. That what the exceptions to prior art in the team research model actually do is make things not prior art to the team, to a large team, that wouldn't have been prior art to a competitive small team. It actually is a leveling of the playing field, things that would -- because of some unusual provisions of our laws, called 102-G, and very strict views of inventorship being the source of prior art disclosures.

On the double patenting side, that in particular is something that does not favor the team. And the most recent decision affecting our industry, Lilly v. Barr, where a Lilly patent went down on a double patenting issue, because they have obtained -- they obtained a patent that if anyone else in the industry had obtained that patent they -- the patent at issue for Lilly would have been valid, but because they obtained it the patent at issue was invalid. You know, and that clearly -- double patenting is clearly something that is aimed at reining in the team in large part.

With the research fair use proposal -- I won't go on about why it's a bad idea but rather point out that de facto there is such an exemption in that if it is not commercially economically competitive at the patent holder they don't go through the time and expense of patent litigation to stop it.

Finally, when we talk about uncertainty and the inability to bring challenges and uncertainties over validity going forward, another real problem with patent law I think is our interference system, and that we are a first-to-invent system versus first-to-file. We have much more certainty abroad where it's first to file. It's almost always the outcome that it is in the United States anyway.

And what I think is not quite appreciated broadly in the United States, versus the foreign systems that are first-to-file, is you actually end up with more stakeholders in that system. Because prior-filed applications which are unpublished are only available as a novelty destroying prior art. They are not available for obviousness-type prior art.

So the second to file, I mean literally, if they disclose -- if Henry Ford filed first on the black Model T and they disclosed and they said it could be any color, blue, red, green or black, they could get a patent

on blue, red or green Model Ts. And so now there's two people in the marketplace.

So there's both a pro-competitive aspect to a first-to-file system, and certainly a huge clarification of certainty of who gets patent rights.

Thank you.

MR. WROBLEWSKI: Okay. Thank you.

David.

MR. EARP: Just to summarize a couple of things that we've heard this afternoon.

From my perspective, representing a small biotechnology company, patents are indeed the key asset for us. They enable us to have access to the capital markets and to continue our innovation and development.

The patent office does a remarkably good job with the resources that it has today, but the continued diversion of funds from the patent office to other branches of the government is a problem that we all agree needs to be addressed. And I'm sure you've heard it from everyone who uses the patent office that maintaining the level of service, with the challenges that the patent office faces as new technologies emerge, is going to be increasingly important.

With respect to the issue that was raised on patents that are out there that may have flaws in them

that we would like to challenge in order to enable competition and to have access to those technologies and to allow companies to make the decision to put the investment to move towards that technology, the current re-examination procedure is not effective, it's not used. Even the pending legislation that would amend the re-examination procedure probably wouldn't convince a whole lot more people to go forward with it. And consideration of a system somewhat similar to the European opposition system I think would be a substantial step forward.

With respect to antitrust and patent misuse issues, and particularly DOJ and FTC guidelines, from a user of those guidelines, from the perspective of a user of those guidelines, I would like to see perhaps them updated and revised in light of some of the new issues that are coming forward. The reach-through royalty issue would be a good issue I think to have some guidance from the FTC and DOJ.

The guidelines offer -- well, largely -- I mean, very good fodder for academic antitrust professors to discuss rule-of-reason analyses and market power, but it's very difficult for a small biotechnology company, counsel in a small biotechnology, to provide clear, concise guidance to the company based on what are, you know, relatively academic principles that are being

addressed in those guidelines. So more specific consideration of those guidelines and addressing examples, we'd benefit from that.

The patent office has done that quite recently, and regardless of what you think of the new utility procedures and guidelines and written description, the patent office provides training manuals with examples of the application of the guidelines to real-life examples that we might come across every day. And I think if FTC-DOJ took a look at some of those examples, which are perhaps a little more concrete than the examples in the '95 FTC-DOJ guidelines, I think we'll benefit from that.

MR. WROBLEWSKI: Okay. Thank you.

Michael.

MR. KIRSCHNER: I think I'd basically like to reiterate what I said before. That first of all this industry would not exist but for the existence of predictable patents. We need, and I believe we have, fundamentally a good system in the United States that has allowed the biotechnology industry to flourish like it has nowhere else in the world.

However, patents can certainly be a drag on innovation, and it's particularly painful when that's kind of a self-inflicted wound, because we are not providing proper resources to the patent office to do the

job that they need to do.

I agree with David Beier, that over the course of time the patent office has been extremely responsive to concerns raised by the industry. That doesn't change the fact that at the moment the individual examination being done on the ground in the patent office is being done under a sense of desperation, as reflected by a 120-way or a 180-way restriction requirements that we are now seeing.

The administration, to its credit, has greatly increased the funding for the patent office this year. However, if that funding is going to be split up in a way that's designed to promote better pendency times, I think in a way, at least in group 1600, you're going to end up with a quality problem that's even worse. I would urge the administration or the patent office to focus on improving quality, at least within group 1600. Perhaps other industries are more concerned with pendency than the biotechnology industry.

And then finally, certainly in Congress we've got some bills to try to improve the re-examination process. I think we may want to go beyond that and look at perhaps incorporating a European-style opposition process in the United States as the way to perhaps do the most to reduce the drag on innovation that patents that

have been poorly examined can place on the system.

MR. WROBLEWSKI: Thank you.

And Ross, final word.

MR. OEHLER: In view of the hour and the comments that proceed me, I think I'd just as soon turn the time over to questions from the floor.

MR. WROBLEWSKI: Well --

MS. DESANTI: Can I say a final --

MR. WROBLEWSKI: Sure.

MS. DESANTI: Well, I'm not going to have a question, but I do want to make a thank you to our hosts at Berkeley for yet one more day of wonderful proceedings. They've really enabled us to bring all of you here.

And I also want to thank Mike and our audio-visual guys who are keeping us running smoothly through all of this, and we shouldn't take that for granted. Thank you very much.

And I'll let you wrap up, Mike.

MR. WROBLEWSKI: Well, I'd just like to ask the audience to join me in thanking the participants today for their excellent remarks.

And to remind everybody that tomorrow's, tomorrow morning's panel starts at 9:30, and it is the business perspectives on patents from the software and

the internet industries.

Thank you very much.

(Whereupon, the workshop was adjourned.)

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C E R T I F I C A T I O N O F R E P O R T E R

CASE TITLE: COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY IN THE KNOWLEDGE-BASED ECONOMY

HEARING DATE: FEBRUARY 26, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: MARCH 8, 2002

KENT ANDREWS

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I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

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