# EXHIBIT 2

# Transcripts of the Public Hearings on Biotechnology

PUBLIC HEARING ON THE

PATENTING OF BIOTECHNOLOGICAL INVENTIONS

BEFORE THE UNITED STATES DEPARTMENT OF COMMERCE

PATENT AND TRADEMARK OFFICE

The Copper Room

San Diego Concourse

202 C Street

San Diego, California

Monday, October 17, 1994,9:00 a.m.

Panel Members From the United States Patent and Trademark Office:

THE HONORABLE BRUCE LEHMAN, CHAIRMAN

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WITNESSES

Congressman Dana Rohrabacher, 45th District, California

Ken Widder, Molecular Biosystems, Inc.

William Rastetter, Idec Pharmaceuticals

Congressman Bob Filner, San Diego, California

Jerry D. Caulder, Mycogen Corporation

Dave Gollaher, California Health Care Institute

Bernie Rhinerson, Biomedical Industry Council of California

Bill Otterson, National Cancer Patients Association

Eugene Schonfeld, National Kidney Cancer Association

Martin Simpson, Office of Technology Transfer University of California

William Beers, The Scripps Research Institute

Kathy Behrens, Robertson, Coleman and Stephens

Douglas Obenshain, Ernst and Young

William N. Epstein, Hoffman-La Roche, Inc.

Laura Handley, Weil, Gotshal and Manges

Timothy Gens, Fenwick and West

William Kennedy, Morrison and Foerster

Elizabeth Enayati, Weil, Gotshal and Manges

William J. Scanlon, Foley and Lardner, Biotechnology Industry Organization

Stanley Crooke, Isis Pharmaceuticals

Vincent Gioia, Christie, Parker and Hale

Mark G. Toohey, Spencer, Frank and Schneider

Allen E. Dow, Klarquist, Sparkman, Campbell, Leigh and Whinston

Ned A. Israelsen, Knobbe, Martens, Olson and Bear and Vical, Inc., Alliance Pharmaceutical

Barbara Rae-Venter, Weil, Gotshal and Manges

Timothy Gens, Fenwick and West

Elizabeth Lassen, Calgene, Inc.

Daniel N. Chambers, Viagene, Inc.

Thomas G. Wiseman, Cushman, Darby and Cushman

George Johnston, Law Department, Hoffman-La Roche

Richard C. Peet, Foley and Lardner

John Sanders, Mycogen Corporation

Micheal B. Farber, Merchant and Gould

Michael J. Roth, Pioneer Hi-Bred International

Margaret Connor, Office of Technology Transfer,Agricultural Research Service, USDA

Steven Brostoff, The Immune Response Corporation

Robert Schaffer, Darby and Darby

Bertram I. Rowland, Flehr, Hohbach, Test, Albritton and Herbert

John W. Schlicher, Crosby, Heafey, Roach and May

Alain Schreiber, Vical Corporation

Eric C. Woglom, The Association of the Bar of the City of New York

Ronald Tuttle, Houghton Pharmaceuticals, Inc.

Jeffrey Miller, IXSYS Corporation

Gail M. Kempler, Regeneron Pharmaceuticals, Inc.

Andrew D. Fortney, Oblon, Spivak, McClelland, Maier and Nestadt

Robert Benson, Genelabs, Incorporated

Lynne Parshall, Isis Pharmaceuticals

Susan Perkins, Cambell and Flores

Robert Sobol, San Diego Regional Cancer Center

David A. Lowin, Syntex, Inc.

Jeffrey G. Sheldon, Sheldon and Mak

Ted Green, Amylin Pharmaceuticals

William J. Scanlon, Foley and Lardner, Wisconsin Biotechnology Association

P R O C E E D I N G S (9:00 a.m.) COMMISSIONER LEHMAN: I'm going to start the hearing right now. We're expecting Congressman Filner, San Diego, to welcome us and introduce us, and when he comes we will interrupt for him so that he can do that officially. But I'd like to begin with my opening remarks so that we can get the hearing underway and try to keep on our schedule as much as possible; otherwise, we'll be here until midnight tonight.

First of all I'd like to introduce who we are. I'm Bruce Lehman the Commissioner of Patents and Trademarks and with me here are Chuck Warren, Deputy Group Director of Group 1800, our biotechnology examining group; Barry Richman, Group Director, Group 1800; Charles Van Horn, Deputy Assistant Commissioner for Patent Policy; Nancy Linck, the solicitor, our head lawyer in the Patent and Trademark Office; and Jeff Kushan of the Office of Legislative and International Affairs, and Jeff organized this hearing and has been dealing with quite a few of you.Now, Mike O'Neil is here someplace. He's there at the door. If you have any administrative problems or questions or anything like that, please, ask Mike O'Neil about it, and Jeff Kushan also would be sort of a second backup on substantive matters.

Also here we have Esther Kepplinger and Dave Lacey of Group 1800 who are in the audience.

Since I was appointed the Commissioner of Patents and Trademarks by President Clinton, we've worked hard to make this office responsive to our customers, and our customers are the users of the patent system and this hearing is an example. In fact, this is our fourth round of public hearings on patent issues and our second round on patent issues in California. I think it's appropriate that we come out here to California because, really, more than any other state, the center of creativity and probably where we get most of our business and the largest single concentration of our customers for the Patent and Trademark Office are in this particular state.

Last January we were in Silicon Valley and at that time we held hearings about problems in the -- patent problems in the software industry. Last July we held hearings in Washington, D. C. on the obviousness standard, and just about a year ago we held hearings on patent law harmonization and those were really our first hearings in this area.

We've used these public hearings to identify the needs and concerns of our customers -- the patent applicants -- as well as their goals for the patent system. For example, we use the public record from our patent law harmonization hearings when we decided to suspend negotiations on the patent law harmonization treaty. We relied on comments made during our harmonization and software hearings, both of them, to shape the legislation to implement the Uruguay round agreement which is now pending before Congress.

By the way, I note that nearly every witness in our harmonization and in our software hearings that addressed the question of patent terms supported a patent term of 20 years from filing.

We also listened carefully to what the software industry said to us during our public hearings in Silicon Valley. Their comments were very important, if not the deciding factor, in our decision to forward legislation to Congress to reform re-examination procedures and then our decision to support prior user rights legislation. That's why these hearings are very important because they can help us identify problems, provide us with useful solutions and create an important public record of where our customers stand on the important issues in the patent system. This is particularly true for the biotechnology industry which is particularly dependent on effective and meaningful patent protection.

The availability of patent protection has made it possible for biotechnology companies to attract investments, undertake risky product development and ultimately put products on the market. And because patents play such an important role in this industry, we have a special obligation to ensure that the patent system is serving its needs.

We cannot grant patents that can be taken to the bank -- literally -- or impose requirements that are so strict the patents cannot be obtained. We can't do that, we will undercut a primary purpose of the patent system which is not only to promote innovation but also commercialization, and this is very important. That's really what the patent system does, it promotes the commercialization of the remarkable advances in biotechnology that we are witnessing today.

Before we began to hear from our witnesses, I'd like to give you some feeling for where the office stands with respect to its biotechnology examining operation.

During the mid-1980s, we began to feel the strain of an explosion of activity in the biotechnology industry. Applications were being filed at a rate that exceeded our capacity to examine. This created a backlog of cases waiting resolution and led to increasingly long patent pendency; a pendency on a per application basis that reached nearly 27 months in 1987. This prompted us to make a serious commitment to improving the

examining operation in this particular area and we started by creating a special biotechnology examining group, which is now Group 1800, in 1988. It then recruited highly-skilled examiners, invested in advanced computer systems, to support searching DNA and protein sequences, and increased its collections of non- patent literature and expanded its access to on-line information resources.

The office also reached out to industry, academia, the bar, and government organizations by establishing the Biotechnology Institute to assist in scientific and legal training of examiners. These efforts have all paid off and pendency has decreased from nearly 27 months, in this particular area in 1987, to a current average of 20.8 months, despite the fact that filings have nearly doubled during that period. And we have cut the time that we take to issue a first office action from 14 months, in 1988, to less than eight months today. I think this shows that we can keep patent pendency down, if we simply keep on top of the system.

I'm particularly proud of our success in recruiting extremely qualified examiners in Group 1800. Currently there are 165 examiners in this group, up from 67 in 1988. Seventy percent of these individuals hold advanced degrees in biotech-related disciplines. In fact, over half of our biotechnology examiners have Ph.D. degrees.

With regard to our efforts to automate, the biotech group has spent over $2 million so far on advance computing equipment related to sequence searching. This is addition to our larger capital project to automate the entire search system which is pretty much complete now in the Patent and Trademark Office.

We have also increased our holdings of specific non-patent literature such that we now have over 1,700 periodicals in our library holdings and through the National Library of Medicine, the National Agricultural Library, and the Library of Congress we have ready access to over 8,000 periodicals.

We currently use 12 sequence information databases and we have access to over 30 more through commercial on- line services, and we're studying more solutions to getting usable information on prior art.

All of these steps represent a serious commitment by the Patent and Trademark Office to provide an effective, efficient examining operation for biotechnology applications.

The Clinton administration has also supported the biotechnology industry in other ways. When we heard that the biotechnology industry had concerns with the Uruguay round implementing legislation -- and I should note that the Uruguay round itself will provide protection for

biotechnology inventions in many, many markets and countries in the world where there currently are no such protections, such as Brazil, for example, which provide no protection whatsoever for most pharmaceutical inventions. And when you think that the pharmaceutical industry alone in the United States is a $100 billion a year industry and that we're receiving less than $1 billion in revenues from a country of 120 million people, you can imagine what the impact of the Uruguay round is going to mean; it's going to mean billions more dollars flowing into the United States economy because we recognize protection for intellectual property in this area. But we also recognize that it's very important to fine tune the implementing legislation and so when we talked to the industry and knew that they had concerns we listened very carefully. And I would note that Senator Dianne Feinstein was very instrumental in bringing these concerns to our attention and worked closely with us to amend the legislation before it was introduced so that these concerns could be addressed.

We have also supported legislation that would change how determinations are made with regard to obviousness of biotechnology process inventions. For example, we testified in support of legislation in both the House and the Senate that would have addressed problems that were identified with the biotechnology industry.

Our hearings today represent another example of our commitment to serving customer needs. We will take your input today and we will use it to refine our examining operations and to make policy decisions that will ensure that our biotechnology group not only produces a high quality patent but is also responsible to the biotechnology industry's needs.

Now, before we begin the hearings, I'd like to briefly review the ground rules for the witnesses. We have 57 people today and so these turned out to be the most popular, probably, set of hearings that we've had. We keep getting more and more people and we should have arranged for two days but we didn't expect this large number and so we'll just stay here until the end of the evening, as long as necessary, to make certain everybody does get to speak. It does limit us a little bit in that it makes it a little harder for us to have a dialogue and answer and ask, you know, questions with witnesses, which is what we ideally like to do.

Each witness will have approximately nine minutes to present their remarks, and to the extent that you can do it in less than that, we would really appreciate it, and I think Jeff has talked to some of you about special needs that individual people have and so we have that taken into consideration. But, again, to the extent that we wish to have anybody in the panel -- any dialogue, if you can keep your remarks limited it would be very helpful. Also, to the extent that the points have already been made by other people, especially as we go through the day with 57 witnesses, it may not be necessary to repeat all those points. You can

just say, "I agreed with Mary Smith or Joe Small," and we'll write that down and make certain that we have that -- that we can consult their testimony.

Now, to help you out keeping on time, we're going to have a monitor. Apparently we've have had some technical problems for the first time during these hearings. We're going to have a monitor but for right now we'll have to do it manually, and Jeff will be responsible for timing people and he'll signal you when you're two minutes away from your nine minutes being up. In other words, at the seventh minute. And, hopefully, a little later we'll have a computer monitor here that will help you on that, and when we have that set up the screen will turn red when your time is up and it will turn yellow when you have two minutes to go.

We have, as I mentioned, Jeff Kushan has consulted with just -- or Mike O'Neil, at least one of the two of them, with all of the witnesses and we know that some of them have asked for additional time to address particular issues where they represented more than one group or had more than one set of issues and we have tried to accommodate those requests. And, as we go through the hearing, if you feel there are problems, that you need additional time, you can try to contact Jeff or get a message into Mike O'Neil who is back here and we'll try to see if we can provide the time that everyone needs, but keeping in mind that we have 57 people.

Has Congressman Filner arrived yet? If he has not, then we will recess for him, but I do see that our distinguished representative, Mr. Rohrabacher, has come all the way down. Got up early in the morning, I presume, and drove down here from Orange County, a neighboring county to San Diego, and so we've had lots of dialogue with Congressman Rohrabacher over the last few months. We have a few disagreements but I know that we share a common goal and that is a dynamite intellectual property system that's second to none in the world. So I'd like to start out -- our protocol in Washington is that we let the members of Congress go first so I'd like to start out with Congressman Rohrabacher and invite him to be our first witness.

CONGRESSMAN DANA ROHRABACHER-45TH DISTRICT CALIFORNIA

CONGRESSMAN ROHRABACHER: Thank you very much, and I appreciate the fact that we do have disagreements and that I am given this forum to express my opinions on the things that are happening in terms of biotech but also in terms as it relates to the overall patent situation. I will try to keep my remarks to ten minutes, and I appreciate that, and I will refer to you as Mr. Chairman whereas you are the chairman today of this hearing.

Mr. Chairman, America is in the forefront of the biotech revolution and that we can all be proud of. Biotech is an American creation financed by private American capital and brought to market by Americans. The German government tried to develop the biotech industry but it failed, turning instead to American technology. Given the German experience and the similar experiences in the rest of Europe and in Japan, government subsidization of industry start-ups has certainly had a dubious success and I would say it's cast a pall on that concept. But our foreign competitors in the biotech arena are not giving up, they are watching the American biotech industry and are waiting for the technology and markets to fully develop and then the copying will begin.

Our patent system acts as a strong shield protecting America's innovators from this theft, thus maintaining the incentive for the investment of future venture capital in R&D. So it should be no surprise to any of those here today that our competitors are working at this moment to weaken our patent system. The evidence of a wide- ranging and heretofore low-key assault on patent rights -- on the patent rights -- enjoyed by Americans is now beginning to surface and that is why I am here today.

The Clinton administration, the Japanese and multinational interests are the aggressors and they are justifying their aggression by waving a banner of patent harmonization. If this is successful, U.S. patent holders or technology creators will be robbed of billions of dollars in royalties by those who will use their technology; people such as huge foreign corporations who will be let off the hook for the licensing revenue they would otherwise owe to Americans under current law. This, Mr. Chairman, is what I consider to be a crime in progress. That is why I am so upset and that's why I have been so vocal on this issue. If the perpetrators are not stopped, American technology will be stolen and used against us just as the incentives for future investment in technology creation evaporates.

The growth in our biotech industry, in particular, would be severely stunted. This insidious reduction of patent rights is being, as we have discussed before, Mr. Chairman, done under the cover of GATT, the General Agreement on Tariffs and Trade. The questionable intent of this administration is apparent when one considers that the most egregious threat to the patent term -- and there's the change that is being proposed by this administration -- is not, and I repeat -- is not -- mandated by the Uruguay round agreements.

According to Article 33 of GATT, a patent must have a minimum -- the operative phrase "minimum" -- of 20- years protection from the filing date. Therefore, we would be in full compliance with GATT by changing the patent term to 17 years from grant or 20 years from filing, whichever is longer. Our historic patent term of 17 years from grant has

guaranteed U.S. investors and inventors a fixed period of protection regardless of delays in the issuing of the patent.

Conversely, starting the patent clock running at filing leaves little incentive for the Patent Office to be diligent in issuing the patents and being diligent in the reforms that you have outlined today, seeing that they are implemented. Any delays will detract from the patent life and, therefore, its economic value and, therefore, lessen the incentive. For example, a biotechnology patent on average takes 10 years to issue. Under the present system the inventor still receives 17 years worth of protection; however, under the proposed change, with the term measured from filing date, the inventor would only get 10 years worth of protection.

The U.S. patent commissioner, yourself Mr. Lehman, suggests that 20 years from filing that date term will actually give inventors a longer period of protection. That's something you've said over and over again, and I'm here today to testify that I believe that is a falsehood and every inventor's group in this country recognizes it as a falsehood. If what is being said is true, the administration should have no problem whatsoever, and should have had no problem, with the compromise that we proposed. Those of us who were vocal in Congress, we proposed a 20 year from filing or 17 years from grant, whichever is longer. That compromise would have guaranteed a minimum of 17 years of patent protection and be fully compliant with GATT. This administration rejected that language because I believe the intent of this administration is to cut the time of patent protection, not to improve the system.

I believed, Mr. Lehman, that the -- that it is a misleading statement also to say that the patent pendency average is 19 months, which is something else that you've stated. The 19 month figure treats totally inconsequential matters, like the stripe on the bottom of a toothpaste tube, to be on par with world-changing inventions like the ones we are seeing in biotech and other such inventions. This figure also treats incremental and revolutionary patents on an equal footing. The claim that a patent term of 20 years from filing would produce longer patent terms is, I believe, disingenuous at best. I think the American people deserve to be leveled with.

Under this change that is being proposed, valuable patents whose revolutionary products keep America competitive will receive shorter terms and less protection. It will mean billions of dollars in royalties that should be going to American inventors will now be in the bank accounts of huge Japanese companies and multinational corporations. It has been stated that the U.S. must change to the filing date term because of mischievous and avaricious inventors who distort the system with submarine patents. Well, that, reducing patent protection for 99.5 percent of all inventors who do not practice submarine patents in order

get at that one-half of one percent is ridiculous, but also we actually proposed a change -- those of us in Congress proposed a change that would have dealt with the submarine issue but, again -- and that was basically if the inventor delays the time of grant then it will be published with the -- the patent would be published immediately. But this was also rejected what again demonstrates that the purpose of this administration is to reduce the time of patent protection for American inventors, not make the system better.

And if anyone has any doubts as to who officials are looking out for, there is an agreement that was signed with a Japanese patent office on August 16th which basically will require a change in U. S. patent law so that all of our patent applications will be published after 18 months. Yes, you've got it, this is premature publication mandated by an agreement by our own government. This blanket publication provision will open U.S. patents to scrutiny to foreign competitors in most instances even before the patent is issued and our technology protected; it will invite foreign competition to steal American technology and to use it against us when our own corporations have exhausted the revenue in the development of that technology.

In Japan, which has both a 20 year from filing term and 18-month publication, the competition can use the published patent application to practice patent flooding, and that is basically surrounding the original invention with patents of their own with unfair cross-licensing. Basically, premature publication would also allow the competition to challenge the issuance of American patents. Patent applicants should only be published -- it should only be published after -- after -- a patent is issued. The U.S. patent system has served our country well. This is no time to delude its protections.

Let me say in summary, American biotech companies are at this moment in a very dangerous position. They need large capital infusions which will not and cannot come from government. So far the private sector has financed tens of billions of dollars worth of research and development. Tens of billions of dollars more will be needed to protect and perfect this technology, but the private sector will not fund this great scientific advance if their work can be copied and if royalties are diminished by a weakened patent system. Trying to muffle the cries of pain from industry, the administration has offered a small, small compromise of relief, and I would say that is a scrap of relief based on a horrible proposal. This scrap of relief will provide a windfall to lawyers but will not protect this industry from its foreign competition, and it's sad to see that the industry has knuckled under to this intimidation. And my recommendation, in closing, to the biotech industry is that they should fight this because it's not good for your industry and it's not good for America. We've got to stay in the technological forefront and this change that's being done in a very disingenuous way

will reduce the patent protection and hurt all Americans and American competitiveness in the future. Thank you very much.

COMMISSIONER LEHMAN: Mr. Rohrabacher, could I ask you just one question?

CONGRESSMAN ROHRABACHER: Go right ahead.

COMMISSIONER LEHMAN: You know, you referred to the Japanese agreement which was basically designed to open up the Japanese patent system so it would be more effective for U.S. applicants and obviously you disagree with some of the modifications that are proposed in U.S. laws as part of that agreement. What would be your recommendation as to how to get effective patent protection in Japan?

CONGRESSMAN ROHRABACHER: Well, it certainly wouldn't be to try to harmonize our patent system with what the Japanese do, which seems to be the Japanese have a very -- I know, you know, they are very notorious for their ability to negotiate but the last thing we should be doing is trying to harmonize our patent system by basically making our system more like theirs. Our system is based on individual creativity; it's based on our culture. The Japanese don't have that same cultural appreciation for the individual. And, in terms of publication, the specific question that you're asking, I don't think that should have been a compromise at all. We should never have reached that agreement with the Japanese.

COMMISSIONER LEHMAN: So your answer is that you have no recommendation for how you would open up --

CONGRESSMAN ROHRABACHER: We have a market -- We have a market in the United States that the Japanese depend on in order to have any type of a thriving economy. The economic well being of their people is totally tied to our market. Now, if we can't use this incredible leverage that we have in order to prevent the Japanese from forcing publication of our inventors' inventions so they can steal them, well, then, we -- whoever is handling the negotiations on our side is incompetent,because it's not just a matter of an issue of patent negotiations, this is a matter of relationships between the United States and Japan. And, in that relationship, we have tremendous leverage which should have been brought to bear so we wouldn't have had to give up this sacred right which I consider the property rights of inventors to be on the same par as the property rights of homeowners, of farmers, and the rights of freedom of speech and every other right that we hold dear in the United States.

COMMISSIONER LEHMAN: Thank you very much.

I think our monitor is set up now that I described so we'll -- you're bringing it up now? -- get it set up and then Mr. Widder can come

forward. If Ken Widder could come forward, please. And I think what we'll do is we'll do you manually and then we'll have the monitor for everybody else.

KEN WIDDER, MOLECULAR BIOSYSTEMS, Inc.

MR. WIDDER: I'm Ken Widder, Chairman and Chief Executive Officer, Molecular Biosystems, a biomedical company here in San Diego. I appreciate the opportunity speaking with you and also I wish to thank you for coming to San Diego. We're honored to have you here.

Aside from being chairman and CEO of MBI, I'm also chairman of the San Diego Technology Council, a member of the Governor's Advisory Council on Biotechnology here in California, and president of the San Diego Biomedical Industry Council, a consortium of CEOs -- local CEOs -- of 65 of the local biotech companies. I'm also representing BIO here for the purposes of this hearing.

For your information the biotech industry here in California represents over 50-percent of the companies total in the country and here in San Diego we have about 120 biotech companies spanning pharmaceutical development, device development, and agriculture. San Diego itself is really the fourth largest conglomeration, if you will of biotech companies in the country.

From our standpoint in the biotech are, the work of the Patent and Trademark Office is absolutely critical to the biotechnology industry. Without strong intellectual property laws we, as an industry, would cease to exist. I think it's safe to say that patents represent almost a cornerstone of our industry.

Mark Twain called inventors "the creators of the world after God." That may have been stretching it a little bit but the bottom line is that the technology laws that govern this country are critical to us as an industry to raise money. Without it, we would not be able to raise one dime.

A little bit about my company just to give you a sense of where I'm coming from. Our company started in 1980. We originally were involved with the development Antisense and DNA probes. Both of those patents, incidentally, took about 10 years to issue and still are in some form of prosecution. So we have had some excellent experience in the Patent Office with patents issuing very early or much sooner, but some key, very generic patents that we were involved did take a very long time to get through the system.

We are now are involved, though, since about 1986, in developing contrast imaging agents for ultrasound, MR, and CT. Our first product

has just been approved by the FDA which has been heavily patented, without which we would never have been able to raise the money it would have taken to get through the FDA process.

Throughout your history we've raise a little over $150 million. That's since 1980, and that's really been based on two factors:

One, the quality of our technology and, secondly, the strength of our patent positions. And virtually no money would have been raised if the latter hadn't been in place because the first question anybody asks is: "What patents do you have and what protections do you have?"

Biotechnology companies, in general, are constantly raising money. That's an activity as a CEO that you are constantly involved in. You never rest because there's never enough money. One could look at biotech companies virtually as money machines, we just constantly are consuming it. Very few companies are profitable. Only a handful are really making significant revenues. In fact, I think someone was asked what's the definition of a -- "What is a biotech company?" and the answer was that a biotech company is very similar to a pharmaceutical company but unincumbered by revenues. And I think that's a fair analogy of what the situation is even today. It's a very competitive field. It burns a lot of money to get product through the pipeline, roughly $100 million to $150 million depending on the type of product you have, and it's a long time coming through.

Not only do we have to wait for patents to issue in the length of time as the Congressman described, but, additionally, the extra burden of FDA approval can take anywhere from five to eight years so I think there will be a number of comments about GATT and the 20-year proposal. I won't get into that but I just ask you to consider the fact that it's not just the patent review time that's of question, it's also the development time for a product and the FDA approval time that a company could easily burn up a significant amount at 20 years just getting the product out and maybe have two or three years of patent exclusivity at the back end.

COMMISSIONER LEHMAN: Can I ask a question?

MR. WIDDER: Yes.

COMMISSIONER LEHMAN: Do you favor a revision of the patent term extension legislation that was enacted I think in 1984?

MR. WIDDER: I think that's very helpful. I know it's a very complicated formula in terms of -- getting an additional patent extension is based on a variety of factors, and I'm sure there will be some discussion of that later and I think that's very --

COMMISSIONER LEHMAN: If we just did away with the formula and said however many years of FDA delay there is you get --

MR. WIDDER: You would add on?

COMMISSIONER LEHMAN: -- an extension of patent term?

MR. WIDDER: Well, we're just in the process of extending one patent and I think we have -- you know, we have gone back and utilized that formula to try to figure out which patent would be the best to extend, so I'm not familiar with if the laws have changed on that.

COMMISSIONER LEHMAN: Well, the laws haven't changed but what I'm saying is if that's a problem, if what you're saying is that FDA approval is a serious problem so that in any event you end up losing patent term, then, you know, shouldn't we change that law?

MR. WIDDER: I guess that's one reasonable suggestion, yes, because -- I think some of the other CEOs will discuss this, but it is a long, long process and we are constantly looking at -- I mean, you're penalized basically for having a patent issue early. If you start from the creative process, go through the product development cycle into clinical trials and then --
COMMISSIONER LEHMAN: I understand that, and the difficulty is that, generally speaking, in most technologies you want the patent to issue early because most technologies, if you're in the electronic business, for example, which is a very rapidly moving business you -- as a matter of public policy I think you want to encourage the innovator to get in there, make the innovation quickly and get into the marketplace quickly, compete, because you've got global competition, and you're in an unusual circumstance so --

MR. WIDDER: That's correct. We are in a different --

COMMISSIONER LEHMAN: So probably the best way to deal with that, since you have the problems of regulatory delay, is to -- and which Congress has already recognized -- is to go back and look at the solution that they have devised for that and make that work better.

MR. WIDDER: I would endorse that. I think extending -- instead of some formula over a percentage of the time that the product is being put through the FDA, I think giving full credit for that would certainly be a benefit. I think -- How am I doing on time here? Yellow. One minute, okay.

I'd just like to say two more things: One, I think the retention of patent examiners is a very important item, from our perspective, having people there that have some perspective on the other types of patents

that are going through that have a decreasing turnover I think is critical from our point of view. And one other item: We found it very useful and I would certainly endorse to continue the policy of the interview process. I think it's been very helpful when very tricky patents or ones that are tough to describe in writing, to be able to go in and interview has been a very positive experience for us and would hope that that process would continue within certain bounds so the examiners aren't overburdened, but it really has been a very good type of activity for us. And we're committed as an industry to work with the Patent Office and try to make recommendations that hopefully with streamline the process. With that, I think I'll stop and turn it over to Bill Rastetter.

COMMISSIONER LEHMAN: Thank you very much. I'd just like to say that retention of patent examiners is very important. It's extremely important that we have the resources that we need to do our job in the Patent Office that has been provided for us in legislation and that we are fully fee-funded agency. However, Congressman Rohrabacher and other critics of the system have voted consistently to take fee money from the Patent and Trademark Office and divert it and use it as tax revenues. This year some $30 million is being diverted, so you might want to bring that to their attention and others.

MR. WIDDER: I appreciate that, yeah. I think we'd clearly like to keep the money in the Patent Office where it can do the most good.

COMMISSIONER LEHMAN: Thank you.

Mr. Rastetter?

WILLIAM RASTETTER, IDEC PHARMACEUTICALS

MR. RASTETTER: Mr. Lehman and colleagues, thank you for coming to San Diego this morning. My name is Bill Rastetter. I'm the president and chief executive officer of IDEC Pharmaceuticals. I also serve on the board of directors of two trade groups in town: BIC, the Biomedical Industrial Council, and BIOCOM, the Biocommerce Association. I also serve on the Governor's Council on Biotechnology. I Should also mention that IDEC is a member of BIO and the opinions I'll express today are mine and those of IDEC Pharmaceuticals.

We are one of about 150 biotech or biomed companies here in San Diego which collectively employ about 14,000 individuals. The biomedical community here in San Diego is certainly ia very active and cohesive one and we work very closely with the city. The city, in fact, has embraced us as part of its economic future and I think, in no small part, the issues which we will discuss today will certainly impact our companies' ability to timely secure and build patent portfolios which will

ultimately drive the growth of our companies. And that growth, I think it's important to point out, will entail a transition from our status as R&D organizations which, as Doctor Widder pointed out, consume copious amounts of capital to companies that are driven by cash flow from product sales. And certainly that transition will ultimately truly drive economic growth in this region, so patents are a critical part of our future.

I'd like to place the comments I'll make this morning in the larger context of strangely enough health care reform. It has been said recently by many that health care reform is dead, and I'd like to point out that nothing could be further from the truth. In fact, health care reform is occurring and is occurring rapidly through private sector market forces without legislation and without direct government intervention. And certainly those forces are changing the way that every company or every practitioner in health care does business.

And to continue to place my comments in context, the largest pharmaceutical companies seem to be gaining ground on the mid-sized companies. I would not include the biotech companies in the mid-size -- we're certainly much smaller than that -- companies like Merck and SmithKline who have moved aggressively to acquire pharmacy benefit managers as their paradigm for doing business changes. The analogy might be that the hardware makers (read the drug developers) will now also be in the business of software (read pharmacy benefits management and outcomes research.) In doing so, they will optimize the way their drugs are used and they will capture further economic benefit.

But I think they're doing this because the pipelines of the large pharmaceutical companies are not as full as they might be and revenue growth is eroding with blockbuster drugs coming off patent, and with generic substitution, and the broad pricing pressures that we're seeing from the private-sector- driven health care reform. Well, to finish that context, all of this is actually good news for the biotech company if we can continue to innovate, and provided that we can timely secure and build intellectual property positions.

Now, the revenue erosion and pressure on the bottom line for large pharma is leading to internal R&D budget cutbacks at large pharma, if you will. So they will be looking increasingly to small companies, such as IDEC or Molecular BioSystems for late-stage, development products where the risks, both technical or clinical risks and the intellectual property risk, has been largely removed from the product development process. So, small may be beautiful, speaking of companies, provided we can continue to discover and efficiently develop protectable, proprietary products.

The small company in the era of health care reform may well emerge as the predominant engine of innovation in partnership with large companies.

The large companies will consolidate their power as the worldwide marketing partners. Clearly, patent protection is paramount to the health of such partnerships.

We have all heard that the era of health care reform has damaged the ability to raise capital from the public markets for biotech. It is, indeed, impossible today for small companies to rely routinely on the public equity markets as a source of capital. We look increasingly then to a large pharmaceutical company to fund research and development and to sustain us as viable R&D organizations until our products are launched and royalties and/or profit sharing arrangements begin to pay the bills. And that may take 10 to 12 years after a company hires its first scientist to reach that position of cash flow sufficiency.

Let me make two points from the perspective of a small company:

First, the trend at the Patent Office towards requiring human clinical data to demonstrate utility hurts the small company. Generally, we need to find corporate partners in order to fund clinical development because clinical development is extraordinarily expensive. But without clear patent position it can be hard to get a partner. Catch 22.

The second point, the "first to invent" system in the U.S. certainly helps the small company. I am certainly glad we have not changed this element of our patent system. We, as small companies, just cannot file patent applications as efficiently or as early as the large companies. We just don't have the resources. We need to spend as much as we can on discovery and on development of product leads. A "first-to-file" system would divert dollars away from R&D, curtail innovation, and weaken the small company. You know as well as I do that a "first-to-file" system, rather than the "first-to-invent" would also burden the Patent Office with premature applications on incompletely conceived inventions.

We had the pleasure of hosting a group of patent examiners at IDEC to talk about our technology. We talked about our products which are antibodies to treat cancer and autoimmune disease. We talked about our innovative, we hope, proprietary system for making antibodies in Macque monkeys for treatment of chronic diseases. We talked about or host/vectors' system. It was a very productive interaction with the examiners.

We also would urge that the system of interviews with the Patent Office be continued. We think it's mutually beneficial, and especially for very complex systems tends to expedite the process.

I see that my time has expired.

COMMISSIONER LEHMAN: I would like to ask a lot of questions. I'll try

to be brief. You know, we're setting up in Sunnyvale a -- it's really inexpensive to do this when you think of the benefits. We're setting up a video conferencing facility so that people can go there, you know, up in Silicon Valley, and interview. You know, conduct face-to-face interviews with the examiners. Would something like that be helpful down here in San Diego?

MR. RASTETTER: Yes. Absolutely. We at the company have used that quite extensively. We had two locations: One in the Bay area and one down here and were connected by 24-hour -- just walk into a conference room and your colleagues 500 miles away were there. Very, very useful system.

COMMISSIONER LEHMAN: Also, we have included in the legislation that is now pending in Congress, it's part of the 20-year fast-tract legislation, but it's a provision for provisional applications so that -- which you can file for $75; it's very inexpensive, and then have a full year for the full application. I assume that will help you when you say that, you know, it's hard for you to get into the system. At least that will put your marker down and help you out a lot.

MR. RASTETTER: Certainly. The first I've heard of this but it sounds --

COMMISSIONER LEHMAN: Well, we have done that. I just also would like to say that changing our system from a "first to invent" to a "first to file" system, the Bush administration had proposed to do exactly that, along with all of the other horribles that Congressman Rohrabacher outlined. So I would just point out this is not exactly a Clinton administration plot. In fact, we pulled back from those efforts because we're not going to -- we're trying to develop a world patent system that will favor U.S. inventors. That is our primary purpose, and that means your company, too. We really appreciate your input here and thank you very much.

MR. RASTETTER: Thank you for coming today.

COMMISSIONER LEHMAN: Next I'd like to ask Jerry Caulder to come forward from Mycogen Corporation.

Oh, he is here. I'm sorry -- Mr. Filner, we have 57 witnesses so we wanted to get started right away but we'd be happy to have you welcome us right now to San Diego.

CONGRESSMAN ROBERT FILNER - 50TH DISTRICT CALIFORNIA

CONGRESSMAN FILNER: Thank you very much. I apologize for being late. My name is Bob Filner and I represent the 50th Congressional District in

the United States Congress, and we certainly do welcome you here in San Diego today. It's important. It's timely. Certainly the issues around the intellectual property protection apported to biotechnology inventions is one that's critical to San Diego. Not only San Diego, to California and the nation and we are very concerned, obviously about the local development of our biotech industry. It's a growing source of investment and employment, and with its solid base of academic institutions, non-profit research institutions, and innovative companies San Diego is surely on the cutting edge of this whole movement.

You all know the policy issues involved. I would like to take a few minutes, if it's appropriate, to talk about some of the intellectual property issues, the way I see it as a member of Congress. I'll try to do it very, very briefly. It's certainly well known but I want to make sure that everybody knows that the Congress also knows it; that valid and enforceable patent rights are a prerequisite for success in this industry.

I think it's essential that the Patent and Trademark Office be provided the funding and resources it needs to properly examine patent applications and I support full appropriation of fees collected by the PTO and oppose measures that would diminish the PTOs ability to handle the volume of application that it presently receives. In particular, I opposed the version of withholding appropriations of fees collected from patent applicants for any purpose other than PTO operations.

I think you'll hear from the industry its serious objections to the practice of PTO examiners and others regarding standards set for determination of the utility of an invention. These objections undermine the competitiveness of the biotech industry and it will make it much more difficult to become profitable. The patent protection afforded in the United States is in many cases less than that afforded to the same inventions abroad and we cannot put ourselves at a competitive disadvantage in this highly competitive international marketplace.

The issue is not about the patent laws. What the industry needs is a non-discriminatory application of those laws to biotech inventions. And I urge the PTO to review those issues carefully and forcefully instruct its staff to apply a standard for biotech that is consistent with the standard applied to other industries.

I think you're well aware of the Biotechnology Protection Act that the industry has championed, HR-760 in the House. Those bills did not go through the present session. I hope that you will continue your support of those. They are absolutely necessary for competitiveness.

With regard to international trade. I have concerns, like many in this room, with the 20-year patent term requirement in the GATT-implementing

legislation. I urge the PTO to look very carefully at this issue to ensure that the 20-year term does not apply to any biotechnology patent applications pending at the PTO and that biotech firms do not lose patent term with the shift of the 20-year term. And I think implementation of the PTO of the recommendations on the utility and other issues that you will hear about will go a long way to ensure that the patent term is not in fact lost.

Those are the issues that I have -- at least want to highlight for you. Obviously, the PTO can play a major role in providing the protection in which this industry is entitled to under current patent laws. We really welcome your visit here to San Diego. We thank you for your openness to the initiatives that will be talked about today. Thank you so much for getting me on.

COMMISSIONER LEHMAN: Thank you very much, Congressman Filner, and I really appreciate your looking into these issues and we will work closely with you to make certain that the interests of the biotechnology industry are taken care of in the Patent and Trademark Office in all the policy decision. And anyone that represents a constituency where there are 14,000 jobs in biotech certainly has a strong incentive to work with us and I'm really looking forward to having a friend in Congress next year.

CONGRESSMAN FILNER: Thank you so much.

COMMISSIONER LEHMAN: Thank you.

Next, Jerry Caulder.
JERRY CAULDER, MYCOGEN CORPORATION

MR. CAULDER: I assume since I've been introduced I get twice as much time; right? Wrong.

Good morning. I'm Jerry Caulder, Chairman and President and CEO, of Mycogen Corporation. We certainly appreciate this opportunity, as Bill and Ken, to have you come to California and let us talk to you about what we're trying to do in this industry to turn our products into jobs.

By way of background, I grew up on a cotton farm in Missouri and I've been involved in agriculture all my life, and we're the only agriculture biotechnology firm here in California. I also served as chairman of bio trade organization, Industrial Biotechnology, for three years, so I worked early on in getting the Patent Office and the trade association working together about eight or nine years ago in the problems that we were having. So this is certainly not new to me and I certainly appreciate the opportunity to see that we're continuing to do this. I know I worked with Charles Van Horn quite a bit when Don Peterson was there.

I've been CEO of Mycogen since 1984. That's almost as long as some of our patents pending, so I do know that we have some and this 19-month thing is kind of interesting to me. We're a diversified agriculture company. We're basically in the business of developing alternatives to chemical pesticides using recombinant DNA and using biotechnology.

We're building our business around these genetically engineer microbes so that we can have substitutes for chemical pesticides, and we're commercializing these things through two basic delivery systems that we consider breakthroughs: One is Mycogen's proprietary cell cap system which is a delivery system that allows us to efficiently produce these insecticidal proteins that we then put in microbes and then we put these on plants to keep the plants from being harmed by particular insects that are present there.

We are the first company to receive EPA registration for products that are genetically engineered as alternatives to chemical pesticides. And I would say that the question that you asked Doctor Widder about the length -- it is not just the FDA, we also have delays in EPA, and USDA. So, I would suggest to you and submit to you that anything that -- and we don't want to delay the patent situation, we want to speed up the regulatory situation, so don't confuse those two. We would certainly like to get our patents as quickly as possible because it does allow us to establish our property rights. And I would suggest that the patent starts when you get regulations, if you're delayed in any of the regulatory arenas. Because this does put us behind the eight ball when you get a patent and then you spend 10 more years getting it through the EPA, so you've used up most of your patent life.

I think the spirit is you have 17 years of monopoly for marketing your product so I think the regulatory delay was totally unanticipated.

COMMISSIONER LEHMAN: I should point out that's one of the weakness of the existing patent term extension legislation. It's called "the drug price competition," a patent term extension legislation and it doesn't deal with EPA delay, and this might be something that we would want to look into to see that we deal with that problem as well.

MR. CAULDER: Well, agriculture, as you know, is the Rodney Dangerfield of biotech. Drugs get all of the play and we are not unincumbered by revenues. We are making money. We are one of the profitable companies so we feel that agriculture should be specifically addressed because our needs are different.

COMMISSIONER LEHMAN: Having grown up in Wisconsin, I'm very sensitive to agriculture.

MR. CAULDER: Good. Good.

The second thing we're doing is transforming plants, particularly cotton and corn. We're putting genes in these plants that protect them against insects and we're using these as alternatives. Two weeks ago we filed for an experimental use permit that would allow us to test our first genetically engineered corn plant that's resistent to European corn bore, and we hope to receive that registration pretty sure so we can get into field tests. We do not have our patents covering that yet.

We spent over 12 years and tens of millions of dollars developing our technology and we recognize that the Patent Office is faced with an unprecedented number of broad, fundamental biotechnology patent applications representing inventions that we think have truly opened up many new fields in agriculture, pharmaceuticals, medical devices, and other industries. These inventions and their related patent applications represent pioneering, next generation technology. They are not incremental improvements to old technology but rather whole new fields.

Many of these patent applications have been under examination for five, ten, even more years. We ask they question, why is it taking so long? I think there are fundamentally two reasons: One is a reluctance now to grant broad applications in this area. This is influenced primarily by the fact that the fundamental nature of many of the biotechnology inventions are being evaluated in hindsight. You mentioned you have a lot of new patent examiners with advanced degrees. Many of them were still in high school when we applied for some of these patents and we are very biased by this area in which we live. So the things that we are doing today may look obvious but 10, 12 years ago they were not quite as obvious. Some of the things it took a post-doc to do 10 years ago high school kids can do today.

Second, the Patent Office is not consistent in applying the fundamental standard of patentability. Patent law requires that to have a patentable invention you need to satisfy two things:

One, the claimed discovery must be unobvious to a person of ordinary skills, and I emphasize "ordinary skills," in the art. In other words, the discovery can't be easy and it can't be obvious to figure it out.

The second is the description of the invention in the patent must be sufficiently detailed to teach a person of ordinary skills the claims of the invention. This is where we think a problem comes in. On the front end of the invention, of determining whether the invention was easy or obvious to figure out by a person of ordinary skills, that mythical person of ordinary skills is presumed to be damn near a genius. On the back end, however, once we have convinced you after four or five years that there is truly an invention, this person is viewed as nearly

incompetent. So, in order to get a biotechnology breakthrough recognized as an invention, you have to have a real stroke of genius, argue the point for five or ten years, after you have convinced the examiner that you have an invention the scope of your claimed invention is then narrowed because some mythical person of ordinary skill is not viewed as being competent to apply it, this breakthrough, across the board.

The benefits of the true pioneering nature of these biotechnology inventions are being lost by the companies, and these are the small companies, not the large ones, I think, and I'm biased toward that, who are responsible for these inventions. The patent process is biased against us. Consistency by the patent office in applying this standard of ordinary skill I think is the single most import element to patenting biotechnology innovations and inventions. Consistency on this issue would help the ability of our industry to attract the financial and people resources that you've heard both Ken and Bill talk about earlier.

Thank you very much.

COMMISSIONER LEHMAN: I take it that the problem here, from your point of view, is that you get some -- when you say "consistency" is really the issue, you get some examiners who have a unrealistic view of what is ordinary skill in the art, and so it's a little bit Russian roulette, is that the problem?

MR. CAULDER: It comes from this hindsight thing. If you have someone who has recently gotten a Ph.D or a postdoc in biotech, or a master's degree, they view biotech -- and they're 22, 23 years old, maybe 25, they view it very differently than the pioneering people who made the invention in 1980.

COMMISSIONER LEHMAN: I see.

MR. CAULDER: So to get them to look at the context of the invention as it existed in 1980, rather than 1994, is a big problem.

COMMISSIONER LEHMAN: I understand that. And you find that with the younger examiners who come right out of --

MR. CAULDER: Well, I don't want to categorize it. My personal opinion is all of us have that problem, that when you are totally emersed in something you tend to judge it the way it is today rather than the way it was submitted to you 12 years ago.

COMMISSIONER LEHMAN: Okay. Thank you very much.

MR. CAULDER: Thank you.

COMMISSIONER LEHMAN: Our next witness is Dave Gollaher from California Health Care Institute.

DAVE GOLLAHER, CALIFORNIA HEALTH CARE INSTITUTE

MR. GOLLAHER: Thank you, Commissioner Lehman, for presenting us with this opportunity to give you the perspective of our industry. What I'd like to do this morning is open up the lens and talk about the perspective of California as a whole when it comes to biotechnology and what we see as the broader collection of health care technology industries that are becoming so important to the state's economy.

I'm David Gollaher. I'm the director of the California Health Care Institute which is an organization of some 80 research universities, private research institutes, like Scripps, and La Jolla Cancer, biotechnology companies like many of the ones that will testify today, as well as pharmaceutical and medical device firms who have a significant stake in the State of California.

The State of California is interesting economically in the sense that if California were a separate nation it would be the sixth largest economy in the world. It would be the seventh largest trade export economy in the world, so its magnitude makes it virtually a nation state, and yet the interest of the emerging biotechnology and health care technology companies in California have, it seems to many of us, received less attention than their economic scale merits.

What I would like to do is briefly review a couple of statistics from a report that we're in the process of preparing to be released next month on the current state of the industry with respect to jobs, employment growth and it's overall scope and scale in the California economy.

To begin with, in 1993 alone California companies in the broader area of biotechnology invested more than $2 billion seeking solutions to diseases like AIDS, cancer, heart disease, genetic disorders like cystic fibrosis, and multiple sclerosis, Alzheimer's, et cetera.

By and large, biotech -- let me just skip ahead because I realize in summarizing this report that I'm not going to be able to make my time. I'd like to start with our estimate of current jobs in California this year. We have estimated in our report that approximately 111,000 Californians are directly employed by organizations developing diagnostics and therapeutics using recombinant DNA technology as well as other technologies that are largely labeled biotech.

In addition, there are 33,000 Californians who work in health care research in the life sciences at major universities and federal facilities within the state. In fact, the University of California alone

accounts for nearly 22,000 jobs in biomedical research and an additional 8,500 people are employed at the California Institute of Technology, Stanford, and the University of Southern California.

If you look at direct employment in the health care technology industry in the state, you see that already in 1994 health care technology jobs -- 111,000 jobs -- place the industry ahead of aerospace, ahead of computers, and not far behind electronic components. In other words, this industry which is growing quickly will soon overtake aircraft with its 150,000 jobs as a major backbone of the California economy.

What makes the industry all the more attractive is its annual average salaries. Currently, pharmaceutical manufacturing and biotechnology salaries in the State of California average over $43,000 a year which puts them far in advance of average manufacturing salaries at $33,500 a year in the State of California. Because it's based on information and knowledge, biotechnology and health care technology is exactly the kind of industry that the administration has pointed to as an industry of the future; high tech, high growth, information-based jobs.

Manufacturing employment for pharmaceuticals and medical devices is up 45-percent since 1984, up 45-percent, in other words, during the past decade with direct employment in those sectors at 70,000 plus jobs. In fact, by itself the manufacturing segment of the health care technology industry will likely employ more than 100,000 Californians by the turn of the century.

If we look not only at the direct jobs, though, but look in the spinoff jobs, the spinoff technology that sort of ripples around the center in areas like construction, we can see that the health care technology industry accounted for $2.4 billion in new construction in the period from 1987 through 1992, and over the next four years that amount is expected to increase to $3.7 billion. Again, this is in marked contrast to California's overall construction picture which has reflected the downturn in the aerospace and defense-based industries that sustained California after World War II.

In terms of revenue growth, revenues for the 142 largest California health care technology companies increased by nearly $2 billion to $13 billion for 1993 despite a general decline for many high technology industries. Much of the gain can be attributed to new products in the biopharmaceutical sector. In fact, 47 biopharmaceutical companies reported revenues of $3.57 billion in 1993. This is up almost $800 million, even though we've read many reports that the biotech sector is having trouble attracting new capital and has been having trouble meeting its cash flow needs. Nonetheless, even in the overall context of a down economy, it has managed not only to hold its own but to grow in California during the past year.

Finally, health care technology companies spend more of their revenues on research and development than virtually any other industry. So the industry is a very good investment with respect to its spinoff revenue. In fact, biotechnology spends three times more than any other high tech industry and five times as much as the U. S. average on R&D as a percentage of its revenues.

How am I doing on time? I have two minutes.

I guess I would like to close in saying that we had a board meeting a couple of days ago, a roundup, a biotech meeting that happens once a year in Laguna Niguel, and it was the strong consensus of our board of directors and most of the chief executive officers I talked to there to support the GATT treaty in its current form and to -- in fact, we wrote a letter to all members of the California delegation urging them to support it in the lame duck session which is coming up. Our attitude was that the treaty is far from perfect but that we should not let the perfect become the enemy of the good, and that the potential for biopharmaceutical companies to realize gains with the lowering of tariff barriers represented by GATT far outweighed some of the intellectual property and patent term concerns that many companies had. As Doctor Widder said, most biotech companies are not embarrassed by revenues but they all hope to be soon.

Thank you.

COMMISSIONER LEHMAN: Thank you very much. That was really helpful testimony and I'd really like to have a copy of those statistics that you gave us.

MR. GOLLAHER: We'll provide a copy of the report. It will be published within the next 30 days.

COMMISSIONER LEHMAN: Great. Because that really -- you know, in going around the country, Secretary of Commerce Ron Brown and myself and others have been making exactly those points that you've been making; that this is where the jobs are; this is where the growth in the American economy is and we really have to fine tune that economy to support everything that you're -- that industries like the ones you've described are doing. That's why we're here in San Diego, to listen and see what we can do to adjust public policy to give you all the support that you need. So thanks very much.

MR. GOLLAHER: Just a follow-up comment. We found in talking with members of the congressional delegation that over time there's been a kind of automatic response on the part of every member of the delegation to classical California industries -- defense, movies -- so that when

issues about those industries come up they're automatically interested. That hasn't been true up to now with biotechnology but it should be, and we're working hard to make that the case.

COMMISSIONER LEHMAN: Thank you very much.

Next I like to call on Bernie Rhinerson of the Biomedical Industry Council of San Diego.

BERNIE RHINERSON, BIOMEDICAL INDUSTRY COUNCIL

MR. RHINERSON: Thank you very much. I'm also going to give you a little bit of background about the industry here in San Diego. Much of what I was going to say has already been mentioned by previous speakers, so I can be brief.

I want to thank you for coming to San Diego on behalf of the Biomedical Industry Council. We're a local trade organization that's associated with BIO at the national level. We work closely with Mr. Gollaher and the California Health Care Institute, and other trade associations. We represent about 60 local San Diego biotechnology and medical device companies. We range in size from very small companies urgently in need of patent protection with employees of less than 20, somewhere 10 to 20 employees, very small start-up firms, to companies that have manufacturing operations and sales with 500 to 1,000 employees.

Biotechnology is very important to this local area, to San Diego. You've heard that mentioned. We have over 100 companies here and we estimate, as you heard earlier, about 14,000 employees, and we expect that that could grow to 30,000 to 40,000 employees here locally by the turn of the century.

Nationally, according to the Ernst and Young report, Biotech '94, San Diego ranks fourth in the nation as a concentration of publicly held biotechnology companies. In 1993 alone approximately $223 million was spent in our local economy on research and development, and that was just by the publicly held companies alone. To that number you have to add tens of millions of dollars that were spent by companies that have not yet gone public that are working with venture capital, and moneys spent by our public and private research institutions.

San Diego is a hotbed for biotechnology research, specifically because we are graced with excellent research and university institutions in this area: The University of California at San Diego; UCSD; the Salk Institute; the Scripps Research Foundation; La Jolla Cancer Research, just to name a few. These institutions are the principal sources of the ideas that come out into commercial biotechnology ventures and become start-up companies here in San Diego and elsewhere in the nation.

Protecting those innovations as they move from those initial stages into the commercial ventures is very critical, and that's of vital interest to us here in San Diego. We're working very hard here at the local level to continue to help these companies grow and to take these ideas into research and into manufacturing. You've heard one of the concerns here about the waits that these companies experience with FDA approvals and that has been a concern that they're not penalized for that wait for patent protection. The Patent Term Registration Act is a partial remedy to that problem.

We're also working hard with local companies to help them to be in manufacturing here locally so that they don't have to move that manufacturing process offshore and into other companies; they have to compete in a global marketplace and it's very important that patent protections be applied to manufacturing processes also.

Here locally, over the last three years, many companies have began to move into that manufacturing process. Several companies have built major manufacturing facilities here in San Diego: IDEC who you heard from earlier, Telios, Tenomi Research have all built facilities that represent millions of dollars of investment in research and manufacturing.

Basically I'd like to just end with those remarks and thank you for being here, and we appreciate your interest.

COMMISSIONER LEHMAN: Thank you very much, Mr. Rhinerson.

Next I'd like to call on Bill Otterson from the National Cancer Patients Association.

BILL OTTERSON, NATIONAL CANCER PATIENTS ASSOCIATION

MR. OTTERSON: Good morning and thank you very much. I am Bill Otterson and I'm a spokesperson for the National Association of Cancer Patients. We were asked by BIO to speak to you today from the standpoint of cancer patients, not from the companies but from the ultimate beneficiary of patents. I'm certainly not an expert in the arcane rules of the Patent Office but you might be surprised to learn that patients support patents. Perhaps we have a broader view of patents as benefitting us. Without patent protection, we cannot expect biotech companies and medical research institutions to put in the enormous amounts of money that they must do after the research is done at a SCSD or UCSF or whatever, so we do understand the need for patents.

I take alpha interferon and, as you all know, the alpha interferon -- I take it three times a week. I am a cancer patient myself. I've been taking it for three years. This is an outgrowth of the recombinant DNA

patent initially issued I believe to UCSF and to Stanford which then became the basis for Genetech's work in recombinant interferon that was then passed on to Hoffman-La Roche. My bottle was produced in Switzerland at Hoffman-La Roche.

What I would like to say is that these companies are permitted extended timed to enjoy the benefits of their research, an extension for regulatory delays through the FDA, which I understand you are looking at, and perhaps extending to 20 years the time that the companies will have protection. You might say but that's going to cost you more as a cancer patient. I think we all understand that the free market -- you may give 20-years protection but just at this time other people are working very hard to develop alternative interferons and the free market will surely chase Hoffman-La Roche to produce better and faster interferons. Thank you very much.

COMMISSIONER LEHMAN: Thank you very much, Mr. Otterson. You're sort of speaking to the converted on this point about the importance of patent protection, but I think one of the things we will consider very seriously as a result of this hearing, assuming some of our other legislative reforms passes, is a revisitation of the patent term extension legislation. But I can tell you right now that there are going to be people on the other side that are going to say, no, you know, we need more generic drugs, and they're going to be representing themselves as being from consumers, just like you. So I think people just like you are a very important linchpin of this, and there undoubtedly will be a big fight over that. But already I think we're starting to hear that the existing drug price competition and patent term registration legislation is not adequate to deal with the problem so we'll be wanting to work with you and others as we move on studying that issue. Thanks.

MR. OTTERSON: I am available to testify whereas and if you would like me. Thank you.

COMMISSIONER LEHMAN: Thank you.

Next I like to ask Eugene P. Schonfeld from the National Kidney Cancer Association to come forward.

EUGENE P. SCHONFELD, NATIONAL KIDNEY CANCER ASSOCIATION

MR. SCHONFELD: By way of introduction, I am a cancer patient. I've also founded five high tech companies, although not in the biotech or health care area.

Patent policy in biotechnology is extremely relevant to the well-being of patients with cancer, Alzheimers, AIDS, and other life-threatening illnesses. Patent policy can speed scientific progress or retard it,

accelerate products to patients or delay cures. Therefore, as health care consumers, patients cannot be indifferent to the work of the Patent and Trademark Office. If these folks are your customers and users, I'm your shareholders; you work for me.

Sometimes we find people in government get confused about that, as to who they are supposed to be working for, so I just want to take a moment to remind you. When patent policy is either too restrictive or too lax, corporate managers and outside investors would be less willing to commit capital to research and to research intensive ventures. At the same time, if it's -- well, too restrictive or too lax, either way it's no good.

What we're looking for is a patent policy that maximizes the value of invention and stimulates the process of innovation.

The second thing I would like to recommend to you, from a patient's point of view, is that you should make all patents for life -- or patent applications for life saving inventions special and treat them as a special class of patents. The public has a unique and special interest in such inventions as opposed to inventions which are purely, shall we say, commercial. There is a significant precedent for doing this. During the Carter administration, at the time of the energy crisis, certain patents for energy conservation inventions were treated as special patent applications, and I think the public deserves no less today when it comes to life saving innovations. We must remember that moving these things to the public faster will help reduce our health care costs. President Clinton tapped into the latent discontent of many Americans when he proposed health care reform and he's expressed his concern about health care costs. I believe the Patent and Trademark Office can help address this issue by moving life saving inventions through the system faster.
The second thing I'd like to comment on is the whole question of practical utility and clinical trial data. It's very nice for a patent examiner to have before him extensive clinical trial data. Unfortunately, he usually doesn't have it. In fact, there is the whole question of whether clinical trial data should be the basis for approving a biotechnology patent.

In recent times, the FDA itself has moved away from using clinical trial information as the gold standard for FDA approval of drugs. In fact, the FDA in the case of AIDS has moved to surrogate markers, surrogate end points and other ways of looking at application for marketing drugs.

I believe the patent office itself needs to also think along similar lines as to what end points and markers might be an adequate substitute for clinical trial information. The reason it should do this is that clinical trials, as we know them today, are, frankly, becoming obsolete.

The National Kidney Cancer Association started a research project three years ago to try to develop technology which would allow physicians to better match specific therapy to a specific patient, rather than simply saying the average response rate for a drug is, you know, 20-percent. What you really care about is whether you are one of the 20 or one of the 80, if you're a patient.

What we need to develop is patient specific therapies and techniques and technologies which will allow us to move away from the time-worn clinical trial paradigm which only deals with average response rates. In doing these things, the Patent Office should accelerate the approval of patent applications for life saving inventions.

Let me sum up by saying that we really think of a number of different goals for the Patent and Trademark Office. First, the development of a patent policy which maximizes the value of patented inventions, a policy which is neither too restrictive nor too lax.

The second is to adopt a policy of making special all patent applications which involve life saving inventions and, in so doing, accelerate the patent process for these inventions.

Operationally, the Patent Office needs to beef up the corps of biotechnology examiners, particularly retain them. As I understand it, there's a significant employee retention problem within PTO in this area.

Also it needs to develop, as I say, a system of standards moving away from clinical trials, making clinical trial data less important in the approval process. It needs to develop surrogates perhaps to do this, and perhaps it needs to even reach outside and build an advisory board which would advise the Patent and Trademark Office on the use of surrogate end points and surrogate markers. There is I believe expertise in the outside world related to this and it may be beneficial if the examiners had an external group to go to in developing a comprehensive system of surrogate end points and markers. Thank you.

COMMISSIONER LEHMAN: Thank you very much, Mr. Schonfeld. I would like to just point out that we do actually at the present time have a system whereby biotech applicants can make their cases a special case. If they're a small business, which is still a pretty big sized business, it's up to I think $5 million in revenue and 500 employees, just for a $65 fee you can expedite your case. And we're finding that only one and a half of one percent of the applicants are doing this, even for big companies. It's only --

MR. SCHONFELD: Well, I should tell you something. As a manager, you know, I believe that the specialness of something should not be related

to the size of the company.

COMMISSIONER LEHMAN: I said for a big company it's $135.

MR. SCHONFELD: I see.

COMMISSIONER LEHMAN: So, in other words, everybody, every patent applicant can make their case special. It's just we have a two-tiered fee system. You know, we have a -- for all the fees. It's half for a small company. In effect, the big companies help to subsidize the small companies, but for $135, even if you're Hoffman-La Roche, you can get your application special.

MR. SCHONFELD: Can you tell us what the time length is for those patents to move through the system?

COMMISSIONER LEHMAN: Well, there --

MR. SCHONFELD: As I say, we judge by results, not effort.

COMMISSIONER LEHMAN: As I indicated, you know, the average is 20.7 months for all biotech patents, so presumably, if you've made yours special, it's even less. But, you know, I didn't want to have an argument about it. I just wanted to point out that we've already done that. But I would point out that you're absolutely on target in that we have to have the resources necessary to do this job, and that's why I mentioned -- everybody wants to criticize us and so on and so forth but there are things that we can do and will do as a result of this hearing.

Internally, we will make changes in our internal policies but there are some things that we cannot do without help or without permission from our board of directors, and, in effect, our board of directors is Congress. And you've already heard it said that $30 million a year are being siphoned off of our fee revenues -- $30 million a year that could go to providing better biotech patent examiners in this area.

In addition to that, we have had imposed upon us a reduction in the number of employees. We're one of the few growing businesses in America probably that's fully supported by revenues. Every time you file a patent applicant a check comes along -- a patent application -- a check comes right along with the patent application to sustain doing the business and yet we find that we have some arbitrary limitations being put on us in the number of examiners that we can hire simply because of government bureaucracy. So I think organizations like yourself need to work with us so that we can go to these outsiders that have some impact on us and -- to enable us to do our job better. So hopefully we can work with you on not only making these changes, which will be made, we're going to make some changes as a result of these hearings. We're going to

propose legislation probably as a result of these hearings, but there are things that we are going to need help from the outside and what we'll need are customers like --

MR. SCHONFELD: I've twisted a few arms on Capital Hill. I'll be happy to twist a few for you.

COMMISSIONER LEHMAN: Great. Thank you very much.

Next I'd like to call on Martin Simpson from the Office of Technology Transfer, University of California.

MARTIN SIMPSON, UNIVERSITY OF CALIFORNIA

MR. SIMPSON: Thank you for coming to listen. Universities license their patents in order to get them commercialized so a strong patent system is essential to having technology transfer work properly from a university. In addition, when we're talking about resources, over 80-percent of our licenses are to small businesses so resources are a problem for our licensees as well.

When you're talking about the first topic of your Notice about practical utility of biotechnology inventions, you have Brenner v Manson stating that any substantial or practical utility is enough. And that traditional chemical standard we would urge would be something that is predictable and it will permit people to make investment decisions on pending cases.

University inventions are frequently at an early stage. When you're talking about utility, you can have utility in the research market; you can have utility in a diagnostic market; in a vaccine market or in a therapeutic market. But when you're talking about university inventions that are early stage, you're talking about things such as assays that may be detectors; you're talking about things that may be screening tools; you're talking about things that may be probes with fluorescent markers on them. If they're being used as a tool and actually showing that something is happening, that's not simply research. When you're talking about early commercialization, one of those characteristics is no or minimal FDA approval; one of them is much less investment for a return and you see, from a university point of view, our commercialization is through finding licensees, that's why this is important; therefore, it's a lower barrier to finding licensees.

If you have early commercialization, you have an early utility supporting work on a later utility, thus the adverse effect on university licensing by demanding what one could call the highest utility is you decrease the number of licensees we can find because of lack of available patent protection and you also mean that our programs will have fewer big

hits, which help pay for the programs.

One of the things that happens is that if -- Licensing of patents is a very empirical process so you get them out there, you license them and some of them work and some of them don't when people start trying to develop the technology from the early stage, typically at a university.

When you talk about the topic of "Proof of Operability for Human Therapeutic Inventions," I come back to the theme you'll see running through it about the chemical art as being your guide, but the key is predictability. And if you have in vitro data that is predictive, why isn't that sufficient for a minimal standard? If you have animal data that is predictive, why isn't that sufficient? If you have human data short of an FDA efficacy showing, why isn't that predictive? It is in the chemical arts. And when you're talking about FDA showings of efficacy you have to remember those are very highly stylized: they have a certain dosage given certain lengths of time and they can't vary it in the middle of the proceedings. It may be also that they show growing hair on bald men in the middle of the process that may be another utility. So, again, you just have these adverse effects if you decrease the available patent protection by how the system is operated.

With respect to the next topic of "Nonobviousness and Enablement," I have to agree with the chairman/CEO of Mycogen that we're seeing that instead of treating these as straight chemical art, you're seeing that there's increasingly narrow room between enablement and utility. And if you get it so narrow that you have virtually no protection available then that means that you either get a narrow patent through the system or no patent through the system and, again, that doesn't call forth the venture capital needed to fund a new invention through development.

With respect to pending legislative patent reform, the 20-year term is a disproportionate disadvantage in biotechnology. There is frequently lengthy prosecution and, as in the Mycogen case, we are seeing very lengthy prosecutions, far beyond the 20 months you're talking about. We see frequently interferences. We've been in multiple- party interferences. We see also -- frequently on appeal in this area of developing law -- and you also run into a disincentive in pioneering cases if the patent examiners are, in essence, nervous about issuing broad claims.

With respect to prior users rights. They are really the antithesis of the patent system. You've got somebody who decided to keep something secret instead of doing what the Supreme Court termed in Brenner v Manson, that it's the incentive to disclose, not the other way around. That's, in essence, a royalty free compulsory license.

With respect to restriction practice. One of the things that's

happening there is that by saying you get a 12-way restriction and when you try to talk to the examiner about, well, can't you group these together and can't you group these together, and they say, no, what you're doing for either a university, such as we are, or for -- with our over 80-percent licensees who are small businesses, you're telling them that you've going to have to spend a lot more money for that patent application to get that coverage that you tried to file for. And if you go to a 20-year term, you're also saying you have to spend it simultaneously instead of stretching it out if you really want that protection.

With respect to broadening patent term extension. We would suggest that with respect to these things like lengthy prosecution, interferences, appeals, and so forth, so that when somebody runs into a longer process than is normal that there is some provision for patent term extension. Also, the patent is the right to exclude others. If you effectively don't have the right to exclude then the question becomes: What right do you have? So some thought, we would suggest, would be given to some form of patent trial court or something that would be speedy and inexpensive, moreso than the current process. Also, I want to say thank you for keeping "first to invent."

With respect to the experimental use defense. Basically the comment is, please keep 271(e) narrow.

With respect to plant patent issues. Recently plant variety protection was amended to include the harvest products, such as fruit as well as parts of the plant down to cell lines. We would ask that that be done for plant patents asexually reproduced as well. Also add import and export as they are for plant variety protection and for asexually reproduced plants.

The University of California is into about every kind of technology you can think of so whether it's agriculturally related or it's straight biotechnology into pharmaceuticals for humans, we're into all of it, so we're interested in a very strong patent system, and we very much appreciate your coming to listen. Thank you.

COMMISSIONER LEHMAN: Thank you very much. First, I'd note that the University of California has a very effective Washington operation and, you know, you might want to work with them a little bit and work with the California delegation on perfecting some of these ideas that require statutory approval. You know, we can do that, the administration can submit legislation but obviously you are another venue there, I just point out, to work with.

I had a question about -- getting back to this utility issue, really, which I could have asked other witnesses too, but assume hypothetically

that we adopted a presumption that the utility standard had been met with some very low threshold.

One of the problems that I feel that we have is that we could, in effect, almost do away with it, I mean, internally in terms of our examining procedures. But then the problem is we issue the patents; they get out to the court of appeals for the Federal Circuit and the court of appeals for the Federal Circuit overturns one of our patents that we issued because we haven't met the utility standard. That's where we're really getting this from, we're getting it from the courts. That tends to run a little counter to the notion that what you really need is a patient that you can take into the marketplace, that you can take to the bank. So I'm wondering what kind of thoughts you have in dealing with that. If you could ask us to do anything -- I mean, would you be satisfied if we simply -- if we administratively in the Patent and Trademark Office established a presumption of utility and then we I guess would fight it out in the courts.

MR. SIMPSON: I think we would because right now what's happening is that we're spending a lot of time on the subject and that takes away from the resources up front where you have nothing on the market with your licensee, and what you're doing is spending a lot of time worrying about the topic when you would rather have the time spent later on where there are a lot of resources if it's successful.

COMMISSIONER LEHMAN: Thank you very much.

MR. SIMPSON: Thank you.

COMMISSIONER LEHMAN: Next I'd like to ask William Beers from Scripps Research Institute to come forward, please.

WILLIAM BEERS, SCRIPPS RESEARCH INSTITUTE

MR. BEERS: Mr. Lehman, members of the panel, I'd like to thank you for this opportunity to come here this morning.

I'm the senior vice president and chief operating officer at the Scripps Research Institute. The Research Institute is a non-profit biomedical research operation. We have over 200 individuals that if we were a university you would consider faculty. We have in total about 2,000 employees and of those more than 700 are at the Ph.D. or M.D. level.

We get a lot of government support for our research and most of that comes from the National Institute of Health. What that means is that our technology transfer, which we very aggressively pursue, is governed by the Bayh- Dole Act which was passed in 1980. And, under Bahy-Dole, an institution such as ours, which is in receipt of federal funds, may elect

to retain title to discoveries made with those federal dollars. If a decision is made to retain title, the institution must be able to demonstrate that it is duly attempting to convert the discovery into a product. And at the Scripps Research Institute that conversion is accomplished by licensing discoveries to for profit entities for further development.

Now, in order to be licensable, the discovery must be protected by a patent. Without that protection no company will try to develop it. Now, with that as a background, I would just like to comment on a couple of issues that are being raised here this morning. The first has to do with what should a patentable invention be in biotechnology. My research institute is in the business of basic research, we are not in the business of developing technology. And, as I indicated, a strong patent system is what makes our technology transfer system work. That is, if we are able to license our technology it must be covered by a well defined patent. As I said, the ability to license provides us with our means to comply with Bayh-Dole.

We believe that this means that patents should not be issued for ideas or for discoveries before use is known. If ideas become patentable a restrictive and counterproductive research environment will result. Consequently, we strongly endorse and support a historically consistent view that the utility requirement should remain for biotechnological inventions.

The second issue I'd like to touch on is that of proof of operability for human therapeutic inventions. In an academic research environment such as ours, timely publication of results is terribly important. Consequently, it is also important if technology transfer is going to occur that patents be issued relatively early on, that is once the plausibility of operability has been demonstrated in vitro or in vivo but non-human models' systems. In essence, that is to say when it's fairly clear that there is good predictive data available.

If proof of operability would have to wait for complete or advanced human trials, the pressure the academy puts on rapid publishing would likely put the information in the public domain and thereby deny exclusivity which is an important engine driving technology transfer. Indeed, it's next to impossible to license technology that is not protected by a patent. We have been in that position a few times and it's terribly, terribly hard. It simply isn't worth the risk to industry. Consequently, this situation would terminate the development of promising but not necessarily fully proven therapeutics when the original findings emerge from an academic research environment.

Thank you very much.

COMMISSIONER LEHMAN: Thank you very much for those statements, Mr. Beers. I'm glad you brought out the connection between NIH funding, Bayh-Dole Act, an institution like yours and the commercialization of the technology. I think it does point out that we are capable from time to time of making adjustments in the system that works, and that's one that has worked pretty well. And actually I was involved in that myself back when it was enacted in I think it was 1978. I think roughly 1978.

MR. BEERS: That sounds about right.

COMMISSIONER LEHMAN: That's when I was counsel on Capital Hill. Thank you very much.

Next I'd like to ask Douglas Obenshain of Ernst and Young to come forward, please.

I really want to thank our witnesses for being cooperative and moving right along because we're on schedule. We're actually a little bit ahead of schedule so it will help us get through our 57 appearances that we have today.

I guess Mr. Obenshain isn't here. How about Kathy Behrens?

KATHY BEHRENS, ROBERTSON, COLEMAN and STEPHENS

MS. BEHRENS: Thank you. You've heard a lot of numbers, you're going to hear a few more, unfortunately.

I'm Kathy Behrens. I'm a managing director with Robertson and Stephens and Company. Robertson and Stephens is an investment banking firm focused on providing investment banking, brokerage, money management services and venture capital to emerging growth companies and investors. The company manages approximately $1.2 billion in public and private equity funds. And I would add that my comments reflect both the views of the venture group at Robertson and Stephens as well as the investment banking group.

By way of introduction, as everybody in this room knows, patents play a fundamental and a critical role in the availability of capital and willingness of institutions and individuals to invest in biotechnology. They are as important as any factor in the decision to invest in any idea, entrepreneur or company in this field. The reason for such dependency upon patents is that the provide the favorable economics required to justify substantial capital investment for successful product development.

Historically, biotechnology companies with successful proprietary products have generated significant products' sales levels during periods

of market exclusivity yielding considerable profit margins and high returns on investment. These returns have been necessary given the significant level of risk associated with technology development, regulatory hurdles, clinical testing demands, limited availability of capital and prolonged product development cycles.

While most of the historical information accumulated for this industry has been generated by human pharmaceutical and diagnostic products sold both by biotechnology and pharmaceutical companies, there remains a tremendous commercial opportunity in other areas such as animal and plant of schedule so it will help us get tagriculture. The substantial level of private and public investment in biotechnology made over the last 15 years has accelerated technology development and enhanced U.S. competitiveness.

Over the last two years, considerable new pressures have been exerted upon young emerging biotechnology companies. Enormous uncertainties associated with health care reform and unrealistic performance goals related to quickly moving products to market have contributed to disappointments with this industry by the private and public markets. As a result, capital investment is down from prior years. Additional uncertainty is now being generated by the proposed patent changes included in the general agreement on tariffs and trade. Any alteration of patent practice that might shorten the current period of exclusivity or increase the magnitude of capital required to develop or protect products will have a negative impact on the availability of capital for biotechnology. The cumulative effect of such proposed changes and preexisting market uncertainty could be devastating.

Let me get to a couple of numbers now. Patents have made a significant contribution to the emergence of multiple successful, vertically integrated biotechnology companies. The most mature of these include Amgen, Chiron, Genetech, Byogen, Genzyme, and Immunex which generated combined 1993 product-associated revenues of $3.1 billion.

Sales of the biotechnology industry exceeds $7 billion a year, with 12 biotechnology products contributing estimated 1994 worldwide sales booked by biotechnology and pharmaceutical companies in excess of $4.5 billion.

Since 1980, over $4 billion in private equity has been raised for more than a thousand privately held companies. However, in the first nine months of 1994 the investment rate has been down considerable compared with 1993, and the year will probably close with the lowest amount of private capital invested in biotechnology since 1985.

I have included in the text of my comments a summary of every year since 1980: the individual year, the amount of dollars invested by the private industry, and the number of companies that have been financed in that

time period. And what I, unfortunately, do not have a slide for and that I was making reference to is that through the 5th of October, 1994, the invested dollars by the private sector has been about $168 million compared with close to $494 million for the full year 1993. While there is a considerable lag in generating those numbers in the private industry, it's pretty clear we're going to be at half and perhaps lower than half of the prior year.

Now, getting the public market sector for a minute. Nearly $10 billion in capital has been invested since 1980 by the public equity markets into more than 300 biotechnology companies. The public market investment rate in biotechnology is also down in 1994, as is the number of companies financed and the average offering size. The 1994 public investment rate will probably be the lowest in the last four years. And, similar to my last comments, I've got text that includes a chart showing all of the dollars raised since 1980 in yearly aggregate and the number of companies and the average offering size for those companies.

To give you just 1994 compared with '93, through September of 1994 the public market equity invested in biotechnology is approximately $826 million compared with the full year of 1993 of $1.5 billion. The number of companies is 37 compared with 53 in 1993, and the average offering size in 1994 is $22 million versus $29 million in 1993.

As I mentioned earlier, several factors have contributed to the lower 1994 public and private investment activity in biotechnology companies. In somewhat greater detail, these factors include investor uncertainty due to health care reform and the associated negative impact upon pharmaceutical products and companies; product development disappointments related to aggressive forecasting and the urgency to speed biotechnology products to market; and the large number of biotechnology companies formed between 1991 and 1993.

In addition, the declining availability of public market capital to an ever shortening list of biotechnology companies has had a significant cooling effect upon the private equity sector in 1994. Furthermore, the complexity and cost of establishing and maintaining proprietary product positions is also taking a toll on the industry. In the venture arena, the magnitude of investment -- capital investment -- is high and the duration of biotechnology is long due to both the technology development required and the high product fall-out rate prior to reaching market. As an example, the average biotechnology venture investment runs at least five to seven years in duration. As a result, investors will not finance a company or an entrepreneur idea unless the opportunity for financial return does not far exceed the risk of failure.

Within the venture industry, average annual returns are expected to exceed the Standard and Poors 500 index for the public market by at least

five points. The annual S&P returns for the last 25 years have ranged from 11 to 13 percent. Therefore, venture investors are looking for annual returns of approximately 16 to 18 percent. In other words, a venture investor must double the amount of capital under management or invested approximately every four years to remain competitive.

In addition, venture investors seek opportunities that individually far exceed those returns because when the individual failures have been included the average annual returns are considerably lower. Even the public market investor is seeking to achieve or exceed the annual rate of return of the S&P and, given that the risks of biotechnology investing are substantially greater than with other stock sectors, the initial expectation for return must be higher than the S&P to even consider the investment.

Within the biotechnology sector patents are necessary to allow product pricing stability, generate attractive gross and net profit margins and allow a reasonable period of market exclusivity to overcome all of the risks associated with biotechnology investing. While there agrees some disagreement regarding the ranges of costs associated with pharmaceutical product development, a recent OTA study estimates that the average pretax cost of developing a pharmaceutical product is $359 million.

In closing, patents have been and will continue to be one of the most critical components to investment decision making and access to capital for the biotechnology industry. Furthermore, there is an inverse relationship between the size of the pools of public and private capital and uncertainty regarding the protection of proprietary technology in products within this sector. In our view, the most constructive course would be to use legislation or regulation to cure some of the existing uncertainty and problems that are present in the patent process today. However, any legislative action that could negatively impact such a critical component of biotechnology and U.S. competitiveness must receive a high level of public attention and comment before alternative policy is established. Thank you.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call Mr. Obenshain; is he here now? From Ernst and Young.

DOUGLAS OBENSHAIN, ERNST and YOUNG

MR. OBENSHAIN: Thank you. My name is Doug Obenshain and I'm an audit partner with the San Diego office of Ernst and Young, LLP. I specialize in serving life sciences' companies and have clients from the conceptual stage of an entrepreneur with a business plan up through a number of public company clients.

E and Y, LLP is the leading professional services firm in the world at serving the biotechnology industry. Each year we publish a national survey of the industry in which we request information from the CEOs of some 1,300 companies nationwide. From this we compile a variety of statistical analyses in everything from financing transactions, strategic alliances, planned actions of the CEOs, executive compensation, and a variety of other matters pertinent to the industry. This report has come to be regarded as the premiere state of the industry publication available. We then present this annual report, which this year is titled "Biotech '95: Reform, Restructure, and Renewal," at a series of approximately two dozen 30- to 45- minute roadshows all across the country.

This morning I'm going to attempt to condense this information into a brief five to seven minute overview of the year in biotech and then I will briefly touch upon my perspectives of the importance of patent and patent protection to this industry.

Each year in our report we identify the defining events of the year and in 1995 there were, as always, both positive and negative defining events. The biotechnology industry is one which requires a significant amount of cash, generally in the form of equity capital, in order to realize its long-term product potential. And, as Kathy indicated, the industry's ability to raise cash has historically been very cyclical. It's been marked by boom periods, such as those experienced in the early 1980s, the late 1980s, and the 1991 and '92 period, and early '93, followed by what are generally considered to be busts or famine periods, and a number of factors combined to make the year end of June 30th, 1994, generally a very difficult year to raise capital.

Certainly the industry was negatively impacted this year by the clinical setbacks of Antril, Thymosin, Respiver and other products. These failures were much ballyhooed in the press and by the investor community and affected not just the valuation of the companies involved but truly the valuations of the industry as a whole. Many companies who have continued to make strong clinical progress saw their valuations plummet due to someone elses travails. However, it should be noted that the major pharmaceutical companies also experience mixed clinical trials all the time and product setbacks all the time. But these, in fact, are expected, are accepted and are therefore not as highly publicized and do not have a significant impact upon the market valuations of either the drug companies individually or the pharmaceutical industry as a whole.

And I must point out that the biotech industry currently has over 50 products in phase three clinical trials, which demonstrates the industries long-term ability to discover and develop products. Will all 50 of those products be approved? certainly not. And will all of those

approved end up being blockbuster drugs? certainly not. But will they benefit worldwide health care? most certainly they should. And that's the promise and the value of the biotechnology industry.

Speaking of health care. The other factor which significantly negatively impacted the industries' ability to raise cash this year has been concern over health care reform. One need only look at prospectuses of companies issued before mid-1992 and compare them to those issued subsequent to 1992 and see that a very prominent and ominous risk factor appeared labeled "Health Care Reform." Even though reform has now been delayed for at least a year and formal price controls appear to have been removed from most of the popular proposals, uncertainty over health care reform and the fear of price controls has caused the investment community to be extremely skiddish. So the combination of primarily those two factors, as well as rising interest rates, have combined to create a very cautious investor mentality from late 1993 through 1994.

While our report indicates generally positive news on the year ended June 30, 1994, compared to the year ended June 30, 1993, I would tell you that the majority of 1994 has not been a favorable environment for raising cash. The average market capitalization of the industry is down eight to nine percent over a year ago. But for most companies, other than the top 10 or 15 companies in the industry, the drop has been much more precipitous. And, through the first nine months of 1994, initial public offering activity, which is a company's first foray into the public equity markets, has been significantly reduced. Most of the deals are much smaller than companies had envisioned when they originally drafted the prospectus and most deals are being priced at lower than the initial filing range.

Despite all of this, in the year ended June 30, '94, the industry did raise about $4.5 billion from all sources, which was about a 27-percent increase over the prior year. So, contrary to certain media reports, the capital markets are not completely closed. For a company that's been making good progress and has a good clinical story to tell, the markets are still there. Unfortunately, however, as I mentioned, the average deal size has declined and executives therefore have to spend increasing amounts of their time strategizing about how to raise capital at the expense of spending that time focusing on product development.

Furthermore, the industry ended June 30, 1994, with about $9 billion in cash, which is $1 billion more than the year before. The industry is not out of cash; however, much of that is concentrated at the 10 or 15 so-called breakaway companies. So there is some cause for concern; not panic but concern. The industries' burn rate in R&D spending and net loss all continue to increase, and the medium survival index, which we calculate as cash and committed cash divided by their average monthly rate of spending, has dropped from 34 months to 25 months in the last

year. Twenty percent of all biotech companies have less than 12 months of cash in their coffers, and nearly 50- percent have two years or less. But these survival indices were comparable in 1990 and 1992, so hopefully the industry will be able to raise cash in '95 and it hopes to do so at higher valuations than currently exist for most companies.

Now, what will help these companies out? One, a continued improvement in the public and political leaderships' awareness of and understanding of the industry and its issues resulting in a reasonable approach to health care reform.

Two. More product successes, such as those seen this year in Palmazine, Riopro, the flavor saver tomato, and others.

Third. A reasonable consolidation which would reduce the shear number of companies, and, fourth, a continued influx of funding from the major pharmaceutical companies.

Now let's talk for a moment about patents. If you think about the balance sheet of a typical biotechnology company, the biggest numbers are cash and shareholders' equity. I believe the equity number is simply a reflection of sophisticated investors' perceptions of the value of two things that are either not on the balance sheet or are undervalued: that is the company's people and their ideas. And patents are the primary protection of those ideas; therefore, they're clearly one of the most critical elements of ensuring the future success of the industry.

Legislation was proposed this year, but not passed, to extend patent terms from 17 to 20 years with a patent becoming effective at the application date rather than the issuance date. Given the length of the product development time table in this industry, a sizeable portion of that 20-year period could be consumed by product development rather than product sales. And remember that conventional wisdom suggests it takes 10 to 15 years and as much as $300 to $400 million to bring a pharmaceutical to market. If you had made such an investment you would hope to be able to reap the rewards from that effort for as long as a period of time as possible. The shorter the period in which you have patent protection for your developed product, the more you will have to charge on a per dose basis for that therapeutic in order to recap your investment.

I appreciate the opportunity to have made these remarks to you today, and I have copies of our 1995 report available if you wish to see them. And now I'm prepared to respond to any questions that you may have. in the public and political leaderships' awareness of and understan

COMMISSIONER LEHMAN: I think I don't have any and thank you very much.

MR. OBENSHAIN: Okay.

COMMISSIONER LEHMAN: Next I'd like to ask William Epstein from Hoffman-La Roche, Incorporated, to come forward.

WILLIAM EPSTEIN, HOFFMAN-LA ROCHE, INCORPORATED

MR. EPSTEIN: Thank you, Mr. Commissioner, and I wish to thank the members of the Patent Office for having me as a speaker at this meeting. I'm Bill Epstein, associate patent counsel, assistant secretary of Hoffman-La Roche, and I'm speaking today on behalf of BIO's Intellectual Property Committee.

I just want to point out that BIO has prepared a detailed book on --

COMMISSIONER LEHMAN: You'll have to speak into the microphone because the court reporter needs to --

MR. EPSTEIN: Okay. Thank you.

I wish to point out that BIO has prepared a detailed book outlining all of the issues raised at this hearing. We have 55 individuals under the direction and help in editing of Chuck Ludlum, who without this his tireless efforts would not have made this book possible and the reports in this book possible. I read it last night. It was very interesting reading and I would like to present the Commissioner with a copy. It sets out detailed positions on each of the issues raised at this hearing.

I'm here to speak on two issues: One, the question to practical utility and, two, practical utility versus proof of operability. I guess -- I've just been informed I'm the first patent attorney to speak on these subjects here so my remarks are purely that of a patent attorney.

Question two concerns the belief of whether the PTO is correctly applying the legal standards governing the question of practical utility requirements of 35 U.S.C 101. I believe no. I think the legal requirements are clear; however, I do not think the examiners know what the legal requirements are. Today the patent office has a very effective staff of patent examiners. Never before, since I have been practicing, has there been such highly trained, well-understanding patent examiners as for the science; however, for the legal problems that's to me a different story.

The legal standards are well settled as what is practical utility, and there is no distinction. If you satisfy the requirements of practical utility, you don't need any proof of operability. However, the question is: Do the examiners understand what the legal requirements are? and

since they do not, they are not applying them correctly.

A problem arises very quickly from the contrasting, what are the requirements of, let's say, public policy versus the courts? This is where the problem arises. I think public policy statement is very well put out in the Notice of this hearing which says: "Important public policy justifications for the USPTO to review operability of inventions to treat human disorders." A patent provides the public with a high-quality, technically accurate disclosure of new, useful and unobvious inventions -- nonobvious invention. However, the imprimatur of the federal government, a patent can also affect the commercial prospects of the invention in question and can raise or lower expectations of those afflicted with illness the invention is designed to treat. That contrasts very severely with the decisions of the Court of Customs and Patent Appeals, and the CAFC with regard to this item.

One looks at the old case of In re Anthony, which is the standard case in this area, here the drug Monase was taken out of public -- off the market because it was toxic, it couldn't be used to treat humans. Yet the court said that this was not sufficient for this drug to meet -- was sufficient for this drug to meet the requirements of U.S. patent law. The fact that the drug was toxic in no way stated that it would not meet the requirements of 31 U.S.C. 101 or 112, and that a practical utility had not been disclosed. They define practical utility as not being a commercial utility. They said that it's the FDA, not the PTO that is responsible for the question of whether a drug can be used in human therapy. And this is what is the distinction; this is the dichotomy that exists between the law and public policy. The Commissioner I think very well stated that the utility requirements is for the purpose of promoting commercialization. I agree with that wholeheartedly, it is not for guaranteeing treatment. That is what some of the examiners' standards in Group 180 are, that the applicant must guarantee treatment, and the patent laws are not to promote commercialization.

Let's look at what is considered practical utility. Practical utility is disclosed in Nelson v Bowler as saying that the knowledge of the pharmacological activity of the compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with the arsenal of chemicals having known pharmacological activity. Since it is crucial to provide researchers with an incentive to disclose pharmacological activity in as many compounds as possible, we conclude that any proof of any such activity constitutes a showing of practical utility. Therefore, all of it is needed under Nelson v Bowler, and in a subsequent case of Cross v Iizuka is that it has pharmacological activity, not therapy. Therefore, it isn't -- Therefore, what it is, it does not guarantee treatment.

The requirement of the statute is not -- and as interpreted by the court, is not to guarantee treatment but to promote commercialization. Clearly, this is taken in Cross v Iizuka, in another case, success in in vitro testing will marshal resources and direct the expenditures of efforts to further in vitro testing of most potent compounds, thereby providing an intermediate benefit to the public analogous to the benefit provided by the showing of the In Vivo Act utility. This standard doesn't exist for many examiners, and the question always comes, "What is a therapeutic utility?" "What is pharmalogic activity?" In order to have pharmalogic activity they have to have three things:

One. The activity.

Two. The nexus.

Three. The disease state. This is what the cases hold, you must have all three things. The fact that something burns a hole, a compound or material burns a hole in a piece of paper, that's not utility. What is utility? If you can put what the pharmalogical activity is and relate it to the disease state. There must be the nexus in between the pharmalogical activity that you're claiming what is your invention and what the -- and a disease state. This I think is clear. The question is, and it always gets to this point: How can we better get the examiners to understand or not understand? Educate the examiners in legal issues, because if we do not the problems are very clear. Basically these rejections will be overturned. Basically all they will do will provide roadblocks. They will not provide, promote commercialization. You will get rejections that are to me are just beating dead horses, and eventually a lot of money is spent in beating the same dead horse, which I feel is wasted.

You take, for instance, typical example with an AIDS drug. Here AIDS is a tremendously important disease to cure and treat. Well, we know that an enzyme -- by inhibiting an enzyme, or certain action of an enzyme we can inhibit the reproduction of the virus. Now, based on that utility, suppose the utility is that, we get back the rejection that anything that inhibits this activity, that's the public policy we can accept as a utility statement. Well, based upon this utility and the fact that the compound has been -- is not toxic millions of dollars have been invested in conducting clinical tests. If this utility is sufficient for investors it should be sufficient for the Patent Office.

Now, the recommendation which I think is very important, to my mind, is that the patent office have a what you would call a control group that would pick up cases at random and act as the inventors advocate.

Today the Patent Office has a quality control but they're only, from what I understand, and I may be totally wrong, that they're only there to

look at rejections, to make other rejections. I once got a rejection at the end of the lot and I saw -- and went to the board of appeals, it was reversed. So they put another barrier, but what about looking into seeing that the applicants, that the attorneys are really benefitting the system -- I mean, not the attorneys, the examiners are benefitting the system by looking at rejections and saying, "Are they being well based?" "Are they really applying the law?" and talking to the examiner, not as a harsh reprimand but as a teaching tool. The teaching comes far better from the Patent Office than it comes from me, because when I tell an examiner something he says, "You're only saying that because you're an attorney. Even the devil can cite our cases." So it should come from the Patent Office and the Patent Office should look at these rejections and see are they really following the law. And this way an examiner -- and I was an examiner -- gets an understanding of what the law is about and appreciates the thing. And this way I think with the technical expertise that we have now in the patent office, and with a little understanding of the law, no system can touch it.

MS. LINCK: Thank you, Mr. Epstein. I'm Nancy Linck. I'm the new solicitor of Patents and Trademarks and we are trying our best I think to follow the cases Nelson v Bowler and Cross v Iizuka. The Deuel case you mentioned is on appeal right now and will be argued in about a week and I think one problem we have is this emerging technology and it's difficult to draw the line. As one of the other speakers mentioned, you know, you don't want us issuing patents that should not issue and, therefore, you know, any help we can get, if you really think that the Board decision is inconsistent with earlier law I urge you to appeal to the Federal Circuit and provide us with additional guidance from the Federal Circuit.

MR. EPSTEIN: I don't think the -- Honestly, I don't think the Deuel is inconsistent with law. I don't think it is. Again, there's the nexus. That's a very important thing. I'll never forget a case that I was cited, that I argued, that was argued back to me -- I think it's Hoffman v Klaus. I was Klaus, but there the nexus was missing. You had the pharmalogical activity; you didn't have a nexus. So what was this? There was no nexus involved and that I think is interesting and that's the question. But let's say you cite these cases, whatever they be, you don't get any answer back. There isn't the byplay as if there is to understanding these things. So I think I'm not questioning the Deuel case but I am questioning whether the examiners understand the Deuel case and the other things.

COMMISSIONER LEHMAN: Well, apparently, though, the very fine report that you suggest does question the Deuel case. That's why Ms. Linck made --

MR. EPSTEIN: I'm sorry, if I could just say one thing.

COMMISSIONER LEHMAN: There are two cases that are given as an illustration of --

MR. EPSTEIN: Right.

COMMISSIONER LEHMAN: -- we're not following the CAFC law or where the Board hasn't, are Ex Parte Maizel and Ex Parte Deuel. And I'm not sure that Ex Parte Maizel was ever appealed to the CAFC. So I think the point is we're -- The point of these hearings is obviously we're trying to do what we can do internally, but it also helps us to have the private sector work with the court of appeals for the Federal Circuit to define the law properly, too, or they think that we've made a mistake.

MR. EPSTEIN: Could I just say something about those two cases. First of all I don't think the Maizel case, and maybe I'm wrong, was a 101 case -- a 101 case. I don't think it was. And, if I'm not mistaken, the Deuel case also, that was another rejection which they wanted to re-examine, so I don't -- so they really made an extra finding. I don't think it's part of the holding, and I think the Board asked for the idea of the nexus or to investigate the nexus, so I'm not so sure I agree with the way those cases have been cited in the thing, and they weren't cited -- but I'm saying, look, the document is still a wonderful document. It has certain things, and remember we had very little time to prepare it.

COMMISSIONER LEHMAN: We'll study it very carefully.

MR. EPSTEIN: I appreciate that.

COMMISSIONER LEHMAN: We'll work our way through this. Thank you very much.

MR. EPSTEIN: Thank you.

COMMISSIONER LEHMAN: Next I'd like to call Laura Handley; Weil, Gotshal and Manges.

LAURA HANDLEY, WEIL, GOTSHAL and MANGES

MS. HANDLEY: Good morning, Commissioner Lehman and other distinguished panel members. I'm Laura Handley. I'm an attorney with Weil, Gotshal and Manages. We represent a diverse group of biotechnology clients ranging from universities to agricultural companies to companies designing human therapeutics. I recently completed a clerkship with Judge Plager of the Court of Appeals for the Federal Circuit and on behalf of the BIO Intellectual Property Committee I'll be providing brief summary of the case law concerning the utility requirement. A detailed version of the presentation has been submitted to the record by BIO.

Nine minutes is really not enough time to do justice to over 30 years case law in the utility requirement. Unfortunately, as you'll probably continue to hear today, many here feel that nine minutes is about seven minutes more than the examiners are currently giving the case law.

In any event, I'll now briefly summarize the legal standard for utility; list three common legal errors committed by many examiners, and then describe in detail the case law with regard to each area.

COMMISSIONER LEHMAN: Can I ask when you say that the examiners are spending about two minutes on this, are you talking about all examiners or are you talking about some examiners? In other words, is the problem that we don't -- that we uniformly are misinterpreting the law or that some examiners are misinterpreting it, from your point of view?

MS. HANDLEY: Well, my point of view is based primarily on anecdote from other people. I just left the court about a year ago. I get the impression from my colleagues that it's many, but by no means all examiners. And it may actually be a function of the time constraints that they work under that they don't have time to think through the case law, and they don't have the legal training to think through the case law.

In any event, as for the legal standard for utility. As you know, Section 101 of the patent statute requires that an invention must be useful in order to receive a patent. And that test has been phrased as inquiring whether a patent -- whether an invention has practical utility. What constitutes that practical utility is dictated by controlling case law of the Supreme Court, the Federal Circuit, and the CCPA, the predecessor of the Federal Circuit. Of course all of these are binding precedent upon the PTO.

Brenner v Manson, the Supreme Court's 1966 case on the utility requirement, first set forth this practical utility test. The patent application in Brenner fell far short as the applicants there had completed no testing whatsoever to support the claimed utility. But patent attorneys learn fast.

Brenner v Manson was a 1966 case and today the examiners rarely, if ever see patent applications in which no utility testing whatsoever has been completed. Thus the two cases which provide more helpful guidance on the utility standard rose in the early to mid-eighties and these cases are Nelson v Bowler, decided by the CCPA, and Cross v Iizuka, decided by the Federal Circuit. Both Nelson and Cross apply Brenner to cases in which some testing had been completed and held that practical utility had been demonstrated when the patent applicant provided evidence of pharmacological activity. In Nelson that pharmacological activity was

established by an in vitro assay and also by an in vivo experiment in rats. In Cross the pharmacological activity was established by simply the in vitro assay.

Notably, neither case required clinical data or proof of therapeutic utility. In contrast, the position of the PTO on the utility requirement seems to have shifted dramatically over the last several years and utility has now become a significant procedural hurdle for biotechnology inventors. Applications that do not contain human clinical data, or at the very least mammalian animal data frequently are rejected on utility grounds.

We believe that such rejections deviate from the controlling case law in three respects:

First, the examiners err in shifting the utility inquiry from the claimed invention and instead in focusing on the ultimate therapeutic use which the examiner believes to be the inventor's goal.

Second, the examiners err in routinely rejecting in vitro data.

Third, the examiners err in refusing to accept data that would prove to unskilled in the art that a compound has pharmacological activity.

As for the first error, the examiners cannot shift the focus of the utility inquiry to the product which the examiner surmises is the ultimate goal of the inventor. Instead, the Federal Circuit stated in Raytheon v Roper Corporation that the claims of the patent determine the invention to be tested for utility. As it is the claims which dictate the utility inquiry, each case will be fact specific and there can be no uniform utility requirement. If the claims are phrased in terms of the method of treating a disease then the PTO properly requires data relating to treatment of that disease. If one skilled in the art would accept nothing short of human therapeutic data as predictive of success then the PTO may require that that data be presented. If one skilled in the art would accept one mammalian animal model, or even in vitro models as predictive, then the PTO must accept those showings.

However, when the claimed invention is a composition matter and not a method of treating a disease, the CCPA in In re Bundy and in Nelson v Bowler made quite clear that, quote: "Evidence of any utility is sufficient." Close quote. That utility may relate to a variety of things short of human therapy. For example, pharmacological effects, such as receiptor binding; stimulation of immunicological reaction; or growth of particular cells. Again, as the court made clear in Nelson v Bowler, such showing of pharmacological activity suffice.

In contrast, examiners seem to read the claims that are drawn to

compositions and matter as though the claim instead read, quote: "A method for treating a human disease." This is legal error as it is looking for therapeutic utility rather than pharmacological activity.

COMMISSIONER LEHMAN: Can I ask as question?

MS. HANDLEY: Sure.

COMMISSIONER LEHMAN: If the claimed invention is for human therapy, though, will just mere evidence of pharmacological activity suffice? I mean, doesn't this go partly to what the claimed utility is?

MS. HANDLEY: Right. I would say that the way the examiners approach this is first look at the call of the claim. If the claim is drafted as a method for treating a disease then you look to see if there is evidence in this specification that supports treatment of that disease.

COMMISSIONER LEHMAN: So it's evidence in the specification and then merely shown by, you know, in vitro pharmacological activity would satisfy the test then in that case, in your view?

MS. HANDLEY: I think it all gets back to what would be persuasive to those skilled in the art, and if those skilled in the art would have sufficient confidence in the in vitro assays then that should meet the test. If it's a composition and matter claim, I think the threshold is much lower. I think traditionally in chemical practice composition and matter claims, if you showed any utility whatsoever, that was sufficient because the call of the claim is to the compound itself, and people can later come along and if they have a novel method of using that compound they can then get a method claim. So there's always been a lower standard and broader protection for composition and matter claims.

COMMISSIONER LEHMAN: But my impression, though, is that the problems haven't been with those composition and matter claims as much.

MS. HANDLEY: Well --

COMMISSIONER LEHMAN: Well, that's, you know --

MS. HANDLEY: In my limited experience, I've had almost every one of my composition and matter claims rejected on utility grounds, and the examiners seem to be reading it as if it was a method claim, a method of treatment claim.

As for the second error, examiners frequently refuse to accept the probative value of in vitro or non- human in vivo data, and this, too, is directly contrary to the controlling precedent of Nelson v Bowler and Cross v Iizuka. As the Federal Circuit specifically stated, in vitro

testing is the accepted practice in the industry and is generally predictive of in vivo results.

For example, in Cross v Iizuka, the only data supporting the claimed utility was an in vitro assay showing the effect of the compound in platelets. And I find the Cross case to be interesting because it highlights how dramatically the PTO position has changed in recent years. Cross was an interferons case which reached the Federal Circuit in 1985 and the party Iizuka showing of utility was based on an in vitro assay alone and it was accepted by the PTO. It was then challenged by a disgruntled party, Cross, and Cross's position on appeal was that, one, regardless of the claims the real utility was as a therapeutic medicine for treating disease and, two, that in vitro data was not sufficiently probative. And, as I've argued above, these are precisely the arguments that the examiners are raising today.

On appeal, the Federal Circuit reject party Cross's attempt to shift the inquiry to therapeutic effect and strongly endorsed the probative value of in vitro data. BIO's position then is that the examiners should be following the Federal Circuit and not be reiterating the argument unsuccessfully made by the party Cross.

As for the third error, examiners frequently seem to forget that the evidence of utility, be it in vitro or in vivo data, must be persuasive to one skilled in the art and not to the examiner personally. If the examiner raises and objection to a showing of utility, the inventor can overcome that rejection by offering evidence that the showing would be persuasive to one skilled in the art, and that was the case in In re Jolles which considered acceptance of animal data.

So to conclude then, nothing in Brenner v Manson, which is often the examiners' shibboleth for denying utility, requires submission of human clinical data. The patent applicants in Brenner had conducted no testing whatsoever, and the scientific field is acknowledged by all to be unpredictable.

In contrast to those facts, examiners today routinely reject applications that do disclose some testing. The question then becomes one of how much testing and what kind of testing; questions that are answered by both Nelson v Bowler and Cross v Iizuka. The examiners' conversion of the utility requirement from a minimal threshold into a major administrative hurdle, akin to the showing required by the FDA, is legal error.

Unfortunately, though, many of these erroneous calls simply will not be challenged. Every time the examiner issues a final rejection the inventor is put to the difficult choice of acquiescing or to pursuing costly appeals to the Board and to the Federal Circuit. And,

unfortunately, especially with the increasing tightness of the money market, many clients simply do not have the financial resources to pursue the legal battle. Accordingly, BIO requests that the examiners change current examination practices, study the controlling case law in this utility area and conform with it.

If I may, I'd like to respond very quickly to your point about raising the presumption of utility. I have three points -- three thoughts. One is that a presumption of utility would be consistent with Federal Circuit case law, Tol-o-Matic, Carl Zeiss, and also the old Supreme Court case of Lowell v Lewis that really do seem to treat utility as a minimal threshold.

My second thought on the issue is that it makes --

COMMISSIONER LEHMAN: You mean, you think we don't have a presumption of utility now?

MS. HANDLEY: Right.

COMMISSIONER LEHMAN: We could create one?

MS. HANDLEY: If a presumption of utility were created, it would also mesh very well with -- for human therapeutic inventions -- with Section 271(e)(1) of the patent statute, which basically is a safe harbor provision against patent infringement suits until a company comes out of clinical trials. And that really would allow a company to get its patent, get its ducks in order, get its drug into and out of clinicals and then it would be subject to suit. And, by that point, you would have the clear clinical data to prove the issue one way or the other. Thank you.

MS. LINCK: Ms. Handley, I'd like to ask you one question. It sounds like you've done a fairly in depth review of the case law, and I think it would be helpful for us if you could identify for us any Board decisions or CCPA decisions, but primarily Board decisions, that you think are out of line with controlling case law.

MS. HANDLEY: I am the culprit. I am the author of the section of Deuel and Maizel. My quibble with Deuel and Maizel is that in both cases the Board -- well, in both cases the Board raised the issue sua sponte, and in both cases I didn't think that the Board had focused enough on the claims because in both of those cases there were composition and matter claims, and in both cases all I was working from was the Board opinion itself, and it seemed that the Board in both cases admitted that there was evidence of some utility.

MS. LINCK: Any others?

MS. HANDLEY: Not that come to mind right now.

MS. LINCK: Thank you very much.

MS. HANDLEY: Thank you.

COMMISSIONER LEHMAN: But if we had -- To get back to this presumption question in a situation where we have evidence of some utility then there would be -- if you had adopted some sort of a presumption then that would cross the threshold then?

MS. HANDLEY: Well, as my colleague Elizabeth Enayati will be discussing in a few minutes, however, there is a presumption on the operability issue under Section 112, and the very fact that there's a presumption in place hasn't seemed to have made a practical difference in how these issues are treated by the examiners. So I think better -- a presumption would be a good step but it's only as good as the legal training of the examiners.

COMMISSIONER LEHMAN: So you really think that our -- in many ways an administrative problem is at the core of a lot of this; it's simply the legal training?

MS. HANDLEY: Yes.

COMMISSIONER LEHMAN: I would point out that one of the reforms that our assistant commissioner for patents -- and I'm sorry he's not here today -- he had to be somewhere else now, but we all can't be at different places at the same time, but he's putting in to bring into place a new -- going to be putting into place a new law training program for the examiners so -- where we're bringing the law schools right on site and we're going to try to encourage them to -- but we're not going to give them law degrees because otherwise they'll all join you at Weil, Gotshal and Manges, so we're going to give them -- Larry's idea is we're going to give them a Master of Juridical Science, an MJ degree rather than a JD degree so they won't be able to fly the coop. The only place they'll be able to us it is with us, but we are trying to --

MS. HANDLEY: I think that's an excellent solution for the PTO. As for Weil, Gotshal maybe it's not so good. Thank you.

COMMISSIONER LEHMAN: Our next witness is Timothy Gens from Fenwick and West.

TIMOTHY GENS, FENWICK and WEST

MR. GENS: Good morning Commissioner and other panelists. I am Timothy

Gens. I'm with the -- of counsel with the firm of Fenwick and West which has about 120 attorneys between its Palo Alto and Washington, D.C. offices. Our firm focuses upon providing legal services to high technology companies of which include biotech companies, universities and other types of entities. Personally I've had a little over 16 years of experience practicing before the Patent Office and also before the Federal Circuit Courts with regard to patent issues, and I present these remarks today on behalf of the Biotechnology Industry Organization.

In particular, I'm responding to the first question in the Notice under the issue of "Utility" with regard to whether or not the legal standards governing the requirement for identification of utility developed by the federal courts are clear and concise.

We believe that the legal standards established by the federal courts governing the requirement for the identification of utility are sufficiently clear and appropriate for biotechnology inventions.

We submit that these legal standards are well defined and require a minimum of proof to establish practical utility. The concern over utility requirement for patentability should not be directed to the clarity of the legal standards but rather to the implementation of the standards by the Patent Office. Thus we view the utility issue as one of misapplication of the law rather than incorrect legal precedent.

To resolve the utility issue, we propose that the patent bar be offered the opportunity to understand the content of the examiners' education by the Patent Office on such legal standards and to positively contribute to the content of this legal education. Accordingly, we offer a practical and effective approach to working with the Patent Office in achieving a principal goal of our nation's patent system, that is the promotion of science and innovation.

We commend the patent office for its recent efforts in increasing the number of qualified examiners in the biotechnology area. Consequently, the examiners have evidenced a very positive trend in the technical understanding of the inventions that less than two decades ago were simply pipe dreams.

From the hand-out that was given to us as we came into the room today, with regard to the fact that in Group 1800 over half of the examiners have Ph.Ds, it has been well noted by the practitioners before the Patent Office and we are very thankful for that. But now let's focus on the legal training because that's where we are still running into a major obstacle.

The misapplication of these legal standards governing practical utility is exemplified by the Notice itself. The Notice prominently states that

the Patent Office is interested in ensuring that the practical utility requirement is governed by standards that promote research, development and commercialization of technological advances in biotechnology.

It must be absolutely clear that this laudable interest is of secondary importance. The desire does not grant the Patent Office the right to create policy. Of primary importance to the Patent Office is fulfilling its constitutional obligation to promote science and the useful arts by following and implementing the law decided by the federal courts and legislature. Only when an issue is one of first impression and no direction is otherwise provided by the courts does the Patent Office have the right to extrapolate from the decisions otherwise rendered by the courts. By not adhering to the law, as observed by the inventors and the patent bar, the Patent Office creates confusion in the process of securing a patent which can lead to a variety of deleterious consequences: Notably, the trust and security inherent in the patent system has weakened and our competitive opportunities as a nation are threatened.

The Notice also raises an example of practical utility in the patentability of nucleotide sequences that are produced incident the expression of human gene. There is a concern as to whether the sequence or the gene must be characterized as to its physical, biological or physiological significance in order to establish practical utility. This statement misplaces the focus of the problem. First, the Patent Office must implement the decisions by the federal courts and not respond to concerns by attempting to create policy.

Secondly, the test of utility --

COMMISSIONER LEHMAN: Wait. I completely disagree with you about that. I don't think the federal courts have the right to make policy at all. The federal courts interpret the law. In fact, it's the responsibility of the Commissioner of the Patent and Trademark Office to make the policy regarding the operation of the office, and the responsibility of the Congress to establish statutory policies. I think you've got it all the way around -- completely the other way around. Otherwise, we wouldn't even be here if we didn't have any policy responsibility.

MR. GENS: I don't think that we're necessarily out of sync, Commissioner. The point is that the courts are trying to follow what legislature is giving them as the law. My argument today is that the Patent Office does not have the right to create law. It must follow the law that the court is trying to implement from the legislature that is passed on to them. And from the way that the Notice is written up, it is clear that the focus of the Notice is in terms of what is wrong elsewhere but at the Patent Office. And perhaps what we have to do is -- I'm advocating that we simply focus on trying to reach some common ground as

for what is being decided by the Federal Circuit.

COMMISSIONER LEHMAN: The reason I make that distinction is because I think the Court of Appeals from the Federal Circuit is hardly infallible, and it well may be that the Court of Appeals for the Federal Circuit will make decisions which this industry does not approve of. It may be that we feel that we should even go further than what the Federal Court of Appeals of the Federal Circuit currently is authorizing with regard to the utility standard furthering the industry's direction and that, indeed, we might as a matter of policy decide to test that all the way up to filing a petition for certiorari before the Supreme Court. So I'm just saying don't -- or go to Congress to seek legislative approval, if we feel that we can't, you know, get the court to agree with us. So, I mean, don't -- I'm just saying, don't place too much emphasis on what the Court of Appeals for the Federal Circuit says. That's why we're here.

MR. GENS: I see that my time has expired, but if there's definitely one recommendation that I can make before stopping that is that the PTO concentrate on trying to implement those standards by the Federal Circuit and allow the patent bar access to the legal training that is being made to the examiners. Open it up to the public.

The second point is in terms of opening up what the Patent Office is teaching to the examiners, give the patent bar a chance to influence that. Let's have a two-way communication between us in trying to establish a common ground so that we can avoid unnecessary patent appeals and use as a starting point at least some basis in what we both think the Federal Circuits are trying to say.

COMMISSIONER LEHMAN: Well, that's exactly what these hearings are all about, so thank you very much.

MR. GENS: Thank you.

COMMISSIONER LEHMAN: Next I'd like to ask Bill Kennedy of Morrison and Foerster to come forward, please.

BILL KENNEDY, MORRISON and FOERSTER

MR. KENNEDY: Thank you Commissioner Lehman. I'm Bill Kennedy an associate of Kate Murashige at Morrison and Foerster. I'm in the Palo Alto office.

BIO had asked Doctor Murashige to respond narrowly to question three raised in the context of application of the utility requirement in the USPTO Notice. Doctor Murashige is unable to attend today and asked me to stand in her stead, and I thank you for allowing me to speak today in her place.

Question three asks the following: "Do you believe legal standards and examining practices in foreign systems to assess the patent eligibility of biotechnological inventions, such as those governing industrial applicability and exclusions from patentability, provide a better framework than is available in the United States? Please identify desirable and undesirable practices of foreign offices, particularly in the EPO and Japan." And I will narrowly direct my answer in this limited time.

The utility requirement in the United States is the sole requirement for patentability that addresses the contribution made by the patented subject matter to the well-being and progress to the society as a whole; that is the real world value of the invention. This is addressed in Europe and Japan by requiring that the patented subject matter be susceptible to industrial application.

Additionally, the European Patent Convention, in Article 53, accepts from patentability inventions, the publication, or exploitation of which would be contrary to public order or morality. And also the European Patent Convention excepts from patentability plant or animal varieties or essentially biological processes for production of plants or animals.

Japanese patent law requires that inventions be usable in industry and additionally excludes patentability for inventions liable to be contrary to public order, health or morals.

In neither Japan nor Europe are methods for treating the human body considered to be an industrial application; however, patents may be obtained for the use of compositions whether those compositions be old or new in therapeutic regiments.

It is generally considered that the standard of industrial applicability is a much lower hurdle to overcome than the standard of utility as exercised in the United States Patent Office. This can be particularly apparent where a patent application is being examined in the U.S. Patent and Trademark Office both as a domestic U.S. application and as an international application under Chapter 2 of the Patent Cooperation Treaty. Indeed, it is common experience that claims are rejected in the domestic U.S. case for lack of utility. This comes often, by the way, under the guise of an asserted failure to provide an enabling disclosure. And yet those same claims, on the same specification, are considered to meet the standard of being susceptible to industrial applicability in the international application by a U.S. examiner who, incidentally, is often the very same examiner who authored the utility enablement rejection in the domestic U.S. case. Thus the kinds of data routinely rejected in the United States are routinely accepted in Europe and Japan. This is a scenario but does not bode well for American inventors in a global

economy.

Many problems in attempting to apply the standard of utility, as opposed to a standard of susceptibility to industrial application, are only exasperated by the dictum of the Supreme Court in Brenner v Manson to the effect that the invention must be developed to where specific benefit exists in currently available form, that benefit being one derived by the public. The question is: Who is the public? Does the public include that subset of the population actively engaged in research? And what is "currently available form?" Eventually, every member of the public will potentially benefit from the efforts of those members who are engaged in research. Is that benefit sufficiently direct that an immediate benefit to the research community can be considered to be a currently available benefit to the public?

There's no need to answer any of these questions where a standard of industrial application is applied.

The distinction can perhaps best be illustrated by an example. Claims are directed to new and unobvious compounds which tightly bind a known receptor that is present on a particular subset of white blood cells. Because the cells on which the receptor appears are often useful in conducting research to investigate the nature of human disease, the compounds are clearly susceptible of industrial applicability inasmuch as they can be used to purify these cells for a researcher to study. The applicant in this application further states that the compounds can be used to target these cells in therapeutic protocols.

There's no question that if sufficient proof were offered to show that the latter use had therapeutic value, the public would have a currently available benefit. However, showing that this is the case is quite difficult, as others have pointed out earlier today, and the inventor of the claimed compounds in this instance may be a basic researcher employed by a research institution. The inventor is not able personally nor through the research institution to do the necessary animal and clinical studies that would provide the therapeutic parameters and proofs that seem to be required.

On the other hand, of course, commercial entities that may have the capability to carry out such studies will not be interested in pursuing the matter unless they can be assured that the compounds themselves are protected. If the standard of industrial applicability were applied the use of these compounds for purifying the relevant cells for research purposes would be adequate to support the patentability.

In the face of the utility requirement, the question is raised above now introduce a complication -- is the provision of compounds that are, at this moment, of interest only to the research community a currently

available public benefit?

In short, the standard of industrial applicability removes the value judgment dimension of the utility requirement. The standard is easy to apply. The industrial applicability standard is easy to apply. If the material can be used for something that someone is being paid to do it meets the standard. Substitution of this standard for the utility standard would have the benefit of providing clarity in the law as well as removing an unnecessary barrier to the progress of research in biotechnology.

On the other hand, a requirement that the claimed subject matter not be contrary to public morals can introduce its own complications. The presence of this provision in the European patent law has already caused considerable mischief in the form of oppositions to patents granted on transgenic animals. The multiple oppositions that have been filed with respect to these patents have come not from competing commercial interests but rather from animal rights groups and others having particular political agendas. There is considerable concern in Europe that patent opposition provides an inappropriate platform for such agendas. The recent formation by the European Patent Office of a special panel whose approval would be required in addition to the decision of the Examining Division for the grant of a patent on a transgenic animal may have been in response to such pressures. It would clearly be undesirable to add such a provision to the statute in the United States.

A third clear difference between U.S. and Japanese or European law is the exclusion from patentability of methods for treating the human body. As a practical matter, the effects of this prohibition are minimized by the ability to obtain protection for medical use of compounds, and it will come into play only when the method of treatment involves manipulative steps only.

In summary, we feel it would be helpful to substitute for the utility requirement a standard of industrial applicability, but without excluding from patentability inventions that are supposedly contrary to the public order.

COMMISSIONER LEHMAN: Thank you. Is that something that you think would require statutory change or could we do that just by changing our policy protocols in the office?

MR. KENNEDY: Well, you raised earlier the difficulty that if you change your policy within the Patent Office you still may find yourself going up to the courts. It's difficult to say. A statutory change would effectuate it, if that were possible to bring about.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to ask Elizabeth Enayati, of Weil, Gotshal and Manges, to come forward, please.

ELIZABETH ENAYATI, WEIL, GOTSHAL and MANGES

MS. ENAYATI: Well, I was going to say good afternoon. I can't -- it's noon right now so I'll just say, hello, Commissioner Lehman and other distinguished panel members. Welcome back to California. My name is Elizabeth Enayati. I'm a patent attorney at the Silicone Valley office of Weil, Gotshal and Manges. As you may know, Weil, Gotshal is an international firm representing a broad base of both established and start-up technology companies, as well as universities. Our 20-member Silicone Valley office focuses on technology issues including patent prosecution and litigation. My practice includes biotechnology prosecution for universities and members of private industry.

I'm speaking this afternoon on behalf of the Biotechnology Industry Organization -- BIO -- the Intellectual Property Committee, of which my firm is a member. A detailed version of this presentation is submitted for the record by BIO and you have a copy I believe.

I'll be summarizing two sections of that report regarding operability, the introduction, including case law, and question number three regarding the foreign versus U.S. Patent Office practices relating to operability. The next speaker, Bill Scanlon, will be addressing the other two operability questions raised in that formal Notice.

I'll begin by summarizing the testimony you'll be hearing today from the BIO Intellectual Property Committee members on the issue of operability. Since the formation of the Food and Drug Administration, it's that agency and not the PTO that has the responsibility for ensuring that marketed therapeutics satisfy safety and efficacy criteria.

My personal experience, therapeutics and composition inventions that satisfy the statutory requirements for patentability are being rejected by examiners who cite a failure on the part of the inventor to prove operability, including the safety and efficacy of the claimed method and composition inventions. Often the rejection is based on the examiner's disbelief as to operability without supporting evidence despite the inventor's statements and declarations to the contrary. Such a practice is supported by neither the patent statute, nor the case law as I'll describe in a moment.

Operability of composition inventions should be satisfied by reasonable evidence of how to make the composition -- operability of method of using the composition should be satisfied by evidence of how to use the composition in a reasonably predictive model. However, examiners

presently are requiring proof of operability, including efficacy, of how to use a composition when only the composition is being claimed and no method of use is being claimed. By improperly rejecting therapeutics and composition claims, based on unsupported inoperability allegations, the U.S. Patent Office participates both in avoiding the constitutional mandate to promote the arts and useful sciences, and in weakening the efforts of a growing U.S. industry that is important to the competitive efforts of our nation in the world marketplace.

In support of its operability rejections, the U.S. Patent Office relies on a series of cases that were cited in the " Federal Register" notice for this meeting. A complete and accurate summary of those cases is found in the full BIO Intellectual Property Committee report made of record, and I won't be going through each of those cases in detail as I'm sure you're already familiar with them. But as an initial observation, the case law clearly requires that only one object of the invention be shown to satisfy the operability requirement. This could include in vitro or animal data. The burden rests on the examiner to provide evidence inconsistent with the inventor's assertion of operability. This is most clearly stated in In re Chilowsky, a 1956 case, and I'll quote: "Applicants for patents in this field --" referring to the biotechnology and human therapeutic arts, "as well as in all others are entitled to specific information as to the grounds on which their applications are rejected and should not be met with anything in the nature of a blanket rejection based on the comparatively recent development of the art and the difficulty which it has been experienced in producing commercial devices." That applies with equal force today as it did in 1956; however, examiners are continuously asserting that the inventor bears the initial burden of showing operability.

Operability is also recognized as an element of the disclosure requirement under 35 U.S.C. Section 112, first paragraph. Again, under that approach, the case law cited by the PTO in this Notice of this meeting supports the premise that the truth and accuracy of statements in a patent application are presumed unless the PTO can establish, using evidence provided to the applicant, that the statements are not true and accurate.

It's become common practice -- and my personal experience from the Patent Office -- to require human clinical data in support of therapeutic claims even when in vitro or animal data is provided in a specification. This frustrates the public policy, often expressed by the courts, in early filing of patent applications. For example, one population of inventors who are significantly impacted by this practice is the population of inventors practicing at universities. If early stage research is not patentable, because they don't have human clinical data, then applications cannot be filed; papers cannot be published; or universities lose their rights. The net effect is a distinctive

disincentive to publish and exchange scientific ideas, which ultimately stifles the progress of useful science instead of promoting the progress of useful science.

In addition, these inventors and universities then cannot find commercial partners to take early stage research into commercial product if that commercial partner has uncertain or no possibility of a proprietary position. Thus products are hindered from reaching the market by the Patent Office practice of requiring human clinical data. By maintaining its position requiring that such human clinical data in support of therapeutics' claims, the Patent Office flies in the face of case law precedents, such as In re Langer which held that clinical testing in humans is not required in view of in vitro data. In In re Jolles, a 1980 case that was discussed earlier, specifically rejected the patent office position that animal data was not relevant to establishing utility, and in In re Hardtop the court rejected the Patent Office requirement for human data despite it presented animal data. And In re Malachowski non-human data was found by the court to be sufficient to establish utility for use in humans. Although the Board in Ex parte Balzarini affirmed the rejection of the claims presented in that case, the Board again stressed that human clinical data would not necessarily be required. Clearly the courts and the Board have continuously stated that human clinical data is not a prerequisite to patenting therapeutic inventions.

Finally, the Patent Office is rejecting claims based on the applicant's failure to present safety and efficacy data from human testing despite case law precedent to the contrary. And In re Anthony the court clearly states, and I quote: "Congress has given the responsibility to the FDA, not to the Patent Office, to determine in the first instance whether drugs are sufficiently safe for use that they can be introduced in the commercial marketplace." This is further supported by several cases that due to the time limitations I won't recite.

We respectfully remind the patent office that it is an administrative body charged with issuing patents that satisfy the requirements set forth in the patent statutes. If the patent statutes do not address certain concerns that the public believes are necessary to protect its interests then it's up to Congress to change the statutes which govern the actions of the Patent Office.

Turning now to question three of the public Notice: "Do you believe legal standards and --"

COMMISSIONER LEHMAN: Can I just as a question to clarify something I think is important.

MS. ENAYATI: Sure.

COMMISSIONER LEHMAN: In other words, if we knew for a fact that a particular therapy for which a patent application had been made would have a very toxic effect on individuals and might kill them, that even if that were the case, as long as it otherwise operated against the particular virus or whatever it might be involved and did away with it even though it might kill the patient in the process, it would still meet the utility requirement?

MS. ENAYATI: That's right, and I think that's consistent with what Bill Epstein said previously. And also with the courts, with the case law, where it said if you show one object of the invention then you satisfy the utility requirements for patentability. Now, whether it reaches market or not is a different issue. It also -- Well, I'll leave it at that.

MS. LINCK: I also have a question for clarification. It was my impression from what you said that you've had some experience with examiners requiring human test data but that the Board, in fact, has gone the other way. Is that your experience? Is my understanding --

MS. ENAYATI: That is my experience. I have had examiners say that they won't accept the animal data or they don't accept the animal model that we've presented as being a valid model that shows that this treatment would actually work in humans, and they've required human clinical data in view of a valid animal model data.

MS. LINCK: But that's been reversed whenever you've taken it to the Board?

MS. ENAYATI: I personally have not taken it to the Board, no. So those decisions, we haven't got that far. I haven't had a hearing date yet.

MS. LINCK: All right. Thank you.

MS. ENAYATI: But they are on appeal.

COMMISSIONER LEHMAN: But to follow up on that. What you would like us to do is make it clear to the examiners that animal data are acceptable. Period. That they do not require the human data.

MS. ENAYATI: That's right.

COMMISSIONER LEHMAN: And also to make this other point clear, that it's not their -- that, you know, in effect, the marketplace, the FDA approval being part of the marketplace, will make a determination as to whether the patent is usable or not. Their only purpose -- function -- is is this an invention that kills the particular virus or whatever it may be

that's involved?

MS. ENAYATI: Right.

COMMISSIONER LEHMAN: If it kills that virus it, you know, might kill the person along with it. Might even kill the animal along with it, I suppose. But if it kills the virus then it's, you know --

MS. ENAYATI: It's met the standards of patentability.

COMMISSIONER LEHMAN: Okay. Thank you.

MS. ENAYATI: Okay.

Question three, the legal standards and examining practices in foreign systems, whether they provide a better framework than is available in the U.S. for assessing patentability questions related to operability of inventions for treating human disorders. We believe the answer to that is, "Yes." Both European and, in certain circumstances, Japanese patent laws are applied more favorably and highlight the unnecessarily strict standard of operability imposed by the U.S. Patent Office at this time. Although the laws do not differ significantly in this area, the application of those laws to the examination of biotech patent applications does differ dramatically.

As applied under European patent law, any reasonable statement regarding the operation of an invention is readily accepted. In vitro data generally is sufficient to demonstrate operability of first or second medical uses of a therapeutic composition in human therapy. In some cases a believable, enabling, but "prophetic" description, absent any in vitro or animal data, is acceptable to support claims to a first or second medical use of a therapeutic composition.

Under Japanese patent law inventions to human therapeutics are separated into two classes: Generally, new compounds and then pharmacal compounds with use limitations.

Under the first category, chemical compounds per se, a working example showing that the compound was prepared is required, but no experimental evidence of use is required.

Under the second class, the pharmaceutical compositions with a use limitation, for example, composition for treatment of cancer, in vitro data is acceptable if it's directly supportive of the claimed use. So, for example, if the claim is to pharmaceutical compositions for treating cancer cells then in vitro data demonstrating that the composition kills cancer cells is sufficient.

To conclude, in foreign countries competitors and regulatory agents do not rely on the Patent Office to determine if an invention is operable. The U.S. Patent Office for human clinical data in support of therapeutic use claims prevents the flow of human therapy inventions to the next level of research and ultimately to the marketplace. Consistent with both the European and Japanese patent system, once a threshold of operability has been demonstrated, which may be achieved using in vitro data, the other regulatory agencies charged with regulating the release of drugs and products to the market should make the next level determination of efficacy and safety in operability. Thank you.

COMMISSIONER LEHMAN: I don't want to drag this on, but, you know, all cases -- it seems to me that in all cases you would have in vitro data available, wouldn't you? I mean, otherwise, you wouldn't know whether you had any invention or not.

MS. ENAYATI: Right.

COMMISSIONER LEHMAN: I mean, you wouldn't know whether you had anything that worked, you'd just have an idea.

MS. ENAYATI: That's right. And so what we end up engaging in is a discussion with the examiner whether this is sufficient in vitro data and whether they accept the results of the in vitro data, which is contrary to what the case law seems to be saying.

COMMISSIONER LEHMAN: Thank you very much.

MS. ENAYATI: Thank you.

COMMISSIONER LEHMAN: Next I'd like to call on William Scanlon, from Foley and Lardner.

WILLIAM SCANLON, FOLEY and LARDNER
MR. SCANLON: Thank you, Mr. Commissioner, for the opportunity to speak on this important issue today.

My name is William Scanlon. I am a partner with the firm of Foley and Lardner in its Madison, Wisconsin office, and I'm a member of the firm's biotechnology practice group. The firm represents organizations -- both business organizations and research organizations nationwide.

I've been practicing patent law for 14 years and for the last 12 and a half years the bulk of my practice has been biotechnology. My presentation here is on behalf of the Intellectual Property Committee of BIO, the Biotechnology Industry Organization, not the Association as it says in the program.

I will address briefly questions one and two under part B of the Commissioner's Notice. My presentation is detailed in much greater detail in the BIO paper, which is of record in the hearings here, at pages 61 to 72. Part B of the Notice relates to proof of operability for inventions involving treatment of human disorders.

Question one. Are the legal standards for proof of operability in those situations clear and appropriate?

Question two relates to PTO practices and asks whether the practices are consistent with the law, if not, what are the problems and, if there are problems, what solutions might there be.

As Ms. Enayati just described, the legal standards are clear and we believe appropriate with regard to proof of operability. The problem is not in the legal standards. The problem at present is in the PTO's implementation of the law relating to operability and the imposition of requirements that the courts have rejected long ago under the rubric of operability.

The Commissioner's Notice reflects the problem. The Commissioner's Notice suggests some distinction between, quote, "utility," close quote, and "operability," close quote. This is the distinction that the law does not recognize.

The Notice suggests then, under the rubric of operability, various requirements and policy concerns that are also not part of the law. Safety and clinical efficacy are not proper concerns of the Patent and Trademark Office. Whether the grant of a patent would mislead patients or the public is not a proper concern of the Patent and Trademark Office. The law allocates these concerns to other agencies; the Food and Drug Administration, the Securities and Exchange Commission, the Environmental Protection Agency, the Department of Agriculture, and various state agencies with similar responsibilities, to mention a few.

In the context of inventions for treating human disorders, rejections for inoperability have become routine. I believe it's fair to say that most of these rejections are improper.

Proof of operability is required only if the utility set forth in the application, as of the effective filing date of the application, is incredible or unbelievable to the person of skill in the art. Examiners must be able to establish this credibility or unbelievability with reference to technical data that was available in the art on the date the -- the effective filing date of the application.

The assertions in an application regarding utility must be accepted as true by an examiner unless the examiner has some good reason, again,

based in the technology available on the date -- the effective filing date of the application to prove otherwise.

Now, a claim to a method of curing -- emphasize curing -- a disease, which the art on the effective filing date recognizes as incurable, might well be properly rejected for inoperability, and the applicant in that situation might be put to the test with appropriate data, not necessarily clinical but appropriate data, to show that, in fact, you can cure the disease the art considered to be incurable. But this is different from a method of treating a disease that is incurable. Generally, such a claim would not be inoperable. We treat many incurable diseases: Grave's disease, diabetes, AIDS, to mention a few.

Now, even in cases where proof of operability may be required, human clinical data may not usually be required in accordance with the law, although the PTO itself recognized in the Balzarini case that is addressed in our paper here and that Ms. Enayati mentioned. But now de facto human clinical data are being required in the human therapeutic area.

In our text, at pages 69 to 71, several different practices now in the biotechnology group are described that establish de facto requirement for human clinical data. The requirement for human clinical data is, in fact, wrong as a matter of law in most cases, and it's a travesty as a matter of policy for reasons that have been explained repeatedly here already today in terms of slowing the availability, even denying the availability of new therapeutic methods to the public.

Now, what might we do to correct the problem? Well, we think to begin with PTO policy has to change. The PTO, and Group 180 at least, must recognize its job is to grant patents; it's not to enforce FDA regulations or the SEC rules. Also, we think that better training of the examining corps, particularly with respect to legal standards, would be appropriate. And BIO does support providing to the Patent and Trademark Office the resources it needs to provide such training.

Thank you very much.

COMMISSIONER LEHMAN: Than you very much. I appreciate that.

Next I'd like to call on Stanley Crooke of Isis Pharmaceuticals to come forward, please.

STANLEY CROOKE, M.D., ISIS PHARMACEUTICALS

DOCTOR CROOKE: Good afternoon. I am Stan Crooke. I'm the founder and chief executive officer of Isis Pharmaceuticals, a development stage, technology based pharmaceutical company. Prior to founding Isis, I was

president of R&D for SmithKline Beecham, and before that a vice president of Mr. Myers. I'm a physician and a scientist and in my career I've been involved in the development of more than 15 drugs that are currently marketed, and numerous other drugs in development. I've published more than 300 scientific papers and 16 books on pharmacology and drug discovery and drug development.

What I want to do today is address a single issue and that is the issue of therapeutic utility. As a practitioner of the science, I'd like to address it from the scientists' perspective and conclude with what I think are some reasonably practical recommendations for what the patent office might do.

The issue reduces to one simple question: What data are sufficient to support claims of potential therapeutic utility? Although there is no universal or, in my view, no absolute right answer to this question, I believe there are precedents that have stood the test of time that can provide guidance and can serve as a basis for reaching agreement. The problem and the reason that we're here on this issue is, of course, that the evaluation of the utility or potential utility of an innovation in the pharmaceutical industry is especially complex.

On average, more than 15 years elapse between the discovery of a new drug and its marketing and, depending on which numbers you accept, somewhere in the range of $150 to $350 million has to be invested in that drug before we know whether it works. It would be impossible, and it is impossible, for a company to make this kind of investment without reasonable expectations of patentability, particularly in light of the risks of investments in this area. We know that historically less than one in a thousand compounds synthesized and patented by the pharmaceutical industry has actually succeeded in becoming a drug.

Well, of course, many factors contribute to the risks and uncertainty in drug discovery and development, but I want to focus on one particular problem that I think is particularly germane. And that problem is I think the only way to determine the value of a new pharmaceutical technological innovation is to evaluate the fruits of that innovation. That is to evaluate the activity of drugs that come from that innovation in human beings in detailed clinical trials that require these many years and many millions of dollars.

As an example, let's consider the history of the treatment of ulcer disease. It's been known for many decades that ulcer disease is correlated with stomach acid secretion, and a large number of physiological processes have been identified that influence stomach acid secretion. Early on, the coallergic arm of the autonomic nervous system was shown to increase acid secretion so it was hypothesized that anticoallergic drugs would have therapeutic utility in this disease.

Literally thousands of such compounds were made; they were tested and they were patented. A few of them were even marketed, but the side effects of these drugs were very limiting and so the true therapeutic utility of anticoallergic drugs for ulcer disease was modest at best.

Of course research continued, other factors were identified that influence acid secretion, including histamine. This led to the notion that blockade of a specific receptor for histamine, the H2 receptor, might have therapeutic value. This was controversial. It was hotly debated but research continued and, in fact, the first H2 antagonist that reached the clinic, the Thiamide, failed. But the second succeeded, and that was Tagamet. It revolutionized ulcer treatment. It led to thousands of other H2 antagonist being created and a number of other products. Then came the hypothesis that the inhibition of an enzyme, hydropotassium ATPaz might be beneficial because this enzyme is thought to actually secrete the acid into the stomach. Again, a very controversial hypothesis. Many compounds were tested, synthesized, patented. All failed, essentially, except for one: Amepresol. Amepresol ultimately was marketed and, again, has made a dramatic improvement in the treatment of ulcer disease.

Well, the points I want to make by reciting this well-known history are several and I think they are very important.

First of all, new concepts and approaches. That is new technologies that might result in therapeutic innovations arise constantly.

Second. Only after a drug, based on a particular mechanism or based on a new concept, has been shown to work in the clinic has the technology been validated.

Third. It is a normal part of the process that some members of a particular class of drugs fail, yet the basic concepts that support the creation of these broad innovations have proven to be valid.

Fourth. Innovations are by definition controversial. And the controversies in this area are not resolved until clinical data -- until the compound is tested thoroughly in the clinic.

Fifth, and perhaps most importantly. Despite these complexities, the traditional practices of the PTO result in effective stimulation of innovation and enormous public benefit. Those traditional practices were to allow claims of reasonable scope long before definitive proof of utility was obtained. This was done by accepting reasonable evidence of potential utility and by maintenance of an attitude that was biased toward rewarding and encouraging innovation by giving the benefit of the doubt to new concepts.

I think, as you've heard from several speakers very recently with regard in particular to patents in biotechnology, we feel there's been a substantial change in the practices of the PTO demands for definitive proof of therapeutic utility that resulted in many patent application rejection.

Let's look at the potential impact of this change in the patent environment. In other words, what will happen if the PTO were to continue to require definitive proof of utility before granting therapeutic use claims? What will happen is absolutely simple and absolutely clear: New drug innovation will be dramatically impeded. So the risks of continuing this practice I believe are very large. I believe the risks of relaxing the policy are really quite negligible. The drug discovery, development and commercialization processes have built-in self-regulating mechanisms that ensure the drugs that should fail do.

So, what harm is done if a patent with appropriate claims is granted to a drug candidate and the drug or the technological concept behind the drug fail? Well, of course, the company that's invested in that drug or that technology loses its investment, but that's the risk it takes. Nothing has been lost by society. In fact, the public actually gained from the exploration of the concept of the technology.

On the other hand, if companies stop investing in new compounds derived from novel concepts or technologies, because of patent uncertainty, everybody loses and I don't think the loss will be made up. So what am I actually recommending?

First. Return to traditional practices with regard to pharmaceutical patents. They worked in the past; they'll work in the future; they will work now.

Second. Return to a positive bias to innovation with an acceptance of reasonable proof of potential -- of potential -- utility.

Third. I think you should treat patents from so- called biotechnology companies and pharmaceutical companies equally. We're the same industry, with the same customers, practicing similar science.

The traditional approaches of the PTO were sufficient to stimulate investment in innovation in both sectors of the drug discovery and development-based industry and they would be going forward.

Fourth. I think you should emphasize consistency across and within technological areas. Just because one approach is labeled "new technology" and another is not, does not mean that the basic approaches or risks are necessarily different. Even the most traditional of

technologies, most of the compounds generated by those traditional technologies will fail.

Fifth. When in doubt, grant therapeutic claims based on specific examples provided in the patent application with scope commensurate with reasonable extrapolation from the examples provided.

Finally, I would urge you to be equally or even more prudent in the allowance of broad concept patents. Allowance of reasonable claims based on examples provided in patent applications is sufficient to stimulate innovation in this area. Granting broad concept patents I think is very rarely justified in the pharmaceutical industry.

With that I'll stop and answer any questions that you have.

COMMISSIONER LEHMAN: Your testimony was so clear that I don't think we have any questions.

DOCTOR CROOKE: Good for you.

COMMISSIONER LEHMAN: Thank you very much.

DOCTOR CROOKE: Thank you.

COMMISSIONER LEHMAN: Next I'd like to ask Vincent Gioia, from Christie, Parker and Hale, to come forward.

VINCENT GIOIA, CHRISTIE, PARKER and HALE

MR. GIOIA: Thank you for giving me the opportunity to make these remarks. My name is Vincent Gioia. I'm a partner with the law firm of Christie, Parker and Hale, in Pasadena, California.

I'm here to request the Patent and Trademark Office to consider recommending amendment to the plant Patent Act, to extent the grant to parts of plants. Under 35 U.S.C. 161 and 163, inventors and discovers of new plant varieties are granted the right to exclude others from asexually reproducing plants of the new variety or selling or using plants so reproduced.

The law does not expressly apply to cut flowers and fruit of plants of patented varieties. Consequently, fruit or cut flowers of a patented variety may be imported with impunity to the considerable economic disadvantage of plant patent owners, their licensees and the labor force of the industry adversely affected.

It is in the public interest to close this loophole so that owners of U.S. plant patents and those engaged in commerce in patented varieties

will not suffer unfair competitive disadvantage. Correction of this inequity only requires a modest amendment to 35 U.S.C. 163 to make it clear that in the case of a plant patent the grant shall be the right to exclude others from asexually reproducing plants of the patented variety or selling or using the plants so reproduced, or any part thereof.

There's presently very significant importation of parts of plants, such as fruit and cut flowers of plants of patented varieties, into the United States. Illustrative of the extent and impact of importation of products produced by plants of U.S. patented varieties grown outside the United States is the situation with cut roses.

Cut roses was the subject of a report by the United States International Trade Commission in April 1989. In this report -- summarizing the impact of the cut flower importation -- the Executive Summary of the report states: "The U.S. fresh cut rose industry has steadily lost market share to imported roses over the last decade. In 1985 imported roses accounted for 26.5-percent of the U.S. apparent consumption of roses. By 1988 imports had increased their share by over 40-percent accounting for 37.9-percent of apparent consumption."

The Executive Summary goes on to state that, "Although sales of fresh cut roses increased by 10-percent, during 1985 to 1988, the total growing and operating expenses increased faster and, moreover, the number of firms reporting losses increased from 31 in 1985 and 1986 to 36 in 1988." Again, according to the Executive Summary, those firms reporting losses represented almost 38 percent of the growers. It is logical that a similar impact on domestic industry has occurred with respect to other plant parts, such as berries and other fruit, nuts, and fiber.

A copy of the Executive Summary, which I've just referred to, is appendixed to the report which I submitted for these hearings. A full copy of the ITC report is also available upon request from me or from the ITC.

It is obvious that the impact on domestic industry and those employed by the industry is enormous. Most people working in the agriculture industry are low wage earners without training and skills required for other employment. The adverse impact of the expanding imports of flowers and fruit of U.S. patented varieties is measured by these people in loss of opportunity in jobs and a lower standard of living.

Although the U.S. Supreme Court and U.S. Patent and Trademark Office Board of Patent Appeals and Interferences have agreed that utility patent protection under 35 U.S.C. 101 should be available to plant inventions, in practice, asexually reproducible plants are not able to qualify for utility patents. Even though it has become acceptable to satisfy enabling requirements of 35 U.S.C. 112 by providing a deposit of

biological material in a suitable depository, the fact is that it is not feasible, practical or, indeed, technologically possible at the present time to provide a deposit of biological material of asexually reproduced plants in a manner which would satisfy present U.S. Patent and Trademark Office policies and practices.

Therefore, the Plant Patent Act remains the only viable means for protecting new varieties of plants -- of asexually reproduced plants. Failure to extend this protection to the parts of the plants is not only unjust but would result in a continuation of the severe damage to domestic industries as indicated in the ITC report.

In order to extend full protection of the patent law to inventors and discovers of new plant varieties, amendment of 35 U.S.C. 163 is required to extend the patent grant to parts of plants. This may be done by a simple modification such as the following:

In the case of a plant patent, the grant shall be the right to exclude others from reproducing plants of the patented variety or selling or using the plants so reproduced, or any part thereof. This suggested amendment no only clarifies that the protection extends to parts of plants but would also make 35 U.S.C. 163 consistent with 35 U.S.C. 161, which states that whoever invents or discovers and asexually reproduces any distinct and new variety of plant may obtain a patent there for.

Clarifying the rights granted the plant patent holders, as suggested, is necessary to avoid unfair competition from abroad and would place owners of plant patents in a position comparable to the holders of utility patents.

Thank you very much.

COMMISSIONER LEHMAN: Thank you. Is there a trade association that represents people that you're talking about?

MR. GIOIA: I've been in the practice of plant variety protection for over 30 years and I've represented breeders of new varieties, almost all phases of the plant industry. There are a couple of trade associations, most particularly the Roses Incorporated, which is a trade association of cut flower growers. There's also a national association of Plant Patent Owners who is expressing a similar position as I've described in this issue, and one which I would also endorse and probably they would endorse my comments as well.

COMMISSIONER LEHMAN: Well, the reason I asked that question is because to the extent that you're talking about statutory change, which you are, and we had recent change in the Plant Variety Protection Act to implement an international treaty just recently. It really helps to have some

group that represents, you know, sort of common interests.

MR. GIOIA: Yeah. I would like to mention in that regard that the Plant Variety Protection Act is applicable to sexually reproducible varieties. Asexually reproducible varieties are protected under the Plant Patent Act so, therefore, the changes that you've mentioned that have been proposed for the Plant Variety Protection Act, primarily to bring us into compliance with the treaty, newly proposed convention of UPOV, won't have any effect at all on the Plant Patent Act.

COMMISSIONER LEHMAN: But we could have used that vehicle, that's what --

MR. GIOIA: Possibly we could have. Your announcement of these hearings, however, raised the opportunity to present this issue to the Patent and Trademark Office along with this request for your assistance in making these recommended changes to the Plant Patent Act.

COMMISSIONER LEHMAN: Is there any opposition that you know of to this?

MR. GIOIA: I know of no opposition to this unless it may be from the importers of the pirated plant patented varieties who are exporting from countries in which no protection is available to breeders the cut flowers and other plant parts into the U.S. market for consumption here.

MS. LINCK: Does the American Rose Society take a position on this issue?

MR. GIOIA: The American Rose Society is an organization of amateur rose growers. They're not typically representing the industry, although industry -- members of the industry are active in the American Rose Society. I am a past president of the American Rose Society and also of the World Federation of Rose Societies, which is the international group composed of the national rose societies and they typically do not take political positions on legislature.

MS. LINCK: Thank you.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to ask Mark Toohey, from Spencer, Frank, and Schneider, to come forward, please.

MARK TOOHEY, SPENCER, FRANK, and SCHNEIDER

MR. TOOHEY: Thank you, Commissioner Lehman.

My name is Mark Toohey. I work with Spencer, Frank, and Schneider. I'm

a registered agent at this point in time finishing up my law degree. I have a doctorate in biochemistry and as part of my legal degree requirements I was studying the issue of practical utility so these hearings came at an opportune time for me. I have extensively studies the case law with respect to both 101 and 112, and I have been particularly interested in the pharmaceutical inventions.

I've come to the conclusion that the Patent and Trademark Office is wrong to maintain the policy they have in rejecting certain classes of biotech inventions on the basis of a lack of practical utility. The Patent Office is wrong because it's narrowly reading the statute under Section 101. The Patent Office is wrong because it's misinterpreting the decisional law and it's wrong because I don't feel it even has the jurisdiction to be in this question.

In misinterpreting the statute, the office is following the Brenner v Manson decision in 1966. That decision is really directed toward a question that was first asked in In re Brenner and the question is whether or not someone must state a utility in their application. The court and the office agreed that the utility must be stated. The Manson applicant did not state the utility and so the invention was found not to be patentable to him. It was unpatentable not because of the class of the invention, which is a pharmaceutical, and not for the use, which is in humans. It was unpatentable because of a procedural error in not alleging utility. Yet the office relies on Manson in its rejection of these biotech inventions.

The Manson majority also narrowly construed Section 101. The court later corrected itself, Diamond v Chakrabarty. In Diamond v Chakrabarty, Judge Rich's appellate decision was followed. There Judge Rich tells us that the House Committee reports say that Section 101 is directed to anything under the sun made by man. The PTO has never corrected itself. Biotech inventions are under the sun and they are made by man. They are useful.

Judge Rich also tells us that Section 101 is the first door to patentability. Section 102 is the second door, and it says the applicant is entitled to a patent unless certain statutorily defined criteria are not met. There is a presumption of patentability. There is a presumption of enablement under Langer. There is a presumption, I believe, under Section 101 of utility also.

With regard to the question of statistically significant clinical trials. That is not the law. Case after case says that is not the law yet the Patent Office or the examiners in the office continue to assert that that is the law. Since the 1961 Krimmel decision, it's consistently been held in the CCPA and also in the Federal Circuit that standard experimental animals and the usefulness there is sufficient proof of

utility. That should be so. That is the industry standard. And now more often in vitro tests is an industry standard. Animal tests are sufficient in the EPO. Animal tests are sufficient in the JPO. I routinely run across the situation where I have applications, the claims of which are allowed in the EPO, allowed in the JPO and blocked in the USPTO. I don't understand why we have this policy.

We would assume the Patent Office would try to promote the industry. We've heard this morning how it's not particularly helping in this utility issue. We would think it would encourage the use of animal models because they're economical, they are reliable -- to an extent -- and they are less dangerous. Why have human data necessary? We think the Patent Office should -- or I think the Patent Office should also encourage in vitro tests. There's a benefit to the public there that goes beyond the animal models. That is there are some parts of the public who are concerned about the ethics of using animal experimentation. In vitro tests would allay those concerns.

The Patent Office has also argued in the past and continues to argue that it must be extremely cautious in issuing patents intended for human use. The office relies on a 1957 decision of Eisenstadt v Watson, where the judge expressed concern about the official imprimatur, as is note in the Notice of these hearings, that is associated with a patent, whether rightly or wrongly, and would leave the unsophisticated and the public to believe that the invention works in each and every way described in a specification. But this argument misses the point, which has already been brought up this morning, that the official imprimatur does not give the public anything. The public cannot have access to the drug without approval by the FDA, EPA, USDA and other regulatory authorities. That brings me to the point of jurisdiction. As early as the 1962 case In re Hardtop, the court recognized that jurisdiction in the issue of safety and efficacy belongs with primarily the FDA. The Patent Office has never gotten to that decision.

One need only look at Title 21 of the United States Code, the Food, Drug, and Cosmetic Act, and all the implementing regulations under that Act, to see the FDA has jurisdiction on safety and efficacy issues. If the Patent Office is disregarding the court decisions, it's disregarding these statutes and it continues to assert jurisdiction on the basis of a strained interpretation of a single word -- utility -- in the patent statute. I believe the Patent Office should back off in this regard. I think it should leave the question of safety and efficacy to the FDA. They are the ones who have the expertise to determine safety and efficacy, not the Patent Office.

I will stop here in the interest of time.

COMMISSIONER LEHMAN: Thank you very much, Mr. Toohey.

Next I'd like to ask Allen Dow, from Klarquist, Sparkman, Campbell, Leigh and Whinston to come forward.

ALLEN DOW, KLARQUIST, SPARKMAN, CAMPBELL, LEIGH and WHINSTON

MR. DOW: Thank you, Mr. Commissioner. I'm an attorney with the law firm of Klarquist, Sparkman, Campbell, Leigh and Whinston, in Portland, Oregon. And even as far northwest as Portland our public officials have thought of biotechnology as well as other high technology fields as undergirding economic development for the coming several decades, so this is of great interest to our region as well.

My position in the schedule has reduced my talk, in large part, to a series of ditto marks, so if I stumble and pause for a moment you can utter yourself the ditto. I won't do that myself. That's especially in regards to the citation of case law.

I'd like to respond in part to the Commissioner's comment regarding the presumption of utility and again harken to other areas of technology, like electrical and mechanical cases. In this regard, I do have a cite that I haven't heard before from the attorneys who have preceded me, and others discussing the utility requirement, and that is the dissenting opinion by Judge Smith in In re Joly where he said that the application of the practical utility requirement to -- in that case chemical pharmaceuticals -- if that same standard had been applied to mechanical inventions, for example, or electrical inventions, would have rendered unpatentable the Wright Brothers airplane, the Bell Telephone, the Morris Telegraph, and Edison's light bulb at the stage of development at which they actually reached the Patent Office.

Now, I flew here in an airplane. I dozed much of the flight. I found it safe and effective. I may not have had that same experience if I had flown that 120 feet at about 12 feet of altitude with the Wright Brothers in their first airplane.

I also think the case law, Chilowsky, Langer and others, also support the notion that utility should be presumed, at least until the examiner can cite to relevant scientific data that undergirds the argument of asserted utility.

More generally, in cases in which a pharmaceutical utility is asserted, it just blocks patentability altogether. I've heard a couple of times from panelist here, the solicitor in particular, a request that we simply appeal to the Federal Circuit to get clarification of the case law. And what may be, as the gentleman from Hoffman-La Roche indicated, a roadblock for Hoffman-La Roche just stops small biotechnology companies and universities dead in their tracks. They simply cannot mount the

funds to attack through the Board of Appeals to the Federal Circuit. It's also been stated that the standards of utility, as applied by the Patent Office, may wish to be reserved for the Supreme Court if the Federal Circuit were to find otherwise, and we believed that the likelihood of certiorari being granted by the Supreme Court is simply dismal if we were to try to take the same steps.

MS. LINCK: I guess a this point I'd like to interrupt because, based on what I've heard, it sounds to me like we don't have a lot of Board of Appeals' cases that are inconsistent with the standards that we are trying to apply and we believe that you want applied. So I guess at this point I would say, you know, at least get them to the Board, and if you can cite me cases where the Board has been inconsistent with the standards that you are espousing, you know, I would appreciate that as well.

MR. DOW: I'm happy to do so in my written comments. I haven't really prepared a brief of recent Board decisions. In fact, my basic point was an appeal for the Patent Office to simply apply the standards announced in the CCPA and Federal Circuit cases already discussed here today. It's simply the case -- even an appeal to the Board for clients of ours, such as the Oregon Health Sciences University or Oregon State University and others, is simply an investment that they really feel they can't make and so we really need justice at the level of patent examination. Deep pocket justice won't help us. We've had several cases in which we've gone to the client and actually offered -- in one case in particular -- actually offered to do this as a pro bono effort and, in this case, the university said, "I'm sorry. We just really don't want to go forward. If the Patent Office is going to consistently reject this kind of claim, we're just going to have to stop here."

MS. LINCK: Again you're in an area, emerging technology, and it's difficult to apply case law in well established technologies to cases in emerging technologies, and we do the best we can. But if you stop at the examiner level when we're struggling to do the best job we can, it's very difficult for us to identify the errors that are happening consistently. So that's why --

MR. DOW: We're certainly going to do our best, Madam Solicitor, to encourage our clients to use our services in appealing to the Board.

MS. LINCK: I appreciate that. Thank you.

MR. DOW: You're going to hear some dittos, and I just want to pass through the case law to some experiences I've had in actually trying to prosecute patent applications. I think in one case in particular of a case in which human pharmaceutical utility wasn't asserted but rather a utility as an animal vaccine and, in this case again, we ran into 101,

112 rejection based on lack of utility because we hadn't shown that a herd receiving a vaccine would necessarily be able to mount a response to the contagion. And in this case the claim that was rejected was a DNA claim, and I just -- again, one of the comments from the panel has been that much of the I suppose high-pitch whining of the patent bar has been anecdotal at best.

I just want to toss one more anecdote into the ring. In this case, up through four or five office actions at a cost to our client of tens of thousands of dollars, the claim continued to be rejected as a -- for lack utility even though it was a DNA claim and other utilities had been asserted in the specification, for example, as probes and so forth. And it just seemed, to me at least, abusive in that particular case.

I will say, too, that it seems to be beyond the level of an individual examiner. In this case, due to restriction requirement, there were at least three applications before the Patent Office and we received almost identical rejections in all three cases, which appeared to me to be less a sign of individual examiners being unreasonable than of examiners of a group representing some kind of policy, if you will. And that troubled me more than individual examiner stories, which I think we're going to encounter in any practice group and on any given day.

Let me simply stop by again making my plea that the decisions of the CCPA and the Federal Circuit be applied consistently and fairly to applications in this field.

Thank you very much.

COMMISSIONER LEHMAN: Can I just ask one question. Are there any circumstances under which you think that -- would you say that human clinical data would never be required to prove utility?

MR. DOW: "Would never be required to prove utility." I had actually prepared a short list which I nixed out but now I have time for that. If I could just run through five instances where I think the legal standard would support not requiring human data.

First. When those skilled in the art attest under oath that the test data offered by the applicant shows pharmaceutical utility, that really should be legally sufficient.

Second. Where there's been proof that the animal model used is one commonly used by those skilled in the art. Now, this is a problem especially in biotechnology. I think in Cross v Iisuka, for example, not to require human data is clearly allowed, if you will. And that for many biotechnology inventions there's no such thing really as a standard experimental model, simply because you have a new class of drug. A

brand-new class of drug. And I think there once you simply looked at the literature, what are people using as tests to determine the pharmacological activity of the drug at question. I really don't believe the public will be visited with any great ill as a result of a disclosure, perhaps premature, of pharmaceutical utility where the FDA and the market get to take their shot.

Also, finally, licensing is I think a clear sign of utility; a company being formed to exploit the technology and the fact that a party has undertaken the expensive human trials, notwithstanding the lack of a patent or at least during the pendency of the patent.

COMMISSIONER LEHMAN: Thank you very much.

MR. DOW: Thank you.

COMMISSIONER LEHMAN: Next I'd like to ask Ned Israelsen, of Knobbe, Martens, Olson and Bear, to come forward, please.

NED ISRAELSEN, KNOBBE, MARTENS, OLSON and BEAR

MR. ISRAELSEN: Thank you, Commissioner, distinguished panelists. My name is Ned Israelsen. I'm a patent attorney with the firm of Knobbe, Martens, Olson and Bear. I head up a 12-person biotechnology group and my clients include several biotechnology companies, universities, private research institutions and the National Institutes of Health. In addition to sharing my personal views, two of my San Diego biotechnology clients -- ViCal, Inc., and Alliance Pharmaceutical Corp. -- have asked me to present testimony on their behalf.

As most of the other speakers have, I would first like to touch on the issue of utility and enablement; the rejections that we're getting under the broad heading of operability. And, then, time permitting, I'd like to touch on a few new points that haven't been raised much; the average pendency statistics that the PTO has promulgated; the legal training of examiners; 102(e)/103 rejections; and a new type of In re Katz rejection.

In 1980 the CCPA decided Nelson v Bowler which held that mere demonstration of a pharmacological activity was sufficient to establish a patentable utility even without disclosure of any specific therapeutic use. This decision has been followed in Cross v Iizaku and other cases that have been discussed today. Also, in the Brenner v Manson case, the Supreme Court tied the utility of a method involving a compound to the utility of the compound itself, so I would propose that disclosure of a method for achieving a pharmacological activity is similarly patentable under the Cross v Iizuka standard.

Other speakers have pointed out that it is the FDA, not the PTO, that has the expertise and the statutory responsibility to determine safety and efficacy. In re Anthony is a particular case in point. There the FDA actually pulled the drug from the market and yet the CCPA said that it satisfied the statutory utility standard.

In direct contrast to the case law, I believe that Group 1800, in particular, has promulgated an extremely high standard of utility and that inventions dealing with pharmaceuticals and pharmaceutical treatments are held to a much higher standard in Group 1800 than, for example, comparable inventions are held in Group 1200. I believe there is a clear conflict between the two groups in the way the law is applied.

The meeting Notice asked for specific sanitized examples, if available, of some of the horror stories that we're faced with. Let me give you a couple.

My first example deals with a method for treating animals, a method that has general applicability, is not limited to human therapy, the claims -- although that's discussed in the specification -- the claims are not limited to human therapy. This series of applications was filed five years ago. Three and a half years ago the claims were held to be free of the prior art. Since that time, though, a utility/enablement rejection, under Sections 101 and the first paragraph of 112, has been entered and five interviews later, seven declarations later submitting experimental evidence, and 17 publications by third parties who have successfully practiced the invention and reported the results, we still are faced with a utility and enablement rejection because although the industry has accepted the invention, the operability of the invention, the examiner has not. The question of appeal was raised by Ms. Linck. Should we take these cases on appeal, and certainly we struggle with that. My perception is that appeals take several years now in the biotech area; that because there are fewer examiners-in-chief who have biotech training these cases are put on the slow track. We just can't wait.

The next example deals with a gene therapy invention. This application was allowed. The examiner was then reassigned. The case was withdrawn from issue. A utility rejection was put in place and although the examiner cited no affirmative evidence in support of this rejection for lack of utility, it's been maintained. The FDA had determined that evidence of safety is sufficient that -- and efficacy is sufficient that human clinical trials can begin. Apparently the examiner is the only one who is not convinced.

The PTO in its Notice seeks to justify a high standard under the fallacious argument that a patent places the imprimatur of the federal government on the invention, perhaps to the point that it would mislead

patients and others. As other speakers have noted, it's the FDA, not the PTO that determines safety and efficacy. And there's really no harm if a non-efficacious or non-commercializable invention ultimately makes it through the patent system and if it doesn't get FDA approval it will merely fade into obscurity. And if you look at the statistics, out of a handful, out of I should say thousands of pharmaceutical patents that do make it through the gauntlet, there are only a handful of inventions that are -- new drugs that do receive FDA approval in any given year. So if the PTO is measuring its success rate by whether an invention makes it to the market, that's the wrong measure of success.

There are some who say that applications should not be filed until extensive supporting data are in hand, but this ignores reality. An early filing date is essential because except for the U.S. the entire industrialized world is on a "first-to-file" system, and we rely on our U.S. filing date for that purpose. A patent can't wait, in any event, because inventors publish their results and these published results could then be used to reject the later application that has the more extensive data Group 1800 seems to want.

With a time period required of six, to eight, to ten years and over $100 million to develop these data, small biotech companies simply cannot survive that long, and if they don't have the patent the investment capital will not be available. The problem is even more acute for non-profit research institutions and institutions such as NIH.

Let me jump to a couple of new points. When Congress amended the Section 103 to exempt rejections based on inventions made by people working at the same company, under Section 102(f) and (g), it had a major oversight. That is that it forgot to include Section 102(e). Now, when inventors work together and a CIP is filed, the -- if the inventorship is at all different, the second application is rejected over the first. If the first patent issues the CIP is simply unpatentable. If not, the only cure is to combine the two applications together, file a third application and then split them into fourth and fifth applications all to exalt form over substance and overcome an objection that really never should be made in the first place, that is the rejection of one inventor's invention over co-workers at the same company.

Another solution might be to amend the statute to allow corporations to be applicants for patent and focus on inventions coming out of a corporation rather than just inventions by particular inventive entities.

Next, the push to cut average pendency has been -- of applications in the biotech area has been counterproductive. Although applications average pendency has shortened up, numerous continuations are now necessary with the result that it's taking longer than ever to get our

biotech patents issued.

Thank you.

MS. LINCK: I have one comment, again pushing for the appeals. The Board has a number of new members on it since Mr. McElvy took over and I know that there are at least three that are skilled in the biotech art that have been added to the Board, so perhaps you'll have a little bit speedier action there.

MR. ISRAELSEN: Thanks.

COMMISSIONER LEHMAN: Thank you very much.

That concludes our morning session. We will be returning in approximately 50 minutes, 2:00 o'clock, to begin the afternoon session.

(Whereupon, at 1:10 p.m., the above-entitled matter recessed to reconvene at 2:00 p.m. the same day.)

AFTERNOON SESSION (2:05 p.m.)

COMMISSIONER LEHMAN: We're back on the record and we'll get underway now. I'd like to think the City of San Diego for being so nice and providing this great room for us and this is a wonderful facility for us to have our meeting in.

Our next witness is Barbara Rae-Venter from Weil, Gotshal and Manges.

BARBARA RAE-VENTER, WEIL, GOTSHAL and MANGES

MS. RAE-VENTER: Commissioner Lehman and distinguished members of the panel, good afternoon. My name is Barbara Rae-Venter. I'm a partner with Weil, Gotshal and Manges and head of the biotechnologies practice for the firm. I'm resident in the Silicon Valley office.

Weil, Gotshal and Manges is an international general practice firm with a diverse array of biotechnology and pharmaceutical clients. My personal specialty is patent prosecution and counseling. I'm speaking on behalf of BIO, of which Weil, Gotshal and Manges is a member. I will testify on the case law relating to technical standards used in measuring nonobviousness and enablement of biotechnology inventions. The full text of BIO's testimony on the subject has already been made of record and a supplemental to testimony by BIO in a previous hearing on nonobviousness.

Nonobviousness and enablement are distinct requirements of the patent code. However, both inquiries are grounded in assessment of what the specification or prior art would teach or suggest to a person of ordinary skill in the art. In many instances, the critical question to be answered in an obviousness inquiry is whether a person of ordinary skill in the art would have had a reasonable expectation of success in performing an experiment suggested by the prior art. By the same token, often the critical question to be addressed in an enablement inquiry is whether in light of the teaching provided in the patent specification a person of skill in the art could make and use the claimed invention without undue experimentation.

Logic dictates that the skill level of this mythical person should not change as we move from Section 103 where examiners tend to see this person as one with genius level skill to Section 112 where examiners tend to see this person as one with very little skill. I will focus my testimony around this apparent dichotomy and the effects that this has had on determining patentability of biotechnology inventions.

As regards the level of skill to be attributed to a person of ordinary skill in the art, during an obviousness inquiry, very few biotechnology cases have focused directly on this issue. For example, in Bell, -- and I'm going to omit the cites for the cases -- Engine, and Vaeck, as well as the published cases from the PTO Board, the obviousness issue has turned on what the prior art would have suggested to a person of ordinary skill in the art, or whether that person would have had a reasonable expectation of success in carrying out an experiment, but the scientific attributes of the person of ordinary skill have not been elucidated. Even in In re O'Farrell, the case that contains the most discussion of the obviousness issue in the context of a biotechnology invention, specifics concerning the level of skill in the art are addressed solely by reference to the fact that, quote: "Appellants say that in 1976 those of ordinary skill in the arts of molecular biology and recombinant DNA technology were research scientists who had extraordinary skill in the relevant arts and were among the brightest biologists in the world." End of quote. Nonetheless, there is no apparent basis in the case law to suggest that the standards for determining the applicable level of skill possessed by the person of ordinary skill in the art of biotechnology should be any different than those used for making that determination in other arts. Thus it is clear that the person of ordinary skill in the biotechnology field should be considered to be the designer or problem solver in the art, not the user of the invention. While the person of ordinary skill is presumed to be aware of all the pertinent prior art, she is one who thinks along the lines of conventional wisdom in the art and is not innovation oriented. Consequently, the obviousness of an invention to the actual inventor is acknowledged to be irrelevant because inventors are acknowledged as a class to possess skill that sets them apart from the person of ordinary skill in the art.

Though the cases contain very little discussion of the attributes possessed by the person of ordinary skill, the positions taken by the Patent Office in In re Bell, Duel, and Movva, suggests that examiners may be applying under an obviousness analysis a far higher level of skill than that actually possessed by the ordinary person of skill in the art.

An example of the application of this high standard is that examiners are rejecting claims to DNA sequences on obviousness grounds based upon information concerning the amino acid sequence of a protein and a reference describing at most a general cloning method such as the use of probes.

And in In re Bell, the court considered such an obviousness rejection. In Bell the applicants had isolated the human IGF1 and IGF2 genes and saw it in earlier claims to those compositions having the DNA sequences of the isolated genes and certain DNA genes they would hybridize to the genes. The PTO Board had affirmed the examiner's rejection holding that the examiner had established a prima facie case of obviousness for compositions having the claimed DNA sequences in light of the known amino acid sequence of IGF1, the correspondent link between amino acid sequence and DNA sequences based on the redundancy of the genetic code and a prior art patent describing a general method of isolating a gene for which at least a short amino acid sequence of the encoded protein is known based on constructing nucleic acid probes.

In reversing the PTO's decision holding that a prima facie case of obviousness had been established the Federal Circuit acknowledged that their PTO's decision rested on the assumption that, quote: "Just as closely related homologues analogues and isomers in chemistry may create a prima facie case, the relationship between a nucleic acid sequence and the protein it encodes also makes a gene prima facie obvious over its correspondent protein." The court then held that the PTO had not met its burden of showing that the prior art would have suggested the claimed sequences because the known amino acid sequence, in light of the degeneracy of the code, might have yielded 10 to the 36th sequences but would not have taught one of skill in the art which of those sequences corresponds to the IGF gene which was the claimed invention.

At the same time the court rejected the notion that the prior art patent filled the gap, i.e., when combined with a known amino acid sequence of IGF1, rendered the claimed sequence as obvious. The court noted that when read carefully the reference actually taught away from the claimed invention because it suggested the desirability of designing probes based upon unique code-ons, and IGF had no such unique code-ons.

Finally, the court rejected the PTO's argument that the prior art reference supplied the necessary teaching because the applicant himself

had used the method suggested by the prior art in designing the probes that were used to isolate the cloned gene -- the claimed, excuse me, gene.

Labeling the PTO's focus on Bell's method, quote, "misplaced," end of quote, the court pointed out that Bell's claimed compositions, not the method by which they are made, and cited case law supporting the proposition, that the patentability of a product does not depend on its method of production. This latter statement by the court is quite important in that it is the difference between the subject matter sought to be patented and the prior art to which it is to be compared in the obviousness determination, not the method by which the invention is made that is relevant.

As recognized by the court and is supported by a long line of cases, whether a composition is patentable depends on whether the composition is known in the art or is obvious and not whether the process by which the composition is made is patentable. Unfortunately, the decision in In re Bell appears to have done little to dissuade examiners from continuing to reject claims directed to DNA compositions based on some partial amino acid sequence data and the generalized assertion that a particular prior art cloning method would have resulted in a reasonable expectation of isolating the claimed compound.

In Ex parte Movva and Ex parte Deuel, the PTO again rejected claims as obvious based almost entirely on a prior art method to isolate the claimed compound. In so doing, the PTO is failing to properly consider the statement by the court that it is the claims that define the invention, not the method of making the claimed compositions. A careful reading of the facts in Deuel necessitates a conclusion that the focus of the PTOs inquiry is almost solely on the cloning method, not on structural similarity. That focus runs directly counter to the Federal Court statement in Bell. In Deuel, the prior art supplied only a partial amino acid sequence and only the most general information about cloning. Apparently absent from a general method was any information about the various parameters that one in the art may have needed to vary if attempting to apply the prior art method to a particular desired gene sequence. In fact, this case highlights one of the biotechnology industry's main concerns with the PTO's position that such bare bones information fully satisfies its obligation to make a prima facie case of obviousness. Placing the burden on applicants to prove the negative, i.e., that the alleged method would not be expected to yield the claimed composition, is nearly impossible, especially in light of the PTOs consistent refusal to cite relevant experimental parameters.

Returning to the skill level applied by examiners under Section 103, even if the determination that the skill level is high for the art was correct, examiners take a position concerning the level of skill in the

art in connection with an obviousness inquiry that conflicts with the level of skill applied by the examiner in the enablement inquiry. However, as recognized by the PTO in their brief to the Federal Circuit in the Deuel case, quote: "To that end the prior art must describe the compound in such full, concise and exact terms as to enable any person skilled in the art to make and use the compound." End of quote. In fact, in Hybritech the court reversed the district court holding and labeled internally inconsistent findings by the court that the method for producing monocloned antibodies was well known in the art in a Section 103 inquiry, while at the same time holding the patent deficient for lack of enabling disclosure because it fails to teach how to make monocloned antibodies. As a result, it is disingenuous to argue that a claim to a genus is not enabled due to the lack of disclosure of a sufficient number of species while simultaneously arguing that in light of some prior art reference one of skill in the art would have had a reasonable expectation of success in making one of the claimed species.

In summary, it is BIO's position that examiners are not properly construing and applying the statutory requirements for patentability. In the area of nonobviousness, the PTO had misinterpreted the law concerning the test for patentability of biotechnology inventions. In the case of both nonobviousness and enablement requirements, the law is often misapplied and inconsistent positions are taken. Furthermore, all to frequently patent examiners failed to cite any prior art or other evidence in support of their conclusions, relying instead on supposition or unsupported assertion. The practical effect of the PTO's position cannot be understated. Patent Office statistics readily demonstrate that biotechnology patent applications take longer on average to prosecute than applications directed to any other technology. The cases at issue are often extremely narrow and limited to embodiments that have been actually reduced to practice. As a result, the claims are often of little commercial use. Time is money and, unfortunately, far too many precious resources are being needlessly spent by biotechnology companies to secure protection for the results of their research. At the same time, misapplication of the requirements for patentability effectively deprive these same companies of the full return due on their research investment. Thank you.

COMMISSIONER LEHMAN: Thank you. I would say that I think there is something that you said which is incorrect and that is the biotechnology applications take longer to process. They really don't. They're -- Group 2300 has a longer pendency period, for example, than Group 1800. 2300 is the --

MS. RAE-VENTER: If you take into account the fact that biotechnology cases often get refiled several times, I believe it's correct that they, in fact, take a very, very long time.

COMMISSIONER LEHMAN: Well, one of the things that I think we need to do is have better statistics about what really is going on, and we're going to be working on that. Because we seem to be hearing a lot of anecdotal evidence and we need to know whether that is really, you know, reflective of what's going on.

Thank you very much.

Next I'm going to ask Timothy Gens to come back. He only took five minutes of his time this morning and he wanted the other five minutes this afternoon so that he could discuss the issues that we're talking about here. I assume you're going to talk about the obviousness question as well.

TIMOTHY GENS, FENWICK and WEST

MR. GENS: Good afternoon, Mr. Commissioner and distinguished panelists. I am Timothy Gens with Fenwick and West and I am presenting these remarks on behalf of BIO. A complete copy of the text has been previously submitted.

I'm going to address the first question under the issue of "obviousness," and, respectfully, Mr. Commissioner, I don't think you'll like these comments much better than this morning. Rather than start round two just yet, I'd like to focus on a recommendation so that it is not overshadowed by the differences in other areas, and that is that we suggest to the Patent Office that it open the initial and continuing education program of the examiners to the public so that the basis of the examiners' legal education is known to the public. This should provide a consensus starting point for legal arguments to be applied to the facts of the invention under examination. There are clearly many advantages to establishing a legal education for the examiners which reflects a general consensus of both the Patent Office and the patent bar as representatives of the inventors.

Should fewer appeals result as a consequence, the savings and economic and inventive power alone justifies the effort. Accordingly, we recommend allowing the patent bar to cooperate in the education of the examiners by providing comment on the Federal Court case law. As it appears now, the Patent Office relies upon the appeal process to police the legal standards of the federal courts. This is very costly for both the Patent Office and the inventors. In the "Notice for Comments," the Patent Office recognizes that the body of case law is growing and is helpful in giving direction for implementing the requirement for obviousness. Unfortunately, this is a harmful, self-fulfilling prophecy. This growing body of case law is being generated by the misapplication of legal standards which are already well defined, although in different technological areas or factual situations. This is similar to a drug

company doing away with quality control and gauging the quality of its products on survivors who sue or their family members.

The growing number of recent decisions by the Federal Courts on biotechnology patent issues is only the tip of the iceberg. It represents a small fraction of the examiners' decisions that could have, probably should have, been appealed. Very few inventors have the capital and human resources to challenge a misapplied legal standard; first through the Patent Office's examination, then through the Board of Appeals, and then into the Federal Courts. The current implementation of legal standards through successive appeals saps the resources of both the patent office and the inventors. Opening communication between the patent office and its users hopefully would decrease the number of appeals while more accurately and uniformly applying the requirement of nonobviousness.

Examples of misapplying the legal standards governing nonobviousness are in the "Notice for Comments" authored by the Patent Office. The Notice refers to the suggestion that the Patent Office is imposing a per se rule of obviousness for inventions involving sequencing and the expression of genes once any sequence information has been publicly disclosed, whether the sequence information takes the form of a partial amino acid sequence of a protein or DNA sequence information derived from the expression of the gene. The Patent Office asserts that it does not apply per se rules.

To the contrary, however, specific examples exist in the public record where examiners have expressly stated, and I quote: "...the relationship between a gene and the protein it encodes requires a different type of obviousness determination..." The Patent Office clearly changes the nonobviousness requirement when genetic material is involved. The legal standards have been improperly simplified by focusing exclusively on the function of the DNA sequence as a information transfer vehicle while disregarding its chemical structure and the properties and characteristics resulting from its structure. The patentability of a DNA sequence must include the properties and characteristics of its structure as it is inserted in a vector, the vector in a host, and the host grown to produce the desired protein. It must be made absolutely clear that genetic material, and other inventions of biotechnology, are to be judged by the same legal standards as other technologies on the issue of obviousness.

And with that I'll conclude my remarks, and if you have any additional questions I'd be happy to address them.

COMMISSIONER LEHMAN: Have you ever had any -- made any effort to participate in the Biotechnology Patent Institute that we have set up that I described in my opening remarks?

MR. GENS: No, I have not.

COMMISSIONER LEHMAN: Because that was the -- the whole purpose of that is to deal with the problem that you just suggested, and that is to talk about the training that the examiners get, the standards that are used, and it is basically intended -- and consists of people who are companies and people who are in the bar, so you might want to check that out.

MR. GENS: I appreciate that comment, Mr. Commissioner. The only question that I would have is that it does not help for a two-way lines of communication if I have to go into a situation without any basis of understanding how the examiner is being trained. And if we can maybe open up that information that would make that dialogue much more fruitful for both sides.

COMMISSIONER LEHMAN: My point is that there's a mechanism for raising that kind of issue and that's the Biotechnology Patent Institute, so you might want to -- I mean, obviously, there are two mechanisms: One is this hearing and we're listening to what you have to say, and we will -- we may well make modifications based on it, but there's also another mechanism, too, for you to have an ongoing relationship and you might wish to avail yourself of that.

MR. GENS: I'd be more than happy to do so if that is the intent of this other source.

COMMISSIONER LEHMAN: Well, you're a member of the bar and you're out there representing companies and -- presumably in this sophisticated law firm, and I think you, you know, owe it to yourself to know what's going on if you're going to properly represent them.

MR. GENS: Thank you.

COMMISSIONER LEHMAN: Thank you.

Next, Elizabeth Lassen, please, of Calgene.

ELIZABETH LASSEN, CALGENE, INCORPORATED

MS. LASSEN: Good afternoon. My name is Elizabeth Lassen. I am chief patent counsel for Calgene, Inc. I am here today on behalf of Calgene as a member of the Biotechnology Industry Organization and as a concerned member of the patent bar.

Founded in 1981, Calgene is an agriculture biotechnology company which employs approximately 350 full- time employees, about 160 of which are engaged in research and development. Patents are critical to Calgene.

It has taken 12 years for us to commercialize our first genetically engineered product, the Flavor Saver Tomato. In plant biotechnology the product is the factory, patents are all the more important.

I welcome the opportunity to participate in this hearing. I believe that the BIO's written comments which amplify my remarks here are useful in cogent summation of the issues. The fact that it was possible to generate a 100 plus page document, to get a group of patent attorneys with such a diverse clientele in the biotech industry to achieve consensus in this paper underscores the seriousness of the points raised. I've found the process of working with the other BIO members on our written comments to be both comforting and at the same time disturbing. The good new and the bad news is that Calgene is not alone.

My assigned topic relates to the level of skill possessed by persons working in the field of biotechnology. A correct assessment of this level of skill is necessary for both obviousness and enablement determinations. But, before I begin, I would like to make it clear on the record that my purpose in coming here today is not merely to summarize the issues regarding level of skill or other points but to meet Commissioner Lehman and try to help communicate the absolute seriousness of these types of issues to a company such as Calgene.

The Patent Office practices are effecting companies, universities and other research institutions. They're having an impact on the decisions and strategies made by us all today. These issues are creating uncertainty and increased costs. It is changing the way companies and research institutions invest in research. As patent practitioners advise their clients that it's not clear whether they will get adequate protection for biotechnology invention, research dollars are going elsewhere.

Is the PTO properly assessing the level of skill possessed by persons working in the field of biotechnology for obviousness and enablement determinations? Obviousness determinations are made under 35 U.S.C. 103 based upon whether the invention was obvious to one of ordinary skill in the art. For purpose of obviousness, both the suggestion and expectation of success must be found in the prior art.

Enablement determinations are made under 35 U.S.C. 112, first paragraph, based upon whether the written description of the invention is found in the specification enabling any person skilled in the art to practice the invention. Here the test is one of undue experimentation. In the prosecution of biotechnology application, one finds that a unrealistically high standard will be applied for the evaluation of patent claims under Section 103 and a unrealistically low standard applied to the evaluation of patent claims under 112, even though that hypothetical skilled artisan upon which these standards are based is the

same person.

There's an even greater complication in the improper identification of the skilled artisan because in almost every single biotechnology patent application that I have seen, regardless of who prepared the application, the technology or the examiner assigned to the case, both enablement and unobviousness issues are presented. The Section 103 rejections and the Section 112, first paragraph, rejections become a game. The level of skill in the art shifts during the course of prosecution depending upon whether the Patent Office is making an argument with respect to obviousness or enablement. This liberty to take inconsistent positions on the part of the U.S. Patent Office creates a disbelief on the part of the scientists who look to the patent examiners kindred spirits. It perpetuates an adversarial atmosphere with patent attorneys because the rejections are offered in sort of a checkmate attitude and it generates a lack of credibility in the entire patent system by the business community.

Biotechnology is a rapidly developing field which employs a great number of highly skilled researchers and also relies upon a significant number of laboratory technicians. Who is one of ordinary skill? That of course depends on the particular facts of a given case, but, as a general rule, the highly educated examiners now in the biotech office are exposed on a daily basis to the very best, newest science in the world of biotechnology and they have forgotten that science is done one step at a time and that much uncertainty always exists before the experiment is completed. They've forgotten that an invention can be obvious to one of greater than ordinary skill and they've forgotten that the published literature only reports successes. They've become the Monday morning quarterbacks of science.

For example, I've observed that the PTO readily asserts that the mere knowledge of an assay for protein is enough to render a purified preparation of such a protein obvious. In many cases methods do exist for every step necessary to go from protein to DNA, but it's random luck to chose the purification procedure from the infinite possible combinations of steps, times, reagents, columns, buffers and detergents, et cetera. The skilled artisan cannot extract from a description of an assay for protein any particular characteristic which would assist the skilled artisan in its purification, such as the isoelectric point, size or shape, the requirements vary so much from protein to protein. But obviousness rejections which pull such prior art together are commonplace. Such simplistic views of the level of skill held by one of ordinary skill in the art is analogous to a software examiner refusing to grant any patents on software programs using existing languages.

It is difficult to discuss the PTO's assessment of level of skill without blending into the test for predictability. The PTO frequently

dismisses the types of arguments and months of laboratory research as routine absent special considerations which are present. Ask the skilled artisan, however, and the work required to obtain nucleic acid sequences from an apparently purified protein will be characterized as arduous and unpredictable, and such an artisan would be, and often are, justifiably insulted to hear that such work is dismissed as routine.

As with the determination of the skilled artisan for Section 103 purposes, the proper identification of the person skilled in the art for Section 112 purposes is also critical to a correct determination of patentability. Under Section 112 a patent specification must include a written description of the invention which will enable any person skilled in the art to make and use the invention. The test for enablement requires that the claimed invention be practiced by the person skilled in the art without undue experimentation. The higher the level of skill which is applied the greater the enabling power of a given patent application. Unfortunately, a patent examiner typically defines the skilled artisan to have no ability to extrapolate away from the patent application when considering such enablement questions.

For example, it's apparently the belief of Group 1800 that once a DNA sequence encoding a protein is disclosed that one skilled in the art is incapable of making any modifications to that sequence without undue experimentation. This is an improper determination of the level of skill. The researchers are able to make and test modifications of gene size, code on substitutions and screen for highly homologous sequences from related sources. The fact that the examiners regularly reject claims on this basis is the subject of many appeal brief now before the Patent Office Board of Appeals.

The imbalance between level of skill applied under 112, first paragraph, as compared with the 103 analysis, goes to the heart of the patent practitioner's difficulty in prosecuting patent applications to biotechnology inventions. How can a claimed subject matter be simultaneously obvious and not enabled, particularly when a Section 112 person has the benefit of the specification while the Section 103 person does not? The confusion is to the level of skill seems to work against the inventor in each case, never in favor of innovation. This results is the anomalous and a logical view that the person having ordinary skill in the art, under Section 103, would have had an expectation of success to practice the technology, but once the patent specification has provided additional information the former competent person is changed to a person skilled in the art who lacks the certainty of what to do in order to practice the invention.

A statement made by an examiner in a recent action highlights how free the examiners are with this type of rationale. We were given the argument that the claims were not enabled because the invention was not

shown to work, yet the claims were obvious over the prior art. We've even seen the same references applied for both 103 and 112, first paragraph, purposes.

Some quick examples further highlight this problem: A protein with activity to a particular substrate was obvious over protein with specificity for a similar but different substrate. Taking the prior art sequence with the known encoding sequence -- with the new encoding sequence, a third substrate was not enabled. The expression of a certain protein in any host cell to effect a common metabolic pathway is obvious yet the specification only enables the change which was exemplified, i.e., the claims must be limited to a particular tissue from a particular construct.

The U.S. Patent office is an agency which is charged with promoting science and the useful arts. Examiners are pressured to meet quotas and, as a result, do not seem to be given much encouragement to fully engage in meaningful dialogue with the patent bar. Moreover, examiners are permitted to become removed from the methods and thinkings of science and permitted to engage in inconsistent arguments which result in improper application of Section 103 and 112 standards. These issues are weakening the patent system we enjoy in the U.S., and the difficulties that I've briefly described are reviewed more fully in the BIO paper.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to ask Daniel Chambers of Viagene to come forward, please.

DANIEL CHAMBERS, VIAGENE, INCORPORATED

MR. CHAMBERS: Commissioner Lehman, other members of the panel, good afternoon. My name is Dan Chambers and I work as in-house patent counsel at Viagene, Inc., a San Diego based gene therapy company.

As it's been said before, the effect of the patent system is critical both to the success of my company and many other biotechnology companies. Today I'm speaking on behalf of BIO's Intellectual Property Committee and will address question four under the nonobviousness section of the --

COMMISSIONER LEHMAN: How big a company is Viagene?

MR. CHAMBERS: What?

COMMISSIONER LEHMAN: How big a company is Viagene?

MR. CHAMBERS: I'm sorry, I still can't hear you.

COMMISSIONER LEHMAN: Your company, how -- can you just tell me what size it is?

MR. CHAMBERS: It has about 160 employees full time and about half that number are employed in terms of their research effort. We're basically developing a variety of different systems to the liver. You know, they're genes basically to people -- presently we have at least three different systems under development. The most advanced system is based on retroviruses.

COMMISSIONER LEHMAN: Do you have any products on the market then at all?

MR. CHAMBERS: Not on the market. Six in Phase One clinical trials -- actually two in six different Phase One clinical trials, both in HIV immunotherapeutic and cancer immunotherapeutic.

Like I said before, I'm going to be addressing question number four under the nonobviousness section of the PTO's "Public Notice." Question four asks: "Are there specific practices of the U.S. Patent Office with regard to determinations under 35 U.S.C. or Section 112 for biotechnology inventions that you believe are inappropriate or inconsistent with legal precedent?" The short answer is, "Yes." In more detail what follows are specific examples of recurring rejections based upon PTO positions that are inconsistent with case law.

Specific examples of case law were obviousness rejections confuse tests of novelty, and nonobviousness include an analysis of the elements of a claim lacking consideration of whether the claim as a whole would have been obvious. As an example, an examiner rejected as obvious a two-step method in view of a single reference stating that the preamble of claim one is taught by the reference. Claim element 1(a), the determining step, is clearly met by figure o ne of the reference. Claim element 1(b), the step of comparing is taught by the reference. Here the Patent Office dissected a claim and attempted to show that each element was taught or suggested by the cited reference. This is wrong as a matter of law. For example, the Board of Patent Appeals and Interferences explained in Ex parte Hiyamizu that citing references which merely indicated that the isolate elements or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious.

In another area the PTO often treats claims directed to DNA molecules as if they are presumptively anticipated. Group 1800 has formulated a policy, apparently, where a novel nucleotide sequence does not render a claimed DNA molecule nonobvious, regardless of whether or not the prior art would have suggested the claimed nucleotide sequence. Following this policy, for example, the Patent Office has rejected claims to novel DNA

sequences encoding tissue specific promoters. In one case, the Patent Office stated that "the fact that the claimed tissue specific promoter has a unique nucleotide sequence does not render it nonobvious." It was not relevant to the PTO that the promoter was characterized by novel nucleotide sequence and that the prior art did not suggest how one could modify the nucleotide sequence of a known tissue specific promoter.

COMMISSIONER LEHMAN: When you have an examiner reject a claim, like in the example that you gave a moment or two ago, and apparently that's a case in progress right now?

MR. CHAMBERS: Well, these are not cases that are pending before Viagene. These were basically put together by the BIO committee here.

COMMISSIONER LEHMAN: I mean, do you request interviews with the patent examiner and try to make your case? I'm trying to get at the process hereby which what are apparently perceived to be errors are corrected and you have -- You can have an examiner interview. It's possible to talk to the supervisor involved. That sort of thing.

MR. CHAMBERS: Yes, Commissioner. In one particular instance which I'm involved with, we have added -- like Viagene has had a case pending before the Patent Office for over seven years and, in the case of that, there have been -- in this case there have been interviews with the examiner and -- but I don't know, over 12 declarations submitted. And we've just had an interview with the examiner and his SPE in the last two weeks and hopefully resolved the issues that were basically outstanding in the case, although we're somewhat apprehensive about the situation that previously we had an interview with the same examiner in the presence of his supervisor and the examiner had indicated his willingness to remove basically all the rejections that were outstanding both under 103 and 112, which were the only issues still remaining in the case. Upon submitting the formal amendment, the examiner came back with a 30-page office action basically putting forth new basis, new grounds for the same rejection and, again, it's just this process of trying to jump through the hoops. I think interviews with the examiners definitely help but, in certain instances, certain examiners, for whatever reason, seem recalcitrant to want deal with --

COMMISSIONER LEHMAN: Do you find this is a problem that -- Is this every application that you make or is this just occasionally that you run into what you call an unreasonable response?

MR. CHAMBERS: It hasn't occurred in every case, although it seems to be more prevalent in what I would consider to be pioneering technology that really enables -- it is a foundation basically upon which companies are built. For whatever reasons, those kind of patents seem to be the ones -- or applications seem to be the ones the Patent Office wants to look at

the hardest, and for good reason. We don't object to that, clearly. But when one is forced to narrow claims down to basically a non-effective level of protection or have to dither in the Patent Office for seven to ten years, just at the examiner level without even having to go up on appeal, in certain instances, that seems to be counterproductive and I think those are the issues that are so important.

COMMISSIONER LEHMAN: What I'm getting at, is there evidence that we have a -- that we have examiners all over the place -- you know, you'll go to one -- It's sort of a Russian roulette as to what examiner you get and that determines the ease of the process and whether or not you get the patent? Or is the problem a problem of overall policy, for example, where you have the -- which is what you seem to be saying that it is -- where you have the pioneering invention and you always have a hard time?

MR. CHAMBERS: I'd say that's pretty much the case with respect to pioneering-type technology, and in certain technology fields as well. I mean, gene therapy is obviously a very limited part of the body of technology industry generally, but -- and I don't know actually how many examiners actually are involved with the examination of those types of applications, although, to my knowledge, there are only a handful. And, as a result of, you know, the concern for whether this is kind of groupwide policy or whether or not it's amongst two or three examiners, it might very well be just amongst two or three examiners. But, if those happen to be the only examiners involved in your art area, it doesn't do you a lot of good if, in fact, it's not a policy that isn't being promulgated by the whole Group 1800.

Moving along. As another example, with regard to the PTO promulgating rejections based upon the obviousness to try standard coupled with implicit hindsight. For example, a claimed gene is often considered to be rendered obvious by the prior disclosure of the isolated protein encoded by the gene. In one case, an examiner rejected claims directed to DNA molecules encoding an enzyme as obvious in view of primary and secondary and tertiary references. The examiner's position was that, one, the primary references describe the purified enzyme; two, the secondary references describe methods for determining the amino acid sequence; and, three, that the tertiary reference described the method for isolating a gene encoding a protein for which a shorter amino acid sequence was known. The examiner concluded that it would have been obvious to one of ordinary skill in the art to have purified the enzyme, to have learned at least part of its amino acid sequence, and to have isolated the enzyme using a method in the tertiary publication.

The examiner's analysis was flawed on two fronts. First, it was factually wrong since the primary reference did not teach methods for obtaining sufficiently pure enzyme to sequence the part of the protein.

Moreover, the inventors, as it was described in their specification, actually described the extra step they had to devise in which to purify the protein to a sufficient level of purity in order to sequence it effectively.

Then on a legal front, the examiner's analysis was also erroneous in view of Ex parte Maizel where the Board of Patent Appeals and Interferences reversed a Section 103 rejection claim directed to DNA molecules and recombinant host cells comprising a DNA fragment encoding B-cell growth factor, also know as BCGF, because the protein BCGF had not been isolated to sufficient purity and in sufficient quantity for amino acid analysis. Consequently, the Board concluded that it would have been virtually impossible to do what the applicant had done.

PTO has also stated that a previously unknown human gene is rendered obvious by the prior disclosure of a homologous mammalian gene. As an illustration, an examiner rejected claims directed to DNA molecules encoding a particular human receptor because the primary reference taught the corresponding rat receptor gene while secondary references taught methods to clone human homologues of various rat genes. The examiner's premise was that there was no suggestion in the art or any evidence of record which would suggest that the receptor gene first identified in rats would not also be present in humans. Clearly, the examiner applied the obvious to try standard since the cited references, at best, only gave general guidance and no specifics about the claimed invention and how to achieve it.

Concerning rejections based upon overuse of hindsight to support an obviousness rejection. One example involves an examiner stating that the primary reference teaches a gene encoding a rat receptor with 91-percent homology to the claimed human receptor. Here, the examiner took the inventor's teachings and the specification and combined this information with the teachings of the primary reference to determine the level of homology that in fact existed. That clearly is an improper combination based on impermissible hindsight.

In another case, an examiner decided the claims to an antiviral composition comprising components A and B would have been obvious, explaining that one skilled in the art seeking to inhibit the virus replication would be motivated to combine a variant of the component A described in the reference with the known antiviral agents, such as component B. For their additive effects, applicant has indicated in the application that a synergistic composition results when component A is combined with component B. Thus, according to the applicant, the mere combination of the two compounds is sufficient to achieve a state of synergy. Again the examiner supported the rejection by improperly referring to a statement in the inventor's specification.

Additionally, he disregarded the significance of the synergistic effect between the two compounds which in and of itself is evidence for the nonobviousness of the invention.

As I can see I'm about out of time here, I'm just going to go ahead and move to the last aspect of what I wanted to talk about which is basically recommendations that we would like to see brought about at the PTO in terms of change.

One mechanism for change is obvious. Provide training for examiners that they can:

One. Appreciate the policy behind legal precedent.

Two. Educate in case law concerning biotech inventions.

Three. Are routinely updated on case law.

If the examiners follow the patent laws interpreted by the courts, patent prosecution for a particular case would be more predictable, making business decisions about filing and prosecution even easier. And I think that's a very important consideration, and particular for small companies like the one that I work for. We don't have a lot of resources to devote to haggling with the Patent Office or spending years trying to get our patents allowed. We need things now because long term our company may not exist. We're more concerned about two or three years down the road, not about the effective life of our patent 15 years from now. It's important to us that we get things moved ahead, and I think that's probably true as well for many other small companies.

So I guess assuming that the Group 1800 has the authority to generate its own internal policies and interpretations of the case law, it would be best if those could be aired, those interpretations and those policies could be aired in a public forum. And, in fact, it's our understanding that the Administrative Procedure Act requires that interpretative rules be published. So that's all. Thanks.

COMMISSIONER LEHMAN: As I understand, you know, your testimony coming from the point of view of a small innovative company which right now is still in basically the venture capital state, somebody's paying all those bills and you don't have a market yet, 160 paychecks every month or two weeks is a lot, and, as we've heard, at very high salary levels in many cases. Clearly, you want to get, you know, in and out the door with your patent application, and hopefully a granted patent as quickly as you can, I assume. And then, you know, get on with the process of commercializing the invention.

MR. CHAMBERS: Right.

COMMISSIONER LEHMAN: So, for you, the optimal system would be, and tell me if I'm wrong about this, would be very clear, bright line tests -- rules that you could understand, patent examiners could understand, a very expeditious examination process and issuance of a patent and then get on with it. And then if the -- you know, if you ended up being stuck in the FDA, and so on and so forth, then you'd probably opt for, I assume, some extended patent term registration legislation that would see you through that problem, and that would be really the optimal system for you.

MR. CHAMBERS: I tend to agree, but I think that with respect to bright line rules and those kinds of things, I'm not so sure that's applicable. I think currently the present standards, as have been discussed recently, are ones that are sufficient and easily understood by people who are educated in those areas, and I think --

COMMISSIONER LEHMAN: And examiners don't understand it?

MR. CHAMBERS: Well, right. And maybe it's because they haven't been educated. I mean, they are clearly highly educated individuals and that's something that we greatly appreciate, but with respect to the law I think it's one of those things where a little more effort could perhaps be put in and it would help everybody, including I think everybody in the biotech business and most patentees as well -- applicants.

COMMISSIONER LEHMAN: Thanks.

MR. CHAMBERS: Thanks.

COMMISSIONER LEHMAN: Next I'd like to call on Thomas G. Wiseman, of Cushman, Darby and Cushman, please.

We're running behind this afternoon and it's partly because we're asking so many questions, so if people can be expeditious it would be appreciated.

THOMAS G. WISEMAN, CUSHMAN, DARBY and CUSHMAN

MR. WISEMAN: I'll keep my remarks brief and to the point.

My name is Thomas G. Wiseman. I'm of counsel with the law firm of Cushman, Darby and Cushman. The organization I'm here representing is the BIO organization. It's a trade organization. My relationship to them is as a member of their Law Committee, their Intellectual Property Committee, and their Emerging Technologies Committee.

I could say a lot of things to you now but I'll give you a sense of what

my background is because you may not be familiar with it. I was a government employee for the period of about 22 years, 19 years of which were at the Patent and Trademark Office in a variety of positions. I was also at the National Institutes of Health at their Office of Technology Transfer. I was their acting patent branch chief.

At the Patent and Trademark Office, I had the honor of serving as a member of the Board of Appeals. I was a supervisor, primary examiner, and I was an examiner. My area as an examiner was in what is now called biotechnology. I was examining these applications when it was still fermentation.

Many things have been said about your particular system but there have been some things that have been done that have been done very well. At one point in time the technology that represents biotechnology was scattered amongst four examining groups. It was brought together over a period of years and put into one examining group. The problems which caused the art to be centered in this one particular group was comments like which you are receiving today; different standards were being applied in different groups, and what you're hearing as a bottom line here is that different standards may be being applied in the different arguments.

I trained many of your SPEs. They were examiners in my art unit. I found them all to be a very motivated group, very well disciplined. I found that if I had any problems I would call the SPE and the SPE would work it out. If I had any problems that the SPE couldn't resolve, I talked to Chuck Warren. Chuck Warren would take care of the problem or he would call me back and say, "Tom, you're on the wrong footing. The person who is working for you is making a mistake." I look into it and I have a tendency to agree with Chuck on that particular issue.

I've had some problems where I've had to go and I've called Barry Richman because it was more in his expertise and he took care of the problems. My bottom line is that the system does work. You have to put effort into it.

I am a member of the Biotechnology Institute. I may even be the chairman this coming year. I think there is some education that has to be addressed, but that's nothing new. It's not horror stories all the time. There are instances when I've had to take over the prosecution of a case from another law firm; it's after final. I've an examiner in Group 180 listen to three responses after final and eventually allowed the case. The examiner saw the merits of the invention, felt it was worth his additional time. Since he is on a counter system it is his additional time, it's his own free time, and this individual did help fashion the claims which eventually resulted in the allowance. It's not all bad. There are many good things. If you look at what Chuck Barry

and the SPEs in this particular group have done, they've assembled from what used to be -- I forget what the size of my original art unit was, but it was about 12 to 16 people. They've taken that particular number of individuals and expanded it to a group size of about 188 examiners. That required training lots of new SPEs. When you consider the short time frame relative to what it takes to educate an examiner so that they're up and coming, they've done a remarkable job and they should be given credit for what they have done.

There are many instances where you've run into an examiner who may not understand the law, but it does not help to tell you that all your examiners don't understand the law, because many of them do. Many of them do a great job. They do a terrific job and they sacrifice. They set up committees on their own so they feel that they are more consistent. Sometimes they set up their committees with the blessing of management, sometimes they don't. Jim Martinell, Bob Benson and some others ran a brown bag seminar. They met on Tuesdays, either every other month or every month, and within those particular brown bag lunches they did try to talk about problems and they did try to work out solutions which were similar.

I'm supposed to answer question five for you today, but, before I do that, I want to add just one more thing.

While I was at the Patent and Trademark Office, I was involved in a number of the harmonization projects we had with the Japanese office and also with the European office. I notice that with the Japanese office and also with the European office they used examination guidelines. These examination guidelines were much more detailed than the manual patent examining procedure.

It is known to me that in the formation of these examining manuals by the Japanese Patent Office, and also by the European Patent Office that they did get some industrial input and some input from the bar in formation of their guidelines, and these guidelines are updated. The formation of guidelines may be quicker and faster than Board of Appeal decision. My particular point of view with regards to the Board of Appeals' decisions which have been coming down of late, they've been getting better and better and more on point all the time. I like the Ex parte Anderson decision. I thought that John Caucasian, M.L. Goldstein -- I can't remember the third member of the panel but that's just because my memory is fading with age -- and it was remarkable what the input they went into.

Bill Smith wrote a very good opinion in Ex parte Balzarini, which if you look at it and you look at the proofs and the burdens that were met and that were not met, and the consequences of it, and what could have been done to have changed the outcome, they were all quite clear and it's a

question of proof, burdens, and the like.

Some of the examiners do work on a per se rule, and they are probably wrong in most instances. They have -- there is a general statement in the utility area with regards to the value that the office must accord to the statement of utility, and if the examiner doubts that utility, it's their burden.

With regards to obviousness, the burden in on the examiner to fashion a prima facie case.

To answer question five which is what I was brought here for. It does not appear that foreign systems provide a better legal framework than does the U.S. system. The U.S. case law system provides a comprehensive, analytical framework for addressing issues such as obviousness, enablement, breadth of claims which are commensurate in scope with the disclosed invention.

We do note that, unlike the U.S. system, the foreign systems explicitly recognize the level of skill does not vary whether the inquiry is based upon the assessment of the prior art or the sufficiency of discloser. That point has been made many times before and I don't want to dwell on it anymore, but there does seem to be a little bit of disparate treatment in there. But if you read the review article by Trasanski, which is cited in the BIO paper, he has lots of comments which would go along with that.

With regards to the examiners' education system. Dick McGar and other people at the Patent Academy had expended large amounts of resources in trying to provide the best training possible for the examiners under current budget problems, and Dick has done a good job and he's brought in outside trainers; John White, Kim Practice, John Trasanski are just some of the names. These names are also worth noting because they are the same names that appear in the patent resources group training which is given to the private practitioners. NIH has sent many of our patent advisors to the training that was available at the -- by this patent resources group, and the office is making use of the same training.

Do you have any questions of me? I'll gladly answer them based on my upteen years of experience and being probably at fault for many of the policies that many of the people are complaining about today.

COMMISSIONER LEHMAN: Thank you very much. No, I don't really have --

MR. RICHMAN: I have a question. Who put you at the end of the schedule, Tom?

MR. WISEMAN: It was the draw.

MR. RICHMAN: I'd like to just expand on what Tom mentioned. In many talks I've given -- the Director's office has a function and one of the functions of the Director's office is to resolve problems where examiners stray from acceptable practice -- and 308-1223 is my phone number. I give it out wherever I talk. This office needs to hear about these things so that they don't fester and have to surface in a public hearing like this. This is a -- I'm not -- It is a good place for this to occur, but we need to have a chance to resolve these problems before it gets to maybe a stage that it is perceived to be at now.

MR. WISEMAN: I want to let you know that Barry is a person of his word. He was a union representative before he got into management and he usually delivered and he delivered in a very fair fashion. And I've found over my 20 years or more of knowing Barry that he delivers on his word, and if I've ever had a problem, I've gone to Barry and he solved it and he solved it on a real time basis and it wasn't put off, and it was done in an efficacious fashion.

COMMISSIONER LEHMAN: Well, it certainly is true that our -- we have many mechanisms to resolve problems. One of which is to not only the examiner interview but, to where there's a problem of policy, to -- the examiner may not be following office policy, to bring it to the attention of the SPUD or the deputy group director or the group director, and that's something I would encourage people to do.

Obviously, knowing the inside of the office, you know more how to go about that so maybe what we need to do is do a better job of training practitioners before the office as well.

MR. WISEMAN: It's a cooperative effort and if it gets adversarial it shouldn't be there, because it's only by working together that we can make a good system.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to ask George Johnston, the Law Department, Hoffman-La Roche, Incorporated.

GEORGE JOHNSTON, LAW DEPARTMENT, HOFFMAN-LA ROCHE

COMMISSIONER LEHMAN: I should ask you, Mr. Johnson, one of our earlier witnesses produced a little vial of medicine produced by your company in Switzerland that had been I think funded originally by the NIH, and one of the things we're struggling with in the government and the Department of Commerce, what's an American company and what should our policies be with regard to American companies. Hoffman-La Roche is not an American company and looks like we're funding products that are being produced

abroad and taking away jobs from American citizens. You might want to comment on that a little bit.

MR. JOHNSTON: I really don't want to comment on that, Examiner -- Commissioner.

First off, Hoffman-La Roche is a U.S. company. We do have a headquarters in Switzerland but we're red, white and blue just like everybody else, and we have more than 15,000 jobs in the United States.

COMMISSIONER LEHMAN: Well, I think that's important. We wanted to get that on the record so we're not, you know --

MR. JOHNSON: Thank you.

Good afternoon, Mr. Chairman, members of the Patent Office. My name is George Johnston, associate patent counsel at Hoffman-La Roche. I present this testimony on behalf of BIO's Intellectual Property Committee. I'll be speaking on two topics; the first involves question number two on obviousness, and the second involves the experimental use defense. The specifics of my testimony can be found in more detail at pages 95 and 157 of the BIO submission.

Let's focus on the nonobviousness, question number two. Whether the level of skill under Section 112, as developed by the courts is sufficiently clear and appropriate. I know you're not going to be surprised when I say, "yes."
The case law is clear. The speakers before me have gone into that so I will not do that at this moment. The problem is that many of the examiners misapply the standard as requiring the inventor to demonstrate and provide convincing evidence to the Patent Office that the application is, in fact, enabled, and, as we have heard before, that's not the standard that should be applied. If the examiner feels that we have not met our burden then the examiner should provide credible evidence to that effect -- objective evidence, not subjective evidence, not feelings, but specifics, because subjectivity will give rise to a lack of consistency which no one wants.

We recognize that many of the examiners might be frustrated with the standards that are applied. They're good scientists; they believe they're protecting the public. The Patent Office certainly is not attesting that, and there's a lot of work, frankly, in trying to find objective evidence which they feel they have in their head already. Why do they have to go further? I'm sure many of them ask.

But let me digress for a moment. We hired a patent attorney at Roche a few years ago. Young fellow. Ph.D., super biotech type. Great schools. Very, very bright. Came into the office prosecuting applications, and

every time an inventor came to his office he'd find that invention obvious and he'd find that whatever the inventor did was insufficient for purposes of enablement. He couldn't figure out how they could extrapolate beyond the specific experiment. He was a challenge, as we say, a challenge to the supervisor. They started calling him "Doctor No, the unpatent attorney." His supervisor had to be very forceful and go right to the jugular and explain, "Where is your objective evidence? Why is it unpatentable? Where are the references? Why can't you extrapolate? Where is your documentation?" And slowly but surely that patent attorney came around. Actually became a very good patent practitioner. I think this also applies to many of the examiners at the Patent Office that are equally as bright, equally as knowledgeable in the science, and I think they have to be better educated and more definitely educated in the law. I think their supervisors also have to be of support as they have, and perhaps can be a little bit more, with regard to instructing the examiners as to the standards and asking the same type of questions as we have been asking our people under that example.

We talked about before where there was questions as to quality control and going to the Board, and I would respectfully suggest that it's a bit late at the Board level and that quality should be built in from the very beginning; right from the examiner's stage; right through the supervisor's stage; and right up to the Board.

Our recommendations are as follows:

Number one. Simply apply he legal standards consistently. Provide that objective evidence when required, and, if this is not already being done, what I'd suggest is that at the annual reviews of the examiners and supervisors that they specifically be reviewed whether or not there have been instances where this objective evidence has been applied on a case by case basis.

Now, my second topic, as I mentioned, involves experimental use defense focusing on topic C of your Notice of December 27, 1993. Topic C involves whether or not there's a justification for or against a statutory use defense.

The BIO organization is very diverse. There are pharmaceutical companies in it, agricultural companies, research, tool manufacturers, and they all have their idea as to what and what might be included within the experimental use exemption.

The position of BIO is to support the presently created experimental use defense. BIO is against the erosion of this defense; however, we could not reach any consensus on the expansion of the defense by legislative action. You see, sometimes it's very easy to know when an action is research and, therefore, falls within the experimental use defense.

Sometimes it's easier than when it's commercial. Sometimes it's hard. For example, if you're simply verifying whether or not an invention works, as explained in the patent, I think most people would conclude "that's strictly research."

On the other side of the coin, should you be using a third party's patent to perform an assay and screen your library of compounds to identify certain biological active compounds? I think most people would conclude that's not permitted commercial use. But the problem comes "what about in between?" It's not easy to separate out the permitted research from the non-permitted commercial use.

We feel that however it is best to leave it to the courts who created this doctrine and who would best know how to apply it on a case-by-case basis. The standard is clear. In the Roche/Bolar case it was held that the adopting of a patented invention to an experimenter's business constituted a non-permissible use and did not fall within the experimental use defense. But the dilemma of BIO is as follows:

Some of our organizational members will conduct activities which might be perceived differently as falling within or out of this defense. Companies could, therefore, be on either side of a case.

There's a diversity and this diversity I think you can also see in the comments that were submitted to the Patent Office from many other organizations, both within and outside of BIO. But there's one common thread. The common thread, at least among the BIO organization, is that we believe that the experimental use defense involves after patent activities, normally the domain of the courts while the Patent Office's responsibilities involve pre-patent activities. Therefore, our recommendations would be for the Patent Office to concentrate on areas toward pre- issuance of patents, as have been enunciated in these hearings, and leave to the courts the resolution of the experimental use defense cases on a case-by-case basis, because the court would be in a better position than anyone to weigh the equities and, based upon the specific facts of a case, determine whether or not the defense is applicable.

Thank you.

COMMISSIONER LEHMAN: Thank you. The reason that we're interested in the experimental use defense issue is because we clearly have a responsibility to examine and issue patents, but there's no other place to go to make -- advise on legislative policy, excepting us, too. So we have a policy function, and I have been receiving some complaints about the use of patent rights to unfairly prejudice experimentation. And my impression is that one reason that it has not been as much a problem as this -- some of the recent complaints would suggest in the past -- is

because by and large there's a certain tolerance for experimentation in the industry, which, you know, is sort of a culture of pharmaceutical research since everybody sort of has to do it, is not to just rush in and sue everybody else, particularly when you're talking about experimentation which takes place in the not-for-profit sector. Is that -- Would you say that's true?

MR. JOHNSTON: I think that's a fair statement. I think if you look at the number of cases that have actually come down in this area, there's not a lot. And I think there's somewhat of a tolerance, somewhat of a recognition that, as I mentioned before, that with regards to early stage activities you might find yourself on both sides of that coin, and I think there's simply a recognition as to that fact and the fact that it really doesn't make sense to bring someone to court on such a basis.

COMMISSIONER LEHMAN: So, from your point of view, the present system which basically is a case-by-case method, is adequate? We don't need any new legislative experimental use --

MR. JOHNSTON: I think that says it beautifully.

COMMISSIONER LEHMAN: And that reflects basically the view of Biotechnology Industry Organization?

MR. JOHNSTON: I think there's a diversity in BIO where there are certain groups within the BIO association who would like to see it expanded. There are others who are vehemently opposed to that expansion, and, if the Patent Office or any group were to proceed, I would recommend that they proceed with extreme caution.

COMMISSIONER LEHMAN: Okay. And let me say with regard to Hoffman-La Roche, we're more than happy to have more jobs here in the United States and we do everything we can to make our patent system attractive so there won't be hardly a job left except some, you know, just a management job that, you know, a bean counter left in Switzerland, so anyway.

MR. JOHNSTON: Thank you.

COMMISSIONER LEHMAN: We want all the Ph.Ds over here.

Next I'd like to call Richard C. Peet, of Foley and Lardner, please. We've had Foley and Lardner of Madison so this is Foley and Lardner of Washington, D.C.

RICHARD C. PEET, FOLEY and LARDNER

MR. PEET: Thank you, Commissioner Lehman and your colleagues from the Patent Office for giving me the opportunity to speak today.

My name is Richard Peet and I am, as I've mentioned, an attorney with the Washington office of Foley and Lardner. Foley/Lardner represents a diverse array of organizations in the biotechnology industry, including small start-up companies, universities and multinational corporations.

I am submitting testimony today on behalf of the Intellectual Property Committee of the Biotechnology Industry Organization. A detailed version of my presentation has been submitted for the record by BIO and is found on pages 163 to 171 of that book.

I would like to take this opportunity to commend the Patent Office for requesting comment on a frequently overlooked but very important part of the patent statute, and that is the Plant Patent Act. Specifically, I submit testimony today on whether the Plant Patent Act should be amended to permit a holder of a United States plant patent to exercise exclusive rights with respect to parts of a protected plant, such as material harvested from the plant. I would like to make two points, in particular, in my testimony.
First. A court would likely find that unauthorized use of plant parts derived from an asexually propagated plant variety protected by plant patent constitutes infringement under current law. However, this area of the law is very unsettled.

Second. We strongly recommend a legislative effort to amend the Plant Patent Act to explicitly protect plant parts derived from asexually propagated and patented varieties in order to reduce the likelihood of costly litigation, and to provide breeders of asexually reproduced plant varieties with the same explicit protections under the Plant Patent Act as will be afforded plant breeders of sexually produced varieties under the amended Plant Variety Protection Act, signed into law by President Clinton on October 6th, 1994.

Let me give you a little bit of a historical perspective. Since 1930, American plant breeders, American agriculture and the American public have benefitted from the stimulus to innovation in the plant sciences provided by the Plant Patent Act. Reports of the House and Senate Committees that accompanied legislation enacting the Plant Patent Act state that the purpose of the Plant Patent Act was to stimulate invention in the agricultural sector by providing plant breeders with the patent protection equivalent to that available to inventors in industry. The Report of the House Committee contains a statement, for example, by Thomas Edison that, quote: "Nothing that Congress could do to help farming would be of greater value and permanence than to give the plant breeder the same status and the mechanical and chemical inventors now have through the patent law."

Mr. Edison's prediction that patent protection for the inventions of the

plant breeder would stimulate and foster innovation and investment in agriculture was clearly accurate. For example, the Economic Research Service of the United States Department of Agriculture estimated that cash receipts in this country in 1993 for nursery and greenhouse crops alone equaled $9 billion, nearly 11-percent of all farm crop cash receipts in this country. As a result, this agricultural sector is the sixth largest among all commodity groups. It is even larger than such crops as wheat, cotton and tobacco in terms of farm crop cash receipts.

The plant patent system is not only utilized by plant breeders for the protection of new varieties created for the ornamental plant industry, but is also used to protect new varieties of trees and plants producing fruits, nuts, berries and fiber.

COMMISSIONER LEHMAN: What is your involvement is this? What kind of clients do you represent in this that cause you to --

MR. PEET: Our firm represents a large number of companies involved in the breeding of new varieties, both in the ornamental industry and as well as fruit, crops. Many of these companies are small companies, frequently family owned, and so we represent a diverse array of these companies.

COMMISSIONER LEHMAN: Do they tend to have a big California base? Where would they --

MR. PEET: We represent companies worldwide actually. The United States, the industry is spread all over the country. We represent many companies in Europe and throughout the world.

The Patent Office noted in the "Federal Register" Notice announcing these hearings that, quote: "Growers reproduce and use, outside the United States, plants subject to a U.S. plant patent, and subsequently import products harvested from such plants, to the detriment of U.S. plant patent owner." This very succinctly summaries a very severe problem in this sector of the plant biotechnology industry.

When competing in the market, against lawfully produced plants, these imported products have a decided competitive advantage because the importer has not invested in the research necessary to develop the plant variety. In contrast, the breeder must sell the product at a price that recoups those research costs. Furthermore, the importer benefits from the breeder's promotional and advertising efforts. The income lost by American plant breeders due to the patent infringement inhibits investment in plant research and development programs which are the foundation of a strong horticultural industry in this country.

The adverse consequences of patent infringement are particularly

apparent in the cut flower industry. For example, from data kindly provided to me by the American Association of Nurserymen, a single domestic rose breeder estimated lost royalty receipts in 1993 of $1.5 million as a result of unauthorized import of patented imports produced in five Latin American countries.

In my written testimony, already submitted to the Patent Office, I provide the legal rationale underlying why it is likely that a court would find unauthorized sale or use of plant parts derived from any asexually propagated and patented plant variety to be infringing, so I will not go into that in detail here.

However, we strongly recommend a legislative initiative to amend the Plant Patent Act to include the right to exclude others from unauthorized sale or use of any part of the asexually propagated plant variety. The amendment could be achieved by revising 35 U.S.C. 163 of the Plant Patent Act along the lines already recommended by my honorable colleague Mr. Gioia.

This amendment would reduce the need for companies to engage in costly litigation to combat patent infringement by foreign competitors.

The proposed amendment to the Plant Patent Act would also provide clear uniformity in the laws related to the scope of protection available under the Plant Patent Act for asexually propagated plant varieties, and under the amended Plant Variety Protection Act for sexually propagated varieties.

On October 6, 1994, President Clinton signed into law amendments to the Plant Variety Protection Act which provide, in part, that unauthorized use of harvested material obtained from propagating material of a variety protected by Plant Variety Protection Act certificate constitutes infringement. A separate legislative initiative is necessary to provide domestic plant breeders of asexually reproduced varieties with the same explicit protections under the Plant Patent Act as will be afforded plant breeders of sexually reproduced varieties under the Plant Variety Protection Act.

I'd be happy to entertain any questions that you have.

COMMISSIONER LEHMAN: Thank you very much. I don't think we have any.

Next I'd like to ask John Sanders of Mycogen Corporation to come forward, please.

JOHN SANDERS, MYCOGEN CORPORATION

MR. SANDERS: Good afternoon, Commissioner Lehman. My name is John

Sanders. I'm representing the BIO Intellectual Property Committee. I am the general patent and trademark counsel at Mycogen Corporation here in San Diego. I've been an intellectual property lawyer for about 14 years, all within corporations. Most of that time was spent in the chemical area. For the past 18 months I've been with Mycogen and have concentrated on two areas of biotechnology; biopesticides, namely bacilluster and jensus delta antitoxins, which are biopesticides, and plant biotechnology.

I am here today to emphasize the importance of utility patent coverage for inventions relating to plants. After hearing over half of the speakers before me, and from reading in the PTO Notice of this meeting, I'm pretty sure everybody in this room understands how important patents are to all the companies and inventors involved. I will try not to be redundant but I want to re-emphasize this fact with respect to plants.

Because of the obvious value plants have in our industry, and the fact that everybody here knows that, I tried to make up a cute analogy to stress the importance of patents. I couldn't come up with a cute analogy but I did come up with a spokesperson for plant utility patents. That spokesperson is the 1994 all American hero Forrest Gump. If Gump were an attorney, I'm sure he would be a biotech patent attorney and he certainly would be here today.

To say the biotech industry depends heavily on the patent system is quite an understatement. "Biotechnology Journal" reports that yearly agbiotech R&D expenditures are well over $100 million a year. As a relative newcomer, from the chemical industry, I thought this figure was a little on the low side; however, the same article in "Biotechnology" indicated that there was an over 30-percent increase in R&D spending last year. The private sector is uniquely positioned to comment on the critical role that utility patents play in the agbiotech industry. Staggering R&D investments -- in both time and money -- stringent regulatory review adds unique challenges as well as more time and more money. Without the benefits of a utility patent, there's little hope for recovery to the investor of the substantial costs for R&D. If there's no investor, there's no money. If there's no money, there's no jobs and, consequently, then the research does not get done.

The agbiotech industry desperately clings to the utility patent system to maintain its critical mass from both an investor and science perspective, a critical mass that was shrinking until the expansion that occurred over the last year. The agbiotech is dramatically different from the human health sector.

The human health sector, compared to the agbiotech sector, flourished in the lab, in the marketplace and on Wall Street in the 1980s. As a general rule, the agbiotech industry cannot command the high profit

margins that the drug industry gets. In many cases, human health products provide a solution or a therapy that didn't exist before or, if it did exist, was many orders of magnitude inferior to the therapy or solution offered by the biotech inventions. Erythropoietin, TPA, human insulin, human and animal growth hormones are just a few examples.

The agbiotech industry, on the other hand, faces a perception that there's already adequate technology out there. Let's face it, the average lay person in the industrialized world does not really consider food and fiber production to be a major problem. The do, however, think of AIDS, cancer, heart disease as problems near and dear to them. For all these reasons, a strong utility patent system is the life blood of a successful agbiotech company. Some patent practitioners are concerned that the new amendments to the PVPA to include hybrid seed may result in the PTO relinquishing jurisdiction of plant inventions to the USDA under the PVPA and the examining corps who handles the Plant Patent Act. This should not, and from my perspective cannot, happen. The utility patents have peacefully coexisted with the Plant Patent Act and the PVPA since 1930 and 1970, respectively. Compared to utility patents, the Plant Patent Act and the PVPA provide narrow protection to a particular plant line or variety. Let's remember that the Plant Patent act and the PVPA were enacted in times when plant inventions were only envisioned by using standard plant breeding techniques. These techniques were thought at the time not to comply or be able to coexist with the patent laws at the time. Two issues come to mind:

Namely, the product of nature issue and the written description issue.

COMMISSIONER LEHMAN: Do you think that we should consolidate the administration of the Plant Variety Protection Act under the Patent Office?

MR. SANDERS: I think that would be a good consolidation into an examining corps that has the expertise all located in one location.

Neither the Plant Patent Act, nor the PVPA expressly or impliedly exclude utility patent protection. There's no restriction of utility under 35 U.S.C. 101 in either of the legislative histories of these laws, and is indicated in the landmark case of Ex parte Hibberd. To take the position that the PVPA and the Plant Patent Act cover all plant inventions would preclude patent protection to generic inventions, inventions that apply across the board to all plants, process inventions relating to plants, and intermediate composition inventions, all of which are claimable under a utility patent. Overlap of utility versus plant patent versus PVPA doesn't mean irreconcilable conflict. For example, In re Yardley it was held that under certain circumstances protection under the copyright law and design patent law was acceptable and coexist. There are other examples also.

Some other important issues relating to plant utility patents are the technology in plant biotech was not contemplated when the Plant Patent Act or the PVPA were enacted. Now that the technology is here, we should b e able to protect it.

Plant biotech research is unique in at least one major aspect that I believe is affected in the Patent Office, and that's time. From traditional chemistry and microbiology experiments are measured in chemistry usually on the order of hours or days; in microbiology, in the order of days to weeks, but in plant experiments and plant technology it is not uncommon for an experiment to run up to 10 months in a plant experiment. To make a transgenic plant it involves transformation, tissue culture, selection, regeneration into primary transformance, maturation and progeny preparation and analysis. The research cycle is many more orders of magnitude greater than traditional chemistry. The inventor learns from these experiments and builds upon what he learns in the first experiment for what he does in the next experiment. Because of this long research cycle, and the motivation to file patent applications early, plant utility patents should not be disadvantaged for not having working examples when, in fact, working examples are not required by statute.

The plant biotech invention should not suffer because of the unique attributes. One way they are discriminated against is under 112, in particular, with respect to undue experimentation and breadth of claims. A 10-month experiment with plants is usually quite routine, where in the chemistry lab 10 months may usually result in undue experimentation.

Not only do plants qualify for utility patents, there is no valid general reason that a plant utility patent should be limited to specific plant lines or specific genes. Overly narrow patents are many times useless. Patents stimulate the incentives for agbiotech research. We have seen the revolution in human health sector. Biotech can offer equally exciting results in the agriculture in the abetment of hunger. For the greatest impact, a strong utility patent system is necessary. So if Mr. Gump was here, he'd have very few words. This meeting would probably be over already, but he would have very profound words. He might say, "Transgenic plants happen. Just patent it. Have you patented your new plant today?" or "Say yes to plant utility patents." I agree, and BIO recommends that you make all aspects of utility patents available to the plant technology.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call Micheal Farber of Merchant and Gould. //

MICHEAL FARBER, MERCHANT and GOULD

MR. FARBER: Thank you, Commission Lehman and panelists.

My name is Micheal B. Farber and I'm a patent attorney with Merchant and Gould, in Los Angeles. We are a full-service intellectual property firm, and our biotechnology clients include small start-ups, large Fortune 500 multinational corporations, non-profit research institutions and universities in a broad range of biotechnology areas. I would like to address several issues, particularly with respect to enablement and nonobviousness and the level of ordinary skill in the art.

I think with respect to enablement, which also ties in to some extent with utility, there has been a perceived lack of credibility for biotechnology which has almost put it into the same weird science standard as perpetual motion or cold fusion, and I don't think this is appropriate. I think there's been a failure to realize that this work has built on the advances of the last 40 or 50 years in organic chemistry, genetics, biochemistry, cell biology and other well recognized disciplines.

Specifically, I think in many cases there will be a reference cited on general grounds to yield a rejection under 101 and 112. The rejection will cite generalized reasons, such as, for example, an antiidio-type response for antibody, a human antimurine antibody response for an antibody that is partially derived from mouse or rat tissues, concerns about lack of bio availability or stability, without an attempt to apply it to the particular case. In other words, this is a general research article which gives possible cautions but there is really no attempt to fit these possible cautions to the specific facts of the claimed invention. Moreover, I think in many cases there is a requirement for virtually 100-percent certainty of efficacy even in conditions in which there is now virtually no effective treatment. An example which I am involved in involves an antibody that may be useful for treatment of liver cancer. As you may know, this is for all intents and purposes 100-percent fatal, although I believe there have been some attempts made to treat it with liver transplants.

The question I think would be: Would a reasonable physician conversant with the research and advances in the art, a mainstream physician not willing to try things that are out of the ordinary, believe that this represents an advance that is worth trying clinically? In other words, we have to go back to the constitutional mandate: Does the claimed invention represent an advance of science in the useful arts?

Along the same lines, I think that there has been a serious lack of consistency with respect to rejections under 101 and 112 and then rejections on 103. In another antibody case, I had a rejection in the same office action, under Section 101, based on lack of utility and, in

the same action, a rejection under 103 based on the recognized and accepted diagnostic utility of an analogue, which according to the examiner provided incentive to modify to produce the claimed compound. This, of course, is completely inconsistent. If one of ordinary skill in the art would believe that there was a sufficiently shown utility to make the modification that same person of ordinary skill in the art would then believe that the -- also believe that the new compound would, in fact, have such utility. This goes back to the point that was raised earlier that when you're considering under Section 103 the person of ordinary skill in the art is a genius, when you're considering 101, and particularly 112, that same person suddenly turns into an idiot. There is a lack of consistency in this area.

A third issue I think is a little bit more specific, and that has to do with the use of a couple of recent cases, notably, Amgen and Fiers, to cut down what I think is the proper standard for enablement that was decided by previous CAFC and CCPA decision in the chemical area. And I'm talking about decisions such as Angstat which says that it is not necessary for an inventor to test all of the potential embodiments of an invention, even in a relatively unpredictable art such as organic chemistry. I think this has come up in two areas that I have seen. One is that an inventor has isolated or discovered a peptide or several peptides and now wants to claim nucleic acid that encode these peptides. The second is that the inventor has isolated or discovered a new antigen or a series of related antigens possibly related by allelic variation and now wants to claim antibodies, either polyclonal or molyclonal to these antigens. And what I have seen is even in situations where the peptides are allowed with reasonable scope or the antigens are allowed with reasonable scope, they're saying that there is undue experimentation required in nucleic acid in putting together nucleic acid sequences or making the antibodies, even though when you know the peptide sequence all of the possible nucleic acid sequences that encode the peptide are automatically available by the genetic code.

In the absence, for example, of evidence that would lead one of ordinary skill in the art to suggest that some of the nucleic acid sequences would be inoperable, for example, is used to insert into vectors and used to transfect bacteria for expression, as a result of code-on choice or instability, or formation of abnormal secondary structure, I don't believe there's any basis for this rejection. The Amgen and Fiers cases hold that if you merely are claiming a nucleic acid that encodes a molecule with a particular function with little or no structural data, you have at most a wish to obtain a product of a particular activity, this comes very close to the long proscribed single means claim.

The situation I'm referring to, though, is you have the protein or the antigen or the peptide and the rest of the experimentation, if any, is routine. In the absence of evidence to suggest that, for example, a

particular nucleic acid sequence would be inoperative as a probe or as an expression vector, or that a particular antigen could not be used to make antibodies, according to the generally accepted procedures in the art, there would appear to be no basis to reject the secondary claims. I think this has the effect of giving the inventor less scope than he or she is properly entitled to under the law.

Thank you.

COMMISSIONER LEHMAN: Thank you very much.

MR. FARBER: Any questions?

COMMISSIONER LEHMAN: I think -- I don't have any, unless someone else does, so I think we'll move along.

Next, Michael Roth of Pioneer Hi-Bred International.

MICHAEL ROTH, PIONEER HI-BRED INTERNATIONAL

MR. ROTH: Good afternoon, my name is Michael Roth. I'm a registered patent attorney and patent counsel for Pioneer Hi-Bred International, on behalf of whom I'm appearing. Pioneer is the world's largest agricultural genetics company with about $1.8 billion in revenues, most of that in the United States. We currently invest over $100 million per year in research and development and rely on both Section 101 utility patents and Plant Variety Protection --

COMMISSIONER LEHMAN: Where are your headquarters?

MR. ROTH: Des Moines, Iowa, not Switzerland. And if you were there, you'd notice the difference.

COMMISSIONER LEHMAN: We have to go to Geneva all the time and everybody says, "Oh, wow, it's really glamorous to go to Geneva," but I have to tell you I think Des Moines is a lot more exciting and a lot more interesting than Geneva, Switzerland. The weather is better, too, believe it or not.

MR. ROTH: Well, the last time I was in the Geneva airport I saw someone collecting for the poor of Geneva, and I assume that's a person who has only one BMW.

So, as I said, we invest over $100 million per year in R&D which means that we invest more in a given year than some companies have in total.

We protect our products with Section 101 patents, Plant Variety Protection Certificates whether they are the product of newer methods of

biotech innovation or earlier methods of genetic manipulation.

We have several comments in response to the questions raised in the official Notice. With regard to the issue of enablement of biotechnological inventions, we believe the legal standards governing assessment of enablement and obviousness, as developed and interpreted by the Federal Courts are sufficiently clear and appropriate for biotechnology inventions. Unfortunately, we have considerable difficulty getting the Patent and Trademark Office to follow those standards. Citations of case law are routinely ignored or explained away without citation of contrary decisions and without specific explanation of why the law as cited by the applicants is inapplicable to the facts of the case.

Now, you asked for specific examples, and the one that I have involves an issue that is not specifically covered in the questions, and that is determination of who is an inventor and who is not. Those who are familiar with the world of scientific publication know that co-authorship of a paper bears no rationale relationship to inventorship of any subject matter disclosed in the paper. It's a highly political process by which academic careers are made and lost and by which debts are incurred and favors repaid. Yet there are examiners on some of our cases who are fond of citing In re Katz for the proposition that co-authorsahip of a journal article raises a presumption of joint inventorship. In fact, in that decision the CCPA specifically rejected -- and those were the words, "We specifically reject the examiner's position that the publication of the subject article provided even a tenuous ground for rejection under 35 U.S.C. 102 (g)," and the court expressly held, and they used those words, "We expressly hold that an authorship of an article does not raise a presumption of inventorship with respect to the subject matter disclosed in the article." Concluding, quote: "Co- authors may not be presumed to be co-inventors merely from the fact of co-authorship." Unquote. Nevertheless, we are being forced to appeal these cases in order to have this highly improper rejection reversed, a process that, as has been mentioned, takes two to three years. And in this business time can be even more important than money.

Let me also observe that an appeal isn't necessarily final. We have a case that has been on file for about five years now. A couple of years ago we took the case to appeal and roughly a year ago we got reversal of the examiner's decision. The case is still awaiting issuance and we understand the examiner is looking for some reason to reopen prosecution and enter new rejections.

The office has noted complaints about the propensity of examiners to use a much higher standard when evaluating enablement than is used when evaluating obviousness. As a specific example, we have a substantial effort to identify and patent proteins that have either anti-insect or

antipathogen activity in plants. If we can express those proteins in plants we can make a genetically engineered plant that has desirable characteristics.

We routinely receive rejections that argue that it would be obvious to screen proteins for anti-insect or antipathogen activity, to sequence those proteins, to assemble synthetic genes coding for those proteins, to insert those sequences into plant expression cassettes, to insert those expression cassettes into plant cells and to regenerate those transformed cells into whole plants.

References are cited in support of each of these propositions. At the same time, the claims are rejected if we do not have actual data showing completion of each of these steps on the basis that the specification is non- enabling even though the specification explains how each of these steps is performed. In these rejections, the examiner refers to, quote, "well known," unquote, uncertainties and difficulties in carrying out these steps.

If references are cited, they're often in conflict with the references cited in the obviousness rejections. This reflects a win by any means or checkmate sort of approach to examination that is inconsistent with the ex parte nature of examination and the proposition that the examiner is there to assist the applicant as well as to represent the public.

Again, a specific example is the routine citation of an article by Potrykus, who is a Swiss scientist -- the article is now several years old -- which purports to set up several criteria for establishing successful plant transformation.

Setting aside for a moment the fact that the Potrykus article sets up unrealistically high standards for proof of plant transformation, we also routinely note that the references cited in rejecting the claims for obviousness do not meet the Potrykus criteria.

Even more specific is an example of a rejection of a patent application directed to a virus-resistent corn plant for non-enablement over Potrykus. The examiner argued that the application failed to show that the Potrykus criteria for proving plant transformation had been met, yet the application showed regeneration of whole plants in the presence of selection for the herbicide resistance marker and the survival of their progeny in field testing in the presence of viral infestation in which the control plants did not survive.

We believe that the in vivo or in vitro results meet the criteria normally applied by commercial companies in advancing their commercial projects, and the pontifications by a bench scientist as to the sort of proof that would be needed to assure academic irrefutability should not

stand in the way.

COMMISSIONER LEHMAN: In that particular case -- Is that still pending? -- did you appeal to the Board of Appeals?

MR. ROTH: Well, the case is still pending and we have to make a choice as to whether to appeal, drop the case, or refile it.

COMMISSIONER LEHMAN: In that sort of a situation, do you talk to the group director where you think that the examiner is being -- is applying an inappropriate standard? Or have you just kind of dealt with it -- relied -- gone no further than an examiner?

MR. ROTH: In general, we rely on the examiner. In many of these cases we have examiners who are not yet primary examiners and so we know that the office actions are being reviewed and signed by their SPE.

COMMISSIONER LEHMAN: Do you talk to the SPE at all or try to contact them to raise these concerns?

MR. ROTH: In most of the cases we talk to the examiner and the examiner talks to the SPE, in effect, on our behalf, if at all. In some cases we have an examiner who agrees with us and the SPE is the one who disagrees. We're getting all this secondhand; the examiners are saying, "There's nothing I can do. My boss won't let me make this change."

The patent grant has traditionally been considered a reward for prompt public disclosure of technology. Yet, under the scenario I've described, we're being penalized for filing our applications as early as possible. In many cases, the work involved in laborious and time consuming, as has been mentioned. Plants have their own schedule for germination and development. It could take months, even years to carry out a project, the results of which have already been foreseen by the inventors; foresight that is confirmed by the hindsight of the obviousness objection. None of the work involved is particularly challenging to carry out using the disclosure as a guide.

What is needed is a consistent standard for assessing what sort of disclosure is needed to put biological inventions in the hands of the person of ordinary skill.

Turning to assessment level of ordinary skill. Many of our patent applications are directed to -- directed to plant inventions are routinely rejected over review articles reviewing improvements and progress in genetic improvement of plants over the last 65 years. The improvements achieved over that time period are cited as establishing that the level of skill in this art is such that the person of ordinary skill in the art can routinely make continued improvements of the sort

that have been made over the past 65 years. This approach is clearly defective for several reasons.

First, it's laden with hindsight. It focuses on the record of successes and ignores millions of failures over the same period. Most important, implicit in this approach is the unsupported assumption that successes reported in the past were routine and obvious. It's akin to reviewing the official "Gazette" for the many patents issued in microelectronics since the first integrated circuit and concluding that such inventions have been made on a regular basis, the level of skill is such that one of ordinary skill can readily make similar improvements in the future.

Before closing, if I could, I'd like to raise one issue not addressed in your Notice and that is deposits of biological material.

In our view, deposits of biological material are currently available on terms inconsistent with the limited nature of the patent grant. For example, the patent is limited to the geographical jurisdiction of the United States while anyone in the world can request a sample of deposited material. The patent gives the right to prohibit others from making, using or selling the patented invention yet the samples, which in many cases are self-replicating embodiments of the invention, are available without any undertaking from the recipients not to make, use or sell the patented invention. The PTO should not require that patentees place their invention at the disposal of the public and then aid and abet circumvention of the patentee's rights, either secretly in the United States or openly in other countries where comparable production is not available.

COMMISSIONER LEHMAN: Are you finding that is a problem? Have you had -- actually had experience where somebody --

MR. ROTH: Well, one of the problems we have, of course, is that the recipient of a sample can transfer that to third parties without notice to us. So what we get from the American-type culture collection is a notice that a law firm has requested a sample. We know they don't want it for themselves and who that ends up in the hands of, we have no way of knowing and so we have no way of finding out in whose research plot that material might be found.

With that, let me conclude and thank you for your time and attention.

COMMISSIONER LEHMAN: Thank you very much.

Our next, Louis R. Coffman, has decided not to testify so that will put us right about on schedule now. In fact, a few minutes ahead.

Now I'll ask Margaret Connor, from the Office of Technology Transfer,

the Agricultural Research Service, U.S. Department of Agriculture, to come forward, please.

MARGARET CONNOR, OFFICE of TECHNOLOGY TRANSFER,

UNITED STATES DEPARTMENT OF AGRICULTURE

MS. CONNOR: Good afternoon. My name is Margaret Connor. I'm a patent advisor for the United States Department of Agriculture, Agriculture Research Service, Office of Technology Transfer, and I'm here today representing the USDA.

The USDA employs approximately 3,000 staff and research scientists and supports agriculture research in agriculture research facilities and land grand universities throughout the nation with a research budget of approximately $1.5 billion annually.

This department previously submitted written comments strongly advocating an experimental use defense to patent infringement. Today I will emphasize two points in support of our position: The need for and benefits of a research exemption from patent infringement, and our fear that recent use judicial decisions has seriously eroded the experimental use defense.

In addition, I will provide brief comments in support of broadening coverage of the Plant Patent Act to include plant parts and products.

First, a major contributor to the rapid advances in agriculture, medicine and other forms of technology that have benefitted the people of the United States and the world has been public sector scientific research. That is research conducted by or supported by federal and state governments in government, academic and other public and independent research institutions. The success of public sector scientific research has been shown to be critically dependent on the free exchange and use of ideas, research findings and their products.

The experimental use defense of patent infringement has provided protection for scientists in the public sector to pursue research avenues which have added to the knowledge base and led to rapid advances that have been the hallmark of American scientific enterprise.

We believe an experimental use doctrine is critical to the continued advance of agricultural technology. Several representative examples of problem- solving research that have benefitted from the free exchange of plant materials illustrate this. The USDA has been instrumental in the dramatic increase in crop productivity. In the last 40 years the yields of corn, rice, wheat and potatoes have increased an average of 134-percent, with conservative estimates contributing a minimum of

60-percent of these increases to the development of new varieties by plant breeding.

Varietal development requires access to often dozens of ancestral varieties. Typical of this is the rice variety La Mont, whose pedigree covers more than five generations and two dozen varieties. La Mont rice is an important contributor to the 149-percent increase in rice production in the United States since 1950, yet elimination of access to even one unique parental line likely would have destroyed the chain necessary to create this important crop variety. The result would also be reached in other instances of variety development. For example, another important variety developed through public sector research is a wheat variety, Gaines wheat, that was the basis for the grain revolution in wheat. It, too, was critically dependent on unrestricted access to the germ plasm of unique parents. Lack of unrestricted access could have prevented or greatly delayed the development of these varieties. We believe that continued progress in innovation in agricultural science will only be possible with free access.

Second, we no longer are sure what constitutes the present experimental use defense. The extent of experimental use exception has been eroded by several recent judicial opinions. Notably in Roche v Bolar, the Federal Circuit dicta has labeled as fatal to the experimental use defense any commercial intent or profit motive whatsoever. This presents difficulties for the continued success of research in the public sector which has been placed under -- strengthens Legislative and Executive Branch mandates to transfer research discoveries to commercial applications. The combined effect of the legislative mandate and the administration's technology policy makes it clear that the intent of the congress and the President is to move technology quickly to resolving the critical needs of the public. Achieving this intended goal should not be hindered by counterproductive restrictions on research use of patented or otherwise legally protected technologies, plants or animals.

In the past, reliance on administrative and industrial practice and policy regarding research use of patented technology, coupled with judicial application of the experimental use defense, has allowed rapid progress. There are recent examples, however, showing that public sector research has been hindered because companies have not permitted use of patented technology for research purposes or have made access to the technology difficult. Thus, the past successes may have no future peers without clarification and/or codification of the experimental use doctrine.

The present system has evolved its own cultural checks and balances over the last 200 years allowing for benefit to the patent holder without undue restriction on further innovation and progress. The Patent and Trademark Office has acknowledged the implicitness of experimental use in

the disclosure requirements of the patent laws. Accepted practice has long included both commercial as well as non- commercial development based on patent disclosures. As an example, descendent patents are commonly applied for and issued during the life of the parent or dominant patent, even though the descendent patent cannot be practiced without backer cross-licensing.

Failure to allow experimental use, whether commercial or non-commercial, could create an artificial barrier to the most promising lines of research. The United States Department of Agriculture supports the codification of a broad application of a research use exemption from infringement of patented technology to include not only research use for understanding the invention and its verification and replication but also to include attempts to improve the patented technologies to make new innovations available to the American people. All of these aspects promote the progress of science for the general welfare of not only the public but of the American industry as well.

The research exemption included in the Plant Variety Protection Act has worked extremely well for agricultural research, both public sector and industrial, and could serve well as the model for our research exemption for utility patents. It reads: "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection afforded under this act." In this Act, plant breeding is analogous to new invention or improvement patents. This approach is most consistent with the intent of Congress and with the technology policy of the administration, both of which represent initiatives to boost the commercial competitiveness of U.S. industry and the well-being of the general population.

Finally, in regards to the amendment of the Plant Patent Act. The USDA supports attempts to broaden the extent of protection provided by plant patents to include harvested material, including entire plants and parts of plants.

Current protection can be circumvented by growing the plant outside of the United States and importing harvested materials back into the U.S. for sale. Given recent efforts to extend the protection afforded by both utility patents and Plant Variety Protection Certificates to guard against this kind of act, it is appropriate to guard plant patent owners within this expanded umbrella of owners' rights. The economic effects on the ornamental plant, fruit tree and other industries dependent on plant patent protection warrant this protection.

Thank you.

COMMISSIONER LEHMAN: Thank you. I don't think you gave us any, did you have some specific examples that you witnessed where there has been

discouraging of experimentation based on someone else's patent rights? I mean, that you know of in your USDA experience?

MS. CONNOR: Yes. In our written comments there are some examples, and there was one case where in the breeding area they would not allow the U.S. scientists to have access to what they considered the most important line and, therefore, they had to just go without that and try to do breeding without that line. And then, in the newest instance where there's this patent covering all the lines of genetically engineered cotton, there's an instance that we might not be able to use this without asking for a research license. So it's possible that we may get to use it but it will be -- everything will be made more difficult and that's what we want to guard against, because, for example, in the breeding of the rice and the wheat that I mentioned, if there had been a lot of negotiations and back licensing of those many varieties involved there is a likelihood it just never would have gotten done.

COMMISSIONER LEHMAN: Would you -- In your own technology transfer policies at USDA, do you -- At the time you grant exclusivity to developers, do you include provisions requiring them to issue licenses to other experimenters? If USDA research is involved, you could use your licensing protocols to deal with that problem, couldn't you?

MS. CONNOR: It's my understanding as far as the protected patented property that USDA has control of that we do grant experimental use ability for researchers to use it. Our concern is that the USDA will not get to have experimental use of property protected that belong to other companies, and that's hindering our own research and other public sector research.

COMMISSIONER LEHMAN: Thank you very much.

Next, did you -- Since we missed one witness we'll --

MR. ROTH: Excuse me. I apologize for interrupting. If I had know someone was going to come and speak on this subject from USDA I would have prepared some remarks on this subject. I just want to ask one question that is escaping me and that is, if USDA is part of the U.S. government and rights of eminent domain they don't need a license. They can take it. I don't understand why they need a codified research exemption when the government doesn't worry about patent rights. For example, the Department of Defense issues a contract for an airplane, they don't care who has the patent on the airplane. The only remedy is in the Court of Claims. Why does the Department of Agriculture need a research exemption?

COMMISSIONER LEHMAN: I gather that you disagree with the Department's testimony.

MR. ROTH: Or at least would like an explanation.

COMMISSIONER LEHMAN: Well, then you'll have to address that to them. I think their concern probably goes beyond USDA research to research by others as well who don't have the capacity to violate the law and then just say, "sue me in the Court of Claims."

Next I'd like to call on Steven Brostoff of the Immune Response Corporation, please.

STEVE BROSTOFF, THE IMMUNE RESPONSE CORPORATION

MR. BROSTOFF: I would like to thank you for giving me the opportunity to testify before this hearing. I'm Steven Brostoff, Vice-President of Research and Development, The Immune Response Corporation.

I would like to contrast two different experiences I have had with the Patent Office over the last ten years to illustrate problems that need to be addressed in the patent office. I am the co-inventor on a patent that was filed in 1984. It used a well established animal model of human disease to demonstrate a novel therapeutic approach. After less than three years the patent was issued. The technology was licensed to a biotechnology company and millions were raised to support the development of this approach which is now in Phase II trials for several indications. Five years later, after joining The Immune Response Corporation and using the exact same well established animal model, I was the co-inventor of a new therapeutic approach which was more specific and longer lasting than the first. A patent for this approach was filed by The Immune Response Corporation. The European patent application was filed a year later as was an Australian patent application. This time it took over five years before the Patent Office acknowledged that we had allowable claims. By this time, we had already been issued he European patent and the Australian patent, even though they had been filed a year later.

But wait. The Patent Office changed its mind about issuing the patent because we had not demonstrated utility in humans. This is the Catch 22 of biotechnology patenting. In order to raise the millions in capital needed to pursue clinical trials one needs a proprietary position. However, the Patent Office appears unwilling to grant the patent assuring this proprietary position without clinical data. Moreover, this requirement for demonstration of utility in humans represents a departure from what had been needed just a few years ago. It was not needed to obtain a patent on the previous technology using the same animal model of disease.

In fact, based upon our previous experience that the animal model data would be sufficient The Immune Response Corporation had proceeded into

clinical trials using this technology and expending the millions of dollars needed to do so. The money expended had been raised in the public markets and were not specifically raised to support this technology. The decision by the company to expend this money was based on our assumption that a patent would be granted based upon criteria that had been used in the past by the U.S. Patent Office and that was being used currently by the European Patent Office. We did not know that the rules had changed. Fortunately, however, we had enough significant clinical data to overcome the utility in humans issue and, after another six months, were told once again that we would receive a notice of allowance.

But wait. The supervisor had reviewed the application and had questions about enablement, in spite of the fact that a primary examiner had decided to allow the claims.

I must say this is an experience similar to one we had with an HIV immunotherapeutic that we had developed which took approximately six years for the patent to issue. In that case we did get the patent issued but, once again, had similar experiences and ultimately were required to supply clinical data that fortunately we had and fortunately we had had the resources to expend in doing those clinical trials prior to obtaining the patent.

This kind of behavior on the part of the Patent Office makes it very difficult to make rational decisions on expending the millions necessary to develop new therapeutics. I will use an analogy that I think people here in California can appreciate. Our recent dealings with the Patent Office is like trying to play football in the middle of an earthquake. As we try to execute our game plan the ground keeps shifting under us. Sometimes it takes us sideways. Sometimes backwards, and occasionally forward. What we need is a stable playing field on which to execute our game plan. Moreover, we do not need unreasonable obstacles placed on the playing field. Since our competitors, outside the U.S., do not need to establish utility in humans they have an advantage in establishing a proprietary position in knowing how best to expend their capital in order to develop their technologies. The current policies of the Patent Office can only harm the biotechnology sector and contribute to the loss of the United States dominant position in this field. Most importantly of all, it will impede the development of many therapeutics that will ease pain and suffering and prolong the lives of millions of individuals. Give us reasonable rules to follow, and reasonable criteria to meet, and the biotechnology industry will thrive and we will all benefit by the products that the biotechnology industry will provide for us.

Thank you very much for your attention.

COMMISSIONER LEHMAN: Thank you very much, Mr. Brostoff.

I'd next like to call on Robert Schaffer of Darby and Darby.

ROBERT SCHAFFER, DARBY and DARBY

MR. SCHAFFER: Good afternoon, Commissioner and panel. I am Robert Schaffer. I am a partner with Darby and Darby, in New York. Darby and Darby represents a number of biotech firms ranging from multinational corporations to start-up high tech ventures, and I'm speaking today from the point of view of a practitioner in the Patent Office preparing applications for these clients and responding to office actions.

There has been a consensus developing today that the standards in place, the legal principles in place are appropriate, and I agree with that developing consensus. There also seems to be a developing consensus that those standards are not being properly applied in the Patent Office and that better education for examiners might address that issue.

I think that, however, many of the examiners in Group 1800, in fact, do understand the legal principles or much of them. The examiners understand that in an emerging technology there may be questions about whether the claim of utility in the specification can be accepted on its face. And it is appropriate for an examiner confronted with that doubt to ask the applicant for evidence of utility. The problems arise when the applicant submits his proof, usually in the form of one or more declarations from experts in the field and that response is considered inadequate. I think that the problem is not so much an interpretation or understanding of the law by examiners but, rather, what quantum of proof should be considered sufficient to overcome the examiner's initial doubt that the specification may not provide an adequate basis for utility.

When a declaration is submitted, and I've heard many people here state that they have applications pending for years which have gone through many continuations, and after 12 declarations or so the application is still under rejection. And I've had a similar experience and the response from the examiner to these declarations often takes one of two forms. Either the examiner says the declarations have been carefully considered and are deemed not persuasive -- end of rejection. And that is clearly a misapplication of the law, as has been said earlier.

The examiner should and must set forth specific reasons why that proof was not adequate. But, in many cases, the examiner understands that he or she is supposed to do that and, indeed, attempts to do so, and that usually takes the form of citing other references in the field which express doubts about the state of the art or what the technology can provide today, and so the applicant is in the position of providing sworn testimony that so and so, qualified expert, believes that a person of ordinary skill in the art would find a benefit, a practical benefit from

following the teachings in the specification. And there may be even additional data -- animal data or in vitro data or, in some cases, human data -- supplied but the examiner comes back and says, "Well, nevertheless, I'm not persuaded because here is an article which questions the validity of your animal model." And this basically takes the form of a battle of experts, a battle by the applicant with third-party experts that he can't confront in the Patent Office and this is an insurmountable battle.

It seems to be a position by many examiners that if there is not a consensus within the scientific community or a general agreement in the field that your model is adequate or that this is a disease that can be successfully treated, no declaration that you would present would be sufficient unless, indeed, you then go to the final hurdle of submitting human data which definitively shows utility.

I think that the problem is one of standard and that a more appropriate standard to apply would be that the examiner should review the declarations submitted, the evidence submitted, and if those declarations provide a reasonable basis for finding a utility in the application then, from the Patent Office point of view, it should be accepted that the statutory requirement for utility has been met. And only if defects in the reasoning or logic of the declaration or the scientific underpinnings for the declaration can be shown should those proofs be rejected. It is a standard of reasonableness, and I think that basically the examiner should be asking, "Is the applicant claiming an invention of reasonable scope based on the utility either alleged in the claim itself or in the application, and based on the submitted proofs is it reasonable to believe that this invention is more likely than not to provide some benefit?" And if the answer is, "Yes," then the utility requirement should be deemed satisfied.

There has been a question about whether there should be a presumption of utility and I think to some degree there is already a presumption of utility. The applicant makes a claim of utility and that claim is accepted, and unless there is a reason to doubt it -- and I think that really the examiner should be asking, "Has the applicant put forward a plausible explanation for why his invention should be deemed useful," in the face of the examiner's doubts, and if he does so he's done all that he needs to do.

And the same type of problem applies in enablement rejections which are tied to the utility rejection. Often the examiner will say, "Since you haven't proven that the invention works, you have not enabled a person to practice an invention that works." This is troubling for an additional reason that the applicant can submit proof of utility after the filing date but the applicant cannot supplement his disclosure to satisfy Section 112. And what can happen and has happened is that the examiner

may be satisfied on the utility proof but then will say that the parameters of the experiment that you used to demonstrate utility were not set forth in the specification and, therefore, "Although I am now persuaded that the invention has utility you still don't meet the enablement requirement." And, again there, I think the standard should be one of reasonableness and -- as opposed to a very high standard of definitive proof being required or doubts expressed by others in the field and publications being held against the inventor, and education could help within the Patent Office to some degree, but I agree with the gentleman who proposed that guidelines be promulgated either through the NPEP or through OG notice, and I think that that would be the most helpful mechanism for directing examiners what standards are the most appropriate to apply and how to apply them. I agree also that industry and the bar should review those proposals when possible, and I see that my time is up.

COMMISSIONER LEHMAN: I want to thank you, Mr. Schaffer. I think that was very helpful testimony. There were some specific examples that you gave.

Next I'd like to call Bertram Rowland, from Flehr, Hohbach, Test, Albritton and Herbert.

BERTRAM ROWLAND, FLEHR, HOHBACK, TEST, ALBRITTON and HERBERT

MR. ROWLAND: Before introducing myself I'd like to admonish the members of the Patent and Trademark Office for violating my constitutional rights as well as the other speakers. To request that patent lawyers speak for only nine minutes on these topics I consider cruel and unusual punishment.

COMMISSIONER LEHMAN: I thought you were talking about our constitutional right to not to have to preserve our bottom ends from sitting here through all of these interminable hearings. Sorry.

MR. ROWLAND: Also considering the fact that you're three hours out of phase, I think it admirable that you're still awake and listening to us.

My name is Bertram Rowland of counsel with Flehr, Hohbach, Test. I have the good fortune to have written the first patten in molecular biology in 1974. I've watched the field develop, worked at many academic institutions and start-up companies and I'm still active today.

During this period, we have watched a great industry arise. The industry has not only provided new therapeutic products but also promises to provide us with a continuing stream of new products. Together with the academic community the industry has and is continuing to provide insights into physiological processes which will allow us to understand

life better and to treat diseases better.

This industry has been dependent on the cooperation of academic institutions, venture capital, the drug industry and the dedication of numerous scientists in biological, chemical and electrical fields.

For the most part there has been a common motif in the finding of biotechnology companies. A professor makes a discovery, that opens an opportunity for future development of commercial products, such as drugs and modes of treatment. The professor's institution files a patent application that covers the discovery, and usually claims the use of the discovery toward the product development. Supported by the professor's knowledge and experience, and his colleagues, one or more venture capital companies provide initial funding to carry the development further. At some point the biotech company can raise enough money to do clinical studies or a drug company sponsors the further development for an interest in the product.

The hearing today is not about the exegesis of musty law but whether the development of the biotechnology industry will assume a new course. If academic institutions are unable to obtain patents on their academic discoveries, despite government policies supporting obtaining patents, then the original seed which starts the process of company formation will not be available.

It is essential to academic institutions that their discoveries be promptly disseminated. Patents on the intermediate events leading to the ultimate product, events which may take many years and large investments, will likely not be available to be patented and provide protection for the investment. In deciding what is the basis for Section 101 utility, consideration must be given to the effect such determination will have on the role the Patent Office serves in encouraging investment in technology and who will obtain the reward.

Utility has become a major determinant of patentability in technology, a situation distinctly different from other technologies. This is even true of chemistry where often the purposes for the invention -- diagnosis and treatment of humans -- are the same.

What is the rationale for this divergence? One explanation might be the determination that biotechnology is extremely unpredictable. This was certainly the basis for the decision in In re Vek. Expression in sinobacteria of a pesticidal protein previously expressed in other procaryotes was found to be unobvious, but the experience with the two strains could not be extended to the genus.

A further consideration, possibly a more important one, associated with the many inventions directed to the development of therapeutics is that

biotechnology companies are focusing their attention on indications for which there are no satisfactory treatments. Frequently no treatments at all. This means that there are no established models, no relationships to through gene and vitro models and animal models with experience in humans, no other compounds with which to compare results.

Proof of efficacy in humans is an insuperable obstacle to patentability. Biotechnology provides a logical approach to the development of therapeutics. It allows us to identify the proteins or other compounds involved in the physiological processes associated with an indication. It permits a determination of the physiological pathway as well as the branches, the regulatory mechanism associated with the pathway and potential points of intervention. In elucidating these pathways, processes and regulatory mechanisms there will be many inventions made before therapeutic compound is developed. None of these inventions is free of uncertainties, and all will require large investments. All of these inventions will aid in the development of a therapeutic and may be essential to the discovery of the therapeutic. The possession of these compositions and processes will greatly aid in the identification of candidates for further investigation. They will be used despite the fact that no prior history of their accuracy in predicting therapeutic activity in humans is available.

In rejecting these inventions as not having practical utility, the Patent Office is asking for a risk free guarantee of probable activity. Asking for proof of the next five or ten years of research and development activity will pay off. In the real commercial world, these efforts are calculated risks where the patent serves to reduce that risk.

Biotechnology has changed dramatically since the early eighties. Most of the early work had direct application. Today the targets are less obvious, require much greater effort toward achieving products, would involve multiple steps where new proteins and physiological processes will be identified, and will only occur over an extended period of time and by large investment. In the absence of obtaining a proprietary position the start-up company must rely on trade secrets. This will prevent the early dissemination of information, may inhibit investment which will impede bringing therapeutics to the marketplace, and could substantially diminish the U.S. leadership in biotechnology, all inimicable to the purposes of the patent system.

I would like to read you one example of the standard of utility in Group 180. For claim of a normal protein involved in the homing of white blood cells to sites of inflammation such as associated with rheumatoid arthritis and reprofusion injury the examiner stated, quote: "...further, since there was no clear causal relationship between any of the diseases and the proteins of the invention, it is unclear what value

they would have in vitro, e.g., as diagnostic reagents. Knowledge that the proteins are involved in homing and that lymphocytes are involved in a variety of important immunological functions does not demonstrate that the proteins of the invention, which are only one of many components that allow lymphocyte function to occur, can be used to treat or diagnose diseases or other physiologically important conditions." End quote. The invention may not be useful to this examiner, but its discovery required great ingenuity and expense, and may be very import to our effort to treat arthritis and many other disabling diseases.

The issue I have been addressing is what should be the standard of utility for tools which have a reasonable expectation of success but have yet to be established since what is being studied has no precedent. Brenner v Manson does not mandate the present standard. In Brenner it was the compound produced by the process being claimed that had to be researched to find out if it had any activity. Inventions today are intended to screen other compounds for their activity or to be used for scientific research no less than a microscope which may once have been used to look at organisms which had no known utility.

I'm going to skip to my recommendation. Well, I guess I'll try to get through.

One might decide that a practical utility for a tool, product or assay is a reasonable likelihood of aiding and obtaining a commercial disposable. The devil is in the details of how "reasonable" should be defined. By defining the term one way, one could come to the conclusion that any compound associated with an indication for which there are no known or only a few therapeutics is not patentable. Since one cannot show its utility as a predictor of efficacy as a human therapeutic, no intermediate in the development of the therapeutic would be patentable until evidence of efficacy was available. Patents would then go to the developer of the final evidence of efficacy. Regardless of what prior results had shown, any successful Phase III result would be a basis for patentability. This was the result of In re Gangadero. This approach supports the established drug house. It would sound the death nail to the biotechnology industry as we know it today.

I would suggest that a reasonable standard for utility is that the tool does provide some useful information concerning a natural process or can be used to ascertain useful information about a natural process, or the effect of other compounds on the natural process. The availability of the tool does further the needs of mankind.

Without tool patents, there will be reason for academic institutions to file patent applications. For many companies, it has been these applications which have served as a nexus for founding of a biotechnology company. As you can well appreciate, the question of the standard for

utility in biotechnology is not an abstract issue. It is already having an impact and the ruling resulting from this hearing will determine how the industry develops.

Thank you.

COMMISSIONER LEHMAN: Thank you very much, Mr. Rowland. Next I'd like to call John W. Schlicher, of Crosby, Heafey, Roach and May.

JOHN SCHLICHER, CROSBY, HEAFEY, ROACH and MAY

MR. SCHLICHER: Commissioner Lehman, Mr. Van Horn, Mr. Kushan and other members of the panel, thank you for coming to California. Thank you for having these hearings, and thank you for permitting me to come to testify briefly.

I'm John Schlicher. I practice patent law with the firm of Crosby, Heafey, Roach and May, and I'm here to give my personal perspective on these things. I've worked as a patent lawyer for 20 years, some of that time in a biotechnology company, and have worked and thought about biotechnology and its economic significance for most of that time. I also teach patent law from time to time at Stanford Law School.

These hearings are about biotechnology but the issues transcend biotechnology. I have said elsewhere and I will not repeat here, there is not and should not be any separate body of law for biotechnology. Patent law must transcend technical boundaries. Historically it has. The courts insist they do, and we ought to adhere to that in this area as well.

It's also true that throughout the history of patent law there have from time to time --

COMMISSIONER LEHMAN: Could I ask you a question?

MR. SCHLICHER: Of course.

COMMISSIONER LEHMAN: Is that what you think the people have been asking us to do here today is have a separate law for biotechnology? Is that what you have been hearing? If you were here earlier today.

MR. SCHLICHER: I'd prefer not to characterize what other people have in mind. I certainly hear lots of talk about biotechnology patent law and it seems to me there is a perfectly understandable impulse among lawyers, courts and business people for certainty in this area. Bright line rules, as you referred to earlier, shorthand rules of thumb that help you solve your problems quickly and predictably are very attractive in this area. My perception is that -- and I think history bears it out -- it

usually turns out to be a mistake, because patent standards are difficult to define with great precision; it has to do with the economic purposes they have, the facts in which patent laws have to be applied change from time to time in highly unpredictable ways, and unless you adhere to a formulation that says, "Let's apply general principles to the facts of the situation now before us," I think the system is very prone to error.

My second main point is that the Notice that accompanied these hearings ought to be historically a noteworthy event in patent law, because the Notice insist that the information you want is about the economic effects of various rules and their effects on incentives for people to do research, development and commercialize inventions. That is and always has been the right question. The courts and the Congress and the lawyers have not always asked it and that is the reason, in my view, that patent law has for the last 200 years developed an extraordinarily complicated and confusing set of rules. And only by asking it and answering it over and over again will we improve the situation, and that was the impulse for me to spend an unusual amount of time writing a book to try to do that.

My third point is that the Notice talks about the economic role of patents to provide exclusivity to induce investment and risk taking in research, development and commercialization of inventions. I would define the role of patents somewhat differently. The goal of patents is to induce investment and risk taking in producing technological information about new products in processes that in the absence of patents the market would be unlikely to produce or produces early. If someone produces information about the general character and features of a new product or process that distinguish it from prior products and processes, he or she traditionally has been and should be entitled to a patent even if there are large additional expenditures necessary to use that invention commercially, and even if there is no conceivable benefit that's perceptible at the time for consumers and no perceivable commercial potential for the invention. This view of the patent system is consistent with the general history of patent law as it's operated for the last 200 years.

My fourth main point has to do about the operation of the Patent and Trademark Office and its proper role in the patent system, which is the specific subject of these hearings.

The Notice talks about the importance of enforceable patent rights, and the office I think has recently given much attention to trying to focus on the question of quality and it should be applauded for that effort. However, my view of that, there's one danger in pursuing quality. In my view, an economically sensible role for the Patent Office in the system is that the office should screen out and refuse patents for inventions that plainly and clearly do not qualify under one or other standard for

patent issue. Because patent law standards do not draw bright lines, because the facts that underlie applications of those standards are difficult and expensive to ascertain, and because the patent office has limited resources in time, information gathering capability and technological expertise, the Patent Office cannot possibly make a 100-percent accurate assessment of each particular patent application.

Congress set up the system with that in mind. Before anyone ever has to stop doing anything because of a patent, they must get a Federal Court's order ordering someone to stop. And before anyone has to agree to stop or pay a dime because a patent issues, the marketplace permits people to get together and talk about the decision the Patent Office made about the law and the facts and to bargain out a private marketplace assessment of whether or not a patent should have issued and, if it did, the likelihood that a court would agree with the office.

It seems to me there is a terribly important benefit to that system, not the least of which is avoiding a full-fledged costly, factual examination in all cases, and in confining it to the small number of cases where the patents become commercially significant and involve issues that are difficult for the private negotiation process to resolve. Under that view, it is and ought to be of no concern that 10-, 20-, 30- or 40-percent of the patents issued by the patent office are held invalid or otherwise improper by a court in an enforcement action. And if the Patent Office perceives its job as making a 100-percent accurate assessment, my fear would be it would bias incentives of the examiners and the office against granting patents.

Now, you have raised a number of very important substantive questions and I cannot deal with all of them now and I will give you a written paper in which I have and have proposed I think some tests.

My view, if you haven't guessed it already, is that the law in all of these areas is, indeed, unclear, and making it more clear is our job. In some areas I think we could improve it. In others I think probably there are not. And if I had time I'd like to talk about some of those. The only one that I think I will talk about briefly is the utility requirement because it was first on your list and it seems to me it plays an important role in the second.

The law of utility today is that expressed in Brednner v Manson, which is deemed to be the controlling case simply because it's the last one from the Supreme Court. In my view, Brenner v Manson is one of the low points in patent law. The language in it that causes us so much trouble had no basis in law, no sense in policy, and ought to be utterly and totally disregarded, and, if we have any hesitancy about doing that, I would have no hesitancy to go into Congress on that.

My time has expired. Thank you again for your time.

COMMISSIONER LEHMAN: Can you just sort of complete that thought because, you know, that's very provocative?

MR. SCHLICHER: An invention to talk about Brenner v Manson is an invention to a long discourse.

Brenner v Manson has so many problems it's difficult to know which one of them to pick out first to poke fun at. The language obviously that causes everyone trouble is that until an inventor has developed an invention to the point that a specific benefit exists in currently available form there is insufficient justification to permit the inventor to engross what may turn out to be a broad field indeed. And that language inclines you to believe that a patent ought not issue until specific benefits exists to consumers the day after the patent issues.

Obviousness is applied to a world in which the business and regulatory requirement requires years and hundreds of millions of dollars of investment in development after the fundamental characteristics of a product have been ascertained to some degree of certainty. Brenner v Manson inclines you to try -- inclines you away from granting the patent until that additional development, expenditure, and until that additional time has run. And it seems to me that in this industry, as well as in all others, that's a mistake. That is not a hurdle that Thomas Edison faced when he first went to them with the light bulb, even though there were no transmissions lines and no wires in houses and there were not benefits, and I could go through the whole history of patents and it describes almost every important patent. I think the language is difficult. The decision is easy but I think that it was a fundamentally mistaken proposition that has caused us enormous difficulty.

COMMISSIONER LEHMAN: That completes the thought and I really appreciate that, and I also think it's -- it fits in with my own view that we don't necessarily have to be guided by what, you know, the court's say. I realize that's not what all of our witnesses said, that we have the capacity to develop our own position in the courts from time to time in the Patent and Trademark Office as well.

MR. SCHLICHER: Since you have made that point, I profoundly agree with that, that in this area the Executive Branch has an independent responsibility to determine the policy that will best achieve the economic effects of the system and I would encourage that independence.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call on Alain Schreiber, of Vical Corporation.

ALAIN SCHREIBER, M.D., VICAL CORPORATION

DOCTOR SCHREIBER: Mr. Commission, lady and gentlemen of the panel. I'd like to thank you for the opportunity to testify. My name is Alain Schreiber. I'm the president and CEO of Vical, Inc., a gene therapy biotech company here in San Diego. I'm not a lawyer; I was trained as a physician and in my prior career I was head of preclinical research for a large pharmaceutical company Rompol-Lanke-Rohr.

I first would like to commend you. I don't think biotech CEOs or pharmaceutical executives ever spent a whole day listening to clients and customers and users of their services ventilate frustration or anger and be presumptuous to give you suggestions or recommendations. The other part of this day being very interesting for me, I thought I was being singled out as the only company that couldn't get some patents through the biotech office patent. I see that I have a few other companies that have experienced similar cases.

I'd like to give you the perspective of a CEO of a small and struggling company and the current, difficult capital markets and what I perceive to be the needs of the industry.

We need an efficient system, a fair system. The worst that an investor can face, adding to the uncertainty of clinical development or the drug discovery process, is uncertainty in the proprietary position of his investment. Basically, the longer you drag that uncertainty the less people will be attracted to make speculative investments in, almost by definition, enabling technologies.

My second point is that I would make a plea for reasonableness that there should not be a double standard between how patents can be allowed and obtained for chemical entities, new chemical entities, to which I've been exposed quite a bit, and biotech patents. And I think I'm echoing what some of my colleagues have said, in particular, focusing on utility and enablement and the high standards.

It is difficult to count angels on the pinheads. First you have to show utility in man, that's already difficult to get there. It is even more difficult to teach the skilled practitioner as to dose and regimen, and even FDA approval doesn't always guarantee or ascertain that we know all this. So somewhere finding level playing fields and a dialogue of reason as to what can constitute a reasonable demonstration, in your own minds of a value of an invention, would be very valuable to continue this very exciting industry sector that, for good reasons, is in the United States.

You may have noticed by now my accent is not exactly from San Diego. I am fortunate to come here and benefit from the opportunities of the

American system. The biotech industry i s definitely an American endeavor. That was thanks to a number of factors, one of which is availability of capital, and, two, is the general climates encouraging investments, offering protection through your services. It would be ironical if the European Patent Office or the Japanese Patent Office would now provide competitive advantages to this great emerging technology. As a physician and as a businessman, I think we're trying to do exciting things. You've helped so far and I would make that plea that clearly you have already taken a lovely step by coming to America's finest. Thank you.

COMMISSIONER LEHMAN: Thank you very much.

I'd next like to ask Eric Woglom of the Association of the Bar of the City of New York.

ERIC WOGLOM, ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK

MR. WOGLOM: Good afternoon. I'm Eric Woglom. I'm from the firm of Fish and Nieve in New York. I'm here today in my capacity as the chair of the Committee on Patents of the City Bar Association. The City Bar Association is a voluntary association of 20,000 lawyers and judges. It's composed of a number of committees. The Association speaks to the outside through its committees and I'm here today in my capacity as the chair of the Committee of Patents. The views you will hear today are the views of my committee and not necessarily those of myself or my firm.

Mr. Commissioner, I have to applaud you as everybody else has applauded you for holding these hearings. One of the things that you mentioned earlier this morning was that you wanted to hear what your customers think, and I have some good news and some bad news. The good news is we applaud these hearings. The bad news is I suppose is we wouldn't have come all the way from New York City if we were happy in all respects with everything that was happening in Washington, D.C.

The major issue in the eyes of our committee is the question -- is the perception, and I emphasize perception because I don't know what the fact is. The perception is that about four years ago the Patent Office decided to change its internal policy or its internal standards when dealing with the question of utility or operability. This has created some tension between the bar and the office. The people on my side of the bar are concerned because we seem to be in the dark. We don't know exactly what the policy is -- it's just normal anxiety -- although I think we're getting to know what the policy is real quick.

There's also a concern because we're not able to accommodate ourselves to a policy which has not been announced. There's also a concern because

there's a policy, if it really is a policy, has been implemented without public discussion and, frankly, without an opportunity up until today, perhaps, to try to persuade you that the policy is wrong.

Where do we go from here? I think step one is what you're doing right today, is to listen to the bar, listen to industry, listen to the people, listen to your consumers, listen to the people who are effected by what's happening in the Patent Office.

Step two I think would be for us to hear from you, hear from your office, as to whether or not the Patent Office did change its policy, did change its approach to the utility operability question, in at least Group 1800, about four years ago. It may be that the policy hasn't changed. It may be the view of the office that the policy has remained the same, it's just that the kinds of inventions which are being presented to the office have changed over the past four years. That may be the answer and that may quell all the concern. But the concern lingers nevertheless.

It may be that the policy did change four years ago, and if you could tell us that that would clear the air and make a lot of people much more comfortable about the practice.

The question of accommodating ourselves to a policy is much easier accomplished if we know what the policy is. The opportunity to argue against that policy or try to change your mind with regard to that policy is something which would help also, if we knew what the policy was. When I say "you," I'm talking about you as the personification of the Patent Office. Clearly, if I'm talking about something that was instituted four years ago it's not Bruce Lehman who is the person that instituted that policy.

There's speculation in the bar right now as to what is the purpose or what are the motivating forces behind what we perceive to be the new policy as of four years ago. Is the Patent Office trying to carry out the role of the FDA? Is the Patent Office trying to carry out some quasi SEC functions? The Notice of these hearings referred to the imprimatur of the Patent Office on invention, how that may affect the economic value of the invention. It may give rise or may destroy the hopes of people who have illnesses that might be treated by the invention. These are not traditional patent issues. That does not mean that they are irrelevant to the inquiry and it does not mean that they are irrelevant to the formulation of a policy but, again, if the air would be cleared by your office and to tell us whether or not the policy did change four years ago, that would be a big help for all of us.

COMMISSIONER LEHMAN: Maybe I can answer that right now. As I understand it, I don't think the policy changed four years ago. I think

that your characterization is partly correct in that the nature of the -- the nature of the technology started changing four years ago. I think there have been a couple of factors. That is the inventions for which patents are sought have changed, and then the other factor, too, ironically it's the flip side partly of one of the reforms that we made.

In my opening statement I indicated that now over half of our examiners in 1800 are Ph.D.s. Well, I think that initially when a lot of these younger Ph.D.s came in, many of whom had come from the laboratory bench, there was a tendency -- they're very good scientists and there may have been a tendency to look at their work more as peer review rather than as patent examining.

Now, as part of our training process, I think we've changed that a lot. I think there's an internal perception in the Patent and Trademark Office that we're sort of ahead of what we've been hearing here. That, in other words, a lot of the complaints that you've been hearing are complaints that go back to this transition period that I just described when we had examiners perhaps that got away from us, didn't fully -- were well trained technically but not well trained legally, and that given another six months or year you'd start to see a better response. But I don't think -- bottom line, there was no deliberate change of policy four years ago. I think these events that I've just described are what's happened. And, obviously, the purpose of this hearing is to -- we don't want to just wait for this just to gradually fix itself. We want to try to fix it as quickly as we can so that there is a perception of confidence in the Patent and Trademark Office and that's why we're here today, and we're going to move quickly to try to give that sense of confidence following these hearings.

MR. WOGLOM: Just to back up what I was saying with a few specifics. You heard from others today and I could tell the same stories with regard to people who have been practicing in the biotechnical field for 10 years, people who have been practicing in the pharmaceutical field for 10 years, and up until five years ago a certain showing, whatever that showing might would be, would be sufficient to deal with utility issue.

Up until, maybe starting four years ago, maybe starting with the Balzarini decision, that showing has not been accepted. Now, it might have been as a consequence of the examiners on their own exercising some very educated hindsight, or it might have been a policy. And one of the purposes I said was just to come here and try to clear the air in that regard.

A couple of other specifics, if I may. Often the members of our committee, and other people I've talked to in the bar, complain that utility operability rejections are not supported by adequate scientific evidence that in terms of references to receptive articles. What we have

is, more often than not, examiners exercising their own subjective view as to what success might be predicted by one reasonable skilled in the art at the time.

Another problem is the problem with historical inconsistency. Again, one of the earlier speakers referred to what had happened five years ago and then contrasting what's going on today. What we have in situations is maybe an applicant gets a patent, what I'll call the old policy, acknowledging of course that the policy of course hasn't changed, but under the new system the patent doesn't get issued, and it may be on the same invention. You basically have a patent and an application which interfere, in the classic sense, but interference will not be declared because the applicant cannot meet the utility requirement as is now being applied. Would it not be useful to declare interference in those situations? Especially in the situations where the applicant would be the senior party if an interference would be declared, and let those two parties fight it out between themselves, even if the examiner would like to make a sua esponde motion that there is no utility and ought not be a patent issued to either party.

Another question that comes up, of course, is the Section 112/103 issue that some examiners see only divine inspiration when they look at the prior art in diabolical obscurity when they look at the applicant specification. That's an old issue but it's still a current issue.

Lastly, and I see my time is about to expire, I'd like to refer to the issue of the 20-year term. The biotech members of my committee feel that that's something which would be hurtful to the biotech industry and wished there would be more debate on that and not be subject to an or down vote in Congress on the GATT treaty. Likewise, restriction requirement with any term -- 20 years or otherwise -- running from the date of filing something is something which is very difficult for a biotech applicant.

COMMISSIONER LEHMAN: Thank you very much.

MR. WOGLOM: Thank you.

COMMISSIONER LEHMAN: Next I'd like to -- oh, by the way, Stacey Channing, from the Immulogic Pharmaceutical Corporation, we'll not be hearing and so we're going to move directly to T. Andrew Culbert from Drinker, Biddle and Reath. Mr. Culbert is here? Is he here? If not, we're going to move right ahead. Is Ronald Tuttle here from Houghton Pharmaceuticals? Great.

RONALD TUTTLE, HOUGHTON PHARMACEUTICALS, INC.

MR. TUTTLE: While I'm here I had planned to use this 30 minutes to

organize my thoughts so just give me a second to shuffle my papers, if you will.

COMMISSIONER LEHMAN: I thought you were going to say you were going to use the 30 minutes for your --

MR. TUTTLE: No. You'll be grateful to know I don't have any such intentions as that.

Thank you for the opportunity to appear here. My name is Ron Tuttle. I'm not an attorney, I'm a scientist that's been doing R&D in the pharmaceutical industry for the last 28 years. I want to direct my comments to what appears to be to me, as an inventor, a change in standard for utility. It seems that that advent of biotechnology has caused a change in the practice of the patent offices that impacts not only inventions stemming from biotechnology but those drugs stemming from conventional uses in medicinal chemistry, and I contrast my past experience with my present experience; makes me think you're moving in the wrong direction.

I am the inventor of two patents which have turned out well insofar as drugs for the diagnosis and treatment of heart disease. One of those was in 1972, the more recent one in 1992. I think if we'd had the current standard for utility, that is I must at time of making application prove that the drug works not only in animal models of disease but in human models, neither of those drugs would have come to pass and the present patients who are benefitting from those drugs would not have benefitted. The reason for that is simple. It costs a great deal of money to do clinical trials to obtain human data and we get caught in a cycle that I can't finance to get the money to do the clinical trials unless I can assure the investors of a proprietary position which can only come from a patent.

Lastly, in contrasting my experience at the present time with what I regard as good experience in 1972 and 1992 for the advent of those drugs, is a current patent we're trying to obtain, and, although I have supplied a great deal more data on animal models than we did in the past patents, we continue to receive rejections from the examiner based on the lack of human data.

We have supplied what I think are good arguments regarding the relevance of those animal models, and while we all are aware that there's oftentimes failures between animal models and clinical outcome, that generalized principle or finding that there's often failures should not be applied in the specific. I believe if the examiner is going to reject our animal models of diseases irrelevant, specific reasons should be cited and tell us exactly why it's irrelevant in his view.

In the present application, we've gone so far as to supply the toxicology data. We have supplied the institution review committee approvals for testing of the drugs in humans but still we're faced with rejections because of lack of human data on utility.

Lastly, in the Notice to the hearing, I noticed there was concern, which is probably appropriate concern, that some patients suffering from certain diseases for which a patent is issued may have their hopes falsely raised in believing that the issuing of a patent somehow shows the patients that the government believes in this invention. I think that is a confusion of the mission of the Patent Office and the mission of the FDA. And while it's an argument for better public education I don't think it's an argument for changing past practices of the Patent Office which I think past practices have benefitted patients, the industry and the competitive position of the United States. So, obviously, I'm making an argument for the status quo, at least insofar as the advent of biotechnology should not impact how we view inventions from traditional medicinal chemistry.

Thank you.

COMMISSIONER LEHMAN: Thank you very much, Mr. Tuttle.

Next I'd like to call Jeffrey Miller of IXSYS Corporation.

JEFFREY MILLER, IXSYS CORPORATION

MR. MILLER: Thank you for giving me the opportunity to speak here today. My name is Jeffrey Miller. I am currently a postdoctoral scientist at IXSYS, a biotechnology company here in San Diego. I'm co-inventor on patents arising from my work there at IXSYS. However, today Bill Hughes, who's the founder and chief scientific officer of IXSYS thought that my testimony would shed a different light if I were to address this body as a representative of small, independent scientists who endeavor to protect their individual contributions and ideas in the arena of biotechnology. Therefore, I am here as an individual patent applicant today.

In December of 1992, prior to coming to IXSYS, I filed a patent application for methods and compositions for in vivo sedensynthesis. This is a new and -- In the new terms, terms I'm starting to learn to use, a basic enabling technology. The initial application has been through two office actions and I filed both PCT and continuation applications as well as related trademark applications.

During these two years, I have learned some of the terms and workings of the Patent Office and these experiences are the basis of some of the concerns that I voice here today.

First, it appears that a final action is frequently rendered by the patent office in response to the second office action or following the second office action. This response is advanced without regard or consideration of progress which may be evident in the prosecution of the patent. Now, this action appears to be -- on the outside to be a mechanism for restarting the patent examiner's clock and obtaining filing fees for the Patent and Trademark Office, rather than action necessary or desired for expediting patent review.

Second, I'll say I've noted a lot of people have voiced their views today that there appears to be an inconsistency in the evidentiary standards required to determine the utility in patents related to biotechnology. It is clearly impossible to expect an individual or a small biotechnology company to garner data required to determine efficacy for an invention in a primary patent application.

Current mechanisms for addressing this issue, from the scientist's or patent attorney's perspective, I understand include to continue to the costly and unproductive prosecution of the patent application, basically keeping the ball in the air and claims active while awaiting efficacy data from collaborators with deep pockets. Unfortunately, run into a Catch 22 situation where any potential deep pocket collaborators generally require proof of proprietary position prior to advancing the funds to initiate the costly efficacy trials.

I think that the small inventor in biotechnology would like to see a return to normalized evidentiary standards where simple, reproducible, practical utility meets the basic requirements. Typically, I'll say that patent applications are not requests for a hunting license, rather we're trying to protect ourselves from the large corporations which can turn the crank and circumvent our initial applications with refinements which require resources beyond our reach. Therefore, I think you should let the market forces determine the efficacy or utility of the method or composition.

And one of the points that was brought up earlier is a good point and that is if you can get licensing money for your patent application, your method or your composition, that's a pretty good indication that somebody thinks that -- somebody who's got a good scientific background thinks your patent application, your patent has merit. This approach allows a reasonable extrapolation of claims which will protect you downwind down stream and protect potential uses and serves to protect both the small innovative scientist and the large biotechnology company. This consistent application of existing standards -- existing standards -- will allow exploitation and marketing of ideas and innovation without doing harm to the public. Thank you.

COMMISSIONER LEHMAN: Thank you. Were you here earlier when Mr. Schaffer testified, the lawyer from New York who testified that one of the solutions might be for us to, in effect, establish a presumption in favor of declarations from experts as opposed to, you know, having any --

MR. MILLER: I think --

COMMISSIONER LEHMAN: Would this solve the problem for your company?

MR. MILLER: If you're asking whether expert testimony would --

COMMISSIONER LEHMAN: That's right.
MR. MILLER: -- provide that, I think his point was that that might be useful. However, you might also run into the problem where you would have two schools of thought, both of which are expert witnesses and they could be in disagreement.

COMMISSIONER LEHMAN: In this case the only witnesses would the be witnesses that you produced.

MR. MILLER: That would help.

COMMISSIONER LEHMAN: You don't have oppositions in --

MR. MILLER: I don't have any problem with that.

COMMISSIONER LEHMAN: -- the U.S. Patent Office as you do in Europe.

MR. MILLER: That would be great.

COMMISSIONER LEHMAN: So basically the -- The answer is "Yes," that would solve your problem?

MR. MILLER: Yes, I think that would solve the problem. Thank you very much. Appreciate it.

COMMISSIONER LEHMAN: Next I'd like to call Gail Kempler of Regeneron Pharmaceuticals.

GAIL KEMPLER, REGENERON PHARMACEUTICALS

MS. KEMPLER: My name is Gail Kempler. I'm the patent counsel for Regeneron Pharmaceuticals. We're located in Tarrytown, New York, so I'd first like to thank you for coming to these hearings in San Diego. When I had the opportunity to meet you a couple of weeks ago, at a Council on Foreign Affairs breakfast, I told you that I thought current practices in Group 1800 were paralyzing the biotech industry. You said you thought

that that had all been resolved but, if not, I should testify today -- so here I am.

Regeneron Pharmaceuticals in a biotechnology company that was established in 1989 by two neurologists who were fed up with available therapies for treating neurological diseases, such as Lou Gehrig's Disease. The founders recognize the potential of neurotrophic factors which are naturally occurring proteins which can be used to promote the and/or survival of neurons, and the had the concept that if these factors could be used to help neurons to survive that they would be useful for the treatment of neurological diseases where you have degeneration of neurons.

Although we hoped when the company was founded that we would be the first to identify and clone these new factors, as it turns out, there are a lot of other companies that had the same idea and many of these companies have armies of cloners which we don't have. Unfortunately, we only have currently 200 people at Regeneron. So, more often than not, we lose out to the armies of cloners and other companies are the first to get the patents on the genes and the proteins. However, since our roots are in neurobiology, we do pride ourselves in being able to figure out what a lot of these new proteins do and we do develop both in vitro assays in house, as well as novel animal models. So often we do determine therapeutic utilities that have not been discovered by the companies that have cloned the new gene. Accordingly, we have a patent portfolio that's filled with human therapeutic applications.

I spoke at a forum about a month ago where Charlie Warren was asked -- and I'm quoting the question: "Sometimes an applicant must come up with data sufficient to persuade the FDA to approve a drug in order to persuade your department to issue a patent." In response Charlie said, and I quote: "That is not true. I will say we have had examiners who have taken that tack in the past and hopefully the past is behind us and they don't do that anymore. "However --" and I stress this "however," and I'm still quoting -- he said, "as I did say, there are some disease states where one skilled in the art, given contemporaneous knowledge in the art, will not accept anything less than human clinical data to establish utility and enablement."

Well, obviously, the diseases that we're working on at Regeneron are part of these kind of diseases and basically Group 1800 has held us to this requirement for human clinical data. I think it's common knowledge, at least I've heard this, that there are certain disease states that fall into this category; they seem to be cancer, and they seem to be AIDS treatments, they seem to be neurological diseases. And it seems to be the diseases for which there are not very many therapies. It also seems to be the diseases for which the therapies are most needed and most necessary.

Although Group 1800 says that animal model data will suffice, the current standard requires that such animal models be art recognized. This means not only must the animal models have symptoms that mimic the diseases that you're going to treat but there also has to be a demonstrated correlation between he data derived in the animal model and human utility. So, in other words, if you're a company like Regeneron where you've developed animal models that have never been utilized before, you're effectively punished because you cannot possibly correlate data obtained in these animal models with human data. So, in effect, you have to run a human clinical trial to prove your models. And, so, you know, if you're going to go to that you may as well just run your human clinical data -- human clinical trial and submit your human clinical data. We've tried this, too, in a recent application that we've been prosecuting and have found that trying to submit human clinical data is wrought with even more problems.

The data comes continuously. You don't have just one piece of data that you can submit to the patent office. You have a continuous stream of data and so every time you get more data out of your clinical trial you run into the problem of: "Do I have to continuously update the Patent Office every time I have some new information?" You also have the problem that you have several treatment groups in your human clinical trial so you have to decide: "Do I have to submit to the Patent Office all of the treatment groups or just the ones that work? Do I have to average them together ?" and then you're accused of withholding certain data and only submitting the good data if you only submit the data from the treatment groups that work.

We are also told by Group 1800 that the data has to be statistically significant at the same level as required by the FDA.

And, finally, our biggest problem, which I really haven't heard anyone mention here today, is we are a small biotech company and any data that we derive from a human clinical trial is material. So the SEC requires that we make public any information that we have regarding our human clinical trial. So when we submit data to the Patent Office to satisfy Group 1800's requirements, we also have to disclose the information to the public in some kind of a disclosure; press release, and also in our prospectus.

When you make such a disclosure in your prospectus, you generally have to put in some kind of disclaimer because you don't want to be accused by the SEC of hyping your drug before its time. So we generally put a statement in our prospectus that says: "The results of Phase I and Phase II clinical trials do not necessarily predict the results of the Phase III trial or any further trial or potential regulatory approval of or success of the drug." And we've recently had this statement from our

prospectus cited against us in an examiner's rejection. So not only is Phase I and Phase II clinical data insufficient, you now have to have Phase III clinical data or any disclaimer that you put into any of your SEC-related statements will be used against you.

So the bottom line is that, despite Group 1800's indications otherwise, for diseases such as neurodegenerative diseases only data sufficient for FDA approval will suffice to obtain patent protection. And small biotechnology companies, like Regeneron, just simply cannot afford to run these human clinical trials absent some form of patent protection. The result is only the companies that -- the only companies that can run clinical trials are the ones with the army of cloners. And I think that even though I would say in some cases we'd be happy to take all the works home because we're first to clone a protein, I think it's a problem when a company clones a protein and really hasn't discovered many of the utilities and therapeutic applications of that protein but yet they take home all the bacon because the companies that discover alternative therapies for those compounds simply cannot compete. They simply can't run clinical trials.

We continue to believe that the understanding of novel proteins and what they do is as valuable and as deserving as protection as the cloning of the molecules. The standard used to examine applications relating to the tough diseases such as cancer, AIDS and neurodegenerative diseases shouldn't be so tough that it discourages discoveries of therapies in these areas.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call on Andrew D. Fortney of Oblon, Spivak, McClelland, Maier and Nestadt.

ANDREW FORTNEY, OBLON, SPIVAK, McCLELLAND, MAIER and NESTADT

MR. FORTNEY: Good afternoon. My name is Andrew Fortney. I'm a patent agent with Oblon, Spivak, McClelland, Maier and Nestadt. We have offices in Arlington, Virginia, literally right across the street from the building in which Group 1800 is located, and we have an office in San Jose. I'd also like to thank the Commissioner for informing me of the teleconferencing office to be set up in Sunnyvale. I'm sure our firm will take full advantage of that.

I guess last night when I should have been thinking about what I was going to say today I was watching 60 minutes and if anybody else saw it there's a big story on this cloning of a gene from an Italian family who have really very little, if any, signs of cardiovascular disease even though a number of members of this family have life- threatening cholesterol conditions. Since it didn't cost me anything, I'll submit

the front page of "U.S.A. Today" as evidence of this discovery.

The point of the story I guess is hopefully there is some relevance to everybody -- to the public -- that now biotech has some really exciting offerings that can effect everyone directly.

Doctor Shaw, who I guess is a doctor at Cedars Sinai who did the rabbit testing studies in this case, he was, you know, on TV telling the public this technology exists. We can bring it to you now. This is what biotechnology has to offer to you. So, with that in mind, I'd like to actually go into a couple of things that I'm kind of curious about from a policy perspective which maybe we haven't really talked much today. I guess I should also read the papers and listen to the news more often than I do, but from what I gather the Clinton Administration is interesting -- or interested in maybe three policy goals which the Patent Office can have a direct effect on.

One is advancing the business atmosphere in high technology. This is an area in which the U.S. is concerned about losing its competitive advantage, biotech being one of these fields.

In the area of health care reform, they're interested in lowering the cost of pharmaceutical agents most prominently.

And another policy goal of the Clinton Administration, as I understand it, is minimizing the duplication of effort and of overlap between the different agencies. I think some of the ideas we've heard today sort of address these things, but particularly the need by the biotech industry for early issuance of patents and getting some kind of reasonable claims' scope. At least scope a little bit broader than the working examples.

I'd like to address this last issue that the industry wants, getting reasonable claims' scope. Earlier we heard some testimony that over the last 10 or 12 years biotech has become somewhat more predictable than it was earlier. I think this supports position of allowing somewhat broader claims' scope at the Patent Office, and, if necessary, maybe the Patent Office can consider looking into some kind of preponderance of the evidence standard for determining what the level of ordinary skill in the art is under 112 in order to evaluate what sort of claims' scope is allowable. Over the long term this will also help to lower the cost of pharmaceuticals and primarily in the fact that it will help to give a little bit more certain atmosphere for conducting the business transactions necessary for the smaller companies to get the capital to do the studies later on. It will help establish the proprietary positions with greater certainty, and it will kind of minimize the reliance on the doctrine of equivalence, if a patent ever needs to be enforced. It will make it easier to establish direct infringement I think for very minor modifications. Overall, that's going to lead to lowering the cost of

pharmaceuticals.

I think under the utility issue, again we still would like to see your early issuance of patents with reasonable claim scope. I think one -- although this will be the only comment I have about any direct practices of the PTO. I think the issues for compound claims specifically, and it is proteins and polynucleic acids in biotech, should be addressed separately from the issues under -- or relevant to composition -- pharmaceutical composition claims and method of treatment claims. For pharmaceutical composition claims, typically you have to recite an effective amount to achieve some desired medical result. In method claims, typically you are counting on some sort of human treatment as the utility. So I think the issues are different.

For compound claims specifically, there are a number of different utilities which are often asserted and I think the case law is fairly clear that if a compound claim has a utility other than for human treatment then it's met the utility statute. However, as far as the pharmaceutical composition claims and method claims go, and this may be somewhat professional suicide for saying it, I think the Patent Office has legitimate concerns about whether the public is actually being served by issuance of a patent if there's some question about whether the thing is going to be effective or not.

I think again the suggestion to simply accept at face value a declaration tying whatever results are there to prediction of in vivo effectiveness I'm also hesitant to support, because I think if there is evidence that the Patent Office is aware of that maybe the test isn't accepted, or that may challenge directly the evidence that was submitted by applicants in that case, then it raises some questions perhaps of the validity of the patent. And it's certainly going to be a lot cheaper and easier to resolve this at the Patent Office than it will be to try to resolve it later on in litigation. So I'd like to suggest in this case that maybe a preponderance of the evidence standard also be looked at as a possibility for resolving utility issues in applications where pharmaceutical compositions and methods of treatment are being claimed.

I guess that's pretty much it. I do have a couple more quick comments. You asked for specific cases, and even though my firm really doesn't want me to speak about any specific cases for reasons of, you know, possibly generating estoppel or any bad will at the Patent Office, and believe me we regard our good will with the Patent Office with the utmost respect, we did have one case in the AIDS treatment area where we had a notice of allowability for a number of years. I think it was there for about two years and every once in a while we'd check and see when we were going to receive the notice of allowance and it never came. You know, we were real curious about why that was but I don't think we ever got a straight answer. And I think it kind of underlies the perception that maybe there

was some policy change at the Patent Office, even though, you know, we hear that there wasn't any. Whether there was or wasn't, you know, I think is almost beside the point because it's -- it's obvious that some things have changed and, you know, at least personally I'm glad we're having this hearing to try and resolve the issues.

Also I think we heard some comments earlier about educating examiners on the cases, and I'm not so sure that's the best use of time and resources. My experience in interviewing examiners is that it doesn't really matter too much what the cases say, it depends on whether their supervisor is going to agree with what they say in the office action that counts. And I think at least the preponderance of evidence standards that I suggested earlier, that's a pretty easy test to look at and see whether, you know, the evidence is on one side or another.

If I can make one last suggestion to you, Mr. Commissioner. You were concerned about the length of prosecuting biotech applications relative to those in other areas of technology. I think that can be resolved pretty quickly just by looking at the front cover page of most patents issuing from Group 1800. It's pretty rare when there aren't any earlier filed applications cited in support of it, but I think in other areas, and I think most particular in polymer areas, it's pretty rare to see that there was an earlier filed application. At least looking at the front page of each issued patent, that should give you some idea of how many continuation applications were filed in the prosecution of a particular case. And, at least on our side, we look at cases rather than applications. You know, we consider continuation applications to be part of the same case.

With that, I see my time is up.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call Robert Benson of Genelabs, Incorporated.

ROBERT BENSON, GENELABS, INCORPORATED

MR. BENSON: Thank you. My name is Robert Benson. I'm vice-president and general counsel for Genelabs Technologies, in Redwood City. We have about 220 employees and we deal primarily with viral diseases. We isolate novel nucleic acids. From those we do assays for detecting the virus. We do vaccines and therapeutic agents, and I think there's a tremendous need for isolating new viruses. Quite a few of them are adapting themselves to the human host and we need to stay very active in this area.

The patent issues in this area of viral isolation are very critical to my company, and I think to all small companies in that the FDA regulatory

testing required cost a great deal of money. And it's been said already many times today, and I'm not going to belabor it, but delays in the patent process creates a tremendous sense of insecurity on the part of our investors and our corporate collaborators.

It's very important that we have a sense of patent stability in order to move these discoveries through to commercial products. In many instances, the lack of a clear patent position undermines the ability of small companies to attract the needed resources.

In the interest of having listened to almost seven hours to other people talk, I'm going to summarize some of the things I was going to say, sort of a short ditto.

In the area of FDA data -- FDA-like data in order to get a patent allowed, that is human clinical testing, I think it's beyond the scope, or should be beyond the scope of what the examiners require and I think a practical utility basis is all that should be necessary.

I'd also like to comment on something that hasn't been brought up too much today and that is the patenting of novel nucleic acid sequences and their use, particularly in the area of reductions of practice either actual or constructive. It's our position that nucleic acid sequence composition claims should not require a description of the best final utility, be it dependent upon human clinical data or any other kind of data; that what you need to have is a statement of practical utility together with enabling application.

There seems to be an awful lot of flux in the area of what a partial nucleic acid sequence qualifies you for in the U.S. Patent Office. I would like to just drop back and say you should get whatever you disclose in your patent application, and that is if you can show that you can do something with it that is practical and that has a real utility then you should be able to get a claim for it, because others in the future will find improvement patents or other uses for it, that's fine. We shouldn't foreclose that kind of improvement either.

Next I'd like to address briefly what I like to refer to as the double standard that the Patent Office practices in the area of 103 versus 112 enablement issues. It's always been hard to explain to an inventor how if he published something it becomes prior art against them that's going to block them, but if he puts the same information in a patent application it won't be sufficient for him to get a patent. I have never been able to quite get that information across to an inventor. In fact, sometimes I have trouble understanding it myself. And I would like to see some type of reduction in this type of double standard where the ability of a patent applicant in -- to publish his research or to file a patent application is not made difficult.

And, finally, I would like to emphasize the importance of training and keeping a well experienced examining corps. I know that the corporations and the law firms bear an awful lot of responsibility for their recruiting efforts on the trained examiners. It's a problem that is largely economic until the Patent Office has the money necessary to retain the examiners the problem will continue, or until the world is saturated with qualified patent practitioners, but that's I think quite a ways off right now.

I was very upset to find out that $30 million of our fee money was going into the general fund as opposed to, as I had been led to understand, to support the Patent Office and the maintenance of a qualified examining corps.

I would like to go into just one little piece of what I would call sort of technical argument here and it has to do with the patenting of partial nucleic acid sequences, which I've recently seen in the press a lot where some are upset about patent applications containing partial sequences. I would just like to put in the record what I think are a few utilities which I think should support the patentability of a nucleic acid sequence.

One example would be encoding a unique antigenic peptide that provides an antigenic site for detecting the presence of antibody of clinical significance, particularly in the area of being able to test for a virus -- something like that.

Another example would be encoding a polypeptide that provides a unique receptor, binding lignin, that modulates the activity the receptor stimulated.

A third example would be providing a unique hybridizing sequence that permits detection of a target nucleic acid sequence having clinical value.

And still another would be nucleic acid primers that give specificity to a polymer chain reaction assay of clinical value.

These are all examples of ways in which a nucleic acid sequence can be used in a very real way but that do not necessarily mean that the patent applicant knows the entire sequence or necessarily what the entire sequence will be able to do. That I would leave to future inventors to go into the laboratory and discover.

Finally I would like to sort of digress a little and that is when I first entered patent law I was in a Washington law firm and a man left the U.S. Patent Office named Irving Marcus. He'd been there for I think

about 30 years. He was in the office next to me and I used to go over to him all the time because I couldn't understand why the Patent Office was doing stuff and he would try to explain to me how the patent office worked, and that sometimes there were champions within the patent office for certain positions, and how he had been a champion for certain issues two or three times and he had been right and it had worked out pretty well for him and he managed to move up within the Patent Office. And I think one of the things I'd like to see is some champions today who take positions for improving the patent system and particularly resolving problems like our current dilemma involving human clinical testing in order to get patent applications. I would like to see more of an ex parte situation and less of an adversarial proceeding in the securing of patent applications.

Thank you.

COMMISSIONER LEHMAN: Thank you very much, Mr. Benson.

Next I'd like to call our second witness from Isis Pharmaceuticals, Lynne Parshall.

LYNNE PARSHALL, ISIS PHARMACEUTICALS

MS. PARSHALL: Thank you Commissioner Lehman and other members of the hearing board, good afternoon. My name is Lynne Parshall. I'm senior vice-president of Isis Pharmaceuticals and Doctor Crooke from our company spoke with you earlier today. Among my responsibilities at Isis is to supervise our patent prosecution. I appreciate the opportunity to talk to you today. I'm going to focus on just one item in connection with our patent prosecution that's affected us significantly, which is something that you've heard a lot about today, rejections that we've received based on incredible utility.

As a development stage research based pharmaceutical company, for many years our most significant asset has been and will continue to be our patent estate. We've invested extremely heavily in this area. Our major focus at Isis has been on the development of antisense technology and the commercialization of drugs based on this technology. We're the leading company in our area and have invested more than $100 million in this technology during the past five years. Many major pharmaceutical companies and other development stage companies also have antisense programs.

In many respects, we think antisense technology epitomizes some of the special challenges that the Patent Office faces in dealing with new technologies. It also epitomizes some of the potential harm that can be done by inconsistent activities with regard to the evaluation of patent applications.

Antisense technology is a true innovation in drug discovery and development, as are many of the technologies you've heard about today. It's very broadly applicable to many different therapeutic areas. It's a technology that has extraordinary promise and importance and it's a technology we believe that needs and deserves the protection of the patent system.

We have focused our technology on a new target for drug discovery, RNA, and used a new class of chemicals, modified nucleotides to approach this target. At Isis, we've simultaneously invented new minuscule chemistry and the basic pharmacologic framework to apply this technology. Even for practitioners remaining abreast of this technology is very difficult. In this way the antisense field is really though no different from any other important field in which rapid innovation is occurring. What is different, however, appears to be how the patent office analyzes the growing body of literature concerning antisense technology.

In reviewing this literature, as you would expect, you will find work of varied quality; good and bad, and work expressing a variety of approaches to and views of the field. In addition, you'll find work which due to the rapid pace of innovation is no longer state of the art. It's the selective use of this literature by the Patent Office to doubt rather than support innovations in antisense that hinders our patent prosecution and which we believe provides an obstacle to patenting innovations in the field.

Not surprisingly, in the beginning of this technological area there were more questions than answers about the potential for antisense compounds to be drugs. Today we believe most of those questions have been answered and the overwhelming wealth of current evidence supports the contention that our technology will, in fact, yield important therapeutic advances. This evidence includes efficacy data from many animal models of disease and from many different laboratories. It also includes clinical data on two antisense drugs that we've studied in humans. Despite this wealth of data, we're continually facing rejections based on utility for our compositions of matter and therapeutic use patents.

In the last year, we've received office action rejections in approximately 70 different applications that included some sort of incredible utility or lack of utility rejection. Responses to these office actions has cost us hundreds of thousands of dollars in legal fees, which probably makes some members of the audience more happy than others.

Patent applications of ours have been rejected for compounds for which we've shown significant inhabitation of viral replication in well recognized models, including models that the government's using in its

agencies for therapeutic screening. In the face of the fact that more traditional chemical showing activity in these models have, in fact, been granted patents, patent applications have been rejected for compounds for which we've shown significant activity in animal models of disease when more traditional chemical showing activity in these models have also received patents. Even patent applications for compounds for which we've shown evidence of activity in humans have been rejected. For example, one of our pending patent application claims composition of matter to certain phosphorothioadal alignin nucleotides used to treat a debilitating viral infection. Today patients are being treated with one of these alignin nucleotides to help the spread of this disease.

In the latest office action we received for this application, the examiner maintained a previous 101 rejection for lack of patentable utility. This rejection has been maintained in the face of declarations from two experts in support of this application. One of these declarations was from a clinician actually treating patients with the drug in our ongoing clinical trial. The declaration detailed the positive activity of the drug in patients. The other declaration came from a well respected scientist who reviewed the current state of the antisense field. These declarations from well known, well respected clinicians and scientists were dismissed by the Patent Office.

COMMISSIONER LEHMAN: How were they dismissed? On what grounds?

MS. PARSHALL: We were told that they were conclusionary and anecdotal.

COMMISSIONER LEHMAN: Can I ask you a question about that, because, you know, I earlier referred to Robert Schaffer's testimony recommended basically that we adopt a policy of providing a presumption to such declarations. And then we heard another witness just a few minutes ago, Mr. Fortney who opposed that because he said: Well, you know, what's going to happen there then is that on the basis of sometimes inadequate declarations a patent is going to issue and then, you know, you'll be out in the marketplace with a potentially invalid patent and, you know, you'll have to spend then not just $200,000 but you'll have to spend, you know, $1 million on a patent infringement case. It will, you know, put you out of business.

What's your response to that? We hear Mr. Schlicher say basically that we should err in favor of getting the patents out the door and literally leave it to the litigation system to sort of round off the edges.

MS. PARSHALL: My feeling is you're talking about two different issues here. One of them is whether or not there's an invention that's truly different from what's both in the literature and what's been claimed in other patent applications. And the other issue is whether or not the Patent Office believes that there's utility associated with this

particular invention to give it -- to grant it the status of something that's patentable. I think the Patent Office's job is to do the former and not second guess experts in the field with regard to the latter. I think the Patent Office needs to look at the existing literature to make sure that something put in front of it is truly inventive. I think that when the Patent Office is faced with physicians and well respected scientists who say, in fact, "In this area this is likely to work," -- the Patent Office I know is composed of, you know, very good scientists as well, but I think they can't hope to be experts in every single area, particularly with the type of innovations going on among the companies that you've heard talk today.

Our frustration is that our science is being second guessed by people who, although they try and be as expert as they can, aren't experts. Not that the Patent Office is making errors in looking at what's out there and what's been invented in the past.

COMMISSIONER LEHMAN: We can certainly say they are experts in the prior art. Probably the best experts because they work with it every day, but they, as you point out, are not experts in what's coming down the pike.

MS. PARSHALL: That's right.

To continue with just another example. We face similar Patent Office rejections in basic chemistry cases. Just a few days ago we received an office action on a process patent application. The invention claimed in the application as an improved process for preparing phosphorothioadal alignin nucleotides, and in the office action the examiner rejected all of the claims as lacking patentable utility. The examiner stated, and I quote: "The antisense activity of the instantly claimed compounds borders on the incredible and such an asserted utility is deemed unlikely to be correct in view of contemporary knowledge in the art." End of quote. It's difficult to understand the examiner's position. The recent scientific literature does not indicate that the activity of phosphorothioadal alignin nucleotides is incredible and deemed unlikely to be correct. In fact, ongoing clinical trial of these compounds do not indicate either that the activity of phosphorothioadal alignin nucleotides is incredible and deemed unlikely to be correct. The declarations that we've submitted from well respected clinicians and scientists do not indicate that the activity of the phosphorothioadal alignin nucleotides is incredible and deemed unlikely to be correct.

I'm not trying to suggest that drug discovery is not fought with uncertainty. We all know -- you probably heard a lot about how long it takes to come up with drugs and how long it takes and how expensive it is. What I do urge you to see, though, is that antisense compounds merely represent yet another example of a new area of innovation similar to those that have been encountered numerous times in pharmaceutical

patenting new classes of chemicals designed to intervene in disease processes in a new way. Support of this type of innovation in the pharmaceutical industry by granting patent protection of reasonable scope has been and continues to be necessary to simulate continuing innovation.

With regards to patents in biotechnology, we feel that there's a different standard applied than that applied to traditional pharmaceuticals. Demands for definitive proof of therapeutic utility which seems to equate to pivotal controlled human clinical trials have resulted in many patent application rejections. As Doctor Crooke said to you earlier today, there's no harm done and, in fact, significant public policy is served by giving pharmaceutical innovators the benefit of the doubt in terms of the utility of their inventions.

I'd like to reiterate the recommendations Doctor Crooke made to you earlier today:

We recommend that the Patent Office return to traditional practices with regard to pharmaceutical patents. This would include a return to a positive bias towards innovation with the acceptance of reasonable proof of potential utility for inventions.

We request that you treat patents from so-called biotechnology companies and pharmaceutical companies as equivalent. We're the same industry with the same customers practicing the similar science.

We request that you act consistently across and within technology areas. Just because one technology is labeled a new technology and another is not does not mean that the basic approaches or risks are necessarily different.

We further request that when in doubt you grant therapeutic claims based on the specific examples provided with scope commensurate with reasonable extrapolation from the examples that have been provided.

Let me thank you for this opportunity to speak to you today. I think this issue is a very critical importance to us and to innovation in health care. I'm confident that as you consider the issue, and hear all that you've heard today and will continue to see in the record, that you will agree that it is in the public interest to continue to encourage innovation in the pharmaceutical industry, not to discourage it.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to call on Robert Sobol of the San Diego Regional Cancer Center. Mr. Sobol? Guess he's not here.

Susan Perkins of Cambell and Flores.

If Mr. Sobol comes back we'll try to fit him in. He might be hanging around because we're about a half hour out of time. I'll call him later.

SUSAN PERKINS, CAMBELL and PERKINS

MS. PERKINS: I was going to make that specific request before I got into my testimony. If he Doctor Sobol -- given that we are about a half hour ahead -- could go after my testimony.

COMMISSIONER LEHMAN: I think we've told people that there was a half hour either way so we're right at that cutoff, you know, at that far edge.

MS. PERKINS: My name is Susan Perkins and I'd first like to start my testimony by echoing many of Tom Wiseman's positive comments he made today. Having worked as a patent examiner for over four years in the biotechnology group, I too am familiar with the fine and hard working people at the Patent Office who are trying to make this system work.

I'm currently in private practice for Campbell and Flores, a San Diego based law firm that specializes in biotechnology patent law. We work primarily for small start-up companies, not-for-profit organizations and universities. You have heard today from a number of our clients -- and hopefully Doctor Sobol. Universally these clients have commented on the more stringent and unrealistic standards that are being applied in Group 1800, particularly as to utility. Our clients have also commented, and I'd like to further emphasize, just how critical patent protection is for the continued research and development to these companies. I would like to add briefly to those comments already provided by our clients. While the views I express are my own, they are derived not only from my recent experiences with the patent office but also those of other practitioners at my firm as well as and, more importantly, the experiences of our clients.

In one application in our office we successfully interviewed the application. It was deemed allowable, having removed all the 103 and 112 rejections. We then got a call from the examiner that prosecution was going to need to be reopened for new utility rejections and new enablement issues. When asked if we could reinterview the case. We were told by the examiner that we could argue the utility issues until we were blue in the face, that this examiner was taking direction from his superiors and that the examiner, and I quote, "feels like a robot in following the mandate of his supervisors."

I cannot help but wonder how happy this examiner must be in their job,

and I'm very familiar with what an enjoyable job patent examining can be. But more importantly, it appears to me that this application has been prejudged and finally determined without us even having had the opportunity to interview or submit a response because of the current utility standards being applied today. This case is not unusual for what we are seeing in our office. We are often having cases reopened for prosecution based on utility and enablement issues which I think speaks directly to the changed standards over the last couple of years. And it is also not uncommon that where we submit sufficient legal arguments or supporting technical data, this does not appear to be enough.

In this particular case, the inventor's response to the utility rejection was he'd be happy to do human clinical trials. If only the examiner would give his right arm for that injection, he'll do the human clinicals. This may seem like a ridiculous statement -- I laughed myself -- but I think it certainly speaks to the frustration that the inventors are feeling today with the Patent and Trademark Office and these enhanced standards of utility.

In other cases, we are now seeing restrictions drawn along in vitro and in vivo lines. Claims to in vitro procedures or uses are held to be patentably distinct from in vivo uses or procedures. We even get this restriction where we have not specifically claimed in vitro or in vivo uses or procedures. The examiners argue that the claims are generic to in vivo and in vitro. One problem with this is that you must realize that restrictions drawn along in vivo and in vitro lines can result in more groups in a single restriction than there are claims in an application. I think these restrictions are really so the examiner doesn't have to deal with the in vivo utility issues until you file a divisional application, not that in vivo and in vitro inventions are patentably distinct. And I don't think a restriction for utility purposes and those additional uses of utility for in vivo inventions warrant a restriction.

Now, there is a positive side to these in vitro/in vivo restrictions. Now, it would appear that the Patent Office cannot apply prior art disclosing in vitro data only as rendering obvious in vivo claims. One of the largest downsides I see to these restrictions is I'm not sure how, where an applicant elects the in vitro group, to prosecute that application where we don't even have an in vitro use or procedure disclosed. And it's not uncommon that we have cases that get these restrictions between in vitro and in vivo lines where we don't even have in vitro inventions disclosed, yet the examiner has made this restriction and indicates we have some in vitro invention. I don't know how we're supposed to prosecute those applications.

On another issue regarding the double standard, which has been talked at great length today, but I'd like to focus specifically there also on in

vitro and in vivo. The examiner is holding in vitro data disclosed in a publication as rendering obvious applicant's invention, but that in vitro data or animal models are not sufficient to meet the current utility standards. While I as a former examiner appreciate the need for compact prosecution and that we make all possible rejections in the first office action, and I even appreciate that there's different standards between enablement and obviousness, it seems to me that the Patent Office needs to really make a decision about whether or not in vitro data in a disclosure renders something obvious or whether applicant's in vitro data and animal model is going to be sufficient for utility. These two inconsistent positions cannot both be correct, and yet we're seeing these rejections vigorously maintained until we refile the application and argue it again in a new continuing application.

When I was an examiner, I routinely made these apparent inconsistent rejections of 103 and 112 and 101, but generally one of those was wrong and had to fall, and I think that's particularly true where you've got in vitro data supporting an obviousness rejection but in vitro data fails to support enablement and utility.

Many people also have spoken on the need for more legal education. I would strongly agree. And as I understand it, Howard Shane's legal precedent course has not been taught since the time when I was back at the Patent Office which is now over two years ago. I know myself and many other examiners considered Howard Shane's legal precedent class to be invaluable, and I would just strongly recommend that he or other superiors in Group 1800 again take up teaching a legal precedent course within Group 1800.

My last comment is that I understand there's been consideration of other time for interviews between applicants and examiners, to give the examiners other time for the interviews. I hope that goes through. I think many people have spoken today about how much interviews help facilitate dialogue, and certainly cuts down on the pendency of applications, which I know is of real concern to the Patent Office.

I thank you very much for the opportunity to testify.

COMMISSIONER LEHMAN: Thank you very much. You know, I just would make the point that we are, indeed, considering giving examiners additional time for interviewing, but, in addition to the $30 million Congress has taken out of our pocket, basically out of your pocket, we also have restrictions that are being imposed upon us from above by -- regarding the number of people that we can hire at the Patent and Trademark Office even if we have the business to do and even though we have the money to pay them, and this makes it extremely difficult to give examiners some of this time. We'll probably do it anyway but we can only stretch so far, and I think it's incumbent upon our constituents to follow these things

carefully; to let Congress know; to let the Office of Management and Budget know, and so on, because, otherwise, we can't provide you with the kind of service that we would like to.

These hearings are two-way streets. They give us a chance to tell you what's going on and hear what you're thinking.

It looks to me like Mr. Sobol has arrived, and so why don't you come forward -- from the San Diego Cancer Center.

ROBERT SOBOL, M.D., SAN DIEGO CANCER CENTER

DOCTOR SOBOL: I'm a physician and have never been on time to anything in my life and today I thought for sure I was going to break that, but here I am late. I apologize.

COMMISSIONER LEHMAN: I want you to know that, you know, in the Bill Clinton Administration that we're over Clinton time now. We're a half hour early, we're not a half hour late.

DOCTOR SOBOL: Oh, I see. I won't feel so badly then.

My name is Robert Sobol. I'm a medical oncologist and a clinical investigator at the San Diego Regional Cancer Center where I serve as the Director of Clinical Science. I appreciate having the opportunity to testify before you today concerning the use of animal models to obtain patent approvals. I provide the perspective of a current patent applicant from an academic non-profit research institution.

In the past, animal data was sufficient to obtain patent approvals. The patent approval process, based upon animal efficacy data, resulted in expenses for research and patent prosecution costs that were within the means of most non-profit research institutions. These issued patents protected the intellectual property of investigators at non- profit institutions which have very strained overall budgets.

In addition, these approvals fostered the clinical development of novel therapies by providing the private sector with the confidence to make the considerable capital investments required to obtain FDA marketing approvals. This process based on patent approvals from animal data has been responsible for the rapid growth and preeminence of the biotechnology industry in the United States.

I would like to share with you from our own experience how the development of novel treatments may be threatened by the recent unwillingness of patent examiners to accept animal data as sufficient for patent approval. We had demonstrated in an animal tumor model the effectiveness of a novel approach for the treatment of cancer; however,

the statistically significant data was rejected by the patent examiner who requested evidence in human subjects that the therapy would be efficacious. The animal data rejected by the examiner was, however, deemed satisfactory to justify clinical application of the approach in human subjects by federal review boards containing scientists and physicians skilled in the art of our developed therapy.

The further development of this particular technology is threatened by the patent examiner's request for human data. This would entail significant expenditures requiring hundreds of thousands or possibly millions of dollars, depending on the manufacturing requirements to generate the clinical grade materials required for human study. These costs are well beyond the means of most non- profit research institutions and the private sector support to develop this technology would be enhanced by an approved patent.

An alternative is to appeal the patent examiner's ruling. However, this process is also formidable as appeals may take several years of litigation with resulting legal expenses beyond the means of many academic institutions which are becoming increasingly strained financially.

We are frustrated by the apparent requirement to expend significant amounts of capital and time to protect our intellectual property if human clinical data is required for approvals. The trend in current policy to demand human data will discourage patent filings from our non-profit academic institutions where many novel technologies originate.

It would be detrimental to the progress of medical research in our country if academic research institutions can no longer afford the costs of obtaining issued patents. Animal models are predictive of effects in humans and the results of these studies should remain sufficient for patent approvals as they are for the clinical application of novel therapies in human subjects. Thank you.

COMMISSIONER LEHMAN: Is there any circumstance under which you think human testing should be required for proof of utility? Can you imagine any?

DOCTOR SOBOL: Well, I think to those skilled in various elements of medical research where certain animal models would be known not to be predictive of what would happen in humans, that under those circumstances evaluation of humans would be required.

COMMISSIONER LEHMAN: I think that's probably exactly what's happened in some cases. We've probably had those kinds of situations and that's what causes --

MR. RICHMAN: That's exactly correct. You have, in essence, competing literature where on one hand someone is saying it is predictive and on the other hand people are saying animal models are not predictive of that disease state, and that's what we have to deal with.

DOCTOR SOBOL: That's always a difficult situation, but I believe that in most circumstances the animal data has been predictive of what does occur in humans and it's on that basis that many clinical trials are approved for humans and therapies are developed for humans. And I think it's perhaps more the exception rather than the rule and that that may be what we need to have guiding the decisions.

COMMISSIONER LEHMAN: Your organization, is it primarily a research organization or is it a treatment organization doing some research?

DOCTOR SOBOL: It's really dedicated to research, translational research, taking the studies that are developed in vitro and in animals and apply them in clinical settings in humans.

COMMISSIONER LEHMAN: And it's not for profit?

DOCTOR SOBOL: It's a non-profit; that's correct. So we really base all of our work on moving things rapidly into clinical trials with humans, and that's all predicated on results that we obtain in in vitro systems and animal models. And that's --

COMMISSIONER LEHMAN: You're of course a user of research as well then and so you would have a sense of -- since you're not really a profit making company -- of the implications possibly of issuing patents that shouldn't be issued, and I assume that you basically don't see much of a problem there?

DOCTOR SOBOL: I think that that's less of a concern than the opposite: Having something not issue and get protected that really requires it to be developed, and I think if one had to err one would prefer to err on the side of making certain that we were able to provide protection for intellectual property, provide the stimulus for development. I think we will harm more people, slow the development of novel treatments for patients that suffer from diseases by being too conservative in what we allow to be patented, and if errors have to be made I think it's better to err on the side of granting and issuing patents.

COMMISSIONER LEHMAN: Have you had any problems with experimental use of other people's patented technology? We heard at least one witness call for the need for a statutory experimental use exception. Is that a problem for you at all?

DOCTOR SOBOL: Not encountered it personally, no.

COMMISSIONER LEHMAN: Thank you very much.

Next I'd like to ask if David Lowin of Syntex is here?
it's perhaps more
DAVID LOWIN, SYNTEX, INC.
MR. LOWIN: Mr. Commissioner, members of the panel, and die-hard members of the audience. It's been about two hours since somebody congratulated you on still being here and listening to us so it's probably time for another counter to that effect. Thank you for staying and listening. It's important.

I'm David Lowin, Assistant Director, Patent Law Department, at Syntex. I also teach patent law at Stanford Law School and at U.C. Berkeley's Bolt Hall. My testimony is offered as a matter of personal opinion, not on behalf of any organization.

Suffice it to say that nine minutes isn't long enough to address the full subject matter of this hearing so I'm also working on a written submission that will hopefully be of a broader scope. My prepared remarks are addressed to the somewhat different approach on the policy behind the utility requirement and the environment in which that policy must be carried out.

The Notice setting this hearing started by reference to the Supreme Court's decision in Brenner v Manson. There the court upheld the rejection of the chemical process patent application for failing to establish a substantial utility. Now, Brenner may not be the greatest decision the Supreme Court's ever handed down and I think a lot of that has to do with the underlying facts, what the application had in it and what was trying to be argued. But I think there are some things within Brenner that can still be applicable today and that can help the Patent Office accomplish what's been requested by the industry here, and that's what I'll turn my attention to.

I think there are two key aspects to the majority's conclusion in Brenner v Manson. First, the majority concluded a patent is not a hunting license; it is not a reward for the search but compensation for its successful conclusion.

Now, whether an invention represents the successful conclusion of the search kind of depends on what it is that you're searching for in the first place. Biotechnology has changed what we're searching for in the first place. It's made it possible for us to understand the complexity of life and to intervene with disease at a level far more precise than was possible when the Supreme Court considered Brenner v Manson.

The successful conclusion in today's search for cellular mechanisms and

ways to modulate them would have probably been considered only an invitation to further experimentation back in 1966, and what we consider to be the successful conclusion today is going to be different 10 years from today. The point is that the legal principles, such as the successful completion of the search, have to be applied in the manner consistent with the progress of technology.

The second key aspect of the Court's decision in Brenner v Manson is the quotation they took from the CCPA decision in application of Rushut. A patent system must be related to the world of commerce rather than to the realm of philosophy. So what's the world of commerce to which the successful conclusion of today's search must relate? It's a different world of commerce than it was in 1966. Just as the patentable subject matter, definition of Section 101, had to expand to cover Chakrabarty's bacteria as part of anything under the sun that is made by man, so now our definition of the world of commerce must expand to cover the state of the art in the commercial impact of today's biotechnology inventions.

When we clone the DNA for a protein that's known to be involved in a disease; when we develop that protein into an assay for screening potential therapeutic drugs; when potential therapeutic drugs are identified as active in that model, and when those drugs are tested in clinical trials, all of these efforts involve hundreds of scientists, thousands of other people performing related tasks in hospitals, in banks, in shipping companies, in equipment manufacturers, in accounting firms, and even in the United States Patent and Trademark Office. Every step along the way entails enormous investment. The successful conclusion of each of these searches triggers even more investment. Ultimately, hundreds of millions of dollars change hands during the development of a single drug, and that's commerce. That's commerce at a level that the founding fathers couldn't even have imagined.

Today's hearing is taking place because the U.S. Patent and Trademark Office has, seemingly more often than not, refused to allow our applications for patents on the DNA, on the proteins and on the screening models, allegedly because they aren't the successful conclusion of the search and they don't relate to the world of commerce. The patent office has refused to issue patents on the drugs because they haven't been proven safe and effective in statistically powered human clinical trials even though, in this first-to- file world, the patent applications cannot be filed containing such data because they have to be filed years before the clinical trials can be started.

And now, if eventually granted, the terms of these patents will have been expiring since the day they were filed, and the GATT implementing legislation appears to require an applicant to make a choice between an extension for appeals or interferences versus extension under the provisions of Waxman-Hatch. It's under 156(a)(2). This is Waxman-Hatch

says if the patent has previously been extended, it doesn't say under this provision that you can't extend it under this provision. That's something that will just get cleared up after the implementing legislation goes through. But that's something that we're facing today.

COMMISSIONER LEHMAN: I assume you favor a revisitation of the patent term registration legislation to make it more favorable to the --

MR. LOWIN: Yes, I definitely do. Particularly in the context of the new 20-year term that's soon to be.

COMMISSIONER LEHMAN: But you also correctly point out that for all practical purposes most global competitors already live under the 20-year term.

MR. LOWIN: Absolutely. I mean, it's a practical reality of the world we're living in.

COMMISSIONER LEHMAN: So we could fashion an equitable solution by -- because the biotech industry is unique in this regard really. By fashioning -- we already have built in of course to the legislation five-year extension for interferences and appeals, and so on. But we also -- Then we have the existing patent term with extension legislation as well, but we could expand on that. That's not violative of any of our GATT obligations, I don't believe, and then we can have hopefully a win/win situation when we get better external access in foreign markets such as Japan. We please other aspects of the patent industry that don't want patent terms going on forever and then we solve your problems at the same time.

MR. LOWIN: That would be just great. Good luck. I will be happy to help with that. We've got some ideas.

If you would put up the first slide. I wanted to put things in perspective on the standard of utility. On the mechanical side, the Patent Office is regularly granting inventions on anything up to and including the kitchen sink, and witness U.S. Patent 53494708 issued September 27th for the foldable kitchen sink.

Next slide, please. Not to mention also issued on the same day the patent on the nail file protector device.

Next slide, please, and the last of these that I'll take your time with. The air cooled umbrella.

COMMISSIONER LEHMAN: I thought you were going to do the paper clip.

MR. LOWIN: No, that one's good.

COMMISSIONER LEHMAN: I still don't understand that one, I must say.

MR. LOWIN: Depends on when it was issued. I'm sure all three of these inventions were worthy of patent protection, but I'm also that even combined these inventions covered by these three patents are not going to effect the world of commerce to the same degree as even one of the legally useless biotech inventions we've been talking about today.

I think the office needs to apply the utility requirement consistent with the current commercial and scientific standards. The utility standards should resolve doubts in favor of the patent applicant, and when an applicant pleads for allowance of its application because its competitors are already practicing the claimed invention, it doesn't make sense to reject the application as lacking utility. We've got room in this area of the law for the principle, "no harm, no foul." The courts are not being clogged and the progress of science in the useful arts is not being blocked by patents covering technology that just doesn't work.

Very briefly. I know I'm out of time. I thought a great suggestion was made earlier and that was establishing a group within the office that occasionally picks up an application and looks at it from the standpoint of the applicant and says: Gee, how would I feel about this? That would be a great balance to the other group that you have.

COMMISSIONER LEHMAN: What would your view be about the suggestion about giving greater weight to declarations to substitute for clinical data?

MR. LOWIN: I think that's fine. I think the procedures already provide for that. If there has been a declaration, then there needs to be some evidence, under oath, to counterbalance it. And when there isn't counterbalancing evidence then the declaration has to have the weight.

COMMISSIONER LEHMAN: Thank you very much.

MR. LOWIN: Thank you.

COMMISSIONER LEHMAN: Sarah Adriano of Merchant and Gould will not be here this evening so that moves us up a little bit further. We're going to probably end up finishing -- looks to me like we'll finish probably about 50 minutes, 45 minutes ahead of time.

Is Jeffrey Sheldon from Sheldon and Mak here?

JEFFREY SHELDON, SHELDON and MAK

MR. SHELDON: Honorable Commissioner, thank you for the opportunity to address you and your colleagues, and my colleagues that are still in the

audience.

I am the founding partner of Sheldon Mak. We're an intellectual property law firm with offices in Pasadena, California; Palo Alto, and San Bernardino. We have a diverse biotechnology practice representing individual inventors; the University of California; non-profit organizations; and some Fortune 500 companies. I'm here on behalf of the firm and myself. I'm also president of the Los Angeles Intellectual Property Law Association, and past chairman of the State Bar of California Intellectual Property Section. I teach advanced patent at Loyola University, but I'm not here on behalf of any of those organizations, just to add some import to the weight of my comments.

Initially I was only going to talk on the 20-hear term; however, you've asked some questions which I'd like to address on two other issues. One is the utility requirement asking should the Patent Office err in favor of issuing patents or continue its present system of insisting on some utility. I believe strongly it should err on issuing patents. If, for some reason, a mistake is made that the patent invention in fact has not utility, who cares? Simple as that. If it doesn't work nobody is going to infringe. The few reported cases, and I think one is at the Court of Appeals -- I use it in my patent law course but I don't remember the cite -- where somebody challenged the patent on utility grounds but when shown to have infringed the patent the court disposed of that automatically. It said: "How can you at the same time infringe the patent and claim it has no utility?" So go ahead and issue all the useless patents you want. David Lowin just showed you three of them. Who cares? So if you're going to err, err on the side of getting these patents out there so that if they do have utility people can invest.

The other point, and, again, I didn't --

COMMISSIONER LEHMAN: One of the concerns, though, is that, you know, foldable kitchen sink or whatever, is an area where somebody can have something very similar. It's a crowded field of technology, and one of the problems of biotechnology is that it isn't, particularly where you are focusing on the more breakthrough inventions. It's not necessarily a crowded field and obviously the concern is that you will place roadblocks to alternative developments because of the power of the patent grant if you issue indiscriminately certain patents. We certainly are hearing here that there doesn't seem to be much of a concern about that here, at least the industry doesn't seem to share that concern.

MR. SHELDON: Again, the marketplace will take care of that. If, in fact, it is a roadblock it must have some utility and generally it's some sort of license negotiation will develop. I -- In my practice, I've not seen a roadblock of a patent who should not have issued because of utility.

COMMISSIONER LEHMAN: Well, of course, you know, if it's a valid patent it's a valid patent and I think the concern is that we would issue invalid patents and also they would be a roadblock to other people and other people's inventions.

MR. SHELDON: In my practice, the roadblocks I've seen are invalidity on 102 and 103 grounds and not utility grounds, and that has been a problem but that's not what you're here to listen to.

I didn't plan on addressing the inconsistency of the Patent Office between enablement and obviousness; however, I happen to have in my briefcase to review in breaks an amendment written by one of my associates on a simple technology, its capillary zone electrophoresis. The patent application discloses six, seven applications for it. It has specific examples. On one of them we have two rejections: One rejection is we're entitled to only the one claim where we disclose how to use this invention for uric acid analysis.

By the same token, I have a 103 rejection. The Patent Office says: "The selection of appropriate anilities, enzymes, coenzyme, and wavelength is conventional and within the skill of the art to which the invention pertains." An obvious inconsistent position, so I can't get anymore current than that since we're responding to the amendment.

I'm not going to take up the suggestion of going over the examiner's head because whenever that happens the next time I have the same examiner life gets very difficult, and it would just be as if somebody went over my head or one of my subordinates' heads in the office. It's politically not a good idea.

Now, let me get to the main points I wanted to deal with was the 20-year term. The 20-year term -- and I have some solutions to the problem. The 20-year term creates problems in view of the Patent Office's position on utility because if I've got to prove the utility by clinical data it's going to take me ten years at best and I'm left with ten years at best, and it also provides problems with the restriction requirement. The current system in the Patent Office strongly encourages examiners to give restriction requirements. It's my understanding there's a quote system, there's a bonus system based on dispositions. If you can examine one application and do all the hard work and do the search and then you can give a restriction requirement and get eight divisionals, you're going to look awfully good when it comes bonus time. So the current system in the Patent Office is encouraging restriction requirements. An example -- and I have a book how to write patent applications, and we talk about in the book how to claim a new protein isolated and purified from natural sources. There's 15 different ways to claim that at least, and the Patent Office in many cases will give you 15 restriction requirements,

but it's really only one basic invention.

The one suggestion I have is, if we are going to have a 20-year term, I think the legislation that's pending that says the longer of 20 years or 17 years from date of issuance should be what goes through. I believe that would comply with all requirements that the Patent Office currently has, so that is one possible solution to a lot of the issues raised on the 20-year term.

COMMISSIONER LEHMAN: When we had a hearing like this in Silicon Valley earlier this year we heard lots of complaints that were just the exact opposite, they were that we should have shorter patent term, not longer patent term. We really have this sort of dichotomy between the two California interest groups; biotechnology and computer software. So how would you respond to that?

MR. SHELDON: Well, if I were probably up there representing my computer software clients and they have a different view -- but I think a longer term overall is best, particularly for the biotechnology. And I have not seen a problem in the fast advancing arts in the computer --

COMMISSIONER LEHMAN: The problem basically, as I gather -- I mean, the problem really boils down to not that a 17-year or 20-year term is inherently inadequate. The problem has to do with the unique relationship of biotechnology to both the regulatory review process and the exceptionally long development period from the invention -- from inception of the invention to, you know, practical application. That's really the problem here; isn't it?

MR. SHELDON: Well, let me suggest other alternatives. A second alternative is if you're -- the Patent Office -- is requiring utility by human testing then built into the statute, much as we have a patent extension term for FDA regulatory delay, a delay in meeting the utility requirement of the Patent Office. Consider as a third alternative a new reissue proceeding where I issue my patent where I claim utility in rabbits, if I can later on show that I have utility in humans get me a reissue patent on that. And it will be a broader claim so it would take a new reissue statute. It's a creative approach. Consider that. Definitely we need less strict application of the restriction requirement and what will go a long way for that is reducing the examiners' incentive for restriction requirements. Either give them no credit for divisionals or less credit for a divisional than they get for original application.

Another way would be to allow -- like in the Trademark Office we can examine in a single application all the so-called separate inventions by paying an extra fee, if necessary, and give the examiner a little bit of extra credit for that. And when the patent actually issues, if we're going to enforce the interpretation of the patent statutes that you only

get one patent per invention and one invention per patent, then require divisionals. Divide it out at that time, at least it will reduce the cost. I don't have to prosecute nine applications and get nine different office actions. I can do everything at one time. I think that will be to the benefit of the Patent Office.

My time is up and I thank you for listening to my remarks.

COMMISSIONER LEHMAN: Thank you, sir. Very interesting suggestion, the one you just made.

Just to give you an example of the problem from some other end that we're getting a few. Tune into the Internet, you'll find on it the following: For those of you who are fans of Jerome Lemuelson, here's yet another of his submarine patents that issued with a continuation division chain back to 1954. For those of you who hate submarine patents your fears of lawsuits will be well fed by the claims to this patent which are infringed by most U.S. industries so, you know, that's the kind of thing that we're hearing loud and clear complaints about in terms, and the 20-year term from filing has attempted to address that kind of concern. But that doesn't mean that there aren't very real concerns of biotech industry and we will do what we can to try to address those.

MR. SHELDON: If I may, the suggestion that all the divisionals are prosecuted at the same time with dividing them out right before issuance would address the submarine patent concern and still meet the objections of the 20-year term.

COMMISSIONER LEHMAN: Thank you very much.

We're getting down near the end. Is Ted Green of Amylin Pharmaceuticals here?

TED GREEN, AMYLIN PHARMACEUTICALS

MR. GREEN: You're actually running a little ahead of schedule according to my chart.

COMMISSIONER LEHMAN: Yes, we are. We had a couple of people that canceled that's why. We had three cancellations and we're just about that far ahead of schedule.

MR. GREEN: All right. Well, my name is actually Howard Edward Green, Junior, and people know me by the nickname Ted. I am chairman and chief executive officer of Amylin Pharmaceuticals, Incorporated, a seven-year old biotech company working to develop novel medicines for treating diabetes. Before becoming a full-time employee of Amylin, I was a venture capitalist and helped start six medical technology companies;

five of which have gone public. Earlier I was chief executive of Hybritech, Incorporated, which was acquired by Eli Lilly in 1986.

I am a named inventor on two patents, both of which have broad method of use claims. The first patent covers Hybritech's product technology for two-site monoclonal antibody assays and is I think considered somewhat of a landmark among biotech patents.

The second patent covers one of Amylin's technologies for treating diabetes and is the focus of a major development program in collaboration with Glaxo, Britain's largest pharmaceutical company.

I'm speaking today on behalf of myself and other inventors in the pharmaceutical field who have made discoveries with broad medical potential. My message is this: We need broad method of use claims in order to raise the investment capital needed to develop our products. Moreover, these method of use claims should not be held to a higher standard of clinical utility than have the composition claims traditionally pursued by drug companies.

Recent pharmaceutical history shows why broad use claims are so important. Two pioneering inventions stand out. The first is the discovery of H2 antagonists for treating stomach ulcers, and the second is the discovery of ace inhibitors for lowering blood pressure. The companies that pioneered these products have now been merged out of existence. Why? Well, partly because they did not have broad enough patent coverage. Within a few years of the first H2 antagonist, that was Tagamet from SmithKline, and the first ace inhibitor, Capatin from Squibb, competitors Glaxo and Merck launched "me too" medicines that treat the same diseases by the same mechanisms of action. In my opinion, SmithKline and Squibb were unable to reap the full rewards of their inventions because they did not have the right patent coverage. SmithKline and Squibb probably would be independent companies today if they had been issued broad methods of use claims for H2 antagonists and ace inhibitors.

Now we read in the newspapers about drug firms buying distribution companies rather than investing in pharmaceutical research. In effect, the industry and Wall Street are now questioning the value of research expenditures which run to hundreds to millions of dollars for pioneering medicines. Why? Because competition from "me too" products within therapeutic classes is killing the investment returns from pioneering products because traditional pharmaceutical patents protection has been narrowly focused on composition claims, because the most important inventions, the sites of drug action, have not been claimed in patents.

We all know that recent discoveries in biology combined with modern pharmaceutical technologies are replacing random screening and blind luck

in the development of new medicines. The disclosure of a novel site of action, such as the H2 receiptor or the ace enzyme now teaches competitors how to make their own drug. Just ask any competent medicinal chemist. Without patent claims to protect these important discoveries inventors and entrepreneurs will not receive the protection to which they are entitled and they will have difficulty attracting sufficient risk capital to carry their inventions all the way to market.

I also wish to state it is very important to receive patent protection quickly for these discoveries rather than after years of negotiating with the PTO.

First, potential equity investors want to know that they will be protected and ongoing rejections from the PTO make investors very nervous, to say the least. I remember when our patent counsel calmly announced that we had received a, quote, "final rejection," for one of our applications, which engendered raw panic in our management ranks. We have since gotten that patent issued.

Second, the big drug companies often don't pay much attention to patent applications preferring to wait to see what will actually issue. Consequently, it's harder to do deals with just patent applications.

Third, the lack of issued claims means the potential competition can't define the boundaries clearly. A situation which may encourage considerable economic waste.

At my company Amylin, we are pioneering new concepts for explaining why diabetes happens and why the disease is so difficult to treat. So far we have dedicated seven years to this effort, recruited over 150 highly skilled employees, and raised over $130 million in capital. I believe we have spent more money on diabetes research than either the American Diabetes Association or the Juvenile Diabetes Foundation have since their inceptions.

For our key products we have received U.S. patents with broad methods of use claims and these claims have played an important role in attracting both investor and corporate partner support. In short, without patent protection there would be no Amylin Pharmaceuticals in San Diego.

Our patent laws have played a central role in making America the world's technological leader in general and in biotechnology. Our patent laws have encouraged innovation and risk taking that is the envy of the world. Our patent laws have helped make pharmaceuticals one of America's strongest industries and have encouraged the birth of our biotech industry. It would be a tragedy to strangle pharmaceutical innovation by denying the breadth of patent coverage for methods of use to which our scientific pioneers are entitled. Thank you.

COMMISSIONER LEHMAN: Thank you very much for your pioneering work that you've done and for your statement.

We're down to the bitter end now and we're going to hear I believe from a witness who's already testified before. Came all the way from Wisconsin so he's still here. If it wasn't for the fact that he's from Madison, which is my hometown, I'd say, you know, we're done, but I can't possibly say that now.

WILLIAM J. SCANLON, WISCONSIN BIOTECHNOLOGY ASSOCIATION

MR. SCANLON: Thank you very much for letting me testify again. I appreciate it very much and so does the party that I'm testifying for here. As indicated in my earlier testimony, my name is William Scanlon and I am a partner with the firm of Foley and Lardner in it's Madison, Wisconsin, office, and other biographical details you can obtain from the earlier testimony. I do have a written statement which I'll give to Mr. Kushin at the end, along with a floppy disk with everything on it.

I'm testifying today on behalf of the Wisconsin Biotechnology Association. This association h as over 70- member organizations which are involved with biotechnology and are either based in Wisconsin or have operations there. Membership has tripled since 1992 and continues to grow rapidly. Testimony has been presented earlier today by representatives of several members of the association, including Mycogen, Pioneer Hi-Bred, Hoffman-La Roche, Ernst and Young, Merchant and Gould, and my own firm Foley and Lardner.

We are h ere today simply to make of record our concern over the patent system of the United States, our concern that it function effectively with respect to biotechnological inventions. I won't take time here to detail these concerns. We will submit a lengthily written statement in accordance with the Notice, the Commissioner's Notice.

Biotechnology is a major industry in our state. Businesses, universities and non-profit research organizations in Wisconsin are heavily involved in biotechnology research and development and diagnosis and treatment of human disease, dairying and agriculture generally, forestry and papermaking, environmental remediation, brewing and food processing, specialty chemical production and other areas. The Commissioner, who we note is a son of Wisconsin, is surely familiar with many of these activities.

These activities are greatly affected by how well the patent system as it relates to biotechnology functions. Our concern that the patent system function effectively involves several issues relating to the Patent Office's handling under present law of patent applications on

biotechnological inventions. Some of these issues are raised in the Commissioner's Notice of this hearing.

Our concern also involves effects that changes in the law pursuant to the GATT, or otherwise, as indicated in the Notice, or failure to enact such changes in the law might have on the patent system generally both in and outside the Patent Office as the system relates to biotechnology.

An effective patent system provides important incentives for the major investment required for advances in biotechnology and commercialization of biotechnological products and processes.

An effective patent system provides legal and economic bases for strategic alliances among business organizations or between such organizations and academic or governmental institutions, and these alliances spur progress in biotechnology and are often essential for commercialization of products and processes of the science.

An effective patent system provides legal and economic bases for economic development, that is for the creation of businesses to develop biotechnological inventions made in academic or governmental laboratories.

To function effectively for biological inventions, the patent system must -- like it must for all technologies -- reward with a grant of exclusive rights of appropriate breadth for a reasonable time discoveries in all fields relevant to biotechnology including, of course, plants and animals.

To function effectively, the patent system must function efficiently in granting such rights promptly and at a reasonable cost when such a grant is warranted, and we are concerned on both counts.

We understand that the Commissioner's responsibilities extend to all of the great range of technologies of concern to the Patent and Trademark Office and we thank him for the special concern for biotechnology he has demonstrated in holding this hearing today and, indeed, in sitting through the entire hearing.

We believe it would be appropriate for the Commissioner to hold another hearing, perhaps in six months or so, to determine how much progress will have been made in implementing the various changes in the law and Patent Office procedures recommended in today's proceedings.

And finally we recommend that this next hearing be held in Wisconsin. A beautiful place. A wonderful place, especially in the spring. But also a hot bed of biotechnology and at the center of major biological activity throughout the midwest.

Thank you very much.

COMMISSIONER LEHMAN: Thank you very much, Mr. Scanlon.

MR. SCANLON: Do you have any questions?

COMMISSIONER LEHMAN: I think not. And it's unusual that we would have this many people staying over that have such an interest in this hearing so I want to thank you all for sitting with us here and keeping us company all day long.

That concludes our hearing and we will be announcing I'm sure, in the not too distant future, a number of policy initiatives will flow out of this.

(Whereupon, at 6:41 p.m., the above-entitled matter was concluded.)

REMARKS SUBMITTED FOR THE RECORD

TESTIMONY PRESENTED BEFORE

PATENT AND TRADEMARK OFFICE HEARINGS OF BIOTECHNOLOGY INVENTIONS

San Diego, CA

October 17, 1994

Stanley T. Crooke, M.D., Ph.D.

Chairman and Chief Executive Officer

Isis Pharmaceuticals

Good afternoon. I am Stan Crooke. I am the founder and Chief Executive Officer of Isis Pharmaceuticals, a development stage, technology-based pharmaceutical company. Prior to founding Isis, I was President of Research and Development for SmithKline Beckman and, before that, a Vice President at Bristol Myers. I am a physician and scientist. In my career, I have been involved in the development of more than 15 drugs

that are currently marketed and numerous other drugs in development and have published more than 300 scientific papers and 16 books on pharmacology, drug discovery and development.

I believe that we can all agree that it is in the public interest to encourage innovation in the pharmaceutical industry by prompt issuance of patents of appropriate scope. We can also agree that public policy, or institutional behavior that discourages pharmaceutical innovation, is not in the public interest and will likely reduce the international competitiveness of one of America's most important industries.

Where we may diverge - and where I think we need to work together to find common ground is the topic I want to discuss today: What data are sufficient to support claims of potential therapeutic utility? Although there is no universal or absolutely right answer to this question, I believe that there are precedents that have stood the test of time that can provide guidance and can serve as a basis for reaching agreement.

The evaluation of the potential utility of an innovation in the pharmaceutical industry is especially complex. On average, more than 15 years elapse between discovery of a new drug and its marketing. Even after marketing, we may gain additional information that indicates that the product does not have sufficient therapeutic utility to remain available to the public. Furthermore, prior to marketing, on average more than $350 million must be invested. It would be impossible for a company to make this kind of investment without reasonable expectations with regard to patentability, particularly in light of the risk of investments in this area. We know that, historically, less than 1 in 1000 of the compounds synthesized and patented by the pharmaceutical industry become products.

Many factors contribute to the risk and uncertainty in drug discovery and development, but there is one that I particularly want to emphasize today: the only way to determine the value of a new pharmaceutical technological innovation is to evaluate the fruits of that innovation, i.e. the drugs that are based on that innovation, in man.

As an example, let's consider the history of the treatment of ulcer disease. It has been known for many decades that ulcer disease is correlated with stomach acid secretion and a large number of physiological processes that influence acid secretion were identified. Early on, the cholinergic arm of the autonomic nervous system was shown to increase acid secretion, so it was hypothesized that anticholinergic drugs would have therapeutic utility in this disease. Literally thousands of compounds of this type were synthesized, tested and patented. A few were even marketed, but the side effects of these drugs were very limiting, so the true therapeutic utility of anticholinergic drugs for ulcer disease was modest at best. Research continued and other

involved factors, including histamine, that increase acid secretion were identified. This led to the notion that a blockade of a specific receptor for histamine, the H2 receptor might be of therapeutic value. This concept was hotly debated, but research continued. The first H2 antagonist to enter clinical trials, Metiamide, failed, but the next, Tagamet, worked and revolutionized ulcer treatment. Then came the hypothesis that the inhibition of an enzyme, H/K ATPase, might be beneficial as the enzyme was thought to result in the secretion of acid. Again, this was highly controversial. Many compounds were synthesized and patented and most failed. Omeprazole ultimately was marketed and has improved ulcer treatment.

The points that I want to make by reciting this well-known history are several and they are important. First, new concepts and approaches (technologies) that might result in therapeutic innovations arise constantly. Second, only after a drug of a particular mechanism has been shown to work in the clinic have these new concepts (technologies) been validated. Third, it is a normal part of this process that some members of a particular class of drugs fail and yet the basic concepts that supported the creation of these broad innovations have proven to be valid. Fourth, innovations are controversial and the controversies are not resolved till drugs based on this innovation are thoroughly tested. Fifth, despite these complexities, the traditional practices of the U.S. Patent and Trademark Organization resulted in effective stimulation of innovation and enormous public benefit.

Those traditional practices were to allow claims of reasonable scope long before definitive proof of utility was obtained. This was done by accepting reasonable evidence for potential utility and by maintenance of an attitude that was biased toward rewarding and encouraging innovation by giving the benefit of the doubt to new concepts.

Very recently, with regard in particular to patents in "biotechnology", we feel there has been a substantial change in the practices of the U.S. Patent and Trademark Office. Demands for definitive proof of therapeutic utility (which I remind you can truly only come after a drug has been marketed for 2-3 years to assure that it is safe with broad use) have resulted in many patent application rejections.

Now, let's look at the potential impact of this change in the patent environment. In other words, what will happen if the Patent and Trademark Office were to continue to require definitive proof of utility before granting therapeutic use claims? What will happen is simple: new drug innovation will be dramatically impeded.

So the risks of continuing this practice are very large, while the risks of relaxing the policy are really quite negligible. The drug discovery, development and commercialization processes have built-in self-regulating

mechanisms that ensure that drugs that should fail, do. What harm is done if a patent with appropriate claims is granted to a drug candidate and the drug or the technological concept behind it fails? The company loses its investment, but that's the risk it takes. Nothing has been lost by society. In fact, the public actually gains from the exploration of the concept or the technology. On the other hand, if companies stop investing in new compounds derived from novel concepts or technologies because of patent uncertainty, everyone loses. The loss cannot be made up.

So what am I recommending?

¥ Return to traditional practices with regard to pharmaceutical patents.
They work.

¥ Return to a positive bias to innovation with the acceptance of reasonable proof of potential utility.

¥ Treat patents from so-called biotechnology companies and pharmaceutical companies equally. We are the same industry with the same customers, practicing similar science. The traditional approaches are sufficient to stimulate investment in innovation in both sectors of the drug discovery and development-based industry.

¥ Emphasize consistency across and within technological areas. Just because one approach is labeled a "new technology" and another is not, does not mean that the basic approaches or risks are necessarily different.

¥ When in doubt, grant therapeutic claims based on the specific examples
provided with scope commensurate with reasonable extrapolation from the examples provided.

¥ Finally, be even more prudent in the allowance of broad "concept" patents. Allowance of reasonable claims based on the examples provided in the application is sufficient to stimulate innovation. Granting of broad "concept" patents is very rarely justified in the pharmaceutical industry.

Again, let me thank you for this opportunity. I believe this issue is of critical importance to the viability of innovation in health care, and I am confident that as you consider this issue, you will agree that it is in the public interest to continue to encourage innovation, not destroy it.

I'll be glad to respond to any questions you may have.

TESTIMONY PRESENTED BEFORE

PATENT AND TRADEMARK OFFICE HEARINGS

OF BIOTECHNOLOGY INVENTIONS

San Diego, CA

October 17, 1994

B. Lynne Parshall

Senior Vice President

Isis Pharmaceuticals, Inc.

Commissioner Lehman and other members of this hearing board, good afternoon. My name is Lynne Parshall. I am Senior Vice President of Isis Pharmaceuticals. Dr. Crooke from our Company spoke with you earlier. Among my responsibilities at Isis is to supervise our patent prosecution.

I very much appreciate the opportunity to talk with you today. I plan to focus on one item in connection with our patent prosecution that has affected Isis significantly: rejections we have received based on "incredible utility."

As a development stage, research-based pharmaceutical company, for many years Isis' most significant tangible asset will be our patent estate. We have invested heavily in this area.

Our major focus at Isis has been on the development of antisense technology and the commercialization of drugs based on this technology. We are the leading company in our area and have invested more than $100 million in this technology during the past five years. Many major pharmaceutical companies and other development stage companies also have antisense programs. In many respects, antisense technology epitomizes some of the special challenges that the patent office faces. It also epitomizes some of the potential harm that can be done by inconsistent activities with regard to the evaluation of patent applications.

Antisense technology is a true innovation in drug discovery and development. It is broadly applicable among therapeutic areas. It is a technology that has extraordinary promise and importance. It is a technology that needs and deserves the protection of our patent system.

Antisense technology focuses on a new target for drug discovery, RNA, and uses a new class of chemicals, modified oligonucleotides, to approach this target. At Isis we have simultaneously invented a new medicinal chemistry and the basic pharmacological framework to apply this technology. Even for practitioners, remaining abreast of this technology is difficult. In this way, the antisense field is no different than any other important field in which rapid innovation is occurring. What is different however, appears to be how the patent office analyzes the growing body of literature concerning antisense technology. In reviewing this literature, as you would expect, you will find work of varied quality (good and bad) and expressing a variety of approaches to and views of the field. In addition, you will find work which, due to the rapid pace of innovation, is no longer state-of-the-art. It is the selective use of this literature by the PTO to doubt rather than to support innovations in antisense that hinders our patent prosecution and provides an obstacle to patenting innovations in the field.

Not surprisingly, in the beginning there were more questions than answers about the potential for antisense compounds to be drugs. Today, most of the questions have been answered and the overwhelming wealth of current evidence supports the contention that antisense technology will yield important therapeutic advances. This evidence includes efficacy data from many animal models of disease, from many different laboratories and it also includes clinical data on two antisense drugs that Isis has studied in humans. Despite this wealth of data, we are continually facing rejections based upon "utility" for our compositions of matter and therapeutic use patents. In the last year we have received office action rejections in approximately 70 applications that included some sort of "incredible utility" or "lack of utility" rejection. Responses to these office actions has cost us hundreds of thousands of dollars in legal fees.

Patent applications have been rejected for compounds for which we have shown significant inhibition of viral replication in well recognized models (including models used by government agencies for therapeutic screening) when more traditional chemicals showing activity in these models have been patented. Patent applications have been rejected for compounds for which we have shown significant activity in animal models of disease, when more traditional chemicals showing such activity have received patents. Even patent applications for compounds for which we have shown evidence of activity in humans have been rejected.

For example, one of our pending patent applications claims compositions

of matter to certain phosphorothioate oligonucleotides used to treat a debilitating viral infection. Today, patients are being treated with one of these phosphorothioate oligonucleotide to halt the spread of this disease. In the latest office action we received for this application, the examiner has maintained a previous 101 rejection for lack of patentable utility. This rejection has been maintained in the face of declarations from two experts in support of this application. One of these declarations was from a clinician treating patients with this drug in our ongoing clinical trial. This declaration detailed the positive activity of the drug in patients. The other declaration came from a well-respected scientist who reviewed the current state of the antisense field. These declarations from well-known, well-respected clinicians and scientists were dismissed.

We face similar patent office rejections in basic chemistry cases. Just a few days ago, we received an office action on a process patent application. The invention claimed in the application is an improved process for preparing phosphorothioate oligonucleotides. In the office action the Examiner rejected all of the claims as lacking patentable utility. The Examiner stated (quote) "... the antisense activity of the instantly claimed compounds borders on the incredible and such an asserted utility is deemed unlikely to be correct in view of contemporary knowledge in the art." (end of quote)

It is difficult to understand the Examiner's position. The recent scientific literature does not indicate that the activity of phosphorothioate oligonucleotides is "incredible and... deemed unlikely to be correct." Ongoing clinical trials of these compounds do not indicate that the activity of phosphorothioate oligonucleotides is "incredible and... deemed unlikely to be correct." The declarations we have submitted from well-respected clinicians and scientists do not indicate that the activity of phosphorothioate oligonucleotides is "incredible and... deemed unlikely to be correct."

I am not suggesting that drug discovery is not fraught with uncertainty or that the road from drug discovery to commercialization is not long. What I do urge you to see is that antisense compounds merely represent yet another example of a new area of innovation, similar to those that have been encountered numerous times in pharmaceutical patenting: new classes of chemicals designed to intervene in disease processes in a new way. Support of this type of innovation in the pharmaceutical industry by granting patent protection of reasonable scope has been and continues to be necessary to stimulate continuing innovation.

With regard to patents in "biotechnology", we feel there is a different standard applied than that applied to traditional pharmaceuticals. Demands for definitive proof of therapeutic utility (which the PTO seems to equate with pivotal, controlled human clinical trials), have resulted

in many patent application rejections. As Dr. Crooke said to you earlier today, there is no harm done and, in fact, significant public policy is served, by giving pharmaceutical innovators the benefit-of-the-doubt in terms of patenting.

I would like to reiterate the recommendations Dr. Crooke made to you earlier today. We recommend that the PTO return to traditional practices with regard to pharmaceutical patents. This would include a return to a positive bias toward innovation with the acceptance of reasonable proof of potential utility for inventions. We request that you treat patents from so-called "biotechnology" companies and pharmaceutical companies equivalently; we are the same industry with the same customers, practicing similar science. We request that you act consistently across and within technological areas. Just because one technology is labeled a "new technology" and another is not, does not mean that the basic approaches or risks are necessarily different. We further request that, when in doubt, you grant therapeutic claims based on the specific examples provided with scope commensurate, with reasonable extrapolation, from the examples provided.

Again, let me thank you for this opportunity to speak to you today. I believe this issue is of critical importance to the viability of innovation in health care, and I am confident that as you consider this issue, you will agree that it is in the public interest to continue to encourage innovation in the pharmaceutical industry, not discourage it.

I'll be glad to respond to any questions you have.

Honorable Commissioner and panelists, my name is Michael B. Farber. I am a patent attorney at Merchant & Gould in Los Angeles, specializing in biotechnology. Merchant & Gould is a full-service intellectual property law firm. My clients include Fortune 500 companies in pharmaceuticals and diagnostics, smaller start-ups, universities, and research institutions.

I would like to address three points in particular. The first of these points is that the Patent and Trademark Office seems to see a lack of credibility of the science on which biotechnology is based, leading to an inappropriately high standard for utility under 35 U.S.C. ¤ 101 and enablement under 35 U.S.C. ¤ 112. The second point is inconsistency in issuing rejections under 35 U.S.C. ¤ 101 or ¤ 112 and under 35 U.S.C. ¤ 103, even in the same office action. The third point is more narrow and is what I believe is a misinterpretation of the Amgen v. Chugai and Fiers v. Sugano cases to narrow the scope of enablement under 35 U.S.C. ¤ 112 in certain situations, a narrowing which I believe is contrary to previous case law.

I. LACK OF CREDIBILITY GIVEN TO BIOTECHNOLOGY

Recent actions by the Patent and Trademark Office have suggested that biotechnology is almost placed in the same "weird science" category as cold fusion and perpetual motion. This is a distortion of the basis of biotechnology, which is an outgrowth of the work of the last 40 years in genetics, cell biology, organic chemistry, biochemistry, microbiology, and other disciplines. This seeming lack of credibility given the science has led to an enhanced standard both for utility under 35 U.S.C. ¤ 101 and for enablement under 35 U.S.C. ¤ 112. This is contrary to case law on "incredible utility", such as In re Chilowsky, 229 F.2d 457, 108 U.S.P.Q. 321 (C.C.P.A. 1956). The science on which biotechnology is based is not contrary to recognized physical laws or is of such a nature that it cannot be tested by known scientific principles.

In particular, this reluctance to credit the soundness of the science involved has led Examiners to strain to make rejections under ¤ 101 and the first paragraph of ¤ 112. A frequently used tactic has been to find a research article or review that cites a potential problem with a treatment method, such as the possible existence of a human anti-murine antibody response ("HAMA"), an anti-idiotype response, or concerns about the stability or bioavailability of a reagent such as a monoclonal antibody, and then use this article or review to reject the claims to the reagent or to methods for its use. This rejection is made even though there is no specific basis for believing that the problems set out in the article would apply to the claimed reagent or method; the concerns are general in nature.

Another aspect of this reluctance to credit the science on which biotechnology is based is a seeming requirement for a cure in 100%, or nearly 100%, of the cases when human treatment is contemplated. I had one application, involving a monoclonal antibody for which one of the possible indications was renal cancer, in which a rejection was made because the Examiner considered that the success rate was not likely to be more than 20%. This rejection was made on general concerns of the type discussed above, and there was again no specific basis for asserting that these concerns would limit the success rate to 20% in the use of this particular antibody. However, even accepting the soundness of these assertions, a 20% success rate in a disease now almost completely untreatable and uniformly fatal represents a significant advance in the art. I believe that we must go back to the constitutional mandate of "progress in science and the useful arts," and consider the situation from the standpoint of a well-informed physician who is conversant with recent medical advances, not a quack or a fringe practitioner, but one who is willing to try new advances in an otherwise hopeless case. If such a practitioner would accept a 20% success rate in an otherwise untreatable condition such as renal cancer as an advance in the art, the Patent and Trademark Office should do likewise.

II. INCONSISTENCY

The second point that I would like to raise is inconsistency in issuing rejections under ¤ 101 or ¤ 112 and under 35 U.S.C. ¤ 103. I recently received an office action in an application for a monoclonal antibody directed against a CD antigen (i.e., an immune system antigen) in which a rejection was made under ¤ 101 for lack of utility, and, in the same office action, under ¤ 103 based on the accepted diagnostic utility of a prior art antibody considered analogous by the Patent and Trademark Office. This is inconsistent and illogical. If one of ordinary skill in the art would believe that there was a sufficiently shared utility to provide an incentive to make the modification resulting in the claimed antibody, that same person of ordinary skill in the art would also accept that the claimed antibody would have a similar diagnostic utility. These rejections should not be based on inconsistent reasoning. When the Patent and Trademark Office seeks to make a rejection under ¤ 103, the "person of ordinary skill in the art" seems to a be a genius; when the rejection is sought to be made under ¤ 101 or ¤ 112, that "person of ordinary skill in the art" suddenly turns into an idiot.

III. IMPROPER USE OF AMGEN AND FIERS TO NARROW SCOPE OF ENABLEMENT

The third issue on which I would like to speak is narrower and more technical. It concerns the use by the Patent and Trademark Office of Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 U.S.P.Q. 2d 1016 (Fed. Cir.), cert. denied, 112 S.Ct. 169 (1992), and Fiers v. Sugano, 984 F.2d 1164, 25 U.S.P.Q. 2d 1601 (Fed. Cir. 1993) to narrow the scope of enablement and thus the scope of claims.

This arises particularly in two situations:

(1) An inventor isolates or discovers a protein or peptide and determines its complete amino acid sequence, and now wants to claim nucleic acid sequences encoding the protein, for use as probes or in a recombinant expression system.

(2) An inventor has isolated or discovered a new antigen, such as a protein or a peptide, that occurs in several different forms, as a result of allelic variation or other factors, and wants to claim antibodies (monoclonal or polyclonal) that bind the different forms of the antigen, after actually making one or more antibodies.

In either of these cases, the claims should be allowed absent specific evidence of inoperability or specific reasoning that compels a conclusion that species within the claims are inoperative. In the first case, once the primary amino acid sequence is known, all possible nucleic acid sequences can be determined by the genetic code. Unless there is evidence that certain nucleic acid sequences would be inoperable, e.g.,

as probes or for expression vectors, as a result of peculiar secondary structure, abnormal codon utilization in hosts for the vectors or other factors, the claims should be allowed. In the second case, in the absence of specific evidence that any of the forms of the antigen would be non-immunogenic, the claims to the antibodies should be allowed even if the inventor has not prepared antibodies to all possible antigens.

The Patent and Trademark Office is wrong to reject claims of this type as lacking enablement under the first paragraph of ¤ 112 by analogy to cases such as Amgen v. Chugai and Fiers v. Sugano. These situations are in no way analogous to a claim that seeks to encompass all nucleic acids having a particular function without any structural information. Here, a specific structure or structures are known. The situation in cases such as Amgen v. Chugai and Fiers v. Sugano resembles a "single means claim," a type of claim long proscribed. Here, by contrast, a defined structure or structures are recited, and the inventor is seeking additional protection for molecules produced by generally well-understood processes using the information contained in the original, completely defined, structure.

Therefore, it is improper to reject claims of this sort as "broader than the disclosure" or for "undue breadth" under the first paragraph of 35 U.S.C. ¤ 112. Rejections of this sort, which are sometimes purportedly justified by recitations of the potentially large number of structures encompassed by the claim, are contrary to much Court of Customs and Patent Appeals case law in the organic chemical field, such as In re Angstadt, 537 F.2d 498, 190 U.S.P.Q. 214 (C.C.P.A. 1976). The inventor need not make or test every possible species within the scope of claims in order for enablement to exist under the first paragraph of 35 U.S.C. ¤ 112 under this line of cases. These rejections, therefore, are improper.

## IV. CONCLUSION

In conclusion, I believe that the Patent and Trademark Office must examine biotechnology applications in accordance with the principles that the courts have developed for organic chemical and pharmaceutical inventions, paying due heed to the constitutional mandate. This will resolve many of the problems encountered by applicants in biotechnology at the present time.

October 24, 1994

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Attention: Jeff Kushan, Office of Legislation and International Affairs

RE: Patent and Trademark Office

Notice of Public Hearings and

Request for Comments on Patent

Protection for Biotechnological Inventions

Dear Sir:

My name is Andrew D. Fortney, Ph.D. I am a patent agent for Oblon, Spivak, McClelland, Maier & Neustadt, where I have actively prosecuted patent applications in all areas of chemistry, biotechnology and medical technologies, and to a more limited extent in mechanical and electrical technologies. I am also a student in the fourth year of the evening program at the George Washington University National Law Center. The following remarks, which represent my personal views, are offered in response to the notices in the Federal Register and the Official Gazette. My views have been influenced by numerous discussions with members of Oblon, Spivak, McClelland, Maier & Neustadt, particularly with Dr. Richard Chinn and Mr. Steven Kelber, and with persons (both clients and non-clients) active in the biotechnology industry and in related fields.

RELEVANT POLICY OBJECTIVES OF THE CLINTON ADMINISTRATION, AND HOW THE PTO CAN MORE EFFICIENTLY ADVANCE PRESIDENTIAL POLICIES

President Clinton has advocated at least three policy- related goals affecting the biotechnology industry which the U.S. Patent and Trademark Office (the "PTO") may affect through its actions, including:

(1) Fostering the growth of "high-technology" industries, including biotechnology;

(2) As a part of an overall program to reform health care, reducing the costs of medical care and particularly of pharmaceuticals; and

(3) Minimizing the size and expenses of the Federal bureaucracy, including resolving conflicts between Federal agencies and eliminating or minimizing duplication of effort among Federal agencies.

As an administrative agency, the PTO can have an effect on executive policies by the manner in which it investigates questions of

patentability (e.g., utility, operability and obviousness). However, the analysis of patent applications is necessarily fact-based, and is performed on a case-by-case basis. Thus, it may be difficult or inappropriate to apply general rules of patentability to examination of biotechnological patent applications, such as granting a presumption of inherent utility to all biotechnological inventions. Such a presumption may result in patents being obtained from applications which may not disclose the utility of the invention. This would circumvent the "quid pro quo" of the patent system, full disclosure of the invention, including disclosure of contemplated uses.

In my opinion, the PTO can more effectively accomplish President Clinton's policy objectives by:

(A) Allowing claims with reasonably broad scope;

(B) Permitting Examiners to accept applicants' assertions of utility and operability unless objective evidence questioning such assertions is provided;

(C) Where assertions of pharmaceutical utility are raised, consistently treating claims to compounds separately from claims to pharmaceutical compositions and methods of use; and

(D) Where pharmaceutical utility is relied upon for patentability, adopting a preponderance-of-the-evidence standard for establishing pharmaceutical utility.

Adoption of proposed policies (A)-(D) by the PTO above will result in (i) earlier issuance of patents and (ii) greater patent protection for inventors. The proposed policies will achieve the President's policy goals by more adequately rewarding inventors for the knowledge which they provide, thus encouraging further research and development of biotechnological products and services, in turn fostering the growth of the biotechnology industry.

Earlier issuance of patents and broader patent protection will reduce the costs of prosecuting patent applications, and thus contribute directly to reduced costs for pharmaceuticals and medical services. Earlier issuance of patents will also result in an earlier end to the patent right, thus allowing competition to enter the marketplace at an earlier date, further resulting in lower costs through competition.

Finally, where the PTO has challenged asserted utilities and broad statements of operability in an application, adopting a preponderance-of-the-evidence standard for resolving questions of pharmaceutical utility and of predictability in the art will reduce the amount of evidence which Examiners must review, and thus, the amount of

time spent reviewing such evidence. As a result, the costs of running Group 1800 will be reduced, and duplication of effort between the PTO and other regulatory agencies, such as the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), which must independently analyze data supporting assertions of safety and efficacy, will be minimized. Consequently, potential conflicts between such agencies can also be avoided.

THE BIOTECHNOLOGY INDUSTRY PERCEIVES PTO ACTIONS AS NOT MOST EFFICIENTLY FOSTERING ITS GROWTH

The Public Hearing on Patent and Protection for Biotechnological Inventions held by the PTO in San Diego, California on October 17, 1994 demonstrated the effects of perceived practices by Group 1800 of the PTO on the biotechnology industry. Many industry representatives believe that the PTO requires clinical data in many cases asserting pharmacological utility. Many of those in the industry also perceive Group 1800 as viewing the levels of ordinary skill under 35 U.S.C. 103 and 35 U.S.C. 112 quite differently (and in the opinion of some, almost antithetically). Such practices are viewed by the biotechnology industry as impeding the progress of the industry, and thus, as not advancing President Clinton's policy of encouraging the growth of biotechnology. For example, many representatives of "start-up" biotechnology companies and of non-profit research organizations explained that, due to rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, for lack of utility and lack of enablement, they cannot obtain patent protection unless clinical data are submitted. Typically, the start-up company or non- profit research organization does not have the capital necessary to conduct clinical studies, and must look to larger pharmaceutical companies or venture capital firms for funding. However, unless the patent is granted, they are unable to make business agreements (e.g., licenses) and thus obtain the capital necessary to conduct clinical studies. Thus, the PTO is perceived by the biotechnology industry as pursuing a policy which impedes further growth and development in the industry.

Furthermore, patents which are issued by the PTO are too often restricted in scope to working examples (e.g., to a protein having a particular sequence, to a particular deposited strain of microorganism or cell, etc.). As a result, it becomes fairly easy for competitors to design around the patented invention. In addition, patent owners must rely to a greater degree on enforcement under the Doctrine of Equivalents (as opposed to direct infringement), thus increasing the costs of enforcing a patent. The increased costs of litigation in turn increase the costs of any products or services covered by the patent. Consequently, considering the value of the contributions offered by innovators in biotechnology, the value of the patent is frequently not as

high as it should be to justify the costs of bringing a product to the marketplace.

PROPOSED POLICIES IN GREATER DETAIL:

ALLOWING CLAIMS HAVING REASONABLY BROAD SCOPE

The proposals stated above will achieve the President's policy objectives in a manner both consistent with the law and more to the satisfaction of the biotechnology industry. First, I would like to address the topic of allowing reasonably broad claim scope in biotechnological patent applications. Of the issues detailed in the Official Gazette and Federal Register Notices, the degree of disparity in the levels of ordinary skill under 35 U.S.C. 103 and 35 U.S.C. 112 may be the most important because it affects every application filed in Group 1800. (On the other hand, the perceived requirement for clinical data in applications asserting pharmacological utility affects only those applications asserting pharmacological utility). As described above, allowing claims with reasonably broad claim scope increases the value of the patent. This will directly increase the reward for innovators, thus directly fostering the growth of the industry.

Such a policy on the part of the PTO is consistent with the law and with President Clinton's policy objectives. Reasonably broad claim scope will also provide greater certainty of patent protection with regard to modifications of the disclosed invention. As a consequence, one's patent position will be established to a greater degree of certainty, and one's business position will be more stable. In turn, more reliable business agreements can be made based on the protection provided by the patent. As a result, business agreements can be made at an earlier stage and with less effort, thus lowering the cost of the effort involved and the amount of time needed to develop and market the product. These factors all contribute to (1) a healthy business atmosphere for biotechnology and (2) an overall, long-term lowering of the costs of biotechnological products.

Allowing claims with reasonably broad scope is legally acceptable where the technology is reasonably predictable. As we heard in a number of comments at the hearing, biotechnology is in general, becoming more predictable. An noteworthy example of the level of predictability in biotechnology as it exists today was provided on October 16, 1994, by CBS' 60 MINUTES. A story on the cloning of a particular mutant gene from an Italian family was reported. Many members of this family had life-threatening cholesterol conditions, but showed little or no signs of coronary disease. Doctors identified the gene, and Pharmacia apparently cloned it in a recombinant microorganism. Sufficient quantities of the mutant protein now appear to be available to conduct the studies necessary to bring the protein to the marketplace.

Tests with the mutant protein in rabbits displaying coronary disease conditions (i.e., fatty tissue deposits in arteries) showed a 70% reduction in fatty tissue deposits. Dr. Shah of Cedars-Sinai Medical Center and UCLA explained to the American public that this technology presents a potential cure to coronary disease the like of which has not been seen before. Further, Dr. Shah also explained to the public that the means and the technology for bringing therapies based on the protein (including gene therapy) to the public exists now. In the absence of human clinical data, this assertion is strong evidence of the predictability of the biotechnological arts in bringing useful, effective products to the marketplace once they have been identified and once preliminary test data in an acceptable model indicate a reasonable likelihood of effectiveness.

Furthermore, the leading cases interpreting predictability in the art of biotechnology are based on technology that is generally from 7 to 15 years old. Thus, the state of the law regarding predictability of biotechnology a level of skill considerably lower than that which exists today. In fact, the most recently decided cases indicate that there is some predictability in modifying biotechnological inventions. Thus, where the level of ordinary skill is such that one can make minor modifications to the disclosed invention reasonably predictably and without undue experimentation, one should be entitled to claims having a scope commensurate with (1) that supported by the application and with (2) the level of ordinary skill.

What can the examining corps in Group 1800 do to achieve the President's goals? One low-cost, low-effort option is to accept patent applicants' statements at face value, unless there is a reason to question such statements (and preferably, where such questions are supported by objective evidence). However, as an administrative agency, the PTO may have a reasonable public policy interest in challenging statements of operability, particularly where they are not believable on their face. Where legitimate questions of operability exist, a preponderance-of-the-evidence standard (as explained above) should be acceptable for establishing the level of ordinary skill.

Thus, at the Examiner level, the Examiner should be permitted to accept assertions in the application at face value, particularly in the absence of objective evidence challenging such assertions. However, where objective evidence challenging operability assertions exists, the Examiner may shift the burden onto the applicant to provide evidence supporting operability for the scope of protection sought. However, once applicants rebut such a challenge with objective evidence establishing the level of ordinary skill and/or the level of predictability in the art, the Examiner should weigh all of the evidence on the record objectively. Where the weight of the evidence supports operability and

predictability of modifications commensurate in scope with applicants' assertions and with the claimed invention, the Examiner should rule in the applicants' favor. However, where the weight of the evidence does not support the applicant's assertions, the Examiner may properly reject an application for lack of operability over the entire scope of protection sought.

THE UTILITY ISSUE

With regard to the perceived requirement for human clinical data, again I would like to encourage the Group 1800 examining corps to accept applicants' assertions at face value. Thus, where the assertions are believable on their face, an Examiner should be permitted to find the application and claims acceptable under 35 U.S.C. 101.
However, where an application asserts a medical or pharmaceutical use, there may be a public concern regarding whether the assertion is true on its face, particularly where supporting evidence is scant or not yet widely accepted in the art. In such cases, the PTO should consistently treat compound claims separately from pharmaceutical composition and method of use claims.

Compound claims (e.g., drawn to a protein or polynucleic acid) often rely on non-pharmaceutical utilities, such as use in an in vitro diagnostic assay. As a result, compound claims often do not rely solely on pharmaceutical utility to comply with 35 U.S.C. 101. Thus, challenges to compound claims on the basis of failure to demonstrate medical or pharmaceutical effectiveness in humans should be made only when only pharmaceutical or medical utility is asserted utility for the compound.

On the other hand, pharmaceutical composition claims typically recite an effective amount of an active agent. Where the desired effect may be in a human, the claims may rely on effectiveness in humans for utility. Naturally, claims to methods of treating medical conditions and/or administering pharmaceutical agents necessarily rely on pharmaceutical utility to comply with 35 U.S.C. 101. Consequently, questions regarding effectiveness in humans are more easily raised in claims to pharmaceutical compositions and methods.
However, the biotechnology industry perceives an over- reliance by the PTO on clinical data to resolve such questions. As explained above, this perceived over-reliance is causing some difficulty for the biotechnology industry and appears to impede rather than advance President Clinton's stated policy objectives.

In resolving questions regarding claims which rely on effectiveness in humans for utility, I propose that a preponderance-of-the-evidence standard is appropriate.

The leading case on pharmaceutical utility is Brenner v. Manson. In Manson, a method for preparing a compound structurally related to, but distinct from, a certain steroid known to have pharmaceutical utility was claimed. Manson relied on homology of the product of the claimed process to a steroid have tumor-inhibiting effects in mice, and the potential usefulness of product of the claimed process for patentability. Although the C.C.P.A. held that a novel chemical process is patentable so long as its yields the intended product and so long as the product is not itself "detrimental," the Supreme Court held that until the product of a process claim has been shown to be useful, the metes and bounds of the monopoly of knowledge encompassed by the process patent are not capable of precise delineation. The process patent would grant its owner the right to prevent others from finding the first use for the product of the process, and thus, the patent may block off whole areas of scientific development without compensating benefit to the public (i.e., the knowledge of the usefulness of the products of the process).

As a result of their holding, the Supreme Court struck down the concept that an invention is useful so long as it is not frivolous or detrimental. I believe this would make any presumption that biotechnological inventions are inherently useful to be inconsistent with the Supreme Court's interpretation of 35 U.S.C. 101 regarding chemical process or pharmaceutical inventions.
Manson failed the proposed utility evaluation tests explained above. First, the application apparently made no assertions of utility for the products of the process. Accordingly, the usefulness of the process itself was not readily apparent on its face, and could be challenged. Secondly, Manson provided no evidence that the products of his claimed process were useful. Consequently, after the PTO shifted the burden onto Manson, Manson failed to provide sufficient evidence to outweigh the PTO's concerns.

Subsequent cases decided by the Federal Circuit and the Patent Office Board of Appeals are also consistent with the suggested tests above. For example, in Nelson v. Bowler, claims to prostaglandins shown to be effective in rat blood pressure and gerbil colon smooth muscle stimulation tests were found to be useful under 35 U.S.C. 101. Although the Board of Appeals upheld the rejection for not showing adequate proof of practical utility because the tests were "rough screens, uncorrelated with actual utility," the Federal Circuit found that tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use. Thus, in weighing the evidence, Nelson's evidence, which was held to be reasonably indicative of the desired response, and which was challenged on the basis of statistical significance rather than on the basis of objective evidence, were found to have a utility under 35 U.S.C. 101. The weight of the evidence in this case was clearly on the side of the applicants.
In In re Jolles, a pharmaceutical composition and a method for the

treatment of acute myeloblastic leukemia were claimed. Declarations reporting the results of clinical treatment were submitted. A rejection of the claims under 35 U.S.C. 101 and 112, first paragraph, for lack of proof of utility were based on assertions of incredible utility and that the clinical data were not convincing. The rejection was reversed by the C.C.P.A. because the Board of Appeals dismissed the evidence as not being relevant to human utility. Again, the weight of the objective evidence was on the side of the applicant.

In In re Langer, claims to a dentifrice and method for reducing enamel solubility were rejected under 35 U.S.C. 101 for lack of proof of utility. Langer provided both in vitro and in vivo animal test data showing that the claimed composition reduced enamel softening and erosion. The Examiner cited a number of references disclosing in vitro test data supporting an assertion that those skilled in the art would not accept applicant's allegation [of utility] as obviously valid and correct. The animal test data were attacked on the bases that (i) the tested material appeared to be a denture adhesive rather than an emollient dental paste, (ii) the concentration tested was insufficient for the claimed range, and (iii) the test animals may have received fluoride in their drinking water. However, the unsupported assertions by the PTO regarding the in vivo data were rejected by the C.C.P.A., holding that the evidence submitted was sufficient for compositions and methods reciting Sn2EDTA, but insufficient for generic claims. The logic of the C.C.P.A. was based largely on the weight of the evidence submitted.

In Ex parte Balzarini, the Examiner established with objective evidence a lack of correlation between applicants' in vitro test method and a reasonable expectation of effectiveness in vivo. In response, Balzarini made the unsupported assertion that the test conditions resembled circumstances in vivo as much as possible. Thus, in this case, the PTO provided the greatest weight of evidence regarding the utility on which the claimed invention relied (treating retroviral diseases in an animal or patient and treating human cells in a manner effective to inhibit the replication and effects of HIV).

In Ex parte Deuel, the application apparently failed to disclose the use of the claimed protein. The Board of Appeals recognized that this application necessarily fails to comply with the requirement set forth in Brenner v. Manson that at least one use of the claimed product be disclosed. As a result, the Board of Appeals issued a new ground of rejection under 35 U.S.C. 101 and 112, first paragraph. Again, in this situation, any asserted utility could be properly challenged, and in the absence of evidence, applicants fail the proposed weight-of-the-evidence test.

Similarly, Ex parte Stevens also concerned an application claiming a therapeutic or prophylactic composition and a method for treatment of

cancer, rejected under 35 U.S.C. 101 and 112. The rejection was affirmed because Stevens expressly acknowledged that no actual evidence of the effectiveness existed. As a result, Stevens necessarily failed a weight-for- the-evidence test after having the burden of proof shifted onto them.

In Ex parte Heicklen, a composition and method for retarding the aging process were claimed. A rejection under 35 U.S.C. 101 for incredible utility was made (i.e., questioning the assertion of utility on its face). The evidence submitted by Heicklen merely showed that mice receiving the active agent lived longer than mice which did not receive the active agent. In the Board's opinion, insufficient evidence was submitted to establish that the increased longevity resulted from a retardation of the aging process (the utility relied upon by Heicklen for patentability). The rejection was thus maintained by the Board. Naturally, Heicklen failed the weight-of-the-evidence test for establishing the relied-upon utility.

In Ex parte Aggarwal, a method for the treatment of tumors was claimed. A rejection for lack of utility under 35 U.S.C. 101 and a lack of enablement rejection under 35 U.S.C. 112 were issued by the Examiner, based on inoperability over the broad range of cancers and tumors claimed. The Examiner provided a list of reasons why treatment of tumors is essentially unpredictable. The prior art relied upon by the Examiner and appellants confirmed the Examiner's skepticism regarding the relied upon utility. Furthermore, in the Board's opinion, the evidence submitted Aggarwal by was not shown to have been recognized by the art as being predictive of success in the treatment of tumors. Consequently, the rejection was maintained by the Board. Coincidentally, Aggarwal also failed the proposed weight-of-the-evidence test.

In Ex parte Rubin, claims to a method for improving the effectiveness of interferon in the treatment of neoplastic conditions and a composition containing interferon and an agent for inhibiting tyrosinase were rejected under 35 U.S.C. 101 and 112, first paragraph for incredible utility. However, the evidence in the case showed that the anti-neoplastic utility of interferon was known. Further, the Examiner failed to provide any objective evidence to support the challenge to the asserted utility. Thus, Rubin passed the proposed weight-of-the-evidence test. Furthermore, the rejection under 35 U.S.C. 101 was reversed by the Board.

In Ex parte Busse, claims to a method for reducing metastasis and neoplastic growth were rejected under 35 U.S.C. 101 and 112. The specification expressly asserted utility in humans. Consequently, the claims were held to rely upon effectiveness in humans for utility. Evidence submitted by Busse established only that further study of a compound tested for suitability as a human anti-neoplastic and anti-metastatic drug was warranted, rather than any likelihood of effectiveness for the claimed method. Thus, the Board maintained the

rejection, and regarding the proposed weight-of-the-evidence test, no evidence was provided supporting the asserted utility.

Consequently, I believe that a preponderance- or weight-of- the-evidence test is appropriate where assertions of pharmacological activity are (1) not believable on their face and (2) relied upon for patentability.

WHAT POLICY OBJECTIVES ARE ACHIEVED BY THE PERCEIVED PRACTICES OF GROUP 1800?

Looking at the issues from the PTO perspective, what policy objectives are furthered by the perceived practices of the PTO regarding biotechnological inventions? There may be a general public concern with the effects of biotechnological inventions. Many, if not, most of the members of the public are unfamiliar with biotechnology. In the wake of recent, highly publicized environmental disasters and increased health risks associated with the products of high technology, a significant section of the public may be uncomfortable with biotechnology, and may wish to suppress advances in the field until the technology receives wide public acceptance.

The PTO may also be concerned with the imprimatur of the Federal Government, which may raise or lower expectations of those afflicted with illnesses which biotechnological inventions may be designed to treat. Further, some consumer organizations and government representatives have expressed concern over the costs of pharmaceuticals. Patents are typically cited as one cause of excessive pharmaceutical prices. Thus, by reducing the availability of patents or by discouraging obtaining patents as a means of protecting intellectual property, the PTO may be effecting a control on the pharmaceutical industry to keep expensive products out the market.

There are a number of problems with such policy objectives. First, the effort exerted by the PTO to examine data regarding the ultimate effectiveness of pharmaceuticals in humans and to address concerns over safety and efficacy of biological products unnecessarily duplicates the effort of the FDA and/or the USDA, who must review such data independently in order to evaluate whether such products should be allowed into the marketplace. The patent right concerns only the right to exclude others from making, using or selling the patented invention, rather than any right to enter the marketplace. On the other hand, one cannot market a new pharmaceutical drug or a new biological product without obtaining approval from the FDA or the USDA, respectively. In response to public concerns, the FDA has evaluated several recent, highly-publicized biotechnological products quite closely. Thus, public concerns regarding safety and/or acceptability of biotechnological products are best represented by the FDA and the USDA.

Furthermore, in the conventional medical marketplace, medical doctors and patients typically look to the FDA as the ultimate authority on safety and efficacy of pharmaceutical compounds. However, in the "underground" medical marketplace, actual examples of efficacy in patients are the basis upon which judgments to use a particular pharmaceutical agent are made. Sources of information regarding actual examples of efficacy are readily available through scientific publications, approval notices by the FDA at an introductory or intermediate level (e.g., Phase I or Phase II trials) and word-of-mouth stories of successful treatment therapies. Approval of a patent application may indicate some probability of effectiveness, but ultimately, actual examples of effectiveness are the most persuasive evidence of effectiveness, both to those in the FDA- regulated marketplace and in the "underground" marketplace.

The policy also conflicts with Securities and Exchange Commission and EPA regulations, which may prohibit inventors from asserting pharmacological utility or from testing recombinant organisms in the field prior to their approval. Furthermore, if the Clinton administration is concerned over the appearance of unfair prices established by a particular company for a particular pharmaceutical agent, it seems reasonable to have the SEC investigate and resolve the situation. Increasing the difficulty level in obtaining patent protection as a means to reduce the price of pharmaceuticals appears to punish all practitioners in biotechnology for the perceived sins of a few.

With regard to pricing of pharmaceuticals, the SEC may be the most appropriate agency for evaluating such concerns. The current PTO policies actually result in an increase in the cost of pharmaceuticals and of other biotechnological inventions. As explained above, the perceived practices of Group 1800 result in increases in the costs of application prosecution and of patent enforcement. Further, relatively narrow claims are less valuable and result in increased uncertainty as to the scope of protection. As a result of this uncertainty, licensing arrangements are riskier and take longer to consummate, thus causing delays in taking the steps necessary to further develop and market the product. As a result, approval by other regulatory agencies and the entry of competition into the marketplace is delayed. Competition may very well be the key to reducing the costs of pharmaceuticals. By delaying issuance of the patent, the end of the patent term is extended, thus increasing the period of time under which a marketing company may price its product without competition. Thus, the perceived PTO policies serve to increase the costs of pharmaceuticals.

In summary, other agencies, such as the FDA, USDA, SEC and EPA, may be more appropriate for addressing policy concerns regarding the effects of individual products entering the marketplace.

CONCLUSIONS

President Clinton has advocated at least three policy- related goals affecting the biotechnology industry, including (1) Fostering the growth of biotechnology, (2) reducing the costs of medical care and of pharmaceuticals; and (3) minimizing the size and expenses of the Federal bureaucracy, including minimizing duplication of effort among Federal agencies. As an administrative agency, the PTO can more effectively advance the President's policies by

(A) Allowing claims with reasonably broad scope;

(B) Permitting Examiners to accept applicants' assertions of utility and operability unless objective evidence questioning such assertions is provided;

(C) Where assertions of pharmaceutical utility are raised, consistently treating claims to compounds separately from claims to pharmaceutical compositions and methods of use; and

(D) Where pharmaceutical utility is relied upon for patentability, adopting a preponderance-of-the-evidence standard for establishing pharmaceutical utility.

Adoption of proposed policies (A)-(D) by the PTO above will result in (i) earlier issuance of patents and (ii) greater patent protection for inventors. The proposed policies will achieve the President's policy goals by more adequately rewarding inventors for the knowledge which they provide, thus encouraging further research and development of biotechnological products and services. Earlier issuance of patents and broader patent protection will reduce the costs of prosecuting patent applications and enforcing patents, will increase the certainty of patent positions and license agreements, thus increasing the speed with which further product development occurs, and will result in an earlier end to the patent right, thus allowing competition to enter the marketplace at an earlier date, further resulting in lower costs through competition. Finally, where the asserted utilities and statements of operability in an application are challenged, adopting a preponderance-of-the- evidence standard for resolving questions of pharmaceutical utility and of predictability in the art will reduce the effort of Examiners on reviewing such evidence. As a result, the costs of running Group 1800 will be reduced, and duplication of effort between the PTO and other regulatory agencies, including the FDA and the USDA, will be minimized, and potential conflicts between such agencies can also be avoided.

Respectfully submitted,

Andrew D. Fortney, Ph.D.

ADF:dsf

Mr. Commissioner, members of the panel and the audience:

I'm David Lowin, Assistant Director of the Patent Law Department at Syntex. I also teach Patent Law at Stanford Law School and at U.C. Berkeley's Boalt Hall. My testimony is offered as personal opinion, not on behalf of any organization.

Suffice it to say that 9 minutes isn't long enough to address the full subject matter of this hearing, so I am also working on a written submission covering a broader scope. My prepared remarks are addressed to a somewhat different approach on the policy behind the utility requirement, and the environment in which that policy must be carried out.

The notice setting this hearing started by reference to the Supreme Court's decision in Brenner v. Manson, where the Court upheld the rejection of a chemical process patent application for failing to establish a substantial utility. Now, this may not have been a great decision, but that is mostly due to the underlying facts. I believe that the decision is not, however, inconsistent with the positions urged at today's hearing, and it is to this that my remarks are focused.

I think there are two key aspects to the majority's conclusion in Brenner v. Manson which shed light on practical utility problem faced by biotech inventions today.

First, the majority concluded that "...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Whether an invention represents the successful conclusion of a search depends on what you're searching for in the first place. Biotechnology has changed what we're searching for. It has made it possible for us to understand the complexity of life, and to intervene with disease at a level far more precise than was possible when the Court considered Brenner v. Manson. The successful conclusion in today's search for cellular mechanisms and ways to modulate them would have probably been considered only an invitation to further experimentation back in 1966. And what we consider to be a successful conclusion today is going to be different again ten years from now. The point is that legal principles

such as "successful completion of the search" have to be applied in a manner consistent with the progress of technology.

The second key aspect of the decision in Brenner v. Manson is the quotation taken from the CCPA's decision in Application of Ruschig, "[A] patent system must be related to the world of commerce rather than to the realm of philosophy."

So, what is "the world of commerce" to which the successful conclusion of today's search must relate? It's a different world of commerce than it was in 1966.

Just as the "patentable subject matter" definition of Section 101 had to expand to cover Chakrabarty's bacteria as part of "anything under the sun that is made by man," now, our definition of the "world of commerce" must expand to recognize the state of the art and the commercial impact of today's biotechnology inventions.

When we clone the DNA for a protein known to be involved in a disease, ... when we develop that protein into a model for screening potential therapeutics, ... when drugs are identified as active in that model, ... and when those drugs are tested in clinical trials, these efforts involve hundreds of scientists and thousands of others performing related tasks in hospitals, banks, shippers, equipment manufacturers, accountants, and even in the United States Patent and Trademark Office. Each step along the way entails enormous investment. The successful conclusion of each of these searches triggers even more investment. Ultimately hundreds of millions of dollars change hands during the development of a single drug. Now that's commerce, commerce at a scale our founding fathers couldn't have even imagined.

Today's hearing is taking place because the United States Patent and Trademark Office has more often than not refused to allow our applications for patents on the DNA, on the proteins, and on the screening models (allegedly because they are not the successful conclusion of the search, and do not relate to the world of commerce). The PTO has also refused to issue patents on the drugs (because they haven't been proven safe and effective in statistically powered human clinical trials) even though, in this first to file world, the patent applications cannot contain such data because they have to be filed years before clinical trials could even begin. And now, if eventually granted, the terms of these patents will have been expiring since the day they were filed. [At this point erroneous mention was made to a perceived problem in the GATT implementing legislation that could preclude Waxman-Hatch extensions. The error was brought to my attention by Mr. Van Horn upon conclusion of the hearing. I regret any inconvenience or misimpression that may have resulted.]

Just to put things in perspective, the same United States Patent and Trademark Office regularly grants patents on mechanical inventions for anything up to and including the kitchen sink, such as U.S. Patent No. 5,349,708, issued September 27, 1994 for "Foldable Kitchen Sink," not to mention the patents on the "Nail File Protector Device" and the "Air Cooled Umbrella" both issued the same day. Now I'm sure that all three of these inventions were worthy of patent protection. I'm also sure that even combined, the inventions covered by these three recently issued mechanical patents will not effect "the world of commerce" to the same degree as any of the "legally useless" biotech inventions we're talking about today.

I think that the Office needs to apply the utility requirement consistent with current scientific and commercial standards. The utility standard, as applied, should resolve doubts in favor of the patent applicant. When an applicant pleads for allowance of its application because its competitors are already practicing the claimed invention, it doesn't make sense to reject the application as lacking utility.

There is room here for the common sense principle, "no harm - no foul."

The courts are not being clogged, and the progress of the useful arts and science is not being blocked, by patents covering technology that just doesn't work.

Thank you for your attention.

BIOTECHNOLOGY PATENT POLICY

A Consumer's Perspective and Recommendations

Testimony before the Commissioners of the U.S. Patent & Trademark Office

October 17, 1994

Eugene P. Schonfeld, Ph.D.

President and Chief Executive Officer

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1234 Sherman Avenue

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By way of introduction, I am a kidney cancer patient.  Chemotherapy and radiation are not effective in treating kidney cancer.  Biological response modifiers created through biotechnology are helpful, but these agents are far from perfect and most patients are not cured despite rigorous therapy.

I am also President and Chief Executive Officer of the National Kidney Cancer Association, a non-profit charity which provides information to patients and physicians, sponsors biomedical research, and acts as an advocate on behalf of the nation's 75,000 kidney cancer patients.

I hold a Ph.D. in Management from the J. L. Kellogg Graduate School of Management at Northwestern.  I have also worked as a new product consultant in the Advanced Methods Group of N.W. Ayer, a major advertising agency.  In addition, I have started five high tech computer-related companies, including one that has been publishing economic information on research and development expenditures for 15 years.

I have no financial interest in any drug, biotech or health care company.  However, I am a kidney cancer patient whose life depends upon private industry efforts to find a cure for my disease.

General Perspective

Patent policy in biotechnology is extremely relevant to the well-being of millions of Americans who suffer from cancer, AIDS, Alzheimers, and other diseases for which there are no effective treatments.  Patent policy can speed scientific progress or retard it, accelerate products to patients or delay cures.  Therefore, as health care consumers, patients cannot be indifferent to the work of the Patent and Trademark Office.

If patent policy creates high hurdles, companies will be granted few patents or have to expend extraordinary resources to get a patent.  If too few patents are granted, incentives for invention will be diminished and the public will get fewer medical advances.  Similarly, if tremendous resources are consumed obtaining a few patents, the public will get fewer medical advances as dollars are shifted from laboratories to legal offices.

Similarly, a patent policy which is too lax would generate too many patents.  These patents would represent a cheap currency.  It would create intellectual assets devoid of real economic value with limited

protections. It would also water down the incentives for legitimate discovery. The public would enjoy fewer advances.

When patent policy is either too restrictive or too lax, corporate management and outside investors would be less willing to commit capital to research intensive ventures. No manger or investor wants capital consumed by an overly complicated patent process that adds little value to products delivered to the public. No manger or investor wants capital committed to creating intellectual property which has no value and limited protection even though it is patented.

From this perspective, the Patent & Trademark Office and the patent process itself should add economic value to inventions. An optimal patent policy should maximize this value. The public will be served because maximized value will stimulate investment and the development of more life saving inventions.

Making Life Saving Inventions Special

In addition to maximizing value, the Patent & Trademark Office should speed the processing of patent applications so life saving advances reach the public more quickly. As I understand current operations of PTO, patent applications are supposed to be processed within eighteen months. However, this goal is not always achieved.

The public has a unique and special interest in life saving inventions in contrast to inventions which are primarily commercial. Therefore, as a matter of public policy, the Patent & Trademark Office should automatically make "Special" all patent applications for inventions which diagnose and treat life threatening illnesses.

There is significant precedent for accelerating the processing of important patent applications. During the energy crisis of the 1970's, the PTO embraced a policy of making "Special" all patent applications for energy conservation inventions. Public health and the lives of the nation's cancer, Alzheimers, and AIDS patients are no less important than energy conservation.

Many life saving inventions also reduce the cost of health care. Too often, I see cancer patients go from therapy to therapy in search of a drug which will stop their disease. Great sums of money are expended on treatment after treatment which does not work. Accelerating the patent process for life saving inventions will help control health care costs by bringing new, more effective treatments to market faster.

To implement the policy which I have recommended, the Patent & Trademark Office should expand its core of biotechnology patent examiners through new hiring and retention of its existing staff. Congress should

appropriate the funds to support the needed staffing.

The eighteen month goal should be a "hard target" for life saving inventions both on the part of the PTO and the applicant. Additional computerized systems and other resources may be needed to expedite and support the processing of patents. Investment in PTO infrastructure is probably money well spent and Congress should be urged to make the required investment.

Practical Utility and Clinical Trials

As we all know, Practical Utility is an essential criteria in patent decision making. While human clinical trial data are valuable for documenting Practical Utility of a new invention, the standard for determining Practical Utility should not be a human clinical trial.

In clinical care, many intervening factors may determine clinical efficacy or safety. It is often impossible for an inventor to control or even anticipate these factors, such as:

1. The characteristics of an affliction such as a tumor, bacteria, genetic damage, or injury. For example, you and I can both have

the same type of cancer, but biologically yours is different from mine because genetically our tumors are different even though we share the same diagnosis.

2. The characteristics of the host which bears the affliction. For example, biologically you and I are unique and different from other individuals suffering from the same illness.

3. The effect of a drug on both the affliction and the host may depend upon unique characteristics of the drug or agent, the amount of substance administered, the route of administration, the method of administration, the timing of administration, and where it is administered. For example, it is recognized that many living organisms, including people, have circadian biological rhythms which are extremely important to health, yet we know little about these rhythms except that we know that the same drug can produce different side effects and different benefits depending upon the timing of its adminstration.

From this perspective, there is a biological and clinical gestalt which must be understood in order for the utility doctrine to be meaningfully and reliably implemented from the perspective of human clinical trials. Unfortunately, it is often impossible to forecast the gestalt itself let alone control it. The development and clinical use of Interleukin-2 provides interesting proof of this point.

Interleukin-2: A Clinical Case History

IL-2 was first identified as an anti-cancer agent in 1976. It was first given to humans about 1984. It came up for review before the FDA in July of 1990 and was not approved even though it had been approved in nine European countries and had been shown to be safe and effective when tested in thousands of patients with advanced kidney cancer.

The reason that it was turned down was that it produced only a 15 percent response rate and the side effects of IL-2 were so severe, patients were put in intensive care when they received the drug. Eventually, with more research and a push from the National Kidney Cancer Association, IL-2 was approved by the FDA in early 1992.

During its review, the FDA focused on IL-2 as a single agent given in high doses by IV. However, that is not the way the drug is used today. One of the most effective ways for a cancer patient to get IL-2 today is to inhale the drug using an inhalator like asthmatics use. Since metastatic kidney cancer occurs most frequently in the lungs, inhalation of the drug delivers high concentrations of the drug where it is needed while avoiding the side effects of systematic therapy.

In German clinical trials for metastatic kidney cancer in the lungs, inhalation therapy has produced a 65 percent response rate and is an outpatient therapy with almost no side effects. Many clinicians now believe that the human body produces and uses IL-2 locally rather than systemically. Inhalation therapy may be effective because it more closely approximates what the body itself is doing.

The lesson in this case history is that nobody ever envisioned that IL-2 would be inhaled when it was invented, or when it went through U.S. clinical trials, or when it came before the FDA. In fact, initial clinical trials shed little light on Practical Utility and the initial trial data almost led the FDA not to approve the drug at all.

Accelerated Patent Processing and Human Clinical Trials

In addition, requiring lengthy human clinical trials is completely at odds with a policy of accelerating the patent process for life saving inventions. Animal experiments are one substitute for human clinical trials, but even more is possible.

Surrogate end points are often needed and used as precursors to human clinical end points. In fact, modern clinical practice itself is moving away from a blind reliance on average response rates derived from clinical trials. For example, in vitro drug tests using a patient's living tumor tissue are now being used to determine a specific individual's drug sensitivity and resistance, and to design "patient

specific" therapies.

The FDA has adopted a policy of using surrogate end points in its evaluation of AIDS drugs. T-cell counts and other markers have been used by the FDA as a basis for the approval of new drugs.

Many of the same scientific advances which allow gene fragments and other tiny biological components to be evaluated, also enable the Patent Office to adopt surrogate end points for patent decision making. What is required is the motivation by the Patent Office to develop and use an evaluation system composed of valid surrogates.

In this regard, it may be wise for the Patent & Trademark Office to develop "advisory boards" as the FDA has. These advisory boards, however, would not advise on any specific patent applications. Their responsibility would be confined only to the system of evaluation and assist the Patent Office in the selection of appropriate surrogate markers used in evaluating biotechnology patent applications.

Summary

To sum up my recommendations:

1. Develop a patent policy which maximizes the value of patented inventions, a policy which is neither too restrictive nor too lax.

2. Adopt a policy of making "Special" all patent applications which involve life saving inventions, and in so doing, accelerate the patent process for these inventions.

3. Beef up the corp of biotechnology patent examiners.

4. Do not rely on human clinical trial data for decision making. It is helpful but is not the proverbial "gold standard" for decision making for clinical practice or for the FDA.

5. Develop a system of surrogate end points for use in evaluating new life saving inventions and in evaluating biotechnology patents.

6. Build an advisory board to help the Patent & Trademark Office develop and update its system of surrogates and decision making criteria.

I urge you to consider these recommendations because, if adopted, they will enable the Patent & Trademark Office to better serve the public, particularly those of us who are suffering from life threatening illnesses. Thank you.

STATEMENT OF JOHN W. SCHLICHER

CROSBY, HEAFEY, ROACH & MAY

OAKLAND, CALIFORNIA

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

CONCERNING NOTICE OF PUBLIC HEARINGS AND REQUEST FOR COMMENTS ON PATENT PROTECTION FOR BIOTECHNOLOGICAL INVENTIONS

ON OCTOBER 17, 1994

Commissioner Lehman, Mr. Van Horn, Mr. Kushan, and the other members of the panel, thank you for the opportunity to appear and give my personal views on these issues. I am a patent lawyer with the firm of Crosby, Heafey, Roach & May in its Oakland, California office. I also teach patent law at Stanford Law School as a part-time Lecturer.

My comments are arranged in the following order:

1. Patent Law Should Be Based On Sound Economic Analysis

2. The Economic Purpose Of Patent Law

3. There Is Not And Should Not Be A Separate Set Of Patent Law Doctrines For Biotechnology

4. Practical Utility For Biotechnological Inventions

5. Proof Of Operability For Human Therapeutic Inventions

6. Standards Used In Measuring Nonobvious And Enablement Of Biotechnological Inventions

7. Experimental Use Defense To Patent Infringement

8. Implications Of Pending Legislative Reform On PTO Operations And Examination Procedures

9. Other Issues

10. The Most Efficient Use Of The PTO's Resources In The Overall Patent System

These hearings focus on patent law and biotechnology. Patents are important to the biotechnology industry. The advances of the past twenty years have created vast opportunities for future research. However, the policy and legal issues transcend the biotechnology industry. The policy and substance of patent law should apply to all technologies in the same way. Biotechnology inventors should be treated no less and no more favorably than any others.

1. Patent Law Should Be Based On Sound Economic Analysis

I commend you for holding these hearings and for preparing a thoughtful notice to focus the issues. The notice is a model of good sense in one critical respect. The notice focuses on the economics of the patent system. The notice asks for information about the effect of the law on the amount or rate of investment in attempts to create the technological information about new products and processes that patent law calls "inventions." Patent law has not always developed to best serve the United States economy because the people responsible for making and interpreting the law failed to ask that question or to answer it correctly. A classic example is the Supreme Court's decision in Brenner v. Manson. By asking the right question, these hearings have improved the likelihood that patent law will develop to better serve the country. My concern about the economic effects of patent law lead me to write a book to focus attention on this question and to try to help answer it. Much of what I say here is described in greater detail in that book.

2. The Economic Purpose Of Patent Law

The notice is fundamentally correct when it says the patent system exists to induce investment and risk-taking in research, development and commercialization of biotechnology inventions. The notice is right on target by focusing on increasing incentives to invest in inventing and take the risk of failure. There are other theories of patent law. The notice provides a valuable insight by ignoring them.

For purposes of developing patent law standards, I would define the role of patents only slightly differently. Patent law exists to alter the private incentives for use of resources that the market would otherwise provide. By "resources," I mean anything that is scarce and that, if put to one use, may not also be put to another. A market may misdirect resources, if people do not expect to capture all the benefits their investments provide to other people. In the absence of corrective laws, potential producers of technical information are likely to spend too few resources over a given period attempting to produce technical information. They will do that, because they anticipate being unable to capture all of the value of the information they produce.

I would say the economic goal of patents is to induce investment and risk-taking in producing technological information about new products and processes that, in the absence of patents, the market would be unlikely to produce or produce as quickly. Whether this information-generating activity is called "research" or "development," the goal is to identify and grant rights in those situations where the cost and risk of production would likely have been sufficiently large that potential profit-motivated producers would likely have shunned the effort in the absence of patent rights.

Patent law seeks to assist markets to induce the owners of resources to use more of them in producing new technical information about potential new products and processes. This means patent law also induces the owners of resources to use fewer of them in producing the products and processes available from existing technical information. United States consumers benefit from this better use of the country's scarce resources. The improved supply of technology may permit different or better products to be produced in the future or to be produced more cheaply.

If the level or rate of information production increases due to patents, the level or rate of commercialization of new products and processes will also increase. However, patent law leaves commercial use to the market, not to legal regulation. Like all other property rights systems, the patent system relies on self-interested decisions by producers, consumers and the market to decide which inventions to try to make, which to develop and use commercially, and how much to pay for that use. Patent rights were historically granted by the government without regard to their potential benefits to consumers or their potential commercial value. The patent system leaves it to producers and consumers to make those judgments, however wise or foolish they might appear to the government. It is entirely likely that a rational patent system may induce many patentable inventions and only a small percentage of them will be used in a commercial product. That fact is and ought to be no cause for concern.

There is one decision by the Supreme Court in 1966, Brenner v. Manson, that can be read to say the patent system exists to induce the development and bringing of new products to the market. If the goal is to induce developing and bringing new products to market, the standards for patent availability would be quite different than they have been for the last 200 years and are today.

3. There Is Not And Should Not Be A Separate Set Of Patent Law Doctrines For Biotechnology

United States consumers benefit from advances in biotechnology and all other technologies. For that reason, patents apply to all areas of technology where there are opportunities for profit-motivated people to

conduct research and produce technical information. Because the policy of patent law applies to all technologies, patent law doctrines must apply across the board to all technologies.

There is not or should not be a special subset of patent law doctrines for biotechnology. One risk is that a separate set of biotechnology standards may develop in a way that makes patents for biotechnology inventions more difficult to obtain or less valuable than patents in other areas. Patent law would be unwise if it created greater relative incentives to invent in the 10,000th mouse trap design than the first therapy for a previously untreatable human disease.

In general, I find the notice to be consistent with that view. However, the notice refers to the Court of Appeals for the Federal Circuit "refining" the law of nonobviousness for biotechnological inventions. I do not understand the Court of Appeals for the Federal Circuit to have created a subset of patent law doctrines for biotechnology. While the decisions cited in the notice discuss patent law in the context of biotechnology, the legal standards found in the decisions are the same standards applied to all types of technologies.

In the patent area, people sometimes confuse legal principles with decisions applying legal principles to particular facts. It is important for patent lawyers and the Patent and Trademark Office ("PTO") to understand that a decision by a court to find a particular invention unpatentable or a patent invalid for lack of utility, obviousness, or lack of an enabling disclosure does not establish a new legal principle. For example, if the PTO issued a patent on an invention based on research that identified a gene that encodes a particular protein (by identifying the protein sequence, creating sets of probes and probing DNA libraries), and a court were to declare that invention obvious and unpatentable, this decision does not change the law of nonobviousness one iota. That decision is and ought to be irrelevant to the obviousness of a different invention based on research that identified a different gene that encodes a different protein (again by identifying the protein sequence, creating sets of probes and probing DNA libraries). The decision declaring the first invention obvious and unpatentable does not and ought not provide a basis for the same decision in a second case that looks superficially similar.

People who work with patent law often try to find certainty in the law where certainty does not exist and to simplify the process of applying the law to the facts, where simplicity is not possible or wise. The easiest way to achieve certainty (and predictability) and to reduce the cost of decision-making is by applying formal or informal (that is secret) rules of thumb across all fact situations that appear at some general level to be similar. Lawyers, patent examiners, courts and others need to resist that impulse. They need to apply the same general

legal standards to the particular facts in each particular situation. The notice affirms that is the operating procedure in the PTO. The notice, borrowing a phrase from antitrust law, affirms there are no per se rules. Each application is examined based on applying general legal principles to the unique facts surrounding the application. That declaration is very important. The challenge is to make this approach effective.

4. Practical Utility for Biotechnological Inventions

The notice asks about the purpose of the utility requirement. That is the right question. Unfortunately, the Supreme Court in Brenner v. Manson gave the wrong answer. The Court said:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

In my view, the Court was wrong.

In Brenner v. Manson, Justice Fortas, and six other Justices, implied that inventors seeking a patent must first show that the invention had been developed to the point where "specific benefit exists in currently available form." Justice Fortas seemed to believe it undesirable to issue a patent on the process of producing a chemical, if the only known use for the chemical was to conduct further research into uses for it. Justice Fortas also seemed to believe that research is useless and researchers do not count as consumers in need of better products and processes. I find it startling to suggest that all of the instruments and all of the reagents sold by numerous companies to the biotechnology industry for conducting research are beyond the pale of the patent system, because research is deemed an inherently useless activity. If someone might be willing to pay for a material, whether an isolated strand of DNA, an isolated polypeptide, an isolated protein, or an isolated microorganism, that material has, in my view, sufficient utility to be patentable.

In my view, Brenner v. Manson's language is unclear and, if taken literally, inappropriate for a well-functioning patent system. I have explained why elsewhere. If someone produces information about the general character and features of a new product or process that distinguishes it from earlier products and processes, he or she traditionally has been and should be entitled to a patent even if (1) there may be no perceivable benefits to consumers or others and no commercial potential for that invention, or (2) there is commercial

potential, but there are large additional development expenditures necessary to use that invention commercially. In my view, Brenner v. Manson should also be of limited importance. That decision is inconsistent with more recent Supreme Court decisions defining the purpose of patent law. The Brenner v. Manson majority decision is premised on a "quid pro quo" theory that diverts attention from the real issue - incentives to invent. The dissenters, Justices Harlan and Douglas, asked about the effect of that decision on the incentives to do research into new processes, and reached the correct result. I believe the dissenter's approach consistent with the theory the Court applied in its later patent decisions in the 1970's and 1980's, such as Chakrabarty, Dawson, Kewanee Oil, and Diehr and that the Federal Circuit often applies.

Rather, the test articulated by Justice Joseph Story (who sensibly defined most fundamental patent law rules in the early part of the last century) made clear that the criteria for issuing patents had nothing whatsoever to do with the anticipated benefits of the invention. Under Justice Story's test, that prevailed until 1966, any invention was patentable if it might be put to a beneficial use rather than being useful only in harmful enterprises such as poisoning people. If the invention might be put to some use that was not "mischievous or immoral", it was patentable even though consumers and the market might attribute to that invention an economic value of zero. Under that standard, one asked only whether the patented invention might be useful for any lawful purpose, and was invalid only if it could not possibly be used for any such purpose.

Are there desirable changes to legal standards? If the Brenner v. Manson language is the legal standard, change is plainly desirable. Under a better rule, the whole question ought to be whether an invention may or might be used by anyone for any lawful purpose. Among the lawful purposes for which an invention might be useful is the conduct of additional research.

I should note that many of the points I have made here and elsewhere were articulated by Judge Rich in his dissenting decision in In Re Kirk, 376 F.2d 936, 946 (CCPA 1967).

5. Proof Of Operability For Human Therapeutic Inventions

The notice characterizes the next substantive issue as the requirement that an invention be "operative." "Operativeness" is a word sometimes used as a synonym for the utility requirement and for the enabling description requirement in Section 112. The notice directs attention to application of these requirements for inventions whose sole use is the treatment of human disorders. While I do not believe that the law in this area is as clear as it might be, I do not propose to discuss it in

any detail. I offer these thoughts.

First, I believe much of the confusion in applying the utility requirement to that type of invention derives directly from the misstatement of the utility requirement in Brenner v. Manson. Assume the law is that an invention is not useful, until a "specific benefit exists in currently available form" presumably to consumers. If the regulatory reality of development and introduction of human therapeutic agents requires many years of development before anyone may lawfully make a product available to consumers, this utility rule seems to preclude a patent until all testing is completed.

Because I do not believe that the utility standard should have anything to do with potential commercial significance, it is an error to require that an applicant have in hand all of the information that will be necessary to immediately introduce a commercial therapeutic product. While some decisions expressly renounce tests that would require possession or disclosure of all commercially significant technical information, the language in Brenner creates a danger that the rules will be applied by decision-makers to require such information. The Supreme Court uttered those words in 1966 and it is difficult to put that genie back in the bottle. However, I think it is necessary to utterly ignore Brenner v. Manson for purposes of applying the utility requirement to human therapeutic inventions. That is a proper thing to do because the applicant in Brenner v. Manson did not assert that its process produced a human therapeutic agent.

Second, while patent law, as I understand it, formally rejects application of Food, Drug and Cosmetic Act standards for safety and efficacy as having anything to do with patent standards of utility, the danger is that in practice they will applied. If the law insists that the PTO and the courts make judgments about whether "specific benefit exists in currently available form," it is likely that many decision-makers will be tempted to take that regulatory reality into account in applying and developing patent standards. The law and the PTO would do well, in my view, to repeatedly and emphatically make clear that the requirements for distributing a drug under the Food, Drug and Cosmetic Act, or under any other regulatory regime, have no applicability at all to patent law.

Patent law seeks to increase the rate of research about potential new products and leaves it to people and market forces to choose the nature, type, timing and commercial use of the results of the research. The Food, Drug and Cosmetic Act seeks to decrease the rate of research about potential new products, and to replace private, market-driven decisions with government decisions. Adopting Food, Drug and Cosmetic Act standards for patent law (whether formally or informally) would be economic folly.

Third, the utility requirement in this area raises an issue that patent law does not address with much specificity. The question is whether the patent law does, or ought to, require some minimum level of certainty that the technical assertions in a patent application are true before a patent should issue. Should the patent law permit inventors to patent their guesses? Should an inventor be permitted to patent the use of a certain agent for treatment of a certain disease because he or she has some theory that, while somewhat plausible, is more likely than not to be untrue? Should Linus Pauling have been able to patent the use of Vitamin C for treatment of the common cold in the early 1970's? In my view, the law does and must insist that the information in a patent meet some minimum level of accuracy and correctness. I would impose that requirement not out of concern that some apparently goofy idea will in fact turn out to be goofy and an utterly useless patent issue. Rather, I would be concerned that issuing a patent to the first person to take a wild stab, or even an educated guess, at a potential therapeutic invention decreases the incentives of other inventors, who are undertaking the costs and risks of determining whether such a therapeutic invention in fact will work. By "work", I mean have some biological or pharmacological activity in humans that might potentially be useful in treatment of disease.

The difficult question is how certain one must be before an application is filed. I do not have a good answer. For the near term, I can not do much better than suggest a "reasonable degree" of certainty, recogizing that test is not very meaningful. I would be inclined today to ask whether there is sufficient certainty that we would be willing call-off all research by others on the same invention and rely on the person who developed the basis for that degree of certainty to carry on the work. It is clear to me is that absolute certainty is the wrong standard, and that certainty to the extent required by the Food, Drug and Cosmetic Act is the wrong standard. Again, I understand the law to endorse those two views. The more difficult, but necessary, task is for us to decide how and where to draw that line.

Fourth, if the law imposes a requirement that there be some degree of certainty about the correctness of an assertion of therapeutic utility, what is the standard that should trigger the PTO's ability to ask for proof and what is the proof that an applicant must provide? Those are difficult questions. I have no clear answer. However, there are two things I would caution against.

The notice asks about "incurable" diseases. This is an area in which it is unwise to attempt to develop a particular legal standards for each type of disease and each type of therapy. I do not believe it is wise to automatically require proof or require more persuasive types of proof for proposed therapies for "incurable" diseases than for any others. The

standards for requiring proof and the nature of the proof should be the same regardless of one's judgment of the history of success or failure in the past. With the exception of a person's ability to patent a machine that violates the Second Law of Thermodynamics, I do not believe that patent law has historically applied any different standard in other areas of technology with a long histories of failure. Bell, Edison, Marconi and the others faced no special obstacle when they pioneered new fields. I would not treat medicine differently.

I also believe it important the law avoid placing patent applicants in this area in a substantive and, perhaps, procedural disadvantage that does not exist in other areas. My concern is with the operation of rules that shift some type of "burden" from the PTO to the applicant. First, if the law says some "burden" has shifted to the applicant, the law may unnecessarily bias the decision-making process against issuing patents in this area. In the close or difficult cases, and there are many, there is a temptation to say the person with the burden losses. Second, the law may bias the process against issuing patents if the threshold for requiring proof is low and the threshold for satisfying the burden is high. For example, assume the rule (1) requires the PTO to insist on proof if the assertion of utility is not "likely to be true" or if there is a "reasonable" basis for doubt, and (2) requires that the proof must be "convincing," "persuasive" or some other word meaning very highly likely to be true. This is also an area where there is often a reasonable scientific basis for some uncertainty about therapeutic effects. In an area where the legal standard is not easy defined and there is always some inherent uncertainty about the facts, these rules may operate to require proof in all situations and then require very highly probative evidence, such as substantial human clinical trials, before a patent application may be filed or a patent issued. I believe we should be cautious about such a rule.

6. Standards Used In Measuring Nonobvious And Enablement Of Biotechnological Inventions

The law governing the application of the nonobviousness requirement, Section 103, (and its predecessor nonstatutory invention requirement) has been the most difficult patent doctrine to define and apply, in an area of the law with many serious contenders. The enablement requirement has been less difficult in practice, but no less difficult in theory. These rules defy brief explanation. I would offer only these comments. First, the notice refers to many decisions in this area by the Court of Appeals for the Federal Circuit and the Board of Patent Appeals and Interferences and notes that they provided "much needed guidance" when applying those standards to "biotechnology inventions." That statement prompts me to repeat what I said earlier. There is not as I understand the courts, and should not be, as I understand the purpose of the law, a separate body of biotechnology nonobviousness or enablement law. Nor

should the actual decisions in particular factual settings be extrapolated in decision-making into other settings that look superficially similar.

This is not the first technical field in which the urge to develop shorthand formulas for deciding obviousness has been exhibited. The law books are full of cases that tried to articulate rules of thumb for determining obviousness. Perhaps the most famous was the so-called synergism test for determining the obviousness of "combination" inventions. These rules of thumb have been repudiated. We should be careful not to repeat those experiences in this important technical field.

Second, the notice frames the discussion of nonobviousness in terms of one of its elements, namely, determining the level of skill of an ordinary person at the time the invention is made. In my view, the law has not articulated wonderfully clear standards for decision-making about that subpart of the Section 103 analysis. The Court of Appeals for the Federal Circuit has pointed us to six factors to take into account, but it is far from clear how to do so. On another one occasion, the Court of Appeals for the Federal Circuit announced that a person of ordinary skill is one who "thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, often expensive, systematic research or by extraordinary insight, it makes no difference which." However, that standard does not seem to uniformly run through all the that court's decisions.

One of the factors the Court of Appeals for the Federal Circuit has said should be considered in determining the level of ordinary skill is whether the act is "advancing rapidly." It has never been clear to me how to employ that consideration. The fact that technology in a particular area is moving rapidly does not suggest to me that, if patents are eliminated, the same advances will continue at the same rate. The patent system must be applicable to all industries and technologies, whether the pace of technical change appears to be fast, slow or nonexistent. Of course, the pace of technical change does alter the administrative burdens for the PTO in ways that Congress may dimly or slowly perceive in budget considerations. However, it is important that the PTO avoid any effort or tendency to micromanage the rate of technical change. If technical change in a particular technology appears to be slow, that is no reason to try to issue more patents to speed it up. Conversely, if technical change appears to be very fast, that is no reason to issue fewer patents to try to slow the pace.

Third, the notice refers to changes in the state of the art affecting determinations as to the level of skill possessed by individuals working in the field. While it is true that skilled people are deemed to have available to them the state of the art, I would caution against taking

that notion very far. The danger is that, because the state of the art may, for example, include many examples of researchers successfully identifying and isolating genes for particular proteins, all similar efforts are deemed to be within the level of ordinary skill and all such activities deemed obvious and unpatentable. That is very unwise economic policy. The fact that many success stories are reported in the scientific and patent literature does not indicate to me that there are not many failures we can not read about or that the successes came easily and with little risk of failure.

My reading of the decisions in this area over the past about 150 years is, stated generally, that the economic purpose of the unobviousness requirement is to identify and eliminate from the realm of patentable inventions, those that involve such little cost and so little risk that it is highly likely, if not certain, that private producers of products (and today those who make a living as researchers) would have produced those inventions and done so at about the same time. In short, the market would yield those inventions without the additional incentives provided by a patent. If that is the general economic purpose, the fact that many people have used generally similar strategies to, for example, identify and clone genes for particular proteins in many prior situations, tells me little about whether it is economically sensible to grant patents for people investing effort and taking risks in attempting to identify and isolate other genes. If the costs and risks of that activity in a particular situation are significant, any resulting invention should be a serious candidate for a patent. The fact that many other people have followed similar strategies earlier and many had succeeded does not indicate that patents do not have an important role in inducing researchers dependent on the market from continuing to invest effort and take risks in that activity.

Viewed this way, decisions by the PTO and the courts under Section 103 are not merely technical decisions. They are technical and economic decisions of vast importance. If we lose sight of the economic purpose of the rule in the overall system, we may apply the rule in a way that is inconsistent with achieving the goals of the system.

The difficult issue is that the law has not defined with much precision the minimum levels of cost and riskiness that we require before we say that an invention is not obvious. Perhaps, we will do somewhat better in the future. However, the law does not and should not find inventions unpatentable, because a researcher sitting somewhere in an office would probably have recognized that (1) the invention was one of many possible ones to which attention might be given and (2) the most likely way of making it was a strategy sometimes used successfully in the past on similar problems. That those thoughts would have passed through the mind of an ordinary person should not render the invention unpatentable, if there were significant risks and costs of carrying out the project. The

reason is that simply because someone recognizes the possibility of making an invention and a potential way of doing it, does not mean that, in the absence of likely patent protection, researchers operating in the private marketplace, attempting to make money from that endeavor, would in fact have undertaken the program at about the same time.

7. Experimental Use Defense to Patent Infringement

The December 27, 1993 notice about hearings on the experimental use issue asked many important questions about the economic purpose of patent law and an experimental use doctrine. However, it frames analysis in two respects that I find less helpful than the current notice.

In my view, the purpose of the patent system to promote innovation requires that a person who receives the patent for a particular product or process should not be able to preclude others from using that invention (and making embodiments of it) for the sole purpose of making improvement inventions or substitute inventions. The basic reason is that, if we permit an inventor to capture the value of commercial embodiments of the product or process embodying his or her invention (namely, those supplied to consumers or used to make products supplied to consumers) and the value of all subsequent potential inventions whose development depends on use in research of the patented product or process, we would permit an inventor to acquire a patent whose value exceeds the value of that inventor's particular contribution. Hence, I have always assumed that a patent did not give the owner a right to exclude others from making or using the invention in order to make complimentary or substitute inventions. While I believe there is room for disagreement about my view of the economic consequences, my understanding of the development of patent law over the years by Congress and the courts is that this view is the prevailing one.

Until the early 1980s, I believe there was a doctrine which generally permitted others to use an invention in conducting research. I believe that the reason there was so little litigation to test that proposition and so few cases, as the earlier notice indicated, was that there was universal consensus about that rule. While the words in the cases seemed somewhat narrower, most patent owners either understood (or operated on the implicit assumption) that others could conduct research using their inventions, when that research was designed to make other inventions, whether complementary or substitute, or to do research simply for the sake of doing research, historically the function of our universities. The Federal Circuit's Roche decision in 1984 and Congress' response to it, as well as other cases, have created confusion and uncertainty. The problem with the Congressional response is that it left unclear whether experiments other than those protected by that section are non-infringing activities under the general experimental use doctrine.

Therefore, while I find nothing implicit in the public disclosure of the invention in the patent on the day it issues or in the quid pro quo theory to lead me to believe that use of an invention for experimental purposes should not be infringement, I believe it generally should not be. There are two situations where experimentation may be infringement. The first is experimentation involving the use (or making) of an embodiment of an invention, that is useful only in research and is incapable of any other use, such as use by ordinary consumers. Hence if someone invents and patents scientific instruments or reagents useful only by researchers, the making and use of such inventions for their intended purposes should be infringement. However, their use (and making) for the purpose of inventing improved or substitute versions of those instruments and reagents should not be infringement. The second is research conducted only for the purpose of developing a commercial product or process that would itself embody the patented invention. In other words, research undertaken solely and, perhaps, principally to implement a business decision to make, use or sell an infringing product may be called infringement. Such research is no different than building a plant to make the infringing product. It is logically infringement, since the principal value of that activity depends upon some subsequent infringing use of the invention in commercially used products or processes. An alternative is to reach the same result by permitting an owner to bring an action for threatened patent infringement, whenever it appears that someone else has made a definite decision to infringe and has begun to invest in projects or facilities (including research projects) whose only use would be as a step toward the make, use or sale of an infringing product. However, the courts have limited that availability of that action to such an extent that it may be useful to alter infringement doctrines to make clear that the activity is an act of infringement. The hard cases will be where a company undertakes research that might logically be designed (1) to improve an invention or to find a substitute for it or (2) to use the invention commercially.

I do not find it helpful in these contexts to describe one kind of research as commercial or for business reasons, and another kind experimental or for philosophical reasons. Those distinctions seem to me to bias decision-making against private sector research enterprises that may be conducting research primarily for the purpose of developing improvements or substitutes, and yet, by virtue of their very nature, operate with a commercial and business-oriented goal.

I do not have a view at this time about whether this is a problem best taken to Congress, to the courts, or for patent owners and users simply to work out among themselves. My impression is that legislation might be appropriate in this area. If legislation is proposed, I do not believe that the legislation enacted after the Roche decision was necessarily a happy model.

8. Implications Of Pending Legislative Reform On PTO Operations And Examination Procedures

The notice invites comments about potential changes to the patent system, including a 20-year term measured from the United States filing date and automatic publication of application 18 months after the earliest effective filing date. I am not a proponent of these so-called reforms. My view is that, on balance, this 20-year patent term diminishes the expected economic value of a patent and hence the incentives to do research. The effective term of a patent now depends directly on the length of prosecution. For complex inventions, prosecution is likely to exceed three years, and the value of patents for such inventions declines. The length of prosecution for all inventions depends in part on the resources available to the PTO. Those resources depend on Congress, and the political process. If the political process allocates too few resources to the PTO, the system is devalued. I am not aware of sufficient benefits to offset that cost and risk. I would much rather have dealt with with the trivial number of so-called "submarine" patent holders by extensions of estoppel and laches defenses to conduct before the PTO. My view is that these changes are unwise and that, if we were the only country in the world, no one would have dreamed of suggesting them. However, we are not and the events of the last ten to twenty years cannot be rewritten.

If I am correct that the 20-year term will have some effect in reducing incentives to invent, this will in the long run reduce the number of patent applications filed. Of those that are filed, the term rule will have some effect of inducing applicants to respond more promptly to the PTO and generate increased pressure on the PTO to promptly process applications. My principal concern is that, if the net burdens on the PTO increase, Congress will not provide the additional funds that will permit the PTO to effectively meet these increased demands that rule will place on the system.

The change to a 20-year term from filing, particularly if it is ultimately coupled with a rule that the filing date is used to determine priority, will force applicants to make very difficult decisions about when to file. These will be particularly difficult depending upon how the courts apply the utility requirement. In in order to win priority contests, one's incentives will be to file quickly. In order to sustain the basis for a patent under the utility requirement, one's incentives are to file after the proof is in hand.

The notice directs attention to the restriction practice. I believe a first step in reconsidering restriction practice is to ask what restriction practice is designed to accomplish? There seem to me two possible candidates. One is to confine an application to an invention or group of inventions so closely related that the fees reasonably relate to

the costs the Office anticipates with respect to searching, examining and other procedures on that application. The second is to confine an application to an invention or group of inventions that are sufficiently closely related to that, if a single patent issues, it will be possible for the PTO and other people who wish to know about patents to identify its subject matter from the title, the abstract and the classifications that are assigned to it. For both purposes, a standard of "patentable distinctness," whatever it means, is one that I do not find terribly helpful. This is an area in which I believe the Commissioner has considerable discretion and some modifications would be helpful. I cannot today suggest what they are.

9. Other Issues

The notice invites comments on other issues. There are a number of changes to patent law that I believe would have a positive impact on the patent system. I have described many of them elsewhere. Among other substantive issues I would focus on are (1) the patent misuse doctrine that overregulates agreements between owners and users, (2) the Lear doctrine and related rules that limit potential agreements that reduce the risks and costs of litigation, (3) the interpretation of Section 102(b), (4) the application of Sections 102(e) and 102(g) as sources of "prior art" (in the latter case where the prior inventor is not himself or herself seeking a patent), (5) the rules determining the scope of a patent, (6) the inequitable conduct doctrine and (6) the damage standards.

10. The Most Efficient Use of the PTO's Resources in the Overall Patent System

These hearings are, in part, about the application of patent law in the Patent and Trademark Office. The notice refers to the importance of "enforceable patent rights" to the value of those rights to inventors. Throughout the history of patent law, there have been those who criticized the performance of the PTO in its review and patent-issuing responsibilities. That criticism has often focussed on the frequency with which the courts in enforcement actions found patents to be invalid under one or another of the criteria for a patent to issue. This type of criticism is largely misplaced and may bias the PTO's decision-making process against issuing patents.

Because (1) patent standards do not draw bright lines, (2) the facts that underlie application of those standards are difficult and expensive to ascertain and (3) the PTO has limited resources in terms of time, information-gathering capability and technical expertise, the PTO cannot possibly make one hundred percent "accurate" assessments of each particular application. Congress set up the system with that reality in mind. Before a patent permits an inventor to capture any of the value of

the invention by excluding someone from using one or more of the rights, the owner of the patent must bring an action in a federal court. In that action, the person accused of infringement may seek to prove that the PTO incorrectly issued the patent. Moreover, before anyone will agree to be excluded or pay for the privilege of using a patented invention, the market place permits patent owners and users of inventions to review the PTO's decision and make a private assessment of the likely application of legal standards in a judicial proceeding and make a financial accommodation based on that assessment.

There are several important benefits to that system Congress adopted, not the least of which is confining a full-fledged, costly factual inquiry to those small percentage of patents that become commercially significant and involve issues that are difficult for the private negotiation process to resolve. This concept of the role of the PTO in the system is that the PTO should screen out and refuse patents for inventions that plainly and clearly do not qualify under one or another standard for a patent to issue. Under this view, it is and ought to be no cause for concern that ten, twenty, thirty or forty percent of patents litigated in the courts would be found invalid under one or the other of the criteria applied by the PTO. If the PTO perceives its job as making a one hundred percent "accurate" assessment of the facts and application of the law (meaning that only a small percentage of its decisions will be overruled by a court), it seems to me the PTO may operate with a bias against granting patents. While one should commend the PTO for its focus on doing a quality job, I think it would be unfortunate if that important goal translated into a bias against issuing patents. Rather, it seems to me the system is designed to operate most efficiently if the PTO were to issue patents unless it is not clear that the facts and the law require that a patent not issue.

[FOOTNOTES:]

[1] I have worked as a Research Fellow in chemistry at Stanford University, a scientist with Syntex Corporation, an attorney with Fish & Neave in New York City, and in-house counsel for Genentech, Inc., a leading biotechnology company. I am the author of the book Patent Law: Legal and Economic Principles (Clark, Boardman, Callaghan 1992).

[2] "Molecular genetics has made a beginning; a wealth of detail about many biological systems is already available. But the successes do not amount to a complete or even a very profound understanding. on the contrary, current ignorance is vaster than current knowledge." Paul Berg and Maxine Singer, Dealing With Genes (1992), Epilogue, p. 241.

[3] I refer to the notice appearing in the September 1, 1994 Federal Register p. 45267.

Schlicher, J., Patent Law, Legal and Economic Principles (Clark Boardman Callagan 1992).

The notice also refers to patents as a device to facilitate relationships between "government, university, and private sector partners by providing an impetus and a mechanism for commercializing advances at the cutting edge of biotechnology research." Patents provide a mechanism for a researcher in any type of institution, and even one working alone at home, to capture part of the commercial value of the invention he or she makes. If the producer is incapable of using the rights commercially or is less capable than others, the law permits transfer of the rights to a person able to better put them to commercial use. However, the purpose of patent law is not to shift income from private sector businesses to universities or government or to encourage commercial use of inventions that a university or government producer is incapable of using. The purpose is to increase the value of inventing whether performed by a private sector, university or government entity. While it is probably true in many cases that the existence of patent rights lowers the transaction costs of licensing between any two entities, I do not regard that effect as a principal purpose for a patent law.

[4] Research by the government or a university, whose principal endeavors are presumably not to develop and sell products commercially, is important in one respect. To the extent the patent law standards are interpreted to encourage development and commercial production of products, the law will bias the system against the ability to patent inventions produced by university or government researchers. Indeed, one of the principal advantages of the patent system is that it permits a number of different people, acting separately, to make inventions that may ultimately be used together to produce or sell a commercial product. This permits those best able to make certain parts of a total bundle of technical information more efficiently than other parts to focus their energies on the parts they are best able to produce. The market in rights will permit these separate to be combined to yield a commercial product. The ability of patent law to permit researchers to specialize in different parts of a total technological puzzle has that important benefit and operates best if each part of a commercial technological puzzle is separately patentable. Again, to the extent that patent law is perceived as devised to induce investment in the development and commercialization of products, the law will tend to bias decision-making against issuing patents that contain less than a total bundle of information necessary for the commercial production and sale of a product.

[5] Schlicher, Patent Law, chapter 2 and particularly ¤ 2.18.

[6] I refer here to the notice appearing in the September 1, 1994

Federal Register p. 45267.

[7] Those effects on others are sometimes called "external effects" or "externalities."

[8] For a more detailed explanation, see Schlicher, Patent Law, chapter 2.

[9] Many people own resources (such as their time and energy, and the resources they may buy with their savings) that they may devote to making and selling an existing product or to trying to design a better product. If they make and sell the existing product (or invest their savings in companies that do so), others can not use the products unless they pay for them. If those people try to design the new and better product (or invest their savings in companies that do so), others may use the design without paying. There are many ways a producer of a new design may lose exclusive possession of it. The design may become available to others who contribute nothing to producing it and who benefit from it without being required to pay. In that situation, people may devote to many resources to making existing products and too few resources to trying to design new and better products.

[10] Schlicher, Patent Law ¤ 3.02.

[11] Brenner v. Manson, 383 U.S. 519 (1966).

[12] Today, the standards of patentability are not directed exclusively to whether anyone previously introduced the same product into the market. If an invention is described in an article on a library shelf and has never been developed or marketed, it may not be patented even though the patent would increase the private profitability of undertaking development and marketing. Patent law standards do not even ask whether an inventor intends to market a product or thinks there is a market for the product. Indeed, a person may obtain and enforce a patent even though he or she plans not to use the invention commercially. Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 426-30 (1908); cf., Special Equip. Co. v. Coe, 324 U.S. 370, 371-77 (1945).

[13] Brenner v. Manson, 383 U.S. 519, 534-35 (1966). The utility requirement, as interpreted by the Supreme Court in 1966, has not been part of the patent system for 200 years. Brenner v. Manson was a totally unexpected and significant change in the formulation and application of that standard.

[14] Schlicher, Patent Law ¤ 3.02[3].

[15] Id. ¤¤ 1.05, 2.18[1], 3.03[5][c], and, e.g., Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed.Cir. 1985). An added feature of Brenner v.

Manson is that the Supreme Court said that it should not permit a patent to issue, unless the court could determine that Congress's intent was to "clearly command" that a patent issue in that situation. The Supreme Court during that period often invoked this notion that patents should be made unavailable and construed narrowly unless Congress clearly commanded otherwise. The Court's later decisions in Chakrabarty, Diehr and others expressly reject that approach to interpreting the Patent Act.

[16] Id. ¤ 3.02[2].

[17] While Section 112 focuses on the nature of the specification in the application, the Court of Appeals for the Federal Circuit, as noted in the notice, has interpreted the "how to use" language of Section 112 to incorporate the utility requirement of Section 101. In other words, if the application does not disclose a "practicable utility" for the invention, then the invention is not patentable under Section 101 and Section 112.
I do believe it is legitimate to ask whether people skilled in the art would consider the historical difficulty of developing a treatment for a particular disorder as bearing on the likelihood that a particular proposed therapy will yield a biological response that might be useful in treatment.

[18] Id. at ¤ 5.03.

[19] Schlicher, Patent Law, at 5.03[13] and 5.03[18].

[20] Id. ¤ 5.04[2].

[21] Environmental Designs v. Union Oil Of California, 713 F.2d 693, 696-98 (Fed. Cir. 1983).

[22] Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454 (Fed.Cir. 1985).

[23] Environmental Designs v. Union Oil Of California, 713 F.2d 693, 696-98 (Fed. Cir. 1983)("...(4) rapidity with which innovations are made ...".).

[24] Graham v. John Deere Co., 383 U.S. 1, 10 (1966)( "The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that "the things which are worth to the public the embarrassment of an exclusive patent," as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."). The Court said one should weed out

the inventions that would not be "disclosed or devised" but for the inducement of the patent. The issue is how to do that. One way is to focus on the costs and risks of making the particular invention. If they are significant, the invention should be patented. If they are not, it should not be.

[25] First, the notice asks about "the balance of rights" between patent owners and "the general public regarding research oriented use of patent protected technology." That notice inferentially includes as part of the "general public," the United States government and the country's universities. My concept of a patent system is that it exists to increase the level of investment in producing inventions by increasing the value of those inventions to their producers. The general public benefits from that reallocation of resources because, in the absence of rules, people would have too little incentives to direct their efforts toward that activity. When too little resources are devoted to inventing, the products and processes ultimately used to provide goods and services to consumers do not improve as quickly as they should or at all. If an experimental use doctrine is justified, and I think it is, the reason for it does not lie in finding some proper trade-off between patent owners and the general public. Rather, it can be found only by asking whether the rule will induce patent owners and others in the long run to behave in ways that would benefit the general public.

Second, and more importantly, the earlier notice, unlike this notice, says there are two primary objectives of the patent system. One is the promotion of innovation that provides the frame of reference in the current notice. The second is the "public disclosure of inventions." This is the quid pro quo theory, a variant of which I criticized earlier and which I have criticized elsewhere. Schlicher, Patent Law, ¤ 2.18[3]. While I recognize that the courts have from time to time tried to explain the patent system on that basis, I do not find it a satisfactory or sufficient explanation for the system, and I find it uniquely unhelpful in developing sensible patent law.

[26] Schlicher, Patent Law, ¤ 8.04.

[27] Schlicher, "If Economic Welfare Is the Goal, Will Economic Analysis Redefine Patent Law?" in 4 The Journal of Proprietary Rights 12 (Prentice Hall, 1992); "Department of Justice Antitrust Policy, Economic Growth, and Intellectual Property Licensing," Intellectual Property/Antitrust 1993 (Practicing Law Institute, 1993); "A Lear v. Adkins Allegory", 28 Journal Of The Patent And Trademark Office Society 427 (1986).

TESTIMONY OF MARK G. TOOHEY BEFORE THE U.S PATENT AND TRADEMARK OFFICE

October 17, 1994

San Diego, CA

Honorable Commissioner and Distinguished Panel:

I thank you for the opportunity to testify today.

I am a registered practitioner working with the private firm of Spencer, Frank & Schneider. Our firm is a multifaceted intellectual property firm covering all aspects of intellectual property practice. The views I will express today are my own and are not necessarily espoused by Spencer, Frank & Schneider.

I hold a doctorate in Biochemistry and am currently completing the J.D. degree. As part of my legal training, I have extensively studied the 35 U.S.C. 101 and 112, first paragraph, so-called "practical utility" requirements. Thus, when notice of these hearings was recently published, I felt more than obliged to testify upon the issues presented.

Having thoroughly studied the issue of "practical utility" under the patent statute, I come to the conclusion that the Patent and Trademark Office is wrong to maintain a policy of rejecting certain classes of Biotech inventions on the alleged basis of a lack of "practical utility."

The Patent Office is wrong in narrowly reading the statute.

The Patent Office is wrong in misinterpreting the decisional law.

The Patent Office is wrong in asserting jurisdiction that it does not rightly have.

That is my view.

Let us first look at the statute. In misinterpreting section 101, the Patent Office follows the 1966 Supreme Court decision Brenner, Comm. Pats. v. Manson (148 USPQ 689 (U.S. 1966)). This reliance is, at best, misplaced.

Starting with the case of In re Bremner (86 USPQ 74 ( CCPA 1950)), the court and the Patent Office agreed that a patent applicant must state the usefulness of his invention in his application. Contrary to this doctrine, the Manson applicant, however, failed to assert any utility for

his invention. For this reason alone, the result in the Manson decision was correct. The invention was not disclosed in compliance with well-settled case law and was therefore unpatentable to the applicant.

Unpatentable, however, NOT because of the class of invention -a pharmaceutical. Unpatentable NOT because of its intended use - as a treatment for, inter alia, humans. Rather, unpatentable for a procedural error on the part of the applicant.

In dicta, the Manson majority indicated that section 101 should be construed narrowly. The Court later corrected itself in the ground-breaking Chakrabarty (206 USPQ 193 (U.S. 1980)) decision in 1980. The Patent Office has never corrected itself accordingly.

The Chakrabarty Court followed the eloquent exposition of the Honorable Judge Giles Rich in the appellate decision in that case. Judge Rich, a co-drafter of the 1952 Patent Act, set forth in that decision the statutory scheme of the Act. Judge Rich reminds us, and the Supreme Court echoed, that the Committee Reports accompanying the 1952 Act states that section 101 is intended to include "anything under the sun made by man."

Are Biotech inventions encompassed in "anything under the sun made by man"? Certainly, certainly YES!

There has been some discussion this morning as to whether the Patent Office should adopt a policy holding a presumption of "practical utility." I would like to briefly address that issue.

In In re Langer (183 USPQ 288 (CCPA 1974)), the C.C.P.A. ruled that a patent application "must be taken as sufficient to satisfy the utility requirement of section 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope." (emphasis in the original). That would seem to be a clear statement that a presumption of "utility" already exists, though perhaps unrecognized by the Patent Office.

As further evidence of a presumption of "utility," one need only look to the presumption of patentability embodied in section 102. That statutory section states that the patent applicant is entitled to a patent unless certain statutorily defined conditions are met. I argue that a presumption of patentability, expressly stated in the statute, necessarily implies a presumption of "utility" under the Patent Act.

Another focus of these proceedings is the Patent Office policy, whether intentional or not, of requiring applicants with certain types of Biotech inventions to show "statistically significant" results of "clinical

trials" in humans. The Office often takes the position that anything short of completely successful human trials is insufficient to show a "practical utility" for the invention.

The court, however, has consistently held since the 1961 Krimmel (130 USPQ 215 (CCPA 1961)) decision, that proof of "utility" ("operability") in "standard experimental animals" is sufficient to satisfy the requirements of section 101. One would think that the Patent Office would embrace such a position. Animal tests are less expensive than human tests. Animal tests are less time consuming than human tests. And most importantly, animal test are less dangerous than human tests. Again, one would think that the Patent Office would embrace such a position. It does not. But the Patent Office does not justify why it would require testing in humans for patentability when the statute has no such requirement.

More and more these days, animal tests are being replaced by in vitro models of human disease. These tests have all the benefits of animal models with the additional desirability of not using animals. This is a particular policy concern for that section of the public that questions the ethical propriety of animal experimentation. One would think that the Patent Office would embrace such a policy, whereby the needs of science are met and animals are spared. But the Patent Office does not. I respectfully submit, something is amiss.

One also questions why industry accepted standards, be they animal models or in vitro models, would not be acceptable to the Patent Office. Certainly the fact that the industry relies on these models ought to carry significant weight with the Patent Office, absent compelling policy reasons to the contrary. The courts have long recognized the realities of the pharmaceutical industry and the nature of its research. It is high time that the Patent Office make a similar recognition.

At this point, I note that I have routinely had client's claims allowed in the European Patent Office and the Japanese Patent Office with data in the disclosure showing "utility" in laboratory animals. In other cases before those Patent Offices, no showing of "utility" has been required because the foreign examiner recognizes the clear "utility" of the invention. Yet counterparts to these same applications, claiming substantially the same subject matter, are forever blocked in the U.S. Patent and Trademark Office.

The Patent Office has argued in the past (and continues to argue) that it must be extremely cautious in issuing patents for inventions intended for use in humans. The Patent Office relies on the rationale of the 1957 decision Isenstead v. Watson, Comm'r. Pats. (115 USPQ 408 (D.D.C. 1957)), where Judge Holtzoff expressed concern that the "official imprimatur" associated with a patent, rightly or wrongly, would lead the

unsophisticated in the public to believe that the patented invention works in all ways disclosed in the specification, including use in humans. Without reference to the Isenstead decision, the Official Notice of these proceedings brings this argument to the table.

What the Patent Office must recognize is that regardless of an "official imprimatur," if one exists, the public cannot legally obtain the pharmaceutical in question without that product first complying with the requirements of the Food, Drug and Cosmetic Act. The issuance of a patent is thus neutral with respect to public safety and/or drug efficacy.

This brings us to the issue of jurisdiction. As first pointed out in In re Hartop (135 USPQ 419 (CCPA 1962), and subsequently reaffirmed, the issue of drug "safety" and "efficacy" is squarely within the jurisdiction of the Food and Drug Administration (and the EPA, OSHA, SEC, etc. to a much, much lesser extent). To discover the proper jurisdictional basis in this regard, one need only look to the pages upon pages of detailed statute in Title 21 of the United States Code - the Food, Drug and Cosmetic Act, as amended - and the hundreds of pages of implementing regulations. Jurisdiction on the issues of drug "safety" and "efficacy" is certain.

Yet the Patent Office disregards the courts; disregards the proper interpretation of the statutes; and asserts jurisdiction on the strained interpretation of a single word - "useful" - in the Patent Act. This jurisdictional assertion by the Patent Office is clearly wrong.

The Biotechnological industry needs valid patents to protect its intellectual property. We have already heard this common theme from early on in these proceedings. The Biotechnological industry needs patents to spur investor interest and fund further research. We have heard this also this morning. The public needs the speedy issuance of valid Biotechnical patents to promote research and hasten valuable new products based upon this technology to the market.

I conclude that the Patent Office should discontinue its practice of slowing the progress of Biotechnical inventions to the market place and impeding the Biotech industry under the policy of issuing legally baseless "practical utility" rejections.

Thank you for your time.

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