FEDERAL TRADE COMMISSION

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In the Public Hearing on)
COMPETITION AND INTELLECTUAL)
PROPERTY LAW AND POLICY IN)
THE KNOWLEDGE-BASED ECONOMY.)
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March 19, 2002

Room 432
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C.

The above-entitled matter came on for hearing, pursuant to notice at 9:21 a.m.

SPEAKERS:

FIRST SESSION:

Lynn J. Alstadt, Shareholder, Buchanan Ingersoll & Adjunct Professor, Duquesne University

F.M. Ross Armbrecht, Jr., President, Industrial Research Institute

Makan Delrahim, Republican Chief Counsel, Senate Committee on the Judiciary

SPEAKERS (Continued):

Joanne M. Hayes-Rines, Vice President, United Inventors Association

Brian Kahin, Visiting Professor & Director, Center for Information Policy, U of MD

James Love, Director, Consumer Project on Technology

Ronald Myrick, Chief Patent Counsel, G.E.; President-Elect, American Intellectual Property Law Association

Cecil D. Quillen, Jr., Senior Advisor, Cornerstone Research

SECOND SESSION:

Robert A. Armitage, Vice President & General Patent Counsel, Eli Lilly & Company

Monte R. Browder, Senior Intellectual Property Counsel, Ivax Corporation

Barbara Caulfield, Executive Vice President & General Counsel, Affymetrix, Inc.

David Coffin-Beach, President, Torpharm, Inc.

Gregory J. Glover, Partner, Ropes & Gray, Counsel to Pharmaceutical Research & Manufacturers of America

Rochelle K. Seide, Partner, Baker Botts, LLP

SPEAKERS (Continued):

Edward A. Snyder, Dean & Professor of Economics, University of Chicago Graduate School of Business

P R O C E E D I N G S

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MR. KOVACIC: Good morning. My name is Bill Kovacic, and I'm the General Counsel of the Federal Trade Commission. On behalf of the Department of Justice Antitrust Division and the FTC, I want to welcome you to the resumption of our hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy.

We resume after an absolutely wonderful week in February, when at the University of California at Berkeley, we had the benefit of extraordinarily insightful presentations by the academic community in the Bay area, and extremely important to us, from the business community that lives day in and day out with these issues. I want to repeat the thanks that we gave there to our hosts at the University of California at Berkeley for putting on such a wonderful setting for us to hold our hearings.

I have to emphasize to you, and I can't do it strongly enough, just how valuable it is to have all of our speakers here today. And I can't quite capture for you how grateful we are that in the spirit of the hearings today, they've thrown themselves into preparing so assiduously to give us the benefit of their thoughts.

We simply could not do what we hope to do without your extraordinarily generous contributions. We know you have many pressing demands on your schedule, and we are most grateful to you for carving out a half day or so to help us with this important project.

I simply underscore to you also that we are learning a great deal in this process. This is absolutely vital to the ability of our colleagues at the Department of Justice, to the Federal Trade Commission, and indeed to our colleagues at the Patent and Trademarklea T dew

months, and working indeed with the whole project team from the division and the Commission on this project, I can assure you that we are in very good hands.

So let me welcome you again, and to turn you over the Hillary. Thank you.

(Applause.)

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MS. GREENE: Thank you much, Bill Kovacic. First of all, I'm delighted to be here. The one caveat I'll put on what Bill said was these folks would be lucky if they were able to surrender just a half day to the FTC and get away for free. You know, lots of them have already come in and spoken with us. I've spoken to lots of them on the phone. They have sent in various publications that they have written.

And so the process is really ongoing. The dialogue is really ongoing. And this is just hopefully going to give you a very useful glimpse into what it is that we have access to in terms of all of these extraordinary people willing to share their insights with us.

With regard to the panel at hand, all of you who followed the hearings to date know that we typically organize each one of our sessions around a number of features. Sometimes it's along industry; sometimes it's along the type of legal issue. And then after we organize it in that manner, we try to have as many diverse perspectives on whatever the category may be.

invariably going to come up.

And before I turn to getting into some of the specifics that we discussed, I realize that despite Bill's generous introduction of me, I failed to introduce the people who have really made this possible.

First of all, to my left, we have Ed Polk, who is the Associate Solicitor at the U.S. Patent and Trademark Office. And this is, I think, the second time Ed has joined us on a panel, and we're grateful to have you here. And I'm really looking forward to your questions, because I'm sure lots will come up that you'll want to question.

And then to my right, we have Bill Cohen, who's the Assistant General Counsel for Policy Studies. And then to his right, we have Frances Marshall, who's leading the charge from the Department of Justice. She's in the Office of Legal Policy.

And so we are all collectively delighted to have you here.

Getting back to that nasty little question of what exactly is the panel about in terms of specific topic. The conversations that I've had with all of the people here, as well as the conversations we've had more broadly, may start at one spot and end at different spots. But invariably, they encompass three elements.

And it's upon those three elements I've asked our panelists to focus, the first of which is looking really at the granting of patents: the application process, the quality of the patents granted, those types of issues.

The second is once a patent has been granted, what can you tell us about how it's used or abused within the economy?

And thirdly, we all wanted to step back and look institutionally at the system. And it's a very complex cast of characters. We have multiple agencies, we have lots of goals, et cetera. And we have the legislature, the executive independent agencies, and the judiciary, obviously. And with that complex cast of characters, throw that into the mix, and then what does that tell us as an antitrust agency as to what we should be doing?

From this, we hope to better understand the role that the competition agencies can play, either in terms of policy or in terms of actual enforcement. And though

do justice to them, but we've got to leave some time to

Mr. Love has been an invited expert on intellectual property and economist issues in forums organized by the World Trade Organization, the World Intellectual Property Organization, and other global organizations. He has advised several national governments and NGOs on national policies on intellectual property.

And then we have Ron Myrick, who is the Chief Intellectual Property Counsel for General Electric, and was formerly a principal of the law firm Fish and Richardson. He is active in many industry and bar associations, including he is currently the President-Elect of the American Intellectual Property Law Association, and the immediate past President of the Intellectual Property Owners Association and Chair of its Amicus Committee.

And last but not least, we have Cecil Quillen, who is a Senior Advisor with Cornerstone Research, an economic consulting firm. Cecil held a number of posts prior to joining Cornerstone Research, many of which were at Kodak. While at Kodak, he was the Patent Section Manager, the Licensing Manager, the Director of Patent Litigation, the Director of Antitrust Litigation. And I'm assuming because you ran out of things to do, they made you General Counsel. He has spoken and written widely on innovation and the U.S. patent system, and has

testified at the Patent and Trademark Office Public Hearing concerning the non-obviousness standard, and has served as a guest lecturer on patent strategies at the Wharton School of Business.

Okay. We have lots of folks, lots of information. Why don't we start in with some

MR. MYRICK: Thank you very much. Good morning. As you've been told, I'm Ron Myrick, and I'm very pleased to be here to offer my own perspective on what was characterized as the real world experience with patents. I'll dispense with any remarks about my background, as you have heard my resume from Hillary, and it's also included in your materials.

I am appearing, though, today before you in my personal capacity to provide whatever insights I can based upon my experience in intellectual property over the last 30-some-odd years.

Let me begin by commending you for seeking the views of the business community and the IP and Antitrust Bars on the issues to be addressed in these hearings. Hopefully, we can provide some useful real world experience for your consideration.

I start with the basic proposition that I see no fundamental crisis in substantive patent law, or in the interface between IP law and antitrust law in this country. In my view, the relationship between the IP laws and the antitrust laws is not out of balance, and should not be modified through changes in antitrust law enforcement. Rather, to the extent the changes to the IP system may be warranted -- and I have some suggestions in that regard -- those changes should be accomplished

through legislative modification of our IP laws and improvements in the administration of those laws.

Systemic substantive IP changes should be made, in my view, by Congress, not by using the instrument sometimes referred to as the blunt instrument of the antitrust law enforcement. I would not characterize it so just now.

Before stating my own recommendation for changes to the IP system, I would like to briefly address several areas that have been identified by others as causes for concern. In my view, these concerns may be somewhat overstated and do not justify using antitrust law enforcement to fix perceived inadequacies in our system of IP laws.

Concern has been expressed about the quantity and quality of patents issued by the U.S. Patent and Trademark Office, the agency responsible for reviewing and processing patent applications filed in this country. There is no question that the PTO could use and should have additional resources to assist it in speedily and effectively carrying out its mandate to insure that newly-issued patents satisfy the statutory requirements of novelty, utility, and non-obviousness.

In fact, I see a looming crisis in the ability of the PTO to administer the patent laws in a timely and

effective manner. The crisis is caused primarily by Congress's persistent efforts to withhold a substantial portion of Patent Office fees from the Patent Office budget.

The PTO is entirely supportive of the fees paid by patent and trademark applicants that receive those taxpayer funds. Without proper funding, however, the PTO's ability to process patent applications and to issue valid and enforceable patents on a timely basis, or to deny them timely, has been and continues to be threatened. I urge the FTC and the Antitrust Division to add their voices and their unique perspectives to the ongoing battle for proper PTO funding.

The priorities of the PTO should be -- and I have to congratulate the PTO on saying they are -- quality, pendency reduction, and digitization and modernization of their processes. That's laudable. They have their priorities in the right place.

In my view, the increase in the number of issued patents in recent years is attributable to three factors, none of which is a cause for great concern. The first factor is the increasing importance to businesses, investors, and even now, securities regulators of patent protection. Patents play a critical role in the competitive environment for new technologies.

The second factor is the increased uniformity and certainty of patent law that has resulted from the establishment of the Federal Circuit. It is true that the CAFC has upheld the validity of a higher percentage of patents than many of the circuits did in the past, some of which seem to adopt the view that all patents were invalid.

But while the CAFC has brought balance and improved jurisprudence to important areas of patent law, such as obviousness, it would be a serious mistake to view the Court as a captive to patent holders. Indeed, the Federal Circuit's recent decision in Festo, which

generally. And that has been a benefit to our IP system, not a detriment.

A third factor fueling the growth of patents is the stakes, of patent litigation. The value of patents is often realized through royalty-bearing licenses, but on rare occasions, a patent dispute actually gets to trial. Actually, in my written remarks, you'll see the number of trials last year was 52 in this entire country. At least that's the data I have. That's a small number of trials.

The very size of the stakes in patent litigation, both with respect to what patent owners may stand to gain and what accused infringers may stand to lose, had put a premium on effective patent protection for inventions.

I do not think that any of these reasons for the increasing number of patents should cause great concern. We must consider that patents do not only provide encouragement above and protection for innovations by granting exclusionary rights; they primarily are intended to insure public disclosure of inventions. The alternative to more patents is more reliance on trade secret protection.

Patenting thus serves the public interest by encouraging still more innovation, which in turn must be

publicly disclosed to be entitled to patent protection. This is a cycle to be welcomed, not feared.

Moreover, while I believe the USPTO can do a better job regarding the quality of its work, I have not seen sufficient evidence to suggest that the overall quality of patents issued by the office is poor. Some are; most are not. What the press picks up is always those that aren't.

The application of modern sixth-sigma quality methodology to PTO processes could afford a significant improvement in quality and reliability of the examination and issuance process. That effort should be funded, along with the modernization of today's paper-based patent application processing techniques.

The business community, antitrust enforcers, and members of the IP and Antitrust Bars must share a common interest in a properly-funded PTO, one that can expeditiously and rigorously review and process the large number of patent applications. A PTO with the resources it requires will simultaneously serve the interest of those concerned with strong patent protection, and those concerned with encouraging competition and innovation.

Before I leave the subject of the proliferation of issued patents, let me briefly address the concern that some have raised about "patent thickets." This is a

term that is sometimes used to refer to a large number of blocking patents in a particular industry. While it may indeed be difficult to navigate around a multitude of patents, it seems to me that the benefits of having to go to the effort to innovate in this context are often overlooked.

Blocking patents force innovation. Absent blocking patents, it would be easy to compete using existing technology. In a short run, such increased competition may lead to lower prices and more competitors. But in the long run, technological progress is encouraged by blocking patents.

And all of society is the better for it. Even an industry such as the computer industry, where blocking patents are alleged to have hampered competition, the staggering rate of innovation and new product development is powerful empirical evidence that the patent system works without untoward effects from a patent thicket.

I believe that some of those who have expressed concern about a patent thicket and about so-called paper patents -- that is, patents covering inventions that the patentee does not himself manufacture -- are trying to re-balance the system of incentives created by our patent system to value the patents of some inventors more than the patents of others, particularly more than small or

academic inventors. This is not the proper role of the antitrust laws, particularly because these small inventors can rarely be considered to have the market power that is the proper concern of the antitrust laws.

To the extent that patent thickets do present a problem, there are legislative solutions, including, one, expansion of the prior user right to all patents, not just patents on methods for doing business, and elimination of the one-year prior use limitation applicable to such a right.

Two, elimination of the right to opt out of the requirement that patent applications be published at 18 months, and the requirement that patent applications be processed either by granting or denying the patent within 18 months, or some other suitable period deemed reasonable by Congress.

Three, adoption of a first-to-file patent system, admittedly controversial, but as an adjustment to the patent thicket problem, a possibility, which would increase incentives for inventors to file patent applications promptly.

Let me turn to some recommendations that I believe would promote certainty in the IP laws and balance between the goals of the IP and antitrust systems. Certainty and clarity of the rules that govern

IP protection and antitrust enforcement are critical to the continued investment and innovation that the patent system rewards and that ultimately benefits us all.

First, lingering uncertainty remains in the case law concerning whether patents confer market power. As the IP guidelines recognize, such a presumption of market power simply makes no sense. There may be hundreds of patents for mousetraps, each claiming an improvement over its predecessors. But I dare say that none of them confers market power on its own.

In order to remove uncertainty in this area of the law once and for all, I would urge the FTC and the DOJ to support efforts in Congress to make clear that ownership of patents should not create a presumption of market power.

Secondly, intellectual property owners need certainty in a related area: clarification of the right to unilaterally refuse to license lawfully-acquired intellectual property, or license it under certain limited terms.

The essence of a patent is constitutionally based and is the right to exclude others, which the patent laws in the Supreme Court have long recognized. It is not the grant of a mere right to remuneration for the use of the claimed invention. In this context, the

disagreement between the Ninth Circuit, as expressed in the Kodak case in the Federal Circuit, as expressed in the Xerox case, is concerning the possibility that a refusal to license may constitute misuse, or an antitrust violation fosters uncertainty among IP owners as to the proper boundaries of their rights.

It would thus be helpful for the unfortunate agencies to make clear that Section 271(d) of 35 USC, which provides that a refusal to license is not misuse or unlawful extension of the patent, and applies to both antitrust and misuse claims, and for Congress to make it explicit that a mere refusal to license a patent cannot violate the antitrust law, just as it cannot give rise to a claim of patent misuse.

In closing, I wish to emphasize again that fundamental changes in the relationship between the IP and antitrust laws are not warranted by what I see happening in the real world. The patent system continues to fuel innovation and technological advancement, and antitrust enforcements should not be used as a blunt instrument to effectuate changes in the IP systems where improvements are needed. Instead, appropriate changes in IP laws should be made directly by Congress, and the proper administration of the patent system by the PTO should be supported by proper funding.

Thank you for your attention and the opportunity to present my views. And I am submitting more complete written materials. Thank you.

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When you take into account what the Federal Circuit is doing, and the lowered standards, all of a sudden, you discover that you've got to file a whole lot more patent applications in order to carry out the preemption strategy, which, as I indicated, is essentially a universal strategy followed by innovators. Your costs have gone up, and it's that simple.

The effect can be seen -- it's quite dramatic in terms of the growth in application filings. You can see it starts in 1983. 1983 is the first full view -- these are Patent Office fiscal years that begin in October of '82, which is when the Federal Circuit began working. And it's perfectly obvious that innovators, in order to file and preempt others from getting patents, they've had to increase their filings from maybe a hundred thousand in 1983 to nearly 300,000 in the year 2000, which is the last year for which I have statistics.

The study that Brian Hall and Rosemarie Ziedonis have done in the semiconductor industry determined that there was a doubling of the number of patents in that industry between 1982 and 1992, although I think each -- Rosemarie will be here tomorrow, and she can answer her own questions. But I think their finding, essentially, was that the filing was not motivated by any increase in innovation or invention, that this was simply necessary

consider the evidence collectively. I'm not quite sure how you consider the evidence collectively, but the effect, of course, has been to increase the cost of patent litigation, and to make extremely difficult the giving of advice.

The increased uncertainty was well-illustrated in our Polaroid litigation. The litigation started with 12 patents. Ten were tried. We lost on 7 of the 12. That's a 4/17 batting average. The Court was called on to critique our patent clearance process, and ruled that our patent clearance process could be a model for what the law requires.

Mr. Myrick mentioned sixth-sigma technology, and I can assure you that a 4/17 batting average for a model process doesn't qualify for sixth-sigma technology.

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announcement of the $909 million judgment. And that increase, of course, means the cost of capital for the Kodak Company suddenly went down. And it's probably close to a hundred basis points that it went down.

So the effects of the uncertainty on hat

The total number of applications is there. It goes through examination. Maybe you get it allowed and file a divisional, which is permitted by the statute, or a continuation in part. Maybe you're unhappy with the outcome of the examination. You refile, abandon, away you go.

I worked on a case two or three years ago where the patent was granted on the sixth filing. It was an original filing and five successive refilings. Mark Lindley and John Allison, in one of their papers, report having looked at a patent that was granted on the ninth filing.

The point of this is that the Patent Office, in reporting its statistics in their annual reports, does not mention the existence of continuing applications, and so it is not possible from the annual report statistics to, in fact, determine the performance of the Patent Office.

I was fortunate a couple of years ago in getting data from the Patent Office as to filings of continuing applications for their 1993 through 1998 fiscal years. And Slim Wexter, who was Chief Patent Counsel at Kodak at the time -- I was the company's General Counsel -- and I worked our way through the numbers, determined two performance measures for the Patent Office, one of which

is the grant rate, which is published on the trilateral web site. And it's simply applications allowed by application disposals. The other we determined was allowance percentage, which is applications allowed divided by applications filed.

But with the data we got, we were able to correct for continuing applications, those that were refiled going around again. And the results that we got -- which this is a published study that was published in the Federal Circuit Bar Journal this fall, their August 2001 issue. And as you can see, if you base it simply on the grant rates, which are the published figures, you assume that all of the refiled cases were starting over again. That rate was 97 percent. And you work your way down to this other series of assumptions: European Patent Office, 67 percent; Japanese Patent Office, 64 percent.

So it's quite obvious the ultimate examination in the U.S. Patent Office is less rigorous than in the other patent offices. Same results when you calculate allowance percentages, which is, again, applications allowed divided by the number of original applications, and depending on how you define it.

The most interesting thing, there's a study of the German Patent Office that was done by Mike Shara and

rolling average to recognize the fact that a two-year pendency period is really an approximation, and if you look at the time frame.

So there are a number of implications in this that are discussed in the paper, and the paper is available on the web site.

MS. GREENE: Thank you very, very much. And now we're going to turn to Lynn, who has props.

MR. ALSTADT: Good morning. I appreciate the opportunity to participate in these hearings. Throughout our nation's history, there has been a tension between the patent laws and the antitrust laws. The patent laws grant inventors of a patentable invention the right to exclude others from making, using, and selling and importing his or her invention for a limited period of time in exchange for disclosing that invention to the public.

Some have called this exclusive right of monopoly. The antitrust laws, of course, were enacted to prevent illegal monopolies and promote competition.

There's been a continuing debate over whether the patent laws are stifling competition. Those who argue in the affirmative went to Microsoft and others who have patents on widely popular technology and then they urged a tightening of the antitrust laws limit or avoid

what they see as the evils of the patent system.

I disagree with that point of view. The patent laws encourage competition in many ways and provide the proper incentive for the development of new products.

I come here today to offer some real world examples, and I also come to encourage that no significant changes be made in the antitrust laws relative to patents or in the intellectual property antitrust guidelines, particularly as they relate to licensing.

I'm a registered patent attorney who practices in a large general practice firm. We have a diverse client base ranging from individual inventors to large institutional or multi-national corporations. I'm also an adjunct professor at the University of Pittsburgh and Duquesne Law School, where I teach a patent practice course. Each year, I teach several continuing legal education courses, and have done these things for over 20 years.

I usually begin my courses with an explanation of the reasons that our forefathers created the patent system, because I think it's helpful to have that

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Furthermore, the inventor must fully disclose his or her invention in a published written document called a patent. The hope was that the disclosure of the invention and the limited exclusive would encourage others to learn from that disclosure and improve upon it, and then we would have a system of disclosure, invention, disclosure, invention, improvement. And this continuing process would enable our society to advance, and I think that's precisely what has happened.

We should recognize that there's one very important difference between the letters patent issued by the feudal king and our patent system today. The king's letters took from the public what otherwise weren't patent available to them. Whereas the United States patent gives to the public something that is new and not previously known to the public.

Let me give you some real world examples of how the patent system has encouraged the invention and created jobs for Americans.

One of my clients is a small company in Portersville, Pennsylvania, which is a small town north of Pittsburgh. The company makes suction cups, which are brought here, and clips and hooks like this clip here, refrigerator magnet type clips. Their president has created some innovative designs from these molded

products. All or nearly all of our client's competitors no longer produce molded products in the United States. They moved their manufacturing to China and the far east. Yet this company continues to make high-quality products in Pennsylvania that have been quite successful.

The reason for that is the company's patents have prevented competitors from copying the client's innovative designs, and have kept jobs in Pennsylvania. These jobs are not limited to the employees of Adams Manufacturing. They're also jobs that suppliers as well as retailers and service providers in the town that have as their customers Adams employees.

I have another client in the toy industry. About 20 years ago, a competitor introduced a miniature battery-operated car, of which I have one here. The competitor obtained a patent on that car, and the patent related to the position of the battery, which is on this portion, and the motor, so that the car was balanced and children could play with it. It would climb over obstacles they put in its path without tipping over.

Our client wanted to sell a similar vehicle, but did not want to infringe the patent. So he had his engineer design a miniature toy vehicle, which is this little one, that did not infringe the patent. And, in fact, they created a different design with a different

battery placement and motor that enabled them to get their own patent.

I can tell you that absent the patent on the original car, my client would have had no incentive to design the new product, and probably would have just copied what had been available to them from the competitor.

I have another client in the metals industry. They're one of the few companies in the United States who are doing research to develop new corrosion-resistant and high-temperature elements. The cost to develop these new products is significant. Therefore, the company wants to be sure that a competitor will not simply copy a new product they have spent years and hundreds of thousands of dollars to create.

Well, they have a concept for a new alloy. They asked me to first determine if it would infringe another's patents, and also whether they can get their own patent protection for this proposed alloy. If a patent protection is not available, they usually will not make the investment to develop the product. The patent system provides to them the incentive to make the investment to create new and better products for their customers.

Now, while the patent system has fulfilled the

purposes for which it was designed, the effectiveness of the patent system depends upon the quality of the patents at issue and the speed and effectiveness of the courts in enforcing those patents. Here, there are many problems, but I think the solution lies with the Patent Office and the courts, not the FTC or the Justice department.

The lawsuit between Amazon and Barnes and Noble that was recently in the news illustrates one of the problems. As you may know, Amazon filed a patent application back in September of 1997 for its One-Click system for ordering books over the Internet. The patent issued on September 28, 1999, for a method and system for placing an order with a customer so the customer can complete a purchase using a single action. Amazon called this ordering system their One-Click system.

Since the information of the customer was already in Amazon's database, the customer could simply order the product by moving the cursor with his mouse over a display on the screen of the product, then click the mouse, and the order was placed.

Within weeks after the patent issued, Amazon sued Barnes and Noble for infringement. They alleged that the express checkout service used by Barnes and Noble infringed on its patent. The trial court agreed that Amazon was likely to prove infringement and issued a

preliminary injunction as the 1999 Christmas shopping season began. Barnes and Noble then had to change its ordering system to require the consumer to make multiple actions to place an order from their web site.

After two Christmas seasons had passed, the Court of Appeals for the Federal Circuit vacated the preliminary injunction on February 14th, 2001. The Appeals Court decided that Amazon's patent was of questionable validity, because the claimed method was similar to a CompuServe trend system and an August 1996 web basket ordering system. The patent examiner who had approved Amazon's patent application had not considered either of these prior systems for making orders.

Amazon and Barnes and Noble announced on March 6th of this year that they had settled their dispute. The terms of the settlement were not released. But when this suit was filed, it set off a firestorm of complaints about what was being granted in terms of patents in this field of technology. There was much criticism of the Patent Office for its inability to find the closest priority.

I could give other examples of patents that are issued in technology, in particular, computer-related technology, that simply were not patentable. Clearly, there are significant costs to competitors who must

defend themselves against infringement claims involving patents that never should have issued. However, again, I think it's the Patent Office, not the FTC or the Department of Justice, that should be addressing the problem. And, in fact, I believe they are addressing the problem. They're making efforts to improve the search capabilities of examiners. They've hired and are training examiners who are knowledgeable in these technologies.

Finally, I would like to comment on the antitrust guidelines that are in place concerning licensing. I think the Justice Department did a service to all of us in providing some guidelines concerning the use and licensing of patents. When these guidelines were introduced, my colleagues and I took time to read them and understand them. We attended continuing education programs that presented and discussed the guidelines.

Many of us in the profession have advised our clients concerning proposed licenses and other business arrangements based upon these guidelines. Consequently, there are thousands of licenses, contracts, distribution programs, and other practices in place that meet the current guidelines. And indeed, many of them were put in place specifically because lawyers had told the business people that the proposed practice could be adopted.

Therefore, I encourage the Justice Department and the FTC not to make significant changes in these rules. Such a change would have widespread implications and cause many businesses to incur substantial costs in reviewing and perhaps changing existing business practices.

And I thank you for the opportunity to be here. I'm glad to participate.

MS. GREENE: Thank you very much. Thank you all

that you have a chain of disclosure, improvement, disclosure, and improvement. And in a minute, I would like to throw that open so that other people can comment upon whether or not they think that's the dynamic that occurs.

The other issue that clearly was raised was the role of the Court of Appeals for the Federal Circuit, and the impact that the Court of Appeals has had on both things that are more unique to patents in terms of patent standards, and whether or not it's impacted the -- whether it's raised or lowered the bar. And then also more directly questions of what happens when competition claims are joined with the patent claims, and then appear before the Federal Circuit.

And then lastly, something that I know that lots of folks will touch on, but that Ron has really gotten us off to a running start with, is a few of those legislative proposals. Ron has mentioned just a few. And they are very controversial, and I look forward to hearing what everybody has to say about them. And I can assure you that they're part of sort of the ongoing dialogue, and will be reappearing in other sessions as well.

So with that, let me say that if you have a question, just turn your table tent to the side, or if

you want to make a comment, and we can take it from there. Anybody want to start? Ron?

MR. MYRICK: This reminds me of WIPO, where you do the same thing.

First a couple of comments, and I'll not take too much time with them. I know we have limited time.

Regarding the Constitution, you're quite correct that the Constitution does not provide many specifics, except it provides one. It provides for exclusive rights. That's explicit. So we shouldn't ignore that point.

As far as determining whether or not the system really works, I best would judge that from the empirical data of the United States economy being the most efficient and effective in the world, without question, after 200 years of this system, and it's not been harmed. In fact, I think one could say that we've done a pretty good job for it. I think Director Rogan spoke to this in his address at the beginning of these sessions.

As regard the Court of Appeals for the Federal Circuit, I would like to direct your attention to the most recent edition of the Antitrust Law Journal, which is newly out, and its entire journal is directed to the Federal Circuit and antitrust.

Interestingly, on page 665, there is an article

by Janicke, who drops a couple of footnotes, which I commend you to read, footnotes 115, 116, and interestingly, 117. In 115 and 116, he differs with Mr. Quillen in regard to -- may I call you Cecil?

MR. QUILLEN: Sure.

MR. MYRICK: Thank you, Cecil.

MR. QUILLEN: Everybody else does.

MR. MYRICK: He differs with Cecil on the numbers. He cites the following: "One critic, Professor Merges, says the percentage of patents being held valid five years after the Court's creation was about 45 percent." And that's 115. And then he cites 116, which had varying numbers, somewhat higher, I must add.

But most interestingly, the discussion of 117 is particularly significant. It says, "See the web sight dah-dah-dah-dah-dah listing the numbers of the Federal Circuit patent infringement decisions for the year 2000 favorable to the patent owner or favorable to the accused infringer. Patent owners won only 12 decisions in the literal infringement area, while accused infringers won 47. On the infringement under the Doctrine of Equivalents, patentees won five, while accused infringers won 44. Now, is that a patent-favorable court? I question it."

As respects other issues, I would say that the

Court has demonstrated its objectivity in the extreme with the Festo case. And that's going to be reviewed by the Supreme Court.

But also on this issue, which I think probably, Cecil, really fits something you should speak at the upcoming oversight hearings of the PTO and the Congress.

issue. I think for the purposes of these hearings, much of what we were discussing really is interesting, but they're not antitrust issues. What goes on in the Patent Office should be addressed by the Patent Office and fixed in the Patent Office. Recommendations from this body to

And I think that piece of it is a very important role that the FTC and Justice Department should be definitely involved in.

In fact, as you'll see in my written remarks, I even suggest a role, perhaps, that could be in place for the FTC and the Justice Department to bring to the attention of the PTO in post-grant review proceedings, problem patents that they think should be reviewed. I see no reason why that couldn't be something we could install. It's certainly, you know, a *Parens Patriae* type of authority. The Justice Department and the FTC could exercise that kind of a role. But they should provide that -- they should initiate that proceeding in the organization with the primary jurisdiction over patents, and that's the PTO.

MS. GREENE: I have a completely vested interest in this comment. I also recommend to people the Antitrust Law Journal issue you brought to their attention. My disclaimer is that I'm on the board of the journal. But what I would also urge you to do is actually to read the articles because there are a number of different perspectives on the Federal Circuit. And while Professor Janicke makes some excellent points, they are contested and statistics are addressed throughout, as well as in multiple other sources.

Let me turn now to Ross.

MR. QUILLEN: A quick comment. The best source I know for numbers right now is the John Allison/Mark Lemley paper, "Empirical Evidence on the Validity of

you can find another way to reach that market, then you've made a major advance.

Carrying this to thickets, I would like to build on your sixth-sigma suggestion for the Patent Office. For those of you that maybe you're not familiar with that concept, sixth-sigma is a quality methodology, pioneered in large part by G.E., but now used quite broadly.

Just last night, someone said to me, "But that's no different than the total quality management thing that was going on maybe five or six years ago," and actually ten. My comment to him, because I hadn't thought about it, was that the difference between sixth-sigma is that it set a totally new set of standards that you had to go after. Total quality management was incremental improvement. Sixth-sigma says, "Get to where you really ought to be now, and find an innovative way to do it."

A patent thicket operates on a man's or woman's mind the same way sixth-sigma does. You look at that thicket. Instead of having the single pattern saying, "Okay, I'll figure out that principle," you now have to say, "Wait a minute. I've got this barrier here."

principles when you see where other people are working.

And now on the other side, the person who's building the thicket, if you come up with a technology -- and I'm just talking in the terms of a plane -- the technology covers one piece, on a platform like this, of value. It's absolutely imperative that you cover the rest of this plane, because someone could come with another technology to do the same thing. So you build your thicket when you're on a level surface that you talk about, say, a technology spike.

If you have a technology that is so unique that other ways to the marketplace are not going to give you the same value, you don't worry about building that thicket.

So there are reasons for building the thicket. And in every case when you put a patent in as a part of that thicket, you are fully disclosing the thinking that went behind it, and that will cause someone else to find another way to extend that plane.

So there are advantages to thickets from the person that's doing it, and disadvantages, and it has to do with the disclosure process.

I'll make one comment on the circuit. I did go out and poll some of my members as to what they thought, and you mentioned that this would be brought up. And I

would have to agree with Ronald that my membership -- and probably not having the advantage of your data, Cecil -- said that it is their feeling, and they are acting as if the circuit has brought a lot more stability and predictability to the patent process. And that was universal across industries.

The last comment, again on the PTO, it is believed by the membership that if the PTO was able to use the funding that it generates to improve its processes to give examiners a chance to continue to educate themselves on the leading-edge technology, then the concerns that we have about inconsistency sometimes in the granting of patents could be greatly alleviated, and that possibly the wrong metrics are being used to drive performance at the PTO.

MS. GREENE: Brian?

MR. KAHIN: Well, I will have a lot to say about that last statement, and I agree with it. Let me say that my industry background here is that for 10 years, I was General Counsel of the Interactive Multimedia Association. And in that position, I would like to go around asking people, "Do you read patents? Does your attorney recommend that you read patents in your field as they come out?"

And the answer to the last question was, if I

have to do a full-blown gazillion-dollar, gazillion-year antitrust case in order to get a compulsory license granted, or could we vest government agencies with much lower burdens in terms of stepping and doing obvious stuff to protect the public interest?

MS. GREENE: Joanne?

MS. HAYES-RINES: Thank you, Hillary. Being now the spokesperson here for the independent inventor community, I wanted to talk a little bit about quality, and what do independent inventors think about patent quality.

For the sophisticated inventor -- and this is someone who is maybe a professional product developer -- patent quality is extremely important. I polled some through the Internet, polled some of the folks who have signed up for my e-mail alerts, and I asked, "What do you think about patent quality? Is it important?" I got some answers back like, "Are you kidding?" I said, "No, that's the question they're asking."

And one man, Peter Theis, who is the inventor of interactive voice response and natural speech technology, has had his own challenges with the courts and with his patents. And he says, "Without patent quality, a patent is only a means to rip off the independent inventor and fleece investors. And the PTO today is the stereotype

for the expression, 'I'm from the government and here to help you.'"

In his opinion, the most basic fundamental step for the Patent Office is to keep track and keep records of what the courts do to the patents that are issued. A quality control system has to be implemented so that the inventor and, very importantly, the investors can know that there is some hope.

Another inventor, Ph.D. Richard Holope, with Magicolor, out of Rochester, New York, says, "I think an important factor in patent quality is to make sure that the core of examiners is as good as possible, and that the examiners are not completely overburdened. Improving wages and working conditions would help with the former, and insuring adequate staffing can help with the latter, which has a lot to do with working conditions. All of the foregoing goals would be greatly advanced by making sure that the fee income to the USPTO is not siphoned off for governmental purposes. I resent the idea that as an independent inventor and entrepreneur, I am paying indirect taxes, whose effect is to reduce the quality of services that I intended to pay for."

That's a very big response from independent inventors and small businesses, and obviously, from corporate America, that the inventors are paying, patent

applicants are paying, a fee for services. This is not an additional tax that the government has a right to. So we have those folks, the sophisticated inventors who are developing for products.

The other end of the spectrum are the newbies, somebody who working on a Saturday morning in the yard or working around the house gets an idea for a new product. They've solved the problem that they have. They are very vulnerable. Because most often, they don't have an experience in developing a product. They don't know anybody who has ever done it.

So to their chagrin for years, if they're up late watching television and listening to the radio, they hear one of these ads from an invention marketing company. "Do you have an idea? Do you have an invention? We can help you. And the more money you have in your life insurance or the more equity in your home, the more we can help."

them at the Patent Office, the only organization that looks at these applications -- and believe me, they're worthless. Someone who has a new engine, it should be a

encourage them to look at the patent files, because first of all, it's an education. They don't even know what a patent looks like when they start out, most of them. But beyond that, they see what else has been developed in their field, and they're encouraged to out-invent themselves, come up with an idea. If you've really got a good idea, how can you make it better so that it will stand out in the marketplace?

Ron made a comment about small inventors rarely having the market power to justify the concern of antitrust laws and agencies. And I would agree with that for the newbie, the small, the person who is just doing maybe one product just starting out. But when people really have a good idea for a product, and they can get it licensed or make their own business around it, they stop being a small inventor. That's how they started, but that's not where they're going, hopefully, in the future.

I was on the airplane flying down from Boston last night, and I picked up Sky Mall. And as I started flipping through it, I thought I had to rip out some pages. You've probably all seen the "Evacuate," this kind of strange-looking thing. But we know now there's a real need for it. In case of a fire, it will give you oxygen. I know the independent inventor who came up with

that product and got it on the market.

We've got Sky Roll, which is produced by Magellan. It's a duffle bag that has a travel bag wrapped around it, over your shoulder, has the core inside. It's hollow. You can put in your shoes and toiletries and all. I know Don Churnoff, who invented this. He lives here in Virginia. And he got it licensed to Magellan. He by himself is not a market power, but Magellan certainly is.

MS. GREENE: And we're going to switch gears. Because I notice that Ed, while you were talking, was nodding his head, I think in agreement in some instances, and perhaps --

MS. HAYES-RINES: You got a feeling for what I'm saying.

MS. GREENE: We do. Thank you. And so Ed, can you --

MR. POLK: No, just to piggyback on what you said as far as the -- of mission corporations. I definitely wholeheartedly agree with you there.

The office I work in at the PTO, that is one of our responsibilities. I'm one of probably six attorneys in the office who do go after those individuals. We bring charges against them. So we have six of us against a group of corporations that are doing that. And there's

themselves came up with. That was something that's imposed by the Supreme Court in Graham v. John Deere. That's not something --

MR. QUILLEN: Excuse me. In the Graham case, they were at conditional relevance. Nothing to be considered in the absence of doubt. And the Federal Circuit has mandated their consideration.

MR. POLK: And, if I remember the reading, Graham agreed to a secondary consideration of the presentation, be considered.

MR. QUILLEN: That's not what Graham says.

MR. POLK: Maybe we should go --

MS. GREENE: We'll agree to disagree at this point.

MR. POLK: Yeah, I'm going to agree to disagree on that. But as far as the other thing you said as far as continuing applications, it's just two points. One, maybe I just didn't follow what you were saying there. One, I don't necessarily see the problem with continuing applications, as opposed to maybe the drain on the resources. Yeah, I agree with that. But as far as the problem, I don't understand what the problem is.

MR. QUILLEN: The Patent Office is not in the position of being able to force a final decision. The persistent applicant can always avoid the final decision

by refiling. If we're concerned about quality in the Patent Office, we ought to arm the Patent Office with the weapons it needs to do its job.

MR. POLK: Okay, yes. Maybe I just didn't follow that. But as far as your statistics when it comes to the allowance rate, the continuing application seems sort of counter-intuitive to numbers that you've got there. Again, maybe I didn't understand it.

If you are saying that the continuing

ithdn't 10fol5er application somehow **raids** the allowance rate, I didn't

that looks like a 16 percent allowance rate, because there were six filings, five abandonments, and one grant. And that's one patent per original application, although it went around in a circle six times before it finally dropped out.

MS. GREENE: This raises some really good questions about what data is available, how is the data interpreted. Obviously, one of the entities that could be providing some insights into the impact of the patents on competition is the Federal Trade Commission, or other agencies. So I want us to be included in the mix in terms of what additional types of information is it that you would want.

We've got a lot of empirical questions that are lingering out there with question marks. They may be question marks because we can't ultimately come to a clear answer, or because we may not have assembled the data in a way that it can be used. So that's something that I just want to flag more generally, because I doubt we'll be able to settle this here. Ross?

MR. ARMBRECHT: Just a few comments. One is on the continuation in part in refiling, and with respect particularly to the foreign offices that you mentioned. And this is purely anecdotal in my own experience, but it has to do with whether to continue to try to push for a

MR. COHEN: Before we leave the area of continuations, I would like to flag one issue which I know Cecil has raised in some of his written statements. You've talked a bit about the possibility that continuations can be used in ways to I think you used the word "ensnare" these post-initial application developments by making changes to the initial application after the fact. You were able to bring in -- extend coverage to something that the competitors have done.

Could you elaborate a little bit on this? And I would be interested if anybody at the table sees this as a substantial issue or a substantial problem.

MR. QUILLEN: You mentioned Mr. Lemelson earlier in the day, and Mr. Lemelson without a doubt was the most accomplished practitioner of the practice of -- I guess I should adopt Carl Shapiro's jargon rather than mine -- of issuing hold-up patents. And he would start with a very broad disclosure and keep it alive by filing continuing applications. And as people came along and commercialized products, then he would shape his claims so that he had an opportunity to claim them.

So as far as I know, none of the Lemelson patents have ever been litigated to a final determination of leading an infringement, but essentially served as extortion troops to make a lot of money for the late Mr.

Lemelson.

I suspect that anybody here who was ever in active patent practice has had this done to them. I know I have. And I suspect some of us may have done it to others, although I'm not ready to engage in true confessions. But it's a common practice, and some people are more skilled at it than others.

MS. GREENE: Yes, Ron.

MR. MYRICK: If I may. I would refer you back to the testimony of Pauline Newman, because she addresses this issue, and what the Federal Circuit is doing in making it harder to do this late realization of what you had when you filed it 35 years ago.

But there have been some changes in the law since Lemelson started his escapades, and one of them is that the patent term is now based from filing date. So the submarine patents of yesteryear, and certainly of vintage '54/'56, which is Lemelson's date of filing, are passe, or at least they will be passe, based upon the fact that the filing date is the beginning point of the patent term.

So every continuation takes more term, and it takes more money; you have to pay fees. The Federal Circuit's determination laches in the Lemelson case is going to have a bearing upon that and the Federal

Circuit's more restrictive use or more restrictive approach to interpreting claims based upon "spec". It's going to be harder to originally file a specification. It's going to make it harder to do that in the future.

So these problems are being addressed organically as the law develops in the United States. Problems are perceived as being addressed. And I think that's important.

I would like to address a couple more points that were made earlier. One, I think the blunt instrument aspect that Jamie referred to in regard to a compulsory license after years litigation, I think, is exactly correct. And I think if there is to be a compulsory license approach, it should be adopted as a result of the social contract being changed by the Congress, as opposed to individual cases that have such difficulty, shall we say, proceeding through the Court.

So I think there is a -- it's exactly the kind of debate that should be had in the Congress. I think that Jamie is going to respond to that comment.

There was also another point in that if there is a blocking patent out there in this particular area, that "Oh, geez, that's bad." That's not bad; it's good. That's exactly what Ross is talking about. It causes that innovation to find their run.

particularly in favor of treble damages. And they certainly cause Corporate America a great deal of grief.

So I would say that that may be something that should be looked at. If that was what was causing your folks not to read their patents and learn and get the benefits of the system, maybe the system should take a look at that again.

Finally, I think that the one thing that comes out of all this that I've heard is that quality is critical, and that all of us, I think, agree that the PTO should be funded properly so that it does a quality job and has the resources to do a quality job. And the diversion of funds, or beyond the diversion of funds, we have now a new proposal to add a surcharge on top of the current fees of the Patent Office for further diversion of other purposes all wrapped in the laudable rubric of Homeland Security. But we cannot ignore the fact that patent system exists for the economic security of this country, and that is a very distinct part of Homeland Security. Thank you.

MS. GREENE: Thank you. And actually, what I'm going to do is completely revise the schedule that we had, because we have until noon. And I propose we just keep going, because it's only one more hour. If you take a 10-minute break, it will turn into 20 minutes, and then

we'll be shot to hell.

So what I would like to do is actually have

fees, the FCC's fees, and all those, they didn't get to -- what's that?

MR. MYRICK: The FAA figures.

MR. DELRAHIM: The FAA and a number of -- all the agencies, they rarely get to keep -- I think a very small percentage of the funds go to the general treasury.

But having said that, the PTO, it is an agency where it is for the inventors. They collect fees. They cost the general taxpayer, I believe, nothing, and it is just fully funded by the users of the office. And it is a shame that the money is being diverted for other general purposes.

It is a phenomenon of the Appropriations Committee, of which Chairman Muris is before today, probably being drilled on the FTC's and DOJ's agreement to create some efficiency and make some sense out of the merger review process, in our view, of how they go about and how they have divided the practices between them.

But the Appropriations Committee each year has taken some fees. And once you get to the end of the year and need to balance budgets, especially in a shrinking economy, there are pools and funds that they can reach into, and that's one.

Other areas have been, as many of you may be familiar, in the Hart-Scott-Radino merger review fees.

an agency should be looking at? The PTO? The Congress? A little bit of all three?

MR. DELRAHIM: This, I think, if there is going to be input from the public, needs to go to the appropriators, the subcommittees on Congress, Justice, and State, on both the House and the Senate. They are the folks who write out the checks to the agencies, and they appropriate the agencies and determine who gets to keep what.

And I think the authorizing committees, Senator Hatch, Senator Leahy, and on the House, Congressman Conyers, and including the Subcommittee on Intellectual Property in the House, Chairman Coble and Berman, both -- they all agree. They're all in agreement with respect to the appropriators keeping the funds. This is bipartisan, the approptrmineropat fully,

that the best quality patents or the best examined patents are not necessary for their social good. Because once you internalize externalities -- that means the cost you impose on others -- society will determine that the most efficient player will be appropriated the right patent. It does not seem to make a lot of sense intuitively, but there is an economic theory, and that is just basically, I think, pure economics, pure theory, and good for the academic world.

I think in the real world, a lot of people would argue that once you do see a patent -- folks from the private sector would be able to comment on this in a more educated way: whether you see a blocking patent, whether you still do it in the hope that social good would transfer those patent rights to you, or whether that would be a block from you continuing on in that market and perhaps going a different route of achieving those market objectives.

There is also Professor Lemley, who has argued that only five percent of patents issued by the PTO ever get litigated or licensed. So therefore, it's rational ignorance by the PTO to not focus more resources on examination, and allow for examination of only those patents that are litigated or licensed. I just throw that out there for other theories that Congress and other

folks do hear. But I believe this is one that's just pure numbers. It's just balancing the budget, balancing the appropriations, and making enough money for various pet projects that may be out there.

Other legislation that's before the committee -- and we happen to be in a unique position on the Judiciary Committee, both in the House and the Senate -- can throw back to the Senate of having exclusive jurisdiction of both the antitrust laws and the patent laws and other intellectual property laws. So we get to hear both sides, and the different perspectives from both competition policy and intellectual property policy.

The major debate going on in the committee deals with the sovereign immunity issue. It has not -- I don't know to what extent it has been a practical problem. We commissioned a GAO study that only reported back a handful of cases where the state has invoked it's Eleventh Amendment sovereign immunity right from lawsuits.

And let me just briefly get into that. That's from the Supreme Court's decision in the Florida prepaid case that held that Congress did not have the right or did not appropriately abrogate a state's Eleventh Amendment rights, and those rights being the sovereign immunity, from being sued in the federal courts.

And despite what some folks may argue, that this is a new phenomenon starting with the Seminole decision in 1996 that overturned Congress's enactment of the Indian Gaming Regulatory Act, it started back in 1985 in Atascadero, which was a case dealing with the Rehabilitation Act, where the Supreme Court said that abrogation of the Eleventh Amendment needs to be explicitly and unambiguously written in the statute itself.

In response to that, when there were some courts turning down some patent cases, there were some -- not a lot. In some cases, Congress enacted in 1992 amendments, both the patents and copyrights in other areas, where they did specifically abrogate the right of states and allowed them to be sued in court, deriving from its constitutional authority to enact intellectual property rights.

It was the 1992 amendments that were in question in the Florida prepaid case, both under the Lanham Act and the Patent Act. And that's where we are now.

So if you have a patent, and a state is infringing, and more and more, you see states involved in commercial activity, whether it's a genetics market testing lab or copyright uses for educational purposes, that may not qualify under the fair use defense. But

they can invoke the Eleventh Amendment.

The proposals before Congress range from a constitutional amendment. Could you imagine states enacting that? You would hope that they would, if you could find 37 states that would ratify such a constitutional amendment, assuming it gets passed by the Senate and the House.

MS. GREENE: Are there additional issues in addition to those of sovereign immunity that you want to flag for our --

MR. DELRAHIM: No, that's the only two. That's the last one. And the proposals that have been laid before Congress on that issue, one deals with allowing states to sue for damages on state-owned patents in exchange for them waiving their sovereign immunity, and the other one would simply not allow them to obtain patents from the Patent and Trademark Office unless they waive their sovereign immunity.

MS. GREENE: Thank you. And I know that you mentioned Lemley and his piece on rational ignorance, and I know that's something that Brian has given some thought about. So why don't we turn to Brian to give his presentation. And then after Brian, we'll have Jamie. And then we'll have a few minutes left to talk.

MR. KAHIN: I would like to have had a single

paragraph on Lemley. I don't have to say anything. I think an interesting question that might be raised about Lemley, while I entangle myself, is it possible that one would want to have a registration system for software, but not for other kinds of technology? Or business matters? It may be that when you get down to that level that a registration system does work better when there is a proliferation of information.

But in either case, it seems to me you have to address the presumption of validity. That's a major factor in determining whether the examination standard is correct. I have a few visuals.

Let me say, first of all, that I am going to focus my comments on some software patents and -- there we go.

MS. GREENE: I have no problem having the technology dictate the order of the presentation. Whatever we can find.

MR. KAHIN: Let me begin by saying that

administrator plays no further role, and can therefore be indifferent to how patents play out in practice.

So the USPTO was focused on its internal operations, rather than the proper functioning of the patent system as a whole. It does not engage an economist, and does not participate in mainstream debate on innovation and competition and economic growth.

The PTO is charged by statute with advising the President and the executive branch on intellectual property policy, and in practice, takes the lead in policy development within the administration. But instead of performing integrated policy research and analysis, the PTO has styled itself as an advocate for expanded rights, as shown by the performance goal in recent corporate plans, which, say, help protect, promote, and expand intellectual property rights systems in the U.S. and abroad.

The 2002 plan drops the term "expand" and introduces an element of balance for the first time. So you can see that in that second paragraph there, there is some configuration that it champions intellectual property rights and forges a balance between the public's interest in intellectual property and each customer's interest in the particular patent or trademark.

But in an operational level, the PTO's

set substantive policy, and points out that the policy is set by the Court of Appeals for the Federal Circuit, which has not been shy itself about expanding the scope of its jurisdiction and a certain confidence.

Much may be said about the influence of the Federal Circuit, but let me build on Cecil Quillen's observations with some figures reported by Glynn Lunney in his recent article, "E-Obviousness." He adds to the better-known figures on holdings of invalidity with information on obviousness as the grounds for invalidating.

So you see the middle line there is the patents held invalid. That's the figure that we've been talking about. But on the upper line, there is obviousness as the basis for invalidity. It's the proportion in which obviousness is the critical factor in holding the patent invalid.

And when you multiply Lunney's figures out, you get the bottom line, which is the frequency of appellate decisions in which the patent is e, there is r5 0 51p.75mbviousnes

be keyed to the creative and innovative individuals that the patent system is intended to incent. In other words, whether the PTO awards patents at a level which meets their standards of merit and practicality. Inadvertent infringement should become rare, and the risks that it creates should be manageable, even for small companies.

The ultimate test will be whether developers, rather than lawyers, choose to read the vTi-, be whetes.5

disputes over broadly claimed patents that would be too costly and distracting to contest.

This build-up of information and transaction costs favors large companies over small, because they enjoy economies of scale and scope in the management of patent-related knowledge, and can internalize and spread costs while maximizing revenues through in-house patent and licensing departments.

This high transaction cost of contesting patents has created an array of tactics that can be exploited against those least able to bear them. For a small company accused of infringement, the cost of a $10,000 license will look very attractive compared to a similar cost of securing an outside opinion on validity infringement that may still point to the need for a license.

As for going to court, consider the cost of litigating patents where the amount of dispute is under $1 million. These AIPLA figures for 2001 show an average of $499,000, up 25 percent from two years earlier. You double this to see that both sides will now on average spend more on legal expenses than the amount in dispute. And this calculus has changed substantially in the last two years. This is why so few cases go to court, not because there are so few disputes. Many are settled

because alleged infringers have no choice facing costs like these.

In conclusion, although the PTO is the only executive branch agency specifically charged with addressing intellectual property policy, intellectual property is far too critical to be left to an agency that styles and conducts itself as an advocate, and it measures its effectiveness by how *ex parte* applicants judge it, and how many patents it grants.

While I commend the Department of Justice and the Federal Trade Commission for examining the role of intellectual property and innovation and competition, this engagement should be continual and not occasional. The competition agencies can bring broad expertise to bear that will help provide an economic understanding of innovation that comes to grips with how it works for different technologies in different industries and at different points in the value chain. This must be based on a deeper understanding of how patents work in practice, and how the costs of evaluating and negotiating patents play out.

While neither Justice nor FTC are positioned to conduct extensive empirical research, they could be empowered to collect information that would help monitor this vast amount of economic activity that takes place

industries. There's very weak consumer representation, even within the government review process. And I think the FTC has to inform the United States Trade Representative.

There's actually a big debate on this issue in a different context right now. And to the extent they understand, there's a reason to be -- you know, not to put a strait jacket on countries would be good.

We think that not one-size-fits-all is wrong. We think these are just examples, as other examples. But certainly software business methods, surgical procedures, are examples of areas where the benefits of the patent system in these fields, in our opinion, are very weak, and I think the costs are great. And I think, you know, that society ought to be able to decide it's not a great system for everything.

I don't think we should be forced to choose the patent system as a method of funding innovation in every system. I think it should compete against other ideas in all of these areas.

And even when you do feel like maybe exclusive rights models -- I mean, patent system or some kind of incentive is -- you can see, for example, your research tools, biotech rights and data. A lot of people now are saying the exclusive rights model is not the right way to

think about this. You might think about liability

A lot of times, you shouldn't have to prove that the people who got in the dominant position, or whatever are creating the problems, are necessarily part of the Mafia or anything like that. You should just be able to prove that the consequence of allowing them to exercise their rights in an unfettered way is contrary to the public interest, more like the European approach in a lot of these things.

And I think that -- it also protects, I think, the inventors in areas that don't have things that are really challenging, big problems. Like, you know, say you've got a patent on a toy. Well, you don't need to drag out the compulsory licensing mechanism to the U.S. Government to solve that problem. But you might end up totally complaining about the whole patent system because you're unhappy with the impact on genes or something like that.

So the ability to distinguish, I think, benefits people that don't present these kind of social public interest products by providing a safety valve for solving these social problems.

The explosion of *sui generis* rates are a real big problem. There's been all these problems with the data exclusivity provisions, in our opinion. And the Hatch-Waxman Act has created a lot of problems, like in

the pricing of Taxol, the cancer drug. You have big problems with the orphan drug marketing exclusivity, which is a *sui generis* right, which companies gathered, then they used it to build up all kinds of patent thickets on process patents and stuff to maintain that forever. And then like Epigen, for example.

Then you have the pediatric patent extensions, which are a colossal waste, another thing that just extends the life of these patents. And you have all these sort of various proposals on data.

So basically, the patent system isn't even the first and last role about intellectual property rights. It's just basically like they got patent rights, you got contract rights, you got *sui generis* rights, you got everything you can pile on top of it. So it's basically this just sort of what can you get the government to do for us to basically protect the monopoly?

The Orphan Drug Act, I'm not going to go through all the data here before you right now, except to flag this data, which is to say we look at the tax returns on companies that filed the orphan drug tax credit. And you find on per approval basis for orphan drug approvals, they have to report how much they spent on clinical trials to get the tax credit. It only amounted to around, the last two years we looked at it, a little

under $8 million per approval, half of which is paid by the U.S. taxpayer.

So in the afternoon panel, when you get to the two times the gross national product of most countries is the cost of developing a drug, you might ask them how they reconcile that with what they filed their income tax returns for the orphan drug, and ask them to explain why it is that we have this multi-billion-dollar subsidy for orphan drugs, and their only -- you know, huge subsidies, and their only gain out of it incrementally after the tax credit an extra $141 million a year. Well, that's over two years, actually.

Some examples of some of the products that are qualified as orphan: Paclitaxel, which costs $4,000 a month for the rest of your life, a huge amount of trials not funded by the NIH; AZT; Epogen and Neupogen together generate over $3 billion a year, so there is a half

the benefits of the six-month pediatric extension for different blockbuster drugs. You have to realize the FDA guidelines said you have to do -- maybe 18 patients is the low end of the scale in a Phase II trial, which could cost you a couple tens of thousands of dollars in order to get these benefits. It just shows you the impact of consumers on these kind of monopolies.

According to their federal income tax returns, U.S. taxpayers pay about 7-1/2 percent of their sales on R&D, of which we probably care about less than half of that, because a lot of it's sort of "me-too" research.

The best study of direct development cost is done by the TV Alliance Report. If you read the report, it's very thorough. It has very detailed appendices. It actually breaks down the cost of drug development, even within clinical trials and things like this. And these are the numbers that it takes it at.

The Tufts number that you're going to have thrown around, those guys are industry consultants. They drag them out all the time to sort of prop up, you know, basic arguments. Incredibly ridiculous study they put out where they said that the average cost of clinical trials, $282 million before capital costs. And these numbers are a little bit more realistic.

The big issue in innovation, and I think Brian

brought this up, is the issue of -- you know, it's the way people are now thinking about innovation. It's not really so much that we're thinking about patents as being the be-all and end-all.

I mean, in the software thing, a lot of people were influenced by that. When Eric Raymond wrote this little article, "Cathedral and the Bazaar," it got people to think about how research and innovation actually takes place in part of these collaborative research laws.

The Human Genome Project was pretty interesting. This is a map of some of the people that participated on the sequence of the human genome. Now, if you look at this, you realize that not only a lot of players, but a lot of these people were doing this to prevent Craig Ventner from getting patents on human genomes, and basically, there's massive public and donor support to prevent a private party from getting a patent. And the pharmaceutical companies, they actually were cheering this on, because they didn't want anyone to get those kind of patents either.

But another thing that was taking place here was this idea, the thinking that biology is too complex for any organization to have a monopoly. When a company starts researching a new project, most research is being done by someone else. If there are blocks on the data,

they are held privately. Companies missed out on the analysis.

And so with fewer people blocking access, the data will have a less value. But the idea they had there was by putting the data out, sharing it widely, getting rid of the proprietary nature of the whole thing, and speeding up the time table on things, they essentially -- it was more of an open model to research. And there's a lot of belief right now that in the pharmaceutical area, this has become a really important thing.

On gene patents, his recommendation is -- Tim Hubbard was the number two guy in the Sanger Project in England that was doing the human genome sequencing, and he's really a person you might want to invite down the road. He's a very bright guy. Now, he just says they should allow sort of basic gene patents. And I'll let the patent lawyers here figure out where to draw the line on that. Or supplementary, make compulsory license easier, faster, and less costly. And I think a lot of us think that's really essential in that area.

And then I'll skip over this, except to say that we're involved in South Africa right now on the drafting of a complaint to create the equivalent of this kind of a patent pool compulsory license for AIDS drugs in South Africa. And one of the bases for that is the development

of fixed-dose combinations of drugs, which are important for resistance of AIDS patients. You can buy them in India. You can't buy them in South Africa. You can't buy them in 37 African countries, because GlaxoSmithKline has got patents on combinations of AZT and Combivir, and in 3TC, and other companies have patents on other things.

And so the combinations you want to make involving different companies' products, you can't buy, except for the Indian generics companies. And so the public health guys think those products are essential for easy compliance and lack of resistance. And so we're going to sort of follow the old FDR model in the South Africa case.

MS. GREENE: I'm going to just cut in here, because you're obviously focusing upon issues that are beyond important. I mean, they are literally life and death. And I don't mean to be giving short shrift to that, but we have a lot of additional comments.

And what I urge you to do, in addition to all of our panelists, is there's incredible information that everybody brings to the table that they can't even begin to present in the few minutes that they're slotted to give a presentation. And I know that Jamie Love and the Consumer Project on Technology, you have a whole section that looks at pharmaceutical issues and all of this type

of thing.

So I urge you to submit for the record, you know, links so that people can go and continue to look at that. And I know that we have several folks in the audience who will be on the pharmaceutical and biotechnology panel this afternoon with Robin Moore and Susan DeSanti. So I'm going to let them continue on, perhaps, some of the dialogue this afternoon, and we're going to switch back and let everybody get in a few more last remarks.

Okay. Oh, my. Where to begin. I know Makin might have a time problem, so let me turn to you first.

MR. DELRAHIM: Just one -- legislation. There's a number of issues, obviously important issues, that Jamie presents working for the author of the Orphan Drug Act and the Hatch-Waxman Act and a proponent of the TRIPS Agreement, and (inaudible).

But what it did remind me of, there is a piece of legislation that has passed the Senate, which I forgot to mention that has some specific bearing on grants and antitrust. It deals with pharmaceutical agreements between pharma and generic companies that -- which agreements need to be reported with the FTC now. Actually, it's passed the committee. It's pending on the seventh floor. It's a Leahy legislation. Senator Leahy

has worked on this. His deputy chief counsel has been intimately involved. Any comments you have, if you are not familiar with it, the next panel is intimately familiar with it. And you guys probably are.

But that's something that will increase your burdens, reviewing those agreements. And I think it touches on a lot of the issues with respect to antitrust agencies being aware. I'll just leave it at that.

MS. GREENE: Cecil?

MR. QUILLEN: As to reading patents, it was our practice at Kodak to make patents available to all of our scientific and technical people in the fields in which they worked, and they could subscribe to whatever they wanted.

Reading patents is mostly a matter of competitive intelligence to understand what your competitors are doing. If you really want scientific information, you need to go to scientific literature. On the other hand, if you're trying to do what your competitor is doing, reading his patents is the best way of figuring out how to get there.

As to fee diversion, at the risk of sounding excessive and cynical, the Patent Office is in the business of selling monopolies. If they can earn a profit doing that, the profit ought to be returned to the

people who pay for them, the American consumers. And I don't know of a better proxy in the federal government than the federal treasury. If they hurt products selling monopolies, the people who pay for the monopolies are American consumers, and the money ought to be returned to the American consumers.

MR. ARMBRECHT: Just a comment on that. It's an interesting thought, Cecil. But what that says is that we already have created a monopoly in the monopoly business, and that's the Patent Office. And if they're forced by this practice of returning to the consumer poor quality in their business, it hurts everyone. So I'm a little concerned about your comment in that sense.

I'd like to just say I'm very interested in Brian's and James's comments on software as being different from some material products, to some extent. And I think partially that's driven by the culture of the people that are dealing with the development, in that generally, I don't think the software people have been trained as scientists, and so there's a whole different standard with respect to driving the technology forward.

Likewise, I think probably, from what I've heard, and this is just my perception, it's a lot more difficult to decide in the software case whether something is obvious to someone skilled in the art or

not. And so this, I believe, causes maybe some of the differences between the types of things we see in the industrial side, although Microsoft is one of our people.

The comment on treble damages that was made, I will say that there are some reasons for having treble damages, and part of it is that business up here of the 499,000 that you mentioned.

Because in one particular case that I'm very familiar with the client, treble damages was not awarded in a willful infringement case. And it wound up that the inventor went out of business because of the legal fees he had had to pay to enforce infringement in this business. And he had been successful eight different times. And in his ninth case, his business went out of business because of the legal fees when treble damages were not awarded. So there is some reason for it, I believe, in certain cases.

MS. GREENE: Ron?

MR. MYRICK: Thank you. Just a few comments. The last remark about treble damages, I understand your point. However, treble damages and attorney's fees are different things. So attorney's fees could have been awarded and resolved that issue.

I want to especially comment on Brian's presentation, particularly with the comment, or his

I would like to mention, though, the mission statement. One of the things that wasn't mentioned at all today -- and I'm loathe to bring up too much, because I'm not empowered to speak for the Patent Public Advisor Committee; although I serve on it, I'm not empowered to speak for it -- we have not developed a public statement for this set of hearings.

But in 1999, the AIPA authorized the Secretary of Commerce to appoint a Patent Public Advisory Committee, and that was done. The committee is now about two years old, and we are a quasi -- I don't know what our legal status is, but we actually are special government employees. And our role is to oversee the Patent Office in many respects; not all respects, but in many respects -- policy respects, budget respects.

When I say "oversee," that's an overstatement. It's consult. It's advise. It's an advisory body, as its name implies.

When the mission statement that you quoted was first presented to the Public Advisory Committee, it's an outgrowth of Commissioner Lehman's term, unchanged by Commissioner Dickinson. It was presented about 18 months ago. And on the record, the public record, the Public Advisory Committee took that mission statement soundly to task as being inappropriate with regard to the public

interest that patents are affected with, (inaudible) Atkins case and before.

I think what you see in -- and if you harken back to Director Rogan's testimony before this body some weeks ago, and you see it in the corporate plan for 2002, you see a change. Now, whether that came from the Patent Public Advisory Committee is irrelevant. What's relevant is that balance between the interests of patentees and the interests of the public. The Patent Office is looking at that now. And I suspect that that mission statement may be changed under the new director, Mr. Rogan.

Finally, I think that every time we hear concerns about the CAFC, I do recommend to you, as Hillary did, the entire copy of the Antitrust Trust Law Journal, because it is replete with arguments on both sides. But what you come out understanding is how complex the assessment of the Federal Circuit really is. There is no easy, bland, and plainer analysis of the Federal Circuit, and certainly one cannot separate the Federal Circuit's decisions or its analysis of its decisions on validity from its analysis of its decisions on infringement. They're very, very different in some senses, but certainly the Federal Circuit has not missed the boat on trying to constrain and make more clear --

providing more clarity around patent claims.

I would say in response to a further comment, far and away, more patents are read by developers than by lawyers. I think most major corporations, you couldn't stop it if you wanted to. There's the Internet. The patents are all out there. And the inquiring minds of engineers and scientists and IS people, information sciences people, are going to get them out there looking at the patents that are being issued, including software patents, and the software patents have a great deal of value to those folks.

All the problems that we saw with the quality of software patents in the early days have been mitigated by the fact that there now is an established vehicle by which art is available for searching and so forth. So the software patent issues are much, much better today.

Finally, with regard to Jamie's comments, I would say that -- I've already made some comments about dealing with the social contract. That's really an issue between Jamie and Maken Delrahim. But I think DOHA reflects the -- and the DOHA declaration reflects a change in the direction that TRIPS is going, and remains to be seen how far that will go. But the TRIPS counsel is commissioned to come up with some solutions at the end of this year, addressing particularly the concerns that

outrageous. I think that it is very difficult for an individual inventor or even a small company to get involved in those. And some changes, I think, have to be made there. I'm not sure where that should come from.

And finally, the concept of registering notice letters from the FTC, I think, is a horrible idea. We don't need the government to get involved in that. And a lot of times, we'll send out letters to companies to ask them if they are infringing. "Well, you've got a product out there. You've advertised this product. We haven't seen it yet. Here's our patent." Should that be registered for the FTC?

MR. KAHIN: Absolutely.

MR. ALSTADT: I disagree with that. I don't think that there's any value in having the government involved in that.

MR. KAHIN: I've seen a lot of people at the receiving end of those letters, and it's pretty painful if you're a small company. And I'm not suggesting the government do anything at this point, other than requiring that information be made public.

MR. ALSTADT: Thank you.

MS. GREENE: Thank you. Jamie.

MR. LOVE: I think that Brian's presentation on the business plan, this whole definition of people get

patents as customers, and as a member of the public, you wonder, "Well, I'm not a customer. Who am I?" I mean, apparently, you even pay the salaries of the patent officers.

I testified before Congress back when they were putting into effect this quasi-privatization plan in the mid-'90s that, would it change the character of the agency if the operation was paid for by these user fees? And everybody said, "Oh, no, no. It's just some way of making these people, you know, pay the cost. It's not going to change the mission of the agency."

But you look now. It's really true. They see themselves as turning out patents like McDonald's hamburgers or something like that.

And if there's one good use for the fee, I think it would be to fund some kind of office of advocacy and the other half on the behalf of the public, the people that are confronted with abusive practices or -- you know, part of it's patent quality. But even with good patents, public interest issues about whether or not it's -- you could have a high-quality patent, very expensive litigation, and it could have a monopoly situation. And if people can't afford the cost of the antitrust litigation, they could never get the kind of relief that maybe would be socially efficient.

had the privilege of talking with inventors overseas. In fact, that's how in 1989 I first learned about first-to-file. I was contacted by a French inventor explaining how difficult it was, because they had to operate in a total cloak of secrecy, where our inventors have the grace period and could go out and do market research and do things before they ever filed a patent application.

And then the other is prior user rights, and how if our Constitution does say that patents give the inventor the exclusive rights, prior user rights, by definition, dilute the value of that patent. They are granting rights to someone who chose to keep a trade secret. And the independent inventor community is very opposed to both of those.

On these issues, when you say that the Patent Office, one of its responsibilities is to advise the President about the value of intellectual property, how it should be changed, how it could be improved, I have talked to Director Rogan and said, "How can you propose" -- or "How could the Patent Office previously propose to change to first-to-file, or to make other" -- such as 18-month publication -- "make other proposals that support

there's one solution, and we ask what the solution of that could be. And Mr. Delrahim, maybe you could have some insight on how this is going.

I know the PTO has been pushing for an appeal process to the Federal Circuit from *inter partes* reasoning. That is a process we have now. Very few people use it. And again, the number in my head from private practice was people don't want to use it because of the estoppel effects of getting it to court.

I guess something we've been pushing for is, again, to have direct appeal to the Federal Circuit from that. And that, obviously, is not having the same litigation cost. It is a reduced cost. It's administrative proceedings before the PTO, and after that, it's just a matter of writing an appeal, brief, and argument to the Court, which is a whole lot less cost than going through the discovery process and the private litigation.

I guess Mr. Kahin will put some statistics up as far as the decline in the obviousness standard. I would simply ask could that possibly be as a result of increase in anticipation findings by the Federal Circuit? Did you account for that, that that could be a possible reason that obviousness standards are going down, that these patents are being called invalid on 102 grounds, rather

probably not worded the best that it should be. But I don't think that really affects how the examiners do their job.

I mean, my wife would probably beat me up if I didn't say something. She is an examiner. So then I guess I better say something on their behalf. But I think most examiners, they're conscientious individuals, they do try to do a good job, and they do work within the limits that they have right now.

I can sit here, the job that I do belongs to appeals to the Federal Circuit. I have much to see and look at the patent references and get prepared to argue before the Court. They don't have months in which they have to look at something. They have a number of hours in which they have to examine these patents. But I think they try to do the best job that they can.

So I think it's so misleading to think that the examiners are just sitting out here, just can't wait to issue something. And I know that's not the case. They do try to do the best job that they can, and they do work within certain constraints.

MS. GREENE: Frances? From the Department of Justice.

MS. MARSHALL: Just a couple of comments. I think today's panel has again laid out this bifurcated

nature of our proceedings here. A lot of discussion about patent quality, policy concerns, and then talk about what drives innovation, and how the competition policy can affect those concerns.

And I think what we've heard a lot in Berkeley, what we've heard some today about is there are differences, or there appear to be differences, in what drives innovation-specific industries, and that we have on the one hand a patent system that has what people call a one-size-fit-all formulation for granting patents, and then some empirical evidence appearing that there are differences in the different industries about how they're used and what actually is driving people to move forward in those industries, and that, again, I think, as Brian was pointing out, there appears to be not a whole lot of empirical data on these issues, which are very important to how we proceed from a competition policy standpoint.

And then I just wanted to point out that we are going to be looking at some of these issues in even more detail coming up. We're going to have a session on patent pooling, on standards, on refusals to license, IP bundling, then taking a look also at practical issues, about how you go about analyzing patents within the context of an Anacosta investigation, and then also looking at patent settlements. And some of these issues

about innovation and how you should take them into consideration in looking at them in an antitrust context will again come to the fore.

But they are difficult issues, and I think this -- many of the issues that you've been raising just to point out to all of us how complex each one of these questions are, and how there are no easy answers.

MS. GREENE: Well, thank you all so much. I am grateful that you participated. Excellent exchange. Thank you for going without a break. But what can I say? You all had too much to say, so it's your fault. Thank you, thank you, thank you. And our session will start this afternoon at 1:30.

A F T E R N O O N S E S S I O N

(1:30 p.m.)

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MS. MOORE: Good afternoon.

I'm Robin Moore, and I'm a staff attorney in the Office of Policy Studies in the General Counsel's Office here at the FTC. To my left is my supervisor and my co-moderator, Susan DeSanti. She's Deputy General Counsel in the Office of Policy Studies.

To my right, I have Sue Majewski. She's in the Office of Legal Policy at the Department of Justice.

MS. MAJEWSKI: I'm actually an economist.

MS. MOORE: Okay. I stand corrected. And, to Susan's left, I have Edward Polk, who is the Associate Solicitor at the PTO.

This afternoon's panel is the first of three panels focused on obtaining business perspectives regarding the world of patents and antitrust systems in either encouraging or discouraging innovation in various industries. It's a topic that we started at Berkeley in these hearings.

This particular session will focus on pharmaceutical and biotech, and tomorrow's panel is going to focus on hardware and semiconductors and software and

from the University of Maryland.

Continuing around here, to my right, we have Greg Glover. He is a partner at Ropes and Gray's Washington, D.C., office, where his practice focuses on advising pharmaceutical, chemical, and biotech companies, as well as trade associations, on FDA regulations and intellectual property law. He also holds an M.D. from Duke University. Today, Mr. Glover is representing Pharmaceutical Research and Manufacturers of America, or PhRMA, which represents the country's leading research-based pharmaceutical and biotechnology companies.

To Greg's right, we have Barbara Caulfield, who is the Executive Vice President and General Counsel of Affbara Caulf5 Tc TD (12) 0the Exea3PhRMA, wnts the country's.75

Intellectual Property Counsel at IVAX, a company which specializes in proprietary and generic drug products. Prior to coming to IVAX, he worked at several big pharmaceutical and chemical companies, including Merck, Zeneca, Abbott, and DuPont.

With this impressive table of individuals, I'm hopeful that we will have quite a lively and good session this afternoon. We're going to address two topics. The first is the role that both patents and competition plays in driving innovation between research companies in the pharmaceutical and biotech industries. The second is what impact the threat of generic entry or generic entry outright has on the innovation of the pharmaceutical industry.

Before we get started, let me just lay out a couple of ground rules, one of which I've already broken, which is to try to speak into the microphone so that we have a good record. The second is I will guide the conversation in the sense that I'll throw some general questions out to either a specific individual or to the panel as a whole. If any of the panelists wants to add something, all you need to do is just tip your nameplate up like this.

So I'm going to throw the first question out to Bob and ask him to explain how drug development works,

and how the patent term of drug discovery works.

MR. ARMITAGE: Thank you. I'm glad you asked me that question. Because there's a very short and simple answer to how the drug discovery in an innovative pharmaceutical company works. You simply take about a billion dollars, and 20 years later, you have, if you're lucky, an innovative medicine bill. That would at least be the short answer. But perhaps you would like me to elaborate a bit on the short answer.

There are basically what I would call two distinct stages of innovation. One is going from idea to molecule. The other is going from molecule to innovative drug product. And indeed, this can be for many significant medicines a 15- or 20-year effort beginning, of course, with the scientists figuring out what among the 10,000 medicines that have already been developed would be the next medicine that would be effectively competitive with all the medicines on the market, and actually make a substantial contribution to human health.

The ways in which ideas for new medicines go from ideas to molecules are probably as numerous as the number of products on the market. Modern biotechnology can play a role with drug targets and receptors. Scientific insight, hunches, and sometimes someone who's simply so relentless, refusing to give up on an idea

until finally the idea for that -- the time for that idea has come.

Getting to the molecule requires an enormous investment in experimental chemistry, chemists or biotechnologists willing to take molecular innovation to places where no human being has gone before. When you have a molecule and you've established that there's at least some hint of important biological activity, then the real hard, expensive effort commences of figuring out, whether through animal testing, and then eventually human clinical testing, you will have a drug that will be safe and effective. And we'll leave for a later discussion whether that drug actually could ever be successfully and competitively marketed once approved by the FDA.

Normally, once you've finished your animal testing, sufficient testing to establish that the drug is likely to be able to be used in human beings, you go through the traditional three phases of clinical study mandated by the FDA. Phase I studies, where you take healthy people and at first maybe give them but a single dose of the drug to see the effect on a human being. Finish your Phase I studies, largely designed to determine that the drug can be in some ways safely administered to human beings.

Phase II is more expanded testing. Often, some

important contribution next to sanitation in all human research.

MS. MOORE: Thank you very much. Before we go on -- and then I think what I would like to do is hear from Greg, who has some prepared remarks, followed by Barbara Caulfield from Affymetrix, is to have the panel give a one- or two-sentence introduction beyond what I

where it's perhaps 80 percent of our revenue or more, and not rely on the generic segment for our revenues.

In terms of the business drives of our company, Dr. Frost has maintained an international strategy, and so he's gone into places -- or we've gone into Latin America, Hungary, Czechoslovakia, England, and the United States to establish our company. And the worldwide operations are throughout the world, and he intends, or we intend, to develop that even further.

Therapeutic categories is a focus of the company in the sense that we don't have huge numbers of therapeutic categories. But the respiratory franchise is a large part of our business. We acquired Norton Health Care in the United Kingdom, and they have some devices called Easy Breathe that puts albuterol and betamethasone and various other known asthma drugs. And we hope to uIet nh0nnd th 1ious.hs

branded company and a generic company in terms of some of the issues that we have to deal with.

And that is pretty much the basic --

MS. MOORE: Thanks. Bob?

MR. ARMITAGE: We also have patents listed in the Orange Book at Eli Lilly.

(Laughter.)

MR. ARMITAGE: We're about a $10 billion pharmaceutical company in sales. Actually, a little more than that. We spend about $2 billion a year on pharmaceutical research and development efforts. Our major area of innovation in the last several years has been in the neurosciences area. I'm sure you've all heard of the drug Prozac. It literally revolutionized the treatment of depression. Probably many of you, particularly in light of John Nash's recent notoriety, have heard of our drug Zyprexa, which indeed is one of the most important medical advances in the treatment of schizophrenia of all time.

patent system that does provide adequate and effective protection for innovations. However, like other innovators in all fields of technology, our patent system is a bit complicated and expensive to use. It has many subjective elements that reduce its predictability and drive up the cost of litigating patents very substantially, and for many of the products, particularly in the biotechnology area, it often takes too long for the Patent and Trademark Office to establish patent rights, which only serves to amplify the uncertainties. Thanks.

MS. MOORE: Thank you. Barbara?

MS. CAULFIELD: Affymetrix is a company of 900 people. It's a research company. It's what's called a biotech tool company. We make the Affymetrix gene chip array product. It is the ability to manufacture, using computer type manufacturing techniques, a biological testing device where you can put down 100,000 genes on a single slide the size of your fingernail half of DNA sequences. Then other DNA sequences are added by researchers, and where there's a match, it lights up. Those sections that light up are read by computers, and are e-mailed all over the world. It is a revolutionary tool. It's used by all the major universities in the United States, as well as worldwide.

One of the very interesting things that we found is that what used to take a post-doc in the laboratory approximately six months with proper front-end research can now be done in 20 minutes. And the reason why this is so critically important is you can see how much more quickly biotech research and genetics is going to move.

The impact is yet unknown. It is an infant science. Let me just give you three examples of things that have been found in the last three years using this gene chip array technology. And there are many other companies that do the same kinds of technology.

Working with Harvard at the medical school as well as the biotech, they discovered, actually, the gene that is the metastasis gene for cancer. Now, that's not to say there's a cure for cancer, but now they know where in the genome the metastasis gene lives. That doesn't mean it can be shut off yet, but the research is ongoing.

The second major piece of research was that there's two kinds of leukemia. I'll spare you the biotech details but both are very difficult to cure. They have a very short life span once you're diagnosed. But you can increase the possibility that a person will live through these two different kinds of leukemia if you can tell which one is which, because they have very different chemotherapy interventions. If they use the

wrong one, it can increase the death rate.

It used to be done with a microscope and looking at slides, which required a tremendous amount of expertise. But because with the gene chip, you can take it down to the level of the DNA of which kind of leukemia is at work, that that test can now be given to people who have this particular disease, and a chemical intervention strategy created for them.

Now, those are three things within the last three years5

MR. COFFIN-BEACH: My name is David Coffin-Beach. I'm down from Toronto, Canada. I am the President of Torpharm, which is a division of Apotex, which is Canada's largest privately-held pharmaceutical company. Similar to IVAX, we have both generic and proprietary pharmaceuticals. The Proprietary Division has a product that is now sold internationally. It's an oral iron chelator.

The majority of Apotex's revenue stream comes from generic drugs. It's a 30-year-old company headed by Dr. Barry Sherman. Apotex thrived in the Canadian environment under a compulsory licensing law that was in effect until the early '90s with the advent of NAFTA, and then it was repealed.

Torpharm has been a company that I've had the pleasure of leading from a greenfield start-up in 1993. We currently employ some 600 employees. Apotex employs some 4,000 people in Toronto, commercializes products in some 115 countries around the world, and does both innovative research and generic. Our major thrust into the U.S., however, is generics, and that's who I'm here today to represent. We're not a household name, but we hope to be one day.

MS. MOORE: Thank you. Ted?

MR. SNYDER: Thank you, Robin. I will just use

this time to introduce myself a little bit more. I'm Edward A. Snyder, Professor of Economics and Dean at the University of Chicago Graduate School of Business. I began my professional career 24 years ago with the Antitrust Division, and also served as staff to the National Commission to Review Antitrust Laws and

intellectual property issues of downstream and companies. And we look at all the facets of this technology, from procuring patents for our clients to rendering opinions and counseling on what is patentable, what's not patentable, how to avoid problems -- you know, mainly how to avoid problems if they come to us early enough -- and enforcement issues. We also get involved in litigation. So we've seen it from the whole spectrum in these issues, and mainly in this area that we're going to talk about today.

MS. MOORE: Thanks. Why don't we go now back to Greg, and he can give us his prepared remarks.

MR. GLOVER: Good afternoon. On behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to appear before you today to present testimony on the Issues of Competition in the Pharmaceutical Industry.

PhRMA represents the country's leading research-

and the fundamental role intellectual property rights play in this cycle, the importance of maintaining incentives for pharmaceutical research and development, and the compatibility of competition and intellectual property rights.

Achieving the promise of pharmaceutical innovation requires the maintenance of strong and predictable intellectual property rights. The social value of the pharmaceutical industry is apparent and profound. Not only is it the source of cost-effective treatments that continue to increase life expectancy and bring better lives, it is also a significant contributor to the strength of the United States economy.

The strength of intellectual property rights protection profoundly impacts investment decisions. The investment secured by intellectual property rights supports the constant efforts of research-based companies to develop innovative products to compete with the products of other research-based companies in a given therapeutic class. This investment also promotes competition between research-based companies and generic companies, as this is a crucial point to understand.

Simply stated, generic companies are in the business of copying products developed by research-based companies. To the extent investment does not occur to

innovation.

In addition, innovation and competition in the pharmaceutical industry require the ability to make economically efficient decisions regarding intellectual property transactions and disputes, whether with regard to licensing or settlement of infringement claims. Good faith efforts to protect internal innovations and to make economically sound decisions regarding their use should not be subject to extraordinary antitrust scrutiny that discourages such conduct.

I would now like to describe the drug development process, the vast commitment in time and money it demands, and the magnitude of risk inherent to it. The key to the pharmaceutical industry's innovation is the ever-growing investment in research and development. Pharmaceutical companies are investing more in research and development than ever before. Enormous investments are necessary to support this time-sensitive, extremely expensive, and risky effort.

On average, economists estimate that it takes 10 to 15 years to develop a new drug. Most drugs do not survive the rigorous development process. Only 20 in about 5,000 compounds that are screened enter preclinical testing. And only one drug in five that enters human clinical trials is approved by the FDA as being both safe

and effective.

Since 1980, the average number of clinical trials conducted prior to filing a new drug application has more than doubled, and the number of patients in clinical trials has tripled. Cumulatively, several thousand patients may be studied during the clinical phase. Numerous medical procedures are performed on the patients to acquire the necessary safety and efficacy data to support the marketing application. Beyond these pre-approval requirements, sponsors often take additional post-marketing steps to insure that their products can easily be used safely. Accordingly, the average cost to develop a new drug has grown significantly, and has been estimated $802 million.

At the same time, average returns from marketing a new drug have dropped. A 1998 Congressional Budget Office report estimated that average returns to a pioneer from marketing a new drug had declined by approximately 12 percent since 1984. Despite popular misconceptions about the invariable profitability of pharmaceutical companies, most marketed drugs failed to cover their research and development costs.

Even the largest pharmaceutical companies cannot diversify the underlying research and development-based investment risk. They must rely upon a handful of

flagship products for the majority of their sales, and the commercial life of a drug is generally less than seven years.

Consequently, even major companies must develop a blockbuster every two to three years or face massive financial contraction. The frequency of mergers of research-based companies is a direct consequence of this basic market dynamic. As market conditions have continued to become increasingly competitive, this dynamic has become even more significant.

In contrast, the costs to develop a generic drug are, in both relative and absolute terms, extremely low, allowing generics to enter the market at dramatically reduced prices, as they have done increasingly at high rates.

In 1984, generics accounted for 19 percent of the prescription drug market. By 2000, generics accounted for 47 percent of the prescription drug market. Pioneers lose more than 40 percent of their market share on average generics soon after patent expiration.

With the scale of investment and risks necessary to develop new treatments, strong intellectual property protection is essential for the preservation and growth of the research-based pharmaceutical industry, and thus for the continuing development in new and better

lengthening development and FDA review times mean reduced effective patent lives. That is, the time on the market following FDA approval.

The average period of effective patent life for new medicines introduced in the early to mid-1990s that received patent term restoration is only 11 to 12 years. Innovators in other industries who do not need regulatory approval before going to market typically receive up to 18.5 years of effective patent life.

Pharmaceutical patents impact competition both between research-based companies and between research-based and generic companies. Pharmaceutical patents confer exclusive rights to market a specific product for a limited period of time. Pharmaceutical patents, however, do not grant the manufacturer a monopoly on the treatment of any specific disease. Other manufacturers are free to produce and offer different medicines to treat the same disease, and there is strong competition between products within therapeutic classes. For example, different patent medicines to reduce cholesterol and limit blood pressure compete vigorously against each other.

Increased competition in the rush to find new

medicine can hope to be alone on the market. For example, Tagamet, an ulcer drug introduced in 1977, had six years on the market before another drug in the same class, Zantac, was introduced. In contrast, Invirase, the first of anti-viral drugs known as protease inhibitors, was on the market only three months before a second protease inhibitor, Norvir, was approved. Patients and the American health system benefit from this robust innovator competition.

With respect to competition between research-based and generic companies, first it's important to understand the 1984 Hatch-Waxman law stimulated the development of a generic pharmaceutical industry in the United States. Since the law's passage, the generic industry's share of the prescription drug market has jumped from less than 20 percent to almost 50 percent today. The economic realities of non-innovator commodity production allow generics to enter the market at a significant discount, and for prices to decrease with increased generic entry.

These market developments, carefully balanced with protections for pioneer intellectual property, have spurred additional innovation and competition. Brand name manufacturers have introduced new dosage formulations that provide superior therapeutic products

drug to the needs of the individual patient. And the substantial demand for improved variations of pioneer drugs, even after the introduction of lower-priced generic competition, attests to the consumer benefits attributable to the sequential innovation.

To conclude, the pharmaceutical industry is alive and well. Innovation continues apace, and competition is robust. The system works. However, it is delicately balanced. It relies ultimately upon enormous investments of time and money to support an innovative process that is inherently uncertain. Maximizing the certainty that a research-based manufacturer can obtain, enforce, and make full legitimate use of intellectual property rights is essential to maintain the cycle of innovation upon which the industry and the public rely. Thank you.

MS. MOORE: Thank you, Greg. And now we'll hear from Barbara.

MS. CAULFIELD: I had introduced Affymetrix a little bit earlier, and now let me go to the first slide, which is what I call Baseline for Genomics Research. And I want to say that this is a very different market, and it's a very different approach than I think some of the other speakers are going to be discussing today. And here's why.

Genomic research, there is no doubt about it, is in its very early stages. I mean, I think many of you remember from headlines in the New York Times or Washington Post, there's 350 human genomes, and now we're down to 35. And before this is all over, it will go up and down a few times.

The other thing to remember is we now have the 50,000-foot view of the human genome, if I can put it that way. We're going to drill down deeper. We're going to know a lot more about it. And it's rapidly moving, but it is an infant market with infant research.

The effect of this market is going to be on every kind of health research we do worldwide. It's going to have a profound effect on oncology. It's going to have a profound effect on medical research, both clinical and diagnostic. But we just can't predict what it is now, which is why it is so interesting from an infant market perspective, and why it probably needs more monitoring, surveillance, and/or protection, however you like to look at that, at this stage by government authorities.

The tools are just now developing for how we look at this research. Databases -- everybody hears about bioinformatics, but what really is that? Right now, they're huge databases of what we do know about the

human genome. Eventually, it will include data about individuals. It will include data about particular tumors. And so it is not going to be how you collect the data, but how you release the data, package the data, help medical researchers analyze the data. And all of that is a submarket called bioinformatics.

Now, the public importance of rapid research built on the public database is what distinguishes this market from a lot of others. You know very well that we had a debate as, you know, who owns the genome? And we all decided that it was no one, that there was going to be a public database equally accessible. It was some of the things we decided a long time ago about tumor databases in the medical field, that they should be something that's open to all researchers to do.

So that also is a distinction here. We've already made the decision that this is a public database. And as the data becomes more real, more effective, more rapidly developed, it is our position that it should stay in the public sector. And that is not to say that we disagree that people ought to have IP rights. It's just that the balance is very, very delicate in an infant market and in such an important area.

The other interesting development here is the oncology research, which I've touched on a little bit.

But we are now beginning to see that oncology research has a very important genetic component. We always thought that. We always counseled people about families who have certain kinds of cancer that repeat. And now we're going to be able to figure out interventions, possible early chemical therapies. And it's a worldwide research opportunity.

Now, the reason why that is important is because if the oncology research is being done worldwide, then how the laws of the United States play into a worldwide research effort are critical. Because if we have a different balance, for example, than France or Canada, you may see that research will leave the U.S. and go overseas, which is something that no one wants to see from a U.S.-centered perspective. We would rather see greater cooperation worldwide.

Now, the bottom point is we have to look at this as novel research in infant science and infant markets to get a perspective, which is very different from a lot of the other subjects that we will probably talk about today.

Just to give you one slide on why we need to understand a little bit about the science is if you look to the left of this slide, it shows, you know, a representation of a DNA sequence. And what we're going

to be doing literally is mining every little spot on that database. And then once we figure out where things are -- and we haven't even gotten very far yet; we're still at the 50,000-foot level -- we have to measure the variation between people -- very difficult -- and what the function of the variations are.

Once we do that, and we're just now getting into this issue, then we have to go through and say, "Is there a group of genes?" That's what's called genotyping. Is there a group of genes that leads from one thing to another? It's not a single gene leads to this and a single gene leads to that. What is the interactive phase to it? And we're also just starting that.

Then we have to go down to expression, and what's important about expression. That's what these genes do. They express proteins. And even if we understood how they work together, if they work together, what is the expression component of it? One group of genes may express one thing, another group of genes may express another, or it may vary from individual to individual. And then you have a disease mechanism or health mechanism that is dependent upon this. So this is important to see how early we are in the sequence of all these issues.

Now, if you want to take sort of a view of what

does that level of complexity, being very infant about it, where are we going to go? At any one of these integrations, there's going to be both a legal process, a court process, a patent process that will be engaged. But the balance is very delicate.

And one of the questions is -- and I will come to it in a minute -- can anyone really own the genome? Can they own a spot on the genome? Is it like real estate? Can you own somebody's tumor sample, and thereby prevent other people from doing research on it?

Then there's the research tools. What kind of research tools do we need? They are patentable, obviously. And then there's the analysis. Once we figure out that there is a certain genotype that causes or doesn't cause a human health result, can that knowledge be owned? Not the drug to intervene, not the test to do it, but the knowledge about it. And how do you price a database that includes that information that is really derived from human beings?

So here's the fundamental questions that I don't think really have been answered yet. And I know there are cases that have danced around some of these issues, but they have never really dealt with the human genome issue. And there are some people that say this could also well be a plant genome issue. But from my

perspective, I'm only talking about the human genome.

So who owns the genome? And the answer to that, from my perspective, is no one. Now, there are people that say because of a Supreme Court case in 1980, 20 years ago, the Chakrabarty case, which said that you can patent a human-made microorganism, that because of that case, you ought to be able to patent a sequence of DNA.

Well, even under Chakrabarty, you shouldn't be able to patent it unless you made it. And you don't make human genome sequences or DNA sequences as they occur in nature. You may make them further down the line for intervention, but you don't make them. You simply look at them in many different ways.

Who controls access to the genome? And the answer to that is the individual patients who are being examined or consulted, and the individual researchers. But it shouldn't be a blocked access. And again, one of the big intervention issues is who owns the genome and who owns the sample that a person has contributed to the research -- is it the researcher; is it the individual -- at this level?

Who can monetize the genome? And again, this is the commercial question. And the answer right now is anybody who can prove to the Patent Office that they have got an honest development off of the human genome.

Now, here's the first question, I think, this particular human genomic research market faces. Should naturally-occurring gene sequences be patented? And this is a very significant impact question for the research, for the market, and for the future of this research, I think on an international competitive basis, as well as a U.S. competitive basis. I think you can tell from my remarks that we believe no, that Chakrabarty said you have to make something in order to patent it, and that means you can't patent a particular gene, or a sequence of a gene. You can patent a process. You can patent a drug. You can patent a cure. You can patent all of those downstream things.

But there are many who say, "No, I own the patent on a particular gene, because I know that it contributes to a particular disease." And there's no turning back the clock on this issue, but I think it deserves greater scrutiny in the U.S., because as we move from just in gross knowing about sequence and databases to really doing the research, those that have a gene patent can charge everybody who wants to do research on it. And eventually, it will get highly prohibitive.

So what I call the land-grabbing gene patents may already be started. It is our position that it needs to be stopped, and it needs to be stopped with both

courts could be about that particular event very quickly, rather than going through the whole patent process. Then you wouldn't have the chilling effect of, I'm a small innovative research company, I'm a small researcher, and I get notice of a huge patent lawsuit. Can I continue with that research, or do I have to give up? And it depends whether you have the ability to fund the defense of the lawsuit.

Alternatives to patents on naturally-occurring gene sequences, all that has to be done is move the IP process downstream in an effective way. If you find a method to make the gene operate differently, if you find a protein or you manufacture a protein that can cure a disease or lead to other research, absolutely patentable. No doubt about it -- it's just the early stage of saying that somebody owns where a gene is in the sequence. Or somebody owns the drill-down of what exactly is the group of genes that created genotype. That's where the danger lies.

And that patenting is going on right now. And it's because the last case that seems to be directly on

to patent it.

So the alternatives to patents are just protecting, as we always have done, the downstream innovation, not the source of the research. And it's drawing a distinction between early discovery versus early innovation.

I'm just going to go through some statistics which I think are interesting. Not only is there a high cost, but there's an explosion in patents, doubling of the filings in that time period -- and look, that is eight years after Chakrabarty -- and there's a threefold increase in patent litigation in the same two decades. And then the high cost of biotech.

Obviously, one of the ways to deal with all these issues is an appropriate licensing policy for different companies. One of the concerns is -- and I've heard a number of researchers say this -- that it's just easier to go to Europe and do your research than to do it in the U.S. And that's a brain drain; the genomic research in this country should not have to worry about it.

Let me just give you a quick slide on what are the components of the human genomic research market. Obviously, the center circle, which is the information -- this is an information-selling system. You have to

acquire the information, you have to interpret it, which is the hard part of the science, and then you have to manage thousands upon thousands upon thousands of pieces of data about the sequence in order to get anything out of it.

And there is the story. And there are many ways to intersect that. But only one of them is an intellectual property way. And another danger is that you want to make sure that each of the supports for this genetic information is free to operate in a competitive system.

Two suggestions I have -- well, actually, three. I already gave you one. The first one is no patents on naturally-occurring genes or gene sequences. Second is codify the research exemption, which allows the universities to operate, because they may have non-commercial uses for what they do.

Right now, the research exemption exists only as a gentleperson's agreement. It's been going on for years. And what we need to do is to encourage universities and other not-profits to be innovation incubators in genomic research. And in order to do that, they have to have the freedom to do it through the research exemption.

Another possibility, because there's been a lot

of complaints about patent thicketing in this area of research. And how do you ever decide whether something is a thicket or an appropriate use of patents and licenses? That's the tough question. And one of the things that would be helpful, and it's a possibility, that because there's an infant market, there could be a license database excluding trade secrets maintained by a government entity to bring sunshine to the licensing process. So if a person needs to know who's operating in any given area, they would be able to go to the government to find out.

The PTO may need help because of the rapidity of this research, and there's a model. The bio-pharma agreement with the FDA on PDUFA-2, where it allows people to use independent experts to get help, is one way to give the PTO some help in steering where one patent starts and the next one stops.

So here's the actions. Codify the research exemption, monitor the patent process, strict penalties for patent misuse, a license database, and specific examination of component integration, vertical integration in the biotech market. Thank you.

MS. MOORE: Thank you, Barbara. I would like to first get into one of the issues that Greg raised, and that is the importance of patents to the pharmaceutical

industry. I would like to delve down and then really flesh out exactly what role patents play in influencing a company's willingness to undertake drug development. And I throw that open to the whole panel. So whoever wants to speak first can speak up..... Bob?

MR. ARMITAGE: I'm old enough to remember when patents were important, but they were not absolutely critical. If you go back prior to 1984, and the Drug Price Competition and Patent Term Restoration Act, there was an expectation that a pharmaceutical product would have an extended period of marketing exclusivity. And there would come a time when there would be competitors in the marketplace who would come, often one at a time, as the FDA approved follow-on companies to market the same product that you were marketing. And indeed, I can remember patent expiration days passing and not being an event for a company.

As I said in my opening minute or two comment, in 1984, Congress basically eviscerated trade secret protection for innovative medicines, and in doing so, profoundly shifted what was a synergistic balance between patent protection and trade secret protection, so that the only long-term engine that drove exclusivity that, frankly, provided the basis to file back revenues into research was the patent profile for a product.

So you, I think, in the year 2002, cannot underestimate the fact that the half-life for an innovative pharmaceutical product is somewhere on the order of five to seven years. And that half-life is wholly dependent in the United States on the effectiveness of patent protection. And when I say "half-life," if we stopped innovating today, more than half the current thousand or so medicines that are currently protected by some form of marketing exclusivity would be generic. And within another few years thereafter, there would be no more patent-protected medicines. I think as Greg said earlier, we would have an entirely generic marketplace.

So patents are now the alpha and the omega of what really drives innovation and the ability to fund innovation both in the pharmaceutical industry, and for that matter, in the biotech industry, although the funding mechanism is obviously driven in that case by a venture capitalist willing to take a bet that the patents will hold up if the product is actually successfully developed.

MS. SEIDE: I was just going to say also, just to add on to what Bob said, to expand on into the biotech industry, and also maybe to answer to Barbara a little bit, also from the perspective of her position, it's

absolutely crucial to the biotech industry to have strong patent protection for products and innovations that are early stage, and especially if it is driven by the venture capital investment in biotechnology, that is exactly what they're looking for. Because in many cases, the early stage biotech companies don't have products on the market. What they have is technology, and what they have is trying to get protection for that technology.

And that even spawns all the way down to the university. I mean, universities are also in the business of obtaining patents on university inventions, and spawning off companies that are used to market those inventions from technology ultimately to product. So it's not just big companies that are looking to tie up products in patents, but everybody is looking to try to protect their developments, which ends up being able to further that development.

I would like to just address Barbara's comment for a minute, also, on the issue of the genome versus genes versus everything else from the perspective of not only patent work, but of a geneticist. You cannot patent something that is a product of nature. Our genome is the sum component of all the DNA that's in everyone's cells, okay, which from one individual to another is about 99.9 percent identical. That goes into detail. I mean, we're

98 percent identical to chimpanzees. We are 99.9 percent identical pretty much to everybody else in this room. So the differences in the genomics are very much tied up in those little details.

Now, I think what people tend to look at is that genes are somehow rather magical and mystical, and they are different from any other chemical entity in the body. We have for many years been patenting vitamins, hormones, other bodily product cells and the like that have never raised the controversy of patenting genes.

What the individuals who are looking to patent DNA molecules are looking for -- they're not patenting DNA sequences. A DNA sequence is a chemical representation of a DNA molecule. You cannot get a patent on a molecule unless it has some utility. And I think Bob had a very famous case many years ago on prostaglandins. Wasn't that your case, the utility issue? It doesn't have to be the ultimate commercial pharmaceutical utility. It has to have some real utility to be able to get a patent on that molecule. Now, it doesn't have to be the commercial ultimate use of it, but it has to have some real-life perspective.

The PTO does not grant patents just willy-nilly on DNA sequences. And as a matter of fact, it is very difficult to get patents on DNA molecules. It's not an

easy perspective and not an easy thing to do. And despite the fact that there are multiple filings with huge amounts of data and everything else, it's still different. I'm sure Edward can talk about that a little bit too. But it's not a grant without a lot of difficulty, and you spend a lot of time arguing back and forth to get those patents issued.

And as a matter of fact, today, at the same time this hearing is going on, the PTO is having one of their quarterly biotech customer partnership meetings, which members of the PTO meet with practitioners in the area of biotechnology and pharmaceuticals to discuss issues in regard to patenting of biotechnology products. As a matter of fact, these meetings have been going on for the last five or six years.

So there are a lot of complex issues. It's not a very simple thing. But in regard to certainly the biotech industry, patents are the lifeblood of this industry until a lot of companies actually have real products on the market. And again, it's also the lifeblood of the pharmaceutical industry, because I don't think there would be a significant investment in developing useful drugs as there would be without this kind of protection. Ted?

MR. SNYDER: Just to go back to your question,

if you go back to '84, and you say Hatch-Waxman eliminated a lot of the protections, and you're left with patents. And then you ask the question if you got rid of the patents, what's left after that? In effect, what you have is the market only. And the market affords two types of benefits to innovators. One is you get some degree of what I would call de facto exclusivity from being a first-mover. It takes some period of time before an imitator can follow, and the amount of that time will depend on the regulatory process for generics.

The other thing that you have in your favor is there is a sizable significant segment of consumers who prefer branded products over generics. I wouldn't say it's a majority, but they're willing to pay more. And that is a fact of life about products outside of pharmaceuticals. There's no reason to believe it would not be a fact of life for pharmaceuticals absent patent protection.

In our research, what we find is that if you look at the difference between worlds with patent protection and without patent protection, the profits that fuel R&D and innovation would fall significantly, in the range of 60 percent, and so reduce the flow of new chemical entities, new molecular entities, that it wouldn't go to zero. I think that's important to point

out. It would be a significant reduction.

One reason why it's not a bigger percentage drop-off is what Mr. Armitage said, which is the effective life of patents is now lower than what it used to be. So we're already starting from a point where the effective duration of patents isn't all that great. If we were back up to 12 or 15 years, going from patents to no patents would have, in percentage terms, a more significant effect.

MS. MOORE: Greg, did you want to respond?

MR. GLOVER: I simply wanted to point out that there are some unique things about the pharmaceutical industry that I think are a little different with respect to other industries, as linked to your comment concerning the preference for branded products. Once products have gone generic, it is not only the circumstance that you have physicians and patients who are very influential in the decision-making process, but it is also the case when you have pharmacy benefit managers and formulary managers who are basically forcing the hand of physicians and patients to use the cheaper generic product. So therefore, what you see is perhaps even a more rapid decline in the pioneer share of the market than might be justified simply by virtue of the preference of the consumers.

MS. MOORE: Let me ask a follow-up question. You both mentioned that the effective life of patents is no longer as long as it used to be, and I'm wondering if you could clarify what's been going on to reduce the effective life of patents.

MR. GLOVER: Well, certainly. We start --

MS. MOORE: All of you.

(Laughter.)

MR. GLOVER: Let's just start with probably more history than we need. But in a circumstance that really existed in this country where you did not have to demonstrate that a product was safe and effective before it got on the market -- that is, before 1962 -- you had a circumstance where you get it on the market relatively quickly.

Now, that doesn't mean that you're getting on at

You then add to that, the safety and efficacy pre-market requirements that came along in 1962. All of a sudden, you now have the need to have two randomized double-blind trials. With many patients, the cost goes up, et cetera, et cetera. The time that is associated with that also eats away at your patent life.

We now then move towards where we are today, where over time, we have not been focusing so much on simply replacing things that are in the body. We're planning on many more complex things with respect to the pharmaceutical targets we have, so that we're trying to modulate the immunology system, we're trying to do more subtle things with the endocrinology system, et cetera.

So obviously, we now are going for things that are much more complex. The trials are much longer, the end points are much more subtle. So therefore, it takes a much longer period of time to get through the process that can demonstrate to the FDA that things are safe and effective.

You then add to that that once you finally get on the market with whatever patent term you have left, it will be a very short period of time before your branded competitor is on the market with something similar. Because your research is not really going on in isolation, many people are going after similar targets at

the same time because of the flow of information that is available in the scientific community, and by virtue of patent documents getting published in the U.S. and abroad.

MS. MOORE: Monte?

MR. BROWDER: Yeah, I have just one comment to that. We're not really talking about one patent here that expires. Ultimately, the process of pharmaceutical discovery relates to first the ground-breaking generic patent. And that could occur in the early years, covering a large chemical class that one of the companies is focusing on. And then most of the time, the company would ultimately find the development candidate and then file a separate patent on that, and that starts the 20-year term from that moment that that patent is filed.

And so what you ultimately have, again, as we see in the Orange Book, could be over the life cycle of the particular drug, if it makes it to the drug. Because, you know, ultimately, 15 patents, but maybe at a minimum, four, could cover the generic compound, the specific compound, enantiomer, the salt, the hydrate, polymer, whatever that may be, and then a unique formulation, for example, like Prilosec. You know, again, those patents were filed much later than the earlier patents claiming NCE compounds, per se.

So it isn't just that we have, you know, the earliest patent early on. It's a strain of very valuable and very important patents that cover what are 99 percent of the time real inventions that are focusing on, ultimately, the goal, which is the compound that then becomes the product, or the approved product, that then has whatever life it has fro Tfro t t ytl itowhaenver

Which is the bigger aspect of reducing the term of drugs?

MS. SEIDE: Actually, you know, in regard to getting patents issued, it is, in many cases, a long time. But it pales in consideration to getting drugs approved and on the market. I mean, you're talking about maybe two to three years. I mean, I know that the patent term, you would like to have it at 18 months from filing to approval. It's going in the other direction again. It is certainly in pharmaceutical biotechnology.

But it pales in contrast to the 10 to 12 years that have to go through clinical testing for some products to get it on the market. And I know for a fact that, some of the things that I'm familiar with, that patents on the core part of a product will be expired by the time the FDA approves the product for marketing in certain areas of pharmaceutical and biotech products that are being developed.

MS. MOORE: Bob?

MR. ARMITAGE: I, unlike Rochelle, was not trained as a geneticist. I'm actually an old math major. So I'm going to approach the answer to the effective patent term issue just by doing some basic math.

At least prospectively going forward, we have a 20-year patent term from filing. And in the pharmaceutical industry, because by and large the entire

industry works on global patent strategies, you file as soon as you possibly can, which means as soon as you've identified the molecule that may be a potential drug candidate, within a matter of months, you're going to file.

Now, it is true that there are ways in which drug patents can be extended under the 1984 law. But the reality is the way the extension actually works, and you look at how long the extension you're going to get is, it ends up historically being an average, I think, of about 2.3 or 2.4 years, and prospectively will probably be a bit longer than that.

So from the time you have your molecule until the time you get FDA approval, you are typically talking about perhaps a decade, perhaps a little longer. It just depends.

You end up there with an effective patent life -- and I think Greg's quoted figure was around 12 years or thereabouts -- which is probably a good average. Again, under the 1984 act, 14 years is pretty much the ultimate cap.

So if you look typically at any time, therefore, for innovative products on the market, the half-life, how many of them will be off patent within the next decade, it's literally most of them.

Now, let me quote you another mathematical statistic, and it's what I refer to as the 98/2 Rule. And while there are many exceptions to the rule, and I suppose exceptions can disprove the rule, normally, about 98 percent of the prospective net present value of the pharmaceutical innovation at the time you launch it is tied up in the NCE patent. In other words, that patent application you file, when you first make the innovation, that discloses the molecule, discloses its pharmaceutical compositions, discloses a method for making it, and obviously, what in many cases proves to be its principle or one of its principle indications for use, when that basic NCE patent expires, that innovation, the way the patent system has worked for 212 years, can simply be copied.

Well, it's true if there had been improved innovations along the way, if there were more convenient dosage forms for the patient, or perhaps new uses, it can't be copied, including its improvements. But the default assumption probably to the extent of about 98 percent of its NPV, Net Present Value, is that that NCE patent will be the end of the game.

And occasionally, you have other patents that provide effective marketplace exclusivity, and then there, frankly, are circumstances where the 98/2 ratio is

reversed. It turns out that the NCE patent -- and this,

So if you're honestly talking about an innovator who largely does all of his work in public so that his work can be copied long before he actually gets to market, how much effective first-mover significance he would have in a zero IP environment, I submit to you it would be approximately zero.

And for those of you in managed health care plans, I submit to you that increasingly, as your plans seek to drive costs that they paid to provide you medical care out of the system, that we'll all have less choice about our benefits where significant differences exist in pricing.

And so you're literally talking about a competition environment, where a first-mover would invest billions of dollars over decades in hopes, without intellectual property, that somehow he would recover enough money to justify venture capitalists who demand 20, 30 percent return rates. I think that innovation in the pharmaceutical industry, absent what IP protection we have now, absent making it more certain, frankly, than it is now would indeed go to zero.

MR. SNYDER: I think maybe my remarks might have been misinterpreted. I was trying to explain how markets work out of some patents. I don't think innovation would go to zero. That's an area of disagreement. I think it

would be greatly reduced. Reduced from a level that generates huge consumer benefits. And whether the number is 60 percent reduction or a hundred percent reduction, the cost to consumers, which is what I'm going to talk about later, far outweighs the benefits from short-term greater access.

And the other thing to keep in mind, and I think on this point we agree, our research is consistent with what Mr. Armitage and Mr. Glover said. The effective patent life now is very short. So we're measuring -- when you talk about a zero IP world, you're measuring that delta from a world where you don't have much patent protection now anyway. So if it's 70 percent or 60 percent off of the current levels of innovation, that's a big drop off a relatively low-level patent protection.

Now, as I said -- and I think Mr. Glover's point is well taken -- there are differences when it comes to these particular products. I as a consumer, I can go into a drug store, and I can decide to buy Advil or a store brand version of ibuprofen. And when it comes to prescription drugs, I'm not the only decision-maker.

But my point is simply if you take away patents, all you have left are those two things: first-mover advantages and consumer preferences for branded drugs. I don't think that's much of a threadbare suit for

continued innovation.

the Patent Office, but there you go.

And my question is that that is something -- those molecules, those gene sequences should not be owned. They are existing in nature, and they should not be owned.

What should be owned, then, what should be available is that which is downstream. And we don't even know what all the downstream products are now, but at least we know the timing of it.

Now, why do I see it as a big issue right now? You know, we sit as a tool in the middle of a lot of research. And so we work with a lot of universities. We work with a lot of other companies. We work with a lot of database companies. And soon you start getting more and more calls about what is it exactly are you using -- and the universities are getting those same calls. And the calls run like this. "What is it that you're using, because we want to look at it, because perhaps we have a patent on it. And we will charge you 10 cents every time we drop this into a slide to do research on it."

are in this research market, it's critical, and we need a lot of sunshine on the issue. And I think also, we need a research exemption for universities so they are free to be the innovation incubators. We have to kind of re-look at the system.

I don't think the PTO, doing the very best they can with the laws we have, just because of where this market is, can possibly do the balancing act with the

limits. You can only patent, as Rochelle said, a product or a process. There are public domain limits. You could never take something away from the public domain. There are substantiality limits. You can't patent something that's obvious. There are enablement limits. Your patent can only extend to what you can enable someone to actually carry out in the real world. There are utility limits. The utility you describe has to be both substantial and immediately available. And you can't patent something you don't possess. You can't simply say, "I want to patent something because it produces a good result or function." You've got to actually describe what the thing is you're patenting.

And lastly, as to whether we need a statutory experimental use exemption, I don't know. But it is at least my view that even the court in Roche v.Bolar recognized, going back to Robinson on patents in 1890, that indeed, scientific and philosophical inquiry was beyond the realm of the patent system.

And certainly, were one in a university or in any other environment, it is merely seeking to understand how an invention works, what it's basic properties or characteristics are, is seeking not to commercialize the invention, but to develop improvements or alternatives to the invention, or find new and improved uses for the

invention. These are all in the realm of the scientific or philosophical inquiry, and I don't think offend the holding in Roche v. Bolar, and have longstanding judicial precedent going back almost to the beginning of the patent system.

So the idea that somehow patents shut down basic scientific and philosophical inquiries in the patented inventions, I would reject on its face. So I see the sky as still being quite a high elevation.

MS. MOORE: Rochelle?

MS. SEIDE: Also, I did actually write a formal response to Rebecca Eisenberg's article a number of years ago in regard to the anti-commons. I was asked by Science magazine. It's still online in regard to that. And I went back to a number of issues relating to patent issues and licensing issues.

In answer to your question, I think, it depends on whether or not you do -- if you're developing products that ultimately, you have -- and every company faces patents. It's a fact of life, you know. You have your own, and you have other people's patents. And to develop a technology or a product, you have to have freedom to operate. And it's a matter of how much you can tolerate in regard to freedom to operate, or what you have to derive and what you look at as a fair amount to

recompense somebody who has an intellectual property right.

And if you go into it with a rational design as to, in a sense, what is called in the industry royalty-stacking. I mean, you know you need a certain amount of technology, say, to develop a product. And all of these technologies are patented. And you go into the decision whether or not to develop a product based in the face of these technologies, based on whether or not you risk assessment of it, and whether or not you need to take a license. And if you go in to say, "My royalty stacking would be to tolerate 10 percent on any product that I ultimately develop," and you can carve out all of the pieces of technology, a contribution of that piece of technology to the ultimate product, it depends on the product.

A patented DNA molecule -- and I'm going to be somewhat heretical -- I don't think the real value in all of this research in pharmacogenomics is going to be in the genome. It's going to be in the what's called structural genomics, the 3D structure of proteins, which will give you rise to rational drug design. It will be in proteonics, proteins that are encoded by the drug, because those are the ultimate gene targets for drugs and to do rational drug design. And we have to go way beyond

the genome and way beyond mutations or differences in individuals' genomes' to look at what those mutations and things do to protein's 3D structure, where molecules find what's involved in disease states.

I think that's where the real value of all of this is going to go, and that's where it is going. I mean, I think there are going to be much more attendant problems to patent issues in those areas, as opposed to patents and DNA molecules.

But again, if you go into this with a rational decision as to how much the market will tolerate, you know, late-stage drug development, if you're looking for small molecules -- and what you have is you have a beginning molecule that's your lead or your target -- how much does that value into an assay for maybe identifying something further, if way down the line, five, ten years from now, the ultimate product is a small molecule?

That's where I think the focus has to be, and that has not affected or stymied as far -- I second and third Bob's comments. The sky has not fallen. It has not stymied research in this area.

MS. MOORE: Edward, you had your hand up a couple of minutes ago. Did you want to make a comment?

MR. POLK: Well, no. Bob pretty much covered exactly what I was going to say as far as patents are not

ever going to stop pure, again, philosophical research being done just for the knowledge of it. I mean experimental use doctrines. If I take off my PTO hat and go back to the private practice end, it's been part of our law for quite a while. It's only when you come to the commercialization aspect that you start -- you know, if you want to step on a few patent land mines, the whole patent system comes in when you start commercializing, not just a pure recent aspect of it.

MS. MOORE: Okay. With that, why don't we take a 10-minute break. It's 3:15.

(Whereupon, there was a brief recess.)

MS. MOORE: We're going to continue with a presentation from Ted Snyder. Go ahead.

MR. SNYDER: Thank you, Robin.

MS. DESANTI: Excuse me just a moment. We do have a request from the sound people we should have announced to you at the beginning. Please turn off your cell phones, because that, for some reason, screws up our microphones, to whatever extent they are working today. Thank you.

MR. SNYDER: Thank you, Robin. Thank you for the invitation. My testimony today draws directly on a research paper by Jim Hughes, who's Chairman of the Economics Department at Bates College, and Michael Moore

benefits from reductions in the flow of new molecule entities.

The bottom line on this trade-off is as follows. For every dollar and consumer benefit realized from providing greater access, other consumers would be harmed at a rate of $3 from reduced innovation. This three-to-one ratio of harm to benefit indicates that consumers would not be served by policy changes that would reduce patent protection or accelerate generic entry.

This ratio indicates the effects of an extreme policy experiment whereby, as we talked earlier during an

significant. The gains to U.S. consumers from purchases of prescription drugs now on the market sum to $180 billion per year. Consumers gain $64.5 billion in surplus from prescription drugs that are patent protected. Consumers gain $115 billion in surplus from the purchase of prescription drugs that are not patent protected. The bulk of that comes from generic drugs, and $12.5 billion from branded drugs that are off patent.

These estimates of consumer surplus are conservative in light of other research findings concerning the overall value of medical research and know-how. Frank Lichtenburg's research indicates that much of the unprecedented increase in longevity in the last century is due to the development of new drugs. My colleagues, Kevin Murphy and Robert Topel, found that the longer life expectancy increased consumer welfare in the United States by an amount that matched the gains from increased GDP.

Interestingly, William Nordhaus frames the issue of consumer welfare in terms of a choice concerning the second half of the twentieth century. Which of the following combinations would a typical American prefer?

Two choices. The first is the combination of life expectancy and quality of life in 1950, along with the goods and services in the year 2000; or the

combination of life expectancy and the quality of life in 2000, along with the goods and services in 1950.

Not an obvious choice. The difficulty of that choice makes the point, and I quote Murphy and Topel, "Over the last half century, improvements in health have been as valuable as all other sources of economic growth combined. Looking forward, the aggregate consumer evaluations from further increases in life expectancy are huge."

Murphy and Topel find "U.S. consumers would be willing to pay nearly $10 trillion for 10 percent reductions in both cancer-related deaths and heart-related deaths."

While the Murphy and Topel figure of $10 trillion measures consumer evaluation before subtracting the cost of such treatments, it is confirming evidence of our finding that U.S. consumers derive significant amounts of surplus from prescription drugs.

From our estimates of the annual consumer surplus, we also derive estimates of the present discounted value of current and future consumer surplus from the stock of prescription drugs now on the market. Present value of current and future consumer surplus from those drugs, the drugs now on the market, using a three percent real discount rate is in the range of $6-$10

trillion.

This figure is based on three components. The first, consumers benefit from patented drugs during the remaining period of patent life. Second, consumers will benefit from prescription drugs already off patent. And third, consumers will benefit as patents now in force expire.

The next step in our analysis is to consider how much U.S. consumers would benefit from greater access to the stock of currently available pharmaceuticals not now subject to generic competition. In particular, we estimate the consumer benefits from eliminating patents on all branded pharmaceuticals. We measure these effects compared to the status quo, where the currently-available patented drugs go off patent in the normal course.

So this first part of the analysis focuses on the first part of the trade-off that I identified at the outset, the question of consumer gains, consumer surplus from greater access. Consumers will benefit for two reasons; both, I think, fairly obvious. First, some incumbent consumers switch to lower-priced generics. Second, new consumers, those who value the drug enough to pay more than the incremental cost of the drug, but not enough to pay the price when the product is patent protected, will gain from having access to the drug at

lower prices.

Our estimates of the incremental gains to U.S. consumer surplus from drugs going off patent are based on the stylized set of facts observed from the actual workings of markets for prescription drugs. In particular, our analysis accounts for the average elasticity of demand for branded drugs, price cost margins in the industry, and a range of market outcomes where generic manufacturers offer the drug at significantly lower prices, the volume of prescriptions rise, a minority at sizeable subset of consumers prefer to continue to purchase brand name drugs, and brand name manufacturers may indeed raise prices slightly after patents expire, in effect ceding the bulk of the market to generic competitors.

The effects of this Napsterization policy will be to move forward the time that patents on currently-available drugs expire from an average of about six years to the present time. If all such branded patented drugs were subject to competition immediately, consumers would gain an additional amount of consumer surplus in the range of $120 billion to $140 billion annually in the near term.

In present value terms, therefore, we have one side of the trade-off identified at the outset, the so-

called static efficiency gains. The present value of consumer gains over time for making the current stock of patented prescription drugs immediately accessible is in the range of $540 billion to $620 billion. Even though these gains would be realized over time, we refer to these gains as static efficiency gains due to the fact that the added consumer surplus would be realized from the existing stock of patent-protected drugs. This figure in excess of half a trillion dollars represents real gains to consumers.

To assess the other side of the trade-off, we investigated the lost consumer surplus associated with the reduced flow of newly-patented drugs. These dynamic efficiency gains include the consumer surplus from the flow of new drugs while they are under patent. They also anticipate the fact that eventually, the patents on these new drugs will themselves expire, and the drugs will become "accessible."

The significant issue with this step of the analysis is the extent to which incentives to innovate would be weakened as patent protection is weakened. The earlier exchange is relevant to this very point. If one were to assume that all innovation would cease absent patent protection, then this ratio that I identified at the outset, the lost consumer surplus, would be huge, and

the ratio of consumer harm-to-benefit would be in the range of eight-to-one, rather than the three-to-one figure that I identified.

But I do not believe that innovation would cease absent patent protection. I believe it would be greatly reduced. Manufacturers would be motivated to innovate, albeit at a significantly lower level, for two reasons. And I mentioned them earlier.

First, manufacturers would still realize a de facto period of exclusivity from being first to market. Second, a segment of consumers prefer brand names absent patents, as they do in other markets.

Given these market realities, we investigated a range of market equilibria to assess the extent to which profits of brand name manufacturers would fall. Consistent with research by Elizabeth Jenson, we then posited that the flow of new drugs would fall by the same percentage that profits would fall. Using those data, we then returned to focus on consumer welfare and calculated the loss in consumer surplus from a reduced flow of new branded drugs.

So now we have the other side of the trade-off,

1.9 trillion.

I'll conclude, therefore, by going back to our bottom line. While providing greater access to the current stock of prescription drugs would yield large benefits to consumers in absolute terms, realizing those benefits has a yet greater cost in terms of lost consumer surplus from reductions in the flow of new prescription drugs. Specifically, the ratio of harm-to-benefit is three-to-one.

Now, let me just pause and add here that as I said earlier, if Mr. Armitage's view is right, and all innovation would cease, then that ratio would go to eight-to-one. Another way to ask this question, what percentage reduction in innovation would make Napsterization an even trade? And the answer to that is it would only take probably about 20 percent reduction in the flow of new drugs to make Napsterization an even bet. And if the percentage reduction exceeds about 20 percent, then it becomes a bad bet for consumers.

So again, for every dollar in consumer benefit realized from providing greater access, other consumers would be harmed at a rate of $3 from reduced innovation. This specific ratio of harm-to-benefit indicates that consumers on that would not be served by policy changes that at the margin would reduce patent protection or

accelerate generic entry.

On this point, I'll just mention that this particular ratio was influenced by the extent to which consumers prefer branded products absent patent protection. One of the further insights to our analysis is that weakening patent protection is less costly to the extent that consumers there is a significant amount of consumers who prefer branded drugs, and thereby would sustain some incentives for innovation.

Thank you very much.

MS. MOORE: Thank you. And now we will hear from David.

MR. COFFIN-BEACH: Thank you, Robin, for asking me to speak here today. Given the forum, given the nation's capital, I certainly want to qualify my statements as being as the president of a generic company or a company from Canada, and not necessarily representative of the entire generic industry.

That being the case, I have some mom-and-apple-pie statements to make, what we consider to be the problem, and some concluding comments.

By way of introduction, I want to state clearly, and based on this afternoon's conversation, that Apotex certainly believes in true innovation, and believes that innovation should be rewarded. Apotex supports innovator

intellectual property and patent rights. Apotex is committed to citizens' access to affordable medications, and has a 30-year history of providing the same in Canada. We believe generic drug products offer a safe, effective, affordable alternative to more expensive innovative brand drugs at patent expiry.

The public benefits from rapid availability of generic drugs through expanded access to medicine, better health, billions of dollars in savings on drug costs. Americans -- and world citizens, for that matter -- and generic drug companies are entitled to a fair, predictable regulatory regime. We believe that that regime should encourage competition, innovation, and investment.

The statement of the problem, then. We believe the problem can be easily stated as brand name company tactics that seek to delay and defeat generic competition. We believe that brand name companies -- some brand name companies, not all -- currently game the system. They abuse the courts and FDA regulatory systems to delay and defeat generic competition. Brand name product life cycle strategies seek to extend patent monopolies beyond the patent expiry of the new chemical entity.

FDA Orange Book listings are used to obtain

successive 30-month stays on generic approval. We're currently enjoying that right now with a product that we're attempting to bring to the U.S. market.

Generic companies have no effective remedy before FDA or the courts. Approval is delayed or denied, even when FDA has determined that the generic drug is safe, effective, and approvable.

The drug approval regulatory system has become unfair, unpredictable and inconsistent. There is both legal and regulatory gridlock. The legal and regulatory climate is uncertain for generic drug companies currently.

A perspective for the Hatch-Waxman Balance that we believe was struck in 1984. In 1984, the Hatch-Waxman Act struck the balance between innovators, government, consumers, and generic drug companies. Innovators were protected with expected access to affordable generics.

The Hatch-Waxman intent, we believe, was to provide consumers speedy access to safe and effective generic medicines through generic competition after patent expiry.

We believe the assumptions have changed in the 15 years since Hatch-Waxman. Well, more than 15. Actually, 17, 18 years since Hatch-Waxman was implemented. Health care and drug costs are rising.

pediatric studies. Some examples of the delay tactics: Paxil, we believe, is a poster child for Orange Book abuse; Tramadol, this has a labeling issue associated with it brought up by the innovator at the eleventh hour at patent expiry.

In conclusion, we believe the U.S. drug regulatory scheme is not working, the climate is unpredictable, and it's uninviting for generic drug companies. We believe that citizens are being denied timely access to generic alternatives. Excessive prices are being paid by consumers, insurers, and governments, with no remedy at law currently. We believe there is gridlock at FDA. We believe there's gridlock within the District Court system.

We believe that the U.S. Patent Office continues to issue frivolous and invalid patents which assist brand name drug companies in the current status to, again, properly extend their monopolies. Standards need to be addressed at the Patent Office.

Research and development dollars are spent on brand name product life cycle management, and not on searching for the medicines and drug therapies. We seek a balanced, predictable, fair, competitive regulatory environment. We seek a level playing field in the drug business in the United States. Thank you.

I think it's unfair, in a sense, to challenge the pharmaceutical companies that list patents in the Orange Book or send the patents to be listed in the Orange Book pursuant to the dictates of the FDA -- is a difficult situation. I think perhaps in this case, the law needs to be changed. And I know Congress is addressing that, and this is not an area where the FTC wanted to get involved in regard to changes in Hatch-Waxman. That's an issue at this present time for Congress to be addressing, and it is addressing.

But in regard to that, I think in reality, most patents that are listed, with a few exceptions, are not frivolous, and they are actual real innovations. Or perhaps patents that exist later or come along later that cover the actual commercially-valuable drug that's on the market, rather than perhaps the generic original new molecular entity, which in many cases is a -- if you're looking at a small molecule in a new molecular entity, you have a small molecule with a lot of different radical groups on it that could cover thousands of compounds. And subsequently, you define and refine the most preferred compound there with a later drug and a later compound and later use, as you do more and more research and development. And in most cases, the patents that are listed actually cover real innovation, and not just

frivolous additions.

That's not to say that in some cases, there may be some mysterious and frivolous additions, and the courts are now working that out in great detail.

The last part here is in regard to looking at what -- we've been talking about patent protection in the generic sense, and during the break, I went back -- and I know Bob mentioned the issues and what was required to obtain a patent. But again, I think most people lose sight of the fact that what you really have to look at is what's contained in the claims of a patent. A patent is a document that describes an invention.

But the real metes and bounds of what your invention has and your intellectual property right is in a claim. And the claim is really what defines your metes and bounds. Your claim can't read what's out in the prior art, what's out in the general knowledge, what's beyond what you're in possession of, what's beyond what you've described and enabled. Your claim actually has to be what you invented. And it's really, in a sense, your narrow circumscribed invention. And I think we can't lose sight of the fact that that's the most important aspect of what we're dealing with here.

And I think at the present time, despite the fact that there is a tremendous amount of litigation,

patent litigation, I venture to say since I also practice in a large firm where we don't only represent pharmaceutical companies and biotech companies, a lot of the patent litigation that we see also is in every industry, from mechanical downward, you know, including a very large one -- I don't know that anyone saw the Wall Street Journal today -- of hair dryers.

So I think this is a general phenomenon of our society, not just in this particular area of business in regard to patent litigation.

MS. MOORE: Thank you. I guess the first question I would have goes directly to a couple of new points that Ted made. First, I want to make sure that we're all clear. Your presentation was dealing specifically with the pharmaceutical industry, correct?

MR. SNYDER: Yes.

MS. MOORE: And then here comes the follow-up question. What does your study assume about the extent of investment that needs to be recouped in order to make innovation worthwhile?

MR. SNYDER: The extent of innovation that would -- I'm sorry. I don't understand the question, Robin.

MS. DESANTI: Let me follow up. One question is does this research apply only to pharmaceuticals? Implicit, it seems to me -- and correct me if I'm wrong

-- implicit in your study is the notion that in order to make an investment in the R&D, in order to make the investment in R&D worthwhile, you have to recoup on your investment.

MR. SNYDER: Right.

MS. DESANTI: And so the question is what were your assumptions about how much you have to recoup on your investment in order to make pharmaceutical research worthwhile?

MR. SNYDER: Here's the way we handled that in our research. We followed the finding of Elizabeth Jenson. And I think there's some practice-based information that's relevant here. The simple fact is that research-based pharmaceutical companies fund their research out of current revenues and profits. Our specific assumption was that to the extent that those profits would fall, they would reduce R&D by the same proportion. That begs the deeper issue of if you think about the R&D process in real option terms, exactly which projects would survive and which would not?

I think it's clear that you can identify cases in the case of I think it was Novartis with their leukemia drug. That particular drug and that particular effort would not have survived without the promise of patent protection. There may be others. And we were, I

out of it."

And I'm just wondering how that plays in innovation strategies and competition to innovate strategies for both brand and generic companies?

MR. COFFIN-BEACH: I'll bite first.

MS. DESANTI: Thank you, David.

MR. COFFIN-BEACH: Well, certainly what strikes us as we look at the patent information that's available -- and again, we do read patents, because we find them instructive in terms of formulating generic drugs -- is that an entity can be discovered, its kinetics well-known at the time of first commercialization, and yet, it's 10 years sometimes and longer before a sustained release or once-a-day dosage form comes along.

And is that timing accidental? Is that not part of development? It's a question, I think, that's open. Certainly that becomes, then, another source for innovation.

Similarly, in this day and age of pharmaceutical development, different types of processes are available to formulate the oral dosage forms in particular, which is my area of specialization. There will be patents issued for an entity to a known process, basically -- I mean known for a good long time, basically, in the literature -- that will still find themselves or find

their way into listing under Hatch-Waxman provisions.

So it's interesting. Is it again part of life cycle strategy management? Can't say for certain. But it's interesting that it takes so long in these hot beds of innovation, which is our competition, to come up with

paths, they do not have the flexibility in retaining the recruiting examiners that they need. And particularly in the areas of the most complex technology, where examiners are most heavily recruited out of the PTO, it's essential that they have the kind of private sector-like business-like orientation to running the office.

It's also quite clear that the PTO got started on automation way too early -- indeed, at the beginning of the Reagan Administration -- trying to put in place

morning -- initiatives in this Congress to change that. But until it's done, I don't think that in the high-technology industries, we're going to have the PTO that we need, a combination of high-quality examination done in a much prompter manner than we're doing today. And

product life cycle management?

MS. MOORE: Certainly.

MR. ARMITAGE: I heard a very narrow statement that it would be desirable to have a balanced, predictable, and fair regulatory environment. And I call that a narrow statement, because I think that what we really want is a balanced, predictable, and fair legal environment overall. I think to the extent that that's in the interest of the so-called generic manufacturing industry, it's also, frankly, very much in the interest of the innovator industry.

Now, I think sometimes this term "product life cycle management" is misunderstood, particularly when it's applied in the context of the patent system. There is a fundamental immutable principle of patent law. Once a product is first marketed -- once a product is first marketed -- no invention that you made after the marketing begins can validly protect that marketed product in the sense of preventing someone from copying the product. I think I made this statement earlier. And it therefore follows that nothing an innovator company can do, either in getting follow-on patents or in listing patents in the Orange Book, is ever going to repeal that fundamental principle.

However, product life cycle management, as

practiced in the innovative pharmaceutical industry, actually relies on a much different principle of patent law. And that is that follow-on innovations, while they cannot stop copying of the pre-existing product, they certainly can prevent copying the novel, useful, and non-obvious improvements made to that innovation product. And indeed, more convenient dosage forms, easier-to-manufacture formulations, new indications for use, new treatment protocols, new delivery devices, and other types of information that make better medicines are indeed the very stuff of consumer benefit in the pharmaceutical industry.

And clearly, the pharmaceutical industry is in no way different from any other industry practicing identical product life cycle management strategies. Somebody did put color in black and white TV, somebody did put fluoride in toothpaste, somebody did put transistors in old vacuum tube computers, and someone made injectable penicillin oral.

So I assert that product life cycle management isn't a way to delay the start of generic competition, but indeed, it may leave someone who does not innovate at a competitive disadvantage in that they may not incorporate the novel, useful, and non-obvious innovations. And this is always a risk in the patent

So I'll throw those two issues out to the panel.

MS. MOORE: Bob, did you want to respond? Your tent is up. Is that --

MR. ARMITAGE: Oh. It's because I didn't take it down.

MS. SEIDE: I was going to say I think the number from start to finish on examining a patent is something like 21 hours or thereabouts. And in many cases when you're reading a patent application that's 150 to 200 pages, it sort of stretches the time and the consideration.

In addressing the issues of looking at invalidity, and especially if you have many, many more hours to look and do a -- you know, when you're looking to invalidate a patent, you have to go way, way beyond the issues that were raised in patent prosecution that got to get the patent issued. Because again, the patent, once it's issued, is presumed valid. So if you ever take it to court to challenge it, the standards are much higher, so you have to come back in with a much higher issue.

Edward, in regard to th bag6

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never talked about. The U.S. patent system again, is particularly unique in a lot of the structures that we go through, including who actually was the first to make an invention. In many cases, that's a long, drawn-out procedure also.

But again, it's a -- I don't know anybody, really, who goes in that much to challenge by a reexamination or submission of prior art. It's not an easy patent, and you run the risk sometimes if you go in and challenge it for reexamination. The patent succeeds in re-examination and comes out, in a sense, stronger than it went in. It's not always the best way to go in and challenge it.

MS. MOORE: I wanted to move back to something Bob said a little while ago, and that's the 98 percent of the time, the entity, or the new chemical entity, is the patent, or the patent on that is the one that really matters.

Given that -- I guess I would ask, and I would throw this up to the entire panel -- if there is an incentive, and what that incentive might be for companies to get patents claiming the drug after the NDA has been approved. Rochelle?

MS. SEIDE: I think the NDA being approved is, as Bob would say -- it's 10 years down the line, usually,

long after you've started the research. In one sense, what you're trying to say is you're going to keep your patented invention as a trade secret. And in that case, you run the risk again.

innovations become relevant to the product as it evolves in the marketplace. And I'll give you the most classic example of the 0/100, where the NCE patent effectively was of no use, but a follow-on use patent turned out to be the entire commercial value of the product to within a minuscule amount.

If you remember back in the '70s, I believe it was, a little pharmaceutical company in Kalamazoo, Michigan, got approval of Loniten. How many people have ever heard of the drug Loniten? No one has. It is a blood pressure medicine that largely sold a few million dollars a year, an NCE drug, one of the ones that was a tremendous medical innovation, but not a commercial success largely because of another class of drugs, the ACE inhibitors.

However, this drug had what was perceived initially as a side effect. It grew hair. And its active ingredient, Minoxidil, was then the subject of a use patent, a use for topical application to grow hair, which indeed became Rogaine, which indeed sold more than a few million dollars, but was by no means a blockbuster drug.

So there you had a situation where, indeed, it took a very long time for both the NCE drug and for the later-use drug to be patented. And for, I think, a

period of somewhat less than 10 years, the use patent was still around and protected Rogaine. The NCE patent expired quite early.

It is, I think, also true, as you look at -- and I was trying to do the mental exercise, which is difficult for me on the fly here. We've had a number of Hatch-Waxman patent challenges at Lilly, and we have a number of patents for Lilly products listed in the Orange Book. I can't remember a single time in which we have actually sued a generic manufacturer for filing a patent challenge for a patent that issued after the NDA was approved. Indeed, we have sued on patents that issued before the NDA was approved.

But I think in each case -- and I may be wrong -- where it was an NCE drug, it was the NCE patent. And

said. He described a situation in which he would have disclosure and innovation, and then more disclosure and innovation, and so the cycle goes. I guess my question to the entire panel would be do you see that in the pharmaceutical industry on either the branded side and generic?

MR. GLOVER: I might have said that, or I might have said something similar. If what you're suggesting is that by virtue of the disclosures that result from a patent being published, or a patent application being published, that you then spur innovation by virtue of other competitors, whether it be brand name or otherwise, I think the answer is absolutely yes.

But as you know, the general bargain that is struck with the government with respect to patents is that you get the period of exclusivity, where you are simply able to exclude others from making, using, and selling your invention, giving you no affirmative rights yourself.

On the other hand, the trade-off is that you have to disclose fully what you do so that others can practice what you do. And so the benefit to the public is that your invention goes into the public marketplace and can be used to work on other discoveries and things of that nature.

So the answer is absolutely yes. I think what you will find in the industry is that people do read each other's patents and pay attention to what they're doing. And generally, you're going to know to some extent, by virtue of whatever sources, where other people's development plans are with respect to moving into a new class of drugs and things of that nature. And all of that is important to the innovation process.

MS. MOORE: David?

MR. COFFIN-BEACH: Well, certainly we incorporate, or because we've also got assigned chemical capability, different synthesis in formulating many of the new entities that we develop. So if it is truly innovative, patents are issued out for that as well.

So there is innovation on both sides of the street. It is a platform on which other things are growing. So as my comments indicated at the opening, we certainly don't want to do away with the Patent Office or the patenting of intellectual property.

MS. MOORE: Bob?

MR. ARMITAGE: Going back to your original question, were you alluding to the discussion this morning that related to the filing of continuing patent application, where an application is filed, then a subsequent patent application is filed, et cetera? When

you said --

MS. MOORE: No, no, no. I was alluding to -- and I don't remember which panelist it was, frankly. This panelist was describing what the patent system, what the Constitution envisions in terms of the disclosure itself, fostering further innovation.

MS. SEIDE: Well, one of the goals, what's called designing around. I mean, that's innovation also that it spurs innovation in another way to avoid what's patented, and if you're an innovator company, to come up with your own innovations that don't fall within the patented protection.

MS. MOORE: This is going back to a point that Monte made a little bit earlier, and that's do pharmaceutical companies patent defensively? And if so, what is driving that? Monte.

MR. BROWDER: I can't speak for Bob. But just based on my experience on the brand side -- you know, defensively, again, you're chronologically going along the development path and ultimately selecting a development candidate -- that if you're going to then invest hundreds of millions of dollars or something in clinical trials, you choose that one over some other ones. And then at that point in time, you still sort of maintain the franchise with the complete awareness of

Hatch-Waxman, and the complete awareness of all the market exclusivity and the new formulation development.

And so as you bring the compound to market, people don't just shut down their innovation, as Bob implied. The patent department, in conjunction with the clinical people and formulators and everybody in these companies, at IVAX or any other place, both on the generic and brand side, you are continually patenting, if you can, the new inventions.

And to the extent that's going to be,

practicing that invention to IVAX anyway.

I mean, principally, that's maybe the only current problem with Hatch-Waxman as we see it. Because the other exclusivity provisions, both on the brand side and the generic side, are great incentives to innovate, both for generic companies to design around, to be the first to file and challenge all these formulation patents that, for the most part, it does take a lot of work and a lot of energy.

I've heard the word "copying" a million times. And to the extent that that's pejorative, it does take a lot of energy and time to actually find these bio-equivalent formulations and design around the various patents that may be there both on the third party side and on the brand company side.

So it's a world of patents out there that it's -- again, each company may be different in the numbers of patents and their internal, you know, how patent attorneys communicate with clinicians. Some companies, the patent attorneys may never even see them. Others, they're actually in a room together, arm-in-arm, and helping that drug product all the way through, and continuing to make those improvements.

MS. MOORE: Thank you. Greg?

MR. GLOVER: I just wanted to comment on where

-- that we have waded in to Orange Book listings, where we have said we would not wade. And while we probably need a separate hearing to really give enough background to understand that, I do want to make the point that where certain people will see abuses in the listings, others see the opportunity and the right to vigorously defend the rights that have been set up in the Hatch-Waxman Act.

And in the context where the Hatch-Waxman Act created a circumstance where the pioneers were not able to fully assert their patents, and the circumstances that they could previously; and where the data protection for our confidential data was restricted to a certain number of years, as opposed to being more infinite; and where we have patents that are presumed to be valid, and the generics are claiming to be making an identical copy of our products; we believe that at a minimum, our vigorous support and adherence to the rights that are provided by the act should not be viewed as abuse, nor should they be viewed as anticipative.

MS. MOORE: Thank you. Bob, did you have a comment?

MR. ARMITAGE: Just a comment on the defensive patent question you raised. And the comments I'm going to make are sort of a case study that is only grossly

accurate, because I don't know all the details. And this follows on, again, some comments from this morning.

There came a time when SmithKline revolutionized the treatment of ulcers with Tagamet. And SmithKline not only patented Tagamet, but they had a huge number of patents, perhaps a dozen, perhaps more patents, on things that were like Tagamet, but not Tagamet. And indeed, one could look at those as defensive patents, since they defended around the already-patented Tagamet molecule.

In fact, of course, what SmithKline was doing unsuccessfully is trying to find a successor product to Tagamet. They were never able to do that. They were never actually able to find the super Tagamet they were looking for.

On the other hand, you had another tiny, insignificant pharmaceutical company that looked at all these patents and said, "Gee, what's left for us to do? What innovative thing can we do, given all of these patents?" and made a significant but fundamental change to the H2 receptor in Tagamet. They changed the chemical ring structure, and almost immediately discovered another chemical component called ranitidine that became Zantac, that became a far bigger product than Tagamet, that, at least in Glaxo's eyes, had advantages for patients that Tagamet didn't have.

And I notice today that company is called GlaxoSmithKline.

So sometimes you have defensive patenting, because you are unsuccessful at offense, and sometimes that defensive patenting, as you heard this morning, really is the trigger for that next leap forward of innovation.

MS. DESANTI: Let me ask a follow-up question, because to some extent, the question about defensive patenting is prompted by trying to do some of the cross-industry comparisons that we've had with different panels. And one of the things that we've heard in the semiconductor industry and in software, to some extent, is that defensive patenting occurs in the sense that you need to have patents to trade in order to do cross-licensing deals, because in order to develop your products, you need to be able to have access to others' products as well.

providing yourself with patents that you will have as chips in trading negotiations for cross-licensing deals.

MR. ARMITAGE: I was trying to confine my comments to the pharmaceutical industry in the classic sense we've been talking about it today. But as I indicated earlier, one of the leading biotechnology companies in the United States is Eli Lilly and Company. And it does work a little differently in the biotechnology industry, where you had a good deal of similar innovation done, obviously from Cohen-Boyer patent onward, where I think you heard in Berkeley more concerns about alleged royalty-stacking and multiple inventions.

And I would say that in that industry, there are situations where I think you see more of the classical defensive patent. Although I have to tell you, frankly, that the way I see patent strategies work best to protect innovative biotechnology products are really not that much different today, at least, from traditional pharma products. You really want to have an NCE product.

For example, our insulin analog, Humalog, is protected by an NCE. It's a chemical compound that we devised in our lab.

And I think increasingly, biotechnology patenting will be more like traditional pharma patenting.

MS. SEIDE: I was going to agree with that, because traditionally, biotechnology patenting has been more what now is referred to as tools. It's technology needed to -- and it wasn't product oriented, whereas pharmaceutical patenting was more product oriented. You filed for patent protection on the chemical molecule, rather than the way to get to that molecule. Whereas, in biotechnology, perhaps like with Barbara's comments, you filed patents on the DNA molecule.

The DNA molecule is not what's going to be the drug. What's going to be the drug is the use of that DNA -- the use of the information, that an assay using that DNA molecule, or something like that, to derive the drug.

And that's the technology, and I think that's where a lot of this is. And I think a lot of pharmaceutical companies are facing that issue also with the technology type patents that are out in the biotechnology industry in regard to royalty-stacking and licensing, if you want to develop certain products using old technology to do it.

MS. MOORE: Ted?

MR. SNYDER: Thank you. I wanted to just comment and step back. I think that economists and non-economists alike now have a pretty good understanding of what I would call static competition, that in markets, we

are comforted when a price goes to something close to marginal cost. We understand that that means that consumers are willing to pay more than incremental cost to get the product.

I think there is, by comparison, less understanding, less appreciation, less comfort with dynamic competition. And that's what this industry is concerned with.

And I find very interesting this line of questions, because you've got -- once you've set up a patent system, you're going to have -- well, first of all, you can't suppress competition. The patent system will change the way competition is manifested. And once you have a patent system, you're going to get efforts to

appropriate -- I suspect that even experts, however, would be able to predict exactly what kinds of R&D efforts led to what kinds of innovations, that when you start out this process, there is oftentimes no logical link between where you start out and what your intentions are with R&D, and even with patenting efforts and where you end up. That is simply maybe my way to getting to a fairly obvious conclusion, and that is given that, it's very difficult to then identify and channel this dynamic competition exactly how you want it. It's just a very tough problem.

And I go back to the fundamentals of our research. Whatever policy options that are considered down the road, I would hope that we would keep in mind the interests of consumers. The people I'm thinking about are people who are looking for better treatments of diabetes, Alzheimers. We should, as I said earlier, keep in mind the interests of these future consumers and caution ourselves.

And, in effect, this is March madness. It's, you know, get a time-out on changes, knowing that exactly what effects they have are extraordinarily hard to predict.

MS. MOORE: I would like to shift gears for just a moment. We've talked a lot this afternoon about

patents and their role. I don't think I've directly posed the question of the role that competition plays in the pharmaceutical and in the biotech industry. So I throw that open to the panel.

MS. DESANTI: To be as specific as possible. I mean, what role -- we've talked a lot -- and Ted, your paper goes to the role of patents in inducing innovation, and what would happen if you didn't have patents as one of the pillars to induce innovation. Is there a role of competition in pharmaceuticals to promote innovation? If so, how does that work?

MR. GLOVER: I can start and take a gander at this the....While competition is important, as we discussed, perhaps, in my prepared comments, and we've been discussing all along, which is that when you see that somebody else has made an innovation and it's a market that you want to get into, then you will try to find a way to innovate around whatever has been done. So that is, in fact, competitive.

However, because the cost of playing the game of the pharmaceutical industry is so large, and because the risks are so large, you will not get into that game to be competitive without patent protection.

And I know that's not what you wanted to hear. You wanted to hear how they were separate. At least from

our perspective, that does not work for this industry. That is, as much as I might want to have the better drug than the other company, I'm not going to get into the game of trying to play that and trying to do the research and take the risk if I do not have the R&D protection.

MS. DESANTI: Well, I'm not asking for competition in the absence of patent protection. I'm asking for how does competition work, and is there a supplementary role that competition plays in promoting innovation in addition to having the patent protection?

In other words, if you -- I thought where you were initially going in your response was to say, you know, in some sense, you need a market niche in order to justify going forward when you have such great expense and risk involved. And then when you added at the end "absent IP protection," then I got a little confused.

MR. GLOVER: Well, let me try again, and I'll defer to others. But we did describe that one of the circumstances that has changed over the last year is that if you go to, for example, Tagamet, where it took some six years for the next good drug of this class to get on the market. And then with some of the newer drugs, for example, the protease inhibitors, it took three months.

That is all about competition, that as you know, if you get up to the market, whether you have IP

protection or not, and you fail to innovate, you will be off the market soon, because somebody else will come along with something that is better.

So the overwhelming incentive is that what you developed already is going to be surpassed by every other drug company that might be trying to get into the same therapeutic promise.

So that is the inherent competition that is going to push you along, as well as your ultimate knowledge that eventually your patent will expire, and the Hatch-Waxman Act will allow the generics to enter the market.

MS. DESANTI: Thank you. That helps.

MS. MOORE: Monte?

MR. BROWDER: I think just early on, before anything becomes a product, if each -- you know, three or four different companies are going after an identical target, like the CRF receptor or something like that, then clearly, they pay attention to the publications, the patent publications, what's happening in the science.

And there has to be sort of healthy competition to maybe be either the first company to get an actual drug candidate, ultimately a drug that is specific for that receptor, then it has an indication, a proven indication, that they're going after. And that occurs

constantly throughout the drug business, where it would be, you know, just like the H2 in Tagamet or any other kind of now novel targets that people have, in essence, may be racing after to find a new drug. So I think that's wise in the industry.

MS. MOORE: David?

MR. COFFIN-BEACH: The generic piece of this is interesting, because there's acute competition for the six-month exclusivity that's granted, certainly. But even after that. If we look at the generic price erosion that typically occurs, where, you know, if brand pharm is a dollar, the generics end up at five cents on the dollar, that is also forced by competition.

So irrespective of intellectual property rates on the generic side of the street, competition certainly drives down the cost of generic pharmaceuticals.

MS. MOORE: Ted?

MR. SNYDER: I felt that point is important. I mean, you can talk about this in terms of second and third generic. You can talk about the competition conditional on patent protection. There is a whole huge economic literature on what is the optimal industry structure to promote R&D and innovation. And I will reduce it to what I firmly believe in, which is competition is good.

I mean, if you compare a world where you have only one firm allowed to take advantage of, for example, the ability to get patents, and compare that to a world where you have competition, you would be much better off with competition.

I would agree that given the nature of competition in this industry, we would not expect to see huge numbers of firms. And there is some economic literature that would suggest when you get a large number of firms, sometimes you get less than optimal innovation.

But I don't think there are many firm take-aways from economics and public policy, except to say competition is better than a single firm. After that, it gets complicated.

MS. MOORE: Okay. Bob?

MR. ARMITAGE: I think that research-based pharmaceutical companies would like competition to drive innovation, but I don't think they know how to do it. And I say that because even today with the industry as consolidated as it is, there are no really big pharma companies. There are no big three pharma companies. There are no big five pharma companies. There are just lots of market companies with relatively small market shares and focuses in one product area or another.

And the second is that the process of innovation

is not predictable enough. Even if I decided that I wanted to -- even if I decided after Tagamet, for example, at SmithKline that I wanted to focus my research so I could drive my market share to be the Jack Welch number one or number two in the treatment of gastroenterology, it's so unlikely that I'm going to succeed that I can't let just competition drive the way I do innovation.

And then the other reality is that product life cycles for innovative medicines are so short that you run the risk of being totally out of an area where you want to focus innovation before you ever can find the next two or three products that indeed would give you the kind of market share that Proctor and Gamble has in toothpaste, for example, or dental care products.

I mean, the model is nice, but I don't think anybody knows how to make it work.

MS. MOORE: Have biotech tools had any impact, either made it more efficient or less efficient in trying to bring some certainty to this process?

MR. ARMITAGE: I'm just going to give you one sentence. Several years ago, a large number of companies, three or four companies in the genomic area, claimed that they had the sequence of every gene in the human body. And in fact, they had the sequences of three

times more genes that were, in fact, in the human body, but they didn't know it at the time.

And the reality is knowing everything is a lot like knowing nothing. In other words, so far, this revolution has been a revolution of information, rather than a revolution of knowledge and insight.

So I think we're a generation away from that being a driving force in a lot of information. Dumb luck is still better than the genome.

MS. CAULFIELD: I think on the biotech industry -- and I was going to reflect that we really have such a different opportunity here, and it's such a different market here, because the market is actually being driven from both ends. It's being driven from what Bob just said, which is the sort of gross what's-in-the-genome. And the other end is starting with diseases and health care issues and working back towards the genome, you see.

So the competition is actually in two parts there. There's R&D competition coming from what we know about diseases and what we know about tumors and people that have diseases, and working back towards the genome or proteins or haplotypes or genotyping, and coming this way also.

So what you've got is a completely dynamic, if you will, as Ted says, effect here. And competition is

the name of the game, because the more people that are innovating, going towards sort of the golden spike, if you will, in the middle of the research area, the better off and the quicker the innovation is going to be.

The other advantage is that the research in the genome is going towards the middle or going towards disease, and there is obviously none of the kind of regulatory effect everybody was talking about here. That's a big one. And there's not the high cost of innovating or the long term. There is down here at the other end, coming this way.

And when genetic research hits, you know, small molecule research, if I can put it that way, it is going to be very interesting in this middle group as to how competition is going to affect innovation in that sphere. And I would say we're closer to it -- I think, Bob, when you said "generation," you meant "technological generation." But that's moved so quickly in the past five years that a lot of people are projecting in three more, we're going to be very close to that middle ground. And it's going to be in oncology, because there's so many initiatives in the area.

MS. SEIDE: I was just going to say the same thing. The generational issue, again, it's not in the genome where we are now in the genomic sense. It's where

we're going to be in the next technology, again, which is the information from genomics, which is structure, which is function, and which is proteins, which will be the targets for correlating that. And that's already happening. I see it a lot, certainly.

And a lot of that area is not even in the biotech companies or even in the pharmaceutical companies. A lot of that's in the universities. There's a tremendous amount of technology that's being developed in that area in maybe the very small biotech companies, and also in the university area, which are developing technologies that will have great ramification in that interface, you know, several years down the line.

I mean, the whole area -- I mean, the buzzword has always been what's called pharmacogenomics, basically using this information to develop better drugs. And I don't think we've even talked about that particular area at all.

The classical model for pharmaceutical development is you develop a drug. And that drug is used to treat a population who have different responses to the drug. And what some areas are going in is to maybe target and focus drug development and drug discovery to populations that will respond better, have fewer side effects. And a lot of that information is going to be

coming out of biotechnology. You know, better drugs developed using this information.

MS. CAULFIELD: And I think one immediate impact of that is going to be if you could have the information to drive a clinical trial, for example, to people where the drug is genetically more effective.

MS. SEIDE: It's working already. GeneSense is doing that already. And there are companies that are actually looking at that information, and they're doing a very big study on known drug statents in targeted populations based on their genetic composition, and showing information in that regard.

MS. MOORE: We have a couple of minutes left, I

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I don't have anything to add.

MS. MOORE: Okay. That was short. David?

MR. COFFIN-BEACH: Same for me. I appreciate the opportunity to be here with this panel and to hear the discussions of today.

MS. MOORE: Greg?

MR. GLOVER: Research-based industry looks forward to the opportunity to continue to develop new and improved cures and treatments into the next century, and we hope that we will maintain a strong and certain IP protection system that will allow it to occur.

MS. MOORE: Barbara?

MS. CAULFIELD: I guess I come out very close to where Rochelle is, which is I'm advocating taking a look at a whole new way of doing research, and asking some very serious questions about how we manage IP protection when you have a whole new market and industry development.

MS. MOORE: Bob?

MR. ARMITAGE: I would just concur with almost all the closing comments of everyone else and add that indeed, my hope is that we do have a patent system that works well for the consumer in the future, and that today's hearings, and particularly some of the things said this morning, can help it be a better patent system

for consumers in the future.

MS. MOORE: Monte?

MR. BROWDER: Yes. Thank you, Robin. And also, we strongly support a strong intellectual property position, and also data exclusivity, market exclusivity, the whole scenario of incentives as it currently stands.

MS. MOORE: I would like to thank all of the panelists for the multiple conversations that they have had with me, as well as taking the time to come in this afternoon and talk with us. Thanks.

(Applause.)

(Time Noted: 4:41 p.m.)

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C E R T I F I C A T I O N O F R E P O R T E R

CASE TITLE: HEARINGS ON COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY IN THE KNOWLEDGE-BASED ECONOMY

HEARING DATE: MARCH 19, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION, to the best of my knowledge and belief.

DANIEL WILSON