

>>FEMALE SPEAKER

We'll get started with the last panel of the day. We'll talk about the life sciences industry. Or industries. Industries obviously that depends heavily on patent protection. Our panelists today are Christine Valin (ph), PhD chemist and Vice President of intellectual property and legal affairs for Hydro Biosciences where she's responsible for all legal matters for the company. She was an attorney at Fish and Richardson. Intellectual property for Infinity Pharmaceuticals before joining Hydro Biosciences. We have Steve Jenson here partner in the Orange County office where he works on intellectual property litigation, licensing and strategic counseling matters with clients in a wide range of technology including large portion of his work in the medical device industry. We have Jeff Meyers who is Vice President and assistant general council for property enforcement for Pfizer where he manages all of Pfizer's worldwide patent litigation. He's drafted and prosecuted patents in chemical and biotechnology for Synaptic (ph) Pharmaceutical Corporation and he was a patent attorney at Fitzpatrick Chello Harper before joining Pfizer. We have Maggie Shafmaster, thank you, who is senior Vice President and chief patent counsel at Genzyme Corporation and she's responsible for managing and licensing and enforcement worldwide. She has also been a patent attorney at Fish and Richardson in New York. And over on my right, Steve Singer, who is chair of the technology

transactions and licensing practicing group and co chair of the life sciences group at Wilmer Hale. He has focused on the life sciences industry for three decades.

>>MALE SPEAKER

1979.

>>FEMALE SPEAKER

He serves as counsel for public and private companies in the life sciences sector including biotechnology, medical device and pharmaceutical companies. His practice focuses on joint ventures and corporate and security law, public offerings, venture capital transactions involving the biotechnology and other life sciences industries. Thank you all very much for joining us today. I think you can see that we have a -- people from coming at these industries from different perspectives, startups, medical devices, biotech, pharma. And we'll have an interesting discussion I would like to start with a broad general discussion to allow each of the panelists to tell us about your company and why -- or your clients, and how your company or clients use patents primarily. Why patents are important and why you were willing to very generously give us your time today to talk about this topic.

Maggie.

>>MAGGIE SHAFMASTER

Thank you very much for having us and thank you for giving me this opportunity to actually -- I'm looking forward to talking

about Genzyme and what we do. I think we have a unique business model in terms of where we started and where we've ended up. And hearing about that, you'll understand why patents are so important to us. We're now a global biotechnology company dedicated to making a major positive impact on the lives of patients with serious medical needs. We started as a very small start up in 1981 and since then grown to a large enterprise with more than 11,000 employees bringing services and therapies to patients in more than 100 country around the world. We are technology agnostic. We don't do just small molecules or biotech proteins we have diagnostic and genetic testing services, cell therapies, biomaterials and a lot of research efforts in Gene therapy. The diseases we target are also diverse including rare inherited disorders, kidney disease, orthopedics, cancer transplant and immune disease. We have a substantial investment in these diseases as well as neurodegenerative disease, Cardiovascular, et cetera. Throughout our history we partnered with University, research institutions and private companies in order to find and develop these products and bring them to market. We consistently spend 20% of our revenues on research and development. And that has allowed us to bring to patients first in class therapies addressing serious unmet medical needs at an average rate of about one new therapy per year over the last six years. And in 2003 we launched two new products, Fabrazyme (ph) and Eldorzine

(ph) the first ever approved in the United States to treat rare, often fatal genetic disorders. In 2005 Chloar (ph) first leukemia for treatment for children in a decade. And Myzine (ph) from Pomp disease or any inherited muscle disorder. The list goes on and on. And of these products, seven in the last six years, five are protected at least in part by intellectual property we licensed in from University and two were based on IP that was developed either at Genzyme or by ask the company we acquired. In 2007 they were chosen to receive the national medal of technology the highest honor award bit President of United States for technological Innovations. Our primary patents are in the packet place is to protect products for a period of time sufficient to ensure we're going to continue to innovate as everyone here knows biotechnology is risky business and development time lines are lengthy and given that enormous investment, it's critical that we are able to achieve enough sales revenue for the products and of a sufficient is duration we can recoup not only the development costs but generate enough profit to fund new products. Prior to making any decision to embark on development, whether it's home grown or looking at a product as a potential acquisition target we engage in very detailed financial modeling. And the strength and duration of patent protection is very critical factor in those models. Our projected revenue curves decline rapidly upon loss of exclusivity. The process of -- new IP is behind our decision to

fund early research both within Genzyme and academic institutions. We do some out licensing of patents, generally around reserve tools. And we non-exclusively patent third party just for freedom to operate purposes. We take great care in our freedom to opportunity searches we thoroughly analyze all the patents out there and keep an eye on third part pap enters and what is happening with them and make sure before embanking on development pathways that we'll have all the right we need.

>>SPEAKER

Thank you very much, Steve.

>>STEVEN SINGER

Thank you for inviting me here. First I ought to mention that since I'm not here from a particular company or representing any particular client I need to state that views I express are not those of my firm or any particular client. They're my views. And shouldn't be attributed to any given matter that we have going on. I have to be careful about that. And so I don't have any particular company to give the views of but I can tell you where I come from and where my views come from. I'm an electrical engineer by trade turned lawyer and originally started representing companies principally in the giant technology computer industry. Shortly after I started practice I became exposed to what we call life sciences and in my case, mostly medical device technology companies involved in improving medical monitoring or other types of things. I quickly

turned most of my attention to those types of clients that I found them much more interesting. And a large portion of my practice therefore is taken over by that particular segment of the market. I represented companies to give you an idea of where my views come from in just to name a few pulse offer symmetry on what we saw this morning from chairman of the MBMA. Non-invasive blood constituent monitoring and glucose monitoring, cardiac output measurements. Respiration rate, interventional cardiology, refractive surgery, medical lawyers. Core Neil surgery, infusion pumps and something going on freakily today the use of semi-conductors in actually diagnostics where you might put a drop of blood on the semi-conductor and it will tell what you kind of cancer you are or genes. It's evolving quickly and it's excited. Where do these companies, patents fit with these companies? They are used mostly to protect their technology thin vest heavily in technology. Much like a drug company would, there's a great deal of runway to get these products to market to make sure they don't hurt patients, none one. And then to make sure they do good. And, the early stage companies in this arena will spend usually at least 10% of their R&B spending in protecting that technology through the patent system. Their spend on intellectual property goes up as they get closer to product release and start looking for clearance information, which they start very early in the process, most of these company start

that very early in the process to try to understand the patent landscape, what they have to deal with, what else, is out there and do what the system is designed to do, which is to speak to Innovations and encourage the Innovations. I think our -- you know, it's pretty important to note that our constitution recognizes that patents were put in place to encourage innovation and that's what they have done in the medical device world and give my clients the confidence to know they can invest in the technology that they can raise money in the technology and that they can make business decisions and move forward with the technology and if you think about the list of technologies and there's been many more I worked in that how many of us haven't been touched by one of those technology or many of them improving our medical care? And in many cases, making medical care less expensive and better and bringing things to improve our lives. So that's what my clients use them for, is to protect. Now, sometimes they're also defensive. They may be acquired licensed in, because there's a particular area in the clearance process that we find a stumbling block or thorn. We evaluate those much like the last panel spoke in determining what -- where the problems are and we look at those and figure out which ones will cause a problem and which won't and some we purchase and some we license in and some we believe are not a problem and we go forward and provide those clearance matters. So that's what my clients use them for. I think any

adjustments to the system have to be done very cautiously.

There's been a lot of talk today about the changes in the law and I'm not sure we know what those are going to entail just yet because they have not been there long enough. But, certainly, I think there is one thing noted that I've been in practice for almost 20 years and that is that since 1982 when the federal circuit was put into place I think it's hard to argue that Innovations has not flourished in our country. And that the patents system has not been accomplishing what it is intended to do. That doesn't mean it's perfect. But it's been foster erring Innovations by giving confidence to invest in and take risks. These are risky ventures. If there's no risk it's not worth had. There's been talk of a secondary market today. There's not much left over if there's a half a billion dollars invested in a product getting into the device world.

>>FEMALE SPEAKER

Jeff.

>>JEFFREY MYERS

Thank you for inviting Pfizer and thanks to Bill, Susan and to. I think Pfizer is known, Lipitor, Celebrex among others and involved in lots of different therapeutic areas. We're a global company, researched-based and our goal is to apply innovative science to improve world health. We spent billions of dollars on REB efforts. 20% of our review. Our spend on R&D is simple reminder that discovery is very, very expensive. It's also time

con fume assuming and unpredictable. There's a little bit of a Ben. Mark. Typically one out of only thousands of compound will be proven to be both medically effective and safe enough to become an approved medicine. That the take a long time to show to the FDA and other agencies. It could be ten years from discovery to approval. And after all of that, a product that receives regulatory approval may not achieve commercial success. Exuberant people one if people are familiar with that. Within this content innovations by R&D operations and strong patents are critical to the success. Our Innovations come from a lot of sources, internal resource, contracts with third parties, collaboration was University and biotech companies and with other pharmaceutical companies. We also seek out promise is -- and innovative technologies by third parties to incorporate into our discovery and development processes as well as our product lines through acquisitions and other arrangements. So, given the challenges and risks adherent in the drug development process strong IP production for innovation in the United States and abroad is critical to our success. To put a sharp point on the issue, our business mod sell highly dependent on our ability to obtain injunctive relief to prevent copies of medicines in violation of -- so if you're a generic manufacturer stay out of our front yard as long as possible. And so it's already noted we are licensee. We're more frequently licensee than licensor and we're acquirer and acquisitions are

as big as the one right now. But if you look at our 10 K you can see that just in the last year we acquired several companies and different for different amounts of money 300 million or a couple hundred million is on the scale for a normal acquisitions for us. You know, because we are licensees there's a lot of IP both in connection of products development with making those products and we're not only a plaintiff but sometimes a defendant and I think I just wanted to sort of stop and move on to the questions that sue and posed to the groups with the note that we're very keenly aware of the need for balance addressing the needs of different innovative industries that we have been hearing about technology, universities, pharma and diversified products companies and it's interesting virtually everybody that has come in here basically that for a long time says, let's be careful. Let's not be afraid to ask but careful in crafting legislative solutions for everybody that don't necessarily leave any one-industry sort changed.

>> FEMALE SPEAKER

Steven.

>>STEVEN SINGER

Like the other Steve I'll make the statement that my views are my own not the firms or any clients. And I'll also make the statement unlike anybody else on the panel I'm not a patent lawyer but corporate and I have to put things in perspective I worked with companies in the life science sector exclusivity

almost for about 30 years as you said. And I've had a substantial opportunity to observe these companies and really get a sense of what makes them tick. What does it take to discover a potential drug? To test in extensive clinical trials? To launch the product in competitive markets? And deal with generic competitors and finance the heavy costs involved at all stages and process and financing part is write get most involved? And I work with a broad span of companies. So the views I have are influenced by that. I work with professors at University who have an idea, but not much else. With early stage companies trying to raise financing and mid stage trying do move forward with products and single raised to capital to raise these funds with more mature biotech companies getting ready to launch products with Pharmaceutical companies seeking to access the pipelines of the biotech companies and timely with the financing sources. Companies like venture capital firms, investment terms and the like. There's one clear and consistent message. You heard that from everybody today. But it's particularly true in life science and that is without a strong vibrant and productive patent system, I strong patent system there won't be a biotech industry. When investors are considering making an investment in biotech company the first diligence item they face after they look at the science is the patent position. When a pharma company is exploring with a biotech company, if there's no strong patent position it simile

will not happen. And this focus on patent protection is not irrational. It takes ten years or more of sustained substantial effort and investment to develop a drug from concept to markets. The average cost independent sources estimated it's over a billion dollars per drug. Most promising drugs as Jeff said fail along the way. And when a drug is finally approved, after all those years, a good chunk of the patent life is already gone. And generic competitors are chomping at the bit to interfere. When you consider the fact that we're addressing an industry today that [defers](#) products that are life preserving and life saving, that's incredibly productive and considered to be one of the most productive, the best in the world, employees hundreds of thousands of people and has the prospect to increase employment when you think about biofuels and everything else, I just think we need to be really careful and cautious when you make change to the patent systems that may impact the system negatively.

>>FEMALE SPEAKER

Christine.

>>FEMALE SPEAKER

Unlike a lot of the other companies today Hydro Biosciences is a new time name to a lot of you. I appreciate the opportunity you to talk about hydra and hydra view on patents. Hydra biosciences is a private venture-based company in Cambridge, Massachusetts. We're trying to develop drugs against

a lass of ion channels crawled trip ion channels. Ion channels regulate the flow of ions across cell membranes, which affects nerve and cardiac function. In the past the ion channels were hard to design drugs against because a lot of the ion channels are Homologous they look and act alike. If you tried to develop something that hit one ion channel you would inadvertently hit another one like the one that controls cardiac function. Trip ion channels are a new class discovered ten years ago government what makes them special they're not homologous other ion channels or Homologous to others. You could select one and not others. So you can do things like treat pain without stopping the patient's heart. So hydra doesn't have my products yet and probably won't have any products for several years. So we rely on venture funding and partnerships. And as you've heard today, it costs a lot of money to develop a drug. So we need a lot of money. Because the trip channels are such a compelling target, a lost the large Pharmaceutical companies have their own programs. So we're competing with companies like Pfizer like Novartis and Amjet. Hydra has 36 people. We don't stand a chance against other companies unless we have something that brings value. One of the most important assets is our IP portfolio. We have a strong patent estate and that is the what allows us to attract venture capital and partners. And this has been said throughout the day. I'll repeat it one more time. A strong IP portfolio is critical to hydra's survival.

>>FEMALE SPEAKER

When did hydra start developing the IP portfolio? You're a young company and already have a portfolio. I want to understand the life cycle and when IP starts coming into play.

>>FEMALE SPEAKER

Some of the IP for hydra started because we licensed in technology from a university. This is typical of how a lot starts up especially in the Boston Cambridge area gets started. So we license some technology from university but hydra was sort of very forward thinking in that as soon as they started doing research they also started building their IP portfolio because they knew you know I was not there at the time, but they knew that would be the value driver for the company. So it starts you know almost the moment that research starts, they started building the IP estate.

>>FEMALE SPEAKER

Right and other early stage technologies, Steve, you can talk about these very early stage developments and how the IP plays in there?

>>STEVEN SINGER

Well, sure the way products typically get developed is you have an idea that comes in from university, professors as I mentioned, **who** has a particularly good idea. And the university licensing offices works with venture capital firms or angels in some indications but more likely venture capital firms and the

crux of the transaction in licensing of an interesting patent estate. And without that patent estate there's really nothing for venture firm to make investment in it the. That's how the companies get started. Hydra is very typical.

>>FEMALE SPEAKER

Christine, can you talk about how start up keeps building the patent portfolio. You don't stop with the first patent from the professors do you as you continue to develop new technology how important is it to keep patenting?

>>FEMALE SPEAKER

It's important for everyone I think in the life sciences. I think it's particularly important for small companies like hydra. One of the advantages of hydra that is they're a pioneer in the trip ion channel field. Because hydra was one of the first companies reserving these trip ion channels there was essentially a lot of IP space. And so we were able to build a very strong portfolio around the space.

>>FEMALE SPEAKER

This concept of their being a lot of space. How important is that in think about where to put the money and where to do more research?

>>FEMALE SPEAKER

It is really important. And I think a lot of us have the same views that we would not invest hundreds of millions of dollars into developing a new drug if we didn't think we had clear IP

space. If we thought there was going to be an FTO problem we would not go into that area or try to license in what we could to take away the FTO problem.

>>FEMALE SPEAKER

All right. Jeff?

>>JEFFREY MYERS

I think this notion of space illustrates a lot of problems and sort of the conundrum and the differences between sort the tech industry and biotech industry and Pharma. Someone mentioned in the chemical arts terminology is clear and established. The chemical arts are more than a hundred years old. That is totally different in the biotech space and sort of the high tech space. And as a parent I'll say that also gives rise to some problems. Because when you give your kids too much room sometimes they run around and make trouble. Right? So one of the reasons -- I mean in some of the early days of the biotech industry you saw very, very broad claims for admittedly pioneering technology. Of course, I think uncertainty around how far the claims could be enforced was to some degree an impediment to innovations and so again this goes to the need for balance. I think pioneers and the courts have always recognized this, pioneers deserve broad patent protection. You have to balance that against the need for sort of a fair disclosure of what it is you really invented and when you have arts where the terminology and maybe technology are fairly immature, which I

think is frankly the case with the software industry and you know the semi-conducts tore industry, you know, you have people grappling and trying to get as much as they can, working with terms that not everybody agrees on and tests that not everybody knows how to perform. And so, I think have you to be willing to live with that a little bit, and I guess my view, jumping all the way towards soft, the later parts of your questions, how do these case affect that? A lot of times we see a case come down and it doesn't look so great at first glance. We all freak out and run around and say that is the end of whatever. Right? And then we watch as the course, which has a lot of common sense develop these doctrines. So I think sometimes we're in a hurry for certainty. Businesses are in a hurry and we look at court cases and think oh, no, now it's uncertain and we have to work through that. What you see when we have a lot of space in a particular technology is that it can be difficult and time consuming and a bits of sausage making to watch the courts and companies and the government try to figure oar out what to do with it.

>>FEMALE SPEAKER

Steve.

>>STEVEN SINGER

I think that races an issue of something that came up earlier in the day the notion of the continuation practice in patent applications. It's very hard, particularly when there's a

pioneering technology and my clients are principally, I'm not a chemist. It's not the drug it's the devices. These are technology devices, computers, semiconductors, sensors, catheters, things you can hold. And you're not always sure right when you start an a lot of these startup companies don't have the funds to try to figure out or pay the patents lawyers enough to figure out exactly where that fence can properly be drawn.

>>SPEAKER

Especially those lawyers at law firms.

>>STEVEN SINGER

Exactly so the continuation practice is very important for the particularly low start up companies so as the portfolio develops they can craft it to it properly develops the space versus oops we were too broad or too narrow and only captured precisely what we were doing. Everybody can do exactly what they're doing without stepping on the patent. So the continuation practice which has come up a few times is critical to developing that portfolio as the client and as the company learns really what is the protectable space.

>>FEMALE SPEAKER

Do any of the other panelists have comments on this concept of the importance of the continuation of protecting this space outside the medical devices, chemical, biotech, do you face the same kind of problems, yes?

>>MALE SPEAKER

I think we see that and we see that when we're trying to evaluate technology, trying to figure out whether we have freedom to operate in a particular area. And so one of the things I think that is offset that to a degree is the publication of U.S. patent applications. And as one of the earlier panels on the earlier panels mentioned at some level you look at it and figure out what can reasonably be granted out of the specification. And I have to tell people internally at Pfizer all the time, there's no such thing as a risk-free path right? You have to figure out what the big risks are, what risks you can address and what risks you have to live with. So a continuation process creates uncertainty. But by the same token, it is probably better than kind of forcing companies to either give up too early or unduly narrow their patent claims versus forcing the patent office in into a position where they're not granting anything or letting things out that are too broad. With continuation practice we need to be careful to not throw out the babies with the bath water.

>>FEMALE SPEAKER

Maggie.

>>MAGGIE SHAFMASTER

Would I like to agree and expand a little bit. And the continuation practice extremely important. At the time you're filing your original application, this is work that is being

done at the bench. You may have some invitro studies and few animal studies but it's years before you would even get into your first human patient. And then continuous years through the clinical trials and all that time you learn more about the drug and how it works and how to formulate it and how to dose it. And the continuation practice allows us to ultimately come out with stronger patents that are more specifically directed towards the final product and stronger patents means more certainty and it means less risk and it means we're more likely to invest in that product. With regard to the criticism of continuations that you don't know what someone is going to claim and therefore there's no way to clear them, we don't seem to have that problem. I think we're very capable of reading a specification and being able to tell what kind of claims might come out of that specification. There may be some uncertainty about changing standards at the patent office in terms of what is valid or patentable. But in terms of the scope of what that specification will support we don't see an issue with that.

>>FEMALE SPEAKER

Okay. And, how is your ability to assess what patents are out there that you will need to license in ordeal with in order to get freedom to operate.

>>MAGGIE SHAFMASTER

So that's when we do a patent clearance search we look at granted patents and look closely at pending applications and the

question is not what claims are in that application, the question is, what claims could that specification support?

>>FEMALE SPEAKER

Okay.

>>MAGGIE SHAFMASTER

Could they write a claim that would cover us?

>>FEMALE SPEAKER

Do you have any concerns about the ability to interpret the claims predictably. Claim interpretation has been called a very unpredictable process in a lot of industries, 50% reversal rate and that sort of thing. Is that a concern that you face when you're thinking about where to invest money and what kind of freedom to operate you need, Christine?

>>FEMALE SPEAKER

It is a concern. I want to point out you don't get faced with be issued patent and wonder how the claims would be interpreted. The vast majority applications nowadays the prosecution history is available on public pair. So you can go into any pending application and look to see how the applicant himself or herself is in fact defining the terms in the claims. So you get a lot of guidance as the application is going through the patent office on how both actually the PTO and applicant are going to interpret those claim terms.

>>FEMALE SPEAKER

Okay. And once the patent issues are the doctrine surrounding

claim interpretation satisfactory at least in your industry, biotech, to have some confidence in how a court might interpret those claims and be able you to identify those claims that you need to deal with? Jeff?

>>JEFFREY MYERS

I think that the uncertainty around or notion that there's a lot of uncertainty around the scope of issued patent claims, echoing what Christine said, to the extent it's out there I think suspect it's probably over blown. We also have not just a file history now but Festo which really provided you know some clarity about where -- what you can do with the file history. So, I'm thinking back a few years ago to the Perdue farming case where they reached back into the specification and continuation and pulled out basically an example and wrote claims around it. They said no, no, no, that's not an intention [investigation](#). There are companies where companies over reached in trying to say oh, somebody else, is out there we want to capture them and we have a continuation pending so we'll go back and write the claims to cover these guys by turning this example, which was not clearly not part of the invention per se, we're going to turn that into a claim. You know and the court said, wait a second, this is not correct. It is not an invention. Out goes the patent. So you know, I think there's enough case law out there to give us sufficient guidance. It's never a matter of having zero risk. You start with granted patents and move along

the spectrum to the things which are less and less clear and therefore at some level have you to accept they present a less you know clear -- less clear of a risk. So you're not going to value those as a -- as bigger risks.

>>FEMALE SPEAKER

Maggie?

>>FEMALE SPEAKER

I was going to say there is some uncertainty. There's always some uncertainty that the court may not come to the same interpretation you have come to. That plays into risk and how much risk you're willing to accept and that plays again right? Your models of what is the value here and how much am I willing to invest given this level of risk?

>>FEMALE SPEAKER

Okay. Do you have any thoughts on how to improve that situation? In an ideal world when patents would be predictable we take it, look at it, here's what it covers. You know as a business how to react. Is that something to be strived for and if so, do you have any thoughts on how to move in that direction?

>>FEMALE SPEAKER

Well, throughout the years, there was a time a few years ago when people thought the case law was pretty clear about claim interpretation and whether or not it was permissible to read limitations from the specifications into the claims and things

changed again and now I think that some cases open the issue didn't give a whole lot of guidance. Again it kind of comes down to what does your gut tell you that a court will do with this? And if you're really not sure, are you willing to accept that risk?

>>FEMALE SPEAKER

Okay and you're referring to the Phillips case?

>>SPEAKER

Yes.

>>FEMALE SPEAKER

Steve?

>>STEVEN SINGER

When we talked about predictability. And yet the reversal rate, I think they're not necessarily exactly tied. Okay.

>>MALE SPEAKER

When juries were deciding claim construction we had very little ability to predict what would be the construction of the claim at the end of the day. Or less than we have today. And so, it may not have been reversed by the appellate court because there was more deference given and standard harder to overcome but predicting in advance before the case started what the eventual construction was I believe was harder then than it is , even though we may get a reversal I think it's more often that we have an understanding of where that reversal will come, because of the claim construction rules that we've been given. In

addition, the claim construction rules I think the unpredictability is coming more for the changes as was just mentioned of those rules when we know what the rules are. We as patent lawyers are able to look at the claims and say here are the rules given. If the rule changes, that just changed the advice we gave to clients sometime ago and we may be in the middle of litigation while the rules change. And that sometimes I think that throws more unpredictability into it because we don't know what the law will be tomorrow.

>>FEMALE SPEAKER

Okay.

>>MALE SPEAKER

At the IT panel early the number one concern raised regarding risk was sheer number of potentially applicable patents. I want to confirm whether that's not a major issue in your view.

>>FEMALE SPEAKER

When we do freedom to operate searches we will review thousands of patents come up on the serves we will look at to make sure they're okay. I don't we've had to contend with hundreds of thousand if that's what they're contending with. We're willing to put in a lot of effort. Because by the time we go to market if we have a freedom to operate problem, we're -- that's not a problem you can get around by design around. We -- there's way too much money and time invested to find out you have a problem that late. So we have to do that work. We do that

work.

>>MALE SPEAKER

We do extensive freedom to operate work on projects as they're ongoing typically when a compound is sort of nominated to be clinical candidate then the level of that work goes up. But I think you know honestly to be fair to our IT colleagues their product life cycle much faster. Right? So we have more time to do those FTO searches and of course, you talk about how much it costs to get a drug to market, most of those costs the greatest proportion of the costs are in the large scale clinical trials. So we don't have sort of this huge bowl us of money dumped into a project at the beginning and then ten years later we find out if we get approval. It's a continuous investment that goes up and you up and up. We have the luxury if you will even throat patents are going down we get term extension. There are various fixes for affecting that. I don't think generally for small molecules we're not looking at thousands of patents, maybe a couple dozen. And we have time. And you know, the amount of money invested in a single project and product is substantial enough to justify a bigger investment in that FTO effort. On the other hand, if you know, you're developing a product and already taking a hundred licenses to various components and you're thinking, well, now I have to look at 500 more patents there's a risk benefit ratio in that evaluation which is different when have you a fast product life . So I think we

sort of have to recognize there are differences that are adherent in the different industries. I would just echo that further.

>>MALE SPEAKER

I would echo that further in saying representing device companies that really are computers, in many respects, their can be very, very large numbers of patents that have to be looked at. We have processes we can go through to funnel those down to the point we get them to the point -- to a point where they are the ones we think we are looking at the right ones. I think the main difference in that technology and the IT space from the panel earlier today has to do not so much with the sheer numbers but with the time period of the duration of the market, right? It's a shorter life cycle for those products. And so even though we may have as many patents to look at, with my clients that are in the medical device sector there is usually a second year product and it has a longer life cycle and doesn't change as quickly because of many ever the regulatory and other issues that touch the medical device industry.

>>FEMALE SPEAKER

The development also and time it takes to develop the product is also important?

>>MALE SPEAKER

That timing gives you the runway to view the clearance so even if there are thousands of patents to look at, you don't have to

read all of the thousands of patents, right? And look at the abstract at one level. You might pull 20,000 patents and look at abstracts as a paragraph, right? You're looking at that. And then you drill down deeper maybe and look at the pictures. Yeah, but that ramp gives you more time to do the clearance work that needs to be done in the medical device area.

>>MALE SPEAKER

And in the biotech it's not an optional thing to check out very carefully the patent landscape. It's mandatory. Companies -- I'm not aware of any companies that don't undertake that review. And I don't think the boards of directors of small companies would permit them to go forward unless they were doing that in a very regular space.

>>MALE SPEAKER

Neither will the venture capitalists.

>>FEMALE SPEAKER

One last comment the point about doing clearance as development occurs is a very important one because you can in the beginning just look at the patents around the protein. And at that point you're not really sure how it's going to turn into a product. Then as the Scientists start figuring out this is the expression system we want to be use to express it then you can clear those patents and this is the way we want to formulate it and you can look at those patents. It's much more minimal to stinking than having everything all of a sudden at once have you to clear the

entire product and every step you used in manufacturing it.

>>FEMALE SPEAKER

Okay. Christine?

>>FEMALE SPEAKER

I want to add one thing. It's not the most fun to do FTO analysis but it's incredibly a rich source of information. You know first of all I'm not sure if I told the sign night my company to stop looking at the patent literature that they would. That's where they get a lot of ideas. As you're looking at other companies' published patent applications in the same fields you get a lot of new ideas how taken to innovate your own research. While we do it you know to protect ourselves from a legal point of view it's helpful for the Scientists to see what other companies are doing.

>>FEMALE SPEAKER

Do you have a question?

>>MALE SPEAKER

One quick one for Steve. Because your devices are of your clients tend to involve high tech issues do you get any suits more son that than you might -- solve your colleagues might here female.

>>MALE SPEAKER

I think it's more come on in the medical device arena than in the drug and Pharma and bio areas. We receive lawsuits and they have increased in the last few years with respect non-practicing

entities. I think it's important that world is a little too broad. We don't see you know attacks from University. They're trying to transfer technology. It is usually or often a failed medical device company that now has the IP which is all that is left which ended up in some kind of aggregator or venture firm that then looks to obtain value from that. And as opposed to technology transfer. And there are -- they are increasing. They aren't overwhelming by any stretch of the imagination. They do occur in that space on a regular basis.

>>FEMALE SPEAKER

Have they increased over the past few years?

>>MALE SPEAKER

Slightly. Not significantly. Not like some of the things we heard earlier today with the IT panel but slightly increased. One of the reasons I think is that you know the nature of those claims changed in the last ten years where many more of those groups are going after the end product developer as opposed to the manufacturer of the particular component that issue. So even the medical device companies will see an attack by an area that really has to do with a technology in the microprocessor. Right? And I would say that that properly belongs in a dispute with the microprocessor company not the medical device company. But those entities do come after even -- it's just started so that they're coming after the medical device companies. We've been able to deal with them I think fairly effectively. But they

are occurring and they're increasing.

>>FEMALE SPEAKER

Why? Do you have a theory why they're going after device manufacturer and not the microprocessor manufacturer?

>>MALE SPEAKER

I don't have a theory. I think it's another target that developed and realization that there are computers out there in the medical device world and so there's another tarring tote go after. This -- it is not a new problem. There have been various ways that these leftover patents so to speak get asserted to try to obtain value from them after a company has failed or they have not seen at the technology make it to market. There's just different avenues and I think when the system can get skewed a little bit if there can be -- if you can choose a path of enforcement that will lead to uncertainty, if it can lead to uncertainty, then maybe you can obtain more value out of those patents than someone would normally and. I think that the most companies in the medical device arena are simply fighting those and succeeding. And I have been involved in several where at the end of the day the cases are just dropped. And with no payment at all.

>>MALE SPEAKER

Put another way once you payoff the blackmailer it never stops. Have you to make choices about going to court with some of these people.

>>FEMALE SPEAKER

It's a matter of establishing reputation of a company as a fighter. Is that a conscious decision if it's possible to settle for less than it will cost to litigate, what's the decision process there in fighting?

>>MALE SPEAKER

Many medical device companies will not evaluate it in that sense but in the sense of is it a meritorious claim and if it is not, most -- if they have the resources, will fight it through. They will not withstand being held up.

>>MALE SPEAKER

I'll add one more comment. I was here for the panel on injunctions and there was analysis by what it someone have Sidley I forget. But the courts, if you look at analysis of cases involving injunctions or requests foreign junctions courts have not been friendly to the non-Quinn sent that practicing entities. They don't get into injunctions and I think it's for a lot of these reasons.

>>FEMALE SPEAKER

Has that affected, Steve, have you noticed, whether that has affected the frequency of suits or amount of settlements or extent to which a company will fight?

>>MALE SPEAKER

I think it has given an added number of companies -- there's varying levels of risk aversion in different clients and some

can take more risk than others that are more comfortable with more risk. I think since the eBay decision more are willing you to stand up to that attack if they believe that there are no merits to the case. And I think that that has also resulted in a reduction in settlement amounts when settlement amounts occur. The threat of the injunction is dramatically reduced and that previously resulted in sometimes some I think anomalies in the system where the patent may have commanded more than it would have prior to eBay.

>>FEMALE SPEAKER

Has eBay had any effect in the biotech industry separate from the medical device industry?

>>FEMALE SPEAKER

Well, I would say both eBay and KSR have certainly had an effect. It's hard in the economic times to tease out sort of the hard economic times versus fear of investing in life sciences because of cases like eBay and KSR. But, to elaborate a little bit on one of Jeff's points earlier. When KSR was decided there was panic in the patent community. Oh, no it will be impossible to get a case through the patent and everything will be found invalid for obviousness. In a while we found out that was not the case. You can still get patents on new inventions. But significantly after the patent community I think had sort of come to that realization I was at a meeting with a bunch of investors and the investors are still referring

to KSR as that Supreme Court case that makes everything obvious.

>>MALE SPEAKER

The one thing would I add to what Chris is saying it is really when do we get to the tipping point. KSR in and of itself Okay. eBay, Seagate, Quanta, patent reform, Met Immune. At what point did you make so many changes to the system that investors will throw up their hands and say it's bet to invest in IT industry or medical devices as owe bossed to drugs. And that's the concern I think that the biotech try generally has. It's not one case in particular it's the parent. And when do we really hit the point that investors are not going to be willing to play anymore.

>>FEMALE SPEAKER

Is it possible to argue KSR was a benefit in patent issues are now stronger. Can investors look at it that way.

>>MALE SPEAKER

Would I defer to the patent colleagues but in talking to companies I work with their belief is that the patent examiners have not known which way to go in terms of analyzing patent applications and there's a lot of uncertainty as a result of that.

>>FEMALE SPEAKER

For us uncertainty about the IP estate is always bad. It makes investors hesitate to invest in us.

>>FEMALE SPEAKER

Who do you feel is the source of that uncertainty right now? Actually, what kind of uncertainty are investors worried about? With regard to the patent estate? Male pale first of all what Chris said is really important which is we're not dealing with a controlled experiment here. And that there's a whole economic situation out there that impacts what everybody does and the risks people are willing to take and to some extent it means that people can point to something when they really don't want to make another investment they can point patent laws are wacky. I'm not willing to make the investment. But investors will argue then serious consideration in making investments. So as I said, I don't think it's one thing over and above others. It's just makeshift things it's the climate for patents and patent enforcement in the sense there's a hostility in the judiciary and hostility in the administrative branch and legislative branches right now against strong patent protection.

>>FEMALE SPEAKER

Okay. I'm curious, how much of that senses hostility is a perception and how much do you think it's really grounded in reality, though? What I'm wondering is how sophisticated are the IP investigators in understanding the impact of KSR on the biotechnology industry and the impact of eBay on the biotechnology industry or is it more just the gestalt that they're reacting to? Maggie?

>>MAGGIE SHAFMASTER

I was just going to say, talking about the uncertainty, I think a huge source of uncertainty is changing case law. And in every case, it seems where the Supreme Court takes a patent case, it's not to affirm the federal circuit. It's to change the last ten or 15 years of law that the federal circuit developed that we've all been relying on in analyzing patent estates our own and third party patent estates and the value of those patents. So I think changing law in the retroactive effect. Those changes is a huge source of uncertainty.

>>FEMALE SPEAKER

Okay.

>>FEMALE SPEAKER

Steve?

>>STEVEN SINGER

I don't think I need to say anything about that. I was going to talk about the investors view the venture capitalist that see it at a high level.

>>FEMALE SPEAKER

That's a better way to articulate my question.

>>MALE SPEAKER

They then try to drill down and I represent venture capital it's firms as well and they ask a lot of questions about what this all means and try to ascertain because they're in the business of taking big risk. And they want to know how much risk they're taking and whether or not the investment is going to payoff and

if the law changes midcourse that just changed the formula under which they invested and that worries them. And so they do ask many questions to drill down what does this mean about each individual one. But the overall sense is that as they drill down on each one is that right now, they're in an environment where the pendulum is swinging against the patent owner.

>> MALE SPEAKER

I was going to say I think to echo maybe a little and expand upon Steve Singer's comments I think the perception out there is that the patent system has been effectively, substantially weakened by some of the actions that the Supreme Court and federal circuit. I was even at a conference about a year ago where Pauley Newman stood up and talked about the historical policy basis for the establish the of federal circuit itself Was to promote Innovations and was a time when Innovations was perceived to be suffering in the United States. And she questioned whether the federal circuit was to some degree losing its way. And in that kind of a climate, IP investigators strictly in our field and in the drug field per se, they're saying, how long are you going to be able to sell this product before generics come on the market. What's your LOED. And that going to what Maggie said before. Our evaluation models and models of the IP investigators you try to quantify that risk. And the fact, simple fact is, that whereas five years ago, somebody in some hypothetical might be willing to put 80%

chance on dispute or issue, now that's 60. You just might have passed your hurdle rate. You don't know. I think that's what's happened is that in cases where you were close to the tipping point, now you're below it and have you to move on to something less risky. So I think it really has had a chilling effect and it has not been any one factor it's just that when you start to add in that kind of uncertainty you, do you cross the tipping point. And I think we're the negative scenario right now on that.

>>FEMALE SPEAKER

Is there an expectation that more biotechnology patent would be found invalid if litigated because of KSR. I'm trying to understand, I'm hearing that a lot of the combination of the cases creates more uncertainty and wanted to drill down a little bit into the individual cases to understand the substance a little more.

>>MALE SPEAKER

Let me speak briefly and defer to Maggie and Chris. But there have been post KSR cases in the chemical arts and it really doesn't seem to be having a very direct impact on the chemical arts. There's a recognition in the federal circuit and courts said look drugs are not gas pedals.

>>FEMALE SPEAKER

Okay. That's better. Christine.

>>FEMALE SPEAKER

To elaborate on that point we took a careful look at statics and cases decided post KSR and in fact it's actually reassuring from the you know being in a life sciences company to see that you know KSR has had I think much less of an effect on life science patents than we thought it was going to.

>>FEMALE SPEAKER

All right.

>>FEMALE SPEAKER

We have that perception hanging over this that there's this Supreme Court case out there.

>>MALE SPEAKER

It's not limited to KSR female fall I was going to break them down and go through it one at a time.

>>MALE SPEAKER

I think eBay is significant and I love my patent colleagues to talk about it. But you know the fundamental issue for a company with a drug going on to the market, with a potential infringer is to be able to get them off the market. I think damage is nice but never really what the game is about. It's getting them off the market. The extent eBay makes it harder or more uncertain you'll get a permanent injunction, it's one of those other negative factors that are affecting investors.

>>FEMALE SPEAKER

All right. And any concrete sense that E bail is actually going to make it harder to get that infringer off the market? Our

injunctions panel, there was a lot of this about this we didn't hear anything concrete.

>>MALE SPEAKER

I think you simply have to sample the cases. Which I have not done statistically. Anecdotally I know among patent firms each time an injunction is denied at a district court with advent ever the internet I think every patent lawyer in the country knows within about 15 seconds these occurring antidote alley from those e-mails I see they're occurring more frequently at the district court level.

>>FEMALE SPEAKER

For one concrete example I think ultimately the injunction was granted. There was Amgen-Verose case and that made a lot of people in the Pharmaceutical industry nervous. Because it really cuts at the heart of the patent of the patent is right to exclude. And if a court is going to say to the patent owner, well, actually, we're going to let this other party on to the market and pay you you know, some royalties it completely takes away the power of the patent.

>>FEMALE SPEAKER

Yes and in the court's discussion of the public interest in that case, as I understand it was one source of the concern there is that right.

>>FEMALE SPEAKER

Yes, it was very much a concern. Because you know one of the --

one of the factors the court used was well, you know, there's a public interest in getting cheaper drugs on to the market and so if we allow the infringer on to the market the drugs will be cheaper. Isn't that good for the public? That's balanced by the public interest in better drugs. If you take away incentive to develop better drugs I think the public is actually very poorly served in the long term.

>>FEMALE SPEAKER

Has there been an increase systemic uncertainty in the sense that the level of change in the system over the last five years creates uncertainty as to whether they'll be a great deal of more change or the next five years?

>>MALE SPEAKER

It is a hard question to answer. When you're talking about systemic uncertainty and you're not dealing as I said before in a controlled experiment environment there's a lot of systemic uncertainty now. How much is attribute to the changes in patent law? I'm not able to determine that.

>>MALE SPEAKER

I was going to add on the right to exclude can I give you data there that is instructive I think in terms of that being the fundamental patent right and we do have good data there probably game from Janakee and that is that the average patent infringement judgment is well below the average place to take it to trial. Right? So the fees exceed on average the

judgment, damages judgment. And that tells you that those cases are principally about excluding and not about recovery on average.

>>FEMALE SPEAKER

Let's go back and talk about the business model in which we have the startup company transferring its technology to a larger manufacturing company that can take it to market. And Steve had you a lot of experience helping, setting up these deals. Can you walk us through one and the kinds of problems that come -- kind of concerns that come up about the IP estate and anything else.

>>MALE SPEAKER

Sure the reason that a bigger company, hydra infinity, Amilam will dot deals in the first place is some of the factors we all talked about before which is that mostly not feasible for a small company to develop a product from you know discovery through phase three clinical trials on its own. I mention the cost before which is average cost. Of the but if it's not a billion dollars it's certainly several hundred million dollars. It's not feasible. Not only that but the smaller company doesn't have all the resources and expertise it needs. There's a real importance collaborate and the crux of the collaboration is what a small company has to offer. It's made a scientific discovery that people find compelling. If that scientific discovery is not backed by the IP the deal won't happen. So you

know in an ideal world a smaller company will talk to several pharmaceutical companies and they'll all do diligence on the patents made and hopefully end up in ideal world for the small company working you know through a term sheet stage with a couple of these companies. And IP is not the -- there's an assumption that the deal wouldn't even be being discussed if there's not a strong IP position. In the term stage the IP is dealt with not in very exhaustive terms. But when you get down to negotiating a final agreement who enforces the IP. Who prosecutes the IP? And so it's a serious point of negotiations between the companies. Usually it's not a deal breaker but it's usually resolved but it's a major point and then another critical question that comes up is intellectual property indemnification. Which is something that as a small company avoid like the plague. And I don't know if I'm answering your question.

>>FEMALE SPEAKER

No that's very good.

>>MALE SPEAKER

That's typically the way the transactions evolve.

>>FEMALE SPEAKER

And in that technology transfer what is transferred besides just the patent right? The inventors go along with the technology? Other know-how going along with the technology?

>>MALE SPEAKER

Slur it's typically license for patent right and know-how and data -- it's a package that goes well beyond the patents but doesn't include people other than on a collaborative basis.

>>MALE SPEAKER

Probably differs slightly in the device arena where oftentimes if picking up technology you want engineers to go along with that to sustain. It because most devices require sustaining engineering as things occur out there you get MDR, medical device records with the FDA and emergency nearing team is usually needed when a technology is acquired. I think we would see an acquisition.

>>JEFFREY MYERS

I think we would see acquisition or licensing typically acquisition when you are getting technology that is new but some has been proven or there's a lot of trade secrets. Getting those people is a big part of the deal. You know, it's fine to have trade secrets but trade secrets have feet and it if they leave out go the trade secrets at a practical matter.

>>FEMALE SPEAKER

Maggie?

>>MAGGIE SHAFMASTER

When licensing technology from a university it may be a straight patent and know-how license. But getting it from a small, private company it's either acquisition or partnership or collaboration. Those are the people that developed it and know

it better than anyone else and where they want to go with it and we want them very involved. They're the experts in that technology.

>>FEMALE SPEAKER

What is the importance of biotech industry that becomes acquired by a manufacturing company versus internally developed technology for biotech? Jeff, your company licenses or brings in this kind of technical rather than -- and develops some internally. Why is that?

>>JEFFREY MYERS

Well, I'll talk about biotechnology versus small molecules. You know in the small molecule space we have a lot of R&D expertise and manufacturing expertise and have all the people in the know-how that's necessary didn't to do that. Biotechnology and Pfizer traditionally had not invested in that area I would say sufficiently to say you could just bring in patent and maybe development project and we don't have the manufacturing capacity. So we do have some -- a lot of the biotech manufacturing that involves things like human growth hormone which we have products you remember that's acquired. We out-source a lot of that. But you know, a big difference, I don't want to get ahead of ourselves here but we all know that Pfizer is proposing to buy Wyeth and that would turn Pfizer an insignificant player in the biotech space to number four or five. As I mentioned before, clearly, you know, the people and

it's not just the Vats and plumbing the people are a huge part of that value.

>>FEMALE SPEAKER

Maggie, do you have any thoughts on why the biotechnology industry is developed in this way, where much of the Innovations is done by start-ups and then brought into a larger company or Christine? It's interesting not every industry operates this way. Do you have a thought about that Christine?

>>FEMALE SPEAKER

To some extent small start-ups are uniquely set up to concentrate and rally focus on a single technology. And these technologies are really complicated. And it really helps -- we have people working at hydra who have been working in the trip ion channel field they've been work in the field since the field started. And you just you can't -- that knowledge is invaluable to the company. And you know a small company you know it's a little more flexible than a Pfizer, for example, and able to sort of follow the technology a little bit more closely I think.

>>MALE SPEAKER

Maybe a fair way to say it biotechnology did not spring out of the Pharmaceutical industry. It came out of University and government sponsored research and so you have longhaired academics and people not really fitting into the corporate environment. We have discussions internally about when you acquire certain types of technology you don't want to -- we want

to avoid Pfizerizing. It I would like to say it's spelled with a P but it sounds like something else. So now we have two independent research units Pfizer global research and development the small molecule group and BBC, which is sort of San Francisco and Cambridge and those are the biotech guys and we're trying not to Pfizerize them. We're trying to let them do what they do, you're Teal dealing with esoteric biology and esoteric physiology strip channels or R&I that didn't come from any of the big pharmaceutical companies. It really came out of academics. We also have this incubator in Lahoya called the Pfizer incubator TBI, funding collaboration was really highly speculative, very academic ventures, and was really -- what's really interesting about there and jumping a little you talked to earlier panels about transparency and value and mentioned others I enlisted to one of our people talking about biotechnology and DNA and genetics revolution there's a lot of knowledge about the value and what people are willing to pay for that technology. And as it has gone from pie in the sky to maybe we can get something into the patients that won't be degraded, the cost is gone up and up and up steadily. Which that makes perfect economic sense. But that -- none of that really came out of Pharma program. That's being honest where that has come from.

>>FEMALE SPEAKER

Steve?

>>STEVEN SINGER

I was going to say after having watched inventors for almost 20 years there's a particular type of person that innovates. And they have to have around them the freedom to innovate. And I think what Jeff was talking about is precisely so. I think there was an article in the "Wall Street Journal" this morning an again tech and rose and acquisition and the same issue and whether or not the engineers would continue the Scientists would continue to be given time and as I watch them come in through our doors they're usually from people who have time to think and they're think about problems and intrigued by it and they will do this as long as they're given the freedom to do it and that is one of the reasons you see that in smaller companies. But large companies can do it as well.

>>FEMALE SPEAKER

Would I agree. As I mentioned in my opening remarks certain of the products that Genzyme developed and brought to market were done completely internally and others were acquired from Universities or small companies that were spin out of technology from university. A lot has to do with focus and being able to do what you're good at and being able to see opportunities wherever that he rice. If we try to say all of our products were going to come from basic research at Genzyme we wouldn't be able to bring products to market. Too many other things need to get done.

>>FEMALE SPEAKER

In sectoring the fields bringing in technology from the outside and making it commercializeable how do you value that technology. How do you set up that deal, Steve?

>>STEVEN SINGER

There are a lot of available sources in terms of transparency issue.

>>FEMALE SPEAKER

Right, and also I would think you have no product. How do we sign a price to this technology when you transfer it?

>>MALE SPEAKER

Right.

>>FEMALE SPEAKER

What do you think about?

>>MALE SPEAKER

People are aware of what is going on with other companies because of FCC filings and various databases out. There executives go from company to company and while they have confidentiality obligations to other companies, they can talk about ranges of royalties and ranges of milestone payments and up front payments. There's a lot of information out there in the system. Smaller companies I don't think are at informational disadvantage to larger companies. And it has not posed a major issue as far as the fact that very often you're licensing early stage technology and don't know how valuable it

will be. That's really what the structure -- how the structure of the deal works. That influences mostly the up-front payment you get. The milestones if successful you get larger payments as you go forward. If you structure royalties to reward the company when it hired -- when the product has higher sales you address the uncertain evaluation to some extent in that way.

>>FEMALE SPEAKER

Even when licensing early stage technology, would you have a royalty based on a product that may come out in the future.

>>MALE SPEAKER

You won't have the deal if you didn't have a royalty in the product based in the future. Company ready typically not doing it for up front payment but what's important for the current practices what hear doing it is to build a company and they need royalties and milestone payments down the road.

>>FEMALE SPEAKER

Okay. I don't have another question at this point. It's been a great conversation. Do any of you have points you like to add to this discussion?

>>FEMALE SPEAKER

I do.

>>FEMALE SPEAKER

Please, do.

>>FEMALE SPEAKER

I wanted to make the point that when you look at our

industry, the biotech and Pharma industry and look at what happened over the last 10, 15 years more of the market is become generic and need to products and smaller product is left for innovators. And there's more and more things happening to accelerate that. We welcome a pathway for bio, but we need to recognize that will accelerate that shift. And any new legislation we can patent right is also going to accelerate that shift. And I think it's important that somebody keep their owe eye on the long-term impact of what happens when the entire market only has a very small part being new products to meet unmet needs of patients.

>>FEMALE SPEAKER

Okay.

>>FEMALE SPEAKER

And all the vest me too products and administrative agencies may be well suited to have that long term view. Would I urge you to try to keep it in line.

>>FEMALE SPEAKER

Thank you.

>>MALE SPEAKER

Would I like to make a point about damages and the calculation of damages. We have not addressed that issue and it's probably the hot button issue in the patent reform legislation for life science industry. And it really is in part immeasurable we were saying before the courts have evolving standards and they apply

them pretty well. There's the Georgia Pacific tests where there are 15 or so tests. One of which account to the contribution of the invention over the prior art. It's not mandated that that has to be the critical standard and the concern I've heard and this is at the investor level as well as at the industry level is that moving in the direction of some of the proposed legislation on damages calculation and mandating a prior arts subtraction method would get you closer to the tipping point of when will people just decide it's not the best industry to invest in.

>>FEMALE SPEAKER

What is the concern by investors with the way reasonable royalties are calculated in damages in that wouldn't it be more likely for a bioproduct to get less.

>>MALE SPEAKER

It might be. The concern is uncertainty caused by prior subtraction method and how that would be applied in the biotech context. It's more uncertainty than how it might actually work out.

>>FEMALE SPEAKER

Okay, yeah, Steve?

>>MALE SPEAKER

Male on the damages topic I have yet to see data to suggest there is a problem on the way it's computed normally. I have yet to see anything that supports that. I see it might be going

the other direction. Although I have not seen good data on that yet. The lost profit its question you pose lost profits for an early stage company is a difficult proof. It requires several factors and they probably will not be able to make out those factors in most instances because they may not be able to meet demand yet. They have not grown to that level yet. The most common lost profits methodology in a lawsuit is a market share approach to lost profits where you obtain your lost profits based on market share. If all have you at that point is 2% have you to make the other proof elements part of lost profits and that's difficult for early staged company to do then they are stuck relying on reasonable royalty even if they have Pioneering technology because proving even if it is but for test that has to be met but for infringement the company would have made the sale they have to be able to meet demand and other things. It's a difficult proof. Not everybody gets to move to the loss profits envelope particularly Earl little stage companies they have to rely on reasonable royalty. If we look at just focusing on the base of the royalty, that has never really made any sense to me. None of these deals -- I've done many, many deals over my career and no deal is about the base. It's about what is the value in that deal that two people can make a good business deal over? And that -- and the base will be chosen mostly out of convenience in most of the deals I've done. I don't know about Steve. But the base more has to do with accounting convenience

once you figure out the value and the deal and maybe you think it should be 10% on a particular piece but the base turns into the whole product and royalty turns down to half a percent. They can't be talked about separately like they are in the current legislation in my view.

>>FEMALE SPEAKER

Okay. Steve, would you agree with that?

>>MALE SPEAKER

Yes.

>>FEMALE SPEAKER

Yes? Okay. One question Steve when you talked about the basically matter of accounting convenience, is that true or does it vary depending on what the claim scope is.

>>MALE SPEAKER

The claim scope of course defines the scope of protection. As patent lawyers we often try to do something with the claim scope to impact the royalty base. However, again it, comes back to what the value is that -- in that invention right? And so, the claims scope may define a particular piece and might find the cap on this bottle. But that's not sold separately. The bottle is sold together. So while the cap is worth two pennies and bottle **is** worth another penny we'll just still over an accounting standpoint look at what is accounted for. So the claim defines what the parties are talking about right? But not at the end of the day how the base -- how the royalties actually

-- sometimes it will if that's already in the accounting systems for the licensor or licensee. If it's not easily accounted for in the database systems for tracking it will usually become something more convene but again scaled back to what the claims covered.

>>FEMALE SPEAKER

Okay. All right. All right. We are out of time. And I thank you all very much. This has been very helpful and interesting. Thank you.

>>MALE SPEAKER

Thank you, thank you for having us.