Public Hearing on the Study of International Patent Protection for Small Businesses

Public Hearing on the Study of International Patent Protection for Small Businesses at University of Southern California Gould School of Law, 699 Exposition Boulevard, Los Angeles, California 90089 Law School Building, Room 3, Tuesday, November 1, 2011. 9:00 a.m. to 12:00 p.m. before Laurie A. Schmidt, CSR No. 12719.

APPEARANCES:

U.S. Government Panel:

Stuart Graham, Chief Economist and International Patent Protection Study Leader, United States Patent and Trademark Office.

Martin Selander, Regional Manager, Export Solutions Group, Office of International Trade, United States Small Business Administration.

Edward Elliott, Expert Advisor, Office of the Administrator for Policy and External Affairs, United States Patent and Trademark Office.

Saurabh Vishnubhakat, Attorney Advisor, Office of Chief Economist, United States Patent and Trademark Office.

Scheduled Testimony:

Bassil Dahiyat, CEO, Xencor.

Scheduled Testimony telephonic appearance:

Christopher Palermo, Partner, Hickman Palermo Troung & Becker.

Jay Kesan, Professor & Director of the Program in Intellectual Property & Technology Law, University of Illinois College of Law.

Vern Norviel, Partner, Wilson Sonsini Goodrich & Rosait

Philip McGarrigle, General Counsel and Chief IP Officer, Nodality, Inc.

Audience speaker:

Matt O'Malley, Chief Intellectual Property Officer of Cenoplex.

LOS ANGELES, CALIFORNIA

TUESDAY, NOVEMBER 1, 2011

STUART GRAHAM: So, good morning, and thank you, everyone, for taking the time to attend this important public hearing on International Patent Protection for Small Businesses, and the accompanying study, the United States Patent and Trademark Office is conducting to weigh the tools available to such companies looking to compete in markets overseas.

Allow me first to thank our host, the Gould School of Law at the University of Southern California, with particular thanks to Professor Jonathan Barnett, and everyone here who helped to make this hearing possible.

I'd also like to take just a quick moment to introduce the panel today of government participants.

I am Stuart Graham, I'm the Chief Economist at the United States Patent and Trademark Office. I am also the lead on this study of international small business patenting.

Next to me is Martin Selander. Martin is joining us from the Small Business Administration. And I will allow him to introduce himself in his own comments just following mine.

Edward Elliott is a Special Expert to the United States Patent and Trademark Office to the Administrator for Policy and External Affairs.

And all the way on my left is Saurabh Vishnubhakat. Saurabh is an Attorney Advisor in the Administrator's Office of Policy and External Affairs at the USPTO.

As the USPTO director, David Kappos, and the entire USPTO team is working diligently toward implementing various provisions of the historic America Invents Act, and ongoing dialogue with our user community is vital, not only for us to remain transparent in the process of enacting the new law, but also to ensure that your input helps guide and shape how new provisions in the patent system will play out.

That's why this study, like the other six studies mandated by Congress under the law, focuses intently on gathering the concerns, your experiences, and your expectations in enforceable IP protection abroad.

And, of course, we are grateful to those who are offering their testimony today, Christopher Palermo, Bassil Dahiyat, Jay Kesan, Vern Norviel, and Philip McGarrigle.

And for those that didn't preschedule to present testimony, we still welcome all of you to chime in and

share your thoughts or reactions that you may have, to encourage a thoughtful and well-rounded discussion.

Imbedded in the social contract between a patent and the rest of the society is an acknowledgement that the American marketplace awards hard work, innovation, and creativity. But when we take a moment to examine the way countries are doing business in the 21st century, there is no question that information and commerce are cutting across global borders with increasing speed. And as innovators seek to tap into markets abroad, it is imperative that the International Patent System provide a consistent, cost-effective way to obtain reliable patent rights in multiple jurisdictions.

Without adequate education on the importance of foreign IP protection, or what tools are available to them to enforce patents overseas, small businesses are often unable to defend their inventions against foreign lawsuits, increasing uncertainty in the patent system, and the increasing probability of copying, stealing, and pirating content. That's why alongside the SBA, our partners, this critical study gives us a chance to earnestly evaluate your business practices with intellectual property rights overseas, and to see how we can devise a system that empowers manufacturers to more

readily acquire protections globally.

By reflecting on current work sharing models offered through the Patent Cooperation Treaty and the Patent Prosecution Highway being championed at the USPTO, we can assess how existing tools can be shaped to best help small businesses and independent inventors.

Moreover, your testimony today will shed light on how financing these programs or general costs for overseas filings impact upon your bottom lines and the ability to develop your products.

This qualitative and quantitative data will allow USPTO, the Small Business Administration, and all of you to determine whether grants, subsidies, loan agreements, or new work sharing models all together can best enhance a small business's ability to compete in the 21st century in our global economy.

Several components of the America Invents Act were formulated with an eye specifically toward our independent inventor and small enterprise users. From discounts on prioritized examination tools, to pro bono assistance programs, the America Invents Act firmly acknowledges that small businesses, your businesses, account for two out of three of all new American jobs and are the life blood of our economic growth.

So the USPTO is working aggressively to ensure

that the small business community has the tools to continue bringing technologies from the lab to the marketplace as efficiently and effectively as possible.

That's why we're making a vocal effort to invite our global trading partners to engage in serious global patent harmonization talks, an effort aimed at promoting a more standard set of patenting practices across all regional jurisdictions that will cut down on costs and redundant work for patent offices globally, as well as to make it easier for businesses of all sizes to participate in the global arena.

We have an important challenge ahead of us in guiding the implementation of the Act. And while we're making excellent headway, sharing your experiences and thinking on international patent protections will enable the USPTO to continue preparing the most accurate and well-informed report possible, and to empower the USPTO to build a balanced and effective innovation of architecture that's the envy of the world.

So in summation, I encourage you not to hold anything back, because we genuinely do look forward to your insights today, and in the days to come.

Thank you.

And now for comments from the SBA, I turn it over to Martin Selander.

MARTIN SELANDER: Thank you.

I want to thank you, Stuart. Thank you for the kind invitation, and thanks to the USPTO. And Dr. Barnett, thank you for hosting us.

I just have a few brief comments.

Again, I'm Martin Selander. I'm from the United States Small Business Administration. I'm the Regional Manager of our International Trade Office in Orange County, here in Southern California.

So, just a few brief comments.

Small businesses are vital to our economy. They represent over 99 percent of all firms in this country, and over 50 percent of the workforce. And Stuart, as you mentioned, they represent over 66 percent, two out of three, net new job growth over the past 15 years.

Our agency, the SBA, supports small business through capital contracting and counseling programs. And this past year was an all-time record for our agency. We assisted over 60,000 small businesses with over $30 billion in loan guarantees. And my office in particular, the SBA International Trade Office, we approved loans for over 1,500 exporters, totaling over $918 million.

Entrepreneurs and high-growth firms are

particularly different and important. They drive nearly all net new growth job -- job growth each year. And we're here today for the critically important task of discussing methods for support of businesses like these.

As part of the America Invents Act, we are trying to identify the best ways to support international patent protection for small businesses.

This protection is a vital safeguard to support innovation and entrepreneurship and for growth and expansion, and also would help us to reach the President's goal, the National Export Initiative goal of doubling exports by the year 2014 to support two million new jobs.

Exporting is certainly on an upward trend. Exports increased in the year 2010 by over 20 percent. And in the first calendar eight months of this year through August, so far up 18 percent. Almost $1 trillion in exports through eight months, $988 billion.

So, I thank all of you for being here today for sharing your thoughts on international patent protection, specifically as we evaluate the need for a loan program or grant program of subsidies to help defray international patent protection costs. And I look forward to participating and hearing your

invaluable thoughts and ideas.

Thank you, Stuart.

STUART GRAHAM: Great. Thank you, Martin.

The team here of government people not only want to welcome you today, but also to offer you some comments about the broader opportunities for participation in the America Invents Act.

And I now ask Edward Elliott to chime in on those issues.

EDWARD ELLIOTT: Thanks, Stu.

I'm here to tell you all about some of our process for the studies that we're conducting under AIA.

Congress has mandated the USPTO to conduct six additional studies in addition to the International Patent Protection Study that we're here to discuss today.

These studies address prior user rights, genetic testing, misconduct before the office, satellite offices, virtual marking, and implementation of the America Invents Act.

The USPTO will follow the same protocol for all of these studies, will publish a Federal Register notice seeking written comments, along with a public hearing to receive oral testimony.

After collecting public input, the USPTO will prepare its report and publish it for Congress. The USPTO will also make its report available on the AIA microsite for the public.

The prior User Rights study is running in parallel with the International Patent Protection study. Both of those have due dates four months from the date the AIA was enacted. We held hearings last week for the prior User Rights study and for this International Patent Protection study at USPTO headquarters in Virginia.

Between the two hearings we received testimony from eleven witnesses. A record of those hearings is available on the AIA microsite.

The USPTO will soon be turning to the Genetic Testing study, publishing our Federal Register notice in January 2012, and our report in June 2012.

The remaining studies will not be due until 2013 or later. So, please monitor the AIA microsite for more information on how to get involved with these various studies.

And with that, I would like to turn it over to Saurabh Vishnubhakat, Attorney Advisor at USPTO.

Saurabh will provide more details about the protocol for today, and the scope of the International

Patent Protection study.

SAURABH VISHNUBHAKAT: Thanks, Edward.

Thank you. I'm Saurabh Vishnubhakat. I am an Attorney Advisor at the USPTO. And our office has been given the responsibility to lead the study. And I'm happy to be here, along with our colleagues from SBA, to take testimony today.

In our request for information, which was posted on October 7th in the Federal Register and in this hearing today, we're seeking comments and information on how best to address issues of international patent protections for small businesses, and whether a Federal program should be established for that purpose.

Recent economic research supported by the Ewing Marion Kauffman Foundation has shown that nearly all net job creation in the United States, present companies less than five years old. Still other evidence from research conducted at U.C. Berkeley shows that entrepreneurs in technology sectors, from biotechnology, to medical devices, to IT hardware and software, rely on patenting to win competitive advantage, and to attract capital so they may grow and create new jobs.

But the economy is often sent evidence concerning the importance of international patenting to young companies. It makes sense to all of us that if the

entrepreneur in the kitchen with a good idea today is going to grow into the Facebook of tomorrow, actually does better by preserving the options to grow into global markets.

We know that we now live in an increasingly global economy, and that internationalization strategies with exporting, franchising, foreign direct investment, are important pathways to job creation and growth. But we know too little about the role played by effective international patenting and enforcement. It's supporting such internationalization and growth of the youngest, most embryonic companies.

We are, therefore, pleased to have an excellent set of speakers today to help us learn more about the issues facing young companies, and as regard to their international patenting, and whether and under what circumstances a Federal program to support such patenting may be useful.

As stated previously, the legislation interacts with USPTO to investigate and report on at least two options. One is to establish a revolving fund to loan program, and the other is to establish a grant program to small businesses, both to defray the cost of international patent applications, maintenance and enforcement, and related technical assistance.

Ideally, our report to Congress will include at least the following information.

First, what role does the international patent protection of patents play for small businesses? It is a significant factor in helping small businesses to internationalize and grow.

Are there certain circumstances or certain industries and sectors in which that protection is more or less important?

Second, what Federal programs already exist or may be created to help small businesses with international patent protection?

How can different Federal agencies, whether the USPTO or the Small Business Administration, or other agencies, better enable the small business entrepreneurs who are seeking help, to actually get it?

And third, what role does the cost of international patent protection play in small businesses' willingness to take advantage of that protection? Are there particular reasons why small businesses need a different kind of program to enable them to do what is in their best interest? And what are the circumstances in which a revolving fund or loan program would be appropriate? Is one approach or even some different approach clearly better for accomplishing

the goals of supporting the internationalization and the growth of small entities?

These three issues are the basis for the set of questions specified in the Federal Register notice. And we encourage those here today and anyone listening through our live stream to consider responding and offering information at smepatenting@uspto.gov. That is smepatenting, all one word, @uspto.gov.

In the meantime, let's turn the program over to live comments from several members of the public and representatives of organizations who have expressed an interest in these issues, and willingness to give testimony.

To guide that process I will describe the protocol here today for our hearing this afternoon. We will invite each witness to come to the podium and give testimony. On the agenda, we have provided each witness 25 minutes for testimony and questions, but we are not pressed. So each witness should feel free to take as long as appropriate.

After each person's testimony we will open the floor for questions from the panel as well as the audience. If you are a member of the audience and would like to ask a question or make commentary, please come to the microphone in the center aisle right here, please

state your name followed by any entity you may represent.

So with that, I will turn it back to Stu to introduce our panelists.

STUART GRAHAM: Thanks, Saurabh.

So without further ado, let me turn it over to members of the public who have voiced an interest in making scheduled testimony.

The first of these people who should be arriving by phone is Mr. Christopher Palermo.

Christopher, are you with us?

(Telephonic appearance by Christopher Palermo.)

CHRISTOPHER PALERMO: Yes, I am. Good morning.

STUART GRAHAM: Good morning.

Christopher is a partner at Hickman, Palermo, Troung & Becker, and practices in prosecution, licensing and technology development, including an active practice in Europe, Japan, and China. He has over 20 years of experience in IP law, primarily advising networking telecommunications and software firms.

Christopher, we now look forward to hearing your comments.

CHRISTOPHER PALERMO: Thank you for the opportunity to participate today. And I regret not

being able to be there in person.

I'd like to begin by noting that my frame of reference is somewhat narrow. My practice has been almost entirely in Silicon Valley working with applicants in the software networking and computer technologies. And therefore, my comments are essentially biased by that type of practice. And there may be other speakers whose perspectives are quite different.

Most of the start-ups with which I work do not express significant interest in foreign patent filings at the early stages of the business. But some do, and for them the cost of the process is material and daunting. Because of the costs, most of them defer filing as long as possible.

They use the entire Paris Convention priority year to defer these costs. They also view PCT essentially as a fee deferral system, mainly because the international search reports prepared for their technologies result in a limited amount of useful information, and because examining standards for IT-related subject matter differ greatly around the world, making centralized amendments. And through the PCT system it is not particularly useful. They prefer to wait for a national stage prosecution.

These SMEs also tend to see foreign patents as a lower priority in the early stages of the business.

Their priorities tend to be finalizing product design, and marketing and sales, to result in winning in the marketplace, and obtaining a U.S. patent position in the first -- as a first priority, taking advantage of the U.S. grace period.

Venture Capitalists and other early-stage investors in the IP businesses that I have worked with tend to view patent exclusivity as a secondary factor because the real problem that they face first is competing in the market against established larger companies on the merits of product features and functions.

Patents, however, including overseas patents, become much more important in years three and later of the business when the future is more apparent. Second -tier investors have entered if a funding source or a revenue stream exists.

And before addressing the merits of Government grants or loan programs, which are the subject of part of the Federal Register notice, I think we need to review the context of all sources of the high cost of patent filings. I've identified at least five components of this high cost that I think are good to

bear in mind as we consider the situation.

The first is official fees. Official fees for filing are higher in most foreign jurisdictions than the U.S., and there are no small entity discounts typically.

In the European Patent Office, excess claims fees are particularly high.

The second component is official annuities or taxes. Pre-grant annuities or taxes can be considerable and can represent a serious unanticipated cost over time if the examining backlog of the patent office is long.

For an example, for an SME considering filing in the European Patent Office, the prospect of paying a tax of $500.00 to $1,000.00 per year for eight to ten years, which is a common examining backlog in the EPO, in the IT space, can be a serious deterrent to filing.

Stated another way, the time involved, the backlogs involved represent a source of costs to SMEs in the foreign patent process.

A third component is translation costs. SMEs typically cannot negotiate for discounts with translators overseas. They're almost always based on volume, and an SME may not have enough to justify a discount.

A fourth component is U.S. outside counsel, if they are used. Some applicants, of course, file

directly on their own. Some U.S. attorneys provide discounts in working with SMEs, recognizing that they add value in counseling and management, rather than just the mechanics of filing. But other firms see foreign filing as a profit center and price it accordingly.

And finally, a cost component is foreign outside counsel used as filing agents for foreign patents. Discounts for SMEs are rare overseas, if they're available at all. Fixed costs and hourly rates for attorneys in places like London or Tokyo are perceived to be significantly higher than those of their U.S. counterparts. And foreign law firms and agents typically don't have the kind of culture that we find in California, and in particular for serving small entities, and seeing them as an opportunity for future prosperity or benefit.

Procurement costs, which I've just reviewed, also need to be seen as only a portion of total overseas patent costs. The cost of enforcement is significant. And I would encourage the panel to keep in mind whether a program results in increased patent procurement will really be a true benefit to an SME if that entity is not in a position to spend much higher costs involved in enforcement in, say, the courts of Germany or England.

Now, finally -- well, the inability of an SME to

procure patents at reasonable costs is also not the only foreign patent issue that SMEs face.

For example, some SMEs may have an interest in opposing or invalidating the foreign patents or applications of others in order to obtain greater freedom of action. I would suggest that the panel should also bear in mind that a funding or grant program might be more beneficial if it also provides a funding source for SMEs to attack applications or patents of others rather than merely procuring them.

It's very hard to judge whether the social benefit to an SME is greater in procurement or in removing applications of others that pose barriers to entry.

Now let's turn to the mechanism for addressing some of these high costs. The Government loan or grant.

One of the issues I think some would have with a loan or grant program if it's funding from taxpayer dollars, is whether the movement of taxpayer dollars into the foreign patent offices to benefit SMEs represents good policy overall.

A cynic's view of certain overseas patent offices is that they appear to offer somewhat less value than the USPTO does.

The backlogs in the European Patent Office in

particular are very difficult for Americans to understand, and for fast-moving Silicon Valley SMEs in particular.

The perception is that EPO examiners are working fewer hours and have overall less productivity, and also have very generous government-based benefit schemes. And so from a policy perspective, Congress may have to justify to the American taxpayer why it's beneficial to move tax money into those benefit schemes on an indirect basis.

In addition, a policy challenge posed by a loan to grant program is how to choose which SMEs should qualify. My experience is that a material percentage of SMEs in Silicon Valley and elsewhere are going to fail or have management who may be poorly positioned to grow a company or pursue products. And it may be very difficult for government to separate SMEs deserving of a loan or grant from those that are mechanically not going anywhere.

And finally, as a policy matter, it seems appropriate to ask whether at least some of the burden of financing SME patents overseas ought to fall on large entities. Large entities tend to dominate the patent system because of their ability to pay high official fees, file large numbers of cases, and wait out the

resulting backlog periods involved in foreign patenting. One could ask reasonably whether the large-volume filing by large entities is a contribution to the cost faced by SMEs in the system.

So for all of these reasons I tend to disfavor a Government loan to grant program. But I do have a couple of alternatives to offer, and then I'll conclude my remarks, and would welcome questions, or just the next speaker.

One alternative is a tax credit approach. Government and Congress could consider establishing a research development tax credit that provides a dollar-for-dollar credit against either investors, capital gains taxes, realized at the exit of an SME investment or against SME corporate income taxes credited for every dollar that is proved to be spent on foreign patent activities.

And in this context, foreign patent activities I think should include spending on both invalidation and opposition, as well as procurement.

The second possibility is that the USPTO could establish a new line item fee surcharge, such as $5.00 applied to every new margin to the application filing, or $1.00 applied to each filing of the paper by a large entity, and then grants or a loan, those collective fees

to SMEs for foreign patent activities. This would reduce some of the -- or eliminate some of the policy challenges involved in using taxpayer funds and place the burden of funding SME foreign patents on large entities who tend to dominate filings overseas. It also increases transparency and awareness of the program, as filers will see the surcharge each time that they use, for example, EFS-Web to complete a submission.

Third, I suggest that there should be some effort to use existing funds to try to communicate with overseas patent offices. The key ones: EPO, JPO, CIPO in China, KIPO in Korea, are the top filing jurisdictions directed to achieving a discount scheme for official fees charged to SMEs that are similar to the U.S. small entity system. One can reasonably ask why the U.S. stands alone in having a small entity discount system. Now, these countries need to see that fostering SME growth will have benefits downstream.

And finally, some sort of similar outreach could be directed to overseas providers of legal services, translations, and annuity payment services. You will remember that we identified these as some of the component costs for high SME overseas patent costs. One could envision, for example, a sort of SME support pledge that these providers could sign, perhaps a banner

for their websites indicating an endorsement of a reduced cost approach for SMEs. All of these approaches might contribute to improving the situation for small enterprises seeking foreign patents.

That concludes my prepared remarks, and I welcome any questions, or the next participant.

Thank you very much.

STUART GRAHAM: Thank you, Christopher, for those excellent comments.

This is Stu Graham. I have a couple questions, then I'll open it up both to my Government colleagues on the panel here, and also to the audience.

I'm very intrigued by your alternatives, and I would like to ask you a couple questions about them.

In terms of your recommendation for some sort of tax credit mechanism, it dovetails on another issue that was brought up at the hearing last week. One of the members of the public who had experience in entrepreneurship had mentioned that help in patenting is much more important upfront when the company is cash-constrained for the initial set of fees, and much less important for things later on, such as -- and these came from the testimony of that person -- enforcement and maintenance fees.

So, I wondered how that maps onto your

recommendation for a tax credit, particularly as regards your suggestion that possibly the tax credit could be used against investors' realization of income, because of course in the early running of these small companies, precisely at the time that they're most cash-constrained, won't have the income against which to enjoy such tax credits.

Any thoughts about that?

CHRISTOPHER PALERMO: Yes. Very valid point. However, I think, in my experience, at least, is that the bulk of the costs incurred in foreign patenting occurred well after the first year. Initial application fees are not small, you know, $5,000.00 to $10,000.00, perhaps, per application. But the annuities, and that's due to the prosecution costs, which are typically encountered four, five, eight years later, are much greater than that; typically three to four times. So the overall cost of obtaining a patent, say, in Europe, I would guess that the initial application fees and costs are on the order of 25 percent, perhaps 30 percent of the total cost. So I think that the credit approach wouldn't be attractive for that 70 percent that's incurred in much later years.

STUART GRAHAM: Thank you.

Any other questions from the panel?

SAURABH VISHNUBHAKAT: Mr. Palermo, this is Saurahb Vishnubhakat.

You mentioned a delay from waiting until the national stage was significant in the international arena, and then also delay from international backlogs was significant in terms of getting from filing to grant overseas.

I was wondering if you could comment on which is more significant, whether waiting for the national stage is really all that meaningful in light of the seven-, eight-, ten-year backlog that's already waiting. And also if waiting till the national stage because of IP standards can be managed somehow through work sharing and the Patent Prosecution Highway and other initiatives?

CHRISTOPHER PALERMO: Yes, that's an excellent point. I think there is a dearth of knowledge among SMEs, typically about those acceleration mechanisms and their benefits. And we can do better in the private bar in educating SMEs about opportunities to use PPH in particular.

So, I think that is very valid.

I think what they seek to defer is simply the national filing. The national official fees for filing in multiple jurisdictions will represent a significant

cash outlay, and that's what they're seeking to defer.

But I agree, the PPH and similar mechanisms can be very effective, and we need to do a better job about educating SMEs on the use of those.

SAURABH VISHNUBHAKAT: Thank you.

STUART GRAHAM: Thank you very much.

Edward Elliott.

EDWARD ELLIOTT: Hi, Christopher.

I have a question about your idea for funding a small entity program based on a surcharge to higher entities when they file at the patent office.

What is the policy rationale behind that? Is it the idea that larger companies oftentimes benefit down the road from these filings by smaller entities, because they buy out the company directly, or they somehow license or acquire the technology?

CHRISTOPHER PALERMO: No. It's actually -- and I can't say it's based in evidence. It would need study. It's based on the perception that large entities, to some extent, are responsible for the backlogs, and therefore, the high costs that SMEs face in the overseas patent offices, simply because large entities file more cases, and because, frankly, the overseas patent offices, can charge the high official fees that they do because they can get them from large entities. So if

large entities are the indirect cause of those high costs, then the policy rationale is that they ought to support almost a rebate scheme, if you will, for SMEs.

But your point is actually very interesting to me. And the more I think about it, it is a valid additional policy justification to say that it's in the interest of large entities to have an ecosystem of small businesses that are innovative, having access to the system and developing strong portfolios that will be valuable in later acquisitions. I think that's a very attractive rationale.

EDWARD ELLIOTT: Okay. Thank you.

STUART GRAHAM: Thank you.

Any members of the audience have a question for Mr. Palermo?

(No questions from the audience)

All right. Seeing none, Christopher, I thank you very much for your testimony. And I encourage you to stay on and listen, although I know that with your business, you have a lot of activities.

CHRISTOPHER PALERMO: Thank you for the opportunity.

STUART GRAHAM: Absolutely. Thank you.

Okay. Next on the schedule of testimony is Dr. Bassil Dahiyat.

Dr. Dahiyat is the cofounder and CEO of Xencor, and a developer of the Protein Design Automation technology.

Dr. Dahiyat is an inventor of over 60 patents and patent applications. And I invite him to stand up in person and offer his testimony.

DR. BASSIL DAHIYAT: Thanks, Stu.

This is a topic that I'm coming to you from the outside. I'm not a lawyer, I'm not a practitioner, but my company pays a lot for patent protection and we spend a lot of time on patent activity.

So a little bit of background.

I'm a biophysicist at Xencor. That's the company I work for. And I'm the CEO of Xencor. It was founded about 14 years ago as a spinout from Caltech in Pasadena, California. We are a biotechnology company. We create new pharmaceuticals. We use our technology to redesign old pharmaceuticals and design new ones that have more effects, to last longer, and to be more beneficial to patients.

Currently we have five of our molecules being tested and used in clinical trials. As an example, international and pharmaceutical businesses. We're a very small company with 30 employees. We do a lot of outsourcing of our workload, but it's all in the United

States. But of those five clinical trials, two are taking place outside of the United States, about half of our revenue. And we are about a break-even company now, so we spend well over $10 million a year on clinical development work, and we bring in similar kinds of revenue, half of that's coming from outside the United States from pharmaceutical or other biotechnology companies that are licensing our technology or accessing our tools.

The basis for our business is that we do have a strong intellectual property portfolio, and obviously the international component of that is a critical driver. So I'm going to give some perspective about how biotech companies do work, and how I think now, with some retrospect, I think they ought to work.

So, international protection is critically important because it is completely an international business. There's no such thing as a national pharmaceutical company anymore, in any developed country at least. So, having foreign intellectual property protection is pivotal. You have to establish that at the outset of your company. And that's a mistake that some companies I think still do make, is that at their founding they don't see international protection as worth the money, because the costs that were outlined by

the last speaker I think were spot on. I think he does discount that the largest single cost is lawyer time. I don't know how you're going to fix that one. Maybe that's not a Government problem. But certainly the translation costs, the foreign filing fees, and the annuities do add up.

Everything that the first speaker said about what happens in the software industry is slightly changed, and put a twist on the pharmaceutical industry, because our product development cycles are very, very slow, because we have to test our products on human beings, and there's very heavy regulatory enforcement of the law with that testing. So a company that's seven or eight years old in the biotech industry could just be getting into its critical clinical trials after four or five years of prior development to refuse early clinical testing. And they would have had to have raised enormous amounts of money to do that. So, for example, Xencor, my company, a relatively small company, has raised over $140 million in venture capital investment over the years to fund our work. And we brought in more than that in money from partners and from licensing, and it was all spent on developing products.

So the extra time lag that you have is obvious that it's sort of contrasted with needing to be able to

access the capital sources and the partnership in markets all over the world, which means you have to really get into the foreign patent files. And the real, the rubber hits the road, and everything the prior speaker said about using the PCT timelines, and all that, is like a delaying tactic. Right? If you file nationally, you get 30 months, and all that other stuff. It does hit, and it hits right at the worst times for small biotechs. And it particularly hurts the companies that are not as well in the mainstream of the biotechnology industries that are trying to often bring new or different ideas, or are not operating in either Silicon Valley or Cambridge, Massachusetts, and that have the access to the venture capitalists. And so you'd end up in a situation where companies are sort of just ignoring some of their future by not prosecuting their patents foreign, or at year four they just go, "I just can't afford to pay, you know, $20,000.00 for translation fees for EP."

And similarly for companies like Xencor, we often prune our patent tree a little more aggressively than we would, because we have to prioritize and say, in these cases, we're going to go national, we're going to file the translation fees. Or even, you know, we just had a case allowed in Europe by the EP for a pivotal piece of

technology that existed in three of our molecules that are in clinical testing, two of which were partners whose downstream payments to us depend on patents being issued in the various countries. And we simply didn't pay the final fee for allowance as biotranslation of claim into some of these major European markets because it was too damn expensive. And this is year seven of that patent; right. So these are real problems that have an impact not just for the tiniest companies, but even for a little bigger company like us. And it's because our product timelines are too long, and certainly different from the software companies.

So, you know, the trick for us is how do we get our product candidates to the point where somebody's willing to pay significant money for them and, therefore take over the development costs, maybe the patent costs. Or by taking over development costs allows us to protect our IP portfolio more effectively, or for an even littler guy to really do it. And it's that sort of valley of death between sort of year three or four when the money really starts to have to get spent on foreign prosecution, and you know, for biotech companies, maybe year seven or eight, or even out beyond that.

And so, you know, the mistakes that people make by not foreign filing do end up cutting into you. Like

I said, you know, half of our revenues are from overseas. Our third largest investor is a foreign pharmaceutical company. So that's the background of how a biotech might differ a little bit. And the pharmaceuticals generally, I would say, not just biotech, but from broader pharmaceuticals, we differ from software. Venture capital investors and large companies that you have to work with in pharmaceutical industry are very sophisticated in international patents, and they value them very highly. And they discount you if you don't have it. Right. They just simply will discount a program if you don't have international protection. "Well, this is a U.S. product, why should I pay all that money if can't meet two thirds of the marketplace, or if I can, but some other joker can come in and just, you know, generic me." Right. Because in pharmaceuticals, patents are real and they're important. And they don't just lose sight. And the largest pharmaceutical in the world is Lipitor. It was invented 20 years ago. It doesn't happen in software. Who has a 20-year-old software? So that's a perspective shift that our industry really needs.

And so, going on to specific points that were raised in the RFC. I'll try to, quickly

address them and not be too redundant.

So the first question was, are international patents important. And again, from my little myopic world view of the pharmaceutical industry, yes, they are, for the reasons I just stated.

It's an international business, and it's a necessity to get partnerships to fund other pharmaceutical companies, and continue funding in the pharmaceutical industry. You just can't bootstrap your way into developing new drugs. It doesn't happen. And we're about as bootstrapped a company as you can possibly have, and we've been about 50/50, and that's because we generate technologies we can license, we're not just a product. And we're lucky in that regard.

So I think questions 2 and 3 are related to that in terms of timing. Right away you need to start filing foreign in the pharmaceutical industry. VCs and the pharmaceutical companies who are licensed are very strict about that. But you get a freebee for three or four years, because of the timing of it. And that national phase is where the money is, by the way. That's when you get the list of translation costs and filing fees. And it's a little list you get from your lawyers. EP is $12,000.00; Japan, $19,000.00; you know, Jakarta in Indonesia, all these ones, and you just

triage it. And so that's when it really, really hits, and that's when it starts really getting troublesome.

So, you know, if you make a bad decision there, it really, really, really hurts you. And I know this from retrospect from my own experience. The value of the equation is reducing and negotiating leverage with the companies you need for further development of your products, and to ultimately market your products.

A specific instance where being able to have foreign patent rights is critical in the pharmaceutical industry is -- one of the most effective business strategies for a small company in our industry is to segment the international rights of a product by region. And it makes a lot of sense. There's different regulatory authorities. So in Japan versus the European Union versus America, a product's going to have a bit of a different lifecycle of time, right. Yours is going to get approved sooner in America and later in Japan, or whatever. And so you can sell the rights to your product for the Japanese markets, and generally significant funding, and also get support to help you drive forward the U.S. development and, therefore, advance the product, increase its value, and get a much better partnership with a lot more money, a lot more ability to grow your company, and keep funding the stuff

you've got behind it, by, having somebody pay in a sense for you to build in America, because they wanted what you had for Japan. Very common strategy, very effective strategy. It's widely used. Because, again, in pharmaceuticals, if it's not patented, people will laugh at you. Because a Teva and a Mylan will just make it off patent and sell it for a tenth of the price, because they didn't have any development costs to worry about.

So without having foreign patent rights, you can't do one of the most successful and important strategies for a growing biotech company that wants to develop products.

One of the things the Federal Government can do, to go to the next point, and this is coming from, again, my myopic perspective, my experience in how my company has dealt with U.S. and foreign filings, is it in some ways to have more cooperation. And to get multi-jurisdiction bang for the buck you're spending in one jurisdiction will be extremely valuable. To be able to have a European search report, or an international search report be useable for the United States, or vice versa, to have that -- you know, for one dollar you pay to get not just the low direct costs of the jurisdiction, but to get some certainty sooner, not

having to wait.

In contrast to the prior speaker, in our particular area, our particular subsection of biotech, the U.S. Patent Office is slower, it is lower quality, and it is less consistent than the EP, the Koreans, and the Chinese Patent Office. And I can see that in direct experience. And I don't know whether that's just bad luck on our part, or if that's a general pattern, but as a result we had to actually leverage foreign prosecution to demonstrate the value of our patent portfolio and give potential partners confidence that we're going to have worldwide coverage.

But having programs like the Patent Prosecution Highway, which in theory sounds awesome, and I know my company is looking very hard on how to use that, that's a terrific thing to do, to get more bang for your buck.

I'll be honest, I talk to a lot of different people, not just my patent lawyers, other patent lawyers, friends of mine from grad school who are now patent lawyers, there's an enormous amount of skepticism that the PPA will ever amount to anything, because there's just this kind of, attitude that, well, they actually got to make it work, and there's no way in hell the patent office is ever going

to cede control to somebody else, to look at somebody else's search. I don't know whether that's true or not, but that skepticism is widely shared by many. I hope it's not true. But that kind of program can really make a difference. If the Europeans would take the American examiner's take on things, and you could have suddenly your patents, boom, all at once go, or vice versa, that would be fantastic. You wouldn't have to spend money doing that. So I think somehow finding ways to further harmonize and simplify how the international system works relative to the U.S. system would be fantastic.

Regarding the specific nature of a program to assist small companies, I don't understand how a grant program versus a loan program would play in terms of political support or for anything like that, or even be easy to implement and execute. But I could say that the feature of a program needs to be sustainable. If there's no confidence that it's going to be there in two or three years, it won't be used, and it won't help. Certainly our timelines for prosecution patent and product development are a decade long. So it has to be sustainable. It can't be seen as risky or short-term, regardless of the funding mechanism. And so that means when I read it, grants for a loan program, my skepticism

radar went up. A new guy gets elected to chair, and it's gone. So what's the good of it? So that's a fear factor for me. And the prior speaker's comments on perhaps some kind of additional surcharge or fee for large entities, that can be in a transparent way used to fund some of program, I think that would be great. And I thought the policy points that were raised by him were exactly spot on.

Large companies do add the majority of the load to the system. And without that, everything would be a lot faster.

I think also there has to be some competitiveness to a process if there's limited dollars to support the most commercial viable technologies. But it should allow for longer timeline technologies to compete. So I've been involved in lots of different scenarios with either investment groups or business point competitions, and one of the issues always is, let's make revenue a criteria. Okay. So some software company is selling a new search widget for your desktop and they made $3 million this year. A biotech company that might have, something that's going to help treat, patients with an intractable disease isn't going to make revenue for another four years, or maybe even they won't ever make revenue. They'll get bought

and face the clinical testing. You have to account for that somehow, that different industries have different criteria of interest. And biotech pharmaceuticals shouldn't be left out.

You have to, of course, consider the nature and strength of the applicant themselves. Without a strong sponsor, no technology is going to succeed. And we shall allow the companies that have received some kind of partnering or capital, it shouldn't be just limited to individual investors.

I think the idea of a tax credit, I'm skeptical would make a difference. Again, most of the small companies, certainly pharmaceuticals, but I'm betting most software companies and technology companies can't use a tax credit because they don't have income, just like what Stu said. I think that the idea that you could have investors apply to actually reduce their capital gains taxes won't be helpful at all because it doesn't affect tax flow, which is what it's all about. So I'm skeptical that's going to be meaningful at all. And even for a biotech company or a pharmaceutical company, year seven and eight you're not making revenue anyway, or you're making it at a loss. We've got to spend every nickel we make just to keep driving forward our programs, otherwise

what's the point of our company.

So I would leave that as my comments. I think it's great that there's thought about how this might happen. And maybe if there's ways to structure a program for grants or loans that could be competitive, fair, transparent, and not be, you know, subject to political whim, it could be very effective, because this is a big problem in certain ways.

So that's my comments.

If there's any questions, I'll be happy to address them.

STUART GRAHAM: Thank you, Bassil.

I have a couple of questions.

So this is Stu Graham, for those on the phone.

A couple of questions about the way your company born, and also some of your closing comments.

So, first is, I'm intrigued, and we actually haven't heard anything yet about the university spin-off licensee interface, and the way in which that might play a role in this issue.

If you have any comments, and if you don't, that's fine, but if you do have any comments about how the universities, or maybe just in your particular instance, have been working at understanding this global patenting phenomenon, particularly for the small

companies that they're interacting with, I would be interested in hearing that.

BASSIL DAHIYAT: Sure.

STUART GRAHAM: And secondly, I'm wondering, and this always strikes me as, you know -- the economist in me, I mean, I recognize there are a lot of market failures in the markets for entrepreneurial capital. But I'm wondering why it is that between years three to seven, if you have any opinion, why isn't the market working sufficiently? Why can't a company demonstrate effectively that it will have -- you know, that it at least has the prospect of earning revenues so that it can collect the kind of capital that is necessary for it to make the investments that are in its and its investors best interests in foreign patenting.

BASSIL DAHIYAT: Right. So I will address the second point first.

I think the markets work in the sense that companies can get capital. I think it's always scarce, it's never enough, it comes with a lot of strings, and it's very expensive capital, and so therefore, it's scarce. And so you use it, and you meter it out in very small aliquots, because you don't know when you'll be able to get more, and you don't know what kind of business hiccup or technical hiccup will make it more

difficult for you to get more. Maybe your plan was we're going to achieve, complete your phase for testing, and that will allow us now with new data to generate more investment interest and investor capital, and, oops, something happened, we're delayed nine months in the clinic. You're going to run out of money unless you're very careful with that money. And facing, you know, $89,000.00 to advance patent prosecution of a case is one of the things that gets chopped off the bottom, at least in my business, and I'm suspecting in others. So I think it's a matter of, it's hard to live for the future when you don't know if you have one. So long-term planning is really hard in the entrepreneurial world. And I think that's why entrepreneurs do such a good job at being innovative, because there's nothing that motivates you like hunger, but you lose things along the way. So I think that's why -- that's my discussion on the industry.

Everything has gotten more difficult and tighter over the last two or three years since the financial crisis. It has impacted venture capitalists enormously throughout all sectors. I think the predictions in biotech are anywhere from 50 percent to 70 percent of VCs won't exist after -- you know, the fallout takes a few years. There's a time constant there. So I think

it's going to get harder.

So these extra things where you can get non-diluted ways to deal with long-term problems, and in particular, if the only way that you can use that capital is to deal with a long-term problem, I think it helps.

Now going to the university side. From my experiences, not just of the founding of our company, but we're constantly dealing with universities around the country, and around the world, actually, licensing in technology because, things keep advancing. My perception is their general goal and hope is they don't have to go international before they license to somebody. They've got that time window, the time frame to national phase to get it all done before they have to spend a lot of money. And they won't do it if they haven't found a licensee to pick up the burden of the costs. They just simply won't do it. So international protection will sort of go away. And what ends up happening, then, is a lot of stuff gets dumped into the public domain as a result from the university transfer system.

STUART GRAHAM: Thank you.

BASSIL DAHIYAT: Again, that's my perception from my dealing with and trying to purchase some license

technologies over the last, decade.

STUART GRAHAM: Other members of the panel?

SAURABH VISHNUBHAKAT: One quick question.

You spoke a little bit about the relative quality that firms tend to perceive. I was wondering if you could clarify, are you talking about patent quality in terms of likelihood of being upheld in litigation, or these costs they're being designed around, or some other interests?

BASSIL DAHIYAT: So, I didn't mean patent quality, I meant the examination quality, to be specific. I meant the consistency of the examination across, say, different examiners, or whatever the proper term is before jurisdiction. I mean, let's see. What's the best way? The quality of examination, because the patent examination process might take three or four years. During that time we try to do business with other entities, investors, or companies that might want to license that patent, when it gets issued. So they're dealing with it. And these people have sophisticated lawyers who have been in this industry for many years who do due diligence on your portfolio. And the ability to have sensible and predictable results from a patent office that match with what sort of a bunch of different companies might see as

what the law might be, is what I'm referring to. I found that consistently in our arc area. We're the monoclonal antibody drug arc area. The foreign patent offices, in particular the EP, are just better, more consistent, more logical, more in sync with what sophisticated buyers that I'm selling to, want to have. And so, you know, it's just better technical quality. And so that predictability is enormously important in raising capital and doing deals. And again, I have one myopic window on the one or two arc units in an enormous institution at the PTO.

STUART GRAHAM: Other questions?

Okay. A member of the audience. Can you please identify yourself?

MATT O'MALLEY: Sure. Matt O'Malley, CIPO, with Cenoplex. Just adding on to that exact same comment, if I may.

You said that the EP is typically much better in China or Japan on your particular arc unit. You are using the U.S. as your receiving office, I assume, for your PCT?

Okay. I guess that's kind of a commentary in and of itself that the EP is actually beating the process in terms of efficiency and speed.

BASSIL DAHIYAT: Yes. So, you know, the first

restriction is usually 30 months in our area in the USPTO. And then you'll have some back and forth, and things just get delayed and delayed and delayed. But what happens is the biggest delays comes from an examiner doing a bad job of not getting it, and simply, you know, creating an enormous amount of additional work for you to have to do in-person interviews and after final kinds of actions, or RCEs. RCE is just the death of a patent. The money goes through the roof. And the biggest fees are the lawyers. The biggest fee is not -- the translation fees and the national filing fees approach that, everything else is dwarfed by the legal fees. That's the biggest fare of entry. But I think what happens is you have bad examinations, and then they go, "No, I just dont get it. I'm not going to allow it." And you go, "ah." And it's that examiner who is three doors down from you, allowed something from one of our competitors that was very similar, with the same facts. Let's try this again. And then two years later, "Oh, okay. Fine." That's what I'm referring to.

MATT O'MALLEY: So the EP is actually --

BASSIL DAHIYAT: Much better.

MATT O'MALLEY: -- beating the speed of the U.S. receiving office.

BASSIL DAHIYAT: It's because of the quality of

the examination. It's the quality of the examination. The slowest thing in patent prosecution is a bad examiner. And there's no system in place at the U.S. Patent Office to deal with that, aside from, let's appeal and then in 30 months we will hear from the board.

MATT O'MALLEY: And the ombudsman --

BASSIL DAHIYAT: And the ombudsman has no power to do anything. So I think that the patent quality is just not -- and maybe this is for another whole other session. But I found that you can even expect consistency and actually unity of the view. I mean, a Chinese examiner, it's remarkable how consistent they are with the EP in the viewpoints, and the legal standards they're applying, and the outcome. Right. Koreans, Australians, same thing.

So that's again, one area, one arc unit, a handful of examiners; I might be completely out of the case.

MATT O'MALLEY: As the inventor in a case like these, it's not only the translation of that application that goes in. As you have mentioned, Japan can be $19,000.00 for a rather large application. When you get into the prosecution, and you get prior arcs sent back that's in Japanese, well, guess what, you've got to pay

for the translation of all those pieces. It gets very expensive, translation as well.

BASSIL DAHIYAT: It does.

MATT O'MALLEY: Yeah, very expensive.

BASSIL DAHIYAT: It does.

Anyway, thank you very much for the opportunity to sort of show a viewpoint from a non-legal perspective.

STUART GRAHAM: Absolutely.

Any other comments from the audience?

(No comments from the audience)

Seeing none, Bassil, thank you.

BASSIL DAHIYAT: Thank you very much.

STUART GRAHAM: Okay. So our next speaker is Professor Jay Kesan.

Jay, are you on? Jay, are you on the telephone?

It might be just a tad early.

How about I suggest the following. Since we're just a tad early for Jay Kesan, shall I suggest a five-minute break, and we will return here in five minutes, and pick up again on the hearing.

Thank you very much. And we will see you back here in five minutes.

(Brief recess taken.)

STUART GRAHAM: So I think we should reconvene.

Our next speaker is on the telephone with us.

Jay? Jay, you're with us, yes?

JAY KESAN: Yes, I am.

STUART GRAHAM: Great.

Professor Jay Kesan is the Director of the Program in Intellectual Property & Technology Law at the University of Illinois College of Law. Jay's scholarship includes intellectual property, entrepreneurship, digital government, agricultural biotechnology, and biofuels regulation.

Dr. Kesan also advises the University of Illinois Office of Tech Transfer and the Office of Technology Management, IP commercialization. So I'm sure Jay will also have comments with us about the role of international patenting protection in the context of university entrepreneurship.

Please go ahead, Jay. Thank you.

(Telephonic appearance by Jay Kesan.)

JAY KESAN: Thank you very much, Stu. I appreciate the invitation.

Good morning, everyone, and members of the committee. And thank you very much for the opportunity to speak to you about international patent protection for small businesses.

As Stu just mentioned, I am a professor at the

University of Illinois, and I am also a registered patent attorney. And in the process of preparing for this event, I'm grateful for the input I received from various colleagues at the university and patent practitioners.

So let me highlight about 15 points that I want to mention in the short amount of time we have.

I have provided a written copy of what I'm going to be discussing, and I have sent it over. I hope you guys have had a chance to look at it, or you will have a chance to look at it.

Point 1: International patent protection is important for small businesses. And it really does depend on the technology space that the small business is working in.

And number 2, it also depends on the particular innovation that is the focus of the patent or the focus of the small business.

In our experience at the university, and in my time in private practice, I noticed that there was a difference between different industries. For example, in the pharma and biotech industries, foreign patenting is seen as being very important.

It is not at all uncommon at the universities to find that a pharmaceutical company may not be interested

in an organic molecule, or something else that's been developed by a small business that has been started by a university professor, unless they have the option to continue to pursue foreign protection, or unless foreign protection has already been initiated. That's because they view, say, the European market as being very large; 40 to 50 percent of the world market, and so on. And so the pharma and biotech industry really cares a great deal about foreign patent protection.

For a long time the computer software industry cared about foreign protection, but in a more limited way. It is not uncommon, even today, to find computer software companies as saying that we want to protect our inventions in the U.S., Canada, and Europe, but will actually pursue national phase only in Germany, France, the UK, and Japan, and then we'll just stop. And so it's a limited protection.

However, more recently we're seeing that in the case of -- this is not true for all the electronic arts. In the wireless handset industry we're seeing vigorous worldwide protection for handsets all over Asia and Europe. And you may be aware of the litigation that is taking place between Apple and Samsung, and how it's played out in the Netherlands and in Europe. And some of these disputes that are very heavily being pursued by

both parties underline the importance of things like international patent protection for things like wireless handsets much more so than what was the case in the past of the electronic arts.

So in other words, I think a short way of thinking about this is to say that the size and distribution of the relevant U.S. and international markets is what really matters to small businesses as well.

This is an area where it's crying out for some good empirical studies on seeing how international patent protection matters in the context of various technological arenas. It's also important from the standpoint of the exit strategies that are pursued by a small business. A large company may find in a buyout situation that a small business that has preserved the options to pursue international patent protection may, in fact, be a better target than one that has sort of given up its foreign rights. So I do think that international patent protection can be important for small businesses.

A point too, this whole issue of foreign patent protection really comes to the fore, and this is a practical point that I have often noticed, when the small business actually tries to sell products and

services abroad. So even if a small business has not thought about it up to that point, the moment they start realizing that there is a market for their stuff outside the U.S. and they want to take advantage of it, you know, it really does become important in that stage.

Number 3: You know, what exactly are the dangers if international patent protection is not sought.

The biggest danger is an obvious one. And that is that if they delay pursuing foreign patent protection, then they may very well find themselves competing with their own inventions, and their own patents, which may be used against them for rejecting their new claims. And foreign patent offices may find that their own inventions are a relevant prior art that prevents them from pursuing foreign patent protection.

I want to announce that if -- these are sort of largely high-level macro-comments, and I wanted to -- in the time I have I want to drill down a little bit more and talk some more specifics.

If you pursue international patent protection, then you have five significant cost components, and it's worth enumerating them so you can actually sort of -- when you are thinking of helping small businesses, I think you really want to sort of focus on these particular sources of costs.

Number one, you have the actual U.S. law firm legal fees and costs that are being charged by the U.S. patent attorneys.

Number two, you have foreign law firm associates, their legal fees and costs.

Number three, you have the PCT filing fees, and then you have the foreign filing fees when you domesticate the PCT and they move to national phase, then you have the foreign patent offices' filing fees.

Number four, once your patents have been issued you have annuity payments, which are akin to our maintenance fee payments. But you have these foreign patent annuity payments that come due every year.

And number five, you have translation costs, and depending on the country you're applying for, it can also be very significant. So I'm going to address some of these cost components at some length.

Point number 5: Focusing on filing fees.

Reduction in filing fees for small businesses for PCT applications would help significantly.

I am thinking of something akin to a small business entity reduction, akin to the U.S., a 50 percent reduction in filing fees that we currently have in place. I'm not even talking about the micro entity issue, which is an additional incentive for universities

and particular categories of small inventors in the America Invents Act.

I am specifically talking about having something that is akin to a reduction in filing fees for small businesses for PCTs. In particular, if the PCT application filing fee is lowered to a level that is roughly equivalent to the typical search fee that might be charged by a search firm for doing a patentability search, then it becomes really worthwhile for the small businesses to file a PCT, because they can obtain good patentability search results from the PCT prior art search.

A reduction in filing fees, particularly to a level that the small business is indifferent, about filing for a PCT or doing a private patentability search, would be very helpful.

Point 6, even if the overall fee associated with a PCT application cannot be reduced, the PCT should consider at least reducing the PCT search fee. Today we have two components to a PCT filing fee. We have roughly a couple of thousand dollars for the search fee, and then another couple of thousand dollars for the application fee. So when we think of a new PCT filing, it includes both components.

Today it is not at all uncommon for a patent

counsel to suggest to their clients that they go and get their PCT search done elsewhere, like in Korea instead of the U.S., because a search in Korea costs about half as much as a U.S PCT search. A search in Korea costs about $1,000.00, compared to the $2,000.00 that it costs in the U.S. This is a significant issue for small businesses. I would suggest that if the PCT -- I'm sorry. If the PTO reduces this search fee, then they may end up doing a lot more PCT search work, and increase their volume of searchs, because then their fees become more competitive. So the volume of search work would also increase, more than making up for any shortfall in revenues if the PCT search fee were reduced.

Now, of course, I've also heard other practitioners say that you get what you pay for, that the quality of the searches from countries that charge less may not be as good. But, in fact, it's been my experience that the searches in places like Korea are, in fact, quite good. And a lot of practitioners do find them to be quite good as well, but also quite a bit cheaper.

Point 7: It would also be advantageous to have a search report for a PCT application, say, within, like, four to five months be completed in that period in all

our large areas. If a client can get a search report from an international patent authority in a few months, then that is akin to completing the patentability search by private firms that I mentioned previously. Now, the advantage here, of course, is that the small business gets the benefit of having filed a PCT in the process, but also they've now got a search as well, which is made available to them in a reasonable period of time, making it even more attractive to go down this option.

Number 8: It would be advantageous for small businesses to coordinate the practice of filing a U.S. application and a PCT application. So, for instance, allowing a small business to file a U.S. patent application and a PCT application in the same submission would be beneficial.

This coordination would reduce some attorney costs for small businesses. In addition, we should consider charging a reduced fee for submitting both the U.S. patent application and the PCT application together.

There are other areas in this regard for coordination and harmonization. It is not uncommon to get different rejections for the same set of drawings that are submitted to the USPTO and the PCT office. This requires applicants to respond with two different

sets of corrections for the same drawings. These kinds of costs may not be a big deal for a large company, but they can be quite onerous if you're a small business. And these kinds of costs can be mitigated by at least having some procedure. So we can agree on a common set of norms for things like drawings.

Point 9: The USPTO's web-based electronic filing system for patent applications and document submission, that we commonly refer to as EFS-Web, works very well. However, if a small business is located outside the U.S., and the inventors are not U.S. citizens, a PCT application cannot be filed with a U.S. receiving office by a U.S. patent practitioner.

In this situation, the patent attorney has to fax the PCT submission to the International Bureau. In fact, this scenario often arises when the foreign small business has already filed a provisional patent application in the U.S., and now they want to take it to the next step and file a PCT within a year in various countries, including the U.S. And, of course, you know, then they can't do that through EFS-Web, and so it will be extremely helpful if U.S. patent attorneys could use the EFS-web system to submit a PCT application to the International Bureau. Even if the PTO charges a fee for this service, this is an area that would benefit

patentees and patent attorneys.

Again, thinking about the same scenario I just mentioned, I want to now talk about certified priority documents.

If a PCT application is filed directly with the International Bureau, for example, it's filed at the International Bureau, then certified priority paper documents from the PTO have to be obtained and mailed to the IB within four months of filing.

Commonly the PTO charges $20.00 for these certified priority documents. It might be great if there could be a reduction in this fee for small businesses, or for electronically transferring these priority documents to the IB at a reduced cost, it could be created, and that would also benefit small businesses.

Some of these things might seem a little nitpicky, but in fact all of these little costs do add up if you are a small business.

Point 11 --

STUART GRAHAM: Jay?

JAY KESAN: Yeah.

STUART GRAHAM: Can I ask you to finish up in two to three minutes just to keep us --

JAY KESAN: I will definitely finish up in about

two to three minutes.

STUART GRAHAM: Excellent. Thank you.

JAY KESAN: There is a need for an intensive effort at educating small businesses about the process and the benefits associated with foreign patenting. Such an education of effort will be very desirable. The PTO website, for example, could describe a few small businesses in different arc areas, highlighting the benefits and then highlighting the challenges associated with international patent filings.

Point 12: Akin to our patent maintenance fees there are annual annuity payments in foreign countries. They are typically between $500.00 to $900.00 per year, which are very significant. It would be helpful to coordinate bilaterally -- I mean, diplomatically with some countries, to mutually agree to some equal percentage in reduction in these annuity payments for small businesses that benefit both countries. There are a number of developed and developing countries that come to mind where such an effort is worth at least initiating to seeing if it goes anywhere.

Point 13: Translation costs are very significant when trying to obtain foreign patents. Translation costs in both Europe and Japan cost several thousand dollars for a national phase application. Studying how

these costs might be reduced or providing other forms of support to reduce these costs for small businesses is a real challenge, and one that is worth thinking about how this might be done comprehensively.

In the U.S. it would also be helpful to permit SBIR grant money to be used to pay for some of the different costs associated with foreign patenting. Using SBIR money to pay for foreign patenting obviates the need for an additional review mechanism for deciding which small businesses should receive a loan or a grant that has been set aside specifically for international patenting. So, in fact, using the SBIR process might help in picking out those small businesses that might be worthy of this kind of support.

Finally, loan programs or grant programs for small businesses for international patenting are worthy of careful study. Without such a study I'm concerned that it might be easy to spend a lot of money creating such programs with little results to show in the long-run.

So I will stop here.

Thank you very much for your attention.

I'm also happy to answer any questions that the panel or members of the committee have.

STUART GRAHAM: Thank you, Jay.

All well taken. And, of course, we do have your written comments as well.

Let me open it to the members of the Government panel to see if there are questions.

Edward Elliott's here from USPTO.

EDWARD ELLIOTT: Hi, Jay.

I wanted to ask about your point number 6.

You had said that the U.S. should consider reducing their search fee to be more on par with Korea's for a PCT search, but then you said later on that the quality of the search that you get from Korea is actually quite good. So what is the benefit to small businesses of the USPTO reducing that fee?

JAY KESAN: I'm just suggesting that the USPTO reduce the fee, then they could reduce it to make it even more competitive than Korea, in which case they actually would get, you know, the search done cheaper.

But also, you know, if the USPTO charged a more competitive fee, then, you know, in fact, it might result in more revenue for the USPTO, because the searches going to Korea might actually go here.

And number two, you know, maybe those revenues can then be used to further subsidize some of the fees that are charged to small businesses.

Either way, it sort of seems like an opportunity

to try and get more competitive on a couple of different levels.

Does that make sense?

EDWARD ELLIOTT: Yeah, I see what you're saying. So, you're talking that it would be an indirect benefit to small businesses if PTO could increase their revenues through this mechanism.

JAY KESAN: Right. I mean, it's my understanding that during -- and I noticed this, you know, when the recession was in full force in the U.S., the PCT office was returning searches literally in a month or two. And previously it would sometimes take a year. And so, you know, that gave me the impression, albeit indirectly, I have no direct data on this, but indirectly, you know, I was assuming that there were just not that many people filing for PCTs, you know, because of the recession. And so I think it picked up a little bit, but even now searches are returning fairly quickly. So I think there is a need to sort of look into these issues. And you guys have, you know, better data on all this.

STUART GRAHAM: All right. Thank you.

Any questions from the audience?

I have one quick one, Jay, just quickly as we end this up.

So we have a representative today here from the SBA, Martin Selander. And so I was quite interested in your comments about the SBIR program.

JAY KESAN: Right.

STUART GRAHAM: And indeed it dovetails on comments from our previous speaker, our speaker from the public, Bassil Dahiyat, who suggested that there should be some means in any program that would offer benefits, some means of allowing for competition, some -- you know, seemingly some quality measure that could be imbedded in the way in which taxpayers' money or ratepayers' money, as the case may be, would be allocated to these companies.

In the end, though, SBIR is a reasonably small program. Is there any way that you can think of that such a selection mechanism could be ramped up sufficiently so that all of the deserving companies with prospects of actually growing into the Facebooks and the Googles of tomorrow would actually have access to the kind of help that they need?

JAY KESAN: I completely understand the point that you're trying to make. And I dare say that universities are in exactly the same position, you know, just like a small business. And indeed a lot of small businesses are started by university science and

engineering professors. And at a minimum, I'm being really cautious here, at a minimum, what is worth pursuing is filing the PCT so that you preserve your ability to go national phase 30 months down the road, or 18 months after you've sort of filed your PCTs. And very often those two-and-a-half years from the filing of, say, something like a provisional, is sufficient time for your invention to percolate, and for you to see if there is foreign interest, and I mean, and if there is other outside licensee interests who are interested in foreign rights so that they can take over prosecution. What I'm trying to say is that the initial cost of preserving foreign rights until you are able to work more on your technology, get more results, preserve the option to keep your technology attractive to a point further down the road, that is valuable. And that doesn't cost that much.

STUART GRAHAM: Thank you.

JAY KESAN: Have I answered your question? Does that make sense?

STUART GRAHAM: Absolutely. Thank you very much.

Okay. Thank you. Thank you, Professor Kesan.

I want to now move on to our next scheduled member of the public in our hearing, Vern Norviel.

Vern, are you online?

JAY KESAN: Thank you very much.

STUART GRAHAM: Hello. Vern Norviel, are you online?

Let me just ask as a possible. Phil? Phil McGarrigle, are you online?

Okay. Maybe what we'll do here is we'll entertain a bit of unscheduled commentary from a member of the public.

I had a discussion with Matt O'Malley during the break. And Matt is the Chief Intellectual Property Officer at Cenoplex. And Matt said that he would like to make a few unscheduled remarks. And we're happy to entertain that.

Matt, if you would come up. It actually helps us provide a bridge until Vern Norviel can join us.

MATT O'MALLEY: Thanks, Stuart.

A couple comments, I guess, on what's been said specifically about the international patent protection for small businesses, but also about small businesses directly.

There's a great study that the SBA did a few years back that talks about the quality of patents. I don't know if you're familiar with this study. And it took roughly 1,300 patent applications over a five-year span. The qualifications for those patents were those

where companies had acquired 15 patent applications, or grants, rather, and when they looked at those they were surprised to see that 40 percent of those were actually done by small businesses. But I think what's very interesting is when you start to do the analysis, and they'd look at impact, generality, originality, and citations. And I'm sure you can't see this as members of the audience, but this white bar, it's significantly larger than the other two bars, are small businesses, and the quality of the patents, and how often they're cited in future applications.

The middle bar that's about two-thirds of that is large business, and the very small gray bars are universities.

So my point is that innovation is coming from the small businesses. And if you follow that study on, it's about a 63-page study, I encourage you to see it online, it talks about, as it was mentioned earlier, that those patents go on to be acquired by big business.

So a big impetus for me as, as Stuart mentioned, CIPO, as a small start-up, also as somebody with well over 20 patent applications that I filed U.S. and worldwide, China, Korea, Japan, India, and soon to be Canada, and certainly the EPO.

We talked about translation fees. If you've ever

had to go through this process -- earlier it was mentioned by the earlier speaker that it was like $19,000.00 that he had to pay for his translation fees in Japan. Realize that when you finally do get that first office action from the JPO or China, Korea, or where, that the office action has to be translated, and now all that art that's been cited has to be translated. And if you could imagine if there are five pieces of prior art from three different countries and each of those are worth 20K, well, now you're talking $300,000.00.

And it was asked earlier, a great question, by year three, do you get a sense of the potential revenue at that point. In some cases these investors are still looking to see where your intellectual property filings internationally have gone. So there's some significant costs, not to mention you're probably trying to maintain a R&D department for several software developers through this time span.

If I may, just a little bit more about the overall impact of the new changes coming down the pike.

STUART GRAHAM: Please.

MATT O'MALLEY: Okay. I think if you go to a few of these events, listen to -- Silicon Valley has their intellectual property group the L.A. and Ventura County.

I try to attend all of these. And it pretty predominately is felt that this is going to favor big business. It's certainly first to file, certainly the fast track. And I'm concerned a little bit about how punitive a lot of the situations are. If you listen to pod cast from Judge Rader who talks about the atomic bomb and how -- let's think about after somebody has gone through all these years of expenses that I just alluded to only to have the atomic bomb of invalidity of some sort. And there's a whole range of those. I would like to see some sort of effort put into helping small businesses not run into those situations, dealing with clarity on 103, and how do we help -- I mean, if it's really about helping innovation, then let's look at it. It's the small businesses.

Of the 219,000 grants last year, I think half of those were international filers. Which if I read the data correctly, 85 percent of those are big business, and only 15 percent are small business, and of course some of those are made up of actual independent inventors like myself.

If that's truly where the innovation is coming, I would like to even see, as we see comments today, a database online where people can say -- I heard some great comments from our last speaker about why isn't the

PCT and the U.S. application simultaneously being prosecuted. I think that's a great idea.

You know, I heard a number of great ideas. But boy, it could be great not just to get a feedback mechanism online at the PTO, but maybe we start to invoke some sort of social networking parameters where you're scoring the feedback based on how many applications that person has pending, how many he's had granted, he or she, and you start to put some weight behind it.

Sometimes I worry that too much of the impetus is being driven by big business attorneys, which are very important, of course, and the PTO. I like some of the changes that I've seen Director Kappos has put in, some great stuff. But anyway, that's it from a high level.

I also worry about the DIP proceedings that we hear that are going to potentially come down the line, and how costly some of these things are going to be. But in the end we'll see where this goes on the international filings. But there are significant costs that you run into.

STUART GRAHAM: Thank you. Thank you very much.

Any members of the panel have a question for Matt?

Members of the public?

VERN NORVIEL: By the way, this is Vern. I was able to get in now.

STUART GRAHAM: Thank you, Vern. We'll get to you in a moment.

Matt, if I can just follow up on one issue.

You did say that help for small businesses, particularly as it relates to these issues of clarity, How do you foresee the best way in which the patent office or other Government agencies could actually provide that help to -- since you're here representing small inventors, to small inventors?

MATT O'MALLEY: Well, I do hear about the new programs Minnesota has a program that's being developed for those that are pro se, and I just heard about its launch, and I heard that at the speech on Saturday, that pro se or pro bono work for independent inventors.

The one thing that, after I heard how fantastic the program was, and not to diminish this, but you had to be almost at the poverty line to qualify. And a comment was made from the audience, there's a big middle ground that 95 percent of small businesses that would benefit, not only from the pro bono program, but from the educational program that they were going to develop. And I think we might just like to see some more of that.

But I still go back to the PTO has really

got to get its hands around the 103 obvious rejection. Especially among software. It is very difficult, costly, very costly for inventors to get their hands around it. It lacks clarity. I even wonder sometimes why applications can go abandoned and why can't you revive them? Internationally as well?

It was said early by our pharmaceutical company that there were countries that years later that he had wished he had been able to maintain it. Maybe there's a fee that these countries would welcome to revive those applications.

STUART GRAHAM: Thank you.

MATT O'MALLEY: Thank you.

STUART GRAHAM: Thanks very much.

Very good. Well, thank you.

Thank you, Vern Norviel for hanging in there and trying again to get back online.

You are with us, yes?

(Telephonic appearance by Vern Norviel.)

VERN NORVIEL: Yes, I am. Thank you.

STUART GRAHAM: Thank you very much.

Let me introduce Vern Norviel.

Vern is a partner at Wilson, Sonsini, Goodrich & Rosati. He leads the patents and innovation counseling practice at Wilson, Sonsini. Mr. Norviel has more than

20 years of experience in corporate IP strategy and represents firms and venture capitalists in diagnostics, nanotechnology, genomics, and personalized medicine.

So with that, Vern, I welcome your comments.

VERN NORVIEL: Thanks very much. And I apologize for the snafu when I was earlier dialing.

So as you said, my name is Vern Norviel. I'm a partner at Wilson, Sonsini. I'm also, by the way, a past member of the Patent Office Public Advisory Committee, and as well, I'm a National Professor at the University of California, Berkeley.

I have been involved intimately with some of the early formation of many life science start-up companies, many of which have grown and I believe today are significantly impacting health care today.

With that, I'm pleased to have the opportunity to present a perspective on the subject of international patent protection for small businesses for the purposes of the patent office preparing a report on the subject, as I understand it's required to do.

I will be speaking today almost exclusively from the point of view of a small life science start-up company. I will not be representing any company or even my firm specifically today, but I'm offering my personal views based on my experience, in which the manner in

which the subject of foreign patent protection impacts a small life science start-up.

I would like to specifically focus today on the manner in which foreign protection could directly affect the delivery of health care to patients.

Wilson, Sonsini is a Silicon Valley-based firm. We have offices throughout the U.S., and we represent companies from Gentech to Google.

I personally represent only life science companies. I am incredibly proud of being a part of the life science industry and the companies that I am associated with. They represent technology that shows huge promise in the main disease areas, including cancer, therapeutics, interdiagnostics, blindness, Lou Gehrig's disease, next-generation sequencing technology, non-invasive prenatal diagnostics, treatments for Parkinson's, and many others.

So the first question in the notice was, how important is international protection to small businesses.

And let me begin before I answer that question by addressing what really is the major problem faced by a life science start-up company today. That problem is very specifically access to capital. As a result of many factors, not the least of which is the economy,

venture capital has become more and more difficult to access. In life science, a large fraction of the companies that are formed are rights from university-funded and NIH-funded research. Often these research efforts are considered just too early today and too risky for today's venture capital industry.

And just last week a forum was held in San Francisco called the BIO Investor Forum. The last session of the conference was, I believe, tellingly called "Opportunity for Apocalypse? Prophesies for 2012."

As a result of the difficulty in raising capital from venture capitalists, many young life science companies have turned to a process by which they obtain small investments. And by that I mean on the order of less than $1 million from so-called angel investors. They then use this money to move their drug or diagnostic technology forward to the point where it is de-risked enough that they could actually still be financed in a larger way by the venture capital community, and move these technologies to the patient.

But there's another problem, and that problem in the life science industry is it's in many ways very much unlike high tech and software industry, in that the need for patent protection is absolutely essential to obtain

venture capital investment.

Tufts University now projects that the cost of developing a single significant drug is over $1 billion. And in my industry it is common knowledge that essentially no drug is moved forward through this process without strong patent protection.

And since the U.S. market is now typically only about half of the world market for most drugs, foreign protection is also essential to obtain venture capital investment in a drug.

So where this leads.

A new start-up with a promising, say, cancer drug or another drug that could change the face of health care is required to live on a few hundred thousand dollars to conduct its experiments during the first years of its existence.

But without the foreign protection at the end of this initial phase, a start-up cannot get venture money to continue to move the drug to the patient.

Moreover, the cost of foreign protection can often be so high that most, or even sometimes maybe all of an initial investment could be eaten up by foreign patent filings.

So finally, the answer to the question of how important is foreign protection in the life science

industry is, incredibly.

And to the extent -- and to answer the second question, at what point do health care companies become important, the answer is also blatantly simple. And the answer is immediately, simply because the patent filings are required early on to support the venture investment to move the drug to the clinic.

Importantly, the consequence of these companies not receiving adequate funding as a result of patent protection is more than just a commercial impact. It really will significantly impact health care.

Just as I was preparing my remarks today, I worked on two such companies working on only angel investor money. One has a drug that could dramatically improve the efficacy of radiation treatment for cancer victims. Another drug that could be the first real treatment for blindness. Both were founded by an incredible well-respected scientist, in this case at the University of Colorado and MIT, and they have great promise. And the victims of these health conditions could be harmed significantly if these health technologies are not translated to the clinic.

I know that others have submitted answers that are colored differently than my answers today as to how important and when patents become important in

international jurisdictions. And one might wonder why our positions would be different.

I think I would agree with others, as to their answers only apply to technology and software companies, but the focus of my life really is on health care. And that's probably why the answers are different.

Question 3 asks how prior user rights would impact protection. And frankly this is not really a question that is of concern to the health care industry, at least for small businesses. And many companies have to file early to get patents in Europe and Japan and China. Again, without any patent there is no company, and no drug is moved forward without it.

The other question, number 4, it asks what role does the international patent protection play in the successful internationalization strategies (such as franchising).

Again, this is not really -- you know, franchising is not relevant in the drug industry. So in a sense, my answers above are the real answer.

Importantly, question 5 asks how can the USPTO and other federal agencies best support small businesses. How can they support regarding international patents with regard to acquisition, maintenance and enforcement.

Of course some of the other comments, I won't go back into them, but I would agree that with the coordination of efforts between countries to increase the cost barriers, it would be incredibly helpful.

When the question was asked in number 6 about what role should the federal government play in assisting small businesses to defray the cost of filing and maintaining international protection, and question 8 and 9 follows by, should that be by way of a loan or grant program, I would like to address them kind of as a group.

And I think what's probably buried within a lot of people's concerns about this question is imbedded concern about whether the government is in a good position to decide when to give such grants and loans, especially in light of recent events.

But specifically with respect to the life science industry, there's a substantial amount of commercial effort going around inventions where the government has already conducted a peer-review process, and conducted it outside of the government to determine whether -- what are most promising that the scientists found. And this comes via the NIH or similar grant programs.

The cancer and blindness companies I mentioned earlier have in-license patents that were developed

under NIH grants. These grants were peer-reviewed before a board. And when a company has obtained some financing at some level to support moving these health care solutions to the clinic, there is at least some independent validation that this science is commercially translatable.

So whether the support is through grants or loans, it would appear to me that many life science start-up companies that would come under consideration for such support have already accomplished a number of things to make a government investment worthwhile.

First, it mentions already moving towards treatment for important health care situations on the company.

Second, outside peer review is validated if the science is compelling.

And third, commercial validation is already seen via the coming together of a team and the investment.

So, in these particular situations it seems particularly compelling to me that start-ups that offer these health care solutions can rationally be supported via a grant or a loan program to support foreign filings of patents, and thereby helping reach these, and having health care solutions for the patients in the clinic.

As to whether a grant or a loan program is most

efficient, I'm not personally strongly of the opinion one way or the other. Perhaps as a taxpayer I might favor a loan or a loan guarantee program; either would have a significant impact on translation of health care from the labs and clinic.

I'll also just make a side observation that matching programs often serve as strong validation if a project is worthwhile, regardless of whether it's a grant or a loan program. And in the case of health care companies, it might be best that any grant or loan program is made as a matching program to ensure that someone else is putting skin in the game.

Thanks for the opportunity to submit a few comments. And I'd be thrilled to answer any questions.

STUART GRAHAM: Great. Thank you, Vern.

This is Stu Graham, and I do have a couple of questions for you.

One has to do with a comment that was -- that's been revolving around a lot today among our speakers, but it was most recently brought up by Professor Kesan. And his suggestion at the end of his comments was that essentially by providing a lower cost to access into the PCT system, that young companies can, for all intents and purposes, buy an option, buy an option to ultimately go into the PCT signatory countries at 30 months.

In the context of the companies that you deal with, since we do understand from Mr. Dahiyat and others that development times and times to market tend to be much longer. Is that sufficient time for the market to catch up?

In other words, by the time we reach 30 months, is there going to be enough demonstration for the firm to be able to go into the capital markets and raise the capital that they need, all other things not withstanding, in terms of how much capital is available?

VERN NORVIEL: That's a great question. And the PCT is not the barrier that I've been discussing today. And it would be certainly helpful if the costs were somehow made more manageable there. But incredibly, the time line for developing a drug almost routinely, from what I see, is such that the PCT is assumed, and often the university has supported that. The problems that I'm discussing come up at the 30-month stage, where to get U.S., Europe, Japan, and China, which I would call the standard check boxes these days. We're talking $50,000.00 to $100,000.00, and that's where the problem comes up. So it would be somewhat helpful to lower the cost of the PCT, but it's a long time line for drug development to prolong as early as the 30-month state, to be honest.

STUART GRAHAM: Great. Thank you very much.

Other questions from the panel?

Edward Elliott.

EDWARD ELLIOTT: Hi, Vern.

I wanted to ask about your comment about matching programs.

Are you aware of any particular matching programs that we should consider looking at as models or examples of how this type of system would work, especially matching programs that take government funding and match it with private investor funding?

VERN NORVIEL: Sure. There have been a couple that actually I was thinking about when I said that. One was, just frankly, IRS grant programming, which was recently in place. It required a matching program, matching money, and so you had to prove to somebody that you really had something that was worthwhile to get their money in order to get the government money.

And another one that I had in my mind is the University of Colorado
where a small company
can get $25,000.00 or $50,000.00, but it has to be able to match. And this makes it very clear to people that they have to go out and get some money to prove, in a sense, that what they're doing is worthwhile.

EDWARD ELLIOTT: All right. Thank you.

STUART GRAHAM: Great. Thank you.

Members of the audience?

(No questions from the audience.)

Okay. Without more questions, Vern, thank you very much for arriving today from your busy practice and being willing to put up with a little bit of slowness on our part. And we're a little bit behind, but only because we've had such good commentary today.

VERN NORVIEL: Well, it's wonderful that you invited me. Thank you very much.

STUART GRAHAM: Thank you.

VERN NORVIEL: Take care.

STUART GRAHAM: You too.

All right. Thank you very much.

Our last speaker of the day is Phil McGarrigle.

Phil, are you online with us?

PHILIP McGARRIGLE: Yes, I am.

STUART GRAHAM: Terrific. Thank you very much.

If I might introduce you to the people here today.

Philip McGarrigle is General Counsel and Chief IP Officer at Nodality, Inc. Phil has over 25 years of experience in patent and biotechnology law. Before joining Nodality, he served for ten years as Vice

President and Chief IP Counsel for Affymetrix. Since the year 2000, he has also taught at the Santa Clara School of Law.

Phil, please offer your comments.

(Telephonic appearance by Philip McGarrigle.)

PHILIP McGARRIGLE: Thank you very much.

As you mentioned, I work at Nodality, and I've worked in the San Francisco Bay Area in the biotechnology area for about 20 years in small-to-medium-size life science companies. I appreciate it -- as Vern said, I appreciate the opportunity to speak to you today regarding the difficulties that a small company faces in protecting its IP, and the possibility of providing assistance to these companies.

My testimony will be presented from the perspective of a small company in the life sciences field. And I would like to draw some relevant examples from my present company and prior companies to sort of put it in perspective.

Nodality has about 40 employees, or actually less than 40, and has done active research for about five years. It's based on technology that originated in Stanford University, which provides a researcher or a clinician the ability to detect what's going on inside

cells, and to understand the specific biology behind a disease, such as a cancer or some autoimmune disorders. This approach allows a clinician to personalize a patient's treatment, and a researcher can focus on a selected patient population in a drug trial.

Understanding the biology behind the disease of course saves a lot of time, and more importantly it saves lives.

Applications for the technology arise in drug screening as well as providing disease diagnosis and prognosis, and it can also assist in selecting patient populations who may benefit from a drug to provide a personalized medicine approach to disease treatment.

I would like to say that it's clear that foreign patent protection is extremely important to small companies, as the bulk of their value is in the IP, as I'm sure that other speakers have told you, especially in life sciences companies. It's clear that the only way a small entity can survive in an environment with companies that have more resources is via the patent system, so I'm happy to be able to support that today.

Previous experience has shown me that the large companies will act very aggressively, and can't seem to capture their new markets that have been pioneered by

the small company. And patent protection's critical in helping small companies protect themselves. I have seen that in some of my prior companies in which we had global patent litigation when we were the small company and other companies were larger.

I'm sure that you've heard testimony regarding expenses for foreign filing. I've heard a little bit of what Vern said. And my numbers are slightly different, but pretty much in the same ballpark. Total budget for foreign filing in a moderate number of countries is about $150,000.00, which is a little bit larger than the number of the small company, the smaller range that Vern had put forth. But biopharmaceutical companies are typically filing more broadly. And if they want to look at a small company for either purchase or working with them, then they'll want those small companies to file more broadly as well, which increases costs. And then after you get through the initial fee, then you have the prosecution issuance fees, which can be reasonably astronomical, and much more than the $200,000.00 you've already spent.

And since the U.S. is about a third of the world market, then international protection becomes even more important, and of course expensive. And the need for cash comes even earlier under the America Invents Act.

Since the U.S. will be the first to file, U.S. filings comes as soon as possible and the foreign filing decisions needs to be stepped up as well.

Much like what Vern was saying with respect to the 30-month date, things come later. You know, many of the actual money-producing events come later. So your foreign expenses and the U.S. expenses are going to be earlier. Moving these expenses up early in the stages within a small company's life is more difficult and the probability increases that these early inventions are not adequately protected, because small companies don't have much available cash, which makes for paying foreign filing expenses more difficult. They need to periodically raise capital to fund their operations. However, they don't typically want to raise too much capital at once in the short-term because it requires selling more equity than they'd want at a small price. As you can imagine, they would sell stocks in groups, and hopefully their stock price goes up, which means they can get more money.

And of course capital is harder to raise now due to the recession, and that's where my current company finds itself. We're trying to both prove our technology, and also to protect our inventions, and both take a substantial amount of cash. In fact, in the last

year Nodality had to actually scrutinize costs, and we made some rather conservative foreign filing decisions, which we hope won't disadvantage us in the long-term. But we're under those conditions where we would like to have some assistance. And, in fact, we have another decision coming up in less than a month in which we probably will make a decision based strictly on the basis of cost.

So deciding to terminate foreign coverage in our own station company, it's probably the most damaging time, because it's these early patents that are the most fundamental, and provide the broadest coverage. Everything else after certain periods is related to improvements.

Even though the life sciences industry focuses on small numbers of patents to protect its business, they still require some overlapping sets of patents to adequately protect the main technology in the market. More patents, of course, are required with additional products in multiple ways to attempt to cover workarounds. And this is very true with technology platforms like we havve had here at Nodality. So abandoning some IP protection at the early stage is very damaging when you have insufficient funding.

So, with that backdrop, I would like to stop and

answer and address some of the questions that were put forth.

The first question being how important is international patent protection to small businesses.

Well, I've said it a few times already, but I'll say it again. International patent protection is extremely important for the small life science companies. It's just as important as filing in the United States. Of course, the only impediment is simply the expense.

And here at Nodality we file -- you know, we're just, as I said, a small company. We file about a third of our U.S. applications overseas. And one immediate benefit is that we are talking to foreign-based companies regarding some partnerships. And of course the first thing they want to see is whether or not they can see some protection for what their technology would be in their home countries. And it enables us to partner up with the various companies a little easier.

With respect to my previous experience, I have seen that international protection's critical, of course, to obtain and protect an IP. And, in fact, one of my earlier companies, our efforts led to one of our inventors getting the Inventor of the Year Award from the European Patent Office, which was quite a coup,

because it was the first time they had given it. And it was based on their previous ten years.

Additionally, having foreign patents in more than one jurisdiction is important because litigation is going more global. And if you're sued in some other jurisdiction besides the United States, you'd want to have a patent in that so jurisdiction that it would be possible to countersue and even the playing field. So not only is it important to encourage partners, it's important to protect yourself when you're going to get sued, and it's also important if you're going to seek additional revenue throughout licensing.

So, question number 2: At what point does international patent protection become important to the small company.

I think, again, they are always important to the life science companies I've been involved with. Our technology was initially licensed in from Stanford, and they had the foresight to foreign file their first applications, so they even recognized the importance before the company was formed. They were expecting the company would be formed, and foreign application and patent would be important for that formation.

We have continued to recognize the importance of foreign filing early for our applications. And it seems

to be the same as other companies that I've been involved with prior to Nodality, and a few others.

Question number 3 is what challenges interfere with the growth and the competitiveness of small companies if they don't seek international patents early.

Of course, the first thing, which you've probably heard many times, is that the valuation of a small company is adversely affected without foreign patent coverage. And small companies won't be able to protect their market, and larger companies certainly will just recognize what are the more lucrative markets that are developed by some of the small companies, and enter those markets if there's no patent protection to prevent them.

Oftentimes, outside U.S. rights are an important source of revenue for small companies because they will out-license and get some licensing revenue, and then fund their own research and development activities in the U.S., and maybe even to product plans in the U.S. for that particular molecule. It happens a lot in drug companies. When they partner with another company they can have the resources to bring a particular target through clinical trials. That strategy won't be possible without foreign protection. And of course if

it ever chose to, a foreign company would be more enticed to purchase a small company if they're successful.

Question number 4: What role does international patent protection play in the successful internationalization strategies.

I've mentioned several already. International partners want to see local protection for the markets if they want to collaborate with a small company before investing in that company and purchasing it. It's critical. As I mentioned, we're engaged with a couple of partners right now, and that's what we're doing.

Question number 5: How could the USPTO and other federal agencies best support small businesses.

Well, I have a couple of suggestions. And the first one, again, you've probably heard some of this already. I've had some conversations with other colleagues, and one or two of them suggested things that are similar, such as the USPTO could expedite small company applications in their mechanisms in the PTO to pick out and accelerate an application, and then prosecute them to a point where they're allowable, then use a mechanism like the Patent Prosecution Highway to file, and issue, and enforce foreign jurisdictions.

The Patent Prosecution Highway is already set up. And it could be that if we can alleviate some of the redundancy, then the costs for the initial filings would be diminished. And with a search, the examination fees, and typically for the European Patent Office it's 10,000, and in Japan it's probably about the same. And other countries, I would imagine, and I don't remember them off the top of my head, but they're about the same.

So this would limit that initial, set of fees that you would have, and it would enable you as a small company to postpone some of those larger expenses further out. And those larger expenses hopefully could be diminished as well. You have other costs such as the translation costs, which is another separate issue that I think that the USPTO would need to work with foreign countries to seek this sort of country-to-country resolution.

Another solution could be to allow small venture-backed companies to compete for SBIR finance, which it can't do currently.

I understand one member of the panel is from the SBA. And Nodality had this issue come up in the last few years. A legislative solution was attempted a few years ago to allow SBIR grants to go to venture-backed companies. And it was passed in the House. It was

H.R.2695. However, when it went to the Senate it got stalled. That was Senate Bill 1223. And these types of grants would have been really good in helping us, at least, if we could have used them for foreign filing and other fees.

And again, we had applied for an SBIR grant. Actually we received a very high score on our grant. I don't know if it was the highest that they give, but it was very high. And when we spoke with the grant examiner to talk to them about our status, corporate status, the examiner was actually disappointed that they couldn't award us the money. And of course those fees could have covered the foreign filing costs, and it would have been adequate for several years, even for the extensive fees that you get when you issue a case.

It's my understanding, although I don't have paperwork here, but it's my understanding that it still may be coming up for passage again. And I don't have the numbers for the House and the Senate bills, but that would be helpful for us particularly, and other companies.

Regarding question 5(b) and (c), I would just say that the USPTO would work with foreign patent offices to try to eliminate these redundancies that every country seems to have to go through the same search and

examination. Again, try to eliminate translations which tend to be the most expensive component to foreign filing.

And then with respect to enforcement. That's another very large expense for the small companies. It's even prohibitive in most situations. But harmonization, if we had it for a particular law with respect to each country, it would open the door for a more friendly environment for using foreign judgments in different countries to be harmonized or brought into another country.

I actually wrote an article about a dozen years ago about that, and the prospects weren't very good. But if the country's laws are the same, it seems like it would be easier to enforce in other countries.

The next question was, what role should the Federal Government play in assisting small businesses to defray the costs of filing.

I suggest that it would be a little easier, rather than setting up new organizations to administer funds for foreign filing, it may be more straightforward to have arrangements with other foreign patent offices to reduce the redundancy and eliminate those costs first, and then rely on the current grant-type systems

that we have in place, such as with the SBIR grants and things through the NCI and NIH.

Oftentimes the entities who are small are seeking these types of funds anyway, and so it might be easier to rely on those formats, and also, the grants might have been -- other grants might have been applied for, and this would be similar to what have already been seen.

Regarding question 7, I feel strongly that assisting small companies with international expenses is still an important idea, no matter which way it's funded. I personally think that it would be better to use existing frameworks in distributing funds. And I don't have a lot of experience with respect to loans and Federal loans. But I would just simply ask a couple of questions such as, I heard the matching issue come up with Vern, and I think that's a good idea.

And another question that I would have would be how would one repay the loans, and whether they would be subordinate to other debt, because that's an important thing to a small company, and if they would be secured by the IP the company owns.

I won't go over question 8 because it's more or less embodied in some of the other responses.

And then regarding question 9, I would just

personally think that a grant program might be a little easier to administer because a structure is already in place for that.

So in summary, I would just like to say that small entities deserve every opportunity to protect their ideas in foreign countries, as their technology is typically in its early and broadest stage. It's here that it's most vulnerable. External funding is difficult to get for these expenses, and an alternative mechanism would be very welcomed, which mechanism can be subject to debate, however, and all methods I would like to see pursued.

Further harmonization with respect to patent laws should be sought to avoid repeating the same tasks in this country, and you get a fee reduction without any extra structuring.

Existing organizations as the SBA and other federal agencies can provide grant funding to small companies in need, and they have the mechanism set up to review the proposals and simply allow the grant money to be used for that purpose.

So that's it for my comments. And I would just like to say that I really appreciate the ability to speak to you, and speak with a voice of a small life science company, which I think really could use some

assistance in the way that you're suggesting.

STUART GRAHAM: Thank you, Phil.

This is Stu Graham. I do appreciate your comments as well. It's very important for us to hear from people who are working at companies who are facing these issues day in and day out.

If I might just make a quick comment.

Yours and other members of the panel who -- your comments concerning harmonization and increased economizing in the work that patent offices do, that's something that we are vigorously pursuing at the USPTO, because we really do understand that this is one of those few win-win-win situations in which patent offices can enjoy some economies at the same time that users of the system can as well.

It does seem like a theme. And indeed we're pursuing it as a goal that has a lot of value imbedded in it.

At the same time, though, I'm very intrigued by some of your comments, and you may not want to share this, some of your comments about having to make the decision where the rubber meets the road about pursuing patent protection as a zero-sum game.

So, if I might ask you, and if you're willing to say, when you choose to pursue that foreign patent

filing, what does your small company give up? What don't you do because you're having to use that money to pursue what is very expensive protection overseas?

PHILIP McGARRIGLE: Well, that's a good question. And sometimes I think that there isn't a specific one-to-one trade. However, we've had to cut costs about a year ago and we had to let people go, and we had to put people on part-time status, and that's a trade-off right there.

Recently the board has looked at the legal expenses, and has overshot the budget for this year, and so multiple board members were concerned about that coming up. And, you know, if we start to -- if we continue to go through the year with this sort of restructuring, this conservatism, then we would certainly have to abbreviate the U.S. foreign -- excuse me -- the U.S. filing plans that we have, and also some of the foreign filing plans that we have too, which is more like a one-to-one trade-off. And for every one foreign filing application we go with, I would say that that would cut out three or four different U.S. applications, which of course is starting off the invention themselves. And we're trying to come forward with a single product, and we have that foreign file. But for the subsequent products, you know, if we can't

file them in the United States now, and then follow them through in foreign countries, then when we come out with those products, we won't be protected for those. So it would be a short-term gain, but a long-term loss.

So, what's the trade-off? The trade-off is ultimately some of our U.S. cases, in the short-term it means that we lay people off. So that was pretty difficult to take.

STUART GRAHAM: Thank you. Thank you, Phil.

Other questions from the panel?

Any questions from the audience?

(Questions.)

All right, Phil. Let me just say thank you.

And let me say thank you to all our speakers today. I very much appreciate the comments and the testimony that was given.

I do thank you for what I found to be very meaningful participation in giving testimony for the International Patent Protection study.

I repeat how much your input is valued by the agency. And it is our goal to make our report to Congress as thorough and thoughtful as possible.

Before I formally end today, I did want to give one more opportunity for anyone in the audience to make comments on this issue.

(No comments.)

Very well.

So, as a final reminder, let me just state that written comments for both the International Patent Protection study and the prior User Rights study are needed by November 8th, as our reports to Congress are due in mid-January of 2012.

We do encourage those listening today, either if you're in the audience or via teleconference, to consider submitting input to the agency through written comments. It is not too late.

I do close today by thanking our hosts here at the University of Southern California for providing such a great opportunity for us to come and speak with the people in the California region.

And I do now officially close the International Patent Protection Study Hearing. And I do wish everyone here safe travels back to home or work.

Thanks.

(End of Public hearing on the Study of International Patent Protection for Small Businesses.)

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