**International Reports and Recommendations Regarding
Gene Patents, Licensing Strategies, and Genetic Tests
Q&A**

DR. EVANS: Great. Thank you. That was great.

If we could get the last two speakers up to answer questions, and then we'll quickly move on to our general discussion. So for Mr. Barton and Ms. Sampogna, if we could have any specific questions, we'll keep it fairly short and then get on with our discussion.

Julio?

DR. LICINIO: For Ms. Sampogna, this idea of a clearinghouse for the life sciences is very intriguing and it's one of the issues that we discussed before in terms of individual patents, how can you develop a (inaudible) if you have to deal individually with a lot of people. So is it more than an idea? Who else is talking about this, and is this going anywhere?

DR. SEGER: Push to talk.

MS. SAMPOGNA: Thank you, and thank you for the help with the technology.

DR. EVANS: It's patented.

MS. SAMPOGNA: It's not always diffused.

That's an excellent question. Actually, there's a lot of interest and there's a lot of enthusiasm about the idea. It's obviously very complicated. They're not easy to set up, and if I look at the ones that were set up in the IT field, it took many years. So this isn't something that is feasible in six months. But there are a number of government reports that have actually recommended the development of this. There are a number of industry players, both big and small and medium-sized companies, that are interested in this and that are interested in working with us to develop this initiative, and we have a lot of countries beyond the reports that are published that are actually very interested in working with us to develop this initiative.

It's a very interesting, it's a very intriguing, it's a very exciting initiative, but I think there are a lot of challenges, so I don't want to over-simplify the issue in terms of saying it's feasible with this type of thing. I don't think it's that simple. But yes, I think there's a lot of interest.

DR. EVANS: Along those same lines, what are the types of incentives that can be implemented, say by government, to encourage the formation of patent pools or clearinghouses? Because these are voluntary things, and I think to some extent the different corporations and et cetera are driven to it by necessity in the end. But are there ways of incentivizing it?

MS. SAMPOGNA: Again, that's also an excellent question. It's one of the issues we're looking at. Actually, I have an entire two-hour presentation I can give on that topic, which obviously I didn't, and I won't. Some of the pools that were formed were compulsory license pools. So the government stepped in and said the industry is not working properly. We need this technology and we need it developed, and they actually sort of brought all the pools into them. The example that many people are familiar with is the one in aircraft industry at the beginning of the 1900s, during World War I.

Many of the others are actually volunteer, and it's not clear why. I mean, sometimes it is, because they need to do business. That was true for the DVD pool, for example. They needed to do business and they were blocking each other, but that's not always the case. So there are a couple of really key challenges, and one is obviously what are the incentives for these being formed? Another one is a standards issue. A lot of the pools that have been formed are around the development of a standard, either an existing standard or the actual development of a standard for that particular sub-sector of the industry. It's a bit more complicated in the life sciences to develop standards. There aren't that many in many ways. So that's another challenge, because although historically there have been standards associated with patent pools, one of the issues is do we actually need a standard? Again, that's one of the issues that we're looking at. Other issues that are quite complicated are the competition law issues because, of course, there have been a number of patent pools that have been formed but they were anti-competitive or they were there for price fixing or whatever, and those have been invalidated.

Now, what's really interesting and encouraging in regards to that issue is if you look at the three major sectors - not sectors but countries or jurisdictions, the United States, the European Commission and Japan, they've all issued guidelines on patent pools, on standardization, standard-setting and how to deal with them. They're very general, but they're very optimistic in another way. The FTC and the DOJ have actually been really, really positive if you look at the more recent formations of the patent pools in terms of actually working with the developers, the initiators of the pools and making sure that the pools actually meet competition law, anti-trust issues.

DR. EVANS: Thank you very much.

Emily, I think you're next.

DR. WINN-DEEN: Yes. So I guess my basic problem with the philosophical approach that we've been taking today is that I think there is probably unanimous agreement that there's a set of best practices out there that everyone should follow, but the problem guys are the ones who don't follow them. So we need something more than just best practices, because best practices would not have kept Myriad from doing what they did. It wouldn't have kept the Canavan story from ending up where it did. I've encountered one or two incidents in my life as an end-licensing person where despite sending a technology transfer office the NIH guidelines and saying, by the way, there are at least three or four of us out here who are interested in a non-exclusive license, the incentive for a tech transfer office is to make a big-money, exclusive license, and that incentive is completely at odds with all of these guidances.

So if you're the poor schmuck working in the tech transfer office, who are you going to follow? Are you going to follow the guidance that's depending on what your raise is going to be that year, or are you going to follow some theoretical thing that emanates from NIH or one of these other organizations?

So I think we need something that has more power to it than just guidance, but we also need to recognize that there is a really big disconnect between tech transfer goals and all the things that we've been talking about today, and I don't know how to reconcile those except by just saying it is NIH policy, if this was developed under NIH with Bayh-Dole money, you will not be allowed to do an exclusive license, rather than saying we think it's best if you consider non-exclusive.

So I think there are a lot of companies, a lot of universities, a lot of people who are doing the morally right thing and trying to disburse things in the right way for patient health, but there are

always some bad actors who are just not going to do what they should unless they're forced to, and I don't know how to deal with that. That is, I think, what we really have to struggle with.

DR. EVANS: Yes, I think that's one of the biggest things we have to grapple with, is that issue. You essentially have to force people sometimes to do the right thing. You have to incentivize people with tangible incentives. You can't just expect -

DR. WINN-DEEN: But in the end we have laws and cops because we recognize that not everyone is going to do the right thing.

DR. EVANS: Right.

MS. SAMPOGNA: Thank you, Mr. Chairman. That's an excellent point. In fact, I was going to actually raise that point but I didn't want to go into it this late in the afternoon. I think you're absolutely right. I think there's a sort of disjunction between how we incentivize TTOs versus these goals that we're trying to achieve, and you're absolutely right. For most of the TTOs, there's a lot of work that's been done in terms of they're interested in the short-term, high-return, get the money in and think about long term at another point in time, and that's a real challenge. But the utility of the guidelines isn't just for them, first of all; and then second of all, I don't think that just because that isn't working, that they're not useful.

Why do I say that? Well, because when we were developing them, we did this public consultation with hundreds of stakeholders from every sector around the world and we got a lot of feedback that even the entities who are trying to be good corporate citizens, sometimes they're a little unsure of what it actually means, and to have the document say, well, here is some guidance, here's how you can do it or not do it, is useful for them. That was one of the recurring themes that came through in terms of, again, saying thank you for doing this, this is great and we're looking forward to the final product and what-not.

So that's one element. Then the other element is - you're absolutely right, there's going to be bad corporate behavior, and it's always going to be there, and so the aim is to try and minimize that. So you can have guidelines, but you can also have the guidelines, as you mentioned, in a very enforceable way. You don't necessarily just need to have them as soft law. There can actually be an enforcement element added to them.

DR. WINN-DEEN: Yes, and I didn't meant to denigrate the work of coming to consensus on what guidelines should be. I think that's very important work, to reach a point where all the voices have been heard and there is some sort of common ground that's emerging, but I still am worried that all the bad stories we heard wouldn't have been dealt with by any of the guidelines that are out there.

DR. EVANS: Kevin is next on the list, and then what we need to do is we'll get everybody up here, go through the last few slides of just general questions and discussion. So if we could get - we've got Dr. Straus and Ms. Sampogna. Excuse me. Dr. Straus, if we could get you up here, and Dr. Parthasarathy, and Mr. Barton.

Kevin, you go ahead.

DR. FITZGERALD: This is for Professor Barton. I'm intrigued by your interpretation of the consequences of Metabolite and the idea that, in a sense, because of what happened, we may end up where the Nuffield Council sort of wanted to go anyway. So speculating, if that had not

occurred, if the decision had gone one way or the other on the Supreme Court, would either decision had gotten us to a place where we didn't want to go?

MR. BARTON: Well, I think that's a very fair question, and I think it depends on who the we is. That is, I think if you're Myriad, a decision definitively upholding this kind of patent would have gotten them where they wanted to go. I think if you're a health administrator, a decision striking down this kind of patent would have gotten you where you wanted to go. Where we are is obviously somewhere in-between.