International Reports and Recommendations Regarding Gene Patents, Licensing Strategies, and Genetic Tests
Christina Sampogna, LL.M.

DR. EVANS: Thank you very much. That was a great talk, very illuminating and very helpful.

Our next speaker is Christina Sampogna. She serves as a lawyer at the Organization for Economic Cooperation and Development, its Biotechnology Division. In this role, Ms. Sampogna manages initiatives pertaining to the life sciences, including intellectual property, R&D, innovation, human genetics and genomics, and counterfeiting. Previously Ms. Sampogna managed the unit that developed the Canadian government's patent policy for the field of biotechnology which required legislative reform, and she's provided legal and policy advice to governments and expert committees on a broad range of topics.

Today she's going to tell us about the OECD's guidelines for the licensing of genetic inventions.

MS. SAMPOGNA: Thank you, and thank you to the organizers for inviting me. I was actually going to thank the organizers for inviting me to a very sunny city, since in Paris it's 11 degrees and rainy. If I had spoken this morning, I could have said that. Right now I can't anymore. So thank you, Mr. Chairman.

As the Chairman indicated, I'm going to be speaking about the OECD guidelines on the licensing of genetic inventions. I understand that the purpose of this meeting is to look at a number of these related issues in the sense of to look at licensing, patents on genetic material and especially the field of diagnostics.

Just briefly, the point of the OECD guidelines is really to address a number of issues when we were developing them in terms of the stifling of innovation, the stifling of research and the stifling of access to technologies, and especially therapies and diagnostics. So they offer a set of principles and best practices in terms of fostering research, fostering delivery and accessibility of products and commercialization, and they do this in a balanced way. What they aim to do is sort of take into account the multitude of factors that have been mentioned all of today that come into play. So what they try to do, they try to actually balance the different competing interests that are in the marketplace, so balance the interests between the researchers and the need to commercialize technologies, the different interests between the private sector and the public sector, and between fostering R&D and facilitating access to technology.

I was going to go through and explain what the OECD was, but given our timing I'll just skip that. I'm going to quickly go through in terms of some of the challenges that are arising in the life sciences. I'll speak to a bit of the context of the guidelines in terms of what was going on when they were being developed and why are they relevant today. Then I'll provide a very brief overview of the guidelines that are actually quite detailed, and there are quite a bit of annotations, and you've all received copies of them I understand. So I won't really go into details. What I'll do is I'll try to highlight some of the key concerns that each of the sections aims to address and some of the points that might be relevant to the deliberations of this committee. Then I'll speak to the issue of implementation of the guidelines and the impacts, which I understand is also of interest to this committee in terms of, again, how can they be useful in the American context. Then just before I conclude I want to speak about a new initiative that kind of flows from a lot of this about Collaborative Mechanisms for IP. The idea there is just how do we use intellectual property and intellectual property rights in a different way. How do we leverage it differently so

as to move research forward, stimulate innovation, and possibly provide greater access to technology?

So just really quickly, these are two graphs that actually show the amount of investment in the pharmaceutical industry, but really all I wanted to highlight on these graphs were the points that investment in R&D has actually been increasing. The graph on the left-hand side is the from the FDA report on stagnation and innovation, and it's mirrored in the chart on the right-hand side, which comes from actually PhRMA's annual report for, I believe, 2006. So they kind of just show an increase in investment in R&D over roughly the same period, and what's interesting is that while investment in R&D has increased for that same 10-year period, actually what the FDA found was that the new products that were brought to market had actually decreased. So the new NMEs brought to market or applied for, actually, if you look at the chart on the left-hand side, had actually decreased, and then what's called Figure 3 here on the right-hand side, again the FDA found that the cost had actually increased of bringing the product to market. It's a more complicated issue than just being captured in two or three graphs, but just this idea of we're investing a lot of money in life sciences and are we really getting value for it, and how do we get better value for the investment that's going into this sector.

So those are some of the challenges and, as I said, those are actually challenges that we're looking at in the new initiative called Collaborative Mechanisms that I'll just briefly cover later on. But another set of challenges, and there's been a lot of talk about this today, so I'm certainly not going to go over it again, but just this idea of patents and the trend in patents and the fact that really there is an increase in the number of patents being applied for. This is a chart that's a little bit dated. It's from the World Intellectual Property Organization, and it just shows the number of patents filed in the biotech industry for roughly about 15 years. Yes, we saw a lot of data today about how the trend is sort of tapering off and there are changes, but I don't think we can say today that overall there will be no more patents on genes that will be applied for or filed. I think that would be rather unrealistic. So we still have to contend with future patents, but importantly we also have to contend with the patents that have already been granted. They're still out there and they're still going to be applicable.

This was just a chart to show trends in patenting both in terms of filed and in terms of granted globally from the World Intellectual Property Organization.

So the context of the guidelines. What do they actually do? Well, this is their main purpose. They try to address the issues pertaining to the licensing and the technology transfer of genetic inventions with the aim of fostering R&D, stimulating innovation, increasing access and diffusion. Really, they provide guidance to the marketplace in terms of encouraging access for the delivery of health care products and services, for research, and for commercialization purposes.

The guidelines were adopted by the OECD Council. That's our highest decision making body, and it's the official body of the organization. It takes the senior decisions. In fact, what it does is it can take legally binding decisions and non-legally binding decisions. There are very, very few legally binding decisions because they become international treaties. There are also very few non-legally binding determinations because they speak to a strong moral commitment on the part of the OECD member countries, and I'll just mention that the OECD member countries are the 30 most industrialized countries in the world. So these were adopted at the Council level, which means there's a strong moral commitment to their implementation.

They were also developed with a wide breadth of stakeholders. We did public consultations with over 200 stakeholders around the world, including developing countries, and they provided very useful input. So their implementation also should involve the wide breadth of stakeholders. So I'll just quickly go through the guidelines themselves and try to give a sense of some of the points that could be useful for the deliberations of this committee.

The guidelines are actually intended to be quite broad. I mean, there's an actual definition of the scope of the guidelines, but really that's just more useful in terms of trying to determine what they apply to. But they're also intended to be forward-looking in terms of future developments and future innovations that weren't yet feasible when they were adopted last year. They're divided into five sections, and I'll go through each of the five sections really quickly.

The first one is actually the licensing generally. So there are a slew of principles and best practices generally applied to the field. Really what it does is this part of the document sets the tone for the rest of the sections. I put up here - I'm not going to go through every single one of them, so rest assured. The very first one I think is the one I put up here, and for a very good reason, that it actually sort of sets out the key objectives in a very simple way in terms of fostering innovation for the development of new genetic products and services, and at the same time ensuring access to those products and services, and on a reasonable basis.

I think those are some of the key elements to the point that there's both a balance, and even within access there's a balance between reasonable commercialization and then ensuring reasonable access.

Pricing had been one of the issues that was of concern when these guidelines were being developed. There was anecdotal evidence that, of course, there were situations that had arisen where there was difficulty in obtaining access to products and technologies, and in addition sometimes there was difficulty due to the fee that was being charged. That's why the principle was put in there.

The next element that this section covered was this issue of stifling research and stifling access to research. What the Principle 1B encourages is it tries to balance this need between the rapid dissemination of information and research, especially from a researcher's perspective, with the needs of the private sector in terms of commercialization. So it does that in a number of ways, which are in the best practices.

The second part speaks about health care and genetic inventions. This section is really about this balance between access and choice in the sense of trying, again, not to limit the choice of patients and health care providers, and it also creates a balance between the needs of health care providers and patients. So it entreats licensees and licensors to not restrict choice of product and services. It entreats them to make them available to both patients and health care providers and to allow health care providers to have the flexibility to determine what is the best product for their patients so that, again, there is a clear choice.

Then another really important point that this section covers is with respect to privacy. Professor Barton had actually spoken about genetic testing and someone had mentioned, one of the committee members had mentioned genetic testing should be done locally. In fact, we've actually carried out a really extensive survey across 18 countries on genetic testing, and what we found is that most of the testing wasn't actually done locally. Most of the testing crossed borders. One of the key issues in that was the concerns of privacy, concerns of quality, and concerns of reporting back were quite significant. There are a number of different issues with that, and in fact we

actually have just published guidelines on quality assurance for molecular genetic testing which just were published actually last week.

So these guidelines actually address the issue of privacy, which is a really important issue for patients, and we entreat, again, licensees and licensors to allow the highest applicable standard to be employed.

Research freedom is the third part of the guidelines, and it's really about, again, this balance between the need for academics, for researchers to publish and to get the information out there versus the needs of the private sector often to delay publishing or to restrict the publishing of some information or some data, and how do you find that balance between them. So there are a number of points that are made in this section about confidentiality, about trying to reduce their scope, and in terms of how do you balance that with the needs for commercialization. Of course, one of the points which is very important was that commercialization should certainly not hinder educational training.

Section 4 was actually about commercial development. The idea wasn't really to restrain it but really to identify practices that had been identified and that were being carried out in the marketplace and that were having undesired effects. So what the Section 4 does in terms of commercial development is it tries to identify a number of behaviors that, while not illegal or illicit and therefore permitted in the marketplace, certainly in the context of biotechnology and in the context of genetic inventions and genetic testing should be avoided or should not be favored because of the effects that they may have produced or had produced in terms of anecdotal incidences. Some of them were already mentioned.

I'll just quickly go through them. Royalty stacking and multiple licensees were some of the practices where, again, not in and of themselves, but these sort of create hurdles. When someone wants to commercialize or develop a technology and there are many, many patents, there are a number of issues that arise with that. Identifying the patents is one of the biggest obstacles, and then obviously negotiating to obtain the license with all of those patent holders is quite complex and involves quite high transaction costs, and then the licenses themselves. So the licensing fee, the royalties, can be quite high, especially if you accumulate all of them. So these are some of the issues that we addressed in several proposed different approaches and make recommendations on.

Another issue that has actually also been mentioned earlier is this issue of reach-through rights. Of course, there are situations where reach-through rights are actually quite useful, but there seem to be some issues around reach-through rights reaching through to the final product which creates, again, a disincentive for innovation.

Then another key point that has been mentioned is exclusive licensing. Of course, it is recognized that exclusive licensing is sometimes very useful for the commercialization of technologies and of products, but there needs to be a balance in terms of when is it useful and when is it not useful, and how to actually limit the effects of exclusive licensing. So there are different ways to do it, and some of these are enumerated in the guidelines.

Then the final section is on competition and competition law. Of course, it entreats licensees and licensors to actually comply with competition law, but more than that, it actually indicates that while some of the behaviors like tied selling, non-compete clauses and the breadth of exclusive rights are permitted, that really in the context of genetic inventions they should be avoided because of the effects that they have.

Then finally, in terms of one of the key points is this fundamental genetic inventions, that they should be licensed non-exclusively. Really, what we had contemplated when we thought of this notion of fundamental genetic inventions is that we were thinking of fundamental inventions like PCR, like research tools.

So one of the issues that I was asked to think about is the implementation and the impact of the guidelines and how can they be useful for the American context. As I mentioned, the guidelines were adopted last year, in 2006, so many countries are actually working through how to implement the guidelines. One of the things that I think would make a significant contribution to their uptake, if you want, is that governments actually support them, and there are different ways of doing it. For example, depending on the resources, of course, some countries, like the Czech and the Polish governments, have actually distributed in English the guidelines to a large segment of the government, of the private sector, and of the public sector.

With that type of diffusion, it's very simple in some ways, just providing information to market players. But what it does, coming from a government entity, is it actually sort of tells the market participants what the government considers to be good corporate behavior. In business law, we have this notion of corporate social responsibility, and I think in the biotech licensing field the guidelines can be used in a way to generate corporate social licensing, how best to license to again retain a return on investment but at the same time not stifle others, not stifle innovation.

Other governments have actually translated the guidelines. They've been translated into French, Japanese and Italian, and they're now being translated under the guidance of Professor Straus into German, and I should mention that actually Professor Straus was the chair of the expert group that worked on these guidelines, and so we actually owe him quite a lot.

Of course, translation isn't an issue in the United States since they're in English, but the other interesting thing that governments have done is they've actually made them available on their websites, and I think that's also a good tool in terms of communicating.

Then there are funding policies. What do I mean by funding policies? NIH was really good at this. They actually developed the Best Practices for the Licensing of Genomic Inventions and published them in 2005. What's really interesting is that actually both of these two sets of guidelines were developed in parallel. The people who developed the NIH guidelines were actually involved in the work of the OECD, and the NIH guidelines have been incorporated into the funding policies and therefore are involved in any of the grants that the NIH makes. Given the amount of grants that the NIH makes, it is actually quite impressive in terms of the full potential that it might have to impact them.

But the NIH is not the only one. There are other funding agencies, whether public or private, that could adopt similar sets of guidelines and therefore have a fuller impact. There are also government research centers, not necessarily the ones funded by NIH but other research centers that are government or public that could also adopt, again, either the guidelines or similar guidelines based on these.

Social licensing becomes really interesting in the sense that industry can adopt the OECD guidelines. Again, they would be guidelines, they would be guiding principles, but they could actually take them and use them as their guiding principles. This has been done in Japan, where the Japanese Biotechnology Association has actually done that. They put the guidelines up on their website. They made them available both in English and in Japanese. They've actually printed booklets of the guidelines in English and in Japanese and distributed it to all of their

members, including the pharmaceutical sector, and they're developing additional guidelines based on the OECD guidelines.

In terms of diffusion, as I just mentioned the JBA, the Japanese Biotechnology Association, actually did quite a lot. But in terms of the equivalent being done in the United States, we can think of BIO association during a similar activity in terms of either, again, distributing the guidelines directly or an adapted version of the guidelines to their members, and again adopting them as sort of guiding principles.

Some of the elements in the guidelines are actually quite practical and they can be implemented directly. Others are more stated as an objective of what good corporate licensing and behavior should be.

Now, the public sector. Obviously, the largest public sector that would be of interest would be the universities, and there are a number of best practices and principles in the guidelines that can be implemented directly by universities in their technology transfer practices, but I think they can also be adopted at a higher level as guiding principles. I was really interested in the nine points that were issued by the 11 universities and the AAMCs just a few months ago here in the United States. I think that's an excellent initiative and I think, again, other universities can adopt the same approach, or an association such as AUTM can adopt a similar approach in developing guiding principles.

So these are some of my thoughts on how the OECD guidelines may be taken out, deployed, diffused and hopefully change the corporate behavior. Just before I conclude, I said I did want to mention this Collaborative Mechanisms for IP. Part of the background research and what we heard in terms of doing work on the IP guidelines was this idea of there being many patents and how do you deal with that and all the uncertainties around that. So what this project is about is exactly that. I don't have a pointer, but it's this idea that there are a number of different mechanisms out there and how do you create these mechanisms for leveraging IP.

Now, most of these mechanisms have actually been used, but they've been used in other industries and not very often in the life sciences. So the scope of this project is to actually see how they can be used in the life sciences. So the blue circle with all the little patent documents is a patent pool, and the reason I have a radio there is because Radio Corporation of America was actually first founded as a patent pool, and it was a very successful pool. In fact, it set many of the standards both for radio and radio frequencies, as well as the standards for the follow-on technology, like TVs and so on.

MPEG LA is actually a patent pool, a more modern patent pool that was put in place in the 1990s. It's been very successful and it's actually moved the industry forward. There are a number of those patent pools that have moved the industry forward. Again, they're not in the life sciences. They're in the IT communications and electronic consumer industries.

On the right-hand side of the screen there's ASCAP and SESAC. They're clearinghouses for, again, music, films, that type of thing, and the idea behind the clearinghouse is you have many consumers, you have many purchasers, and how do you bring them together? So if we think of a song, any song, in a very simple way every time somebody wants to play Song A in every city - well, let's start even smaller than that - in every train station, in every radio station, in every hotel, in every nightclub, in every city, in every country around the world, they would have to go and negotiate with the songwriter, the producer, the performer. It becomes unmanageable. So that's

why these societies came into being, because you actually buy the rights through the societies and it facilitates the exchange of rights.

So the idea is could you not do this in the life sciences where you have many patents, many IP rights, and instead of going and negotiating with every single one of them and not knowing who all they are, couldn't you do it through some other mechanism like a patent clearinghouse? We don't have all the answers yet. They're just some of the questions we're asking.

There are other mechanisms. There's a whole slew of different mechanisms, and a report will come out later this year. I have the International HapMap there because actually the way they were set up and the way the SNP Consortium was set up was very interesting as well, because it brought in different interests.

So simply in conclusion, there are a couple of points I did want to make. I think this is a very complicated field. I'm certainly not going to sum it up, but I think one of the things that is really the key message I'd like to be the take-home message of the day is that behavior will be influenced to change when the entire community, when government, when the private sector, when the public sector, when civil society acts in a coherent manner to affect change so it changes the way they're thinking and the way they approach the problems. It's quite a challenge; I recognize that. But I think that's what documents like the guidelines and discussions like these actually do, that they allow the dialogue and they allow the movement forward. Thank you.