**Intellectual Property and National Health Systems:
Case Studies of BRCA Testing in Canada and the United Kingdom
Q&A**

DR. EVANS: Great. Richard, thank you very much and thanks for also hurrying along. The technical difficulties put us behind, but I think you really got things across very well and we really appreciate it.

We have a very short time for a few questions to both of our presenters, and I'll just go ahead and open the floor.

DR. TUCKSON: Let me just give everybody a notice in terms of a process check. We are aware that apparently human organisms require food.

(Laughter.)

DR. TUCKSON: This has just been brought to my attention by Muin Khoury from the CDC.

(Laughter.)

DR. TUCKSON: So believe me, we're going to take a break. One of the good things about the penthouse is that the cafeteria is right next door. So what we're going to wind up doing is having a working lunch. You'll get enough time to rush over there, get some food and come back.

So just know that we haven't gone crazy. We haven't forgotten you need to eat. We're going to get that. We want to take a few minutes for questions. We're going to get a couple of the public comments in. You'll get your food and then you'll be able to eat. So just hold on. But you're tough because you're intellectually brilliant.

DR. EVANS: I thought Reed was going to declare us non-human organisms to get around that.

(Laughter.)

DR. EVANS: It looks like Julio has a question.

DR. LICINIO: I had a question for Richard Gold. In one of his first slides, it says that a patented gene gives rights over the entire organism in Canada. I wonder like, let's say, if people have genetic mutations or problems that are diagnosed in vitro, let's say, in the case of in vitro fertilization, and you put a patented gene in a person, what happens?

DR. GOLD: Well, that's never been tested. It's an interesting question. My guess is -- and as I said, there's no official policy -- that you can't get any control over a human being. So even though that would apply to a gene artificially placed into a cell of an animal or plant, I cannot see a court ever allowing that to apply to a whole human being. So I think theoretically yes. That's in accord with patent law, but I think the courts will find constitutional or other reasons to limit that. So I'm not overly worried about it.

DR. EVANS: Other questions. Yes, Gurvaneet?

DR. RANDHAWA: It's a fascinating presentation. I'm on an upward learning curve here.

The one thing that I wasn't clear about is if the research that shows a gene is linked to a disease or leads to an intervention that can improve public health, if that funding comes from the public sector, mostly or all of it, does the public sector have any leverage in terms of either the licensing or the actual patenting and how it's issued?

DR. GOLD: Who was that addressed to? Me or to Shobita?

DR. RANDHAWA: I'm sorry. Both of you.

DR. PARTHASARATHY: Richard, do you want to go ahead and I'll answer after you?

DR. GOLD: No. I just talked a lot. I'll let you do it.

(Laughter.)

DR. PARTHASARATHY: Great. Well, I'll give a partial answer then and he can fill in.

That's actually an interesting point with regard to the Myriad case in particular. First, there is the Bayh-Dole Act which allows if the government funds university research and some patentable invention results from that, the government has chosen not to take an interest in it. So they don't get involved.

However, in the Myriad case, there were actually researchers from the National Institute for Environmental Health Sciences involved in the initial BRCA1 research. And in the early days when Myriad first applied for the BRCA1 patent, the NIH in particular said, listen, you need to put our inventors on the patent or else we're going to file a counter-patent, and then this is going to be very problematic for you. So eventually Myriad did put these two individuals from NIEHS on the patent, but in conversations with them, they actually interestingly haven't really received much in terms of royalties.

But it does raise another question, which is the extent to which now NIEHS would have any kind of standing to influence how the patent was being used, licensed, et cetera. To date, they have not taken advantage of that position, but often I get asked that question. So that's a question for NIH.

Certainly the scientists, in my conversations with them, say, listen, we're done with it, and we're so annoyed by the whole situation we just don't want to have anything to do with it anymore.

But it's a policy question that I haven't yet been able to get an answer to in terms of the Myriad case in particular.

DR. GOLD: I have nothing to add on the U.S. side. In Canada, we don't have the equivalent of Bayh-Dole. Each university comes up with its own set of rules in negotiation with its researchers. Who owns it is either the university or the researcher or some combination. The federal government has really no -- even if they provide research grants, the research grants just say whatever your IP policy is applies. So the federal government has no say, and we don't have any march-in rights as exists in the U.S.

DR. EVANS: It looks like Debra Leonard has a question and then I think we'll have to finish up.

DR. LEONARD: This is addressed to Richard. On your penultimate slide of your first talk, you have a statement that licensing practices are part of the solution, but not the entire solution. So

can you expand on where licensing practices would fall short if we took that approach to protecting gene patents for health care use?

DR. GOLD: Sure. Again, this is just my opinion and doesn't necessarily represent the Canadian -- if you took a sample of Canadians.

My view, in talking to especially health care administrators, is yes. Licensing guidelines are wonderful if people actually follow them and everybody acts reasonably and people communicate well and have good trust. However, that's not always reality. There will be outliers and so on. These policy units don't have that many staff. So what they want is very targeted changes to patent law that would give them leverage in negotiations.

So one example would be a very targeted compulsory license that would say -- it could follow something like the French law. French law provides that a compulsory license is available for either a health care product or diagnostic testing. It has never been, or rarely, invoked, but its threat has been invoked and the French government uses it basically to negotiate saying, if you don't comply, we will issue it. And because it's such a narrow exception, it won't threaten the entire industry. So it's seen as a realistic threat. So things like that.

In terms of the research side, they want to see things like a research exemption. Maybe Myriad was right and they were willing to tolerate a large amount, but researchers don't know that. So even if Myriad is right, researchers are acting as if they don't have the right. A clear research exemption would allow research to proceed and preferably a wide one. There's a whole variety of approaches around the world to research exceptions and there's no indication that there's any particular harm to a broader one. And if it reassures researchers, it may be worth doing simply as a symbol. Most companies will not sue people for infringement, but a researcher may not know that. So this is a good symbolic way to do it.

So it's those type of levers that are being asked for, not a substantial change to patent law, but those levers, plus an opposition procedure.

The provinces would say, look, we don't want to have to go to court and wait for years for an answer. We would like a fairly quick procedure that would allow us to challenge issued patents. Especially in an area like genetics where the standards are changing all the time, we want to be able to get in there and have our say so that we can get rid of bad patents. And generally, in at least the Ontario government's point of view -- and I happen to think that they're right -- the Myriad patent is very weak. It is unlikely to be valid, but that's my opinion. So they want a quick way.

So those are the types of solutions that they're looking for not, I don't think, that dissimilar from what you were discussing.

DR. EVANS: So, Richard, is it fair to say -- I don't want to put words in your mouth -- that you feel that perhaps the most effective policy levers involve narrowly tailored, mandated licensing for certain applications?

DR. GOLD: I would say a combination. The way I see the levers are that they should never have to be invoked, but they have to be a real threat. So they should be narrowly conceived. But they don't work unless you know what the proper licensing practices are. I don't think this is an either/or position. I think your licensing guidelines are more likely to have an effect if the governments that are involved feel that they have this leverage in case things go wrong. Almost

no government wants to invoke them. So you play on that by showing them here's a solution that people can live with. Here's a reasonable compromise, and I think it gives greater weight to actually following, in a voluntary way, the licensing guidelines. I'm sure some people in industry would disagree with that, but that's how I view it.

DR. EVANS: Great.

And the very last question because of the fact that he's the chairman and gets to interfere with our lunch is to Reed.

DR. TUCKSON: Well, you know what I'll do? I'm just going to throw this out there. Richard, if you have any answer to this, feel free. If not, we'll just discuss it later with other panelists. Shobita, I don't know. Are you staying or are you leaving?

DR. PARTHASARATHY: I'm staying.

DR. TUCKSON: So maybe I can just sort of tee it up for later. I guess with all this, what I don't understand -- and maybe you've said it and I just haven't understood it -- is if you are a company that operates internationally, like almost every company, what rules apply? I mean, if you figure it out for Canada or you figure it out for the United States, but you decide that you're trying to market a product in Brazil or you want to market it in France or you want to market wherever, they say this rule applies. But you say, but I'm complying with the law in X. Is there any superseding or does it all work out as to international trade politics between different countries and you just basically get your country of origin to beat the hell out of some other country because you win? I mean, how does it work?

DR. GOLD: Well, I do have some comments. I'm sorry I'm keeping you from your lunch, but if it helps, you're keeping me from dinner too.

(Laughter.)

DR. GOLD: And I'm in Geneva. So there's lots of French food around.

DR. EVANS: Yes, yours is worth waiting for.

DR. GOLD: So I think the quick answer is the traditional method is to see if there's any other product, and yes, we'll call our ambassador and we'll beat people over the head if they don't comply. I think the reality is somewhat different, as my presentation and as Shobita was saying. Everybody is coming to the same basic rules. So I don't think there's a big doubt about gene patents being patentable on basically the same grounds. Yes, there might be one or two outliers.

The big question that I have, especially for U.S. companies, is they seem to lack a willingness, or whatever it is, to actually understand the context into which they're entering. Now, that might be okay for chairs. It's not okay for health care. Health care is viewed very differently even across the border in Canada and elsewhere. All of the places where this policy erupted -- and it was much bigger than the U.S. for Myriad -- are in countries where there are public health care systems. It's not a coincidence. So I think it's incumbent on U.S. companies to actually understand the environment they're entering into and that public health has a meaning. And whether they like it or not, that's the reality. The basic same factors applied in Europe, in Canada, in Australia. They were all concerned about the same thing.

So I think it's up to U.S. companies to learn that when there's a public health administration involved, they care about the way services are rolled out and who gets them when. And whether they like that or not, they have to accept that and their business plan must be modified at least internationally.

DR. PARTHASARATHY: I would just add to that that I think it's an important and interesting question, the extent to which -- especially if European and Canadian countries and Australia, countries that the United States would see as primary markets, developed countries, that have -- certainly when we're talking about genetics, genetic technologies -- often likely to have similar diseases, similar mutations to the U.S. The extent to which those kinds of public health care systems and approaches are going to inadvertently then have to shift U.S. company strategy even domestically because if they're going to take one blanket strategy, the fact that all of these other countries have public health care systems and are pressuring in a very similar way may have to shift the U.S. company strategies when it comes to health care --

DR. TUCKSON: Shobita, if you're going to be around later and another panelist, we can probably get back. I'm not going to ask you to comment on it because we've got to go to the public comments.

But the other way to view it is that I don't want us to be -- even though we are an advisory committee to the Secretary of Health of the United States, we certainly are not so provincial that we believe that all innovation in genetics is going to come from U.S.-based companies.

So the flip side of this I'm equally interested in is what happens to new innovations -- and also given just the multinational nature of companies, you can have a country that's grounded in France who decides to market in the United States. They say we passed all the rules in France. It's all clear in terms of our patent and licenses and stuff. How does that then apply flip side? So anyway, I'll just leave that as a hanging participle.

Amy Miller, are you here?

Oh, Richard, are you there?

DR. GOLD: I'm still here.

DR. TUCKSON: I have no manners. Thank you. You are wonderful. You did a terrific job. Shobita, you did a terrific job. I didn't say it right, but it's the best I could do. You did a great job and we really appreciate it. Thank you. Everybody, a round of applause for the speakers.

(Applause.)

DR. TUCKSON: Take care and have a good dinner.

DR. GOLD: Well, thank you, and have a good lunch.