Patents Discussion/Next Steps

DR. EVANS: Okay. Now, the way we're going to structure this is we've got a few slides, and I hope they won't blind you all. As we discuss these, when there are pertinent questions for our panelists, go ahead and I'll put you on the queue.

This first question I think has its answer just below it. How should pending U.S. patent reform initiatives be addressed as we develop recommendations? In other words, this is a rapidly changing field. There's legislation going on, there are court decisions going on, and I think the only obvious way to me is that we should probably have an update at the next session as to the status of such legislation and any court decisions that have been issued. Do people agree with that or are there other mechanisms by which you envision us keeping track of things?

Marc?

DR. WILLIAMS: Just an operational question. How important is it to present this to this entire group at that point in the timeframe of what you're actually doing, as opposed to just making sure that your group is up to speed?

DR. EVANS: That's actually a very good point. I mean, I think it would probably be reasonable to the task force to get an update from the appropriate people. If there are major developments, then we can report back to you people. I think that's a great idea.

DR. LEONARD: Well, going through all the initiatives that Judge Newman went through, there doesn't seem to be much that's directly relevant to patient access issues that we're looking at. So I would say that the update, we need to monitor it and see if there's anything relevant, and if there is, bring it to the entire group, but if not, then we just monitor.

DR. EVANS: That makes sense to me. Okay.

So this gets more to the meat of what we were trying to accomplish today. Are there approaches utilized by other countries or international advisory groups that could be adapted to the U.S. system? Which approaches should be used as models to apply to the U.S. system? That's about an eight-hour discussion, but does anybody want to weigh in with any specific comments or observations?

DR. WILLIAMS: Can you help me with a scope question here? As I understand our abilities, we can really work only through advice to the Secretary. So it seems to me that these questions have to be framed in the context of within all the realm of things that could be done, what can actually be done under the purview of the Secretary?

DR. EVANS: Right, and I think that we can certainly suggest things to the Secretary that are not necessarily exclusively the domain of the executive branch, right? Look at GINA and us weighing in on non-discrimination. So I think that, again, is kind of an operational question that as we begin to define where we're at and what types of recommendations we want to come down on, we have to think hard about how those would be implemented through the Secretary, what kind of advice we can give that is within the Secretary's purview.

DR. WINN-DEEN: Certainly there are things like NIH policy, what you put on a grant award, should there be something formally attached that says "I agree in accepting this money to follow the guidelines," period.

DR. EVANS: Right. So there are actually some very definitive kinds of things that can be done by the executive branch in that sense.

Debra, is this a good time?

DR. LEONARD: Could I ask Alan for clarification? The NIH develops policies, and it's like you're playing nice in the sandbox, but you actually have powers to march in and take rights over patents, I believe. Could you clarify what it would take, if that's true? And secondly -

DR. EVANS: Alan personally.

(Laughter.)

DR. LEONARD: And when you do, can I watch?

(Laughter.)

DR. LEONARD: But what it would take and what the inhibitions are to doing an action like that for a specific patent such as the ones held by Myriad, Athena Diagnostics, the ones that are of concern and have basically generated this whole discussion? As Claire Driscoll demonstrated, most of the patents held or exclusively licensed by Athena Diagnostics come from academic institutions. Therefore, NIH should have some ability to influence at least those patents.

DR. GUTTMACHER: So let me answer Jim's question first. It will be easier. No, you cannot watch, because if we did this, it would be in the dead of night, obviously.

(Laughter.)

DR. GUTTMACHER: To be honest, I don't know all the ins and outs of this, but you can imagine that it would be quite complicated and would have repercussions beyond NIH per se, and would be something that would have to be, even to the degree that it's doable, that would have to be legal counsel and other advice, because this is not a clear-cut, slam dunk that of course the NIH can just do whatever it wants to do in this area kind of thing. But I think in terms of recommendations to the Secretary, it would be feasible certainly to call the Secretary to ask the NIH and other federal agencies to look at their abilities to do this and to consider doing so under certain criteria, et cetera, et cetera.

DR. LEONARD: Well, it's kind of in stark contrast to look at what the U.K. did with Myriad and how the U.S. just kind of laid down and - I'll be polite - took it.

DR. GUTTMACHER: I don't think that's a dysfunction of the difference between the NIH and U.K. funding institutions.

DR. LEONARD: No, no, no. It's not, and I didn't mean to imply that. But looking at the system, why did we as the U.S., why do we allow Myriad to be the sole provider of a medical service that's important to a large percentage of the population of the United States when we've had statements made by multiple people that testing should be done locally, that that's in the best interest of patients and patient access, and I'm not targeting you.

DR. GUTTMACHER: I would think that the answer to that question comes from beyond the NIH.

DR. LEONARD: Right, right.

DR. GUTTMACHER: But I certainly share the view that it's an interesting question.

(Laughter.)

DR. EVANS: I think Michael Amos is next.

DR. AMOS: I think the answer to your question, Debra, is that we operate under a free enterprise system, and we have rights under the Constitution to do that. One of the things I'm a little concerned about is that we're operating in a little bit of isolation here, because we really haven't heard from industry. I think in order to be fair, in order to be balanced, we need to hear from folks other than - I mean, I have the greatest social concern myself, but at the same time I think that there are certainly important economic issues that need to be taken into account when you start talking about changing policy to control industry.

DR. EVANS: Yes, we did actually have a representative from Perlagen who came to speak. We have tried. I think your point is really important, that we have to be very balanced here and we have to take into account industry, and we did have somebody from industry come and present, but we could certainly work on bolstering that.

DR. LEONARD: But one of the problems is there are all these polar opinions, and how do you get an opinion that can balance everything? So there are economic implications of patented health care testing for health care economics. So how do you put all this together? I guess that's what we're trying to do. So you get an industry rep coming, you get a health care rep coming, you get a patient advocate group coming, but how do you put it all together into something that's reasonable and isn't going to hurt one group and yet protect those who need protecting?

DR. AMOS: I think, actually, the FDA is really good at doing that.

(Laughter.)

DR. AMOS: Steve? We haven't heard from Steve at all.

PARTICIPANT: It would be a SACGHS meeting without Steve.

DR. GUTMAN: We'll develop a guidance document to take care of this.

(Laughter.)

DR. EVANS: I would also point out that on our task force, Emily Winn-Deen is from industry, and Marla Aspinal is from Genzyme. So it's very important to us to have the industry perspective because there are many facets to this.

So again, part of this is just to kind of pique people's interests, and appetites will be struggling with these same questions in the task force and maybe calling on some of you all again for further advice.

Finally, did the international roundtable session provide sufficient information regarding approaches of other countries, international organizations, and what other information, more importantly, what other information might be critical for our information gathering process?

Gurvaneet?

DR. RANDHAWA: In response to that second point there on that question, I'm not sure - and this speaks to just my (inaudible) of this field. I'm not sure I've been totally clear as to the utility of patents in promoting innovation. I don't know that the case has been strongly made. Certainly I don't sense a decrease in the number of biomarkers of the diagnostic tests that are coming into the market, be it for predicting cardiovascular disease or other diseases. Again, folks here in this roundtable might know this better, but I don't think most of these are actually patented, or licensed for that matter, but maybe they are.

So it would be useful for me at least to understand how many of the diagnostic tests actually need patenting, are patented, so I can understand the business case for innovation. To what extent does patenting actually get to that? I don't know that that connection has been made.

DR. EVANS: Actually, that's really a focus of Bob Cook-Deegan's group and the types of case studies they're going to be doing and the data that they're collecting. So that is actually a major goal, to try to figure out what data exists. Now, much of the data is simply temporal associations. Here was the Bayh-Dole Act, and then we see an increase in patent applications by universities. Certainly one can infer causation, and in that case probably very reasonably. But one of the ongoing efforts of this committee and of the task force, and by commissioning the folks at Duke, is to really address exactly that, what data can we get that really shows causation.

MS. SAMPOGNA: Just a really short comment, Mr. Chairman. In fact, at Duke there's also Wesley Cohen and John Walsh who actually are doing quite a lot of study in this field in terms of innovation and the role, and it's actually very interesting because they tried to do it from a higher level than Bob Cook-Deegan and his group do in the sense of Bob looks more at case studies and Myriad and HER and those types of things, and Wesley and John try to look at it in a more systematic way, a more high-level way. So it may be useful for this committee to actually look at that body of knowledge in a coherent manner because they might actually bring up different elements that might be of interest.

DR. EVANS: That's very valuable and I think we should, as a task force, look into their work and maybe even get them to come and discuss things.

I would ask, too, what other speakers, what other organizations that the committee as a whole might think they would benefit from.

DR. FITZGERALD: I would just like to ask our panel, we heard today a bit about TRIPS and things like that, but my wonder is do we need to hear more about the role of the WTO certainly from an international perspective? I mean, I don't know. I just don't know how influential you think they're going to be in how all of this works out in an international forum. So I'm just curious.

MR. BARTON: Let me start an answer to that one. I think 10 years ago it was the WTO you needed to hear. I think now it's WIPO. There are currently patent harmonization discussions going on in WIPO. They have broken down, broken down primarily on differences between the U.S. and the developing countries, but that is one of the contexts where law is potentially made, and in that context it will be made by essentially patent office representatives plus senior executive committees who, on the whole, will be more pro-patent than the rest of the society. Certainly within this country, the key decision making centers include the Patent Office, the CIFC, the Supreme Court, the Congress, and the U.S. Trade Representative, and they all have

different policies and different goals. As I go international, I think at this point it's going to be less the USTR and the WTO than it is the Patent Office at WIPO, although there will be coordination and the WTO will draw some lines and there will be plenty of politics between them.

DR. EVANS: Okay. I think, Mike, did you have something? No?

One more comment. Steve?

DR. TEUTSCH: We all know that innovation is obviously important. Patents not only protect that but stimulate that, but we also know that these innovations are driving a lot of the increases in health care costs. I don't know whether it's here in this international forum or another forum where we're going to be looking at some of the tradeoffs in terms of the broader health care system. I think some of the things that Deb was getting at is because we don't have good social decision making for these kinds of things, like we heard in the NHS and how they handled the situation. It's really a matter of the nature of the social contract.

The patent system clearly stimulates the private sector approach to this. I'm part of the private sector. My employer appreciates that because I get a lot of advantages out of patenting drugs. But I think there is something within this innovation that we then need to strike that balance that we heard about, and I don't know where we have that dialogue that sounds like we probably need to have, and I'm not sure who we bring in here to talk about that.

DR. LEONARD: One of the issues that needs clarification, and there's a study out there showing that you don't need patent incentives for diagnostic development innovation, because once a sequence is known and a mutation is identified as related to a disease, and if that's a prevalent enough disease, laboratories will start doing that testing using prior art with no patent incentives whatsoever. So I think that the diagnostic testing - and I say diagnostic but genetic testing in general is what we're supposed to be looking at, and we have to come up with ways of allowing that to happen in the innovative way that it does at academic medical centers across the United States and wherever it happens, the large reference laboratories and everything else, without inhibiting the things that do need to be protected, like pharma development or gene therapy and things like that.

DR. TEUTSCH: Right, and can I just follow up really quickly, because what you then have is multiple places where tests are available and can be done, and you create a different kind of marketplace than you do under a patent protected kind of a marketplace, and that has different financial as well as access and other kinds of consequences.

DR. EVANS: Yes, that's probably a great place to sum up. I would sum up with the theme that I want the committee as a whole to think about.

Dr. Straus, did you have a comment?

DR. STRAUS: Before you summarize, the last occasion, if I may.

Number one, I've heard the intervention about the NIH and how NIH should act and how should it use its power in, let's say, influencing the form of licensing. I would strongly urge you to really think about the entire complexity of this issue. If there is something like the Cohen-Boyer technology or monoclonal antibodies and similar things, you will easily get licensees taking a non-exclusive license, and everybody who is reasonable will only offer a non-exclusive license.

But then you have other cases where the risk is such that you cannot license without an exclusive license. It's not a question that you just like to have a chunk of money from the very beginning. Things are much more complex. And don't forget that Bayh-Dole had some very deep roots and reasons for that. There were 40,000 U.S. patents held by publicly funded organizations, not used, and that has changed. It's not only the increase in patent applications from publicly funded institutions, but it was before very similar.

I have been quoted a couple of times because I said that in the National Academy of Sciences some 10 years ago there was not such a big difference between the Soviet Union and this country. In both countries you had the opinion that what was publicly funded had to be available for everybody, and that doesn't work. So that's number one. Please don't take any rigid, non-flexible decision because that is not an advantage.

Number two, the TRIPS. I a little bit disagree with my distinguished colleague from Stanford. At WIPO, I do not believe that there will be any substantial development progress because even the developing countries now have detected that WTO is probably the more powerful organization because there they can pressure Americans, Europeans and Japanese. But because that point has been made this morning, the TRIPS and GATT, which means the new world economic order, works much better for the developing countries, including India, China and many others. If you take statistics, there is no doubt there is a lot of technology transfer, a lot of foreign direct investment, a lot of move which you would not have without TRIPS and GATT, and I'm just trying to make this point here because also in your country, in certain circles you may have the feeling that this is something working against the developing countries. It does not. It is overall to the benefit, even in the case of Africa. If you take the statistics, that's quite clear.

The last point, of course, is that it's most complicated how to balance the economic interests of two equally important systems, in your country for instance, meaning the health care system with enough innovation in the area of pharmaceuticals. I think there is no clear recipe for that, but it is quite clear that at present internationally, health care systems like in your country, like in all countries, are subsidizing the Australians, maybe even some neighbors here to the north, because yes, it's very simple to say everybody has to have access to the drugs, and who is financing that, subsidizing that? You, us, the Japanese. I mean, that has to be taken into account.

To the extent, as Myriad is at hand, I don't know what John Barton would say to that. I would say that an eBay decision would be very well imaginable, that if Myriad would not give licenses, would not get an injunction, will get some reasonable royalties, and that's probably something that you would also imagine as a balance.

Thank you, and sorry for interrupting the intra-U.S. discussion.

DR. EVANS: That's great, very valuable comments. If you want to finish, Dr. Barton -

MR. BARTON: Am I allowed a response?

(Laughter.)

MR. BARTON: First of all, I think your point about who pays for innovation is absolutely crucial. I mean, one of the clear things that's happening is the United States first, and then to a significantly lesser extent Europe and the other developed nations are paying for the cost of pharmaceutical innovation. I don't know what the numbers are in genomic diagnostic innovation,

but nevertheless the rest of the world is free riding on us in pharmaceuticals. You're absolutely right.

But I'm not at all convinced that TRIPS is that good for the developing countries. I mean, the standard argument -

DR. STRAUS: Together with GATT.

MR. BARTON: GATT is good, no question.

DR. STRAUS: You cannot separate them.

MR. BARTON: Well, the question is whether or not the whole balance came out. The extent of royalty in the United States has increased significantly, particularly from Canada, and the extent to which foreign direct investment was encouraged is, at the very least shall we say, a matter of doubt. It's no question that it was one of the key issues at the time of the debate, but it is not at all clear to me that the nations which have actually received the foreign direct investment have strengthened their IP systems that much.

But with GATT, with the rest of the system, I'm happy to agree. Then there's no question there's a balance. We'll stop at that.

DR. EVANS: So I just want to sum up here. I think one of the most valuable things to come out of this, at least for me personally today, was further confirmation of something that's been emerging as the task force deliberates, as the full committee deliberates, and I think that again, as I mentioned earlier, is the need for nuance and the need for distinction between, for example, diagnostic testing and how that's contrasted with pharmaceuticals, drug development products. Really, I think that Dr. Barton's comment in his sixth slide in the Nuffield report is the explicit theme that to the extent possible, distinguish the sequence as information, kept unpatentable, from the embodied sequence as a chemical, which would be patentable. Now, whether that's patentable, non-patentable or licensed exclusively or non-exclusively, et cetera, is a matter for some deliberation.

But I would just ask the committee as a whole to think along those lines because I think we're all in agreement that our major goal is to look at issues with regard to DNA diagnostics, and as Debra brought out, they're different from issues regarding DNA as drug development.

That really is the end of our discussion. We do have a timeline here that I don't think we need to spend much time with the whole committee going through. Suffice to say that we do have a timeframe, we're trying to adhere to it, and I'm shooting ultimately for a draft report to be presented to SACGHS in the fall of '08.

I want to give a hand again to our speakers, who were fantastic.

(Applause.)

DR. TUCKSON: And can we get a hand for Jim and Yvette?

(Applause.)

DR. TUCKSON: Outstanding. Thank you all very much.