Patents and Licensing Session
Question and Answer

DR. TUCKSON: David, two questions. One, the relationship between the international granting of a patent and the United States granting of a patent, regardless of the process and the criteria being different, does any one trump the other? Is there any relationship? If you get a patent in the United States or a patent in Japan, does it matter?

DR. KORN: I think the answer to that is that generally the international community will respect a patent from Japan, Europe or the United States as valid. However, as you well know, in Western Europe at least, there has been strong pushback on some of the BRCA patents for various reasons, and at least to some extent the action in Western Europe has been articulated as public health access cost stuff. It hasn't really gotten into the fine points of patent law. It's simply been that this is not in the best interest of the health of the citizens of our country. The actions of the European Patent Commission, however, have been, in fact, very technical in terms of their actions against some of the BRCA patents. They have not been based on public health at all. They've been based on things that are normal parts of patent litigation.

So the advocacy is public health-based, access or whatever. The action of the patent authority in Western Europe has been very limited to the technicalities of patent law.

DR. TUCKSON: Okay, because it would seem that with the globalization of everything today, it would seem to be a very important reality.

Secondly, and I think the answer must be no, but since it wasn't talked about at all, was there any look at the relationship between granting of patents and any escalation in health care costs and the expense of health care products?

DR. KORN: No, there wasn't.

DR. LEONARD: Reed, I think Emily has information on your first question.

DR. WINN-DEEN: I just wanted to say something in terms of someone who manufactures a test kit for sale. If there is a U.S. patent and you make, use, or sell something related to that patent in the United States, it covers you worldwide. So I can't make a product to sell in Europe or Japan or Timbuktu in the U.S. if there's a U.S. patent that covers it. So it does have, in some cases, a global effect, particularly when you get into the concept of making test kits rather than providing test results.

DR. TUCKSON: Very quickly, if somebody has a patent in Japan for something, can you sell a product in the United States that is patented in Japan?

DR. WINN-DEEN: If I don't make it in Japan, as long as I completely stay out of Japan, I'm okay. But if I either make, use, or sell anything in that country, it's covered by that country's patent.

DR. TUCKSON: And is this another example where the United States -- I mean, do other countries play the same game, or are we basically, as sometimes we might do, say we're going to do it the way we're going to do it?

DR. WINN-DEEN: Well, I think what we're doing is we're sort of shooting our own industry in the foot because we have a more broad interpretation, and so where in the U.S. a gene patent might issue, which means that, say, any U.S. company except the patent holder can't make a test for that, a company in Europe based in wherever can go right ahead and make a test kit, sell it anywhere in the world except the U.S. So we do, from a commerce point of view, hurt ourselves by having this differential with Europe and Japan.

DR. LEONARD: I would like to ask David a question. It was my understanding that when NIH gave the charge to NAS, the clinical aspects were included in the request, if you will, but then when the charge went to the committee, you clearly stated that the emphasis was on the research and innovation impact and not on clinical practice. So does the paucity of recommendations related to that, are they related to the charge that the committee was given or the inability to reach consensus? Because within the report there's a list of six bullets that basically identify clinical areas where there are concerns that the committee had, but could they not reach consensus on how to address those or was that not their charge, and so they didn't make specific recommendations?

DR. KORN: Debra, you know, I don't remember. I must confess, I just don't remember the exact charge that was delivered to us. But what I have is what the committee staff gave me for your slide on the charge, and it doesn't mention clinical or public health issues. So if this is accurate, then this is what it was.

Getting the six bullets into the final report also consumed a fair amount of energy. I just have to say it didn't flow naturally. It was kind of forced in there because some of us just felt strongly that the report had to acknowledge those issues, and in the end we were able to let it stay.

DR. LEONARD: The six bullets we're discussing on page 148 of your book. I think they're also at the beginning as well. But these were the issues that were identified by this committee as being clinical impact issues.

DR. KORN: Right.

DR. LEONARD: And we'll get to this also later on.

DR. KORN: But the recommendations were as far as the committee could go to achieve consensus, and that's what they are.

Can I just make one other point? There have been a number of recent legal cases that you all might want to be aware of that are kind of related to this topic. One of them was a case in the circuit court last year that upheld the utility criteria of the patent office. So the criteria were published in about 2000 or 2001, and it took this long for a case to be litigated challenging those criteria, and in the one case that has been adjudicated to date, the court upheld the patent office's criteria.

There was another case decided by the Supreme Court this year called Integra that strongly reinforced the validity of a research exemption for work that is leading toward an FDA application, something that's going to go to the FDA, and that was highly contested by the other side that wanted that research exemption also narrowed down the way the common exemption was.

There is a case before the court right now that's very clinical that involves a claim to owning a thought process. In just 30 seconds, it involves the use of a method to measure blood homocysteine, which has correlates with a bunch of things, and the patent says that if a physician receives the results of this test and thinks that they may suggest a Vitamin B deficiency, that that thought is a violation of their patent. So we ain't seen nothing yet in terms of that part of the law. That case is called Metabolite, and you can follow it on the Supreme Court docket.

DR. LEONARD: I'll have information about that also in my presentation.

Any other questions?

DR. LICINIO: I have a comment, which is that I hear this from both sides and get a little confused. So on the one hand you hear the explanation that someone may be a postdoctoral fellow or junior faculty struggling, has no resources, and wants to investigate something important, and the person can't because of the obstruction of all these patents, and that the research exception should really be there. On the other hand, when you hear from the companies, they say we are a small little company. Harvard University is not an ivory tower anymore. It's a corporation. It has $26 billion in endowments and makes more money than we will ever dream of making. So why don't they have to pay us for what we invented? So you hear one side, you hear the other. Who is really struggling? Is it the small biotech company versus the rich university, or the other way around?

DR. KORN: That's a fair question. The problem with the research tools is that, unlike a company, a large research university will often have thousands of faculty, each pursuing his or her own research direction, and often the need for a reagent or a tool sometimes is premeditated. That is, you know that if you're going to do something, you'll need something, and I suppose you could argue that one could make the arrangements necessary to get it. But often the need for something arises very spontaneously during the course of the research, or you hear something at a seminar or a meeting and you come back to the lab and you say, gee, let's try that because it might be the breakthrough we're looking for on this problem, and there's a kind of a spontaneity and a non-planned quality to a lot of basic research that would be exceedingly difficult to put into patent clearance process.

A company has a centrally managed research plan. So they know up front what they're going to be doing, and if they want to check on patents, they have plenty of time and a lot of lawyers and they can do it, but for faculty members to have to worry every time they get a bright idea that somebody might own this antibody or this animal or whatever, this enzyme, it would be exceedingly stultifying of research progress, I think.

That doesn't mean that people who invent and market and research tools are not entitled to make money from them. I'm not arguing that at all. But somehow there needs to be a mechanism. For example, NIH in past years has negotiated on behalf of NIH and its awardees with the makers of important research tools a license agreement that is negotiated in what NIH regards as fair, and that agreement supposedly covers all the awardees. So, for example, the oncomouse supposedly is covered by such an agreement. There's a genetic recombination method, the CRE/lox mechanism, where again NIH said, look, this is really screwing up research for us and our awardees. We've got to make a deal with the owner, Dupont in one case, and they did. They negotiated on behalf of the research community.

So these things are perfectly good ways of making sure the owner gets money and the research is not screwed up.

DR. LEONARD: Agnes?

MS. MASNY: Dr. Korn, I just wanted to ask to whom is this report given, and do you foresee any actions on the recommendations that you have listed in the report? Lastly, is there anything that this committee could do to take up any actions based on your recommendations?

DR. LEONARD: I'll intervene, if you will. At this point maybe, Francis, you want to make a comment in that there has been a committee formed to respond, take action on, decide what to do with this report. So, Francis, do you want to update the committee on that?

DR. COLLINS: Sure. Thanks. We appreciate very much the hard work that went into this report and the leadership of Dr. Tilghman as the chair and the dedicated service of all the people who participated in what was clearly a very challenging set of questions with no easy answers. While I'm sure various people will come down in different places about, gee, I wish you'd been a little more aggressive here or a little less aggressive there, I think the committee took their charge very seriously and put a lot of hard work and time and effort into it.

The report now does come back primarily to NIH as the sponsors of the initiative, and Dr. Zerhouni has reviewed this report with great interest, certainly welcomed I think a number of the recommendations, and realized that some of them have implications, if something is actually going to happen, for what NIH needs to do as far as their own policy decisions. So there is a committee that Dr. Zerhouni has formed to review these recommendations, all 13 of them, and to develop a response to bring back to him in order for him to decide exactly what steps to take in order to make sure these recommendations actually lead somewhere.

I am probably not in a great position to precisely say what the timetable of that review committee will be, but I can tell you that they are certainly vigorously looking at this, have been at it already for some time. So I think NIH is taking this with great seriousness. We see this as a potentially very important issue. There continue to be issues surrounding patents and licenses that are popping up all over the place. In fact, maybe, Debra, with your permission, right after the lunch break, I'd like maybe five minutes to tell this committee about a specific example that relates to the GAIN and GEI initiatives, because I would really be appreciative of your reaction to a strategy we've decided to take in those instances to try to make sure as much of the information as possible stays in the public domain, and it's a strategy that I think is fairly unprecedented. So we'd be interested in your response, if you'd have a few minutes for me to say something about that. But I don't want to do that right now. Thank you.