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## Discussion following the Remarks of Dr. Arnold Naimark

Discussion

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introduction of hybrid products based on convergence of technologies (nanotechnology and biotechnology) may raise new issues.

Our study involving a major field of innovation (gene technology), an important sector of society (health) and a key modality of social control (IP regime) illustrates that the processes involved in innovation do not incur in a vacuum. They are imbedded in a constellation of social, ethical, economic and legal frameworks that vary from country to country and determine how the balance between the benefits of innovation and its social cost is struck.

Although discussions about innovation tend to focus heavily if not exclusively on technological innovation, it is important to keep in mind that social innovation is also critical in improving health status - not only in its own right but also in its interaction with technological innovations. The particular challenges associated with biotechnological health innovations are part of the much larger overarching challenge of how to create the capacity to adopt beneficial innovations in already heavily burdened health care systems. Meeting this challenge fully will require more than refinements of an IP regime. It is also likely to require new institutional mechanisms and perhaps new organizations – but that is a topic for another occasion.

Countries facing these challenges have much to learn from each other and much to gain through active bilateral and multilateral endeavours. I am grateful to the organizers of this conference for the opportunity to participate in the bilateral enterprise this conference represents.

#### DISCUSSION FOLLOWING THE REMARKS OF DR. ARNOLD NAIMARK

MR. NARD: Given that Dr. Naimark is a panel of one, maybe I could exercise the moderator's prerogative to say a few things before we open it up.

Someone like myself who focuses much of his professional time on patent law, there is a wonderful comparative advantage between us. You bring the medicine and the science and a healthy dose of the legal stuff, I must say, where my relative ignorance of molecular biology will probably manifest itself in the next 25 minutes.

But I can bring some of the patent law to it. Let me say this: I think it is important to distinguish between pharmaceuticals and biotechnology. And I think in the patent debate that when it comes to the end product in the pharmaceutical industry, most all policy makers would agree that patent law has a very strong role to play.

In biotechnology, where you are not dealing with small molecule chemistry, you have so many research tools and upstream research that we really don't know what's going to happen with them, but we know they have some use.

And so if you look at it sort of as a developmental system where you have upstream research on one hand and on downstream you have the product itself, that you could go to your local pharmacy and your doctor could write a prescription, the question is: Where on this spectrum does patent law fit in?

Everyone agrees it fits in down here. Where the debate is: What is patent law's role upstream or midstream? So what you have nicely demonstrated when we are talking about genes and proteins there is a controversy there because if you interject exclusive rights upstream, then you create higher transaction costs.

Can we rely on patents to license these products efficiently to get downstream in an optimal way? So that is much of the debate. So when you talk about research exemptions and things of that nature, that's really what we are talking about.

You can talk about it downstream as making the end product, such as antiviral and AIDS medicines, accessible, but that's not really what a debate is in terms of IP service. That's more of a public international debate.

So with that in mind, let's have some questions.

Henry?

DR. KING: Yeah. I had a question: Dr. Naimark, the Government helps finance this research... who determines the price for commercialization of this very important research? Is it the Government or the private party, or how do they work it?

Is it the Government or the private party, or how do they work it?

DR. NAIMARK: Who determines the amount that was invested in the research by government or how it should be valued in pricing the ultimate product or process?

DR. KING: How it should be valued.

MR. NARD: What the consumer will pay for it.

DR. NAIMARK: By and large, the private sector should determine that.

DR. KING: Even though the Government finances it?

DR. NAIMARK: Yes, even though the government may have financed the research. There may be circumstances, unrelated to the issue of who financed the research, where governments may be prompted to intervene in the pricing of novel patented products. In Canada, for example, public concern about drug prices led the Government to introduce compulsory licensing of patented drugs in order to stimulate competition as a means to control price.

When compulsory licensing was removed from Canada's Patent Act in order to meet NAFTA requirements, the Canadian government, responding to public pressure to control prices, introduced a mechanism, the Patented Medicines Prices Review Board. The Board has the authority to monitor prices and set them at an acceptable level within the range of prices being charged internationally using data from a reference group of six or seven industrialized countries.

This mechanism doesn't help in dealing with the prices of increasing numbers of new and very expensive drugs coming onto the market or which international pricing norms are not available.

To illustrate, I sit on a cancer agency board. Our drugs budget will increase by 60 percent this year to cover just five new cancer drugs. Dealing with the cost impact of this trend for both public and private providers is a huge challenge in both the United States and Canada. Sooner or later, there will have to be some serious discussion between the payers, both public and private, consumers and healthcare providers to determine how best to deal with this contentious issue.

MR. NARD: If I may add, in the United States, the legislation referred to is the Bayh-Dole Act, which was passed in the 1980s, allows research universities like Case and nonprofits to keep or have patent rights in federally funded research. So your question implies sort of a double taxation.

So we pay for it to research with our tax dollars, and then we are going to grant Case, let's say, a patent on research that comes out of the medical school. Should the Government intervene and set those prices? The answer so far has been no.

Let the market take care of itself, and the spillovers from the legislation are okay because we are going to have startup biotech companies create an increase in the economy as a whole, and consumer welfare would be enhanced, and the evidence for that certainly in some parts of this country have been pretty good. While it has worked [in some parts of the country]; in other parts it has not worked so well.

Next question.

DR. BARBER: If I understood you correctly, you said one of the requirements of patenting in this sort of area would be the identification of an area of application or use. When you are patenting, is there any requirement for that idea to have already got some sense of safety and efficacy, or is it fairly open?

DR. NAIMARK: Not necessarily safety because in the case of products that might flow from the patent that impact health or safety, they have to go through regulatory approvals, clinical trials, for example. So you might get a patent on a molecule.

You might identify the kinds of uses to which that molecule might be put for diagnosis or therapy, but you do not at the stage of patenting have to do any of the testing of its ultimate safety and so on. So that comes later in the regulatory process.

And it is that later phase that, of course, distinguishes the impact of patenting and licensing on ultimate costs and prices.

So most of the cost comes at the second phase, namely, meeting all the regulatory requirements. And you have to, therefore, distinguish between

different kinds of biotech knowledge-based inventions, things that are subject to rigorous and extensive regulatory requirements and high costs.

Therefore, you need long periods of patent protection versus things like genetic tests or some other things where you do not have to meet the same costs or regulatory requirements, and there the question comes up: Does a one-size-fit-all patent term make sense in that kind of environment?

MR. NARD: Anything else?

MR. CRANE: Can you get this report on the web site?

DR. NAIMARK: The paper?

MR. CRANE: The paper.

DR. NAIMARK: Yeah. It needs a bit of editing, but I will send it by e-mail to someone at the Institute, and they can get it up.

I arrived from Europe, and I didn't have time to pick up all my bits and pieces before getting here.

MR. NARD: Thanks, Arnold.

(Session concluded.)