Comparison of the Patent System of the U.S. and Select Countries
Bhaven Sampat, Ph.D..

DR. EVANS: Our next speaker is Dr. Bhaven Sampat, who is an assistant professor at the Department of Health Policy and Management and the International Center for Health Outcomes and Innovation Research at Columbia University's Mailman School of Public Health. Dr. Sampat's research centers on the economics of biomedical innovation, the law, and the economics of the patent system and science policy. He's currently the principal investigator on a Ford Foundation project examining patent system reform in developing countries, and he created the first freely searchable database of post-TRIPS Indian patents and applications.

Welcome.

DR. SAMPAT: Thank you very much. I stand here before you somewhat timidly because, as the introduction suggested, much to my mother's dismay, I'm neither a doctor, a lawyer, or a scientist, but a mere economist. Much of my knowledge about some of the issues relating to genetic testing was acquired over the past few hours.

(Laughter.)

DR. SAMPAT: I try to do empirical work on patenting, and what I'm going to show you today, much of what I'm going to show you today is data on DNA-related patenting in India, and then also some discussion more generally about the political economy of patent system reform in developing countries. I think that discussion will be relevant for thinking not only about DNA patents in general but also about patents on genetic tests in particular.

One last caveat before I begin. Here again, the lawyers in the room probably know a lot more than me, so I'll just sort of set the stage or fill in the blanks and correct me when I'm wrong during the Q&A. And then along the way I'll also say a few things about U.S. patent system reform in the spirit of trying to draw some lessons from India and from just innovative thinking about patent system design worldwide for the United States.

Finally, I was asked to point out that the slides I'm going to show you now are a subset of the slides you have in the handout. I thought I was over-anxious this weekend and I would never get through what's in the handout in time, so you can read that on your own time sometime.

Okay. As many of you know, the 1995 TRIPS agreement, Trade-Related Intellectual Property Rights, negotiated at the end of the Uruguay Round of the GATT, required developing countries, including India, to "modernize" their patent systems. Basically, TRIPS led to an upward harmonization of international patent laws, meaning that countries were basically compelled to make changes to their patent laws to make them look more like those of developed countries, and in particular the United States. This led to a number of changes in India and other developing countries, including enacting a minimum patent term of 20 years; not allowing countries to discriminate across fields, so countries like India and Brazil previously didn't protect product patents on pharmaceuticals and they had to in the post-TRIPS era; and a range of other things. But generally, the notion is that patent laws got stronger and more in favor of patent holders rather than others in the post-TRIPS era.

So this is kind of interesting and has been a matter of controversy for a range of reasons. The first is just that historically all countries when they were developing basically did so by stealing intellectual property from other developed countries, including this fine nation. So for people like

me who grew up in New England, you hear these stories about Samuel Slater memorizing the mill design technology from England and starting a textile industry in Pawtucket, Rhode Island. Well, that was basically theft of intellectual property rights, right?

But anyhow, the point is that a lot of things countries did before to try to catch up to the technological frontier they can potentially no longer do under TRIPS.

More importantly, in India there is concern that the granting of product patents on pharmaceuticals will lead to increase in drug prices, particularly pronounced in the HIV/AIDS context where Indian generic producers are important or had been and continue to be important producers of lost-cost generics, both for Indian consumers and for other developing countries.

Finally, from the perspective of most bodies of economic theory, it probably makes sense for developing countries to have more lax intellectual property right regimes than those of developed countries.

So important set of issues now generally and with respect to specific fields like genomics or genetic testing, is what kind of patent system should developing countries adopt. And despite the general trend towards harmonization, it appears that there might be considerable room for maneuver under TRIPS, which goes under the rubric of TRIPS flexibilities, which would allow developing countries to design their patent laws to maximize the benefits from the new regime and minimize the costs.

So what are some of these flexibilities? This was one of the points in the presentation where I really should defer to the lawyers in the audience, but at least as I read it, there is some flexibility in how countries define "inventive step" in utility. Countries can, under TRIPS, have a research exemption; India does. In some countries, including India, there are restrictions on patentable subject matter. So, for example, in India, Section 3 of the patent law excludes from patentability scientific principles, abstract theories, products of nature, new forms of old substances without increased efficacy and, relevant for this audience, processes for medicinal and diagnostic treatment of human beings.

Now, as I think was pointed out earlier today, these are just things on the books in India. The extent to which these laws actually hold up as being TRIPS compliant in the actual meaning of these exclusions and standards of patentability is still very much up in the air in India and other developing countries. So, for example, Novartis is currently challenging Section 3(d) of India's patent law, the notion that you can't patent new forms of old substances, and it's not just about how the laws are interpreted but there's also this interesting international political economy going on, so recognizing the presence of TRIPS flexibilities, groups like PhRMA and the U.S. Trade Representative are pressuring India to enact TRIPS in particular ways. The Prime Minister of India is reluctant to, for lack of a better word, offend USTR and PhRMA because he's very interested in attracting foreign direct investment. The U.S. is entering into bilateral trade agreements with a number of developing countries to try to get them to enact a patent law stronger than TRIPS, the so-called TRIPS-plus provisions, and all this is being played out right now, and there's also not much in the way of case law in India right now. So in this context, the issue of what can be learned from India is a difficult one, but I'll try to say a few things about that in the end.

Now, before I get to talking about some data on DNA patenting, specifically let me just also put one other thing on the table, which is that all this stuff here is about de jure patent law, meaning patent law on the books, but there's also this issue of de facto patent law. So it's somewhere

between ironic and paradoxical and sad that at the same time developing countries are figuring out how to enact the new patent laws that were essentially forced upon them by developed countries, there's considerable concern that developed countries' patent systems may not be doing that good of a job either.

So some of you may know that Adam Jaffe and Josh Lerner wrote a book recently channeling their inner Sigmund Freud called "Innovation and Its Discontents: How the Patent System is Broken and How to Fix It." There are all sorts of examples of patents issued that probably shouldn't have been in this country. Some of the more amusing examples include over the last 10 years a patent done on a crust less peanut butter and jelly sandwich, a patent done on a method of swinging on a swing. But more importantly, the USPTO also issues patents in highly specialized fields, including genomics and genetic testing, that would overreach as blatantly to some of you in this crowd as the peanut butter and jelly sandwich patent does to a lay person like myself. Indeed, my own cursory reading of some of the more problematic genetic test patent episodes is that the issue was not just the patent per se but that the patents were overly broad and probably shouldn't have issued as such.

So the point is just that in thinking about the impacts of TRIPS on access to genetic tests in developing countries, even in the U.S. we need to recognize that it's not just about the patents but rather also about patent quality.

So with all that, what's going on in India post-TRIPS? First some general data, and then some data on DNA patenting. So I collected data on the 60,000 or so applications filed at the Indian Patent Office in the post-TRIPS era. This just shows the distribution of applications across the top 10 international patent classes, or IPCs. The thing that stands out here is that at the top of the list are A61K and C07D, which are basically pharmaceutical classes. Also well represented is C12N or microorganisms. Some of the genomic-related patents might show up there. There's also pictorial communication patents and things like that, which might be about Bollywood; I don't know.

So who are the big applicants in India? Hopefully you can see that better than I can on my screen. The top applicant in the post-TRIPS era in India is CSIR, which is a system of publicly-funded laboratories in India that do research in a range of fields. The second largest is Hindustan Lever, which is a consumer products company that does a lot of chemicals work. But what's striking about the list of the top 20 applicants in India in the post-TRIPS era is the prominence of multinational pharmaceutical companies.

So what about DNA-related patenting in India in the post-TRIPS era? Well, that turns out to be a harder question. It turns out to be hard to identify DNA-related patents in the Indian context first because the approach that's been pioneered by Bob Cook-Deegan and others involves looking at specific U.S. patent classes and then looking at specific keywords in claims in patents within those classes. It turns out that in India, they don't use U.S. patent classes. So that's one issue. But more importantly, at this point it's impossible to get data on claims of Indian patents in any large sample. It turns out to be really, really difficult. So all we have is information on titles and abstracts and priorities and things like that.

So I tried to get around this in two ways. As a first step, I simply looked at patenting in the set of international patent classes that Verbeure et al. characterized as corresponding to DNA-related patents in their European Journal of Human Genetics article. Now, what they did is they looked at all patents in those classes, and then they read the claims and figured out which of these are in fact DNA-related and which are not. I can't do that because I can't read the claims, so this is

going to be an over-inclusive list, give you an upper bound on DNA patenting in India, and that's problematic for a few reasons, and I'll try to show you another approach which gets around that in a second.

But based on this IPC-based measure, of the 60,000 or so patent applications filed in India since 1995, about 4 percent are in DNA-related international patent classes. The top 25 patenters in these classes account for a third of patents in those classes, and they include - again, if you look at who they are, you see the prominence of multinational pharmaceutical companies. That CSIR also shows up here fourth, and also the University of California, I believe, shows up on this list, having 20 DNA-related patents in India, which is quite interesting because I believe the University of California is the biggest patenter of DNA-related stuff in the United States.

So that's one look at it. The other way which is a bit more precise is I used data on priority applications in both India and in U.S. patents. So I started by just looking at all the DNA patents issued in the United States in issue years 2000 and 2005 using this search algorithm developed by Bob Cook-Deegan and colleagues for what is now the Duke DNA Patent Database. Then I looked back at the priority application data in all of those patents and then linked that priority application data up to any Indian patents. So any time you see a DNA patent in the United States, is there a related, sort of family member patent in India?

So if we just start with the U.S. patents, there are 3,800 or so issued in the year 2000. As a previous speaker pointed out, it's declining, about 2,700 issued last year, and then mapping them over to Indian patent applications, what you see is this, that in the year 2000, which is the first row, 41 of the 3,800 or so U.S. patents had corresponding Indian applications, or about 1 percent. By 2005, that number increases to about 2.5 percent. But a relatively small share of things that are called DNA patents in this country have corresponding applications in India, although the number does appear to be increasing over time.

It turns out you can also look at whether the things based on the same priority as the U.S. patents are patented or are applications or whatever in India. The vast majority, everything but one, are pending patent applications. So there's only been one DNA-related patent granted in India since 1995.

Now, because I don't know too many things, it's unclear to me which of these are on disease gene associations or genetic tests, but I'll just point out that the number is sufficiently small that if one were interested, I could hand them to someone here and you could try to read them and figure it out. I suspect the numbers are low, but that's just my own cursory reading of them.

Who is filing the DNA patents in India? Using this measure, it looks very similar. Multinational pharmaceuticals turn out to be pretty high or pretty disproportionately represented here. So these are all the assignees that have more than one patent application on DNA-related stuff pending in India.

Finally, given the prominence of academic institutions in ownership of DNA-related patents in the United States and the fact that a number of the policy proposals that are on the table here and internationally try to leverage the fact that academic institutions own some of the key IP, I also looked at the extent to which academic owners of DNA-related patents in the United States were more or less likely to file corresponding applications in India. It turns out that non-academic owners of DNA-related patents in the United States file for corresponding Indian patents for 2.8 percent of their inventions, whereas the corresponding number for academic owners of

DNA-related patents in the U.S. is 1.45 percent. So universities are, in fact, less likely to take out DNA-related patents in India.

A final thing before I wrap stuff up that I think is an interesting set of developments on the scene is that there has been all sorts of movement to enact Bayh-Dole-type legislation in India. Even though TRIPS is silent on this, there are all sorts of interesting academic entrepreneurship in India. Some of the impetus is coming from specific institutions, but Bayh-Dole legislation is on the way. To the extent that Indian academic institutions themselves are or someday will be important producers of DNA-related inventions, this is an important development to watch. If you just look at the top 20 Indian universities, this chart shows their patenting over time. The left bar is the number of USPTO patents they're filing, and the right bar is the number of patent applications they're filing in India. You see that using both measures, academic institutions in India have increasingly begun to take out patent applications. If we were to look at the extent to which they're actually taking out DNA-related patents, however, at least at this point you don't see all that much of it. So I'll just jump to the final bullet point here.

The top 25 Indian "universities" - and I have "universities" in quotes here because they include some public sector research institutes like CSIR - they account for a relatively small share of the DNA-related patents filed in India, at least based on the international patent class-based categorization.

So where does all that leave us? I focus here on India, but I'm going to take the liberty of talking a little bit about patent system design generally here as well since one of my charges is to provide some practical thoughts for the committee. Just to sum up, very limited DNA-related patenting in India thus far. One would have to actually look at specific patent applications and trace them through to know this for sure. My sense is that most of the existing genetic tests out there are unpatented in India and probably, given their priority years, will not be patentable in India, at least the stuff that exists or is widespread right now, which underscores the somewhat obvious fact that others have raised this morning that to the extent that there's an access problem in India, and I'm not sure if there is or there isn't, but to the extent that there is, it probably reflects other stuff as well. So one of the things that we hear in pharma, which I believe is quite true, is that patents are perhaps an important barrier to access to drugs in India, but there are all sorts of other barriers to access too, including things like poor medical infrastructure, poverty and things like that. That's not to say that the patent issues are unimportant.

A second thing, and this is sort of interesting in thinking about it in parallel with pharma, is that even if genetic tests were patented in India, I'm not sure that you would see prices being as high or access being as low as you might see in the context of pharmaceutical patents, and let me just expand on that a little bit. One of the interesting questions is why pharmaceutical firms are taking out patents in India, and if those patents issue what the impacts will be on prices.

From an Economics 101 perspective you say, well, they would price discriminate if these patents issue, meaning they wouldn't want to charge U.S. prices to India. But a number of people argue that, in fact, in effect they don't price discriminate, that they charge pretty high prices for AIDS drugs and things like that in India. Why is that? The answer to me is not entirely clear, but one plausible answer and perhaps the most plausible answer that's been given to me is that they're worried about creating arbitrage opportunities. They're worried about the drugs coming over from India to here. That's less likely to be the case in the context of genetic tests, which are less embodied in pills and things like that. So price discrimination, even if it doesn't work in the context of pharma, probably would work in the context of genetic tests.

At this point, there's very little evidence that DNA-related patents in India have impeded research or any clinical applications, but you hear every once in a while at these European economic history conferences what was the worldwide economic impact of the French Revolution; it's too soon to tell.

(Laughter.)

DR. SAMPAT: And that might be the case. We're looking very early in the post-TRIPS era. So who really knows? That notwithstanding, several policy options - India is in the process of implementing TRIPS right now, and several policy options could, I think, help limit future costs and would have little downside risk. So I'll just conclude on these.

Getting back to a theme I raised earlier, patent quality control is important. So it's not just about patents in the context of genetic tests but overly broad patents. In India, as in the U.S., we have a patent office where it's difficult to attract qualified examiners, technically competent examiners, because technically competent people want to do other things than be patent examiners in India where they get paid very little and don't have that great of a lifestyle. There's a huge backlog of applications in India, huge pressure to clear the backlog, and the infrastructure that patent examiners have for searching through prior art is very, very, very weak. So in this context, it won't be surprising if occasionally bad patents issue.

Now, India has something that's neat. We talked a bit about opposition this morning. India has a pre-grant opposition process so that anybody - well, actually, you have to have some sort of representation, but generally anybody who knows an Indian lawyer can oppose a patent after it's been published in the Patent Office Journal while it's being considered by the examiner, and there's also a post-grant opposition which can be filed by any interested party within 12 months after issue, and the grounds on which patents can be opposed include obviousness, non-patentable subject matter, anticipation, wrongful obtainment and things like that.

Now, opposition has had a number of notable successes in pharmaceuticals in India, though I put "successes" in quotes because it really depends on whether you're looking at it from the patient/activist point of view or from the pharmaceutical industry point of view, but a number of applications that have been filed in India and also filed elsewhere were in fact not granted in India because of this pre-grant opposition, yet patient advocacy groups are teaming up with generic companies and mounting these campaigns to oppose patents that they think would impose hard costs.

There are obstacles in India to opposition. One of them is that it's really hard to search Indian patents, or at least up until recently it's been really hard to search Indian patents which have been published in image PDF form. So it's really hard to go through 60,000 pictures and figure out which of these are worth opposing. Hopefully that constraint has been relaxed a bit.

At the same time, there are concerns about opposition in India. The pharmaceutical industry has argued that, in fact, the alliance between generics and the patient advocacy group is an unholy alliance in that you see groups filing serial oppositions one after another to the same patents to try to eat into patent life, which begins at filing date. So pharma, through the USTR, is trying to basically limit oppositions in India to post-grant. My own feeling is that that's not the way to go. To the extent that that is a problem, that could be fixed. For example, conditional and surviving opposition let's applicants retrieve any patent life lost through opposition, or as Mark Lindley and I have proposed to the United States, provide higher presumptions of validity to patents that have survived the opposition process, sort of gold-plate them. So the notion is that I think that a well

implemented opposition system in India could help prevent harms in India, and also in other parts of the developing world, and potentially in the U.S. as well.

Finally, in the case of public sector innovations, Bayh-Dole is on the way. Bayh-Dole in India is on the way I should say. As a number of people have rightly pointed out, the issue there is not about patenting per se, or not just about patenting per se, but about licensing regimes, and my proposal here is that India and other developing countries should resist the temptation to mimic Bayh-Dole as is, but instead think about doing things that can balance technology transfer and the need to generate revenue with other goals, and ways to do that include building research exemptions into licensing contracts; perhaps, as someone mentioned today, starting with the rebuttable presumption of non-exclusive licensing, at least for certain types of inventions.

Finally, a little shameful self-promotion, and this applies to both - this is a policy proposal that I think applies equally to the United States as well as to India. Recognizing that even for academic patents a number of the problematic cases in, let's say, the United States have been in a context where the ultimate patents that issued were too broad, again a patent quality problem, Beth Novak and I have argued recently that you might want to introduce some sort of a peer review system to review these applications. So it's similar to opposition except it's less formal and it's more diffuse.

Now, as some of you know, there is a community patent initiative that the USPTO started piloting a few weeks ago where firms like IBM and Microsoft have opted in some of their patents to open them up to a peer review process, because in the IT industry you also see these patent quality concerns. But that model relies on opt-in. But the NIH could tell all of its grantees, as a condition of taking money from us, you have to open up your patent applications to a peer review process, and you'd have to think about the right ways to design that and to implement it and things like that, but we think that that is something useful to explore not only in places like India as part of their new Bayh-Dole Act but also potentially in the United States.

Finally, it also has the virtue of, I think, being politically feasible because it would be kind of churlish for academic institutions to oppose this as they have opposed other movements toward patent system reform, like first to file, because they would essentially have to take the position that not only do we want patents but we want patents that wouldn't survive a process of peer review, which would be tough for academic institutions to do. So that's another idea that's on the table in the U.S, and we're trying to bring it to India as well.

That's it.