

## D I A L O G U E

# Discussion on Equity and Commercial Rights for Genetic Resources

April 29, 2009

**Moderator:**

**Richard J. Blaustein**

**Speakers:**

**Susan Finston**, Executive Director of the Access and Benefit Sharing Alliance

**Michael Gollin**, Venable LLP, and founder of Public Interest Intellectual Property Advisors

**Dr. David Newman**, Chief, Natural Products Branch, National Cancer Institute

**Dr. Leonard Hirsch**, International Programs, Smithsonian Institution

**David Hegwood**, former U.S. Department of Agriculture representative to the United Nations Food and Agriculture Organization

**Richard J. Blaustein:** Thanks very much for being here. I'm Rich Blaustein. I'm a member of the D.C. Bar Environment and Natural Resources Section. Thank you very much for coming for this conversation and presentation on Equity and Commercial Rights for Genetic Resources. I say great thanks to Jim Rubin for all the support. He's the co-chair of our Environment Section at D.C. Bar and I'll give him the microphone to say hello on behalf of all our different sponsors.

This will be about the fourth event connected with my own interest in the Convention on Biological Diversity (CBD) that the Bar has allowed me to do. In 2004, we had "The CBD in the U.S.A."; Hamdallah Zedan came down [from Montreal] for that and we had panelists, like Mike and Susan, who were on that discussion. I led another in 2008; Ahmed Djoghlaif came down and we had panelists David and Susan and Len Hirsch. Finally, I led one on international policy on ecosystem services, which connects with the Millennium Ecosystem Assessment focus of the CBD.

I have great appreciation for the Bar for allowing me to pursue this. Before I introduce the panelists, Jim, do you want to say anything on behalf of the D.C. Bar?

**James Rubin:** On behalf of the D.C. Bar, thanks for coming. Thanks to the panelists, speakers, and ELI for putting this together.

**Richard J. Blaustein:** I'll give the introductions one by one. The only point I'll try to make is that access to and benefit-sharing of genetic resources, issues of equity, and commer-

cial rights are quite large and compelling issues in the WTO [World Trade Organization], in the WIPO [World Intellectual Property Organization] forum, in the FAO [United Nations Food and Agriculture Organization], and, of course, in the CBD.

The only sort of backdrop I have about the CBD is that there was a decision. As you know, it was endorsed to have an international regime for actors in benefit-sharing and genetic resources during the World Summit on Sustainable Development (WSSD). And the most recent CBD decision came out of the Conference of the Parties (COP), Number Nine, which would have been in 2008. That was Decision 912, which had its seventh working group meeting in April; Susan attended most of the meetings in Paris. But the decision from the COP directed the working group "to finalize the international regime and to submit for consideration and adoption by the COP at its tenth meeting and instrument to effectively implement the provisions in Article 15 and Article 8(j) of the convention and its three objectives." We know that Article 15 would be biotech and genetic resources and technology transfer, the known indigenous traditional knowledge, indigenous people's right provisions.

So on that background note, we have a timeframe. We're looking at a working group discussion culminating in October 2010 at the COP in Japan.

I'll begin with Susan Finston, who has been a great help for all the meetings we've had on these issues. She is the executive director of the Access and Benefit Sharing Alliance (ABSA), an industry advocacy organization that seeks an enabling environment for sustainable commercial use of genetic resources and related traditional knowledge. She has a background in law and public policy and, particularly, in innovative life sciences in emerging markets. Thanks very much, Susan.

**Susan Finston:** Thank you. Rich has been very active on trying to increase the awareness of these issues. It's fascinating because the CBD always strikes me as: "What if they held a trade negotiation and nobody came?" We don't get the same level of awareness as in WIPO or WTO, even though in terms of U.S. commercial interest, this is probably, right now, the most salient negotiation going on. And as Rich said, there will be Operational Texts finished through the next two ABS Working Groups in the CBD, and it actually has to go to ministers by the end. In the CBD Treaty, there's a six-month period for review of anything that could potentially end up as a binding protocol. So really, you have 11 months between now and when operational texts will be fin-

ished. The key point that I would like to cover is the way that access and benefit-sharing norms have now really been well established across international soil and organizations, some of which Rich has already alluded to and how, in a sense, the ABSIR [Access and Benefit Sharing International Regime] people shouldn't be surprised.

People are going to be surprised, but they shouldn't be because it's been a heck of a long time in coming. There have been a number of COP decisions, even in advance of the WSSD in Johannesburg, but certainly the last two COPs have said we're going to do this. And now, Japan, as the host of Nagoya, has made it very clear that they're committed to having a successful adoption of something, whether it's an individual instrument, a series of instruments, something nonbinding, something binding. It probably will be adopted. Now, you've got a lot of countries that are committed to its success, and I'll go into that a little bit later.

The challenge ahead is that the greatest risk is from those governments that have the most to gain. Essentially, you sometimes get into a situation, either interpersonally or culturally, where you have people who want something so much that they can't stop themselves from creating circumstances in which they can't get it, and it's very difficult sometimes to recognize that the reality has changed. So for example, there is a tremendous resistance to even mentioning the Bonn Guidelines because they'll say: "Oh, that's a subterfuge to avoid a negotiation." But we're in a negotiation, so it's not really a subterfuge because we're already committed, and we're doing it.

I think the keys to success, and this is where I really have to take my hat off to Ahmed Djoghlaif, the executive secretary, as well as his two co-chairs, Timothy Hodges of Canada and Fernando Casas of Colombia, they are really trying to improve the level of trust and cooperation in the room. I would say that the level of success we've had so far almost defies expectations and conventional wisdom, and it's due to the very hard work of those three individuals and everyone who is supporting their efforts. That's really going to be critical going forward.

I think we saw a level of trust that was less in Paris than in some of the previous meetings. From what I can observe, Len Hirsch, who is also going to be speaking today, and others who were in the room for the whole meeting, can speak to that. But there just seems to be less trust and I think the length and the number of brackets in the operational text kind of reflects that.

And then the second thing that I think is going to be key to continued success may sound a little bit self-interested, but I really do think keeping business and industry groups in the room in a meaningful way is going to be critical because it isn't just the question of adopting something. It's the question of adopting something that can be implemented at the national level and internationally. And as I'm going to go through this in just a few minutes, I'll show you what has been adopted by the IBSA (India, Brazil, South Africa) countries or the BRIC (Brazil, Russia, India, China) countries, plus South Africa. It doesn't work. And we can name a lot

of other countries that adopted things that don't work, and I think that where that happens, it's because there's a lack of a connection to reality as to where the market is.

And so if we're not only going to adopt something in Nagoya but have it work, I think we have to have trust, we have to have cooperation, and we have to continue to have business in the room. I've been encouraged by the level of access business has been given, including two meetings that are relatively closed-door meetings, like the compliance expert group that I attended in January. But as we get to the clinches, I know it gets more difficult so that's going to be a continuing challenge.

Very briefly, what is the ABSA? It's a very focused, small advocacy organization. It's much, much smaller than groups like BIO, PhRMA, or ASTA or other groups, and it was just formed in 2005 to focus on these issues across fora, as well as in key capitals, bilaterally, including China, India, Brazil, South Africa, countries where really, we felt that these issues were very resonant, very important politically. We work closely with the ICC [International Chamber of Commerce] and other groups because we are small. One benefit to ABSA members is that decisionmaking is totally transparent. The board is open. The decisionmaking apparatus is open for anyone who is a dues-paying member, and we work closely—we play nicely—with our other industry groups so we try as much as possible to participate in ICC programs, etc. And I think it's been a good model so far in terms of how we can try to move the ball forward.

The interesting thing, which I didn't anticipate, is that developing countries look to the ABSA to provide timely, important, and accurate information. The value of ABSA to our members is obviously only as great as the credibility we have with developing countries. I've been pleased, as evidenced by the number of developing countries that participate in our side-events and come to our side-events, that we've been able to develop a good rapport with a number of developing countries, to build bridges, and, hopefully, to be able then to communicate industry priorities in a clear, and again, a transparent way.

One of the things we've done in the last year or so that has been valuable is we have put on our website and we have handed out in all the meetings ABS [Access and Benefit Sharing] negotiating principles, where we say in writing that ABSA members are committed to prior informed consent (PIC). We're committed to coming to mutually agreed terms (MAT) in writing. We don't believe that it makes sense for any company to go into a market where you can't do that under domestic law. In other words, we're not looking to go places where there isn't rule of law on these issues. And one of the red herring arguments that some organizations try to put forward is that industry doesn't really want to share benefits equitably, and we've really tried to dispel that.

The reality, as others today may point out, is that there frequently aren't monetary benefits and it's much better to get capacity-building or front-loaded research benefits and that's also something we've tried to point out and also, that patent disclosure is pretty much a red herring and a dead end.

So putting these things in writing and having them also validated by larger organizations that might not have been ready to have them out in writing when we work, I think, has been helpful in terms of advancing our role in the negotiation.

Just very briefly on the timeline. ABS originally came out of the CBD Treaty, which came into effect in early 1994. The United States signed it during the William J. Clinton Administration. Most people who are in here know probably that it was never actually put to a vote in the U.S. Senate. It came out of the Senate Foreign Relations Committee before the so-called Gingrich Revolution, with the majority among Republicans and Democrats but they knew that they didn't have the vote. And we have not yet seen the treaty list out of the U.S. Department of State (DOS) and if we don't know what the status will be in this Administration, obviously, there may be substantial changes than during prior Administrations. So far, though, the United States has signed it but has not ratified it.

Now, in the meantime, there has been kind of a leapfrogging of ABS principles across fora. So you could take a CBD that originated the idea, it's not necessarily in a number of fora anymore in the lead, in the sense that you already have the ITPGRFA [International Treaty on Plant Genetic Resources for Food and Agriculture], which has a multilateral system (MLS) for benefit-sharing. (And these slides will be available and handed out on the ABSA website and I believe also from ELI or the Bar Association.)

In the WHO [World Health Organization], there are very well-developed negotiations on pathogens, where you have public health experts trying to sort out the demands, which, on the developing countries' side, seem to be related more to access to medicines than royalties, although it's not always clear, and then of course, the IGC [WIPO Intergovernmental Committee] has developed a lot of expertise on the IP [Intellectual Property] side. There are continuing negotiations and TRIPs [Trade-Related Aspects of Intellectual Property Rights Agreement] councils called the CBD/TRIPs issue which has been twinned with geographic indication, which is problematic, but we don't really have time to talk about today.

And in 2009, as Rich pointed out, we're now developing Operational Text for the ABS international regime in the CBD. Obviously, the fact that you have—and I haven't even mentioned Arctic benefit-sharing and some of the issues in law of the sea. I mean, there are a lot of different organizations that have incorporated this. But the main point is that ABS principles are really very well established now as an international legal norm, and I think that's something that would be really beneficial for developing countries to see that no one in 2009 is out there saying: "Why should we do this? Why should we get prior informed consent? Why should we agree to mutually agreed parameters?" That's really not a position that I've heard any company take, so I think that it's very well established.

So we have now highly bracketed Operational Text, less so in certain areas like Objective and Scope. I brought copies of the draft Objective and Scope texts and you can see

Objective is really only three bullets and a little footer at the bottom, okay? Scope is longer. It's like a little more than two pages but you can see the outline of some kind of agreement in these. It's very different from Part III of the draft Operational Text where you have just pages and pages. Part III includes Access, Fair and Equitable Benefit Sharing, and Compliance. And the difficult thing there is you really have to determine how sovereign states engage with private companies that are responsible for generating the benefits and interacting with indigenous and local communities, non-governmental organizations, and research institutions. It's very, very complicated. It's even more complicated if CBD members take the position that governments are guaranteeing benefit-sharing because the governments aren't going to be involved in any of the transactions directly, to try to have sustainable commercialization, and I think that's where you get to the limits of mandate.

In the Objective and Scope, the main problems are language at this stage that goes beyond what Rich described as the language of the COP Nine ABS Decision itself from the top and language in other previous COP decisions, and, most importantly, the language in the CBD Treaty itself. You can certainly see through I and II (Objective and Scope), which was really the main objective of the co-chairs, that they've met their objective from Working Group 7 of having what really looked like some kind of international regime in ABS and having Objective and Scope mapped out. Yet to come is the Nature of the regime. And as David Miller from the DOS mentioned, this is really a key issue for a lot of CBD members.

Now, by Nature, it can get a little complicated. The Objective is, what is the intent? What are the main things we're trying to accomplish? The Scope is, what kinds of things are excluded? Recently, India changed its position, so for example, India is no longer claiming that human genetic resources are included, even though that's in their domestic law and that's in their WTO proposal, because they realize that goes beyond the scope of the treaty itself.

But the Nature is, what kind of regime is this? Is this a legally binding protocol? Is this gathering together nonbinding elements that come from other systems or is it referring, for example, to the FAO International Treaty? This is where the most important discussions probably will be had at the next working group in November in Montreal, because the Nature will really determine the kind of language that at least certain CBD members will be willing to accept in other parts. That's something where I think if people were going to focus on organizations, companies, NGOs, we're going to focus on one thing, it would be to better understand what are the issues involved and the Nature.

There are 3,000 brackets right now, okay? But as a former U.S. negotiator said, in about six months, you're going to watch these melt. So you cannot take heart in the fact that there are so many brackets, because by the end of Working Group 9, when it's really time, they will just melt away and also, in the Objective and Scope, one member of an LMMC [Like-Minded Mega Diverse Country] said, for example, the

Objective and Scope brackets depend on what's in Access and what's in Fair and Equitable Benefit Sharing.

So they cross reference each other and so some of them are duplicative, so maybe there are 2,000 brackets. That's still a heck of a lot of brackets and that's why there are no agreed definitions because there are such fundamental disagreements. One working group I went to in Montreal, I guess it was in November or December of 2007, the fear was that you're going on this train ride but there are parallel trains on parallel tracks that will never meet because of the number of brackets and the lack of agreed definitions. That's still a risk, and that's where this issue of trust and cooperation and reality check is very important.

So as I said, the Nature is really critical to a lot of issues, including what measures will be included on compliance and what measures will be included under Fair and Equitable Benefit Sharing. Access is trickier because we've seen a number of breakdowns in negotiations where governments like Brazil say Access is a sovereign issue that's covered by the treaty, and the European Commission says it's related to benefits. If we can't agree on Access, we can't agree on benefits. So I've left that off because you could take half an hour just on that one issue.

What you basically have is developing countries insisting that it be legally binding, that there be mandatory elements, and by mandatory elements, they usually mean the compliance element. And then you have Australia, Canada, the European Union (EU), Japan, Korea, New Zealand that do not accept, at least at this stage, a legally binding regime as the only possible outcome. But not Norway; Norway was the first developed state to jump to a mandatory regime. It's important to emphasize that the United States is not in the clinches. The United States is an observer and is not allowed in terms of the chair or drafting or other committees that are critical to what happens because we are not a member of the CBD.

So what do they mean by legally binding mandatory measures? They usually mean disclosure of origin—and Mike Gollin is going to talk about that in greater detail—certificates of compliance, which are indicated to be certificates that prove compliance with domestic regimes at the national level. And checkpoints, which I refer to as chokepoints because these checkpoints, at one point, almost sounded like they wanted a routine “stop and frisk.” I said: “Excuse me, but I don't know what's going on in Idaho on a good day and I'm not certain that I want to or there's any capacity to know what's going on in the Northwest or Midwest of the United States.” But then, they clarified that that's a marketing approval point, regulatory point, any point where a company is going to a government agency and of course—and this is also something I was pleased to see in Mike's slides—as soon as the costs of compliance exceed the commercial benefits, then you end up frustrating the effort that you're trying to promote.

What we see in the markets that have already implemented some of these things, there's tremendous uncertainty, chilling of bioprospecting, chilling even of conservation and some of

the efforts that I'm sure Len Hirsch, as soon as he gets here, will talk about. And essentially, if you have no quiet title, if you have no periods during a 20-year patent protection period, if you have no time when you can count on being able to invest and commercialize, we have seen investment really go down, and I've heard about this from entrepreneurs in developing countries. If anything, they already have a harder time getting capital than American companies so this makes it much harder. Anything that's hard for a U.S. multinational is harder still for an SME [small and medium enterprise]. An ABSA member that is an SME spent two years working trying to get a bioprospecting permit in Belize. Working together, we finally got it just down to the wire when she was about to just give up and move on to something else. So it's really hard for small companies in the United States and even more so overseas.

Under the Fair and Equitable Benefit Sharing, one of the big issues that's come up is technology transfer on a mandatory basis for a region or a set of countries, none of which may have provided the genetic resource or the related traditional knowledge because they talk about how *ex situ* genetic resources should also be subject. This is primarily the Africa group. They seem to be the farthest out in what I would call a parallel universe, let's say. It's hard to come up with a universe in which they think this would actually generate benefits. Sometimes, it's referred to as “benefit-sharing for every use.” And again, it's lovely but they're trying to reengineer human nature and the way the world actually works.

I really appreciate the title of this whole panel discussion, which is Equity and Commercial Rights, because what industry is looking for is very similar to what indigenous and local communities are looking for, and they frequently will come up to me after a site event or after an intervention and say: “Can we have a copy of that? We have the same interests as you do. We want to see predictability and transparency as much as industry. We want to see rules that don't change every time there is a government change, whether it's through election or any kind of other regime change. We want to have transparency. We really think nondiscrimination is important.” And I've had people from developing countries really push back and say: “We have to allow domestic countries to bioprospect. We don't have to allow your companies to.”

But then, the reality is our companies won't invest, because if you ever have to do it through a local company in some kind of a shell game, you're really risking your reputation, and it's not a good idea. I would never tell a company to go in if they can't go in through the front door. You really just can't do that. I mean, you end up on the front page at some point, and it looks horrible for the company. So basically, we're looking at a system that's durable and practical and can be actually implemented.

Now, in Brazil, Russia, India, China, and South Africa, they all have, dating back between four, five, 10 or more years—actually, China is the only exception. They just passed it and the regulations aren't in place, yet they all have disclosure of origin obligations. It has shut down both commercial and noncommercial bioprospecting in Brazil to the

point that they tried to launch a reform, but it got caught in the blender of debates over indigenous rights and I have been told it's not going to go anywhere, at least for the next several years.

In India, they've had much less than they should have. Russia should not be—it's in the title because it's a BRIC country—but Russia is the only country that doesn't have disclosure of origin requirements. And in China, they had a really successful benefit-sharing system. They have nearly \$20 billion of a \$60 billion global market in natural products and herbal medicine and they've just implemented something that I'm kind of concerned that could actually put a stop to that but it depends on the regulations. South Africa's law has been called the anti-tech transfer law of 2005, and pharmaceutical companies tell me that they now just transship. They won't file the patents there. It's clearly a country where you have no quiet title, anyone can challenge any point during your patent life and you can lose the rights to your invention and you can lose your whole investment. This is also the chart that's available in the ABSA website and I'd be happy to share it.

So going back then to the negotiations, because industry has had experience at the domestic level with some of these aspects, obviously we have particular concerns. But what we'd really like to see for the international regime is, for particularly in objective and scope areas, to see the objective limited to Article 15 and 8(j), which we believe is the objective of the treaty and not go beyond it in a lot of ways. That would be true for Objective and Scope in the draft Operational Text. So for example, the terms "products" and "derivatives" are not terms that exist in the CBD Treaty. We're not saying that it shouldn't be properly treated in a regime, but that would be under a section other than Objective and Scope. Right now, they are bracketed and I've been told by the mega diverse countries, depending on what they get in Access, they're willing to go back and look at that.

In addition to looking at the defined jurisdiction of the CBD Treaty, they really ought to look at the limits of the mandatory approach. I think I've sort of given some examples of why that's important, the need for carrots as well as sticks, and the facts on the ground. They really need to recognize that in this intervening decade or more, really close to the 15 years, you have all kind of existing treaties and ongoing negotiation. I guess I wish they were treaties. There haven't been a lot of treaties. And particularly, the FAO and the WHO have vast expertise in this area, and the FAO has shown how a multilateral approach is possible. Those can't necessarily be reflected directly in the CBD ABSIR but they ought to at least be given some comfort and some recognition. More importantly almost, the important thing is to recognize that something like 66 CBD members don't even have Focal Points.

A Focal Point is just a point of entry, so it's not necessarily a one-stop shop, but it's where you know how to go to someone. When one-third or more of CBD members were not able to have a Focal Point, that was the case in Belize, and that was one of the difficulties I had working with a

client there last year. Okay, then, you get to national competent legal authorities, the number goes up even further. Of CBD members and domestic regime, there are fewer than two dozen fully fleshed domestic regimes. Now, if you want fully functioning domestic regimes, I don't want to be negative about it, but bottom line is that we know it doesn't work and we have to look at this in the same way or, as I put it to some developing countries, are we doing this for Brazil and India or are we doing this for 191 countries?

And the other point that's really key is that a lot of the problems that are faced by indigenous and local communities come out of the land reform issue where they are really having their backs to the wall. They don't have anything and then their governments are pointing in the direction of industry and saying: "Those guys over there that took everything don't look at the government." So the relationship between the local communities and government is also a complication that is a fact on the ground that I haven't yet seen reflected.

There was a recommendation in the Tokyo reports from the compliance, technical, and legal expert groups that I attended for the ABSA and the ICC that said that the negotiators should avoid one-size-fits-all, highly bureaucratic approaches and should instead look for particularly in-compliance measures that are cost effective. So hopefully, this being a formal recommendation of an expert group that was asked for by the COP, it will be given at least some recognition.

We would actually like to see some mandatory elements that are necessary to allow CBD members to engage with industry. As a lawyer, I can't recommend anyone going into a country to do bioprospecting if there isn't a Focal Point, if there isn't a National Competent Legal Authority, and if there isn't a guarantee that you'll be able to have a written agreement memorializing that you got prior PIC and MAT.

Interestingly enough, this doesn't have full support within the CBD, and these things are bracketed, which I find fascinating because this is really the best thing for smaller developing countries. If this is in the ABSIR, then they have a way to start. Also interestingly enough, some African countries are really pushing for model clauses as a way to support this process and for capacity-building, and the Ugandan representative in Tokyo also supported that, which I thought took a lot of strength when there were some big countries that were opposing it.

On the voluntary side, codes of conduct and best practices are important because right now, there is nothing to help a company that wants to do the right thing to be shielded. Right now, there isn't a single benefit-sharing agreement that hasn't been attacked by someone and all accusations are of equal weight. That creates additional disincentive for industry to go in.

Finally, next steps, I've gone through most of these already. In Montreal, we'll take on the nature, TK [traditional knowledge], capacity-building, and then we'll go back to these other texts and Working Group 9 is just consolidation and then we have adoption in Nagoya. So in terms of the governments that are the most supportive and commit-

ted, Canada is a co-chair, Germany is the previous host at COP 9, and Japan at COP 10. So you have really important, developed countries and I would say all the OECD [Organisation for Economic Co-operation and Development] countries committed to the success. The question is whether the ABSIR will be able to adopt something that will actually create enabling environments and support and respect other international agreements.

And that's where I come back to the first point that I made, which is that you have the OECD countries listening. You have their attention. They're really committed to doing something. So the question is not whether there will be an ABSIR but whether it's going to be one that will create enabling environments and for that, I think that the ball is in the court of developing countries, and hopefully we'll be able to build on the cooperation and trust that's been established by the co-chairs and the executive secretariat and come to something successful, not to something that's adopted but something that will create enabling environments for growth and prosperity and sustainable commercial use of genetic resources. Thank you.

**Richard J. Blaustein:** Thanks, Susan. And now, we have David Newman. He's the chief of the Natural Products Branch of NIH [National Institutes of Health], acting since Gordon Cragg's retirement at the end of 2004. In the past, he worked with many interactions with sovereign nations using NCI's [National Cancer Institute's] Letter of Collection [LOC] and MOU [Memorandum of Understanding] based on it. I took notes of David's presentation at the Biodiversity in a Rapid Changing World on Ocean Biodiversity. That was a fascinating look at the new possibilities for pharmaceuticals from ocean biodiversity, especially microbial.

**David Newman:** Thank you. Well, I should add that I'm not a lawyer but I have, on frequent occasion, been accused of practicing law without a license, and I plead guilty.

Okay, what is developmental therapeutics? This is where I describe it as Uncle Sam's nonprofit pharmaceutical house. Our sole job is to find treatments for cancer and incidentally, for any other disease of interest to NIH, which means anywhere from athlete's foot to zoonoses. And I'm actually based up in Frederick, but the NCI is the largest institute within NIH.

Okay, now, this is where I open your eyes because everybody considers biodiversity, in the 190 countries plus, as being this part in the red ellipse. Those are the multicellular organisms. Biodiversity, ladies and gentlemen, is in fact in this part. And the figures will blow your minds. Within the area, not included in here (the ellipse), are something like  $10^{35}$  to  $10^{40}$  organisms and you can't see them. Single-cell microbes; Eukarya, which are like us, it means you have a nuclear membrane; the bacteria, which you all know about; the Archaea, which are also bacteria; and then the Eukarya. We sit here as all multicelled organisms, which, by the way, include all plants, all creepy crawlies, us, and any versions thereof, fall within that ellipse. So when people talk of bio-

diversity, they know not of what they speak. A scientist deals with this. Everybody else deals with a little tiny piece of this.

Now, since 1989, four years before the CBD, Uncle Sam has been ahead of the game. It's the only time I think we can ever claim of being ahead of the game. And we are still ahead of the game because amusingly, countries who don't want to talk to us will sign our documentation, and we'll see some of them in a moment. So we have to ignore the CBD because it hasn't been ratified by the Senate but we had everything that is in the CBD in place with the treaty we signed with Madagascar in 1990 for access and benefit-sharing. The sole thing we do not have in there is a royalty statement because as a government entity, one cannot write a royalty statement for something that has not been invented, and the act of collection is not an inventive process. There's a lady here from the U.S. PTO [U.S. Patent and Trademark Office] and she can testify to that as well, I think. It's not an inventive process to pick up a leaf or take a microbe. The inventive process comes when you find out what it does.

So we realized, back in 1986, when we set up a brand new collection program, that significant contributions were made by source country organizations, so we had to have some way of recognizing them. We can't give money. We're not USAID [U.S. Agency for International Development]. That's the only entity in the U.S. government that's allowed to give money outside of the United States. We can give it by competitive grants, but none of these countries will win a competitive grant. So we attempted to balance indigenous peoples, source country, government, and private-sector rights. We signed the LOC in the Malagasy Republic in 1990.

Now, these agreements are signed by a representative of the country, usually a university but sometimes the country and the NCI director. We offered this to the DOS and there was a sort of the classic hex sign came across in the DOS and they didn't want to hear it. Currently, everybody from the DOS who deals with the convention of parties uses our agreement as their basis for discussions, which does make me chuckle.

What we also did, for every one of these countries that permits us to collect in their waters or lands, even though there are no signed agreements, we have stated in writing, signed by effectively the director of the NCI, that even if there is no formal LOC, the tenets of that LOC apply, and we've been quite successful over the years in countries that you wouldn't expect—Cameroon, Central African Republic, even at one time Colombia, before the Andean Pact.

Now, this gives you an idea of our plant collections. From 1986 to 2004, we collected in a variety of areas by a variety of competitive contractors. These are specialists, specialist botanists in this particular case. And because of funding, we had to stop the formal plant collections at the end of 2004, but I was able to perform further collections using a purchase system in fiscal 2008. In the marine environment, on which I still spend a lot of time, we have been collecting since 1986, over the world using specialist marine biologists for the work, with agreements such as the LOC or under conditions where those agreements will apply even if not signed.

Now, what we realized was that back in 1991, we were sitting on a potential gold mine, but the gold was not being mined. The gold was not being mined because we have limited resources, even though NIH has a \$30 billion budget and NCI has \$5.5 billion of that. Eighty percent of our budget goes out in grants and contracts. So we came up with a concept, which NPB [Natural Products Branch] started, of a central repository of materials containing a library of extracts that could be used by outside investigators as test systems came available in addition to our own screens. We collect a kilogram of material for each sample, and we have an industrial strength operation up in Frederick that processes the samples in due course.

However, this just gives you an idea of the scope; to date, the number of extracts is approximately 260,000. We've got approximately 40,000 fungal extracts and about 30,000 marine extracts, with the rest being plants. We have full details, from cradle to grave, of these contents, of these extracts and we now, we have them all in 96 well plates, and for those of you who have never seen these, it's basically the size of a cigarette pack that has 8x12 wells in it. So our complete repository can be put up in basically about one-quarter of the size of this room, even though the full repository is actually 20 walk-in freezers and climbing.

So what do we do with these? Well, we realized that we didn't have the resources. Even the United States didn't have resources. So we opened them, and "open and active" is simply a terminology you don't have to worry about, to any qualified investigator. Now what that meant was anybody who was willing to sign a legally binding document covering the rights of the source country before they saw anything. I can give you the names of a pharmaceutical house if we were not in open session, where they actually threatened me with going to their congressman because I said no to their senior legal counsel because they wouldn't sign the agreement. I'm still saying no, and they still come back, and the answer is still no.

Unless you sign a legally binding materials transfer agreement, which states very simply if you find something from it—and this, by the way, is from big pharma down to the local, if necessary, community college investigator, as long as they have the skills—if anything is commercialized, the country of origin must (nonnegotiable), be involved in the development and the commercialization of that product.

If we find something and we have to patent it, we competitively license it out as we did with Taxol. If we license that potential drug out, the company, within one year, must produce a benefit-sharing agreement with the country of origin. That's the first item in the license. If they don't, the license is pulled. In these discussions only the licensee deals with the country of origin.

Just to give you an idea of the value of items from nature, these, all these and up through here and these, every one of those is either a natural product, or is derived from the natural product and of the 164 anticancer drugs approved worldwide from the dawn of time, one-half of them are either natural products or derived therefrom, in my definition. And

if you take real (meaning approved by FDA [Food and Drug Administration] or equivalent) drugs in other diseases, of which since 1981, there have been 1,200+ approved worldwide for any disease, and by the way, unlike the pharmaceutical industry, I count a drug one time.

I do not care if it's now licensed for ingrown toenails or syphilis when it was first licensed for whooping cough. It's got to be counted only one time. If you read pharmaceutical websites, you will see comments such as over 600 drugs/trials for cancer absolutely everywhere, because every time they put a drug into a trial for another cancer, it is counted again. I do not do this in my analyses. A drug is only counted one time.

So that's one of the reasons why I have—and I spent 25 years in the pharmaceutical industry—a somewhat wary view of the "information" that is put out on such sites. However, the basic point is that natural products are the basis of almost 70% of all anti-infectives. And those of you who have high blood pressure like I do or have high cholesterol like I don't, Lipitor is directly descended from a natural product, even though Pfizer will not admit it.

**Richard J. Blaustein:** Which one? Which natural product?

**David Newman:** Which natural product? Mevinolin. And of the first three drugs that went into use, the first was a natural product, a very slight derivative of a natural product by changing the fermentation conditions and a subtle chemical modification of that prior product.

**Susan Finston:** And where is it derived from?

**David Newman:** The original discovery was made by the Japanese from a fungus. The original discovery was made by a brilliant Japanese scientist, Endo, back in the early 1970s. I can send you full details of this. And once the warhead was seen, what it was, all that was done by every pharmaceutical house ever since was to take that warhead and put different grease around it so that altered the—what I would call pharmacokinetics and pharmacodynamics, so that it would go into certain membranes and not into others. And so every one of those is, in fact, derived from natural products.

So people don't understand this and I don't criticize them for that, because unless you're a chemist with a certain type of training and experience, you're not going to have the necessary background to appreciate it. But suffice it to say, just to give you an example, this is the bark of the Taxus tree. This is a delightful little organism. It actually is a nudibranch that produces the compound that is now in three clinical trials but it gets it by eating a microbe and putting the material on its back. This fungus produces rapamycin, which now has four drugs, rapamycin derivatives, in clinical use. And this one produces erythromycin.

So I can have some fun with the PowerPoint, but the bottom line is that Uncle Sam has been doing benefit-sharing with countries—and by the way, one of the suggestions we have made to countries and it's been acted on—is you do not

need money because we all know that if you give money to a majority of countries, it's not going to reach people who did the work or have the information. It's going to get lost in a variety of ways!

So what we suggested is that developing countries in particular may want, not treatments for cancer, but they may want treatments against parasitic diseases, against infection. So tell the companies who are licensing the compounds from your waters or lands: "We want your materials up to a certain level of—up to a certain benefit from products that are available." An example of this that didn't come from this but predated this idea would be the work at GlaxoSmithKline, albendazole to the Ivory Coast and other African nations, and Merck gave ivermectin to wipe out river blindness and other parasitic disease to the same general area. Now, years ago in another life, I worked out what Merck got from that. It cost them \$7 million to do it, and they got over \$40 million worth of advertising, plus they could take the \$7 million in tax deductions.

So the point is, to—as an old teacher of mine put it—think obliquely because money is not always what a country needs. They need access to materials that they cannot make. And the major point is that I always get the argument about building capacity. But let me give you an example of what happens when you try to build capacity in developing countries. Suffice it to say, it's a country in the Far East that has good intellectual resources and a reasonably good higher educational system. We tried to help them set up an anti-tumor assay that requires clean water, carbon dioxide, and 24-hour power. Well, we've never succeeded because they don't have clean water and they don't have 24-hour power. Therefore, they can't do the work.

But you can't get that through the heads of a lot of the source country politicians or the government employees who are looking at agreements—it has to be capacity-building. You've got to have a certain infrastructure in the country before any significant capacity-building can be put onto that country, and that's the point that is not taken into account in CBD. We actually have it in our LOC that we will, to the best of our ability, aid in capacity-building, but we do not define what capacity-building is. We do that on a one-on-one basis. An example of where it worked was Sarawak. Sarawak actually set up a joint venture with a compound that we licensed to a small American company. And Sarawak now has investments that have now taken effect and they're putting it into themselves. So we have a process that works.

I can give you some examples of where, as Susan eloquently put it and I'll rephrase it, countries are their own worst enemy. I'll give you the example in the best way and where this really started was with the INBio agreement with Merck back in 1991 when INBio gave Merck access to 1,000 kilograms of 1,000 different insects and Merck paid them \$1.1 million. Therefore, everybody said: "My leaf is now worth a million dollars."

What nobody was willing to realize, even though we tried—my old boss and I and others tried many times to explain in words of one syllable that this was just not the

case—and actually, some of the worst offenders were American NGOs, run, dare I say it, ladies and gentlemen, by lawyers, who insisted that the LOC was worthless. They did not understand that what INBio had done was that they had set up an internal taxonomic system that allowed them to identify where those organisms, meaning insects, came from, when they grew, where you could get them again. And so although the CBD effectively says every country has its own catalogue, a whole library of genetic resources, INBio is the only organization in the world, even today, that has a card index to their library. So what Merck was sold was access to the card index; a very subtle, but extremely important difference from what is usually stated.

**Susan Finston:** Can I add just one thing to that? A lot of very well-meaning environmental advocates have decried some of the agreements of companies that no longer exist because they didn't make any money, and said they were too low for commercial development of pharmaceuticals.

**David Newman:** Exactly.

**Susan Finston:** And there are scores of others and they promise anywhere from 0.5% to 2.5% of royalties based on successful commercialization of a product. Well, rather than saying that that royalty was too low and was criminal on and on, perhaps you could suggest that it was too high, that it was uneconomical because none of these companies exist anymore and none of these products were successfully commercialized, including Merck-INBio, where the agreement has expired.

**David Newman:** They found one compound from that work and that compound did not become a commercial success. Now, the point that people need to realize is—and I've been in the trade now for close to 45 years in industry and the government. As Michael would certainly say and as Richard would certainly say: "If you want to make money, play the powerball." The odds on getting a drug like Taxol from nature are  $10^n$  and  $n$  is a large positive integer. However, when you get one, you win. The odds are very high against—let me just give you some figures.

There are three stages of drug development: drug discovery, preclinical work with the pure compound, clinical work with at three phases of clinical work. Odds are all worked backwards because you have to have an approved drug to be able to calculate. For every drug, in any disease that becomes a commercial entity, 10 compounds went into clinical trials. For every drug that enters clinical trials, 10 pure compounds entered preclinical trials. So now, your odds are one in one hundred. And if you want to know how many compounds are extracted, you have to test to get one compound to go into preclinical trials,  $10^n$  and  $n$  is greater than six.

The pharmaceutical industry in the world, over the last 15 years, has moved to combinatorial chemistry. There is one drug and only one, out of the 1,200 that I've looked at, that would have become a commercial entity that was identified

by de novo combinatorial chemistry.. Effectively speaking, combinatorial chemistry as a discovery tool is useless. As a development tool, it's magnificent. This is one of the reasons why the pharmaceutical industry in the world has major problems with their pipelines. They're beginning to go back to look at natural products. But I just came from a meeting this morning where you realize there is not one American company now looking at nature aside from some holdover agents. Not one. The Japanese, Novartis in Switzerland, Sanofi-Aventis in France, and Bayer, that's it. There's more?

**Susan Finston:** No, Bayer, but that is not unrelated to these discussions. I wrote a paper on this that came out in 2005 and I think it's available online that shows that as the polemic and the rhetoric heated up, companies shifted to combinatorial chemistry—

**David Newman:** No, they shifted to combinatorial chemistry for actually something quite different. They shifted because biology exceeded the capacity of a chemist. This is where you have to know the science behind it as distinct from what appears to be the policies. What happened was that by 1990, molecular biology, genomics, and computers had joined together; this gave you robotics, methods of putting screens together rapidly, screens that could use over 50,000 compounds a day for two months, and in that time, they put through five million pure compounds or mixtures. In three months, even today, if you got to work out what is in an extract and then purify the extract, you're very lucky if you find out what's there. By the time you're done, the screen's gone.

So it was actually a combination of science that caused that change. Natural products went to the wall because what was realized was if combinatorial chemistry worked, there was no IP problem because you owned the material. Period.

Now, it's beginning to come back, natural products, as a lead to structures. I've worked extensively on this. Leads to the structures from nature are beginning to be asked for and chemists are now making molecules that look like those. For example, every one of the targeted anticancer compounds that end in -ib, Sorafenib, etc., are absolute chemical mimics of ATP, adenosine triphosphate, which is the thing that keeps all of us alive. As we breathe, we generate ATP. But that's not something that you will find in the regular literature. You have to look in the specific, specialized areas. So that's one of the reasons why we are now the only U.S. organization that does any large-scale collections in the world that I am aware of.

**Richard J. Blaustein:** Thank you, Dave. Mike Gollin will speak now. He is the chair of the Life Sciences Group at Venable LLP, where he is a patent attorney and published *Driving Innovations: Intellectual Property Strategies for a Dynamic World*.<sup>1</sup> Mike also teaches information technology (IT) management at Georgetown University Business School and

Franklin Pierce Law School. He co-founded Public Interest Intellectual Property Advisors in 2002 to match voluntary IT professionals to develop country organizations requiring pro bono legal assistance. And do we call that PIIPA?

**Michael Gollin:** PIIPA.

**Richard J. Blaustein:** PIIPA. And the website would be?

**Michael Gollin:** [piipa.org](http://piipa.org).

**Richard J. Blaustein:** Thanks, Mike.

**Michael Gollin:** You're welcome. So thanks, Rich, for having me and having this sort of low continuing discussion that's been going on for, depending on how you count, maybe 20 years and I guess five since we had, I guess, that session in 2004. And thanks to the D.C. Bar and ELI for organizing this.

As you might tell from my background, I have something you might call SPPD. It's a "split professional personality disorder," so I do a lot of different things from the for-profit and the nonprofit side but the common theme throughout all of it is that I'm a practitioner and proud of it and have 25 years of practice in law firms. And this particular area of natural products research and biodiversity and so forth brings together a wide range of people from the theoretical side, from the policy side, and from the practical side, either from the scientific practical side or from the legal practical side.

So the focus of my remarks would be primarily on the practitioner's side. I will talk something about transnational aspects of access and benefit-sharing agreements from a patent prosecution aspect and a management practice approach of biodiversity IP compliance program.

The CBD's objectives have to do with both conservation and sustainable use of biological resources in everything from health to industry, and the notion that benefit-sharing can tie the two together. And what I say is the two take-away concepts for transacting access and benefit-sharing agreements are the ABS, and prior informed consent, meaning the right to say no, which is exerted actively or passively by many of the countries we've heard from, heard about so far today, and access and benefit-sharing agreement, which is the mechanism for saying yes, I guess, we could say.

The principles of access and benefit-sharing agreements were hashed out, as David said, before the CBD, both by the NCI and by INBio in Costa Rica and others, who took the principle that companies doing bioprospecting should share some benefits. The CBD came along and has layered on that the bond guidelines are now—these essentially say you need prior informed consent, which is a negotiated ABS agreement, that the recipient, the user should limit their use, of course, within the scope of the agreement; and typically, that there should be some documentary evidence maintained.

And I'll skip over the international ABS agreement. The last point, which as a practitioner, is absolutely the central point. That the administration and transaction costs destroy

1. MICHAEL A. GOLLIN, *DRIVING INNOVATIONS: INTELLECTUAL PROPERTY STRATEGIES FOR A DYNAMIC WORLD* (2008).

all the theories and all the policies behind the last point of your thoughts and materials; and that's my main concern.

So again, ABS agreements have to have access, which is after prior informed consent or when clients come to me and say: "So we have this really exciting example. We've got a great prospect, a great lead out of that but we don't have any kind of agreement in place or we only have a noncommercial agreement in place. What do we do?" And so then, we get the prior informed consent that's obtained after the act, which you can call whatever you want, so subsequent prior informed consent or whatever you want. But anyway, prior informed consent is the lingo that's used. And it can be in two steps. It can be the collection itself or it can be until the export or it actually can be before the commercialization, so the consent can happen at various milestones along the way.

The problem is that, as Susan was saying, who's got the right to give consent, the government, the province, the local government, the owner of the land, some local indigenous groups, or some broker or intermediary? It's very blurred. The benefit-sharing is actually well-thought-out. At this point, it's pretty clear. Support for research, contributions of equipment and time, assistance to health clinics and so forth, which meant that pharmaceuticals had a lot of upfront fees, milestones, royalties. I mean, lawyers are very good at this. There are some people who know how to do that. That's the easy part.

From the practical point of view, why would a company go get an access agreement? They get access to source material, which is important. Typically, because these agreements are hard to set up, they're for long-term collections. Local knowledgeable people will participate in the collection effort instead of foreigners parachuting in and grabbing and running. And there is a reliable source for recollection if you need more of a particular sample.

By signing an agreement, you might get exclusive rights from the particular region, although that's proved practically very difficult. You avoid violations of local natural resource and export laws and avoid potential liability. And a lot of this is driven or has been in the past driven by goodwill, marketing, budget, and so forth. In fact, the rumor is, and I haven't heard this contradicted, that the budget for Merck is \$1.1 million. INBio actually came out of the marketing budget, not a research budget, but that's one of those stories that might be just really interesting to be true. And then there can be competitive advantages, although, as David was saying, a lot of companies have just moved out of this space.

Looking at it the other way around, if you do go ahead and collect and don't have adequate agreements in place, we'll talk about the weakened patent posture that can come out of that. There may be claims from the source country. It's arguable and there are theories running around about—and I probably found this a decade ago—about U.S. court action to recover damages for some kind of misappropriations in the source country.

A lot of companies are wise to this now and anytime, if you're an intermediary and you're going to process materials and pass them to recipients, like the NCI does or many

other organizations along the way, your recipients are going to want a clean title and some of kind of assurance that—for example—it's not a hot Rolex but that it is a Rolex watch that has got a clean title all the way along. If you are found to have obtained material without permission, you may be barred from further access in that country or other countries. You may be shamed publicly as a biopirate, although one of my philosophies is that if you haven't been called a biopirate, you're not trying hard enough in the bioprospecting.

So even with the best of intentions, it's sort of somewhat of a badge of honor. But jail is a real consequence and as a lawyer representing clients, that's something you definitely want to keep your clients out of is jail. And there's Marc van Roosmalen, a researcher in the Amazon in Manaus. He had a primate shelter that was a kind of a stick in the eye of some of the local establishments and he was actually found not to have a permit for collecting these primates and jailed for an extended period of time, and there are other stories as well. So this is just sort of a graphic depiction of the flow, I'd like to think, the flow of physical material here. This is late in Kenya, for example, where some microbial enzyme was obtained, and I won't name names but a prospect of a mentor. He used an enzyme from this lake—

**Susan Finston:** Pre-CBD obtained as well.

**Michael Gollin:** Yes, right. But I shouldn't blow up too much on the details because that is not a perfect example, but we can come back to it later.

So the point being that the companies that pull the material out, if they don't have adequate informed consent and benefit-sharing agreements. Passive/Active business partner can tell that there is liability that can flow in several directions, from the country, the host country, and from down to the end user so it's just a liability-rich environment, not one that companies like to participate.

Well, liability-creating situations. So, on the other side, again, what's the problem? Why are we even discussing this? Why isn't this trivial? Well, the problem is that it's very expensive in terms of the transaction costs to go get these agreements, the delay, the length of time, like Susan was saying, a year, two years. Len will tell us about his problem with just getting material back from Brazil, the time he spent there, and cost of money, of course, and the risk of creating public awareness, when a project was done in Chiapas in Mexico through the NIH-funded International Cooperative Biodiversity Group, in the public awareness sector, raising that led to protests by local indigenous groups and blocking of a program that was very fair and equitable and accepted by many of these, most of the local villages around.

Anyway, the bottom line, as Susan alluded to, is that from a commercial point of view, if the benefits don't exceed the cost, nothing's going to happen and to some extent, we can debate how much that is why companies are not involved in the actual product research, but there is increasingly further stigma attached to that. Now, I'm not going to go into this so we could spend all day on these terms but these are

very specific kinds of agreements that merge material transfer agreements, environmental permitting concerns, contracts, IP licenses, and so forth, so it's kind of a hybrid.

So a summary on that point, on the transactional side, is that you need to obtain prior or retroactive informed consent. The benefit-sharing is a cost of doing business. It reduces liability and helps assure return on investment. If you can get your benefit-sharing agreement at a reasonable price and it helps you add value to the innovations that you're doing, then that's a good thing. Long-term relationships are key. Strong knowledge of the people and circumstances on the ground requires local participation, and the advantages should be part of a business plan. So some companies are going into this not necessarily in the drug side but also in industrial and other sides.

So now, let's skip over to patent product fusion and how this ties in. Of course, people are doing this work to generate conventions, to find new drugs or industrial products or agricultural products. And the point about you can't get a patent on finding something but you can procure or find something important, although the criteria are becoming stricter and stricter as far as what we can patent. There's a general matter you can patent—purified compounds, purified cultures, analog, new preparation for formulations, combinations. If you find a new and important use for a known compound, that can be patented, new method of making a compound, a recombinant protein or a DNA variant versus the pure natural kind. A transformed organism can be—and that's the *Diamond v. Chakrabarty*<sup>2</sup> case going back to decades. And then what you make using engineered organisms can also be protected. We could go on, but that's just to get us in the mindset of patents.

So there are a lot of patentable inventions that can come out of access to natural products. And one of the ways in which the theorists and policymakers have been promoting policing and avoiding biopiracy is through disclosure of origin law, which require the patent applicant to disclose where they got any genetic resources or materials used in the invention. And this has opened up just a whole separate can of worms in all the transactional issues about access and benefit-sharing.

And really big problems are how you define the source or origin. And I won't go into that but typically, that's who you got it from versus where it originated, and we can go back to *On the Origin of Species*<sup>3</sup> or depending on, if you're a creationist, the creation of the universe and say it all came from Eden. But the geographical scope, typically, they were limited to materials obtained in the country and questioned so disclosure in South Africa would relate to materials obtained from South Africa but there's a lot of question about what are genetic resources, human or not. Susan had some of this in her materials too.

Traditional knowledge is often thrown into the gap. From a policy point of view, traditional knowledge is huge. It's maybe even more important politically in many countries to

the genetic resources, I think, to every client I've ever had, from the commercial side, even from the research side, anybody, from the scientific side. It's a drop in the bucket in terms of these innovations. But that's sort of from a western model. In India and other countries, the traditional knowledge actually can be very important for local innovation. But it's, in my view, worldwide, less of a practical issue than it is a policy issue.

In some countries, it's just that you say where you got it. Other countries require you to say you had permission. Other countries require you to provide proof in the form of documentation. These laws are scattered in different parts of the law books. They're very hard to find. There's no central source. We've been tracking this for the last year or so. I have an associate who does updates periodically and it's an area that requires a little more academic and theoretical oversight to figure out what the laws are, but from the practical point of view, it's very difficult to comply if you don't know what the law is. And in fact, it can be quite extreme from the validity of what the patent suggests.

So, where are these laws already enforced? The Andean community, a number of European countries, which you can avoid by going through, I don't know how many patent practitioners there are here, but you can avoid their limitations by going through the Patent Cooperation Treaty route. But as soon as India, China, Brazil, South Africa had these laws on their books, it became de facto an international agreement. And I do have a summary table, if anyone wants it. Let me know and that's sort of a more up-to-date table of what the laws are. So again, with this kind of liability-creating situation analysis, let's say, the patent office gives you a patent and there was some fraudulent disclosure and then you go and try to enforce the patent, the infringer comes back and invalidates the patent based on a failure to comply with disclosure laws.

So it's a mess if you're—and I'm putting on my practitioner's hat—advising a user organization, somebody who's obtaining materials rather than the provider, anybody filing a patent application should know, generally speaking, it is now best practice to disclose where you got any biological material. That has been the general practice anyway but it's moved up and at this point, I hear that in the United States, disclosure of origin is not required but is generally, to some degrees, necessary. When you look at any patents involved in microbes, plant materials, generally, they say where the material came from.

Okay, so the time is ripe for organizations to have a compliance program. If they don't, they're running into all kinds of trouble and this type of program identifies where genetic food sources were obtained; who the national focal points are, if there is one; what are the national laws and regulations. And then you have to go get the informed consent, get an agreement, confirm that the agreement complies, and then comply, and make sure that in the transfer of the material, the agreement is very important.

So that's sort of compliance in a nutshell and I have here the flyer on a biodiversity IP compliance program and if you

2. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

3. CHARLES DARWIN, *ON THE ORIGIN OF SPECIES* (1859).

look at these questions, you will see that, actually, it casts a very wide net. My view is that most companies in the life sciences, even those who wouldn't consider themselves to be directly doing it that way should be paying attention to this.

If they obtain the materials from a selection, you need to know where the collection was obtained in the field and so forth. So that would include biotech companies, pharmaceutical companies, and functional foods, the snake oil seller. And if you don't know about where you got them from, then you have to do some due diligence on that. If there is traditional knowledge involved, which is the case in some research and if there's any plan for patenting, especially in South Africa, which are sort of in an upper list of patents that people typically file. And if you haven't asked the inventors where they got the material and what the circumstances were, then you are running into trouble and you need a compliance program if you're unsure of what the legal obligations are. Not everyone is as knowledgeable as Susan or the other folks here. A lot of people in this room probably have a general idea of what we're talking about but most people in research do not really know all that much about it.

So then, the components of an IP compliance program are to identify where materials came from, what requires an active and benefit-sharing agreement, and to make sure in the invention disclosure process, appropriate questions are asked. I talked in my book about policy practices and staff capacity and seeing a large part of innovation and intellectual property and you need to have that in place in organizations' policies regarding how do you get the agreements, how do you maintain them, comply with them, and you need to monitor it.

So on that note, it's important to pay attention to biodiversity compliance and I just want to say one, take one moment. I know we're running a little behind—on PIIPA, Public Interest IP Advisers, which is a nonprofit that was more from the provider side. It provides intellectual property of business in key developing country organizations who are looking to deal with matters that involve IP. And one big area is in negotiating access and benefit-sharing agreements and in establishing laws and practices to comply as well as to work under the CBD and the CBD's guidelines to build capacity and so forth.

So one of the practical problems is that people just don't know what to do or what they should do or they don't understand the implications of establishing a particular law, and the best way to help them do that, in my view is, and the mission of PIIPA is, to provide good access to IP professionals. And PIIPA has a network of IP professionals in the United States and other developed countries and in developing countries around the world who are willing to volunteer to help provide advice to folks in developing countries who are trying to either negotiate these agreements or establish new ones. So I'll stop on that note.

**Richard J. Blaustein:** We're going to go to David Hegwood, but we had a question e-mailed to us that I want us to answer at the end but I want us to get it out so folks know the kind

of questions we're getting. I think this question is pertinent to read now because David's going to talk about the FAO Treaty, which is a different approach and a different fit for genetic resources to focus on plant genetic resources for food and agriculture.

The question is: "How do the different presenters feel about a one-size-fits-all approach, given the various sectors, agriculture, pharmaceutical, etc., can be affected by a regime that must account for vastly different ways in which materials are used and appropriating values can be quite complicated as in plant breeding and where profit margins are vastly different? Do you see opportunities within the CBD or other international negotiation fora for just developing different approaches?"

And then, for example, multilateral access approach is the multilateral benefit-sharing approach, as in some cases, bilateral approaches for pharmaceuticals, as described in Mike Gollin's book. Do you anticipate that the CBD's bilateral approach will be relevant and workable?"

And so for this, we have a presentation by David Hegwood. David, from 2004 to 2008, served as USDA representative to the FAO, where he was lead U.S. negotiator for the FAO Treaty on Plant Genetic Resources. He recently founded [feedingtenbillion.com](http://feedingtenbillion.com), a virtual discussion forum devoted to global food security.

**David Hegwood:** Thank you. I will try to be brief, if only because the Plant Genetic Resources Treaty and the ABS regime it creates are much simpler than the regime the CBD is currently working with. My objective today is to provide an overview from a transactional perspective of the ABS regime that was created by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.<sup>4</sup>

The treaty entered into force in June 2004. It currently has in excess of 120 members. The United States, China, and several other countries that are important sources of plant germplasm are not members. The United States and China have two of the largest national plant germplasm collections in the world, so it is very notable that we are not members. As with the CBD, the United States has signed the treaty, but we have not yet ratified it. We are hopeful about ratification this year, but that will depend on how quickly the Senate can move and what its priorities are.

The FAO Treaty establishes a legal framework for international exchanges of plant germplasm that fall within its scope. Anyone accessing plant germplasm as a researcher or a breeder could potentially find that their transactions fall within the scope of the treaty. In a nutshell, the treaty guarantees facilitated access to plant genetic resources for food and agriculture (PGRFA) in exchange for benefit-sharing requirements. That is the basic trade off.

To understand the background of the treaty, it helps to recognize that in creating the treaty, the parties were try-

4. International Treaty on Plant Genetic Resources for Food and Agriculture, Res. 3/2003, FAO Conf., 31st Sess. (Nov. 3, 2001), available at <http://www.fao.org/Legal/treaties/033t-e.htm> (last visited July 15, 2009) [hereinafter ITPGREA].

ing to reconcile seemingly contradictory goals. On the one hand, countries wanted to preserve the practice of exchanging germplasm that has existed for 10,000 years. With the creation of the first modern gene banks in the middle of the last century, researchers and breeders have had open access, literally free access, to plant genetic resource material. On the other hand, the negotiators were facing the same dynamic that existed in the CBD. Countries that consider themselves the countries of origin of plant genetic resource materials want to extract some benefit from the use of those materials. The balance the negotiators were trying to achieve was between open access on the one hand and the extraction of commercial benefits on the other hand.

The ABS regime in the treaty is comprised of the multilateral system (MLS) and the Standard Material Transfer Agreement (SMTA).<sup>5</sup> The SMTA was negotiated subsequent to the adoption of the treaty. The MLS provides for facilitated access to PGRFA for research, breeding, and training. A royalty on seed sales generates monetary benefits, which are placed into a global trust fund. The proceeds from the trust fund are used to support conservation and sustainable use of plant genetic resources in developing countries.

The U.S. Department of Agriculture technology transfer expert has described the SMTA as a royalty-bearing, non-exclusive licensing agreement between the recipient and the provider. It specifies the trigger for and the level of the royalty payment, the payment terms, and reporting and information-sharing requirements that go along with the access to the material.

There are four significant differences between the approaches of the CBD and the FAO treaty that I will highlight for our purposes today.

The first difference is that under the Plant Genetic Resources Treaty, access agreements are not negotiated for each transaction. A standard agreement, the SMTA, is used for each transaction. There is not even a possibility to negotiate a new SMTA.

The second difference is that the transaction is not bilateral in the sense that the royalties are paid into the trust fund rather than flowing directly back to the country of origin of the material. The benefit-sharing provisions create a mechanism for funding the kind of capacity-building work that others have been discussing here today. There are other ways that could have been done. By asking for financial contributions from parties to the treaty to support capacity-building, the whole concept of benefit-sharing arising from each transaction could have been avoided. Politically, however, that was not tenable for a number of reasons. Instead, the benefit-sharing requirement was attached to the actual transaction, even though the provider of the material would not necessarily be the direct beneficiary of any revenue that eventually arises from the transaction.

Third, the funds generated under the treaty's ABS regime will be used for the objectives of the treaty, which are con-

servation and sustainable use. Under the CBD, any benefits generated can be used for whatever purposes the provider of the material wishes. The funds are not required to be used to promote the objectives of the treaty, except to the extent that benefit-sharing is the objective of the CBD.

A final difference, as I was just reminded by Michael Gollin's presentation, concerns the exercise of control over access. Under the CBD, a country has absolute discretion to reject a request for access. Under the FAO Treaty, because facilitated access is guaranteed, a country's right to refuse access is severely limited as long as the requestor is willing to accept the conditions of the SMTA.

Conceptually, the MLS can be thought of as a virtual network of primarily gene banks and, nominally at least, also in situ genetic resources. Many of the rules of the MLS are operationalized through the SMTA. From a legal perspective, the MLS has four key elements.

*Material covered by the MLS:* Article 11 of the treaty specifies the materials included in the MLS. Annex 1 of the treaty contains a list of 64 crops and commodities that are covered by the MLS. The crops on the list were chosen because of their importance to food and agriculture, though this is not an exhaustive list of the crops and commodities that would be considered important. For example, crops like soybeans, tomatoes, and peanuts are not included.

There are three potential sources of contributions of material to the MLS. First are the contracting parties, which are obligated to provide facilitated access to all covered plant genetic resources under their management and control and in the public domain. The second potential source of contributions is the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). The IARCs hold most of the unique collections of plant germplasm in the world, over 600,000 of them. The collections of the IARCs were placed "within the purview" of the treaty by agreements executed on October 16, 2006, between each of the 11 IARCs holding PGRFA collections and FAO, acting on behalf of the Governing Body.<sup>6</sup> While questions have been raised about the legal status of the IARC collections, as a practical matter, the IARCs will be using the SMTA for almost all of the materials they send out from now on, which could number in the tens of thousands of samples per year. The third potential source is all other holders of PGRFA, who are not obligated to provide materials to the MLS but are invited to.

To date, there have been 11 countries that have notified that they have taken the steps to make the material available to the MLS, even though strictly speaking, the treaty does not require such a notification. As a practical matter, we can not say that access is being facilitated unless countries provide information about what material is available and a mechanism for providing access to those materials. In addition to the IARCs that have put their materials under the MLS, four other international organizations have made

5. Standard Material Transfer Agreement, IT/GB-1/06/Report, Appendix G, available at <ftp://ftp.fao.org/ag/agn/planttreaty/agreements/smta/SMTAe.pdf> (last visited July 15, 2009).

6. See The International Treaty on Plant and Genetic Resources for Food and Agriculture, [http://www.planttreaty.org/inclus\\_en.htm](http://www.planttreaty.org/inclus_en.htm) (last visited Oct. 10, 2009).

contributions. What's notable about these contributions is that they include commodities not covered by Annex 1 of the treaty. This amounts to a de facto expansion of the coverage of the MLS. Finally, one private entity, a French maize breeders' association, has contributed materials to the MLS.

*Uses covered by the MLS:* The treaty specifies that the material in the MLS should only be used for purposes of utilization and conservation for research, breeding, and training for food and agriculture. There are two specific nonconforming uses that are not allowed. The first is the use of material in MLS for direct planting. This is an issue for the international agricultural research centers because they have a practice of making material available to seed companies in developing countries, who then bulk up the seed and provide it free of charge to the local farmers. That is a practice that theoretically would not be allowed if the material is covered by the MLS.

The second category of non-approved uses is the use of materials for research and breeding for bioenergy, industrial, or pharmaceutical uses. The rationale for excluding these uses is that should be subject to separate bilateral agreements, with the assumption that much heftier royalties or licensing fees could be charged. However, because of the way the treaty and the SMTA are structured, it is not clear what, if any, conditions would permit the transfer of material for non-covered uses once it has been put into the MLS. From a practical standpoint, there has to be a way to facilitate the use of materials that are in the MLS for uses that are not approved by the treaty, but this issue has not been addressed yet by the Governing Body of the treaty.

*Status of the recipient:* The treaty requires facilitated access to entities that are within a contracting party. Facilitated access is not required to be granted to entities from noncontracting parties. There is also scope for precluding access to entities from a contracting party if they do not, in turn, make material available to the MLS. I think it is very unlikely that we would ever see that happen but it is a possibility provided for in the treaty and, therefore, of concern to the United States as a non-party. I do not think we would ever be denied access to material, and certainly not from the IARCs, which is where we access most of the materials obtained from outside of the United States. Since we are a large funder of the IARCs, they are unlikely to deny us access.

*Benefit-sharing requirements:* The benefit-sharing requirements, which include both monetary and nonmonetary benefits, are specified in the SMTA. The principal nonmonetary benefit is facilitated access itself. As I said, the treaty continues the practice of germplasm exchange that has been going on for thousands of years. The United States for many years has had a policy of providing material free of charge to anybody in the world who requests it.

The monetary benefits are clearly defined in the SMTA. The trigger for the royalty payment is commercialization of a product that incorporates material accessed from the MLS. No minimum level of incorporation is required. The seed industry argued strenuously for setting a minimum level of incorporation. This is consistent with current commercial

practice, though the level of incorporation varies and is negotiated on a case-by-case basis in licensing agreements. In negotiating the SMTA, many developing countries refused to agree to any minimum level of incorporation. Consequently, once a seed company starts incorporating any material from the MLS into a breeding program, it will need to keep records of what material it is using and where it came from in order to ensure compliance with the benefit-sharing requirement.

The royalty payment is 1.1 percent of gross sales less 30%. The 30% reduction accounts for certain costs, such as shipping and returns, that are deducted from royalty or license fee calculations in normal commercial practice. The effective royalty rate is therefore 0.68%. The royalty payment is not triggered if the product is made available for further research and breeding. In general, this means most UPOV [International Union for the Protection of New Varieties of Plants]-protected products would not be subject to a payment, while most patent-protected products would be.

There is an alternative crop-based payment scheme for which the royalty rate is 0.5% of the sales of a single commodity, whether or not that commodity incorporates material accessed from the MLS. As an example, a corn seed company and you wanted access to all of the corn germplasm from a particular seed bank, the company could sign this agreement, pay 0.5% of the gross receipts from its sales of corn seed and not have to worry about keeping up with the actual incorporation of the material into the commercial product. To date, there have been three SMTAs executed for the crop-based approach.

There is still a long way to go in the implementation of the MLS. Many countries have not effectively implemented it, nor have they provided any type of notification of what materials they would make available under the MLS. Until that information is available, we can't really say that the treaty is effective. By far, the largest number of SMTAs have been issued by the IARCs, which are sending out almost all of their materials with the SMTA. They have the largest collections in the world and receive the most requests, particularly from developing countries.

**Richard J. Blaustein:** Thank you. Thank you. That was very fascinating and quite informative and gave us quite a bit of the substance of the FAO Treaty to look for and look ahead to. We have one question again from e-mail. Why don't I just ask in the audience here if there are any questions? We'll hear a few questions and then let the panelists take them as they like. We have again one outstanding question on the one-size-fits-all. Any questions here that folks would like to ask?

**Susan Finston:** Just in terms of the one-size-fits-all, the Compliance Technical Experts Group composed of technical legal experts from every region and every country came out and explicitly said there should not be a one-size-fits-all. It should be cost effective and what that means is that specific measures should be looked at on a case-by-case basis to see how they would work in practice. That conclusion was taken

by people acting in their expert capacity, not with their country hats on, and was not reflected, I think everyone would agree with me, by what was promoted as operation working for either the access, the fair and equitable benefit-sharing, or the compliance measures in Paris.

So there is a total disconnect between what these governments and experts are advising and what was adopted by a consensus, not as a minority but by a consensus and what the parties are actually suggesting be part of the operational text for the CBD.

**David Newman:** I would say that we do not have a one-size-fits-all. We have one document, yes, but within that, benefits are deliberately drawn by having the licensees decide with the country, and there is a reason for that. Government organizations—it's no longer debatable so we are not telling a sovereign nation what to do. That's done by agreements between the people using it and the country that provides it.

**Richard J. Blaustein:** I would just add that, for example, on the food and agriculture source, the FAO Treaty starts off in its objective with a linkage to the CBD. You might not have a one-size-fits-all but you do have an integrated approach, however imperfect it is, and another large point that maybe we should touch on in the next conference is how the WTO Doha Round has even an endorsement of the CBD, looking at traditional knowledge and how that will sort of go back and forth into a wrapping up maybe of the Doha Round, although that's not the largest issue of the agenda.

**Michael Gollin:** As a practitioner, I would say that every patent is subject to the same thing and I would make I think the more compelling argument that that's an example of the system at work.

**Susan Finston:** Right. How strong was the patent?

**Michael Gollin:** It was a weak patent and it shouldn't have been issued and it was withdrawn.

**David Newman:** I will agree.

**Michael Gollin:** And they learned to use the system to eliminate—

**David Newman:** But the problem was that this was a massive egg on the face of the—abroad, I was getting comments day in day out—

**Susan Finston:** Absolutely and it was a huge misstep.

**David Newman:** Right.

**Susan Finston:** But the good news is that the United States and the EU and other governments have now signed MOUs with the government of India over something called the Traditional Knowledge Digital Library (TKDL) and there are

millions of entries in five or six major languages, including additionally the Indian dialect.

**David Newman:** Oh, I will agree.

**Susan Finston:** And now the examples (turmeric, neem) that came are 10-15 years old and we're not seeing this replicated because India has been very proactive. And it's interesting because Japan, which we also didn't talk about, has a global TK registry or database proposal that would solve this problem, and Brazil has opposed it. Why? Because if you don't have bad patent issuing, you don't have any fire behind the need to amend the WTO agreement, and they are trying to push everything into the WTO instead of taking care of the problem in a way that makes sense. So it's interesting that again, you have some governments like India formally saying TKDLs can prevent issue and patent solutions, or fix the issues of weak patents. And then you have other governments that say we don't want to talk about it.

**David Newman:** Exactly. Well, Brazil doesn't want to talk about it because they don't want that.

**Michael Gollin:** Well, although the Brazilians are climbing up very quickly in the patenting side, I mean, it's a \$3 billion industry. And basically, in my understanding it is that every country wants to protect its own posture in IP in genetic research and innovation and that they're convincing sovereign nations to do so, and the United States tries to protect the interest of these nations.

**David Newman:** And what is actually a very subtle and essential point is that there have been a number of books published in one or last few years covering TK published in the United States or published in conjunction with U.S. operations. Well, what these people don't realize is the moment that TK is published, it's now obsolete.

**Susan Finston:** Right.

**David Newman:** And therefore, you can get—you can still get a patent in the United States. You aren't going to get one in Europe.

**Susan Finston:** Now, the problem is that you have some things that they want to protect from publication and you have other things that they simply want to protect from commercialization without benefit-sharing.

**David Newman:** I agree with you.

**Susan Finston:** And you have to sort of be able to make those decisions.

**David Newman:** But the problem comes if you have people with good intentions, theoretically—I mean, not theo-

retically—good intentions are publishing this stuff when it really should not be published.

**Richard J. Blaustein:** This is all great and helpful and I want to give great thanks to our panelists for a fascinating and compelling discussion. I know I've been a long-term part of the CBD advocacy group or even as an individual and I know it's an arcane issue. It doesn't draw a big audience, but I think it's a most compelling issue.

So I hope we'll revisit this again within a year and we have some ideas to have and get a larger audience but the discussion is fascinating and extremely helpful and substantive so I just want to thank you all very much.