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BR: Thanks, Gerald. In his 1997 book entitled *Biodiversity*, Dan Perlman refers to gene-resource banks as akin to the libraries of the ancient world. It was within these ancient libraries that scribes and scholars essentially determined the fate of now-classic texts. Those they chose to copy by hand are preserved to this day, and those that they did not have been irretrievably lost.

This is a particularly apt metaphor to use as a backdrop for contemplating the social, legal, and ethical issues posed by these new technologies. Conservation biologists are the new genetic librarians, who may very well control the ability of future generations to access biological samples and data being carefully collected, catalogued, and stored today.

Among the important issues that will be faced by the individuals and organizations administering gene-resource banks and databases will be access issues, control and regulatory issues, and ownership issues. Who, for example, will be allowed to access the genes and other biological components in gene- and tissue- resource banks? Who will be allowed to access the growing amount of information stemming from these banks? For what purposes will people be able to access the banks and information, and who will decide? How will access to gene banks and databases be provided? How will access to biological samples and gene- and tissue-resource banks be reviewed or regulated? And how will biological safety issues be addressed and monitored?

What agreements will be put in place to protect both the providers to and the users of gene-resource banks and the databases? What agreements will be put

in place to protect ownership of the gene-resource banks themselves, and the databases, if that is desired? And what agreements will protect the rights to information, or the ownership of potential inventions, derived from the use of gene banks and databases? These and other questions of access, ownership, and control will likely be approached from different perspectives, depending on who is involved. Nonprofit institutions or universities may very well want to use different approaches than for-profit corporations or research organizations.

Let's review some of the available options. Copyrights do not protect information, such as genetic information, alone. Rather, copyrights are available to protect an author's rights to his or her creative expressions and creative arrangements of information.

Trade secrecy. Holding as business or trade secret a gene- or tissue-resource bank, or a biological database, and associated programs to use that database, will make lots of sense to ventures who plan to commercialize their collected resources. However, retaining genetic and other biological information as a trade secret may be very contrary to the goals of conservation biology and the goals of science, in general.

Patenting. As I will touch on in a moment, the federal appeals court has recently confirmed the legality of patenting useful methods of doing business. In those cases, the methods of doing business involved computer programs. Many believe those decisions to be broad enough to protect computer-assisted methods, and systems of any kind, including bioinformatics systems, methods, and products. Numerous patents have been issued recently to universities and companies in the area of computer-assisted bioinformatics methods and databases.

And finally, contracts with both users and providers, to control access to collections and databases. I think it's important to point out that this option is not mutually exclusive with the other options mentioned above. Contractual access to

banks and databases may represent the best solution for regulating access, ownership, and control of resource banks and databases—regardless of whether services and information are provided freely to the public; whether inventions will ultimately be patented; or whether gene- or tissue- resource banks and databases are held as trade secrets by a company who then licenses its products and services.

Contractual provisions to assure reward and compliance with laws protecting biodiversity and conservation could be included. And I've been told that such provisions have been incorporated into the model agreement with China over the giant-panda conservation program.

Because it's a relatively new topic in the realm of patent protection, I'd like to spend my remaining few minutes addressing the ability, after recent development in the case law, to obtain U.S. patents on computer-assisted programs or databases.

First I'll touch a bit on the case law. As Gerald told you, in the early 1980s the Supreme Court interpreted patentable subject matter very broadly, to include any process or product resulting from human manipulation. The court was careful, however, to carve out three exceptions. Mere descriptions of laws, natural phenomenon, or abstract ideas or information are not patentable, no matter how useful they are. Specifically, the case law focused on mathematical algorithms as being unpatentable.

The federal Court of Appeals, which hears all appealed patent cases, has recently upheld that a patent claim may include, in part, an abstract idea— that is, a mathematical algorithm, a computer program, or an information database— as long as it is applied in a practical manner to produce a useful, concrete, and tangible result. For information about what is considered practical and useful, I

refer you to the United States Patent Office's Web site at *uspto.gov*. They have published revised utility guidelines—January 5th, 2001.

In practical terms, what this means is that one can now seek patent protection for methods, systems, and even for products, such as a computer-readable storage medium—that is, a CD-ROM or a diskette—that can contain formerly unpatentable information.

Here, for example, is a recently issued claim to a relational database. The difference between this claim, and one that would have formerly been unpatentable for reciting merely an abstract idea, is that here the relational database presumably takes information—that is, DNA sequence information and DNA probing results in a micro-array—and it applies that information, in a practical manner, to produce a useful, concrete, and tangible result.

The claim itself does not say what that result is. However, the patent says that it provides methods for organizing information relating to the design of polynucleotide array chips, and that a database model is provided which organizes information interrelating probes on a chip, genomic items investigated by the chip, and sequence information relating to the design of the chip.

I'll finish off by showing you two more examples of claims to bioinformatics-related methods that I found online. The first is to a claim to identify coding sequences. And the point of this is that this claim really just entails entering a sequence into a data-processing system, and that system then performs a series of steps to obtain a useful result.

And lastly, a computer-based system for predicting the future health of individuals. Again, it basically consists of a computer program that analyzes biomarkers within a population and performs statistical calculations that will predict future health and illness.

As you can see, the Patent Office is now allowing claims to methods and products that depend on computer programs and databases, and this evolution in the law is helping to create a new bioinformatics industry. It's perhaps important to point out that future litigation over patent claims—such as those we've just looked at—will lead to another step in an ever-changing law governing the patentability of products and methods which contain informational components.

In conclusion, the new genetic, biological, and mechanical technologies available to conservation biologists are already posing complex questions scarcely contemplated when the existing legal framework was enacted. While the current legal framework may appear for now to be adequate, navigating it in a manner that promotes genetic diversity, and promotes the aims of conservation, will be challenging—especially in view of the speed of the technological advances in the biological sciences, and the boom of for-profit companies working in the areas of cloning and bioinformatics.

Thank you.

(Applause)

RD: I want to thank the speakers in this session. And they'll be here, so you can go ask them questions face-to-face. And we're only five minutes behind, so thank you.

(Applause)